

Are the Strategies Taken by the FDA Effective in Combatting Counterfeit Drugs?

by

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Abstract

Counterfeit drugs are a major growing global threat. According to a survey by WHO, one of every ten drugs is counterfeited, and this number can reach to seven in ten in some countries. Counterfeit drugs can cause severe risks and sometimes lead to death. The Food and Drug Administration has initiated many programs like establishment of Drug Task Force and introduction of Radio Frequency Identification Technology to minimize the problem of counterfeiting. But, there is no decrease in number of counterfeit drug cases reported each year. However, further data from future years would be needed to analyze and report the strategies taken by FDA are effective enough to combat the counterfeit drugs.

Key Words: FDA, RFID, counterfeit drugs

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Introduction

The counterfeiting of drugs is a major, and growing, global threat. Counterfeit drugs resemble the original drug in appearance but may differ in chemical composition. Counterfeit drugs may lack an active ingredient or may have a smaller amount of an active ingredient or fake packaging and labeling.¹ Both branded and generic drugs are being counterfeited. WHO defines counterfeit drugs as those that have been deliberately and fraudulently mislabeled with respect to identity and/or source.² The FDA defines counterfeit drugs as those sold under a product name without proper authorization, [which] may include products without active ingredients, with insufficient or excessive active ingredients, with the wrong active ingredient or with the fake packaging.¹ WHO estimates that 60% of drugs in developing countries and 20% of drugs in developed countries are counterfeit.² In 2009, the European Union seized 34 million fake tablets in a two-month period, including antibiotics, anti-cancer drugs, and Viagra.² Though the US is considered a safe country with minimum number of counterfeit drugs, the FDA acknowledged that counterfeiting of drugs is an emerging threat when it acknowledged that growing evidence shows that criminals use highly sophisticated technologies that are very difficult to identify. As a combating action, it established the Counterfeit Drug Task Force in July 2003.

Purpose

- In this paper, the strategies taken by the FDA to combat the counterfeiting of drugs were analyzed.
- The counterfeit drug reports from 2006 to 2013 were analyzed.
- The strategies taken by the FDA are effective enough to combat the counterfeiting of drugs are discussed.
- The reasons for the increase of counterfeiting in developing countries than in developed countries were analyzed.

Background

Counterfeit medicines cause significant danger to public health. Counterfeit medicines may have inactive or incorrect ingredients, may have active ingredients in improper doses, or may have sub-potent or dangerous ingredients.¹ The history of counterfeit drugs dates back to the 16th century. During the crisis of anti-malarial drugs, the counterfeiters started selling fake cinchona bark, which resembles the original bark.³ Later in the 1800s, fake quinine was sold in the markets.³ In the 20th century, in an attempt to make easy money, many people were involved in manufacturing and marketing of fake drugs. As the pharmaceutical market is vast, counterfeit drugs have a severe impact on public health. They can increase the mortality rate or create a drug resistance and loss of medicinal efficacy.³ The adverse events from these fake drugs can cause dangerous health conditions.

The drug distribution chain is a complex process and includes many stages. In the legitimate drug supply chain, drugs are sold directly by pharmaceutical companies to authorized drug distributors; the distributors then supply them to hospitals and pharmacies, where they are dispensed to patients.⁴ There may be middlemen like secondary distributors or wholesalers between the authorized distributors and pharmacies, and it is at this point that there is a chance of entry for an unapproved or fake medicine.⁴ Another point of entry for a fake drug is online pharmacies, which is a danger to people looking online for drugs at cheaper prices. The counterfeiting of drugs is done intentionally by criminals who find this a good source of income, and the income earned from these drugs may be funded to terrorist organizations.⁵ The major source of counterfeit drugs in US is through the drug supply chain, and major sales are done through online pharmacies.⁴ The counterfeit drugs not only decrease the sales and profits of pharmaceutical companies but also pose significant health hazards to

the public. The drug counterfeiters today are more sophisticated and better organized than ever before.⁵

The patients who take counterfeit drugs may experience a variety of problems, depending on the ingredients of the counterfeit drugs. In some cases, the counterfeit version may have no active ingredients or a minimal amount of an active ingredient; therefore, these drugs cannot cure the patient's problem.⁶

In other cases, the counterfeit drugs have had harmful substances such as bacteria, floor wax, boric acid, and antifreeze. In another case with cancer patients who used ERYTHROPOIETIN, the counterfeit version was found to be diluted with bacterial contaminated water which was injected to the patients.⁶ sometimes the drugs contained the wrong active ingredients or the wrong concentration of active ingredients. A counterfeit version of GlaxoSmithKline's over-the-counter weight loss drug contained sibutramine instead of orlistat.⁶ The FDA found a counterfeit drug form of PROCRIT, an important drug used to treat cancer. This counterfeit form contained non-sterile tap water and was manufactured in a completely non-sterile environment, which is very dangerous to the public health and can cause serious blood infections.⁷ Another incident observed under FDA surveillance was the drug insulin substituted by a less expensive injectable drug.⁷ Aspirin tablets were labelled as ZYPREXA, a drug used to treat schizophrenia and bipolar disorder.⁷ This could have been particularly dangerous for patients who are aspirin-sensitive or aspirin-allergic, or who have bleeding disorders.⁷ The counterfeit form of SEROSTIM, a growth hormone used by AIDS patients, contained no active ingredient.⁷ Another example of a counterfeit drug was bevacizumab is a cancer-fighting drug manufactured by Roche Pharmaceuticals.⁸ In February 2012, Roche Pharmaceuticals identified the problem and

notified physicians that there was a counterfeit version of bevacizumab circulating in the market; this version contained salt and starch but no active ingredient.⁸ The first case was reported in February 2012, followed by two more cases: one in June 2012 and one in February 2013.⁸ In all three cases, the counterfeit versions were distributed all over the US. In one of the cases, the counterfeits should have been easily identified, as the labels were in French.⁸ In another case, seven oncologists were found guilty of purchasing unapproved drugs for lower prices but billing them at the original prices; the oncologists were fined \$2.6 million.⁸

Today, there are many channels to distribute counterfeit drugs, such as online pharmacies, pharmacy distributors, and private and government hospitals.⁴ For many years it was difficult to detect and identify the counterfeit drugs due to a lack of skill and/or technology. According to FDA reports, on average there has been an increase of 20 cases per year since 2000.⁹ As the drug manufacturing process has become more complex and sophisticated, it has become more challenging to identify unsafe counterfeit drugs. Strong drug regulations and proper supervision of drug distribution, as well as technological approaches like radio frequency identification devices, are helpful in identifying counterfeit drugs and minimizing their use.

The FDA has initiated task forces to combat the counterfeiting of drugs. The goal of the Counterfeit Drug Task Force, established in 2004, is to implement highly sophisticated technologies to combat the counterfeit drugs, to achieve the goals of the Prescription Drug Marketing Act, and to implement strict anti-counterfeit laws.¹⁰ The 2005 task force has taken the initiatives of securing the drug packages and safe movement of drugs in the drug distribution chain.¹¹

In 2010 and 2012, government agencies took the following actions:

- The FDA opened investigations into 227 rogue Internet pharmacies and convicted 219 individuals.¹²
- One hundred and thirty-eight counterfeit drug investigations by Immigration and Customs Enforcement led to 56 convictions and the seizure of nearly \$7 million.¹²
- The United States Postal Inspection Service worked on 392 counterfeit drug investigations and arrested 560 individuals.¹²
- The IRS conducted 22 counterfeit drug investigations and convicted 5 individuals.¹²
- The DEA seized more than \$1 million in the course of 49 investigations into rogue Internet pharmacies.¹²

Strategies Taken by the FDA to Combat the Counterfeiting of Drugs

To prevent the proliferation of unsafe and potentially harmful counterfeited drugs, the FDA started a task force that works jointly with other government agencies. This force plans and implements new steps to prevent counterfeit drugs from entering into the drug distribution chain and minimize the risk posed by counterfeit drugs.¹³

Use of technology. As there is tremendous growth in the global trading of drugs, there is a need for technological protection to avoid the problem of counterfeiting. An ideal counterfeit technology should possess a high level of security (be non-clonable and cannot be duplicated), have higher product application and authentication speed, meet proven standards, be difficult to remove and reapply, be easy to check, have automatic authentication, be useable by consumers, and be legally compliant by the industries.¹⁴ The FDA suggests that the drug manufacturers use more sophisticated techniques and periodically change those techniques in the packaging of drugs.¹³ Barcoding, Track and Trace technology, and mass

serialization are the main techniques suggested by the FDA to prevent the counterfeit drugs from entering the drug distribution chain.

Track and trace technology. Track and Trace Technology is one of the important techniques implemented by the FDA. With this technology, each package of medication that enters into the supply chain can be tracked from the manufacturer to the final consumer.¹³ The main goal of this technique is to assure that the drug is manufactured and distributed under secure conditions. Radio Frequency Identification Technology is one kind of the Track and Trace Technology used by the FDA. Radio Frequency Identification (RFID) technology is a wireless system that utilizes radio-frequency electromagnetic fields to obtain data for tracking and identifying the packages.¹⁴ RFID uses a small radio frequency chip tied to all medication packages entering the supply chain.¹⁵ Every package can be tracked electronically using unique serial numbers at each step of the chain.¹⁵ There are two types of radio frequency chips used in RFID technology. The first type is passive; this does not contain a power source and can be detected by an RFID source within a 30-foot range.¹⁵ The other type is active. This has a power source and can transmit information continuously to longer distances.¹⁵ The active type is ideal for tracking drug packages, as it continuously transmits data about the location of the package, but the disadvantage is that there must be a continuous power supply. The passive type can be used to transport the packages in harsh climatic conditions or to the places where the power supply is limited.¹⁶

Mass serialization. Serialization includes the processes of generating, encoding, and verifying the unique identity of individual physical items.¹⁴ With mass serialization techniques, the authenticity of a specific package can be identified. Without mass serialization, the authenticity and validity of the pedigree relates only to the lot number

consisting of thousands of packages. Mass serialization, when combined with Track and Trace Technology, will improve the drug tracking process in the supply chain.

Global trade item number. A unique number is digitally assigned by the manufacturer to track the package in the drug distribution chain.¹³

Data carriers. These are graphical systems used to convey the product identifiers and associated information in computer and/or human readable format.

Border study. The task force works closely with US Customs and Border Protection to initiate a study of pharmaceuticals entering the US from all major ports of entry, to better determine the type and extent of drugs arriving from overseas and the degree to which counterfeit drugs are among such imports.¹³

Alert system. In 2004 the task force established a Counterfeiting Alert Network across the distribution chain to improve communication about known or suspected counterfeit products in the drug supply chain and to develop a network of consumer groups and industry representatives.¹³ The Counterfeit Alert Network is a combination of health profession and consumer groups.

Strengthen distribution system. The task force works to identify the mechanism to strengthen the wholesale drug distribution system to avoid the entrance of counterfeit drugs into the system.¹³

Engage private sector shareholder. The task force gathers private sector information and works with pharmacy and health professionals, drug manufacturers and distributors, and other stakeholders on how to best counter this criminal practice.¹³

Higher penalties. The task force works to impose higher penalties for those who are found guilty of manufacturing or distributing counterfeit drugs.¹³ For example, the current

penalty for counterfeiting a drug label is 10 years in prison, but the penalty for counterfeiting the actual drug may be only 3 years.¹³

Authenticating technologies. Authenticating technologies are used to identify and separate the counterfeits from the original products. Authentication technology includes measurement of color-shifting inks, chemical markers, and holograms. Use of these techniques will differ from product to product.¹⁰

Apart from the above actions, the FDA wants pharmaceutical companies to implement strategies like track and trace technologies and product authentication technologies to minimize the counterfeiting of drugs.

Counterfeit Drug Task Force Report 2004

In response to the emerging counterfeit drug problem, the FDA established the Counterfeit Drug Task Force in July 2003. The approaches taken by the task force to protect people from counterfeit drugs are discussed in the following section.

Implementing new technologies. Counterfeiters are using highly sophisticated technologies to duplicate the original drugs. There is a need to implement new technologies to identify and differentiate the counterfeits from the original drugs. Track and trace technologies and product authentication technologies help in minimizing the problem. The FDA is looking to improve modern electronic technology rapidly, to assure that the drug was manufactured and distributed under safe and secure conditions. Reliability can be accurate with electronic technology instead of paper record-keeping.¹⁰ RFID technology is the most promising electronic technique to identify counterfeits.¹⁰ Efforts have been made by the FDA to conduct studies on RFID to confirm that it will provide benefits by tracking packages at a low cost.

Adoption of electronic track and trace technology to reach the goals of the prescription drug market act. The FD&C Act was amended with the Prescription Drug Marketing Act in 1987.¹⁷ This act established legal safeguards for the distribution of prescribed drugs. The wholesalers need to submit a statement or pedigree prior to distribution of wholesale drugs.¹⁷ This was established to prevent the diversion of drugs and samples. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them.¹⁷ An electronic pedigree is an electronic document that provides information about the history of a particular batch of a drug.¹⁷ Using RFID technology, an electronic drug pedigree can be provided at low cost, without a need for paper. The main purpose of e-pedigree is to protect the consumer from counterfeit or substandard drugs.

Adoption of strict and proven anti-counterfeiting laws. States' licensing authorities and wholesale drug regulators have important roles in the drug supply chain. The FDA works closely with the National Association of Boards of Pharmacy to implement strong regulations for the licensing of wholesale drug distributors.¹⁰ Implementing such rules made it difficult for false drug distributors to obtain licenses.

Increase in penalty and punishments. The FDA works with the United States Sentencing Commission to increase the penalties and sentencing periods for those who are involved in counterfeiting, based on the level of risk the counterfeiting might have on the public.

Adaption of secure business practices. To protect against counterfeit drugs, drug manufacturers, producers, and dispensers should follow safe and effective business

practices.¹⁰ These people should be more careful and should reject business with unknown people or people with criminal backgrounds.

Counterfeit Drug Task Force Report 2005

The task force report issued by the FDA in 2005 mainly discussed the following:

1. Safe and secure drug product and packaging.¹¹
2. Drug security during the movement in the drug supply chain.¹¹
3. Improving regulatory oversight .¹¹
4. Increasing penalties for the counterfeiters.¹¹
5. Increasing awareness about counterfeit drugs .¹¹

Counterfeit Drug Task Force Report 2006

The task force report was based on the work done by the FDA. This report includes the necessary precautions and steps to be taken by both the FDA and public and private sectors to increase the security of drugs. The task force report issued in 2006 mainly discusses the following:

1. The extent of the use of track and trace technology and Radio Frequency Identification Technology to detect counterfeit drugs.¹⁸
2. The issues that are to be resolved to maximize the use of track and trace technology.¹⁸

The measures taken by the FDA to combat the counterfeit problem are:

- a. Secure the packaging of product, movement of drugs over the supply chain, and business transactions.¹⁸
- b. Ensure that regulations and enforcement are appropriate.¹⁸
- c. Increase penalties for those who are found guilty of counterfeiting.¹⁸
- d. Increase international cooperation and awareness among people.¹⁸

Reasons for the Increase of Counterfeiting of Drugs in Developing Countries Rather than in Developed Countries

In developing countries, many people cannot afford to buy costly medicines. Therefore, they look for cheap, affordable alternatives. The drug counterfeiters are able to enter the fake drugs into the drug supply chain at lower prices. In 1985, WHO identified drug counterfeiting as an emerging problem.¹⁹ This problem was growing tremendously with the possibility of replacing half of the drug supply chain with counterfeit drugs in some developing countries.¹⁹ The main reasons for the greater increase of the number of counterfeit drugs in developing countries than developed countries were:

- Lack of strict regulatory rules in developing countries
- Easy accessibility of counterfeit drugs in the drug supply chain at cheaper prices
- Lack of knowledge about the dangers of counterfeit drugs
- More people below the poverty line who cannot afford costly medicines.

Evaluation of Strategies Taken by FDA

To minimize the problem of counterfeit drugs, the FDA recommended a multi-pronged strategy.²⁰ Strong defensive measures should be taken because the criminals who are involved in counterfeiting will often have a strong financial background, so they can easily adapt to any measures taken to stop the entry of counterfeit drugs into the distribution chain.

Track and trace technology. The adoption of track and trace technology, specifically Radio Frequency Identification technology, by all pharmaceutical companies will have a great impact on the screening of counterfeit drugs entering the US drug supply chain.

Implementation of RFID technology can help to meet the goals of the Prescription Drug Market Act.²⁰ Although RFID is an effective type of technology to track drug packages

throughout the supply chain, it's important that all companies adopt this technology to get better results. It is not easy to make all companies use this technology, because the cost is very high and data security and integrity are most important.

Higher penalties. Because drug counterfeiting is a profitable crime, criminals can easily pay off the penalty when they are caught.²⁰ There is a need to implement a mandatory prison sentence in addition to imposing higher penalties.

Alert system. In 2004, the FDA established CAN (Counterfeit Alert Network). CAN does not work to stop the drugs' infiltration through supply chain, but it helps to minimize the number of patients who are harmed by the potential penetration of such drugs into the U.S. drug supply.²⁰ In order for CAN to work efficiently, information about the counterfeit drug information should be disclosed to the public as quickly as possible. Disclosure of such information may alert the counterfeiters to divert their drugs.

Table 1 provides a list of Counterfeit drugs reported in USA.

Table 1

Counterfeit Cases Reported In USA

| YEAR | DRUG | COUNTRY | INCIDENT |
|-------------|------------------------|----------------|---|
| 2006 JUL 04 | TAMIFLU | USA | Counterfeit TAMIFLU was reported to have been transported from Beijing to New York for the treatment of Bird Flu. |
| 2006 AUG 08 | LIPITOR | USA | Counterfeit LIPITOR oral pills were reported in New York. |
| 2006 NOV 21 | Counterfeit Diethylene | USA | 43 people died when Diethylene glycol was substituted for |

| | | | |
|-------------|----------------------------------|-----|---|
| | Glycol | | propylene glycol in pharmaceuticals. |
| 2007 FEB 16 | Fake Online Drugs | USA | FDA announced that the drugs AMBIEN, XANAX, LEXAPRO and ATIVAN ordered online were fake. |
| 2007 MAR 03 | Fake TAMIFLU | USA | Counterfeit TAMIFLU was reported in New York. |
| 2007 MAY 18 | Fake Toothpastes | USA | It was reported in Panama that about 6000 counterfeit toothpastes had poisonous substances. |
| 2008 MAR 31 | Contaminated Heparin | USA | Counterfeit Heparin, a blood-thinning agent, was found by the FDA. |
| 2008 JUN 30 | Counterfeit Anti Fertility Drugs | USA | Counterfeit anti-fertility drugs were reported by the FDA in the US. |
| 2009 MAR 18 | Fake Weight Loss Pills | USA | Fake weight loss pills were reported in Lubbock, Texas. |

The data in Table 1 were collected from the Commercial Crime Services Case Study database.

Table 2 provides a list of International Counterfeit drug reports.

Table 2

International Counterfeit Cases

| | | | |
|-------------|-------------------------------|--------|---|
| 2006 JUN 12 | Anti-Malarial Drug Artesunate | AFRICA | A man died in East Burma when treated with fake Artesunate tablets. |
| 2006 JUL 04 | Counterfeit | AFRICA | Counterfeit TAMIFLU was |

| | | | |
|-------------|--|--------|---|
| | TAMIFLU | | reported used in the treatment of Bird Flu. |
| 2006 JUL 17 | Illegal Pharmacies Selling Counterfeit Drugs | AFRICA | Many Illegal pharmacies were established in Guinea selling unapproved and counterfeited drugs. |
| 2006 JUL 23 | Fake Malarial Drugs | AFRICA | Fake anti-malarial drugs were found to be imported from China and killed many people in Africa. |
| 2006 AUG 28 | Counterfeit Sleeping Pills | ASIA | A case of counterfeit sleeping pills containing potentially harmful substances was reported in Taiwan. |
| 2006 DEC 18 | Fake Birth Control Pills | ASIA | A case was reported in Beijing of counterfeit birth control pills which are useless for birth control and contain toxic substances. |
| 2006 MAR 26 | Fake Anti-Obesity Drugs | EUROPE | A case was reported by the European Commission about the counterfeit anti-obesity drug marketed with brand name Rimonabant. |
| 2006 JUL 18 | Fake Lipitor Pills | EUROPE | A case was reported in London about fake Lipitor pills. |
| 2006 AUG 09 | Fake Steroid Drugs | EUROPE | A case was reported in London about fake Prednisolone steroid pills. |
| 2007 MAR 03 | Fake TAMIFLU | AFRICA | Counterfeit TAMIFLU was reported in Africa. |
| 2007 AUG 31 | Fake HIV Drugs | AFRICA | Fake HIV drugs were reported in Zimbabwe. |

| | | | |
|-------------|---------------------------------|--------|---|
| 2007 DEC 01 | Poisonous Substance in Drugs | AFRICA | 471 People were killed due to contamination of cough syrups with Diethylene Glycol. |
| 2007 MAY 31 | Counterfeit ZYPREXA | EUROPE | Counterfeit version of Eli Lilly's schizophrenia drug ZYPREXA was found by the Britain Drug Regulator Agency. |
| 2007 JUN 01 | Counterfeit CASODEX | EUROPE | Counterfeit CASODEX, a prostate cancer drug, was reported in the United Kingdom. |
| 2007 MAY 29 | Fake Antibiotics | ASIA | A case was reported in China when a girl died after taking fake antibiotic drugs. |
| 2007 JUN 07 | Counterfeit Anti-Malarial Drugs | ASIA | Counterfeit case of anti-malarial drugs was reported in Southeast Asia. |
| 2007 JUN 11 | Fake Human Plasma Proteins | ASIA | A case was reported in China that 18 hospitals were using fake human plasma proteins to treat the patients. |
| 2007 JUN 13 | Fake TB Drugs | ASIA | Fake TB drugs were found in India. |
| 2007 AUG 03 | Fake Rabies Vaccine | ASIA | Fake rabies vaccines were reported in Northern China. |
| 2007 NOV 01 | Counterfeit Weight Loss Pills | ASIA | Fake weight loss pills were reported in Taipei. |
| 2008 MAR 09 | Fake Cosmetics | AFRICA | Usage of fake cosmetics was reported to be causing skin cancers in Tanzania. |
| 2008 DEC 01 | Counterfeit Viagra | AFRICA | Fake Viagra pills were reported. |

| | | | |
|-------------|---------------------------------|--------|---|
| 2008 FEB 01 | Fake Di glycol Injection | EUROPE | Fake Di glycol injections were reported in China. |
| 2008 MAR 31 | Counterfeit Heparin | ASIA | Fake Heparin, a blood-thinning agent, was reported in China. |
| 2008 APR 27 | Counterfeit Cialis | ASIA | Counterfeit version of the anti-diabetic drug Cialis was reported in New Zealand. |
| 2008 MAY 20 | Counterfeit Viagra | ASIA | Counterfeit version of Viagra was reported in Hong Kong. |
| 2008 JUN 30 | Counterfeit Anaesthetics | ASIA | Counterfeit anaesthetics drugs were reported in Hyderabad, India. |
| 2009 FEB 06 | Fake Teething Medicine | AFRICA | Fake teething medicine killed 84 children in Nigeria. |
| 2009 JUL 22 | Counterfeit Anti-Malarial Drugs | AFRICA | Counterfeit anti-malarial drugs were reported in Ghana. |

The data in Table 2 were collected from the Commercial Crime Services Case Study database.

Methodology

A detailed report of counterfeit drug case reports was obtained from the Commercial Crime Services Case Study database for the counterfeit drug cases reported from 2003 to 2013. The database includes counterfeit drug cases that have been reported all over the world, but only the cases limited to the US were reviewed. The numbers of counterfeit drug cases reported in the US per year are tabulated from FDA website. However, the FDA does not reveal information about the cases closed and about the cases that are still in investigation, as only as much information as is available to the public via the FDA website has been collected. The task force reports from FDA website to combat the counterfeit drugs have been summarized.

Extensive research has been done and data collected from the FDA and other online Databases like Pub Med, CINHALL. The strategies taken by the FDA to combat the counterfeiting of drugs have been summarized and evaluated. The challenges faced by the FDA to develop and implement these strategies have been summarized. The reasons for the greater increase in the number of counterfeit drugs in developing countries than in developed countries have been summarized.

Results

According to the analysis, there has been substantial growth in the number of counterfeit drug cases reported each year. The major cases were reported on the cholesterol-reducing drug, Lipitor (atorvastatin); the erectile dysfunction drug, Viagra (sildenafil); and Tamiflu; there were also cases reported on drugs prescribed for malaria, cancer, and HIV/AIDS. As the FDA doesn't release the details about the cases investigated and the cases which are still under investigation, it is difficult to summarize the number of cases reported on individual therapeutic drugs by year.

Table 3

Number of Counterfeit Cases Reported from 2003-2013

| Year | Number of Counterfeit Drug Cases |
|------|----------------------------------|
| 2003 | 30 |
| 2004 | 58 |
| 2005 | 32 |
| 2006 | 54 |
| 2007 | 31 |
| 2008 | 56 |
| 2009 | 65 |
| 2010 | 72 |
| 2011 | 59 |
| 2012 | 62 |
| 2013 | 59 |

The data in Table 3 were collected from the FDA website.

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm299777.pdf>

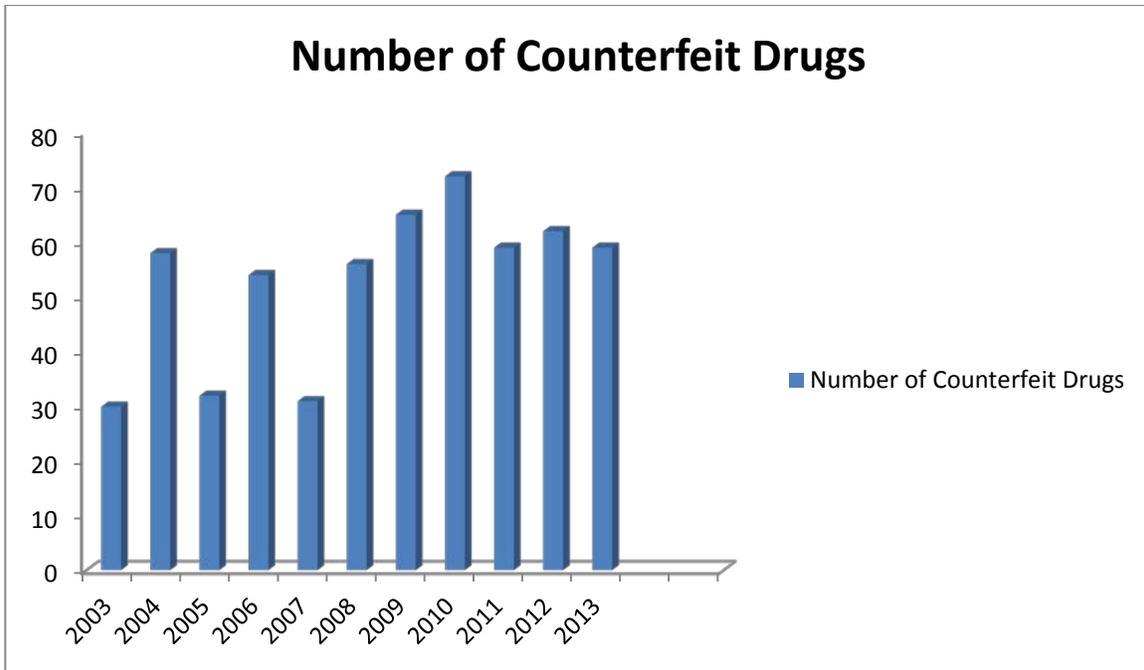


Figure 1. Number of counterfeit drugs from 2003 to 2013.

The data in Figure 1 were collected from FDA Website.

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm299777.pdf>

Discussion

The FDA has initiated many programs to combat the counterfeiting of drugs. One of the main programs they implemented is Radio Frequency Identification Technology (RFID). This involves attaching a technology tag to all of the drug packages, which allows the manufacturers and distributors to track them throughout the supply chain. RFID helps to maintain the electronic pedigree, a record of drug packages from manufacturer to final consumer.

According to the reports collected from the Commercial Crime Services Case Study database and the FDA, 30 cases were reported in 2003. The Counterfeit Alert Network was established in 2004, and the number rose to 58 in that year. This is may be due to the establishment of the Counterfeit Drug Task Force in 2004, as there was an increase in the number of investigations by the FDA, and the FDA released its first task force report. The number then dropped to 32 in 2005, possibly because of the effectiveness of the task force investigations or because the FDA was busy dealing with cases opened the previous year. The FDA released a second task force report about the safe movement of drugs in drug supply chain and packaging. The FDA continued the investigations and implemented RFID technology for use by all manufacturers. In 2006, the number of cases reported rose to 54, but in 2007, the number dropped to 31. The number then increased to 56 in 2008. In 2009, 2010, 2011, 2012, and 2013 there were 65, 72, 59, 62, 59 cases reported, respectively. There are no data available to determine whether the strategies made by the FDA are effective in combatting the counterfeit drugs. But the collected data show that there was no decrease in the number of counterfeit drug cases reported.

RFID technology can be a better solution to track and minimize the counterfeit drugs entering into the supply chain. FDA should work towards improving and implementing this technology by all the manufacturing companies.

Limitations of the Study

The FDA doesn't release much information about the closed cases and about the cases that are still under investigation because the information can alert the counterfeiters to revise their strategy. As there is not much information available from the FDA, it is difficult to categorize the drugs reported each year according to their therapeutic area and source. If the data are available, there is a better chance of analyzing the source, the type of therapeutic area with more counterfeit drugs, and the number of domestic vs foreign counterfeit drugs. There will be a better statistical analysis of counterfeit drugs entering the US drug supply chain each year. There is no information available on the type of drugs using RFID tags; this information can be helpful to accurately analyze the impact of RFID on the counterfeit drugs.

Conclusion

The collected data are not sufficient to analyze whether the initiatives taken by the FDA are effective enough to minimize counterfeit drugs. The data are not easily accessible for the public use. The FDA doesn't reveal much information about the counterfeit drugs reported. But the collected data about the counterfeit drug case reports from 2006 to 2013 show that there was no decrease in the number of counterfeit cases. More data are needed to analyze and report whether the strategies taken by the FDA are effective enough to combat the counterfeit drugs.

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