# The Menace of Fake Drugs: Consequences, Causes and Possible Solutions

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**Abstract:** The business of fake drugs is a lucrative crime that is increasing annually worldwide. It causes therapeutic failure, drug resistance and economic sabotage. Some of the major causes of widespread drug counterfeiting include corruption, inadequate technology for protection of the identity of genuine drugs as well as lack of political will including lack of vigilance and advocacy by the healthcare providers. Combating this menace requires both local and international efforts. This report is aimed at examining the problem of drug counterfeiting business with emphasis on the causes and possible solutions.

**Key words:** Fake, drugs, counterfeit, crime, solutions, combating

## INTRODUCTION

Perhaps, of all crimes, none is as potentially dangerous yet neglected as drug counterfeiting. It causes so much suffering and deaths that some experts, rightfully, regarded it as an attempted murder (Aldhous, 2005; Akunyili, 2007). No agreement among countries on what constitutes a counterfeit drug (WHO, 2005). The most widely accepted definition is the working definition developed by the WHO which defined a fake or a counterfeit drug as a medicine deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredient or with the wrong ingredients without active ingredients with insufficient active ingredients or with fake packaging (WHO, 2005). Generally, all counterfeit drugs are substandard but a substandard drug may not be considered as counterfeit if there is no intent to deceive (Reggi, 2007).

**Extent of the problem:** The problem of fake drugs is wide spread affecting both developing and developed nations. The actual prevalence of counterfeit drugs is difficult to ascertain partly due to failure of the majority of member nations in the World Health Organisation to report instances of drug counterfeiting occurring in their countries (Newton *et al.*, 2006a) but also just like other crimes, drug counterfeiting is an underground business that often comes to light only when deaths occur. The extent of the severity of the problem varies widely between countries, ranging from <1% in more developed nations to 50% in some poor countries (WHO, 2005). According to recent estimate by the WHO about 10% of drugs circulating worldwide and 25% in less developed countries are fake. Africa and some parts of Asia are the most affected regions followed by Latin America. In Nigeria, the problem of fake drugs has significantly improved from 41% in 2002 through 16.7% in 2006 (Akunyili, 2007) to 10% currently.

About 50% of the drugs utilized by patients are purchased from the private places (Pharmacies, patent medicine stores and street vendors; Cars and Nordberg (2005) where control is difficult hence they are expected to be more easily invaded by drug counterfeiters compared to the public health sector.

Almost all kinds of drugs are being faked, ranging from antibiotics, through anticancer agents, to endocrine drugs (WHO, 2006). The type of counterfeit drugs most frequently found in poor countries with huge burden of infectious diseases is principally antibiotics, unlike the case in the developed nations where drugs for the treatment of chronic diseases such as anticancer and lipid lowering drugs as well as life style drugs such as antiallergic and endocrine agents (such as hormones and steroids) as well as drugs for the treatment of erectile dysfunction predominate (Newton *et al.*, 2006b). Counterfeits of antimalarial drugs are widespread in developing countries, particularly Southeast Asia and Africa (Dondorp *et al.*, 2004; Newton *et al.*, 2006a, b; Atemnkeng *et al.*, 2007). Even fake antiretroviral drugs have been reported in Africa (Ahmad, 2004).

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## HEALTH AND ECONOMIC CONSEQUENCES
## OF DRUG COUNTERFEITING

The problem of fake drugs is very important in medicine because of the associated health risks. According to one expert, the negative impact of fake drugs on the society is more than that of either narcotic agents or the combined effects of malaria, HIV/AIDS and armed robbery (Akunyili, 2005a, b). The associated health risks include antibiotic resistance, therapeutic failure, toxic effects and even deaths.

**Antibiotic resistance:** The relationship between counterfeit drugs and antibiotic resistance is two fold. Although, drug counterfeiting is one of the important causes of antibiotic resistance in developing countries, one also has to keep in mind the likelihood of false reports of antimicrobial resistance in an area where drug counterfeiting is widespread (Rozendaal, 2000; Basco *et al.*, 1997).

Counterfeit antibiotics with low doses of active ingredients are potentially more dangerous than that containing no active ingredient at all in terms of the negative effect of drug resistance that may affect the entire community. Antibiotic resistance caused by drug counterfeiting might have contributed significantly to the inability to eradicate or control important infections such as malaria and tuberculosis in developing countries. Resistance to chloroquine and sulfadoxine-pyrimethamine is already common (Meremikwu *et al.*, 2007). The recent emergence of counterfeits of Artemisinin derivatives (Dondorp *et al.*, 2004; Newton *et al.*, 2006b; Atemnkeng *et al.*, 2007; Rozendaal, 2000; Newton *et al.*, 2001; Newton *et al.*, 2003) and antiretroviral drugs (Ahmad, 2004) in some countries of South-East Asia and Africa is an important development which is potentially disastrous because alternative drugs are either inaccessible or unaffordable.

**Therapeutic failure:** Therapeutic failure may also be associated with the use of fake drugs containing insufficient or no active ingradient, leading to loss of confidence by the patients on the conventional drugs and public health program. An estimated 700,000 deaths annually are caused by fake antimalarials and tuberculous agents, suggesting that the total annual mortality due to the menace will definitely be much higher (Harris *et al.*, 2009). Various instances where fake drugs resulted in deaths due to failure to treat life-threatening conditions have been reported in the literature. In 2001 about 192,000

people were reported to have died in China as a result of fake drugs. Also about 2500 people died in Niger following the administration of counterfeits of meningococcal-vaccines (containing no active ingredient) to some 60,000 people during the 1995 meningitis epidemic (Cockburn *et al.*, 2005).

**Toxicity:** Acute renal failure due to poisoning from diethylene glycol packaged as a cough syrup which resulted in hundreds of deaths in Haiti, Bangladesh, Nigeria, India and Argentina are examples of the potentially fatal effects of counterfeit drugs containing a toxic ingredient in place of the original active ingredient (WHO, 1995; Hanif *et al.*, 1995; O'Brien *et al.*, 1998). Also as recent as 2008,62 deaths in the US have been attributed to the use of adulterated heparin from China (Harris *et al.*, 2009).

**Economic impact of drug counterfeiting:** Economic loss as a result of drug-counterfeiting is enormous and appears to be increasing annually. According to the WHO, about 32 billion US dollars were lost to drug counterfeiting business in 2004 (WHO, 2006). This increased to 40 billion US dollars in 2006 and is projected to reach 75 billion US dollars in 2010 (WHO, 2006; Bate and Boateng, 2007). Many pharmaceutical companies are deprived of their rightful profits due to the unjust competition from this brutal crime and have even resulted in the collapse of some of the companies (Akunyili, 2005b).

**Makers of fake drugs:** Why will someone want to make fake drugs? Drug venture is quiet a lucrative business. Routine activity theory of crime prevention states that: A crime occurs when a suitable target and a potential offender meet at a suitable time and place lacking capable guardianship (Cohen and Felson, 1979; Felson, 1986, 1994). This theory is useful in understanding the origin of crimes including drug counterfeiting. Drug counterfeiting business thrives better in a place where the drugs are relatively scarce of the prices are high . According to the WHO, an estimated 2 billion people globally have limited access to essential drugs (WHO, 2004) which is attributed to poverty, high cost of drugs, inadequate health facilities and corruption (Cohen *et al.*, 2007).

Unlike in more developed nations where little or no tariffs are collected from pharmaceutical products (Harris *et al.*, 2009), high taxes and tariffs are usually collected from genuine medicines in less developed countries, leading to eventual increase in drug prices,

decrease in incentive to adequate supply of drugs and consequent scarcity of the drugs that may be exploited by the counterfeiters (Morris and Stevens, 2006) since, most of the patients in those countries pay for the drugs from their own pockets.

Although, drug counterfeiting is as dangerous and as lucrative as the narcotic business, its penalty tends to be less severe. Therefore, it is not surprising that criminal gangs previously known to be involved in the narcotic trade usually switch to drug counterfeiting because they find it quite appealing and less risky. There are also some reports of individuals being singly involved in this offense as in the case of a US pharmacist convicted of diluting patients' injections (Reggi, 2007). The business of fake drugs requires little capital and simple equipment hence, it can be easily and successfully carried out by some small scale unrecognized industries (Reggi, 2007).

Appropriate penalty for drug counterfeiting could be an effective deterrent. Unfortunately, the penalty for manufacturing or distributing counterfeit drugs is very lenient in many developing countries. For instance in Nigeria such an offense is usually punished by imprisonment for periods ranging between 3 months to 5 years or alternatively a fine of 70-3600 US dollars (Akunyili, 2007). Similarly in South American countries, the penalty for such a crime is just six months in jail or a fine (Bate and Boateng, 2007). Such a weak and incongruous penalty is incapable of making any great impact in preventing this lucrative crime.

Unlike developed nations with clear and strongly enforced laws on civil liability against suppliers or manufactures whose product causes harm to consumers, most of the poor countries afflicted with the problem of drug counterfeiting have laws in which civil liabilities are either not clearly defined or inadequately enforced. For example in the US it is not uncommon for victims of fake drugs to seek compensation in the order of millions of dollars from the culprits of the crime. On the other hand, although, the punishment for the supply and manufacture of fake drugs in India and China is very severe (death penalty), inadequate and inefficient civil liability laws is a huge roadblock to successful combat of drug counterfeiting in the two nations (Harris *et al.*, 2009).

The developing countries are not merely the victims of the problem but also serve as the sources of fake drugs with India and China being the biggest culprits globally (Bate and Boateng, 2007). One statistics by the European Commission described India as the source of 75% of fake drugs and according to one report, most of the fake drugs in Nigerian markets originate from India (Raufu, 2003).

Drug counterfeiting business may also be encouraged by the different standards set by the exporting countries regarding the drugs for public use and those for exports with the standard of the latter being less stringent than the former. One expert suggested that abolishing such a double standard could help to a large extent in combating the crime (Reidenberg and Conner, 2001). This factor is particularly important in countries like Nigeria whose indigenous pharmaceutical industries can only cater for 40% of the demand of its teeming population (Akunyili, 2007, 2005a).

## COMBATING DRUG COUNTERFEITING

Combating drug counterfeiting is a daunting task that requires collaboration from international community. This is why WHO recently, alerted the international community on such need (WHO, 2005). Cooperation as well as exchange of information between governments and drug companies in combating this menace is expected to provide better results. Experts believed that the big pharmaceutical industries have a lot of data that could help in combating the problem but are unwilling to reveal it (Gibson, 2004). There is a catch 22 situation in combating counterfeiting. The industries lose money to fake drug peddlers but the negative publicity that usually follows any case of drug counterfeiting is a major fear for the industries whose products were counterfeited. This is also true for countries that are major exporters of drugs. It has been reported that some governments are involved in concealing information on the quantity of fake drugs circulating within their territories to avoid branding of their other products as fake. The emergence of drug counterfeiting business on the internet that seriously affected profits coupled with litigations from affected patients targeted against them have forced major drug companies to start taking action on this issue in the developed nations. However, they remain uninterested in tackling the problem in the developing countries.

Since, the problem of drug counterfeiting is more common in less developed countries where civil laws are either vague or not enforced, one important short term stategy for combating fake drugs is that pharmaceutical companies should focus more on developing better technologies for protecting the identity of their genuine products. Development of complex labels that are difficult to imitate as well as use of SMS text message to check the authenticity of a particular pharmaceutical product are examples of recent progress in this regard. The above mentioned SMS technology, developed in the USA in Dia and Ghana is increasingly being adopted by other countries in Asia and Africa (Harris *et al.*, 2009).

Long term strategies for battling drug counterfeiting include provision as well as enforcement of clear and

adequate civil laws that will compensate and protect the rights of affected individuals as obtained in developed countries like US. Punishment of drug counterfeiting needs to be revised to make the practice harder and less lucrative. Drug counterfeiting is a grievious crime tantamount to murder hence, use of lenient punishment is inadequate and it may even bolster the morale of the counterfeiters. However, use of extremely harsh punishment (such as life sentence and death penalty) may be associated with an increased risk of drug counterfeiting being hijacked by organised criminal elements as well as likelihood of developing corrupt relationships with law-enforcement agents (Harris *et al.*, 2009). Also the judiciary will be more hesitant in giving a guilty verdict because of the grievous consequence of any possible wrong decision (Harris *et al.*, 2009). Without adequate enforcement, state laws may not serve as an enough deterrent to combat a crime as lucrative as drug counterfeiting. In order to ensure such enforcement, stamping out corruption among the staff of law enforcement agencies, government officials as well as at each step of the pharmaceutical system manufacturing registration and distribution may be helpful (Cohen *et al.*, 2007).

Decreasing tariffs and taxes imposed on genuine drugs may also help in reducing the extent of the problem by decreasing the costs of the drugs to the final consumers.

Giving incentives to individuals who provide useful information that leads to the conviction of the culprits of this crime may also help in tackling this menace. China has adopted such a strategy by honoring such informants with as much as 6,000 US dollars (WHO, 2005).

Healthcare providers such as physicians, nurses and pharmacists are in well positioned place to help governments in this difficult fight that requires enormous resources often lacking or inadequate in poor countries. They can help by having high index of suspicion on the possibility of drug counterfeiting in cases of treatment failure or uncommon adverse reactions. They can further contribute by educating themselves and their patients on how to identify fake drugs using visual security tools such as the size and the shape of the tablets or capsules and the quality of the print as well as other aids such as the examination of the holograms. After confirming any case of counterfeit drug, the healthcare provider should enthusiastically convey the information to his colleagues, patients and appropriate authorities. Unfortunately, a recent survey by Odili *et al.* (2006) of 69 pharmacists in Lagos, Nigeria revealed that out of 42 respondents (61%) who have come across at least an incidence involving fake drug only 31% (13) bothered to take the case to the

appropriate authority i.e., the National Agency for Food and Drug Administration Control (NAFDAC). This finding reveals the apathy of healthcare providers on this problem. The need for the contribution of healthcare personnel in fighting this menace is even more essential in the rural areas where control and monitoring of the sources of the drugs in circulation is difficult due to inadequate number of law enforcement personnel.

In developing countries, governments tend to take actions only in response to a public outcry. Hence, there is need for a well-organized advocacy and public awareness from experts and healthcare professionals so as to generate enough pressure for the law makers to change the current laws concerning drug counterfeiting.

## CONCLUSION

The menace of drug counterfeiting is a serious public problem. Reducing or preventing the problem is primary duty of every responsible nation. Drug industries, healthcare providers, consumers and governments are necessary partners in this regard. Tackling corruption at various levels of the pharmaceutical systems is indispensable for the success of the crusade against fake drugs. Also, due to the limited resources of the developing countries that are worst affected with this problem as well as the infectious nature of the problem, there is need for international collaboration in the fight against this crime.

More studies examining the efficacy of the various strategies tried worldwide against drug counterfeiting may be quiet helpful in reducing or even preventing this menace.

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