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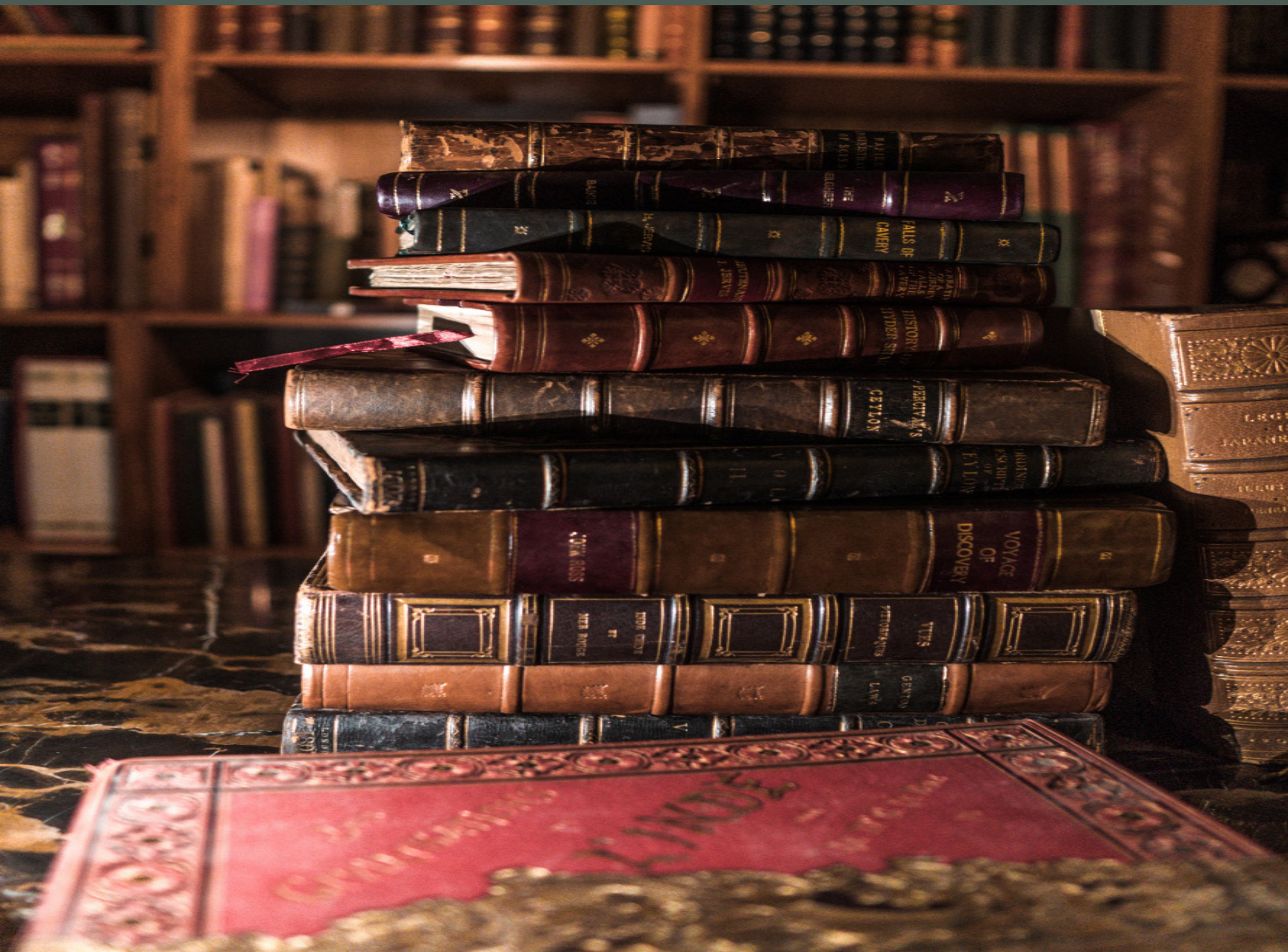

UNMASKING MEDICAL FRAUDS

Exposing the Details and Implications of Illicit Trade in the Medical Sector

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THIS PAPER INVESTIGATES HOW THE EVOLUTION OF THE E-COMMERCE MARKET IN CONJUNCTION WITH THE EXTENSIVE REACH OF GLOBALIZATION HAS BROUGHT ABOUT NEW WAYS FOR ILLICIT TRADE TO CIRCUMVENT REGULATION, ESPECIALLY IN THE MULTIBILLION DOLLAR INDUSTRY THAT IS THE INTERNATIONAL TRADE OF COUNTERFEIT PHARMACEUTICAL PRODUCTS. DEVELOPING COUNTRIES ARE OFTEN ESPECIALLY VULNERABLE TO THE INCREASINGLY SOPHISTICATED METHODS FOR CIRCULATING FALSELY ADVERTISED MEDICINES, MEDICAL EQUIPMENT, AND HEALTHCARE ACCESSORIES DUE TO UNSTABLE POLITICAL ENVIRONMENTS AND LOCAL GOVERNANCE. THE EFFECTS OF THE CONSUMPTION OF FALSE MEDICAL PRODUCTS CALL FOR ACTION IN REGARD TO REGULATION AND PREVENTION VIA LEGISLATION AND TECHNOLOGICAL ADVANCES. ECONOMIC IMPLICATIONS AS WELL AS THE NUMEROUS DANGERS POSED TO CONSUMERS WORLDWIDE MAKE ILLICIT TRADE IN THE MEDICAL SECTOR A PRESSING CONCERN, ESPECIALLY IN THE FACE OF GLOBAL HEALTH EMERGENCIES LIKE THE CURRENT PANDEMIC.

The trade of counterfeit drugs makes up a large portion of the global market in illegal goods, empowered and perpetuated by the growing and easily accessible e-commerce market. According to the OECD/EUIPO (2019) study, the value of global trade in counterfeit pharmaceuticals was up to USD 4.4 billion in 2016. Investigating globalization in the context of the healthcare sector and the implications of the international counterfeit healthcare trade demonstrates the immensity of the impact illicit trade has on both communities and local economies around the globe. Data from Interpol has shown that as of 2020, trafficking of falsified health products is ten to twenty times more profitable than heroin trafficking, emphasizing the magnitude of the dangers of this sector of illicit trade (Sanofi, 2021). The World Health Organization (WHO) has proposed that counterfeit medicine (branded or generic products) can be defined as one that is deliberately and fraudulently mislabeled with respect to identity and/or source, which has obvious potential for endangering unsuspecting consumers. A reiterated version of Matthew Sparke's definition of globalization describes it as "the extension, acceleration, and intensification of consequential worldwide interconnections" (Glass, 2014). When considered in the context of illicit trade in the healthcare sector, this quote emphasizes the consequential nature of these processes for everyone involved in the supply chain, from manufacturers in faraway countries to patients and consumers on the ground. Illicit trade in the healthcare sector, greatly enabled by the ever-expanding reach of the e-commerce market, significantly impacts the global economy and well-being of people across the globe. The counterfeit trade of medicines, medical devices, non-drug accessories, and personal protective equipment (PPE) creates safety and legitimacy concerns as they endanger those who fall victim to falsely advertised products, making technologies and policies that assist in curbing counterfeit trade increasingly crucial in the context of today's global value chains and worldwide challenges in healthcare.

COUNTERFEIT TRADE OF DRUGS & MEDICINE

Access to healthcare and treatment options is limited for many communities, especially in developing countries, sustaining and further increasing the demand for accessible medication and, consequently, for counterfeit medicine and prescription drug suppliers. According to the WHO, "counterfeit medicines potentially make up more than 50% of the global drug market" with a significant presence of these goods circulating in developing countries due to a lack of adequate regulatory mechanisms and enforcement measures and the increasing sophistication of drug counterfeiters. The ripple effect of this trade sector impacts consumer confidence in healthcare and supply chains and undermines the efforts of legitimate pharmaceutical providers. According to Staake et al., counterfeiters can be classified into five groups: 1) disaggregators; 2) imitators; 3) fraudsters; 4) desperados; and 5) smugglers, labels that assist in developing a more organized approach to the issue of counterfeiting in the healthcare market. The Desperados Group represents products with medium to high visual quality, while the functional quality and product complexity is low. Consequently, they are said to pose a severe threat to consumers (Glass, 2014).

Counterfeit products lack active pharmaceutical ingredients (APIs) or include incorrect ingredients which may or may not be toxic and have impurities and/or contain incorrect quantities of these APIs, which are usually less than the stated amount. The United States Food and Drug Administration (FDA) has reported counterfeit and substandard medicines in both developed and developing countries, with 25% of these medicines being consumed in developing regions, such as Latin America, Southeast Asia, or Sub-Saharan Africa (Glass, 2014). The detrimental effects the magnitude of this problem has on the health of developing-world consumers make the efficacy of regulatory measures that much more crucial.

COUNTERFEIT TRADE OF PPE, MEDICAL DEVICES, & OTHER NON-DRUG ACCESSORIES

Illegitimate PPE, medical devices, and other non-drug accessories comprise a large sector of the products involved in the overwhelmingly large scope of the trade circulation of counterfeit healthcare-related goods and are less likely to be intercepted before reaching consumers compared to prescription drugs. This is due to non-drug products often having misleadingly accurate and convincing appearances and basic functionality. There is less data on the extent of the production and circulation of counterfeit medical devices because, according to the National Institute for Public Health and the Environment (RIVM). At the same time, the distribution of prescription drugs is legally restricted to pharmacies and drugstores, the legitimate supply chain for medical devices is broader and includes various other suppliers like supermarkets, department stores, and even public vending machines (De Bruijin et al., 2009). There have been significant differences in the medical device regulatory procedures of the developed

nations of the United States, the European Union (EU), and Japan. These have prompted the efforts and attention of the Transatlantic Trade and Investment Partnership (TTIP) towards its goal of fostering "enhanced compatibility of regulations and standards" (Lee-Makiyama et al., 2021). Market integration among the developed countries of the EU along with Japan and the US comprise almost 90% of global production and consumption of medical devices. Integration would not only ensure a greater level of economic stability but also eliminate several loopholes caused by regulatory discrepancies that allow for a large amount of the trade of counterfeit medical devices (Lee-Makiyama et al., 2021).

SAFETY & LEGITIMACY CONCERNS & THE SOCIETAL IMPACT

The consequences of the growing counterfeit healthcare trade involve pressing safety concerns for those in need and the detrimental effects of circulating illegitimate products on the individual and corporate levels. Those with low income and limited literacy will ultimately still choose to purchase counterfeit products by assuming that non-authenticated treatment options are better than no treatment at all (Glass, 2014). One example of the impact of this stems from the manufacturing of altered and low-quality antivirals: "Antibiotics, antituberculosis drugs, and antimalarial and antiretroviral drugs are frequently targeted, with reports of 60% of the anti-infective drugs in Asia and Africa containing APIs outside their pharmacopoeial limits" (Glass, 2014). The direct implications involve increasing drug resistance and therefore undermining the efforts put into developing effective drug formulas, especially in developing countries where treatment for fatal diseases and infections is imperative to the well-being of many. Counterfeits significantly impact global public health because drugs lacking in quality, safety, correct make-up, and efficacy that are not effectively regulated could result in long-term consequences. These include prolonged therapy and hospitalization, promotion of resistance, and the causation of adverse effects in consumers, which are then not accurately recorded or monitored (Glass, 2014). On the individual economic level, counterfeits contribute to increasing out-of-pocket spending on healthcare, lost income due to prolonged illness or death, and lost productivity costs to individuals and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy (OECD/EUIPO, 2020). The environmental impact is another significant though often overlooked implication of the counterfeit trade since legitimate pharmaceutical companies must adhere to established environmental protection and anti-pollution regulations while illicit manufacturers do not; they often dispose of toxic dyes and chemicals without oversight and disregard the importance of avoiding chemical leaks into streams and other natural resources (OECD/EUIPO, 2020). It is also important to acknowledge that other crimes such as money laundering, human trafficking for sexual exploitation, and the smuggling of illegal arms can be linked to criminals involved in pharmaceutical crime (OECD/EUIPO, 2020), so the scope of this issue expands far beyond the sole impact of fake drugs and medical apparatuses on individuals and companies.

THE ECONOMIC IMPACT & FTZS

Counterfeiters impact both genuine manufacturers and consumers economically, making regulatory measures beneficial to both ends of the supply chain and requiring the attention of regional and international organizations in addressing the problem. The Organisation for Economic Co-operation and Development (OECD), for instance, has contributed significantly to informing policy-makers through detailed research and analysis of the economic impact of counterfeit circulation in the market. They recognize various factors that are conducive to the success of illicit traders, including trade routes and politics. Counterfeit producers determine the who, what, and where of their operations through considering "1) the characteristics of the market, which determine market potential; 2) technological and logistical considerations, which determine the feasibility of counterfeiting; and 3)

"Those with low income and limited literacy will ultimately choose to purchase counterfeit products by assuming that nonoauthenticated treatment options are better than no treatment at all."

the institutional environment, which determines the risks of being caught" (OECD/EUIPO, 2020). The complexity of the trade routes utilized by counterfeit suppliers is vital to recognize because it "facilitates the falsification of documents in ways that camouflage the original point of departure, establish distribution centres for counterfeit and pirated goods, and repackage or re-label goods," all of which often are undetected due to the fact that in-transit goods are outside the scope of local authorities (OECD/EUIPO, 2019).

Counterfeiters also thrive in politically unstable environments where corruption and ineffective property protection policies greatly influence the amount of exports of fake goods from an economy. Despite their beneficial aspects, countries with free trade zones (FTZs) with strong infrastructure and limited surveillance also provide a relatively stable environment for counterfeiters to operate in. Interestingly the existence, number, and size of FTZs in a country positively correlate with increases in the number of counterfeit products exported by that country's economy (OECD/EUIPO, 2019). A notable case of such an occurrence took place in 2006 when a counterfeit shipment from the Sharjah FTZ in Dubai was seized in transit to the FTZ of Freeport in the Bahamas and involved several countries. After the fake products were intercepted in the Bahamas, suspicious products still being stored in the Sharjah FTZ were moved to another facility in the Jebel Ali Free Zone in Dubai in an attempt to evade authorities. The investigation eventually exposed an elaborate supply chain of knockoff drugs that ran from China through Hong Kong, the United Arab Emirates, the UK, and the Bahamas to eventually be sold online to unsuspecting consumers as Canadian medicines. This exhibits the convoluted nature of the crime at hand and how FTZs serve as low-risk stepping stones in the elaborate schemes behind successful counterfeit operations, making regulatory adjustment measures crucial, especially in areas with limited surveillance. Countries that encounter large amounts of counterfeit healthcare products risk discouraging foreign investment, thus limiting their potential for economic growth and opportunities for further innovation and development in the healthcare sector (OECD/EUIPO, 2020).

TECHNOLOGIES AND POLICIES ASSISTING IN CURBING COUNTERFEIT TRADE

Beyond easily targeting those with lower socioeconomic status and limited healthcare availability, the ever-expanding e-commerce market has provided illicit suppliers the opportunity to reach an even greater consumer base, largely including those who unknowingly fall victim to well-advertised illegitimate pharmacies and websites. Many fake drug products enter the market through illegal online pharmacies that operate globally and often beyond the scope of local or international regulators, and digital channels enable these illicit companies to evade detection (Kuppuraj, 2018). Large sums of money are involved in transnational criminal networks and enterprises, with one illicit online pharmacy network earning USD 55 million during only two years of active operations (OECD/EUIPO, 2020).

Another important term involving the dangerous distribution of certain products to specifically targeted countries or demographics is anti-diversion, which aims "to ensure that products that have been developed for a specific market, perhaps with materials that are not allowed in other countries but are authorised for the intended market... are not removed from the supply chain, repackaged and sent into a country that should not receive that item" (Ellison & PRISYM ID, 2019). There are both passive and active approaches to addressing the dangers of counterfeit healthcare, like the aforementioned diversion tactics. The passive strategy focuses on the three levels of packaging of products, with manufacturers being encouraged to include visual deterrents in the form of holograms, UV codes, or unique barcode labels that could assist in proving authenticity. The active approach involves using technology in regulating products as they pass through the supply chain. Unique serial or reference numbers (URN) allow mass serialization systems to check authenticity and assist in tracking products through the supply chain, which is becoming increasingly efficient and effective as technology advances (Ellison & PRISYM ID, 2019).

Several facilitation policy strategies could prove helpful in decreasing the number of counterfeit healthcare products being exported. Specifically, these would involve the availability of detailed information on trade flows, the degree of involvement of an economy in the trade community, transparent and methodical review of fees and charges imposed on imports and exports, and reliable internal cooperation between border agencies and other government units (OECD/EUIPO, 2019). Regarding the specific problem of counterfeit healthcare, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was established in 2006 to coordinate a response to the growing issue of counterfeit drugs and to focus on the

following key areas: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology, and communication (Glass, 2014). IMPACT demonstrates that successfully combating the trade of counterfeit medical products requires the efforts of others beyond the health sector. Collaboration among other sectors including law enforcement, border control, justice departments (at all administrative levels), and the private sector, which includes members of the supply chain like manufacturers, importers, distributors, health professionals, media, and patients and other consumers is essential (World Health Organization, 2019). Initiatives from the WHO's "prevent, detect, and respond" approach have introduced and begun to maintain a global database of reports relating to the interception of substandard or counterfeit medicines for use by regulatory agencies globally as well as a "Rapid Alerts" mechanism that facilitates international communication and data exchange (OECD/EUIPO, 2020).

Governments and regional justice systems hold a great deal of responsibility to be involved in efforts to protect global public health, especially regarding legislation. One example of higher power organizations taking initiative is when the Council of Europe developed the MEDICRIME Convention, which equipped countries with a prototype of a legal framework for facing the threat of counterfeit medicines and other types of medical sector crimes that threaten public health and the economy (OECD/EUIPO, 2020).

The biopharmaceutical company Sanofi has also become a leading example of providers increasing their responsibility for being aware of the importance of screening for counterfeits. In 2008, they opened their Central Anti-Counterfeit Laboratory (LCAC) to counter illicit companies targeting their product design for profit and recorded over 43,000 suspicious products. Furthermore, they developed a specific label containing visible and invisible authentication known as the Sanofi Security Label to prevent mistakes in the supply chain (Kuppuraj, 2018). Their official website provides guidance made available to the public in how to personally inspect products at home before consuming them as well as in recognizing red flags in pharmaceutical websites and online web pages, demonstrating how regulating false products can be a responsibility of everyone involved in the supply chain from manufacturers to suppliers to consumers to ensure safety and damage control.

CONCLUSION & MODERN CONTEXT

Evidently, the increasing amount of counterfeit trade in the healthcare industry is a pressing global public health concern. Economically, ambiguity and lack of effective regulatory systems throughout the supply chains involved in circulating falsely advertised and manufactured medicines, medical devices, and non-drug accessories like PPE impact not only local and global value chains and economies but also the faith of the public in reputable companies and healthcare as a whole. A cooperative, joint effort between suppliers, pharmaceutical companies, manufacturers, customs officials, and even consumers to continue developing more effective policies, technological systems, and protective strategies to decrease the presence of counterfeit healthcare goods in the market is essential to addressing the gravity of this problem, which has only worsened since the onset of the COVID-19 pandemic. A myriad of issues has emerged in the face of the novel coronavirus involving counterfeits that endanger healthcare workers and patients, including the production of insufficient filtering facepiece respirators and masks during the PPE shortage of early to mid-2020 (Ippolito et al., 2020). This problem required the efforts of trustworthy organizations like the Center for Disease Control (CDC) to inform the public on identifying authenticity in protective gear, though the growth of the e-commerce market and dire circumstances often led consumers to feel that unauthenticated equipment would be better than nothing.

N95 masks were also in high demand at the time, creating a new target market for counterfeiters to take advantage of. According to a reputable news source, counterfeits began appearing at the front lines with, for example, Holy Name Medical Center in Teaneck, New Jersey, receiving a batch

"...the dangers of the counterfeit healthcare trade willcontinue to worsen in the face of new global health challenges and an every-changing technological world..."

of 1,000 N95 masks from a trusted longtime vendor that turned out to be fake at the epicenter of the outbreak in the state (Kavilanz, 2020). This incident, among other evidence, indicates that the dangers of the counterfeit healthcare trade will continue to worsen in the face of new global health challenges and an ever-changing technological world, requiring the consistent efforts of countries worldwide in countering its effects in the best interests of both local and international communities.

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LIST OF ARTWORK