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Drug Counterfeiting: Key Factors Affecting Vulnerable People in the World

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Author's contribution

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ABSTRACT

Drug counterfeiting has been a major problem for the government and regulatory agencies since the beginning of the 20th century. Most of the drug counterfeiting reported is in countries where a high demand for drugs combines with poor surveillance, quality control, regulation, and education to make it easy for criminals and cartels to supply it to the market through illegal sources. These fake medications are frequently produced in hazardous conditions, with insufficient, excess, or no active ingredients, and/or by using potentially harmful and even fatal chemicals. Counterfeit drugs mostly affect vulnerable sections of society due to their social and economic conditions. Some critical factors, such as insufficient or no health insurance coverage, disparities with racial and ethnic minorities, government policies, low income, lack of education, and uncontrolled online pharmacies, tend to attract them towards counterfeit drugs. This article explains the key risk factors of counterfeit drugs operating in legal environments and reviews recent adverse cases in the pharmaceutical supply chain.

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1. INTRODUCTION

The term "vulnerable population" has been used to refer to those who are socially and economically disadvantaged, medically underserved, poor, and/or in distress. These include, among many others, members of racial or ethnic minorities, the uninsured, kids, the elderly, the destitute, the chronically ill, those who are physically or mentally unable to care for themselves, those who are homeless, people who live in rural areas, migrants, and those who are illiterate or have limited educational opportunities [1].

Health status metrics at the individual and population levels are directly impacted by vulnerability, as well as health care availability and quality. As per a recent report published by the Guardian, Drug counterfeiting is the leading cause of death and kills more than 250,000 children a year [2]. They mostly die from low-potency or counterfeit vaccines and antibiotics given to them to treat infections and chronic diseases like hepatitis, yellow fever, and meningitis. Due to a significant exposure to disease-causing risk factors, vulnerable populations experience different health outcomes than the overall population [3]. This counterfeit medication, mainly circulated in Europe and America, is presented in such a way that it resembles the packaging of the cancer medication Iclusig, which uses the active component ponatinib to treat adults with chronic myeloid leukemia and acute lymphoblastic leukemia. According to an estimate, up to 10% of drugs in poor and developing countries are of substandard or completely counterfeit, damaging local economies between $10 billion and $200 billion a year. In 2019, the World Health Organization (WHO) issued a global alert and warned patients, doctors, and pharmacies of fake cancer drugs manufactured from paracetamol. A shortage of medical services across the world was also discovered by the federal Office of Disease Prevention and Health Promotion, and variables including age, race, gender, and ethnicity had a detrimental impact on access to healthcare.

Pharmaceuticals Drug counterfeiting is a serious problem that has an impact on global healthcare systems and the health of vulnerable people in society. Vulnerable people may suffer from life-threatening consequences and negative repercussions as a consequence of their vulnerability [4]. The vulnerable communities have been debilitated by a lack of health literacy, or the capacity to comprehend and act on fundamental healthcare information.

The technique of making counterfeit pharmaceuticals is comparable to that of making counterfeits of any other commodity, and the end result is the same: manufacture fraudulent goods and/or labels. Fig. 1, depicts how counterfeit or fraudulent drugs enter into supply chain through illegal supply chain.

In the above Fig. 1, the manufacturer produces counterfeit or illegitimate drugs and supplies wholesale distribution through illegal sources. Further, a distribution network that is a mix of legitimate, semi-legitimate, and criminals, supplies drugs to illegal online stores or healthcare providers. As a result, these counterfeit drugs in developing countries are physically supplied to rural or remote areas where people have no education or are illiterate. In developed countries, counterfeiters or criminals are targeting vulnerable sections of society by offering very attractive prices through illegal online pharmacies or uncontrolled social media platforms. The illegal source of the supply chain makes it easier for defective and fake medications to enter the supply chain. Further in this study, we will cover the following core focus areas.

- **Vulnerable section of Society:**Vulnerable populations include the economically disadvantaged, the uninsured, low-income families, the elderly, the homeless, and those with chronic health conditions, including severe mental illness. It may also include rural residents, who often encounter barriers to accessing healthcare services [5].
- **Social Condition:** Medicines that are substandard or counterfeit have a direct negative impact on health and endanger both patients and the general public. Additionally, they have economic and social repercussions, such as the direct expenses of additional medical care and the indirect societal costs of diminished faith in the medical community and the government [6].

- **Drug Counterfeit:** Counterfeit drugs are fake drugs that are packed in such a way to look like genuine drugs. These drugs do not contain active pharmaceutical ingredients (API) and pose a life-threatening situation as they are manufactured with substandard materials or diluted to a level with expired ingredients.
- **Drug Traceability:** As per the National Institute of Health, the ability to trace the history, application, or location of a medicine is one of the key attributes of the drug traceability process. The source of the medicine must be traceable through the key elements of data encoded into barcodes or in human-readable forms.
- **Counterfeit drugs attributes:**
  - Drugs with wrong Active Pharma Ingredients (API)
  - Drugs with incorrect label
  - Drugs with incorrect packaging
  - Stolen Drugs
  - Expired Drugs
  - Drugs with incorrect strength and potency
  - Re-labelled drugs to hide expired date.

2. VULNERABLE PEOPLE WITH MINIMUM OR NO HEALTH INSURANCE COVERAGE

The counterfeit drug market is rapidly growing among people with chronic diseases in countries where the healthcare system or government do not provide state-funded health insurance for free or where the population does not have enough health insurance coverage to pay for it. The United States federal government has acknowledged that one of the main obstacles to receiving medical care is a lack of proper health insurance coverage, and that health disparities are a result of unequal coverage distribution [7]. Employers, insurance providers, the national government, and the states serve as the four main payers or sources of funding for health care.

In the United States, the disparities in health care coverage, finance, and quality were supposed to be lessened by the Affordable Care Act (ACA), yet it exists due to health coverage inequalities among the people. The Affordable Care Act does not offer financial support to persons below the poverty line for other coverage options because it was intended that low-income people receive coverage through Medicaid. For instance, compared to US citizens, immigrants typically have lower health insurance rates, utilize less healthcare, and receive inferior quality care [8]. As a result, the most vulnerable population in places where Medicaid expansion is not implemented has a "coverage gap" where their incomes are both above Medicaid eligibility thresholds and below the lower threshold for Marketplace premium tax credits. [9]. If low-income vulnerable people are insured, they are mainly covered by plans offered by their employers that offer less comprehensive coverage, resulting in higher out-of-pocket costs for them [10]. Some politicians argue that other nations with better health outcomes, including Japan and Switzerland, have more homogeneous populations in order to disregard negative health indicators for the United States. It is true that systemically racist policies in the United States have led to health outcomes inequality that are much worse for Black, Indigenous, and other people of colour, but even the privileged white population in the country has worse health than its counterparts in other developed countries [11].

Fig. 1. Illegal supply chain of counterfeit drugs

The most vulnerable population in the world cannot afford the treatment of some severe diseases because of their uncovered or uninsured status. Due to their insurance status or the financial burden of treatment costs, they either opt out of treatment or skip their regular dosages. The criminals or drug counterfeiters are considering their situation as an opportunity to lure them with attractive prices. These vulnerable people fall into the trap and buy medicine from these unreliable sources without validating their authenticity. In numerous publications, the Institute of Medicine Committee on the consequences of uninsurance came to the conclusion that offering health insurance to the uninsured would enhance their health and lengthen their lives. The Fig. 2 describes the disparity of health coverage among the general population based on health status.

3. HEALTH DISPARITIES IN RACIAL AND ETHNIC MINORITIES

Frequently, the definition of "health disparities" is "a difference in which less advantaged social categories, such as the poor, racial/ethnic minorities, women, and various other groups, systematically experience more serious health conditions or greater health risks than less advantaged social groups [12]. According to the National Academy of Medicine, racial/ethnic minorities, particularly African Americans, were less likely than whites to receive essential and appropriate medical tests, treatments, and procedures. The recent Covid-19 Pandemic has brought to light and magnified the unpleasant realities of the health disparities that exist in the United States for racial and ethnic minorities. Being a member of a racial or ethnic minority is intimately linked to having a lower socioeconomic level. In the US, people of color—particularly those who are black, Hispanic, or American Indian—are more likely to live in congested quarters, be part of multigenerational households, and hold occupations that cannot be done from a distance, like those of transit operators, grocery store clerks, nursing assistants, construction workers, and household staff [13]. The most vulnerable people in society are at risk for toxicities, side effects, and therapeutic failures that can result in mortality. They include newborns, geriatrics (old adults), pregnant women, those with impaired kidney or liver function, and people with damaged immune systems. The use of fraudulent and counterfeit medications among these vulnerable people would affect them mostly and result in higher mortality rates [14].

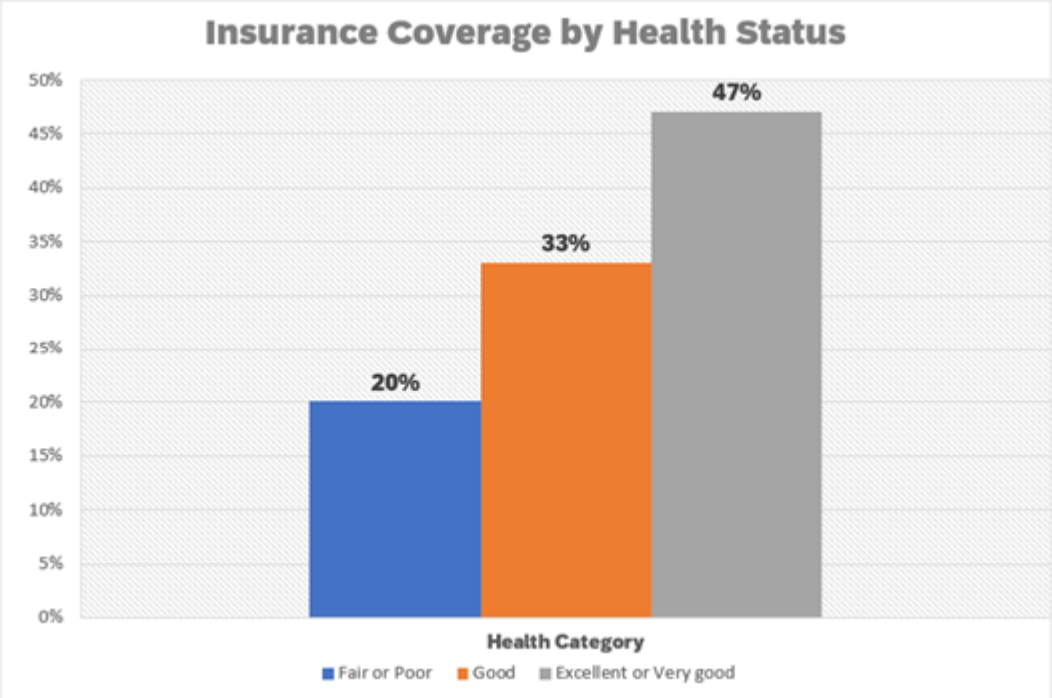

Fig. 2. Insurance coverage of general population based on health status

4. GOVERNMENT POLICIES

The Governments and regulators in many nations are in charge of making sure that their citizens are receiving authentic medications. The current healthcare system scenario in the world is characterized by government spending on the health sector. Despite the numerous restrictions put in place by many nations, the problem of drug fraud is still on the rise, especially in Africa. The majority of the cited government policies have some significant problems. It is rather instructive how laws that are allegedly designed to protect the vulnerable actually help wealthy pharmaceutical companies politically and further their special interests. Some government policies in many nations place artificial and pointless barriers in the way of the impoverished getting the jobs that could help them escape poverty and vulnerability.

5. ILLEGAL SUPPLY CHAIN

The fight against drug counterfeiting involves both end users and pharmacists as key stakeholders. They are the ones who have regular supplies of the medicines from the manufacturers. Thus, it is crucial to make sure that pharmacists and patients are informed about the issue of drug counterfeiting and how to distinguish between real and fake medications. In the US, national wholesalers distribute medications directly to end providers, which are often pharmacies, doctors, hospitals, and clinics, accounting for around 90% of the total market. However, the remaining 10% frequently take a diversion, which raises the possibility of fake goods entering the market [15]. Hospitals and other providers look outside of the usual sources to find pharmaceuticals when supplies are low, which increases the chance that fakes will enter the market. The legitimate supply chain, which also contains a small proportion of online pharmacies, makes counterfeit medications accessible [16]. Some reports indicate that the majority of counterfeit products are marketed via dubious internet pharmacies. The patient must purchase the medications from a reliable source and avoid using sketchy online pharmacies [17]. Key drug shortages in the US and Europe have given illegal distributors new possibilities, while manufacturer supply chains that are getting longer make theft and diversion easier [18]. Counterfeiters are able to take advantage for the drug shortage and charge exorbitant prices of fake medicines [19]. Factors, such as a shortage of critical medicines, may increase the cost of medications, which disproportionately harms the most vulnerable members of society. As customers, vulnerable people look for cheaper medications or buy prescription pharmaceuticals off the shelf; in these cases, they are forced to buy medicines from online pharmacies that are a major source of fake medications.

6. INCOME DISPARITY

A recent study that highlighted at income, race, and self-perceived health status revealed that not only is racial identity independently related to lack of health insurance, but also that low-income vulnerable person with poor health had 68% fewer chances of being insured than individuals with high incomes and good health. Most health insurance policies don't cover the expense of outpatient care, such as visits to the doctor or prescription medications, and instead focus on inpatient healthcare expenses. Low-income people tend to have more chronic illnesses, and those illnesses might sometimes have more severe effects. Racial and ethnic minorities make up a disproportionate number of those with low wages. They might have fewer insurance options due to their low income, which would reduce their contact with the healthcare system. Additionally, those with lower incomes are more likely to suffer from coincide with disorders, which include both chronic medical diseases like obesity or diabetes and behavioral health problems like depression or substance abuse.

7. ATTRACTING VULNERABLE PEOPLE BY OFFERING CHEAPER PRICE

Critical medicine, such as antibiotics or antivirals, needs a doctor’s prescription. Some people use the internet to buy medications that would require a prescription. This is a vulnerable area, as many online pharmacies are fraudulent and sell fake drugs to people without a prescription. The Lancet article claims that the expansion of online pharmacies has contributed to the globalization of fake medications. According to the WHO, almost 50% of the pharmaceuticals marketed online are counterfeited. The National Association of Boards of Pharmacy (NABP) discovered that out of 1000 online pharmacies, 9938 did not follow US federal and state regulations or NABP requirements regarding patient safety and pharmacy operations. The U.S. Department of Justice found that in some cases, counterfeit drugs had been sold through a fraudulent online pharmacy. The Food and Drug Administration (FDA) estimates that 97% of

online pharmacies sell fraudulent medications. Over the past ten years, some 35,000 of these illegal pharmacies have popped up; all of them are against the law and many of them promise to supply medications without a prescription. Some criminals use websites to pretend to be healthcare practitioners in addition to operating fraudulent pharmacies. Cost markups on drugs associated with shortages during COVID-19 Pandemics in the beginning of 2020 averaged 300% and were reported for certain antibiotic medicines, which make access to these medicines almost impossible for poor and vulnerable people [20]. An estimated 36 million Americans have reportedly purchased medications online without a legal prescription [21]. In order to regulate the purchase of drugs online, it is necessary for patients and medical professionals to work together as well as with international, national, and state organizations. Strict action must be done to stop the growing threat of illegal online pharmacies distributing fake medications.

Globally, most people use the internet for social media platforms, chatting, and online shopping, including purchasing medications. When vulnerable people are diagnosed with some critical condition, they tend to search for treatment and medicine on the web. Most search engines, and other websites uses algorithmic method to track all browsing activities and search histories. It generates a list of comparable products using the complete user's data, including accessed web pages, duration on page etc. Criminals use a variety of online social media sites to advertise low prices, offer speedy delivery, and provide freebies in an effort to get individuals to buy fake medications. Customers are initially unaffected by these promos. When a user actively searches for medication, these dark web platforms offer drug-related fraudulent advertisements in their feeds and searches. Further, it encourages them to buy fake medicine by lowering their cognitive ability to get medicine from authentic sources.

8. LOW EDUCTION AND AWARNESS

Most vulnerable people with limited English proficiency, and especially limited health literacy, are also more likely to have worse health outcomes. This concern was recently highlighted in a study that found Black men were less likely than White men to have health-related knowledge. This suggests that public health information may not be disseminated in ways that are equally understandable to different groups. Fig. 3 shows the key attributes affecting vulnerable people's social & economic conditions that motivate them to buy counterfeit drugs unknowingly.

Fig. 3. Key factors of disparity in vulnerable populations

9. CONCLUSION

It is imperative that businesses, nonprofit organizations, governmental bodies, and law enforcement collaborate closely in order to combat the issue and promote the idea that drug fraud is a kind of organized crime. Nevertheless, despite the occasional impressive seizures, the market is still mainly hidden. Rapid, reactive, and global in scope, the response must be based on the threat it is confronting. Fighting counterfeiting and other forms of economic criminality together requires committed international collaboration, especially in the legal sector. The most prevalent social issues relating to health disparity among vulnerable people are unemployment, lack of access to food and shelter, a lack of social support and government schemes, and illiteracy. In order to address these socioeconomic determinants of health, healthcare providers must take a number of proactive measures, such as screening patients. The government and healthcare industries must make investments more strategically so that the most vulnerable people in society can get healthcare services that are accessible and affordable. If these people struggle with government schemes, neither health insurance nor medical advancements can save their lives.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that they have no known competing financial interests or non-financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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