

# Counterfeit Drugs and the Penal Law

– **Country Report on the laws of the United States, California and Florida<sup>1</sup>**

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## **I. Drug Counterfeiting in Practice – Types of Drug Counterfeiting**

### **A. Description of the pharmaceuticals and medical devices sector in the national health system**

The pharmaceutical and medical devices industry in the United States is in the private sector and is primarily regulated by the national (also known as federal) government, through the US Food and Drug Administration (US FDA) a division of the Department of Health and Human Services or the US ministry of health. Neither the national nor local government produces or procures pharmaceuticals or medical devices, in this chapter referred to as medical products, unless the context requires otherwise. The exception is when the US government or its departments purchases products for its international aid and development programs, through its Veteran’s Administration for veterans in hospital, in programs for the disabled and

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<sup>1</sup> The format of all citations in this chapter is based on THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass’n et al. eds., 2005). The “bluebook” as it is commonly referred to is a legal uniform system of citation. For more information please refer to <http://www.legalbluebook.com/>.

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the poor or other federal programs targeted to specific audiences. For the general public a private sector health system functions and through which patients purchase medical products paid for by private health insurance and out of pocket expenditures. National and local governments also finance the purchase of medicines through the social security and other benefit programs. As in all countries expenditures on pharmaceuticals is the largest segment of public and personal health budgets. National health expenditures for 2005 on pharmaceuticals alone were in excess of \$200 billion, an extremely large portion, or 10% of total US health expenditures.<sup>6</sup> Thus the financial gains resulting from diverting some of these funds remains the main incentive for counterfeiters.<sup>7</sup> In one US-Florida case involving counterfeit Procrit, it is estimated the criminals in the chain may have made a profit of approximately \$46 million from the sale of 110,000 bottles of the illicit drug.<sup>8</sup> Unfortunately, another inducement with dire consequences exists. In addition to evidence that these funds are being used to finance terrorist activities, if a counterfeit drug is made of toxic substances that are potent enough to cause severe morbidity or mortality in humans, the drug itself could easily become a conduit for terrorism.<sup>9</sup>

The chain of distribution in the US can be described as follows. The private sector is the only supplier of pharmaceuticals and medical products in the US, although it is financed by a combination of the private and public health finance mechanisms. Private manufacturers produce domestically and import finished products from US and non-US origin companies for distribution within the US. There are three main types of companies that supply the market; those considered “branded“, generic and wholesalers which may trade in branded or generic prod-

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<sup>6</sup> National Health Expenditure Projections 2006-2016. Centers for Medicare and Medicare Services. <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf>. Accessed September 4, 2007.

<sup>7</sup> Testimony of Robert Penezic, Asst. Statewide Prosecutor for the State of Florida to the House Committee on Energy and Commerce, June 24, 2003. <http://energycommerce.house.gov/reparchives/108/Hearings/06242003hearing982/Penezic>. See also: US Food and Drug Administration. Counterfeit Drugs Questions and Answers. <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>. Accessed November 14, 2007.

<sup>8</sup> Testimony of Robert Penezic, Asst. Florida State Prosecutor to the House Committee on Energy and Commerce June 24, 2003. <http://energycommerce.house.gov/reparchives/108/Hearings/06242003hearings982/Penezic...> Accessed June 18, 2007.

<sup>9</sup> World Health Organization. Combating Counterfeit Drugs: A Concept Paper for Effective International Collaboration. Health Technology and Pharmaceuticals. September 2005. [http://www.who.int/medicines/services/counterfeit/CombatingCounterfeitDrugs\\_Conceptpaper.pdf](http://www.who.int/medicines/services/counterfeit/CombatingCounterfeitDrugs_Conceptpaper.pdf) Accessed November 15, 2007.

ucts. A branded company is one that has a well known name with which its products are identified such as Vioxx, the brand name, aka, trade name and the company Pfizer. A generic product may be sold under the labels of many companies such as drug store chains such as CVS or Walgreens. These products, typically sold over the counter (OTC), are generic and are produced under private label arrangements in which a company is contracted to manufacture under the label or brand of another company. Unlike a “branded” drug, which is generally the name of the product such as Vioxx or products associated with the name of the company such as Johnson and John baby shampoo, a generic OTC even if branded is sold as an inexpensive item.

Companies manufacture and place product into distribution through wholesalers or distributors or through their own sales teams who sell to pharmacies, stores that retail prescription and OTC drugs, hospitals, and medical facilities such as stand alone clinics. There are three large wholesalers who account for about 90% of the primary wholesale market. In addition, there are many smaller wholesalers who may have full or partial product lines. Distributors are responsible for selling certain allotments of products, generally branded products, in assigned territories and are granted discounted pricing which they mark up at rates controlled by the manufacturing company. Wholesalers also purchase for their own account and resell but are generally in no particular arrangement with the company. Generally the difference between wholesalers and distributors is that the latter are in an agreement with the company for the particular products for the particular territory. Companies also have internal sales and marketing teams that sell directly to outlets such as pharmacy stores, doctors and hospitals.<sup>10</sup>

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<sup>10</sup> FDA's Counterfeit Drug Task Force Interim Report, U.S. Department of Health and Human Services Food and Drug Administration, Rockville, Maryland 20857 October 2003. Accessed November 12, 2007, [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html#IIA](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html#IIA).

## Template for country reports

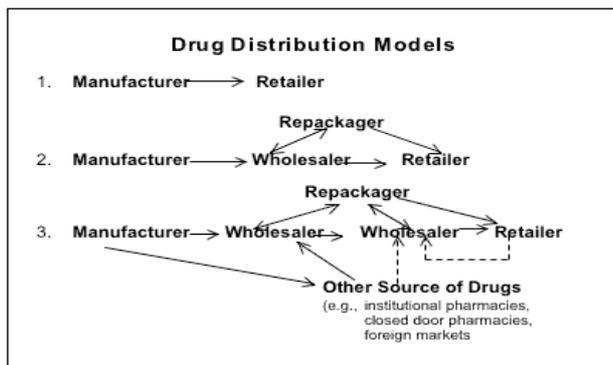


Figure 1

“Figure 1 depicts three models showing the movement of drugs through the U.S. drug distribution system. (The dotted lines indicate potential illegal sales.) In the simplest situation, the manufacturer sells directly to a retailer. However, in many instances, there can be one or more wholesalers, or even a repackager, who handles the drug before it reaches the retailer. It is in these intermediate steps, particularly when the wholesaler(s) and/or repackager(s) obtain products from sources other than the original manufacturer, that the greatest opportunities for compromising the security of the U.S. distribution system exist.”<sup>11</sup>

Medical products are either manufactured within the United States or imported. In both case, all prescription and over the counter medicines introduced into the US market must be approved for marketing by the USFDA and comply with other federal requirements. Excipients and active pharmaceutical ingredients, the components of finished drugs do not have to be approved by the USFDA. The distribution channels for medical products are regulated at federal and state levels; the differences and details of which are later described in this chapter. Generally, the channel for medical product distribution for locally manufactured products includes the manufacture and its suppliers, the wholesaler, distributors, retailers and finally patients. In the case of imported finished products, the manufacturer will be offshore and is effectively replaced by the importer which may be a wholesaler or distributor. Any step in the pharmaceutical supply chain can be replaced by a

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<sup>11</sup> FDA's Counterfeit Drug Task Force Interim Report, U.S. Department of Health and Human Services Food and Drug Administration, Rockville, Maryland 20857 October 2003. Accessed November 12, 2007, [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html#IIA](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html#IIA).

criminal counterfeiter as is postulated by the USFDA in Figure 1 and demonstrated by the samples of US cases described in section I.C.

## B. Counterfeit Products

There have been actual cases and anecdotal reports of counterfeit products for many years in all types of products including foodstuffs, drugs and medical devices and particularly those bearing brand labels. Actual cases of counterfeit Serostim, Cipro, Vioxx, Zoloft, Cialis, Viagra, Neupogen and many other products confirm that in fact counterfeit drugs are in the US marketplace and even in private pharmacies.<sup>12</sup> Counterfeit devices such as polypropylene mesh used in hernia repair and blood glucose test strips have been found in the US.<sup>13</sup>

According to the US Food and Drug Administration the scope of the problem of counterfeit drugs in the US is not widespread within the system of manufacturing and distributing pharmaceuticals. As evidenced by agency criminal investigations there appears to be an increase in counterfeiting activities and increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system.<sup>14</sup> The following table displays the number of counterfeit drug cases opened by the USFDA per year and at the very least represents increased enforcement activity. In this table the term case represents the number newly initiated files opened by the FDA's Office of Criminal Investigations, irrespective of whether there is an indictment or a guilty verdict.

1997	1998	1999	2000	2001	2002	2003	2004
9	5	11	6	21	27	30	58

Another measure of counterfeit drugs is based on US Customs Intellectual Property Seizures (IP Seizures) conducted at ports. IP Seizure data indicates that between 2006 and 2007, the total value of counterfeit pharmaceuticals seized at US

<sup>12</sup> July 11, 2006, ICE Efforts to Combat Counterfeit Pharmaceuticals, accessed August 28, 2007 [http://www.ice.gov/pi/news/factsheets/counterfeit\\_pharms.htm](http://www.ice.gov/pi/news/factsheets/counterfeit_pharms.htm). Testimony of Robert Penezic, Asst. Statewide Prosecutor for the State of Florida to the House Committee on Energy and Commerce, June 24, 2003. <http://energycommerce.house.gov/reparchives/108/Hearings/06242003hearing982/Penezic>.

<sup>13</sup> FDA News, October 23, 2006, PO6-174, accessed August 28, 2007, <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01497.html>.

<sup>14</sup> Remarks by Scott Gottlieb, MD, Deputy Commissioner for Medical and Scientific Affairs at Parenteral Drug Association's Pharmaceutical Counterfeiting Conference. March 3, 2006 <http://www.fda.gov/oc/speeches/2006/pda0303.html> Accessed November 15, 2007.

ports rose from 3 to 9 % of the total value of all seized goods.<sup>15</sup> Countries from which most counterfeit pharmaceuticals originated include China, Hong Kong, Taiwan, and Pakistan.<sup>16</sup>

Private companies and organizations collect internal reports on counterfeiting cases, but these are not made public and otherwise federal and state government agencies do not collect statistics on cases of counterfeit drugs or other goods. As a direct result, it is impossible to know the exact extent of this public health problem, nor to know whether any efforts to combat counterfeit drugs are in fact having any effect.<sup>17</sup>

### C. Modus operandi and Offender constellations

Recent successful prosecutions illustrate offender constellations and their modus operandi. These cases are actual reports from the US Immigration and Customs Enforcement (ICE), a division of the Department of Homeland Security which after September 11 combined other agencies into one and subsumed police activity at all borders.<sup>18</sup> These actual ICE reports are followed by a state case involving counterfeit Lipitor.

Actual reports of ICE cases;

- **“Operation Ocean Crossing** – This ICE investigation began in February 2005, when the ICE Attaché in China received information that a U.S.-based individual, Richard Cowley, and other members of a China-based criminal organization were involved in the sale of counterfeit pharmaceuticals in the United States, the United Kingdom, and other locations throughout Europe. In April 2005, ICE conducted undercover meetings with Cowley and identified his main source of pharmaceuticals in China. Based on this ICE information, Chinese authorities arrested three Chinese nationals in Tianjin province in August 2005 and seized approximately 55,500 blister packs of counterfeit Viagra and Cialis, roughly 75 kilograms of loose pills, an induction-sealing machine, a large quantity of Viagra trademark labels and other pharmaceutical packing materials. **Did they find other counterfeited drugs, too? Apart from live-style drugs?** In September 2005, Chinese

**Comment:** no other drugs were found

<sup>15</sup> Department of Homeland Security US Customs and Border Protection and US Immigration and Customs Enforcement IPR seizures Mid-Year FY 2007. Office of International Trade. [http://www.cbp.gov/xp/cgov/import/commercial\\_enforcement/ipr/seizure](http://www.cbp.gov/xp/cgov/import/commercial_enforcement/ipr/seizure).

<sup>16</sup> Department of Homeland Security US Customs and Border Protection and US Immigration and Customs Enforcement IPR seizures Mid-Year FY 2007. Office of International Trade.

<sup>17</sup> Forzley, M. Counterfeit Goods and the Public's Health and Safety. July 2003. Executive Summary pages ii-iv. Full text can be found at: [www.iiipi.org](http://www.iiipi.org).

<sup>18</sup> July 11, 2006, ICE Efforts to Combat Counterfeit Pharmaceuticals, accessed August 28, 2007 [http://www.ice.gov/pi/news/factsheets/counterfeit\\_pharms.htm](http://www.ice.gov/pi/news/factsheets/counterfeit_pharms.htm).

authorities took additional action against three associated facilities in Henan province that were producing and distributing larger quantities of counterfeit pharmaceuticals. Chinese officials arrested eight Chinese nationals, seized approximately 222,300 tablets of counterfeit Viagra and Cialis, 70,000 loose pills, 260 kilograms of raw materials, 580,000 counterfeit Viagra trademark labels, and 13 pieces of equipment used to produce counterfeit drugs. On the same date, ICE agents arrested Cowley in Washington State as the U.S. distributor for the China-based conspiracy. In February 2006, Cowley pled guilty to the importation of counterfeit pharmaceuticals. His sentencing for this crime is pending.

- **WorldExpressRx.com / MyRxForLess.com / Kolowich et. al.** -- In January 2004, ICE agents in San Diego launched a multi-agency investigation with the Food & Drug Administration, U.S. Postal Inspection Service, Internal Revenue Service, and the FBI, which targeted various websites, Internet payment networks and pharmaceutical supply chains. The targets of this investigation used more than 650 affiliated websites, including *PharmFast.com*, *WorldExpressRx.com* and *MyRxForLess.com*, to distribute more than \$25 million in counterfeit or unapproved pharmaceuticals, usually lifestyle medicines such as Viagra Xenical, Propecia and Celebrex, to distribute more than \$25 million in counterfeit or unapproved pharmaceuticals from Mexico and other nations to U.S. and foreign customers within a three-year period. The distribution network extended throughout North America, while the source country, India, was disguised by the transshipment of products through other nations. To date, 20 conspirators have been indicted, including a practicing pharmacist in California and a practicing pharmacist in Mexico. Eighteen individuals have pleaded guilty to federal smuggling and/or money laundering charges related to the investigation. Search and seizure warrants have resulted in the seizure of more than \$1.4 million in illicit proceeds, more than 1.4 million units of various controlled and non-controlled pharmaceuticals that, if sold properly in the U.S., required valid prescriptions. The primary violator, Mark Kolowich, was sentenced in January 2005 in San Diego to 51 months imprisonment.

A case prosecuted by the Office of Criminal Investigations of the USFDA, involved counterfeit Lipitor demonstrates the offender constellations and modis operandi. A Cuban citizen, residing in Miami, Florida and three other Americans also residents of Florida were involved. Each played a part separately to accomplish the multi-million dollar counterfeit drug smuggling, manufacturing and labeling operation that resulting in convictions for each on separate charges and for all on conspiracy. Criminal activities included sale of counterfeit drugs, theft of drugs, misbranding, illegally importing drugs, acquiring the tools, materials and dies to manufacture counterfeit Lipitor, illegally importing legal Lipitor, creation of false pedigrees, warehousing counterfeit prescription drug both in the US and in Nicara-

gua, repackaging, printing counterfeit labels and transporting counterfeit prescription drugs. The countries of Brazil where fake Lipitor was manufactured; Nicaragua where fake and stolen drugs were stored; Costa Rica where counterfeit product was manufactured; and the US were involved in this case.

A case involving the internet and successfully prosecuted by the United States Attorney's office for the Southern District of Texas involved James George, a licensed pharmacist, who was charged with conspiracy to introduce into interstate commerce counterfeit and misbranded pharmaceutical drugs and trafficking in counterfeit drugs from China.<sup>19</sup> In November 2004, 1,000 counterfeit Cialis tablets and over 4,500 counterfeit Viagra tablets were discovered in a large package labeled as health food arriving from China. In December 2004, undercover Special Agents with the FDA made a controlled delivery of the package to George at his pharmacy. The evidence presented at the trial showed that George ordered the counterfeit Viagra and Cialis tablets from China over the Internet from Joyce Zhen, a co-conspirator, for 30 and 35 cents a tablet respectively. Furthermore, testimony revealed the average wholesale price for Viagra tablet was \$9.55 and that for a Cialis tablet was \$13.55. In September 2006, James George was sentenced to two years in federal prison, without parole.

More recently, in September 2007, an Ohio man, Ryan Wheele, was charged with one count of conspiracy and one count of trafficking in counterfeit prescription drugs, namely Viagra, Cialis, and Levitra.<sup>20</sup> The following is an excerpt of the actual release by the Computer Crime and Intellectual Property Section of the United States Department of Justice:

- **“Man Charged In Online Pharmacy That Sold Counterfeit Drugs”** - The information charges that Wheele met a co-conspirator on the Internet who was acting as an internet pharmacy, and agreed to receive prescription drugs in bulk and distribute these drugs by mailing them to individuals, per instructions from this co-conspirator, for which the defendant would be paid by this co-conspirator, \$15.00 per order. Over the period of this scheme, the defendant received from the co-conspirator over \$12,000.00 for repackaging and shipping pills in this fashion. The information further alleges that Wheele set up a post office box address and would receive packages which were sent by the co-conspirator. These shipments came from such countries as Pakistan, India, and Great Britain, with some of these packages being marked as containing swimming supplies, “swimming treatment” or

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<sup>19</sup> Pharmacist Sentenced to Prison for Ordering and Receiving Counterfeit Pharmaceutical Drugs. <http://www.usdoj.gov/criminal/cybercrime/georgeSent.htm>. Accessed November 15, 2007

<sup>20</sup> Man Charged In Online Pharmacy That Sold Counterfeit Drugs. <http://www.cybercrime.gov/wheeleCharge.htm>. Accessed November 15, 2007

“swimming test supplies,” when, in fact, as the defendant well knew, such packages contained large quantities of pills in bulk of counterfeit Viagra, Cialis, and Levitra tablets. In many cases these counterfeit pills were not uniformly the same. The information further alleges that the defendant would receive an order list of names and addresses of customers, and the prescription drug and quantity these customers had ordered from what was purported to them to be an internet pharmacy. Wheele would then purchase vials and type up purported prescription labels and affix them to the vials so as to give the false impression that a pharmacy actually filled this order. According to the indictment the defendant would then spread out the bulk order of pills, sort through them, and fill these vials by hand in unsanitary conditions such as the sink area of his basement where his pet cats live. Wheele would mail these orders out to the individuals and addresses on the order list, giving a name which was not his name and a fictitious address as the sender and sender’s address on these packages.

In summary, US criminal cases typically involve many actors, many countries, and the importation of counterfeit product of a high value branded drug, re-labeling and misbranding, smuggling, tax evasion and conspiracy.

#### **D. Damages**

All references in the literature on counterfeit drugs indicate that lost sales and tax revenues and the risk to the health and safety of consumers are the damages resulting from criminal activity in counterfeit medical products. All references are however estimates, as is the case even with the latest OECD report.<sup>21</sup> Moreover estimates do not distinguish between losses due to counterfeit medical products or counterfeit goods in general, the losses of which are reported to be in excess of \$200 billion in lost revenue in 2005. Thus any discussion of damages is limited.

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<sup>21</sup> The Economic Impact of Counterfeiting and Piracy. STI/IND (2007) 9/PART4/REV104, Jun-2007. <http://www.oecd.org/dataoecd/11/38/38704571.pdf>.

**E. Prosecution practices and problems**

1. *Measures taken to detect counterfeits (through police, customs, private initiatives) See later section where this subject is repeated in the outline and fits better with US practice*
2. *Organization of prosecution authorities. See II A. 2.*
3. *Private investigations (esp. by the manufacturers of the original products), cooperation with prosecuting agencies – moved to II D. 4.*
5. *Contribution to international cooperation – moved to III B – International Cooperation*

**Comment:** This entire section I believe fits better elsewhere and the topics are repeated throughout the outline and are covered elsewhere. My recommendation is to eliminate it here and to integrate it in other sections. I would suggest the same for section F.

**F. Self-protection by affected companies and consumers –  
Measures taken to educate the consumer**

The National Association of Boards of Pharmacy (NABP) is taking steps to facilitate implementation of the revised Model Rules Model Rules for Licensure of Wholesale Distributors, including: 1) publishing a list of susceptible products and calling for a coalition of national organizations to develop a process to maintain and update the list; 2) serving as bondholder for wholesalers in order to consolidate the need to hold a bond in all states where a wholesaler may do business; and 3) establishing a clearinghouse that will list wholesalers who receive accreditation by NABP and who have passed an inspection by their newly created inspection service, which NABP will conduct in partnership with the states. This is designed to facilitate federal and state pedigree laws.

The US Department of Commerce and the USFDA maintain web sites on counterfeit products. The USFDA publishes alert notices when counterfeit products are discovered in the supply chain. An example of this is the publication of *FDA News*, a web based alert that informed the public about counterfeit blood glucose test strips in October of 2006. This publication included the lot numbers, information on how to identify counterfeit test strips and how to report adverse reactions. Another mechanism the USFDA has developed is the Counterfeit Alert Network, a coalition of health care professionals, consumer and trade associations who have agreed to further disseminate information about counterfeits.

## II. Legal survey

### A. Basic structure of national (criminal) justice system

#### 1. Substantive (criminal) law

At the time the United States government was created political thinkers believed that dividing power between national and state or local governments created the most stable governments. The United States Constitution reflects this philosophy by dividing power primarily in two ways. First, power is divided between the state and federal government. Second, power is divided within the federal and state governments into three branches: legislative, executive and judicial. Administrative agencies or ministries share power with each of the three branches.

Administrative agencies can engage in rulemaking, adjudicating and enforcement. Any regulations promulgated by an agency have the same weight and authority as if they had been passed by the Congress as long as rules are within the mandate of the agency. Each branch of government has appropriate law enforcement capacity to enforce the area of the law against counterfeiting within their subject matter jurisdiction.

The substantive law in the US applicable to counterfeit medical products reflects these divisions. The extent to which federal law is exclusive or concurrent with State laws is governed by the US Constitution. There is exclusive federal jurisdiction over intellectual property and international trade and concurrent jurisdiction over health, its protection and enforcement. On the matter of supremacy of federal laws over state laws, the US Supreme Court, the highest court in the US has recently defined what this clause means.<sup>22, 23</sup>

“It is a familiar and well-established principle that the Supremacy Clause, U.S. Const., Art. VI, Cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. Under the Supremacy Clause, federal law may supersede state law in several different ways. First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms. In the absence of express pre-

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<sup>22</sup> *Hillsborough County, Florida, et al. v Automated Medical Laboratories, Inc.* 471 U.S. 707 (1985)

<sup>23</sup> An update on FDA preemption of state law claims. Tripp Haston and Marc James Ayers. *Defense Counsel Journal* 74.1 (Jan 2007): p 81(6).

emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation. Pre-emption of a whole field also will be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."

"Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility," or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,"<sup>24</sup>" (internal citations omitted)

In addition to the division of power between the state and federal government, the Constitution also delegates exclusive jurisdiction to the federal government in the areas of international trade, intellectual property, and interstate commerce each of which is relevant to counterfeit medical product related crimes.

In contrast, federalism in Germany differs from the system of cooperative federalism in the United States described above. Article 30 of the Basic law reads "The exercise of governmental powers and the discharge of governmental functions shall be incumbent on the *Laender* insofar as this Basic Law does not otherwise prescribe or permit."<sup>25</sup> However, the federal government and land government, *Laender*, share concurrent powers in several areas, including civil law, consumer protection, and public health, while law enforcement is within the legislative purview of the *Laender*.

All imports and exports to and from the US are the subject of exclusive federal jurisdiction according to Constitution Article I, Section 8, and cl.3. As a result, US Customs and ICE have authority over counterfeit medical products entering the US. This is the source of the authority to conduct intellectual property seizures of infringing property on arrival to US borders.<sup>26</sup>

A second and important topic over which the U.S. Constitution gives the federal government exclusive power is intellectual property. Article I, Section 8,

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<sup>24</sup> 471 U.S. 707 at 713

<sup>25</sup> Federalism in Germany. [http://www.germanculture.com.ua/library/facts/bl\\_federalism.htm](http://www.germanculture.com.ua/library/facts/bl_federalism.htm)  
Accessed November 17, 2007.

<sup>26</sup> Tariff Act of 1930 (19 U.S.C. § 1337)

Clause 8 of the United States Constitution gives Congress the power to regulate intellectual property rights and to accord exclusivity to their inventors. It reads;

“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

This provision has given rise to three federal statutes; which codified US law. These are the Copyright Act of 1976 et seq, the Trademark Act of 1946 et seq and the Patent Act. Both the Trademark and Copyright Acts have criminal counterpart legislative provisions as described later in this chapter. It was not until 1984 the US Congress enacted federal statutory criminal laws related to counterfeiting trademarks. The Trademark Counterfeiting Act of 1984 made trafficking in goods and services with a counterfeit trademark a felony, permitted the destruction of articles with counterfeit trademarks and increased civil penalties. The Anti-Counterfeiting Consumer Protection Act of 1996 made trademark and copyright counterfeiting predicate offenses under Racketeering Influenced and Corrupt Organization (RICO) statutes (18 U.S.C. §1961-1968. Pub. L.No. 1050147, 111 Stat. 2678; 17 U.S.C. § 506(a).

And last, according to Article I Section 8 of the Constitution, “the Congress shall have Power...to regulate Commerce<sup>27</sup>...among the several States.” The federal government can regulate in only three ways which are to regulate the channels of commerce, the instrumentalities of commerce, and actions that substantially affect interstate commerce.<sup>28</sup> It is a determination that medical products fall within the channels of commerce that the Food, Drug and Cosmetic Act (FDCA limits the ability of the states to regulate in this area of the law because this subject matter is deemed to be of such great national concern. The Food and Drug Administration thus has a legislative mandate power to make rules and enforce those regarding medical products. This prevents “double” prosecution which would be in violation of the U.S. Constitution and prevents states from “interfering” with the prerogative and discretion of this agency. Nonetheless as will be described later, states retain some authority over drug sales.

All powers not specifically given to the federal government remain under state control according to the Tenth Amendment of the Constitution. Given the tensions between state and federal power, there are areas of overlap. In particular these arise in the areas of intra-state trade, health care within the state and the regulation of

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<sup>27</sup> “Commerce” is trade in any goods or services that can be bought or sold.

<sup>28</sup> US v. Lopez, 514 U. S. 549 ( 1995)

medical and allied health professional practice, and the commercial side of health care. The power to regulate these areas and others subject to state control is referred to as police powers. One of these is the right to enact laws to regulate behavior for morality, safety and security and of course public health. State criminal laws deriving from common laws of crimes in most states are now codified into statute.

In sum, the United States Constitution created a government with powers that were divided both between the federal and state governments and among the three federal branches of government. The powers of the federal government have constantly been expanding, and a list of state laws that have been preempted by federal laws is still growing. Even the area of criminal law, once thought to be an area of primarily state government, is not immune as the federal government has been increasingly passing federal criminal laws in the areas of drugs and intellectual property.

2. *Organization of police and prosecution authorities.*

There are two tiers of prosecutorial authority which are based on the source of the law. Any law established by the federal government is enforced by it also through the United States Attorney's Office, a part of the U.S. Department of Justice (U.S.D.O.J).<sup>29</sup> This office has the authority and duty to pursue all cases of violation of federal law for all federal agencies of which the USFDA is one. The relevant federal agency may have an investigatory arm as is the case for the USFDA, but its officers do not prosecute.<sup>30</sup> Federal prosecutors who are assigned to the districts, in which federal courts are located, can also enforce state law in their districts.

States have separate laws on drugs and counterfeits and their state prosecutors have authority and duty to pursue violations of state law. They cannot prosecute federal crimes, although they can be appointed by a federal prosecutor in a particular case and add a federal charge. For example, violations of the California Business and Professional Code would be prosecuted by state prosecutors or could be prosecuted by federal prosecutors. In the alternative, only federal prosecutors could prosecute a person who violates the FDCA.

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<sup>29</sup> <http://www.usdoj.gov/usao>

<sup>30</sup> See Chart below "U.S. Department of Justice" The Department of Justice, Nov. 18, 2007 <http://www.usdoj.gov/dojorg.htm>

In addition to these, ICE sits within the Department of Homeland Security. It is a law enforcement agency and among their duties ICE agents combat the importation and distribution of counterfeit, misbranded and adulterated pharmaceuticals through investigations along side the Food and Drug Administration (FDA), the Internal Revenue Service (IRS), the U.S. Postal Inspection Service (USPIS) and the Federal Bureau of Investigation. None of these agencies has exclusive authority to prosecute counterfeit drug cases. All US federal agencies that have any regulatory jurisdiction over pharmaceuticals only can assist federal prosecutors with the results of their investigations and if they have relevant testimony for trial they may also testify. Otherwise their role is limited to that of regulation and not prosecution of the violation of the requirements of their jurisdiction.

ICE also participates in the Interagency Pharmaceuticals Task Force comprised of US Customs & Border Protection, the Drug Enforcement Administration, the Department of Justice, the Office of National Drug Control Policy, and the United States Postal Service. This task force fosters cooperation among those agencies involved in the regulation and enforcement of laws governing prescription drugs illegally imported via mail and courier facilities.

## **B. National criminal law provisions**

### *1. Protection of intellectual property*

United States intellectual property (IP) law defines intellectual property rights to include copyrights, patents, trademarks, industrial designs and trade secrets but only defines crimes in relation thereto with respect to copyrights, trademarks and trade secrets and none are specific to counterfeit drugs per se but rather the intellectual property right that is infringed in some manner. State law is preempted by the US Constitution and federal statute 17 U.S.C. § 301 which provides that "... no person is entitled to any such right or equivalent right in any such work under the common law or statute of any state." The role of regulating the area of intellectual property rights is reserved to the executive branch of government in the Department of Commerce in its Patent and Trademark Office. Thus there are no crimes under state law that specifically addresses IP infringement.

#### *a. Copyrights*

While most counterfeiting of medical products is conducted by adulterating products and the use of counterfeit labels it is possible to employ a counterfeit copyright. A copyright is defined as "pictorial, graphic, and sculptural works" to

include "... works of fine, graphic, and applied art."<sup>31</sup> Any author or originator of a work that can be evidenced by a copyright can register the copyright under federal law and receive national protection. State law can also provide protection but it is limited to the borders of the state. In the absence of a registered copyright, an author must rely on common law to enforce his rights of ownership which vary by state law which governs property rights. Given the difficulties of enforcing a common law copyright, such as establishing the date on which it was created, few register state copyrights.

A drug can have a copyright associated with it which can be counterfeited. An example is a tag line for a product such as "a name you can trust." Any aspect of drug labeling, packaging or other marketing materials that includes a copyright, can be counterfeited and thus a cause of action for criminal infringement may apply.

17 U.S.C. § 506 defines criminal infringement as when

"Any person who willfully infringes a copyright shall be punished as provided under section 2319 of Title 18, if the infringement was committed. (A) for purpose of commercial advantage or private financial gain;"

For all intellectual property crimes a separate section of the US criminal code, defines permissible punishments. In the case of criminal infringement of a copyright Title 18 U.S.C. § 2319 provides for punishment in the form of prison for up to five years for the first offense and not more than ten years.

*b. Trademarks*

A trademark is a mark used in connection with a good or service and is identified with the product by the public. The names of many drugs, both generic and so-called "branded" have been trademarked. In fact the common understanding of a branded pharmaceutical is one that has been given a trade name such as Viagra, Lipitor, and others. Even generic companies rely on trade names to enhance market share even if the trade name is that of the company itself such as Aspen or the Indian company Cipla. According to the study, Counterfeit Goods and the Public's Health and Safety,<sup>32</sup> it appears that trademarks are the form of intellectual property most often counterfeited. It is not a surprise therefore that US Federal criminal law broadly defines criminal activity in counterfeit trademarks by making criminal both

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<sup>31</sup> 17 U.S.C. §101

<sup>32</sup> M. Forzley, Counterfeit Goods and the Public's Health and Safety, July 2003. [www.ijpi.org](http://www.ijpi.org).

the activities of trafficking in goods and services using a counterfeit trademark and the trafficking of counterfeit labels or other materials bearing a counterfeit mark such as a an emblem. 18 U.S.C. § 2320 states:

“Whoever intentionally traffics or attempts to traffic in goods or services and knowingly uses a counterfeit mark on or in connection with such goods or services, or intentionally traffics or attempts to traffic in labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature, knowing that a counterfeit mark has been applied thereto, the use of which is likely to cause confusion, to cause mistake, or to deceive...”

The penalties for criminal infringement of a trademark in the case of an individual defendant are fines of not more than \$2,000,000 and imprisonment of up to 10 years for one offense under the section. If a defendant is convicted of another offense under the section the fine can be increase to no more than \$5,000,000 and a prison term of up to 20 years. A corporate defendant can be fined up to \$5,000,000 and if convicted of another offense under the section the fine can be increased up to \$15,000,000. The defendants in the Lipitor case were convicted under this statute for printing and distributing counterfeit labels.<sup>33</sup>

c. *Trade Secrets*

A trade secret is information including a formula, pattern, compilation, program device, method, technique, or process, originating from the owner’s intellectual work, and is used for a competitive advantage in commerce. A trade secret is not registered and as a result, claims of infringement are difficult to pursue as demonstrating the trade secret would be necessary for success. However, the adoption of the UTSA, the *Uniform Trade Secrets Act*,<sup>34</sup> by 45 states and the District of Columbia is expected to strengthen business’ claims on their trade secrets. The famous example is the formula for Coca Cola syrup which has never been patented, but rather is kept in a safe. The company ships the syrup to bottlers who mix it with

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<sup>33</sup> The relationship between 18 U.S.C. § 2320 and 21 U.S.C § 331 is two fold. First they are different sections of the U.S.C. Title 18 covers criminal actions and Title 21 covers Food Drugs and Cosmetics properly titled the FDCA. Second, both statutory sections can be applicable in a crime. It is the same as charging a criminal with two different statutes that apply to the same crime. Title 21 has sanctions (see above) and Title 21 has other sanctions (usually criminal with jail time see above). Therefore, both sanctions apply when the crime falls into the statutory definitions of both statutes.

<sup>34</sup> Text of Uniform Trade Secrets Act. <http://nsi.org/Library/Espionage/usta.htm> Accessed November 17, 2007.

carbonated water but never make the syrup itself which is the product of the Coca Cola trade secret. An infringement of a trade secret can also be the subject of a criminal case of pursuant to 18 U.S.C. § 1832 a person;

“... with intent to convert a trade secret, that is related to or included in a product that is produced for or placed in interstate or foreign commerce, to the economic benefit of anyone other than the owner thereof, and intending or knowing that the offense will, injure any owner of that trade secret, knowingly..

(1) steals, or without authorization appropriates, takes, carries away, or conceals, or by fraud, artifice, or deception obtains such information; (2) without authorization copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys such information; (3) receives, buys, or possesses such information, knowing the same to have been stolen or appropriated, obtained, or converted without authorization; (4) attempts to commit any offense described in paragraphs (1) through (3); or (5) conspires with one or more other persons to commit any offense described in paragraphs (1) through (3), and one or more of such persons do any act to effect the object of the conspiracy,”

The offender shall not be fined more than \$5,000,000. However, defendants may be charged under this and other sections which can lead to increased fines and prison terms.

## 2. *Protection of life/health*

The main agency in the US for the protection of health and the enforcement of laws against counterfeit drugs and devices is the US Food and Drug Administration. The United States Federal Food, Drug, and Cosmetic Act (FDCA) was passed by Congress in 1938 giving authority to the Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics. Congress granted the powers to regulate through 21 U.S.C. § 334 to the FDA and the exclusive right to enforce the act and proceed against violators on behalf of the United States in federal court.<sup>35</sup>

FDA law prohibits many activities relevant to counterfeit drugs by 21 U.S.C. § 331. In general, it prohibits the introduction of any counterfeited or misbranded

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<sup>35</sup> 21 U.S.C. 337

drugs into interstate commerce and the receipt and/or delivery of counterfeited or misbranded drugs.<sup>36</sup> This general and broad prohibition captures the range of activities related to counterfeit drugs, including their making, sale, and distribution. The act of placing expired drugs after changing the date on the label or the entire label into commerce is also covered by § 331<sup>37</sup>.

The FDCA contains several definitions of the term counterfeit in 21 U.S.C. § 321. This all inclusive definition allows for a wide scope of activities to be included in an attempt to encompass every possible criminal defense<sup>38</sup> and clarify words that may have multiple meanings<sup>39</sup>. § 321 (g) (2) defines the word “counterfeit drug” the following way:

“ The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.”

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<sup>36</sup> This regulation is not intended to be applicable to the end user/consumer. In the U.S. there does not seem to be end users or consumers buying counterfeit drugs knowing that they are counterfeit. The “consumers” of the counterfeit drugs are the criminals putting those drugs into the stream of commerce. These criminals can be thought of as “consumers” if they are purchasing counterfeit drugs from a person manufacturing the counterfeit drugs, with the intent to distribute them as real drugs. (as the statute states it must be bought and/or put into the stream of commerce) This type of consumer is knowingly purchasing counterfeit drugs. This “moral” element is not listed as an element to the crime in the statute and is not needed to prosecute. (For example in U.S. v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964), the court found that “ In the area of food and drug regulation, a guilty intent is not always a prerequisite to the imposition of criminal sanctions”) The unsuspecting consumer who purchases counterfeit drugs without the knowledge of such drug being counterfeit is not going to be prosecuted. This is because they were a victim and not a knowing participant. Those consumers who purchase counterfeit drugs with the intention to distribute those drugs as either counterfeit or real are prosecuted under this statute because they had the knowledge that the drugs were counterfeit. However, knowing is not a determinative factor. If someone should have know about the mislabeling and were in a position to know or should have know then they too can be criminally liable. U.S. v. Park, 421 U.S. 658 (1975). Therefore, intent is not written into the statute and knowingly is not either. For finding whether or not a “moral” element it needed case law should be consulted.

<sup>37</sup> 21 U.S.C. § 331 - (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

<sup>38</sup> In this context “defense” means something that will prevent the activity from being prosecuted, or excuse the activity as something not illegal. For example if I was charged with drinking under the age of 21 and I was 22 I would then have a defense because I was not under the age of 21.

<sup>39</sup> Just like the word “like” has multiple meanings (something your fond of or it could mean similar)

Mirroring the federal law on trademark counterfeiting, §331 prohibits:

“Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by [Law]...

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.”

In conclusion, the FDCA prohibitions are extensive and cover a broad range of activities a-z plus aa –ii that easily can be associated with the counterfeiting of prescription drugs. Activities can include: adulteration, misbranding or manufacture of adulterated or misbranded drugs, receipt, delivery or introduction into interstate commerce, and counterfeiting marks, labels or packaging. This broad statute provides coverage for any and all activity that may be associated with counterfeiting.

3. *Special provisions (esp. pharmaceutical law, law on medical devices, as well as provisions against organized crime)*

*a. Pedigree*

The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law in 1988. The PDMA was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, sub potent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and is enforced by the FDA.<sup>40</sup>

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<sup>40</sup> Prescription Drug Marketing Act of 1987, Public Law 100-293 and amendments of 1992 Public Law 102-353.

Under the FDA statute, states are permitted to regulate the licensing and distribution of manufacturers and distributors within their specific state. This is considered intra-state commerce and the protection of public health, the regulation of which is reserved to the States. Such regulation will be examined in section II.C. of this chapter. Most states have chosen to require pedigree papers. These provide federal and state authorities to track and trace a chain of possession of products in order to find at what point in the supply chain a counterfeit might have entered. Given that most states and the federal law have a pedigree paper requirement it is entirely possible for a defendant to be charged with violation of both federal and state law.

Federal law in 21 U.S.C. § 331 declares unlawful the failure to keep, produce or submit pedigree papers and prohibits preventing access to them or other records. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription or over the counter drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a distributor that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug products. A distributor of record is the entity that is listed on the pedigree document as distributor, whether registered or not. Not all states require registration of distributors. However, the PDMA does not define "ongoing relationship", however it is likely evidenced by a contract between the parties.

#### b. RICO

The Racketeer Influenced and Corrupt Organizations Act (commonly referred to as RICO Act or RICO) is a United States federal law that provides for extended penalties for criminal acts performed as part of an ongoing criminal organization. RICO was enacted by section 901(a) of the Organized Crime Control Act of 1970, Pub. L. No. 91-452, 84 Stat. 922 (15 October 1970). RICO is codified as Chapter 96 of Title 18 of the United States Code, 18 U.S.C. § 1961 through 18 U.S.C. § 1968.

Under RICO, a person or group who commits any two of 35 crimes—27 federal crimes and 8 state crimes— within a 10-year period and, in the opinion of the United States Attorney bringing the case, has committed those crimes with similar purpose or results can be charged with racketeering. Those found guilty of racketeering can be fined up to \$25,000 and/or sentenced to 20 years in prison per racketeering count. In addition, the racketeer must forfeit all ill-gotten gains and interest in any business gained through a pattern of "racketeering activity."

To make out the claim of RICO a complaint must assert (1) that a “person”<sup>41</sup> within the scope of the statute (2) has utilized a “pattern of racketeering activity” or the proceeds thereof (3) to infiltrate an interstate “enterprise” (4) by (a) investing the income derived from the pattern of racketeering activity in the enterprise; (b) acquiring or maintaining an interest in the enterprise through a pattern of racketeering activity; (c) conducting the affairs of the enterprise through the pattern of racketeering activity; or (d) conspiring to commit any of the above acts.<sup>42</sup>

A pattern of “racketeering activity” means any act which is indictable under some of the federal law of crimes including 18 U. S.C. 2320 relating to trafficking in goods or services bearing counterfeit marks and section 2319 relating to criminal infringement of a copyright.<sup>43</sup>

Sanctions under title 18 U.S.C. for criminal activity state a person “shall be fined under this title or imprisoned not more than 20 years (or for life if the violation is based on a racketeering activity for which the maximum penalty includes life imprisonment), or both, and shall forfeit to the United States, irrespective of any provision of State law”<sup>44</sup>. Also “the court shall enter a judgment of forfeiture of the property to the United States and shall also authorize the Attorney General to seize all property ordered forfeited upon such terms and conditions as the court shall deem proper”.<sup>45</sup>

RICO also provides for Federal Civil remedies. “Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States district court and shall recover three-fold the damage he sustains and the cost of the suit, including a reasonable attorney’s fee ...”<sup>46</sup>

Finally RICO allows for an action under state law.<sup>47</sup> In essence the state would bring a cause of action under federal law claiming a violation of state laws as the predicate acts.<sup>48</sup>

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<sup>41</sup> “person” is defined to include organizations. (any individual or entity capable of holding a legal or beneficial interest in property. 18 U.S.C. § 1961 (2007))

<sup>42</sup> 18 U.S.C. § 1962 (2007)

<sup>43</sup> 18 U.S.C. § 1961 (1) (b) (2007)

<sup>44</sup> 18 U.S.C. § 1963 (2007)

<sup>45</sup> Id.

<sup>46</sup> 18 U.S.C. § 1964 (c) (2007)

<sup>47</sup> 18 U.S.C. § 196 1 (1) (2007) (... which is chargeable under State law and punishable by imprisonment for more than one year ...)

<sup>48</sup> 18 U.S.C. § 196 1

Traditionally RICO has been used to combat the mafia and other criminal organizations in the U.S.<sup>49</sup> In recent years however, RICO has been a platform for creative prosecutions.<sup>50</sup> Along with providing criminal indictments RICO allows for a civil cause of action, and allows states to enact their own RICO laws to prosecute criminally and civilly.<sup>51</sup>

The relationship to other regulations as mentioned above is that they are listed as one of the offenses that will bring a criminal under the application of RICO. If other statutes not defined in RICO are applicable they will also be charged and as described above they will then become an addition of charges. Therefore, someone can be charged with RICO and other statutes not within the definitions of RICO related offenses and therefore suffer the penalties of the combination of RICO penalties and the other related statutes penalties.

To date there have been no cases of drug counterfeiting prosecuted under RICO, although it should and can be an additional strategy to combat counterfeiting.

*c. Smuggling*

Another approach to combat counterfeit drugs can be found in the crime of smuggling, 18 U.S.C. § 545 which prohibits the knowing and willful<sup>52</sup> introduction of merchandise that should have been invoiced, or is contrary to law, or makes or attempts to pass any forged document through any customs house. The USA Patriot Act increased the potential criminal sentence for a violation of 18 U.S.C. § 545 from five years to 20 years incarceration and has always included forfeiture of smuggled merchandise. Simple proof of possession<sup>53</sup> is sufficient for a conviction if a defendant is charged with smuggling.

*d. Conspiracy*

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<sup>49</sup> *U.S. v. Turkette*, 452 U.S. 576 (1981)

<sup>50</sup> The AP (8/3, Hoffman) reports, "Physicians and executives are among 18 people accused of selling prescription drugs over the Internet to people without any examinations, according to an indictment unsealed Thursday that charges them with federal racketeering." The 313-count indictment denotes "the first time organized-crime statutes designed to combat drug cartels and mafia rings have been used to charge anyone with selling prescription drugs over the Internet."

<sup>51</sup> 18 U.S.C. § 1963 & 1964

<sup>52</sup> Knowing and willfully is a "moral element" of proof. It requires the prosecution to show that the person violating the crime did so both knowingly and willfully. This can be established by showing that the person violating the crime knew of the crime and still was willing to engage in the conduct prohibited by law.

<sup>53</sup> Simple proof of possession is showing that the person violating the crime had the item that was being smuggled either on them or in their control.

US federal law, 18 U.S.C. § 371, Conspiracy to Defraud the US has been used to combat counterfeit drugs. This statutory crime creates an offense when two or more persons conspire to commit any offense against the US or to defraud any agency thereof in any manner for any purpose. The general purpose of this statutory crime is to protect governmental functions from frustration or distortion through deceptive practices. The improper acts or objective of the acts need not be criminal under another statute.<sup>54</sup> The distribution of misbranded prescription drugs in interstate commerce and failure to provide required pedigree resulted in a twenty month prison term to a defendant also charged with conspiracy to do so.<sup>55</sup>

#### 5. *Sanctions*

Penalty provisions in federal health and safety laws are codified in 21 U.S.C. § 333 and § 334. Under 21 U.S.C. § 333 a person cannot be imprisoned more than 1 year, and cannot be fined more than \$1,000. For prescription drug marketing violations fines do not exceed \$250,000.<sup>56</sup> Under 21 U.S.C. § 334 costs associated with seizure can be assessed and fined to defendant

Section 334 also grants authority through its officers and employees to order the detention of any article of medical product found during an inspection, examination, or investigation conducted pursuant to the act, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

A prosecution of a counterfeiter could include charges under both §331 and § 2319 and in such a case sentencing can be combined with both applicable penalties in the case of a conviction. Until 2005, federal judges followed the Federal Sen-

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<sup>54</sup> US v Tuohey, 867 F. 2<sup>nd</sup> 534, 537 (9<sup>th</sup> Cir. 1989)

<sup>55</sup> US v Milstein, 481 F. 3<sup>rd</sup> 132 (2<sup>nd</sup> Cir. 2007)

<sup>56</sup> Prescription drug marketing violations are when

any person who violates section 331(t) of this title by--

- (A) knowingly importing a drug in violation of section 381(d)(1) of this title,
  - (B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,
  - (C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or
  - (D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,
- shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

tencing Guidelines (FSG).<sup>57</sup> In general the sentencing guidelines with respect to counterfeit trademarks and copyrights are ordered by the level of offense, dollar value of the goods or proceeds of the crime involved, the nature of the activities such as whether there has been commercial distribution, reckless disregard for bodily injury or possession of a dangerous weapon. As the level and danger created by the offenses increases so does the prison term and monetary penalty. .

#### 6. Precautionary measures for customs / seizure at borders

US law prohibits the importation of goods which copy or simulate registered trademarks owned by US citizens or corporations. At all borders, US Customs is authorized to exclude and seize infringing merchandise from US territory and subject owners thereof to forfeiture.<sup>58</sup> In order for Customs to be authorized to exclude infringing goods, a registered trademark owner must record its mark with Customs which then provides Customs automatic authority to seize and detain counterfeit goods under the Tariff Act. Case law has established that unless a good is bearing a clearly counterfeit mark, it should refrain from detention of the good and leave the trademark owner to pursue private rights of action. US law could be amended to authorize mandatory seizure of any medical product that appears to be bearing a counterfeit mark, although at present no legislation is pending in this regard.

Under the US legal system, states do not have authority over international trade. Accordingly there is no state law, role or authority over customs or seizures at borders. Any state with an international border or that receives international flights of cargo or passengers would have US Customs federal officials to administer the relevant federal law as described here.

#### 7. Possibilities for and limits to the punishment of extra-territorial offenses

The following fact patterns are discussed in this overview of the question of whether extra territorial offences can be prosecuted in the United States.

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<sup>57</sup> In the case of *U.S. v Booker*, 543 U.S. 220 (2005), the US Supreme Court declared the FSG unconstitutional unless federal judges were using them as only as “guidelines” instead of hard fast formula. This case rendered the legal validity of the guidelines in doubt, although the FSG were a good guide traditionally and federal judges would follow them very closely.

<sup>58</sup> 15 U.S.C. § 1124 and Tariff Act 19 U.S.C. § 1526.

1. Whether the United States or a State has jurisdiction over offenses committed abroad by a citizen of the United States which do not have a direct link to the United States or a State.
2. Whether the United States or a State has jurisdiction over offenses committed by a citizen of a foreign Country B in Country B to the detriment of citizens or pharmaceutical manufacturers in the United States.
3. Whether the United States or a State has jurisdiction over offenses committed abroad which have no link to the United States or a State because both the offender and the victim are sole citizens and residents of Countries B and C.

Bases on which jurisdiction can be exercised include: (i) territorial principle; (ii) nationality principle; (iii) protective (or security) principle; (iv) universality principle; and (v) passive personality principle.<sup>59</sup> These are described as follows.

(1) Territorial Principle

Events occurring within a state's territorial boundaries and persons within that territory, even if that person's presence is temporary, are subject to the application of local law. If an offense occurs in two jurisdictions, then the subjective territorial principle allows the exercise of jurisdiction in the state where the crime was commenced, and the objective territorial principle gives jurisdiction to the state in which the crime has been completed, i.e. the forum of injury.

(2) Nationality Principle

Jurisdiction relates to the nationality of the offender. A state may exercise jurisdiction over any of its nationals wherever they may be and in respect of offenses committed abroad. However, typically jurisdiction based on nationality is utilized more by civil law countries than common-law countries because common-law countries restrict nationality jurisdiction to serious crimes. For example, the United States restricts its prosecutions on the grounds of nationality to such crimes as treason, drug trafficking, and crimes by or against the armed forces.

(3) Protective (or Security) Principle

A state may exercise jurisdiction in respect of offenses which, although occurring abroad and committed by non-nationals, are regarded as injurious to the

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<sup>59</sup> RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 402. These bases were set forth by American scholars between 1932 and 1935, as *The Harvard Research in International Law*.

state's security. The protective principle allows a nation to prohibit conduct outside of its borders where the intent of the act in question produces, or is intended to produce a detrimental effect within that nation's borders.<sup>60</sup> Examples might include plans to overthrow the government or counterfeit its currency.

(4) Universality Principle

The principle of universality gives jurisdiction to any state over all crimes which are prohibited by international law and the international community as a whole. A state has jurisdiction to define and prescribe punishment for certain offenses recognized by the community of nations as of universal concern, such as piracy, slave trade, attacks on or hijacking of aircraft, genocide, war crimes, and perhaps certain acts of terrorism, even where none of the bases of jurisdiction is present.<sup>61</sup> Thus international law permits any state to apply its laws to punish certain offenses although the state has no links of territory with the offense or of nationality with the offender (or even the victim).<sup>62</sup>

To exercise jurisdiction, United States and international law demands the existence of a tangible link between the alleged offender and/or the forum of the incident and the state exercising jurisdiction.<sup>63</sup> Generally, US jurisdiction jurisprudence requires a territorial basis in order for jurisdiction in federal or state courts to be exercised. However, there are exceptions. For example, there will be persons within the US or one of its states who are immune from jurisdiction, and there will be times when a state may exercise jurisdiction outside its territory.<sup>64</sup> Accordingly, the above fact patterns would be determined as follows.

a. **Fact pattern 1**

Under the principle of nationality, a country may exercise jurisdiction over the offenses of its citizens committed abroad. As previously mentioned, the United States is a common-law jurisdiction, and as such, restricts prosecution under the nationality principle to serious crimes, such as treason, drug trafficking, or offenses against the armed forces.

b. **Fact pattern 2**

Under the protective principle, Congress has the jurisdictional power to address the problem of counterfeit pharmaceutical imports even when it involves

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<sup>60</sup> Douglas W. Stern, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 Food & Drug L.J. 544 (2004).

<sup>61</sup> Restatement Third, Foreign Relations Law of the United States § 404.

<sup>62</sup> Restatement Third, Foreign Relations Law of the United States § 404, comment a.

<sup>63</sup> P. 109 (citing Lotus Case)

<sup>64</sup> P. 108.

conduct occurring overseas.<sup>65</sup> As stated by Justice Oliver Wendell Holmes, “Acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a State in punishing the cause of the harm as if he had been present at the effect, if the State should succeed in getting him within its power.”<sup>66</sup> This principle has been applied to situations where the conduct has occurred entirely outside the United States, such as the importation of controlled substances<sup>67</sup> and price-fixing activities.<sup>68</sup>

Moreover, The FDCA prohibits the introduction into interstate commerce of adulterated and misbranded drugs<sup>69</sup> and defines “interstate commerce” to include commerce between “any State or Territory and any place outside thereof.”<sup>70</sup> Courts have held that, where part of a criminal conspiracy occurs in the United States, prosecution under U.S. laws is allowed even for those conspirators who never entered the United States and even if the majority of their conduct may have occurred outside the nation’s borders.<sup>71</sup> Thus, it is possible for the United States to prosecute individuals under U.S. laws, such as the FDCA, for illegal counterfeiting that occurs beyond the U.S. borders, but is imported into the United States.<sup>72</sup>

Moreover, in most countries, the sale of drugs must meet the regulation of a drug enforcement agency. For example, in the United States all drugs must meet the guidelines of the FDA. If a government fails to facilitate the effective pursuit of legal remedies against counterfeiters, it could potentially trigger a complaint under Section 301 of the U.S. Trade Act of 1974, as amended.<sup>73</sup> In addition, the same failure could give rise to a complaint to the World Trade Organization (WTO) under the Agreement on Trade-Related Aspects of International Property Rights (TRIPs).<sup>74</sup>

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<sup>65</sup> *Id.*

<sup>66</sup> *See Strassheim v. Daily*, 221 U.S. 280, 285 (1911).

<sup>67</sup> *See Chua Han Mow v. United States*, 730 F.2d 1308, 1311-12 (9th Cir. 1984).

<sup>68</sup> *See United States v. Nippon Paper Indus.*, 109 F.3d 1 (1st Cir. 1997).

<sup>69</sup> *See* 21 U.S.C. § 331(a).

<sup>70</sup> *Id.* § 321(b).

<sup>71</sup> *See Ford v. United States*, 273 U.S. 593, 620 (1927) and *United States v. Inco Bank & Trust Corp.*, 845 F.2d 919, 920 (11th Cir. 1988).

<sup>72</sup> Bunker, Amy, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property, and Human Health*, Journal of the Patent and Trademark Office Society (June 2007).

<sup>73</sup> 19 U.S.C. §2411

<sup>74</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm). While a detailed analysis of the application of these trade rules to counterfeit medicines are beyond the scope of this paper, there are number of articles on the topic. See, e.g., *Trade Issues of Concern to the Healthcare Industry*, Prepared by Health Sciences Industry Services, Ernst & Young LLP, <http://>

**c. Fact pattern 3**

Generally, when an offender commits actions abroad which have no link to The United States or a State because both the offender and the victims are sole citizens and residents of other countries, The United States or a State can prosecute the offender only if the concept of universal jurisdiction applies. Counterfeit drugs are sometimes regarded as synonymous with piracy, and under customary international law piracy have long been recognized as a crime over which all states could exercise universal jurisdiction, so long as the alleged offender was apprehended either on the high sea or within the territory of the state exercising jurisdiction.<sup>75</sup> This rule of customary international law was reaffirmed in Art. 19 of the 1958 Geneva Convention on the High Seas and Art. 105 of the 1982 Convention on the Law of the Sea.<sup>76</sup> Piracy, for international purposes, is any illegal act of violence or depredation which is committed for private ends on the high seas or without the territorial control of any state.<sup>77</sup>

Under that definition of piracy, a person's participation in the counterfeit of drugs might qualify if no state has territorial control over the act. And for a state to have territorial control over the act, the act must be a violation of local law. Therefore, it is possible for a person's participation in the counterfeit of drugs can qualify as piracy, for international purposes, if and only if the actions are not a violation of the local law in the jurisdiction where the actions are commenced. Only then will the act be outside the territorial of any state, as required by the definition of piracy.

However, no state has exercised jurisdiction exclusively on the basis of universality. For example, in the Eichmann Case,<sup>78</sup> Israel successfully (at least in Israeli courts) claimed jurisdiction on two cumulative grounds:

“a universal source (pertaining to the whole of mankind), which vests the right to prosecute and punish crimes of this order in every state within the family of nations; and a specific or national source,

[www.ey.com/global/download.nsf/International/Trade\\_Issues\\_in\\_Health\\_Care\\_WEF2003/\\$file/TradeIssuesinHealthCareWEF2003.pdf](http://www.ey.com/global/download.nsf/International/Trade_Issues_in_Health_Care_WEF2003/$file/TradeIssuesinHealthCareWEF2003.pdf)

<sup>75</sup> P. 113.

<sup>76</sup> P. 113

<sup>77</sup> Art. 15 of the 1958 Convention on the High Seas; Art. 101 of the 1982 Convention on the Law of the Sea.

<sup>78</sup> *Attorney-General of the Government of Israel v. Eichmann*, 36 I.L.R. 5 (1961).

which gives the victim nation the right to try any who assault its existence.”<sup>79</sup>

Thus, to effectively claim jurisdiction on the principle of universality, it is likely a country would have to show jurisdiction on two cumulative grounds.

But Fact pattern 3 specifies that the Offender is apprehended in The United States or a State, in which case The United States or a State need only exercise territorial jurisdiction to properly prosecute the offender. So, even if the offender’s presence in The United States or a State is temporary, The United States or a State can exercise territorial jurisdiction over the offender if his actions abroad were violations of the local law in The United States or a State.

*8. Overall assessment of the described regulations concerning drug counterfeiting, comparison of the sanctions*

US federal and state law is comprehensive in defining the activities associated with counterfeit activities in order to capture criminals involved. Given the broad and encompassing list of activities prohibited or required, defendants can readily be convicted of some activity related to counterfeiting if not for the actual counterfeiting. Nonetheless, the sanctions in terms of length of prison term and monetary penalties are insignificant relative to the monetary gains from counterfeiting and in light of the potential to cause injury and death. In the case of death, sanctions should include life imprisonment and capital punishment where appropriate and constitutional.

### **C. State criminal law provisions**

Two main approaches are used by states to prosecute criminal counterfeiting. These are business regulation and the protection of health and safety. Regulation in these areas is limited to intra-state commercial activity and public health and health care and any area that federal law permits states regulate. To explore state criminal law on counterfeiting, the laws of California and Florida will be reviewed. These two states have substantial populations and substantial international shipments arriving to their borders and thus as states that confront counterfeits, their laws are exemplary of the two approaches taken at state level. Moreover, Florida has been a leader in imposing pedigree requirements and the registration of members of the supply chain under the business law.

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<sup>79</sup> For Genocide Convention, see U.K.T.S. 58 (1970) Cmmd.4421; 78 U.N.T.S. 277; 4 A.J.I.L. Supp.6 (1951).

The common law or crimes or traditional crimes would seem to be applicable to counterfeiting. Common law crimes include murder, battery and other crimes which are generally prosecuted by all countries. A review of published reports of common law crime cases does not disclose cases in which a person has been charged or convicted of a crime in which counterfeit drugs are involved. While a case could be prosecuted against an individual under federal and state law which would include a common law crime, there are several reasons why there are no cases. These include the difficulty of establishing that the counterfeit drug caused a death or personal injury, the source of the counterfeit and proving the defendant was the source, and finally the discretion allowed to prosecutors to determine what crimes they pursue, a decision based generally on their assessment of the likelihood of success.

Perhaps the greatest impediment to the use of common law of crimes to combat counterfeit drugs is the intent requirement. For example, in the crime of involuntary manslaughter assuming an individual has been affirmatively or circumstantially linked to a counterfeit drug that harmed someone it is necessary to establish a reckless disregard for human life and as a result a death occurred.<sup>80</sup> A case involving a product called Sterno is illustrative.<sup>81</sup> A store owner was convicted of involuntary manslaughter when he sold Sterno knowing the customers were going to ingest the Sterno and this could cause death. The court found that “the record establishes that appellant sold the Sterno with the knowledge that at least some of his customers would extract the alcohol for drinking purposes.”<sup>82</sup> This would be the same level of proof necessary to show that the person who manufactures counterfeit goods would also be held accountable for involuntary manslaughter when they put harmful chemicals into a counterfeit drug recklessly and negligently causing the death of a person who uses that counterfeit drug.

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<sup>80</sup> Involuntary manslaughter, sometimes called criminally negligent homicide in the United States, occurs where there is no intention to kill or cause serious injury but death is due to recklessness or criminal negligence. “Involuntary manslaughter is defined by federal statute as the unlawful killing of a human being without malice in the commission of an unlawful act not amounting to a felony, or in the commission in an unlawful manner, or without due caution and circumspection, of a lawful act which might produce death. Under state law, the offense is generally defined in terms substantially similar to those used in the federal statute. The mental state that characterizes the crime of involuntary manslaughter is the absence of intention to cause death, either actual or reasonably to be implied from the homicidal act. If the accused had an intention to kill, then the offense is not involuntary manslaughter.” 40 Am. Jur. 2d Homicide § 61 (2007)

<sup>81</sup> Sterno fuel is a formulation of denatured alcohol, water and gel. For more information please see <http://www.sterno.com/>

<sup>82</sup> Commonwealth of Pennsylvania v. Max Feinberg, 253 A.2d 636 (Pa. 1969)

The issue is much harder for counterfeiters who use inert chemicals in their counterfeit medications. When this is done the drugs may be less effective (to low dose of active ingredient), or not effective at all (no active ingredients at all). In these cases it would depend on the use of the drug and effect that it had on the person consuming the drug. For example if a person receives a counterfeit pain medication and as a result experiences an adverse reaction which causes the death, involuntary manslaughter may be applicable.<sup>83</sup> However, if a patient is given a medication to extend his life for a day and is subsequently given a counterfeit medication with no active ingredients and dies a day early, a prosecutor may have a hard time making out the elements of involuntary manslaughter because the issue of cause of death is not clear.

Given all of the issues above it is no surprise that criminals have not been charged with both criminal sanctions for counterfeiting drugs and involuntary manslaughter but as the Finburgh case illustrates this is not impossible, it simply has not been applied in the U.S. system.

## 1. California

California, like Florida, has consolidated its approach to the prosecution of counterfeiting by defining all of the parties in the pharmaceutical supply chain and mandating licensing and practice requirements, commencing with the manufacturer and ending with the pharmacy providing drugs to the end user who is the patient.

### a. *California Business Regulation*

**Comment:** This is a descriptive title not a reference to a law or regulation.

California defines the actors who are included in the pharmaceutical supply chain to include manufacturers and those that are involved in the placement of drugs into the supply chain, including the warehousing of drugs.<sup>84</sup> Drugs include both prescription and non-prescription products.<sup>85</sup>

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<sup>83</sup> In the U.S. when a person commits a felony and a death is a result of that felony the criminal takes his victim as he is found, which basically means that the criminal can be held for the death of a fragile individual when as a result of the felony the person dies. A good example is when a criminal commits a felony and a person involved in the crime has a heart attack and dies the criminal would also be charged with involuntary manslaughter or greater degree of homicide.

<sup>84</sup> Cal. Bus. & Prof. Code § 4015 - § 4043

<sup>85</sup> §4025. "Drug" means any of the following:

- (a) Articles recognized in the official United States Pharmacopoeia, official National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement of any of them.
- (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

A manufacturer is “every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.” A wholesaler is: “a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022.

Warehousing and storage are also regulated in California. The law requires that both the warehouseman and the facility must be licensed. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed.<sup>86</sup>

All actors in the supply chain must comply with the pedigree requirements defined in the business code. California defines a pedigree paper in § 4034 as:

“... a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.”<sup>87</sup>

A pedigree must include identifying information on each supply chain actor that has had possession of the drug on the drug itself, and a certification by each actor on the veracity of the information contained in the pedigree.

*b. California Health and Safety*

The California Food and Drug Branch (FDB) is a division of the California Department of Public Health, within the Center for Environmental Health and under the supervision of the Chief Deputy Director of Policy and Programs. This branch administers the health and safety provisions of California law and is applicable to unsafe drugs or those that are unsafe for humans or animals, prescription drugs as defined by federal law.<sup>88</sup>

(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

<sup>86</sup> Cal. Bus. & Prof. Code § 4043

<sup>87</sup> Cal. Bus. & Prof. Code § 4034

<sup>88</sup> Cal. Bus. & Prof. Code § 4022 states a dangerous drug is any drug that is unsafe for self-use in humans and includes those that can only be dispensed under federal law with a prescription.

California law applies to drugs which enter the supply chain in California only. If a drug is to enter interstate commerce or international trade by its export, then it need not comply with California standards.<sup>89</sup>

California law prohibits the sale or distribution and manufacture of adulterated drugs defined as those that contain any “filthy, putrid, or decomposed substance”<sup>90</sup>, or prepared under conditions in which it is been rendered injurious to health<sup>91</sup>, or by processing methods that do not conform to good manufacturing practice to assure that the resulting product has the quality, safety and efficacy it is supposed to have<sup>92,93</sup>, or packaged in a container that may render the contents injurious to health<sup>94</sup>, or it has an unsafe color additive<sup>95</sup> or it differs from the drug recognized in an official compendium that it purports to be.<sup>96,97</sup> California also has definitions on what constitutes misbranding. A drug is misbranded if it meets any of the following requirements:

- 1) “if its labeling is false or misleading in any particular”<sup>98</sup>
- 2) “unless it bears a label containing all of the following information:
  - (a) The name and place of business of the manufacturer, packer, or distributor.
  - (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.”<sup>99</sup>
- 3) “if any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in terms as to render it likely to be read and understood by the ordi-

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<sup>89</sup> Cal. Health & Safety Code § 111315

<sup>90</sup> Cal. Health & Safety Code § 111250

<sup>91</sup> Cal. Health & Safety Code § 111255

<sup>92</sup> Cal. Health & Safety Code § 111260

<sup>93</sup> Cal. Health & Safety Code § 111290

<sup>94</sup> Cal. Health & Safety Code § 111265

<sup>95</sup> Cal. Health & Safety Code § 111270

<sup>96</sup> Cal. Health & Safety Code § 111280

<sup>97</sup> Cal. Health & Safety Code § 111285

<sup>98</sup> Cal. Health & Safety Code § 111330

<sup>99</sup> Cal. Health & Safety Code § 111340

nary individual under customary conditions of purchase and use.”  
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4) Unless it lists all active and/or inactive ingredients including their quantities in a font that is easy to read on its labeling and upon that label it has directions for use appropriate warnings as to dosage and interactions.<sup>101</sup>

5) Unless it was manufactured legally and in conformity of the laws.<sup>102</sup>

Prohibited activity falls within both California’s business code and its health code. The business code prohibits the sale, distribution and manufacturing of dangerous drugs within the state without first getting the proper license issued by the state.<sup>103</sup> Furthermore those who are licensed to manufacture and distribute the drugs may not furnish these drugs to anyone who is not authorized to receive them by a license.<sup>104</sup> This clear and concise statute prohibits activities relating to dangerous drugs and misbranded drugs in § 4169 including:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

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<sup>100</sup> Cal. Health & Safety Code § 111345

<sup>101</sup> Cal. Health & Safety Code § 111355 - § 111385

<sup>102</sup> Cal. Health & Safety Code § 111420 - § 111435

<sup>103</sup> Cal. Bus. & Prof. Code § 4160. Licenses (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

<sup>104</sup> Cal. Bus. & Prof. Code § 4163. Dangerous drugs or devices furnished to unauthorized persons; obligations of wholesalers. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

California's Health and Safety code to large extent duplicates its business code and prohibits the sale, distribution and manufacturing of misbranded or adulterated drugs. The provisions make it unlawful for any person:

- 1) "to manufacture, sell, deliver, hold **Does the term "hold" include possession by the consumer? NO** or offer for sale any drug or device that is adulterated."<sup>105</sup>

- 2) "to adulterate any drug or device" or "to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device."<sup>106</sup>

- 3) "to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Or "to misbrand any drug or device."<sup>107</sup>

- 4) " to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device" or "to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded."<sup>108</sup>

- 5) "to remove, sell, or dispose of a detained or embargoed food, drug, device, or cosmetic without permission of an authorized agent of the department or the court."<sup>109</sup>

The California Health and Safety Code contains sanctions according to the type of activity. <sup>110</sup>that states that individuals who violate the above sections cannot be imprisoned more than one year nor be fined more than \$1,000 for violations of any provision, if found to have returned illegal product into commerce after it has been embargoed, a fine of up to \$10,000 and prison for a year, and if a violation is committed with intent to defraud or mislead, or with intent to cause injury, \$10,000 and one year in prison. Defendants can also be subject to injunction, for-

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<sup>105</sup> Cal. Health & Safety Code § 111295

<sup>106</sup> Cal. Health & Safety Code § 111300 - § 111305

<sup>107</sup> Cal. Health & Safety Code § 111440 - § 111445

<sup>108</sup> Cal. Health & Safety Code § 111450 - § 111455

<sup>109</sup> Cal. Health & Safety Code § 111865

<sup>110</sup> Cal. Health & Safety Code § 111825- § 111915.

feiture and destruction of goods and payment of the costs of destruction. If counterfeiting activity under state law also infringes federal law, the federal prosecutor can charge both federal and state offenses. However, a state prosecutor can only charge the state offense.

The fines and prison terms that can be imposed in state and federal prosecutions are very similar. Neither is sufficient to entirely dissuade criminals from pursuing counterfeiting. Moreover, neither provides increased penalties in the cases of counterfeit products that could cause death or injury or in fact do. This author would entirely agree with proposed legislative changes before the US Congress, described later in this chapter and urge state legislatures to adopt similar penalties.

## 2. Florida

Florida has been in the news as the first state to update its laws to address counterfeiting. **What was the motive/reason of the update?** After gathering a grand jury in 2003 convened by the State Prosecutor hear evidence on the adulterated and counterfeit drug problem caused by among other things the secondary pharmaceutical drug wholesale market,<sup>111</sup> Florida revised its statutes in 2005 to toughen the State's laws on pedigrees which became effective July 2006 and expanded the definition of wholesale distribution to include all transfers of product to persons other than the consumer, thus resulting in a comprehensive set of laws. It remains to be seen whether these new regulatory approaches in effect just over a year will reduce the number of counterfeits entering the system.

**Comment:** See next sentence please

Florida defines the actors and activities that could be associated with the criminal activity of counterfeiting. Like California, it relies on the business and health codes to create a comprehensive approach to combating the problem. In order to be as comprehensive as possible and bring any and all activities related to counterfeiting, Florida statute prohibits "Committing any act that causes a drug... to be a counterfeit drug...; or selling, dispensing, or holding for sale a counterfeit drug,..."<sup>112</sup> The state also regulates "[t]he manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug... that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use"<sup>113</sup>. Florida specifi-

<sup>111</sup> Testimony of Robert Penezic, Asst. Statewide Prosecutor for the State of Florida to the House Committee on Energy and Commerce, June 24, 2003. House Case No. SC202-2645.  
<http://energycommerce.house.gov/reparchives/108/Hearings/06242003hearing982/Penezic>.

<sup>112</sup> Florida Statutes Annotated (F.S.A.) § 495.001 (8)

<sup>113</sup> F.S.A. § 495.001 (1)

cally prohibits “[t]he adulteration or misbranding of any drug...”<sup>114</sup> or “The receipt ... delivery or proffered delivery, sale, distribution, purchase, trade, holding, or offering ...”<sup>115</sup> of any adulterated or misbranded drug...

Florida has a statutory scheme to regulate the manufacturing and distribution of several different industries affecting health and safety.<sup>116</sup> Those industries include all (both instate and out of state) drug manufacturers, distributors, wholesalers, repackagers and warehousemen.<sup>117</sup> Under this section these entities are subject to a two year review of their license and the information contained in the license application. Only licensed entities may engage in business in the pharmaceutical and medical device sector, a requirement that allows Florida to discriminate against companies unwilling to provide the detailed information required by the statute. This effectively “screens” some less reputable businesses from doing business within the state of Florida which if truly criminal will avoid disclosure of the required information. Florida adds a specific definition of a counterfeit drug rather than prohibiting misbranded or adulterated drugs as is done in California. A counterfeit drug is defined as:

“...a drug, ...which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug...manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug...and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug...manufacturer, processor, packer, or distributor.”

a. *Pedigree Requirements*

Florida requires extensive details on what information is to be included in a pedigree paper. The goal of the pedigree is to uniquely identify each transaction along the chain of distribution, to track medical products along the “stream of commerce” and provide a “chain of custody” that can track everyone who has come into contact with a specific manufactured drug.<sup>118</sup> In addition to the name of the drug, the information required is:

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<sup>114</sup> F.S.A. § 495.001 (2)

<sup>115</sup> F.S.A. § 495.001 (3), (4)

<sup>116</sup> F.S.A. § 499.01

<sup>117</sup> F.S.A. § 499.01 (1) (a)-(r)

<sup>118</sup> F.S.A. § 499.003 (31)

“... its quantity, dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers.”<sup>119</sup>

If the drug has a unique identifier like a serial number the statute requires “the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody.”<sup>120</sup> If this is not available the person or entity may elect to provide:

“A statement, under oath, in written or electronic form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intra-company transfer, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug...”<sup>121</sup>

According to the USFDA, counterfeits enter the supply chain at the wholesaler level most often, thus requiring licensure and pedigree paper at this point aids in ensuring the integrity of the drug supply.<sup>122</sup> One of the main mechanisms to enforce this requirement is the that such papers must always be available to inspection and it is prohibited to refuse in any manner to submit to a government inspection of pedigree paper or impede such inspections.<sup>123</sup> Furthermore, the failure to maintain or transfer pedigree papers or failing to obtain papers as medical products move through the supply chain is prohibited.<sup>124</sup> And of course the fabrication or counterfeiting of these papers or label is also prohibited.<sup>125</sup>

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<sup>119</sup> F.S.A. § 499.003 (31) (b) (1)

<sup>120</sup> *Id.*

<sup>121</sup> F.S.A. § 499.003 (31) (b) (2)

<sup>122</sup> Combating Counterfeit Drugs, A Report of the FDA February 2004.

[http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html) (accessed July 2007) Report is not paginated on the web.

<sup>123</sup> F.S.A. § 495.001 (5)

<sup>124</sup> F.S.A. § 495.001 (28), (29)

<sup>125</sup> F.S.A. § 495.001 (9) – (12)

Florida has one of the most complex penalty sections because it provides different penalties for different degrees of crimes, including both misdemeanor and felony offenses.

The following are second degree misdemeanors:

- “1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.
- 2) The adulteration or misbranding of any drug intended for further distribution.
- 3) The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.
- 4) The possession of any drug in violation of [law]...”<sup>126</sup>

The same actions are classified a felony of the third degree as violating the “pedigree paper” requirements<sup>127</sup> or if knowingly committed<sup>128</sup>.

For conviction of

a misdemeanor of the second degree, a defendant may be sentenced to a definite term of imprisonment not exceeding 60 days and a fine of up to \$500,

for a felony of the second degree, a defendant may be sentenced to a term of imprisonment not exceeding 15 years and a fine up to \$10,000,

for felony of the third degree, a person may be sentenced to a term of imprisonment not exceeding 5 years and a fine up to \$5000.<sup>129</sup>,

Florida has a requirement that pharmacies return expired prescription drugs samples to the manufacturer or distributors, but curiously do not require particular methods for the destruction or disposal of non-samples that have expired. This is an area of potential practical improvement.

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<sup>126</sup> F.S.A. § 495.0691 (1)

<sup>127</sup> F.S.A. § 495.0691 (2)

<sup>128</sup> F.S.A. § 495.0691 (3)

<sup>129</sup> F.S.A. § 775.082 and § 775.083

## **D. Prosecution measures and instruments**

### *1. Traditional criminal procedural law, permissibility and application of special investigatory measures*

#### *a. Use of Other Charges*

##### Conspiracy and aiding-and-abetting, 18 U.S.C. § 2371

If a defendant only supplied counterfeit labels or packaging that were attached by another person he may be found guilty of conspiracy and aiding and abetting.

##### Mail and wire fraud, 18 U.S.C. §§ 1341, 1343 – use of the Internet

These charges can be filed if the defendant used the mail (or other interstate carrier) or wires (including the Internet) in a scheme to defraud purchasers, whether direct or indirect purchasers. Mail and wire fraud may be especially appropriate when there are foreign victims and jurisdiction under § 2320 is difficult to establish. The case of *Pasquantino v. United States*, 544 U.S. 349, 125 S. Ct. 1766 (2005) affirmed a wire fraud conviction in which the victim was the Canadian government. In another case, *United States v. Trapilo*, 130 F.3d 547, 552 (2d Cir. 1997) the court found the wire fraud statute applied to a scheme to defraud that involved money or property such as taxes and even if it involves a foreign victim, either private or public. Mail and wire fraud charges may be available if the defendant told his direct purchasers that his goods were counterfeit, so long as he and his direct purchasers intended to defraud the direct purchasers' customers as authentic.

##### Money laundering, 18 U.S.C. §§ 1956, 1957

In cases where there is trademark counterfeiting, such Section 2320 offenses do serve as a predicate offense for a money laundering charge.<sup>130</sup>

#### *b. Enforcement Focus*

The USFDA takes a risk based approach to the regulation of pharmaceuticals and gives higher priority to enforcement efforts based on certain factors. The factors are whether a drug has a high value in the market, or it in short supply (insufficient quantity of the product available to meet the needs of patients at any one time) or high demand, whether there are prior indicators of a drug being counter-

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<sup>130</sup> U.S.C. § 1956(c) (7) (D). See, e.g., *United States v. Bohai Trading Co.*, 45 F.3d 577, 579 (1st Cir. 1995) (charging § 2320 and § 1957 offenses).

feited, and whether there is a reasonable probability a newly approved drug may be counterfeited given its value or history. These factors are used to determine whether an investigation or inspection will be undertaken.<sup>131</sup>

*c. Procedural requirements and Investigatory measures*

Cases commence with investigatory efforts by the USFDA Office of Criminal Investigation (OCI) which shares the enforcement of laws to combat counterfeit drugs with the Federal Bureau of Investigations, although the FDA has primary responsibility for cases that involve a serious threat to life or an actual death. OCI derives its authority from two sources, the first is the FDA act and also from the Federal Anti-Tampering Act, 18 U.S.C. 1365. Its authority includes actual and threatened cases of counterfeit.

The typical tools of investigation are available to USFDA investigators and also those in states. Since criminal procedure is governed by US Constitutional principles, acceptable practice is the same in federal and state criminal procedure. Investigators are able to use many tools including undercover agents and informants but not wire tapping in cases of counterfeit trademarks and copyrights. The FDA has an extensive body of guidelines in its Investigations Operations Manual which divides investigations into cases in which there has been a complaint by an individual who has been harmed, foodborne outbreaks, injuries and adverse reactions, devices, biologics, food, dietary supplements and cosmetic injuries or reactions, veterinary products, disasters including bioterrorism, investigational research all of which could include a counterfeit and finally a section on counterfeiting and tampering. In the section focused on counterfeiting, investigation is further segmented to manage complaints, retail stores, manufacturers and distributors and record requests and refusals.

While investigations operations directions are detailed and specific, describing a few general principles capture their intent. First, any report to the USFDA of a counterfeit, tampering or tampering threat must be reported by staff to the OCI office. The USFDA has responsibility of cases involving drugs, or other products regulated by it and thus its investigators not the FBI will take charge of such cases. The FBI shares investigatory control of cases involving tampering. Investigators

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<sup>131</sup> US FDA Office of Criminal Investigations Operations Manual 2007. [http://www.fda.gov/ora/inspect\\_ref/iom/pdf/ioc.html](http://www.fda.gov/ora/inspect_ref/iom/pdf/ioc.html). See also: Protecting American Consumers Every Step of the Way: A Strategic framework for continual improvement in import safety. A Report to the President Inter-agency Working Group on Import Safety. Cover letter of Secretary Leavitt, pp 3-4. [September 10, 2007.](http://www.importsafety.gov/report/report.pdf) <http://www.importsafety.gov/report/report.pdf>

are provided extensive guidance on what questions are to be answered, to whom they should be directed and how to take interviews and samples, photos, documentation, and follow up. In cases involving manufacturers and distributors, guidance is provided on how to inspect a facility, and related offices, and how to manage the security system in place at such facilities. Investigators may request records even if considered non-routine and if refused how to manage refusals. OCI investigators may use electronic surveillance, postal mail cover by which the information on the outside of envelopes is provided to investigators, and finally investigators can liaison with the law enforcement/intelligence community.

Once a case has been developed to the point where there is reason to believe a criminal violation has occurred, USFDA practice includes Section 305 notices, the use of an information for misdemeanor cases, Grand Jury proceedings for felony cases, injunction, temporary restraining orders, and consent decrees.

Section 305 notice: The US FDA has the ability to provide a notice to a respondent that its activities may be in violation of some aspect of federal health law. This notice is called a section 305 notice and is optional for investigators prior to referring a case for prosecution or for further investigation.<sup>132</sup> The section 305 Notice is a statutory requirement of the Act. It provides a respondent with an opportunity to explain why he should not be prosecuted for the alleged violation. Response to the notice may be by letter, personal appearance or attorney.

Informations are legal documents which state charges and identify defendants in misdemeanor cases. These are prepared by USFDA OCI staff and forwarded to the US Attorneys who file necessary other documents to commence and prosecute criminal cases in federal court. In comparison, in all felony cases, evidence in possession of OCI staff is presented to a jury or group of citizens organized to hear evidence to determine if it is sufficient to warrant prosecution. If so then the grand jury issues a document which commences the felony case. The deliberations of grand juries are secret according to the Federal Rules of Criminal Procedure applicable in US federal courts.

A civil restraint order, called an injunction may be issued by the court which can be designed to stop counterfeit products from being placed into interstate commerce or to correct conditions in an establishment. In practical terms, in cases of criminal conduct which has been intentionally pursued, injunctive relief is not

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<sup>132</sup> Section 305, 21 CFR 7.84(a) (2) and (3).

likely to be effective. Injunctions can also be issued preliminarily prior to the court's final decision on the merits and can be requested ex parte.

2. *Precautionary measures for customs/seizure at borders see above section in national criminal law II B 6*

3. *Health Protection Law is covered in earlier sections.*

4. *Responsibility/involvement of private persons /private investigations, cooperation with prosecuting agencies*

Consumers or purchasers of counterfeit medications are not being prosecuted because they are not purchasing the medications knowing that they are counterfeit, rather they are victims of the crimes. Consumers of counterfeited medications are the victims because they are not consuming the medications knowing that they are counterfeit, it is the alternative, and they are consuming these medications not knowing they are counterfeit and instead believing that they are the real medications. In comparison, a knowing purchaser is likely doing so with the intent to sell or otherwise distribute the counterfeit drugs, activities which are criminalized at state and federal levels.

The Pharmaceutical Security Institute (PSI) is a not-for-profit corporation established in 2002 by the Security Directors from fourteen major pharmaceutical companies in response to the worldwide problem of counterfeit drugs especially in countries with ineffective anti-counterfeiting laws and drug regulatory agencies.<sup>133</sup> The Institute works in partnership with international law enforcement, customs officers, and health care and drug regulatory authorities through the improved sharing of case specific information concerning counterfeiting. These strategies have improved the effectiveness of the anti-counterfeiting capabilities of the members.

The Partnership for Safe Medicines is a coalition of organizations and individuals including pharmacists and pharmacy educators that have policies, procedures, or programs to protect consumers from counterfeit drugs.<sup>134</sup> The Partnership's SafeMeds Alert System has become part of the FDA's Counterfeit Alert

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<sup>133</sup> Pharmaceutical Security Institute. <http://www.psi-inc.org/index.cfm> Accessed November 16, 2007.

<sup>134</sup> Partnership for Safe Medicines. [http://www.safemedicines.org/north\\_america/index.php](http://www.safemedicines.org/north_america/index.php) Accessed November 16, 2007.

Network. The SafeMeds system broadcasts government warnings about counterfeit drugs in real time through free e-mail alerts.

Pharmaceutical companies have corporate security offices that investigate and gather intelligence on counterfeiters, especially the site of production and the chain of distribution. As a result, some pharmaceutical companies, for example Novartis, regularly raid these counterfeit drug labs so as to disrupt these counterfeiting activities.<sup>135</sup> Notwithstanding, the corporate security offices work with local and national law enforcement authorities to bring about criminal prosecutions of the perpetrators.

STOP! (Strategy Targeting Organized Piracy) is another initiative aiming to strengthen cooperative enforcement efforts against the international trade in fakes and coordinated by private-public collaboration. Delegations from the US including government officials and private citizens have traveled to Europe to discuss means to address counterfeit goods.<sup>136</sup>

*5. Civil law proceedings by pharmaceutical companies against counterfeiters/distributors of counterfeit products*

Companies participate in criminal law proceedings by providing testimony and results of internal investigations and can concurrently conduct civil infringement cases as plaintiff seeking any legal remedies provided by law to a rights holder. Sanctions in criminal cases can include restitution to a rights holder by criminals. This was the result in the Lipitor case in which the defendants paid \$18 million in restitution.

**E. National significance of international [legal] instruments/activities, in particular**

The United States is a member of the World Trade Organization and has ratified the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). As previously described in this chapter, the US Constitution reserves the matter of intellectual property rights to the federal legal system. The enforcement of those rights

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<sup>135</sup> Datz, Todd. Drug Busters. CSO Magazine.

<http://www.csoonline.com/read/110105/counterfeit.html> Accessed November 14, 2007.

<sup>136</sup> U.S. Expands Outreach in Campaign to STOP! Trade in Fakes, June 6, 2006. [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2005/June/US\\_Exps\\_Outreach\\_in\\_Campaign\\_to\\_STOP!\\_Trade\\_in\\_Fakes.html?ht=](http://www.ustr.gov/Document_Library/Press_Releases/2005/June/US_Exps_Outreach_in_Campaign_to_STOP!_Trade_in_Fakes.html?ht=)

from a criminal legal perspective is reviewed in this chapter. US law is TRIPS compliant.

The US is a member of the World Health Organization and participates in all of its activities related to intellectual property and counterfeit drugs, such as the International Conference of Drug Regulatory Authorities and the Intergovernmental Working Group on Innovation, Public Health and Intellectual Property.

### III. Reform Proposals

#### A. National law

1. *Substantive criminal law (primary and secondary rights: offense definition, international criminal law (conflict of laws), sanctions)*

In October 2007, the US has proposed through its Office of the United States Trade Representative, Ambassador Susan Schwab an Anti-Counterfeiting Trade Agreement (ACTA) aimed at all counterfeit goods, not just drugs and is joined by Canada, the European Union, Japan, Korea, Mexico, New Zealand, and Switzerland.<sup>137</sup> The goals of ACTA are to develop stronger laws, closer cross border cooperation in law enforcement, and the adoptions of practices that make IPR enforcement real and effective, such as encouraging consultation with right holders and specialization in the IPR law enforcement system. This proposed treaty if signed and ratified by the US would become part of national law and affect federal laws which would be required to be conformed to its provisions.

In 2007 several legislative proposals were presented to amend federal and state law as follows.

The Intellectual Property Protection Act of 2007, H 3155, called for stronger penalties for repeat offenders, increasing the maximum penalty for counterfeiters.<sup>138</sup> This bill, now in the House Judiciary Committee which reconvenes in January 2008 proposes a number of amendments to strengthen existing criminal and civil laws relevant to counterfeiting. If enacted, prosecutors could institute an infringe-

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<sup>137</sup> Remarks by U.S. Trade Representative Susan C. Schwab Anti-Counterfeiting Trade Agreement (ACTA) October 23, 2007.  
[http://www.ustr.gov/assets/Document\\_Library/Transcripts/2007/October/asset\\_upload\\_file110\\_13428.pdf?ht=](http://www.ustr.gov/assets/Document_Library/Transcripts/2007/October/asset_upload_file110_13428.pdf?ht=)

<sup>138</sup> Letter to Nancy Pelosi from the Office of Legislative Affairs U.S. Dept. of Justice, dated May 14, 2007. Accessed August 28, 2007.  
<http://politechbot.com/docs/doj.intellectual.property.protection.act.2007.051407.pdf>.

ment case even if a copyright is not registered with the US Copyright Office on a theory that US prosecutors work for the public good and thus criminal copyrighters could no longer use the defense that the infringed copyright is not registered and thus avoid prosecution. Moreover in cases of alleged criminal copyrighting, records documenting the manufacture, sale or receipt of things involved in violations could be impounded prior to trial. Following the accepted criminal tenet that those who attempt to commit a crime are as culpable as those who do, the proposal now includes attempt in the definition of a copyright crime as defined in 17 U.S.C. § 506(a).

Finally with regards to copyrights, the proposed law would harmonize intellectual property forfeiture laws to allow for civil and criminal forfeiture of contraband, facilitating equipment and proceeds of crimes. A similar provision is proposed with regards to trademark infringement that would include the ability of prosecutors to seek civil forfeiture of proceeds. This proposal is seen as a technical correction to the 2006 Stop Counterfeiting in Manufactured Goods Act which added criminal forfeiture of counterfeit goods, labels, labeling components, other property used in crimes and the proceeds, but omitted proceeds in civil infringement cases.

The definition of a copyright infringement would be amended by this proposed law to include the export of infringing copies so both the import or export of counterfeit property would be expressly prohibited.

The FDCA would be amended by the Counterfeit Drug Prevention Act of 2007, H.R. 780 with enhanced sanctions. Prison terms are increased to 20 years under this proposal especially and if the use of a counterfeit drug by a consumer is the proximate cause of death the term can be for life.<sup>139</sup>

The State of California has enacted a law effective in 2008 that amended its Board of Pharmacy enforcement tools to include the embargo of drugs or devices that an inspector finds, or has reasonable cause to believe is dangerous, adulterated, misbranded or counterfeited.<sup>140</sup>

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<sup>139</sup> H.R. 780 Counterfeit Drug Prevention Act of 2007. Accessed January 14, 2008, <http://www.govtrack.us/congress/billtext.xpd?bill=h110-780>.

<sup>140</sup> Section 4084 of the Business and Professions Code. Accessed January 14, 2008. [http://www.pharmacy.ca.gov/laws\\_regs/new\\_laws.pdf](http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf).

2. *Criminal procedural law (esp. investigative measures, organization of prosecution)*

The Intellectual Property Protection Act of 2007, H 3155, enhanced the range of investigative tools available to law enforcement officers to include wiretap or voice intercept in copyright and trademark counterfeiting crimes.

Sanctions are also enhanced by the proposed law changes to increase maximum statutory penalties for counterfeiting cases that endanger public health and safety. Maximum § 2320 penalties are increased from 10-20 years when the defendant knowingly or recklessly causes or attempts to cause serious bodily injury and increases the maximum penalty to life imprisonment when defendant knowingly or recklessly causes or attempts to cause death.

**B. International activities/cooperation**

The United States has participated in the World Health Organization International Medical Products Anti-Counterfeiting Task Force (IMPACT) since its inception and in other international efforts to combat counterfeit goods which would include counterfeit drugs.

The USFDA participates with the Asia Pacific Economic Cooperation Life Sciences Innovation Forum, the U.S. Department of Commerce, and Singapore's Health Sciences Authority and the U.S.–ASEAN Business Council in a January 2008 seminar on the dangers of trade in counterfeit medical products, the integrity of the pharmaceutical products and medical devices supply chain.<sup>141</sup>

OCI participates internationally also by contributing a full time representative to Interpol. There do not appear to be any international treaties which the US has ratified which address criminal prosecution of counterfeit activities.

In 2007, the US entered into an agreement with China, through their respective food and drug administrations.<sup>142</sup> The agreement signed in December, provides for

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<sup>141</sup> APEC LSIF First Anti-Counterfeiting Health Products Seminar Building International Cooperation to Protect Patients. <http://www.who.int/impact/events/APEC-anti-counterfeit-medprodseminar.pdf> accessed November 14, 2007.

<sup>142</sup> Agreement between the Department of Health and Human Services of the USA and the State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices, dated December 14, 2007. Accessed January 14, 2008, <http://www.globalhealth.gov/news/agreements/ia121107a.html>.

methods to establish cooperation between the parties that will provide each about products exported from China to the US and to encourage regulatory cooperation and enhancement.

**C. Relationship of national and international as well as legal and non-legal measures to one another ( please explain the meaning of this section.)**

**IV. Summary**

**List of Abbreviations**

Cal. Bus. & Prof. Code	California Business and Professions Code
FDA	Food and Drug Administration
FDB	Food and Drug Branch
FDCA	Food, Drug and Cosmetic Act
FSG	Federal Sentencing Guidelines
IP	Intellectual property
RICO	Racketeer Influenced and Corrupt Organizations Act
U.S.C.	United States Code