

**CLRA 695**

US vs. Foreign Source of Counterfeit Drugs Found in US

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## **Abstract**

Counterfeit drugs have been a significant problem for a very long period but have been growing at an alarming pace in the last few years due to increased globalization and Internet commerce. Other reasons contributing to this growth include weak regulations and complex supply chains. This project studied the sources of counterfeit drug cases reported in US and analyzed the role of foreign sources. For investigating the source of counterfeit drugs in US, data was collected from the FDA criminal investigations activities, US immigration investigation activities and literature search. Tracking the sources of counterfeit medicine is difficult as the supply chain extends globally. The counterfeit drug cases reported by FDA, ICE and other government agencies that are available in the public domain were considered for data collection. From the analysis, the foreign sources of counterfeit drugs were found to be greater than US sources. Also, counterfeit drugs which were previously mostly “lifestyle drugs,” are now significantly present in drugs such as anti-cancer drugs. To counter these fake drugs, the US government has been adopting a multi-pronged approach by tightening the regulations, adopting technology for monitoring supply chain and educating public.

*Key Words:* Counterfeit drugs, FDA, Foreign source, Supply chain

## Introduction & Background

### Introduction

In general, counterfeiting refers to the fraudulent copy of another's product without their consent. As per the WHO definition, a medicinal product is said to be counterfeit based on the following definition. "A counterfeit medicine is one which is 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 ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."<sup>1</sup> This definition of counterfeit medicine varies with different countries.

According to U.S Food, Drug, and Cosmetic (FDC) Act, counterfeit medicines are "those sold under a product name without proper authorization, where the identity of the source of the drug is knowingly and intentionally mislabeled in a way that suggests that it is the authentic approved product. This definition can apply to brand name products, generic products, or the bulk ingredients used to make the drug product. Counterfeit drugs under this definition may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer."<sup>2</sup>

The US definition is primarily focused on the consumer perception on the authenticity of the medicines and usually the definition does not apply to the products that are marketed as being similar to or an international version of FDA-approved drugs. Those types of products are known as "unapproved new drugs," but not counterfeit drugs.<sup>2</sup>

## **Emergence of Counterfeit Drugs**

The criticality of counterfeit drugs is one of the serious concerns in both the developed and developing countries alike, with the problem more persistent in poor nations. Counterfeit drugs pose a tremendous risk to public health. Although accurate and detailed data on counterfeit drugs is difficult to obtain, reports indicate a wide range of drug sales is constituted by counterfeit drugs, with 1% of sales in developed countries to over 10% in developing countries, based on the regional area.<sup>16</sup> According to the Centre for Medicines in the Public Interest, counterfeit drug global sales reached \$75 billion in 2010, with an increase of more than 90% from 2005.<sup>16</sup> The number of counterfeiting drug reporting cases have increased continuously over the several years to more than 1,700 globally in 2011 alone, though only 6% of those were in U.S.<sup>14</sup>

The number of counterfeit drug cases handled by FDA is increasing year on year. In United States, every year as many as 40 million filled prescriptions are counterfeit<sup>8</sup>. The Office of Criminal Investigations at FDA opened 59 counterfeit drug cases in 2011, which rose to 170 in 2012.<sup>13</sup> The sources for counterfeit drugs remain unknown as the complexity of drug supply chain is increased by different players, globalization, regulatory differences, criminal activities, etc.<sup>11</sup> A Deputy FDA Commissioner stated that about 80% of active pharmaceutical ingredient manufacturers were outside of the U.S. and the US has been importing 40% of finished drugs.<sup>10</sup>

The major source through which counterfeit drugs reach consumers is unregulated online pharmacies based outside the US in countries such as Canada, China and India. Most of the drugs selling through online pharmacies do not comply with federal, state and pharmacy regulations.<sup>50</sup> Verified Internet Pharmacy Practice Sites (VIPPS) are the authorized websites for

buying drugs online which follow the industry standards recommended by the National Association of Boards of Pharmacies (NABP). About 97 percent of 10,000 drug selling online websites are not standardized.<sup>10</sup>

In 2012, pharmaceuticals constituted 7% of Intellectual Property Seizures establishing the sector as one of the leaders in which patents are violated. While almost non-existent in the top commodities under seizure in 2010, pharmaceuticals were the 6<sup>th</sup> largest commodity to be seized in 2012 demonstrating the rapid rise of the counterfeit drugs in a short period. In terms of monetary value, pharmaceutical seizures have seen an increase of \$82 million. South-East Asia, which includes China, India and Pakistan, was the major source for these pharmaceuticals according to the IPR Seizure report for 2012 by U.S. Customs and Border Protection (CBP) Office of International Trade.<sup>52</sup>

## **Challenges Faced by FDA**

The major causes of counterfeit drugs can be broadly classified into two types; E-Commerce and Supply Chain.

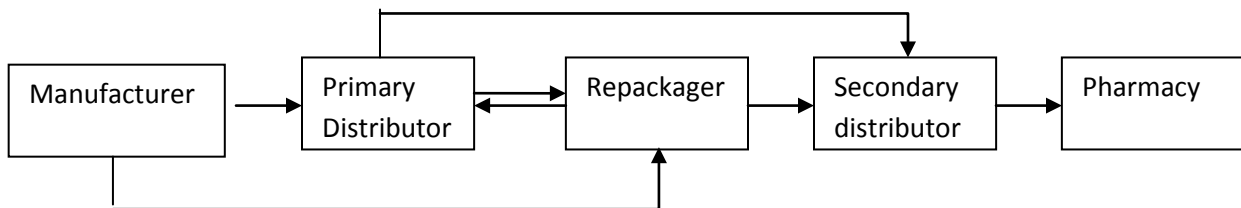
**E-commerce:** Proliferation of websites that sell counterfeit pharmaceutical drugs has taken place in the past few years. More than \$41 million worth of counterfeit medicine that was sold through online pharmacies were shut down by regulators. Around 1700 websites selling these misbranded and unbranded drugs have been closed, but this is only a minor step towards arresting illegal online sale of counterfeit drugs<sup>28</sup>. In a study by the National Association of Boards of Pharmacy, only 257 of 10,275 online pharmacy sites were found to be legitimate. These illegal online pharmacies, which are also known as “Rogue” websites, have mostly foreign

sources, making the investigation process challenging<sup>28</sup>.

**Supply Chain:** Understanding the pharmaceutical supply chain helps in understanding the process by which counterfeit drugs enter the marketplace. The supply chain includes:

- Manufacturer
- Primary Distributor
- Repackager
- Secondary Distributor
- Pharmacy

Globalization of the supply chain led to a complex chain wherein a drug is manufactured in one country, exported and passed through various stages before it reaches the consumer. This complex process increases the vulnerability of the system to counterfeiting. (See Fig. 1.)



**Figure 1:** Drug Supply Chain

*Source:* Bernstein, I. B. FDA efforts: Counterfeit drugs. U.S. Food and Drug Administration. <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm299777.pdf>, Published March 10, 2012.

Some of the challenges that are faced by FDA in case of counterfeit drugs are globalization, corruption, weak regulatory systems and drug shortages. Some of the WHO countries have not adopted national legislation and regulation against the counterfeit drugs which has its severe effects not only in those countries but also affecting the global supply chain. Out of 191 WHO members, 30% doesn't have drug regulation or ineffective drug regulation against



counterfeiting. Ineffective personnel, weak drug regulation, lack of training, weak drug enforcement and penalization are few factors which promotes drug counterfeiting directly or indirectly<sup>1</sup>.

## **Trends in Counterfeit Drugs**

The Office of Criminal Investigations (OCI) Review of FDA in 2011 gives insights on counterfeit and diversion criminal case information. Though there were no empirical outcomes in the report, some of the key findings of the report are<sup>54</sup>

1. The top counterfeited drugs were oral dosage drugs followed by injectables and inhalers. Initially, “life style” drugs were the prevalent ones in the counterfeit market, but more critical drugs like cancer and AIDS drugs were also counterfeited in the recent years.
2. A dominant 86% of the suspects were individuals (Pharmacists, Secondary distributors etc.) and the rest were fake organizations.
3. Considering the players in the supply chain, wholesalers were associated with the highest percentage of suspects followed by pharmacists. This shows the complexity in the supply chain where in numbers increase multiple times at the end of the supply chain, making it difficult to monitor.

## **Anti-Counterfeit Drugs Steps**

One of the major sources for counterfeit drugs is imports. FDA monitors one third of the total imports into USA which includes drugs, food and cosmetics.<sup>45</sup> FDA, along with other

agencies like Homeland Security Investigations (HSI) and Customs and Border Protection (CBP) monitor imported drugs. Many operations, which include Operation Dragon Moon and Pangea V, have been carried out and seized tons of counterfeit drugs.<sup>45</sup> The number of operations increased over the last few years, with majority targeting Internet pharmacies.<sup>28</sup> The “Safeguarding America’s Pharmaceuticals Act of 2013” proposed a set of regulations that focused on increasing the accountability and scrutinizing the drug supply chain process. The players in the supply chain (wholesalers, primary and secondary distributors, etc.) must now inform the national authorities about unusable drugs, thus making each part of the chain more accountable.<sup>52</sup>

To verify the authenticity of an internet pharmacy, NABP provided list of valid pharmacies to cross check<sup>46</sup>. NABP published a list of fake websites which accounted for 97% of drug-selling websites and are not recommended for purchasing drugs<sup>47</sup>. Also, Internet pharmacies are given VIPPS seal by NABP to distinguish them from fake sites. Besides this action, FDA is providing the Counterfeit Alert Network (CAN), News Releases and educational messages for consumer information.<sup>45</sup>

Technology has enabled the process of monitoring the supply chain to be more effective. Among these, Radio Frequency Identification (RFID) technology makes the tracking of a product from production to final purchase a cost effective endeavor. The applications of RFID have been in inventory management but will also be of immense value in case of tracking the drugs from manufacturing to the point of sale. This helps in tracing thefts and adulterations in the supply chain. Track and Trace technology has gained much importance and is used widely in tracking the counterfeiters. For example, Tamper Evident Labels, PUF technology, 2D and 3D

Bar Coding, Holograms, Bar Code within an Image, Synthetic DNA Signature, and Serialization technology is available in the market for the pharmaceutical industry to fight drug counterfeiting and adulteration<sup>48</sup>. Sensors used for smart packaging, such as biosensors, nano-sensors and RFID based sensors, makes it difficult for counterfeiters as the sensors are invisible to the human eye and are only detected by sensor signal detecting devices<sup>49</sup>.

Stringent laws and regulations are being implemented by the states based on guidance of FDA and NABP. FDA developed a task force for anti-counterfeiting in 2003 and also provided guidance on the standards for supply chain security<sup>15</sup>. Licensing of wholesalers and importers of drugs are some of the areas that can be effectively addressed with regulation. The Food and Drug Administration Safety and Innovation Act (FDASIA) enhanced the safety of the drug supply chain. FDA also partnered with not for profit organizations such as “The Partnership for Safe Medicines” (PSI) which makes policies and informational resources for consumers, healthcare professionals to ensure medicines are safe.

## **Literature Review**

The amount of information available on counterfeit medicines is minimal and is hidden in public health statistics worldwide. Government reluctance and commercial motivation were considered as major reasons for this phenomenon.<sup>53</sup> The report, “Counterfeit drugs: a growing global threat”, underlines the increased severe effects of counterfeit drugs including a rising death toll.<sup>5</sup> The report, “Counterfeit goods and the public's health and safety” by International Intellectual Property Institute (IPI) indicates that counterfeit drug reporting to WHO is less than 5 % out of 191 member states. The counterfeit drug reporting to WHO counterfeit database by member states is less due to fear of blame, legal action and negative attitude on report outcomes<sup>7</sup>.

## **Role of Supply Chain**

A stolen or counterfeit drug enters the supply chain at various points, predominantly during the distribution phase, thus making it difficult to trace during investigation.<sup>1</sup> The National Association of Boards of Pharmacy, in their report on wholesale drug distribution, highlighted how counterfeit drugs enter into legitimate supply chains and the required actions to counter it. The Counterfeit Pharmaceutical Inter-agency working group report to Congress provided insights on the process of counterfeiting of drugs and proposed solutions and laws that would reduce the counterfeiting of drugs. Some of the solutions included effective sharing of information across the supply chain, integrating business practices and streamlining the value chain<sup>3</sup>. CREATE.org, a nonprofit organization, proposed increasing accountability of the stakeholders with well laid contracts and improving oversight.<sup>8</sup>

## **Role of Internet**

Alan Weiss, in his study, “Buying prescription drugs on the Internet” provides a detailed analysis on the possible ways a fake drug can be sold on Internet. The authenticity of “Cyber doctors” and violation of privacy policies are some other issues of these illegal websites<sup>6</sup>. The GAO conducted a study on online pharmacies and the process of illegal shipments along with the complex process on which these pharmacies operate. Given the sources of most of the websites are foreign and the people involved will likely not be using real names, the investigation of illegal pharmacies pose challenge for FDA and other legal authorities.<sup>9</sup>

## **Purpose**

Given the sensitive nature of counterfeiting cases, only a few examples registered by FDA and Office of Criminal Investigations (OCI) are available in the public domain. This project aimed to study the nature of these cases and understand the extent of the role of foreign sources, the impact of counterfeiting of drugs on the public, and how the counterfeit drugs were obtained and made their way into U.S.

This paper will also discuss the following questions:

- What percentage of counterfeit drugs reported in US are from outside the US?
- What are the challenges faced by the FDA?
- What difference does the source of drug make in combating counterfeit drugs in U.S?

## **Methodology**

For investigating the percentage of counterfeit drugs reported in the US that are from other countries or from within US, data were collected from the FDA criminal investigations activities, US immigrations investigation activities and literature search of counterfeit drug cases reported in US. From the investigation activities and other reported counterfeit cases, the sources of counterfeit drugs are estimated. These cases were analyzed category wise, source wise and source country wise to obtain insights. The cases were classified based on the criticality of the drug, the source by which it entered the market (e.g. online pharmacy, illegal shipments etc) and the manufacturing source of the drug for the purpose of analysis. From these insights, the root causes for counterfeiting are analyzed and the steps that are required to curb counterfeit drugs were discussed.

## Results

### Published Counterfeit Cases

A majority of the counterfeit cases were not published due to potential loss of corporate image, unless the case was strongly established<sup>53</sup>. Thus the number of cases available in public domain is limited. The following analysis was based on published counterfeit cases where the sources of counterfeit drugs were found and reported in US. The published counterfeit cases are summarized in Appendix 1 and detailed below. These cases were obtained from FDA investigations, U.S. Immigration and Customs Enforcement, and other resources such as “The Partnership for Safe Medicines” which is an online resource on counterfeit drugs and rogue websites.

#### List of published cases:

##### **Montana Healthcare solutions**

Avastin is an injectable cancer medication. The counterfeit version of Avastin penetrated the US market completely. The counterfeit version of the drug was discovered in 28 States. The drug had its origins in Turkey and entered the US supply chain. This is a reminder of how globalization and complex supply chains increases the vulnerability towards counterfeit drugs.

(See Fig. 2.)

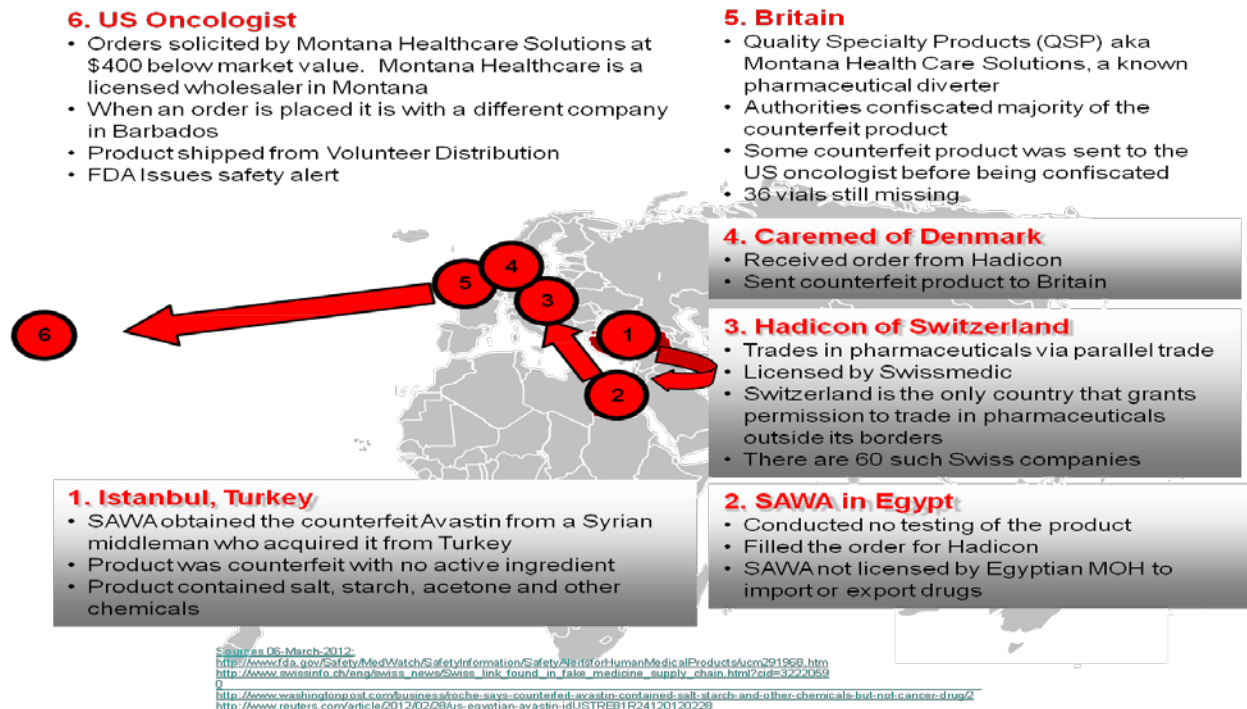


**Figure 2:** Counterfeit Avastin

*Source:* Genentech Statement on Counterfeit drug labeled as Avastin in United States. Retrieved from [http://www.gene.com/media/statements/ps\\_021412](http://www.gene.com/media/statements/ps_021412)

The FDA warned physicians in these states and also prosecuted some doctors for selling these fake drugs. The FDA also issued two other public warnings. During prosecution it was revealed that the roots for these misbranded drugs were from a supplier based in United Kingdom and the manufacturing was in Turkey<sup>24</sup>. Figure 3 provides a summary of the movement of this counterfeit product.





**Figure 3: Journey of Counterfeit Avastin to United States**

Source: Rx – 360(April, 2012). Overview: Fake Avastin® Pulls the Curtain Back on Internet Pharmacies. Retrieved from <http://www.rx-360.org/LinkClick.aspx?fileticket=lkJFI3rKlhw%3D&tabid=278>

### **Novo Nordisk Inc.**

In 2009 Levemir (insulin) made by Novo Nordisk Inc. was stolen. According to the reports by FDA, the stolen amount constituted three lots of Levemir of more than hundred thousand vials. These vials are still suspected to be in the market. The stolen vials were found to be mishandled making it dangerous for use. There were instances where patients suffered due to poor glucose control after usage<sup>37</sup>.

### **Teva Pharmaceutical**

In May 2012, a misbranded version of Adderall, a controlled substance drug for attention deficit hyperactivity disorders and manufactured by Teva Pharmaceutical Industries, was found to be sold on Internet. The fake drug sold via the Internet was found to be counterfeit<sup>38</sup>.

**Biotab Nutraceuticals Inc.**

Extenze is a nutritional supplement to counter erectile dysfunctionality (ED). It was manufactured by Biotab Nutraceuticals Inc. Two lots of the counterfeit drugs were found to contain tadalafil and sildenafil (the active ingredient in Viagra) and could cause lowering of blood pressure to alarming proportions and could be highly risky for patients with a history of heart failure<sup>39</sup>.

**Calvelo**

Calvelo, a Belgian company sold more than 40 misbranded drugs and around one and half million dollars worth of fake drugs through an online pharmacy. Most of the customers were from the USA. The websites targeted consumers looking for lifestyle drugs such as Xanax or Viagra at cheaper rates or discounts. With even a call center service established to support its operations, Calvelo was a harbinger of how dangerous online pharmacies could be<sup>18</sup>.

**Gallant Pharma**

Gallant Pharma, by representing itself as a Canadian company, sold more than \$8 million worth of drugs that were either not in accordance with the FDA standards or not approved in the US. The company had a team of sales representatives across Virginia. Gallant had conspirators in Canada and the United Kingdom and they illegally shipped or imported drugs from South East Asian Countries and Turkey<sup>23</sup>.

**San Diego Pharmacy**

A San Diego Pharmacy run by Martin Paul Bean sold \$7 billion worth counterfeit oncology medicine to doctors at discounted prices through Oct 2011. Mr. Bean served 2 years in prison for this activity. He also admitted he also sold fake oncology drugs under the company Global RX store. The origins of these fake drugs go back to Turkey and South East Asian

countries such as India and Pakistan<sup>33</sup>.

### **Auction Sites**

Shipped from a Chinese Manufacturer, Shem Michahdavid Weissman sold ExtenZe, a male enhancement pill through popular the e-commerce site eBay. He obtained the drugs, which were unapproved in the US, from China.<sup>27</sup>.

### **www.hardtofindrx.com**

Shane Lance, A North Carolina resident, through his website www.hardtofindrx.com, was found to be selling fake Viagra and Cialis without a prescription. The website advertised these Pfizer and Eli Lilly products openly. Upon research and testing, the drugs sold by the site were found to be fake. A Chinese based company manufactured these counterfeit drugs which were distributed by Shane Lance<sup>30</sup>.

### **Internet (www. Alibaba.com)**

Robin Han, A Physician, supplied counterfeit erectile dysfunction drugs, which included Viagra and Cialis, to distributors based out of the West Coast through websites posing as a supplier. He was based out of China before his arrest by the Homeland Security Investigations (HSI) and Customs and Border Protection (CBP). He shipped the fake drugs from China to USA illegally using packaging slips claiming them as plastic stationery holders and pen boxes. His credibility as a physician helped him in reaching suppliers easily<sup>31</sup>.

### **Internet**

Francis Ortiz Ganzalez, through a host of websites, sold imposter drugs, which included Viagra, Cialis, Valium, Xanax and Lipitor, was caught with counterfeit drugs worth nearly \$200,000 in a raid by the ICE. The drugs were shipped illegally to US from China. These drugs

were later supplied to other US regions from Southern California<sup>34</sup>.

Luis Torres, a 41 year old man based out of Puerto Rico, was convicted by the HSI and FDA for distributing counterfeit pharmaceuticals that included misbranded and counterfeit drugs. He distributed fake Viagra and Cialis via the Internet. The drugs were imported illegally from China<sup>35</sup>.

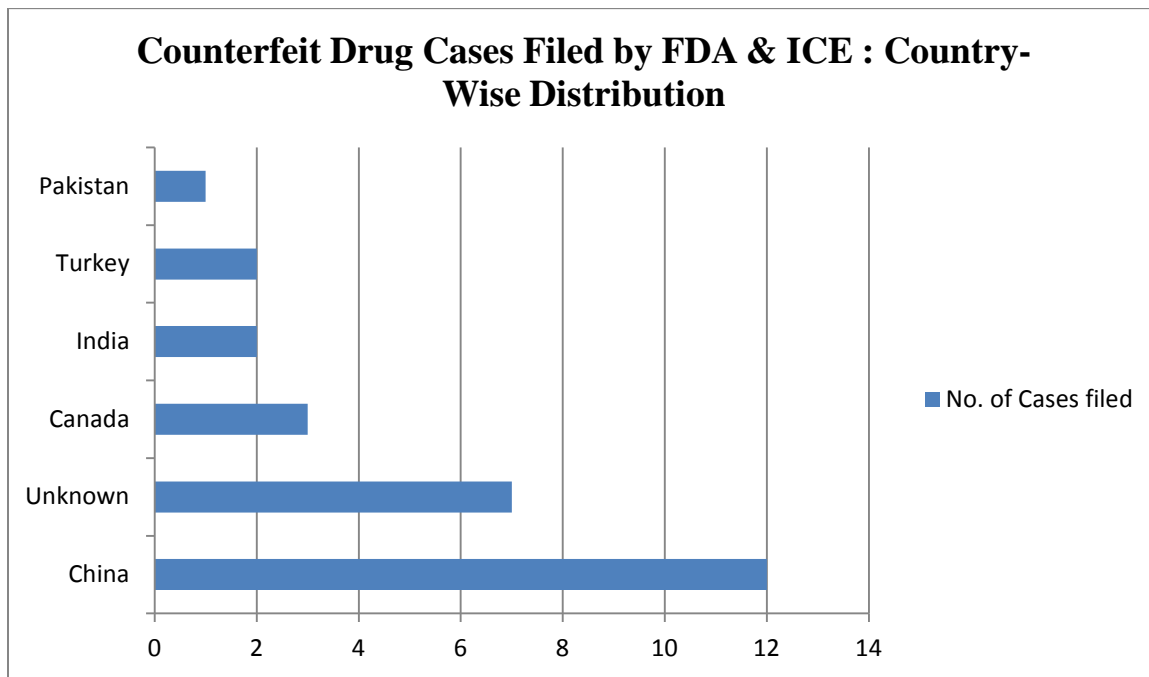
### **Other Cases**

A company by the name JMM LLC was found in 2011 in Rhode Island to be importing erectile dysfunction drugs manufactured in China. These drugs were mislabeled as manufactured in USA before reaching the market, thus making them difficult to track. These mislabeled fake capsules were distributed across Rhode Island, Connecticut and other areas distributors and retailers<sup>19</sup>.

Gabriel Alderete, a Los Angeles resident was found to be shipping several prescription drugs including Lorazepam, Diazepam, Alprazolam, Ketamine, and Sibutramine. These drugs were shipped from international locations. In 2011, around 700,000 pills and tablets were discovered in a raid along with unbranded pills<sup>29</sup>.

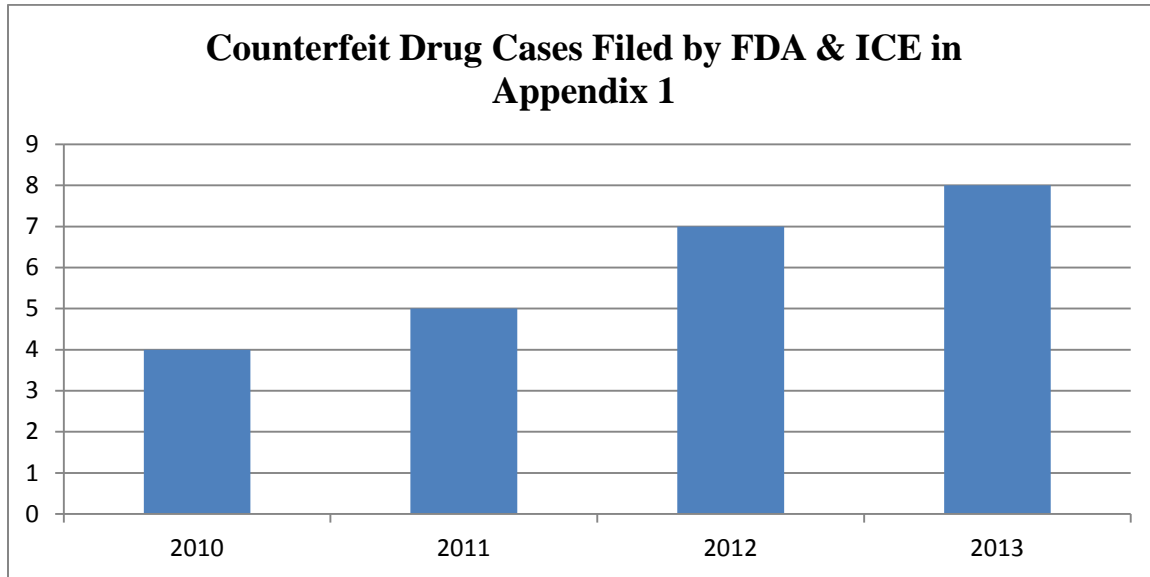
## Discussion

The source of counterfeit drugs was primarily foreign, particularly Turkey (2), Canada (3) and China (12). These are detailed in the Appendix and summarized in Figure 4.



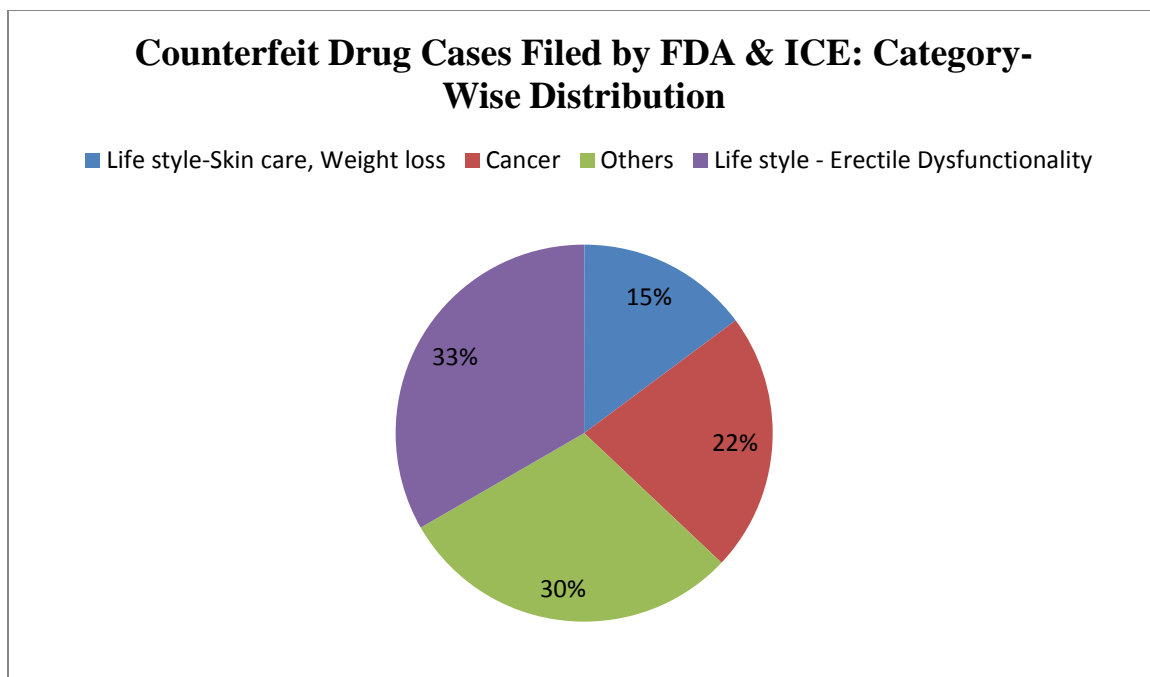
**Figure 4:** Counterfeit Drug Cases Filed by FDA & ICE: Country-Wise Distribution

A total of 24 cases filed by FDA and ICE were considered for the analysis. The number of cases recorded year wise is presented in Figure 5. Clearly, enforcement has increased and is likely to continue to increase given the recent sharp rise.



**Figure 5:** Counterfeit Drug Cases Filed by FDA & ICE Listed in Appendix 1

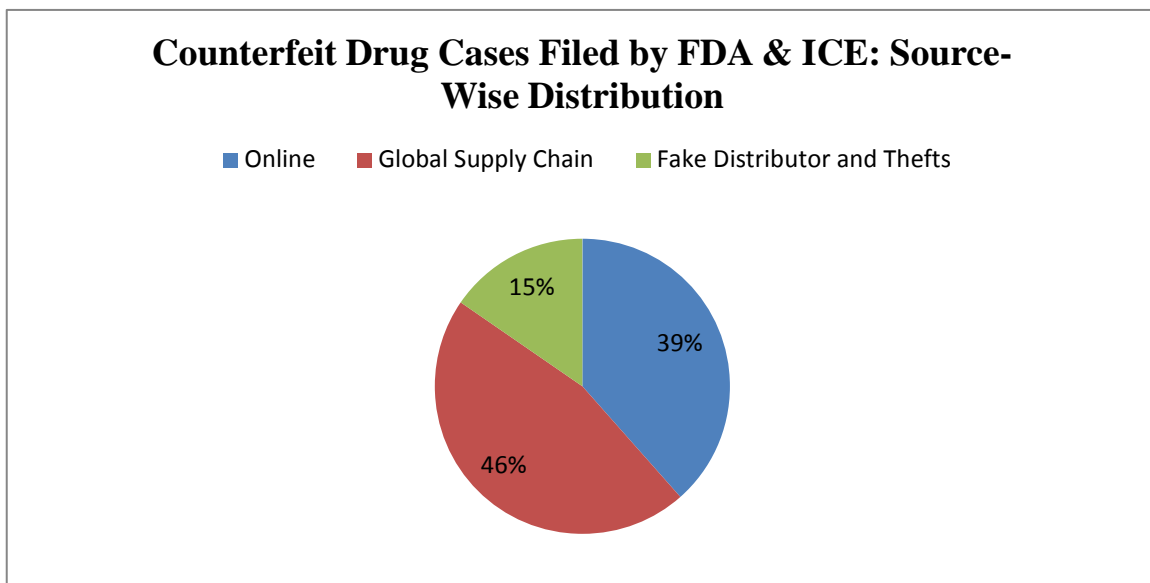
The major use category dominated by counterfeit drugs are lifestyle drugs (48%), out of which erectile dysfunctional drugs constitute the lion’s share (68%) (Figure 6).



**Figure 6:** Counterfeit Drug Cases Filed by FDA & ICE by Category-Wise Distribution.

Lifestyle drugs are most counterfeited as people purchase lifestyle drugs frequently and search for less expensive options. Among lifestyle drugs, sexual enhancement products such as Viagra or Cialis are highly sought on the Internet. Also, counterfeiting has significantly increased in anti-cancer drugs which are associated with higher risks. Almost a quarter (22%) of the cases studied were anti-cancer drugs indicating the alarming increase of fake anti-cancer drugs which had meager presence a decade ago. Counterfeiting of these critical drugs which are associated with higher risks is increasing year by year and is posing a significant challenge for FDA.

Thirty-nine percent of the counterfeit cases recorded were through online commerce sites and 46% were by companies with global supply chains in which the counterfeit drugs are manufactured in one country and are shipped to US (Figure 7).



**Figure 7:** Counterfeit Drug Cases Filed by FDA & ICE: Source-Wise Distribution

Fifteen percent of the counterfeit cases are due to an illegal distributor who shipped counterfeit drugs from other sources which in turn circulated in the US. The majority of the counterfeit drugs (46%) were from online drug websites. Drugs obtained from the Internet have been on rise in the past few years. The e-commerce sites are registered in countries like Canada although these are not the manufacturing sources. The manufacturing source of the drugs included South East Nations like India, China where as the location at which the websites are registered included Canada, U.K. and the USA. The shipments are done illegally hidden along with stationery, stuffed inside toys etc to pharmacies and physicians. In some cases, distributors receive these illegal shipments which are then circulated to other retailers and pharmacies thus spreading the counterfeit drugs to a wider reach.

Emerging technologies developed and supported by the pharmaceutical industry to combat counterfeit drugs helped in tracking the sources of counterfeiters and shutting down the counterfeit business. But the question remains unanswered: is the advanced technology responsible for the discovering increased counterfeit incidents or has the actual counterfeits attacks increased? The complexity of the supply chain has great effect on counterfeit product entry into US. Monitoring each point in the supply chain and reducing the number of participants would reduce the risk from counterfeit drug entry into the complex US supply chain. The advanced technology used for the detection of counterfeit drugs should also be extended to more weakly regulated countries.



## Conclusion

Counterfeit drug incidents are increasing and moved from primarily lifestyle drugs to anti cancer drugs. The manufacturing sources of these counterfeit drugs in US were analyzed and are found to be higher from foreign countries (foreign sources accounted for 54% in all the cases studied). The foreign sources of counterfeit drugs are mostly from countries with weaker drug regulations. Major reasons for this counterfeit drug proliferation are found to be globalization, complex supply chains and Internet purchases. Online commerce has become the major cause of these counterfeit drugs which was almost nonexistent a couple of decades ago.

Technology can be used in tracking a drug's journey from manufacturing to the point of sale. This will help arresting the entry of fake products into the supply chain.

Educating consumers and informing them about latest counterfeit products and particularly providing information on websites selling counterfeit drugs and the risks of online purchases on social media would help in arresting the online purchase of fake drugs.

Partnering with regulatory authorities in the countries of origin of counterfeit drugs would help eradicate the problem at the basic level.

The pharmaceutical industry in the weakly regulated countries should take an initiative to fight against the counterfeits which would help in saving the drugs from being exported from the country of manufacture.

Collaborative approaches, knowledge-sharing on new technologies and other methodologies will assist the industry in controlling production of fake drugs.

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## Appendix

### Appendix 1. Published Counterfeit Cases Available in the Public Domain

	<b>Counterfeit Drug</b>	<b>Category</b>	<b>Purpose</b>	<b>Place</b>	<b>Source</b>	<b>Criticality</b>	<b>Year</b>
1	Xanax, Valium <sup>20</sup>	Lifestyle	Weight loss	Illinois	Global Supply Chain. Manufactured in China	Medium	2010
2	Extenze <sup>39</sup>	Lifestyle	Treating Erectile dysfunction (ED)	Biotab Nutraceuticals Inc	Supply Chain	Medium	2010
3	Viagra and Cialis <sup>50</sup>	Lifestyle	erectile dysfunction drugs	North Carolina	Distribution from Pharmacies- Manufactured in India and China	Medium	2010
4	Sibutramine <sup>22</sup>	Life Style	Weight Loss	Philadelphia	Illegal shipment from China	Medium	2010
5	Cinnamon Extract, Multivitamin Samples <sup>19</sup>	Lifestyle	Erectile dysfunction drugs	Rhode Island	Global Supply Chain. Manufactured in China	Medium	2011

	<b>Counterfeit Drug</b>	<b>Category</b>	<b>Purpose</b>	<b>Place</b>	<b>Source</b>	<b>Criticality</b>	<b>Year</b>
6	Oncology Drugs <sup>26</sup>	Cancer drugs	Cancer drugs	San Diego	Fake Distributor	High	2011
7	Klonopin, Xanax, Ativan and Over 40 drugs <sup>18</sup>	Lifestyle	Lifestyle drugs	Kansas and Ohio	Online Pharmacy operated from Costa Rica	High	2011
8	Altuzan (bevacizumab) <sup>25</sup>	Anti Cancer	Injectable cancer medication drug	Missouri	Global Supply Chain. In filtered by UK Supplier	High	2011
9	Sexual stimulants, heart medications, pain killers and others <sup>43</sup>	Lifestyle and cardiac medications	Lifestyle and cardiac medications	International	Ecommerce internationally- Manufactured in China	Medium	2011
10	Viagra, Cialis, Valium, Xanax and Lipitor <sup>34</sup>	Lifestyle	weight loss, erectile dysfunction etc	California	E-commerce and websites and illegal shipping from China	Medium	2012
11	Adderall <sup>38</sup>	Lifestyle	Attention deficit hyperactivity disorders, Narcolapsy		Internet	High	2012

	<b>Counterfeit Drug</b>	<b>Category</b>	<b>Purpose</b>	<b>Place</b>	<b>Source</b>	<b>Criticality</b>	<b>Year</b>
12	Avastin <sup>51</sup>	Anti Cancer	Injectable cancer medication drug		Global Supply Chain. Manufactured in Turkey	High	2012
13	Lorazepam, Diazepam, Alprazolam, Ketamine, and Sibutramine <sup>29</sup>	Anti anxiety	Anti anxiety and depression drugs	California	Shipment from global sources	High	2012
14	Viagra and Cialis <sup>30</sup>	Lifestyle-OTC	erectile dysfunction drugs	Texas	E-commerce <a href="http://www.hardtofindrx.com">www.hardtofindrx.com</a> with a Chinese manufacturer	Medium	2012
15	Viagra, Levitra and Cialis <sup>31</sup>	Lifestyle	erectile dysfunction drugs	California	E-commerce and websites like alibaba.com	Medium	2012
16	Viagra and Cialis <sup>36</sup>	Lifestyle	erectile dysfunction drugs	Illinois	E-commerce with a Chinese manufacturer	Medium	2012
17	ExtenZe <sup>27</sup>	male enhancement pills	male enhancement pills	California	E-commerce (eBay). Shipped from a Chinese Manufacturer	Low	2013

	<b>Counterfeit Drug</b>	<b>Category</b>	<b>Purpose</b>	<b>Place</b>	<b>Source</b>	<b>Criticality</b>	<b>Year</b>
18	Zometa, Kytril, Taxotere, Gemzar, Eloxatin and others <sup>40</sup>	Anti Cancer	Anti Cancer	Ohio	Imported Drugs	High	2013
19	Altuzan and Avastin <sup>24</sup>	Anti Cancer	Anti Cancer	Missouri	Imported Drugs with Source in Turkey	High	2013
20	Abraxane, Alimta, Avastin, Eloxatin, Gemzar, Herceptin, Rituxan/Mabthera, Taxotere and Zometa <sup>41</sup>	Anti Cancer	Anti Cancer		Global Supply Chain. Based in Canada	High	2013
21	Viagra and Cialis <sup>36</sup>	Lifestyle	erectile dysfunction drugs	Illinois	Pharmacy with illegal online shipment from China	Medium	2013
22	Botox and Juvederm <sup>42</sup>	Lifestyle	Skin care	Missouri	Fake Distributor	Medium	2013
23	Avastin	Anti Cancer	Anti Cancer		E-commerce with base in Canada	High	2013

	<b>Counterfeit Drug</b>	<b>Category</b>	<b>Purpose</b>	<b>Place</b>	<b>Source</b>	<b>Criticality</b>	<b>Year</b>
24	Venofer <sup>44</sup>	Dialysis	Dialysis for kidney drugs	Kansas	Misrepresented iron sucrose from China as Venofer	Medium	2013