The Gray Market Infiltration of a Vulnerable United States Health Care

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I. Introduction

A gray market forms when a distributor buys a manufacturer's goods, imports them into the United States, and competes with the trademark holder's goods, often at cheaper prices. The parallel importation is unintended by the manufacturer. The distributors "pirate" the trademark holder's "established goodwill," reputation, advertising, research and development through this legal exchange. Issues arise when the gray good malfunctions, breaks, or causes harm to the consumer who lacks a warranty or repair service. In turn, consumer resentment taints the trademark's reputation while placing consumer protection and welfare at risk.

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2 See id.

3 See id. The gray market dealer is able to sell the goods at cheaper prices by free riding on the trademark owner's costs spent "advertising, quality inspections, and providing warranties and repair services." Id. at 458. Research and development are the heftiest contributors of high drug prices. Natalie J. Tanner, Understanding the Disparity in Availability of Prescription Drugs in the United States: Compromise May Be the Answer, 2 IND. HEALTH L. REV. 267, 274 (2005). The average new drug costs $800 million to develop and bring into the market subject to FDA approval via the Center for Drug Evaluation and Research (CDER). Id. at 275.

4 See Minehan, supra note 1, at 458.

5 See Lever Bros. Co. v. United States, 877 F.2d 101, 103 (D.C. Cir. 1989). In this case two affiliated corporations used the same trademark language for two materially different soap products, one meant for the United States and the other for the United Kingdom. Infra note 20. The US soap generated lather more quickly, appealing to an American consumer preference for showers whereas the soap meant for the UK took time to lather, appealing to consumer
Gray market proponents argue that the parallel exchange provides consumers with affordable goods otherwise not within their purchasing range; however, pharmaceutical drug shortages in the United States have created an opportunity for gray good pirates to price gouge, taking full advantage of the low supply and high demand. A perturbing recent increase in drug shortages, which affects 93% of drugs the FDA deems “medically necessary,” has spread across the United States.

This note outlines a history of the regulation of imported gray goods pursuant to Trademark Law, illustrating legislative efforts and judicial support in curbing the importation of goods unintended for the United States market. The note then focuses on the domestic gray market by considering our country’s current drug shortage and the ways in which gray good pharmaceuticals’ presence heightens its implications for health and safety. Finally, the note offers resolve, demanding legislative and judicial treatment analogous to the combined effort that the two branches employed to address imported gray goods, but tailored to our domestic problem at hand.

A. A History of Gray Goods

Manufacturers challenging the use of their goods in gray markets have historically had the best chance for judicial relief under Trademark Law. A defendant infringes on a trademark if such person “. . . uses in commerce any word, term, name, symbol, or device . . . which is likely to cause confusion, mistake, or to deceive as to the affiliation, connection, or association . . . as to the origin . . . of his or her goods.”

preference for baths. Id. The US affiliate received letters from angry consumers expressing disappointment because they believed they had received a discounted product. Id.


7 Friske, supra note 6, at 521 (citing FDA, A REVIEW OF FDA’S APPROACH TO MEDICAL PRODUCT SHORTAGES 14-15 (2011)), available at www.fda.gov/downloads/aboutfda/.../reports/ucm277755.pdf. In response to recent shortages, the FDA’s most common approach includes encouraging companies to produce more while simultaneously easing up on regulation and speeding up the review process. See Friske, supra note 6, at 529.

8 Infra Part 1(a); 1(b) and 1(c).

Since the gray good is often identical to the original good, aggrieved parties are not protected under Copyright law the infringement of which requires the distributed product to be "reproduced" in "copies." Under the First Sale Doctrine, the owner of an original copyrighted good may sell or dispose of that copy without the consent of the copyright owner. Therefore, gray goods are legal and only infringe on another's rights when the use of the good’s trademark is likely to confuse or deceive the consumer as to the good’s origin, thus triggering consumer protection under Trademark Law.

1. 1905 Trademark Act

The gray market controversy first developed in 1923 when the Supreme Court affirmed the prohibition of gray goods in the U.S. markets through the 1905 Trademark Act. The Court reasoned that the defendant could only successfully sell the plaintiff's face powder product by illegally using the goodwill the plaintiffs bought through their own business. Justice Holmes wrote that the plaintiff's business was such that consumers understood the products to be from the plaintiff, and therefore mere ownership of the products did not carry the right to resell the goods bearing the plaintiff's mark.

2. The Tariff Act

In 1930, Congress enacted section 526 of the Tariff Act, which allowed U.S. Customs to seize imported parallel goods bearing a registered U.S. trademark when the parallel importer could not produce written consent from the US domiciled mark.

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11 17 U.S.C. § 109(a) (2006); see Minehan, supra note 1.
14 See Katzelve, 260 U.S. at 692. A defendant bought face power products from a manufacturer who packaged their products in France for sale in the United States. Id. at 691. The defendant then sold the face powder in its American pharmacies in the original packaging. Id. The Supreme Court acknowledged the plaintiff carefully selected the colors for packaging so it would be suitable for the United States market and spent a good deal of money in advertising, so the public associated the labels of the face powder as originating from the plaintiff. Id. at 691-92. The parallel imports threatened the reputation of the plaintiff, supporting the Court's decision to grant an injunction based on trademark infringement. See Id. at 692.
15 Katznel, 260 U.S. at 691-92. "The injunction granted by the District court was proper . . . under the Trade-Mark Act . . . of 1905." Id. at 692.
In 1988, the Supreme Court addressed the existing ambiguities of section 526. The Court considered the issue of why the Secretary of the Treasury’s regulation allowed imported goods by entities under the common control of the manufacturer without required consent. The Supreme Court ultimately held that section 526 does not provide protection when a U.S. company grants a foreign entity a license to manufacture goods, and that foreign entity is the parent or subsidiary of the U.S. trademark owner, or if both entities are subject to common ownership or control. The Court’s holding enabled such goods to pass through customs without written consent of the Trademark owner, deeming them automatically genuine, and thus opening a legal window for parallel imports to enter the United States.

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See 1930 Tariff Act, 46 Stat. 741 (current version at 19 U.S.C. § 1526(a)(2006)): Except as provided . . . it shall be unlawful to import into the United States any merchandise of foreign manufacture if such merchandise, or the label, sign, print, package, wrapper, or receptacle, bears a trademark owned by a citizen of, or by a corporation or associated created or organized within, the United States, and registered in the Patent and Trademark Office by a person domiciled in the United States . . . unless written consent of the owner of such trademark is produced at time of marking entry.

Id.


The restrictions . . . do not apply to imported articles when: (1) Both the foreign and the U.S. trademark or trade name are owned by the same person or business entity; [or] (2) The foreign and domestic trademark or trade name owners are parent and subsidiary companies or otherwise subject to common ownership or control.

19 C.F.R. 133.2 (c)(1), (2) (1987). The statute is silent on the circumstance of a United States company owned by a foreign company. See id. The statute can be read as excluding such entities from the restriction on importation, allowing the mark to flow from the United States trademark owner to the foreign entity. See also Lawrence M. Friedman, Business and Legal Strategies for Combating Grey-Market Imports, 32 INT’L LAW. 27, 44 (1998) (pointing out discrepancies resulting when foreign goods bear identical trademarks used in the United States).

See Kmart Corp., 486 U.S. at 292-94. The Court noted the statutory ambiguity of the words “owned by” as referring to a United States domiciled trademark owner when that entity is owned by a foreign parent and further holding a domestic trademark owner has no power to prohibit the importation of goods made by a foreign manufacturer “subject to common . . . control” or by the same entity who owns the United States trademark. Id. “The affiliation between the foreign producer and domestic markholder automatically defines the foreign goods as genuine, [drawing] an important truth – that a trademark holder cannot infringe its own mark.” Lever Bros. Co. v. United States, 877 F.2d 101, 109 (D.C. Cir. 1989). For infringement purposes, the affiliated entities are treated as “constructively one.” Id.

See Kmart Corp., 486 U.S. at 292-94.
3. Lanham Act

In 1946, Congress enacted Section 42 of the Lanham Act to regain some restrictive authority over the gray market:

No article of imported merchandise ... shall bear a name or mark calculated to induce the public to believe that the article is manufactured in the United States, or that is manufactured in any foreign country or locality other than the country or locality in which it is in fact manufactured, shall be admitted to entry at any customhouse of the United States.20

 Customs, however, adopted a number of exceptions to the general rule of seizing products manufactured abroad but packaged with an identical U.S. owned trademark.21 One exception to the rule included imported articles when "[b]oth the foreign and the U.S. trademark or trade name are owned by the same person or business entity."22 In 1989, the District of Columbia Circuit gave Congress' intent teeth by interpreting Congress' intent to mean that customs should prohibit the importation of goods bearing an identical trademark to a valid US trademark when the goods were physically different from the original product despite any common ownership or control of the two entities.23 The aggrieved plaintiff argued that the importation of its affiliate corporation's products meant for the United Kingdom into the United States, while bearing the same mark, induced consumers to believe that the products where in fact originating from the same source.24 The Court clearly stated that allowing the parallel importation by subsidiary or common control entities when the goods are physically different frustrates Congress' intent and the Lanham Act's goal of reducing consumer

21 19 C.F.R. § 133.21(b) (2013).
22 See Vivitar Corp. v. United States, 593 F.Supp. 420, 423 fn. 3 (Ct. Int'l Trade 1984) (interpreting 19 C.F.R. § 133.21). Foreign-made goods bearing the same trademark owned by a United States citizen or an entity associated with the trademark owner are subject to seizure by customs unless the foreign trademark is owned by the American person or entity. Id.
23 Lever Bros. Co. v. United States, 877 F.2d 101, 111 (D.C. Cir. 1989). Affiliates Lever United States and Lever U.K. made two products with differences aimed at different markets. Id. at 103. The soap made for the United Kingdom had a higher concentration of coconut soap and fatty acids, which produced more lather to appeal to British preference for baths. Id. The soap made for the United States takes more time to lather, appealing to a market with consumers who prefer showers. Id. The United States soap also prevents the growth of bacteria, a difference Lever claims arises out of consumer preference, climate conditions and regulations. Id.
24 Id. Lever U.S. received letters from consumers demonstrating outrage and confusion after purchasing what they believed to be a discounted soap that would not lather, evidencing "consumer confusion, imperiling [the plaintiff's] reputation for quality." Lever Bros., 877 F.2d at 103.
confusion as to the source of goods. The affiliation of the two entities fails to alleviate such confusion and in no way creates constructive intent to importation through customs.

4. The Material Difference Threshold and Judicial Treatment of Gray Goods

When satisfied, the material difference threshold enjoins the circulation of goods bearing the same trademark yet possessing substantial physical differences. Under traditional Trademark Law, a mark can be used on two completely different products and yet a Lanham Act infringement violation is not triggered if it is not “calculated to induce” public confusion as to the origin of the good. For example, in one case where the mark “MAYFLOWER” was used for a moving company and for a sailboat company, no infringement existed. It is unlikely that consumers would confuse the source of origin of the two services bearing the same mark because the activities associated with both were so different. However, when the goods are significantly

25 See id. at 111 (remanding case for further review but stating affiliate exception “does not square with § 42”).

We think the natural, virtually inevitable reading of § 42 is that it bars foreign goods bearing a trademark identical to a valid US trademark but physically different, regardless of the trademarks’ genuine character abroad or affiliation between the producing firms. On its face the section appears to aim at deceit and consumer confusion; when identical trademarks have acquired different meanings in different countries, one who imports the foreign version to sell it under that trademark will . . . cause the confusion Congress sought to avoid. The fact of affiliation between the producers in no way reduces the probability of that confusion.

Id. (interpreting 15 U.S.C.A. § 1124 (1999)). The court adopted the above interpretation of the statute and remanded to the district court. Id. On remand, the District Court granted the injunction, holding that the Lanham Act “prohibits the importation of foreign goods that bear a trademark identical to a valid United States trademark but which are physically different, regardless of the validity of the foreign trademark or the existence of an affiliation between the United States and foreign markholders.” Lever Bros. Co. v. U.S., 796 F. Supp. 1, 6 (D.C. Cir.1992). Subsequently, the Court of Appeals found the injunction overbroad, but upheld the District Court's interpretation of the Lanham Act. Lever Bros. Co. v. U.S., 981 F.2d 1330, 1338-39 (D.C. Cir. 1993).

26 See Lever Bros., 981 F.2d at 1338.


29 Id.
similar in purpose and appearance, probability of consumer confusion increases. Courts have often used the material difference threshold to address gray market goods that are significantly similar in nature.\(^{30}\)

In 1987, the Second Circuit introduced the material difference standard as it applies to gray goods.\(^{31}\) The defendant manufactured Cabbage Patch Kids dolls for distribution in Spain under a restrictive license granted by the plaintiff trademark owner.\(^{32}\) The defendant distributed the dolls in the United States in the same market where Cabbage Patch Kids dolls made specifically for American consumers circulated.\(^{33}\) The court held the plaintiff was entitled to injunctive relief since the dolls made in Spain and those made in the United States were materially different.\(^{34}\)

The threshold for determining whether gray market products differ materially is often low and usually considers subtle differences.\(^{35}\) Some courts are even willing to hold a lack of quality control over the imported products as a material difference.\(^{36}\) In

\(^{30}\) Oswald, supra note 27, at 137.

\(^{31}\) Original Appalachian Artworks, Inc. v. Granada Elec., Inc., 816 F.2d 68, 70 (2d Cir. 1987).

\(^{32}\) Id. at 70.

\(^{33}\) Id. The Spanish dolls came with adoption papers and instructions in Spanish and the dolls made for the United States carried papers in English. Id.

\(^{34}\) Id. at 76. The dolls made for Spain came with adoption papers and a birth certificate. Id. at 73. The United States distributors did not mail adoption certificates or birthday cards to doll owners. See Original Appalachian, 816 F.2d at 73. These differences caused confusion as to the source of the dolls and it turn jeopardized consumer goodwill. Id.

\(^{35}\) See, e.g., Gamut Trading Co. v. U.S. Int`l. Trade Comm’n, 200 F.3d 775, 780 (Fed. Cir. 1999). The Federal Circuit held the twenty-four Kubota Japanese made tractors imported by defendant were materially different from the Kubota tractors made for the United States market in strength, speed, and wheel dimensions. Id. In addition, certain parts and services needed for these tractors for the Japanese models were not available in the United States and the imported tractors lacked English warning labels and instructions. Id. The court further found these differences to be material, ruling that the imported Kubotas had infringed on the United States trademark. Id.; see, e.g., HoktoKinoko Co. v. Concord Farms, Inc., 810 F.Supp.2d 1013, 1025 (2011). Here, the court found the material difference argument persuasive as to the organic growing conditions of its mushrooms made for United States markets and non-organic growing conditions used for its Japanese destined mushrooms. Id.(which of the previous two cites is this to?); see, e.g., Ferrero U.S.A., Inc. v. Ozak Trading, Inc., 753 F.Supp. 1240, 1247 (1991) (finding mint with one and one half calorie content is materially different from mint with two calorie content).

\(^{36}\) GrupoGamesa S.A. De C.V. v. Ducletia El Molino Inc., No.CV-95-6086-ER, 1996 WL 443659 at *3 (C.D. Cal. April 9, 1996). The court found cookies and crackers meant for distribution in Mexico materially differ from those bearing the same trademark imported into the United States because the trademark owner lacks control over the quality of the products’ labeling, retail display and freshness. Id; see also PepsiCo, Inc. v. Reyes, 70 F.Supp.2d 1057, 1058 (1999). The fact that the Mexican Pepsi products do not adhere to the plaintiff trademark owners’ quality control standards (due to increased leakage risks, carbonation loss, and deterioration due to shipping complications) results in the existence of a material fact likely to
1992, the 2nd Circuit noted that a good is not “genuine” when it fails to satisfy the trademark owner’s quality control standard. However, to reach the required threshold to satisfy trademark infringement in violation of the Lanham Act, the aggrieved party must show that the inferior product caused consumer confusion. Courts are willing to find that differences in quality control over things such as labeling and preparation coupled with distribution into unintended markets render goods materially different from their counterparts bearing the same Trademark. Alternatively, courts are reluctant to enjoin the defendant from buying gray goods abroad and importing them into the United States if the goods are “genuine.” Goods are “genuine” when they show no material differences from the manufactured product meant for foreign markets or those in domestic competition. The consumer does not need protection if the

undermine the plaintiff’s reputation. Id. “Goods, however, that do not meet the trademark owners’ quality control standards will not be considered genuine goods, and their sale will constitute trademark infringement.” Polymer Technology Corp. v. Mimran, 37 F.3d 74, 78 (2nd Cir. 1994).

Plaintiff Polymer made contact solution for two different markets, one retail and one professional. Id. They packaged the products differently depending on the market. Id. Plaintiff alleged that defendant bought professional solutions and circulated them into the retail market, violating its trademark rights by failing to satisfy its quality control standard for retail solution. Id. The professional solution lacked ingredients information, warnings and anti-tampering seals as required by the FDA. Id. See Polymer Tech. Corp., 975 F.2d at 62-63.

Bayer Corp. v. Custom School Frames, LLC, 259 F.Supp.2d 503, 508 (LA, 2003). The court held the packaging and labeling differences with respect to flea control preparations imported into the United States but made specifically for Australia, the United Kingdom and Ireland materially different. Id. at 507-09; see also Societe Des Produits Nestle, S.A. v. Casa Helvetia, Inc., 982 F.2d 633, 638 (1992). Here, the trademark owning Plaintiff made chocolates bearing the “PERUGINA” trademark, but meant for distinctively different markets. Id. at 365. The chocolates intended for Venezuela differed in presentation, variety and composition and price than those intended for Italy. Id. The defendant bought the Venezuelan made chocolates from a middleman supplier and imported them to Puerto Rico with the “PERUGINA” mark. Id. The Puerto Rican consumers were accustomed to the Italian version of the chocolates and plaintiff claimed the gray market distribution of their chocolates threatened the integrity of their mark as “symbols of consistent quality and goodwill.” Id. The First Circuit made it clear that when two merchants sell physically different goods in the same market using the same Trademark, the Lanham Act protection is triggered to correct consumer confusion and uphold the trademark owner’s goodwill. Id. at 637.

See, e.g., Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc., 922 F. Supp. 299, 308 (C.D. Cal. 1996). In Summit Tech, the plaintiff owned a trademark for eye laser systems, which the defendant bought abroad and imported to the United States, selling them at cheaper rates than their domestic counterparts. Id. The court found the imported products to be genuine and therefore no danger of consumer confusion as to the source of the laser systems existed. Id. at 310. Some of the systems may have had differences but all were Summit manufactured products and Summit could control the downstream domestic disruption of its products sold originally in foreign markets. Id. at 309.
goods are identical. In such a case, the trademark owner manufactures goods designed for foreign markets at its own risk and will assume such risk should a dealer introduce the goods into domestic markets.

II. Pharmaceuticals in the Gray Market and FDA Regulation

Courts show deference to the FDA in its authority and jurisdiction over medical device and drugs. For example, where the FDA has yet to complete its investigation of a new product imported into the United States, the court is barred from deciding if approval will be granted before the FDA takes an official position. In turn, drugs sold abroad under less stringent regulation can enter the United States market without being fully assessed by the FDA, thus posing health risks to consumers. To further protect the consumer and public health, courts are willing to hold slight differences as material in the conglomerate even when the goods are "genuine," satisfying the required threshold for injunctive relief. However, when the parallel imports are identical to the domestic products, the material difference threshold is not met, the Lanham Act is not triggered, and such goods are free to legally circulate the gray market.

42 See Steven Richman, Shades of Gray: Current Legal Issues Regarding Parallel Imports, NEW JERSEY LAWYER, THE MAGAZINE, Oct. 2003, at 9. When goods are identical, meaning the instructions are in the same language, the color, pattern and shape are the same, the caloric content, size and chemical composition are the same, the consumer does not need protection from any differences in the product that would have been relevant in his or her decision to purchase. Id.
43 See Summit Tech., 922 F.Supp. at 309; see also NEC Electronics v. CAL Circuit Abco, 810 F.2d 1506, 1508-11 (9th Cir. 1987). Plaintiffs selling computer chips at cheaper prices abroad did so at their own risk and found no remedy at law when consumers grew hostile toward the United States trademark owner for denied warranty and servicing. Id. at 1507-08.
44 See Summit Tech., 922 F.Supp. at 306. Where the FDA had yet to complete its investigation of laser eye systems imported into the United States, the court refused to impede on the FDA before it had its chance to decide on the similarities between the domestic and imported devices and whether further approval was necessary. Id.
45 See id. (citing Sandoz Pharmas. v. Richardson Vicks, Inc., 902 F.2d. 222 (3rd Cir. 1990)); see also Healthpoint, Ltd. v. Stratus Pharmas., Inc., 273 F.Supp.2d 769, 786 (W.D. Tx. 2001). Under the Lanham Act, relief may not be sought if the court is required to interpret FDCA or FDA regulations. Healthpoint, Ltd., 273 F.Supp.2d at 786. Otherwise, the courts would frustrate Congress' intent that the FDA holds the authority and has discretion to enforce its own regulations. Id.
46 See id. at 786.
47 See Novartis Animal Health U.S., Inc. v. Abbeyvet Export Ltd., 409 F.Supp.2d 264, 266-267 (S.D.N.Y. 2005). In Novartis, a veterinary drug manufacturer sought injunctive relief to stop defendant from selling manufactured goods in the United States in original packaging intended for the British market. Id. Unlike the American version, the British pills were not flavored, sold in different dosages and lacked FDA required information on its packaging. Id. at 267. The court granted injunctive relief due to likely consumer confusion, noting that "[e]ven small differences matter." Id. Consumer confusion can easily occur from such differences when a dog
III. The Intersection of the Gray Market and Pharmaceutical Drugs

The current health care landscape in the United States involves tensions between access, quality of care and high costs. Additionally, the United States' drug prices rank highest in the world. Due to the government's desire to maintain patent takes to the flavored United States pill but not the unflavored British product, causing the consumer to avoid all medication marked by plaintiff's brand. Id. A similar harm to the plaintiff's goodwill may occur when consumers have trouble calculating the correct dosage from the metric units given on the British packaging. Id. See also Johnson & Johnson Consumer Cos., Inc. v. Aini, 540 F.Supp.2d 374, 380 (E.D.N.Y. 2008) (granting relief where defendant imported gray good skin cream not intended for sale in the United States). The skin cream's packing lacked warnings to consumers listed on the original packaging such as "Keep Out of Reach of Children" or "Some users may experience a mild irritation or temporary darkening" and drug interaction information. Id. at 385-87. The court reasoned that each of these warnings could contribute to a consumer's decision not to buy the product and injunctive relief was appropriate. Id. at 387-95. "In such a situation, consumers get exactly the bundle of characteristics that they associate with the mark and the domestic distributor can be said to enjoy in large measure his investment in goodwill." Societie Des Produits Nestle, S.A., v. Casa Helvetia, Inc., 982 F.2d 633, 641 (1st Cir. 1992). The aggrieved trademark owner "simply cannot use trademark law to control the downstream distribution of products that [the plaintiff] itself manufactured and sold." Summit Technology, 922 F. Supp. at 309. See also Am. Circuit Breaker Corp. v. Oregon Breakers Inc., 406 F.3d 577, 585-86 (9th Cir. 2005). Here, the court held that any claim for trademark infringement must fail where consumers are getting the exact same circuit breaker from the distributor as they would the trademark owner. Id. "An action will not arise where the goods being sold are genuine goods bearing a true mark." Polymer Technology Corp. v. Mimran, 37 F.3d 74, 78 (2nd Cir. 1994).

Millions of Americans are just a pink slip away from losing their health insurance, and one serious illness away from losing all of their savings. Millions more are locked into the jobs they have now just because they or someone in their family had once been sick and they have what is called a pre-existing condition. And on any given day, over 37 million Americas — most of them working people and their children — have no health insurance at all. And in spite of all this, our medical bills are growing at over twice the rate of inflation, and United States spends over a third more of its income on health care than any other nation on earth. And the gap is growing, causing many of our companies in global competition severe disadvantage.

Id. The affordability of drugs has the greatest effect on the elderly, who need more drugs as they age, people living in poverty, and the uninsured, who are forced to pay out of pocket. Tanner, supra note 3, at 267, 270-71. American consumer sales make up about half of the global pharmaceutical drug revenue. Id.
holder profits, the United States is one of the only industrialized nations without price restrictions on pharmaceutical drugs. The present discourse surrounding these issues suggests that health care rationing and economic incentives to cut back on unnecessary treatment are essential to reduce overall costs.

In the wake of these discussions, American health consumers, hospitals and physicians turn to foreign pharmaceutical manufacturers or parallel distributors for less costly and otherwise unavailable drugs. These practices have opened a niche which allows the gray market to thrive. Once a drug is developed, the manufacturer distributes it to wholesalers, who then distribute the drug to hospitals and pharmacies.

50 Id. Aside from the limited controls used by health maintenance organizations (HMOs), pharmacy benefit managers (PBMs), and government funded programs (Medicaid and Medicare), the drug manufacturers enjoy free reign in pricing. Id.

51 Id.

52 Id. at 268-69. The high cost of pharmaceuticals in the United States can be traced to the patent monopolies large companies enjoy after obtaining patents for their drugs and, the FDA's high standards for all new drugs. Id. In 1997, the Federal Trade Commission removed restrictions on direct-to-consumer (DTC) advertising by pharmaceutical companies, causing a 50% increase from 1996 to 1997 in money spent on advertising, reaching $1.4 billion in 1998. Michele L. Creech, Make a Run for the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs, 15 EMORY INT'L L. REV. 593, 607 (2001). The increase of DTC has heightened consumer awareness and created a larger demand for physicians to prescribe pharmaceuticals. See Tamar V. Terizian, Direct-to-Consumer Prescription Drug Advertising, 25 AM. J.L. & MED. 149, 157 (1999). Advertising costs increase prices consumers pay for the product, shifting the medical field from service to business, which encourages the companies to maximize profits by increasing prices as demand remains high. Tanner, supra note 3 at 274.

53 See supra text accompanying note 6 (regarding the FDA encouraging production and easing regulations). See also INSTITUTE FOR SAFE MEDICATION PRACTICES, GRAY MARKET, BLACK HEART: PHARMACEUTICAL GRAY MARKET FINDS A DISTURBING NICHE DURING THE DRUG SHORTAGE CRISIS (2011) [hereinafter ISMP 2011] available at http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3 (last visited Oct. 31, 2013). The Institute for Safe Medication Practices conducted a survey in the summer of 2011 on gray market activities and drug shortages at 549 hospitals. Id. One third of the survey respondents from critical access hospitals and another third from community hospitals bought gray market products in the last two years at inflated prices ten times or higher than normal rates. Id. Fifty three percent of respondents from university hospitals reported similar 900% mark ups and additionally high costs for shipping and handling. Id. Another study reported 650% average mark ups and others reaching 3,000% and as high as 4,000% for back ordered drugs. See also PREMIER, GRAY MARKET ANALYSIS 2 (2011), available at https://www.premieinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf.

54 U.S. FOOD AND DRUG ADMINISTRATION, A REVIEW OF FDA'S APPROACH TO MEDICAL PRODUCT SHORTAGES, at 29 (Oct. 31, 2011) [hereinafter FDA'S APPROACH], available at www.fda.gov/downloads/aboutfda/...reports/ucm277755.pdf. The authors urge wholesalers to adopt and publish a universal and uniform distribution policy for shortage drugs. Id. at 39. This
However, wholesalers create vulnerabilities in the links of the chain when they sell to other wholesalers, enabling drugs to disperse out of the legitimate supply and into the gray market.\textsuperscript{55}

\textbf{A. The Drug Shortage}

Prescription drug shortages have tripled over the past five years.\textsuperscript{56} These shortages have often involved medically necessary injectable drugs.\textsuperscript{57} The causes of the could decrease the dissemination of drugs to gray market distributors by decreasing recipient's confusion. \textit{Id.}

\textsuperscript{55} \textit{Id.} at 29. The lack of transparency failing to reveal who gets the drugs, where and how creates distrust between distributors and wholesalers, which is made worse by the “leakage” of drugs to gray market links. \textit{Id.} at 39.

\textsuperscript{56} National Community Pharmacists Association, \textit{United States House of Representatives Committee on Energy and Commerce Subcommittee on Health} Hearing on “Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages” (Feb. 9, 2012), http://www.ncpanet.org/pdf/leg/feb12/ drug_shortages_statement.pdf. The FDA defines a drug shortage as “a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level.” FDA’S APPROACH, supra note 54, at 8.

\textsuperscript{57} \textit{Short-Suppfy Prescription Drugs: Shining a Lizght on the Gray Market: Hearing Before the Comm. on Commerce, Science, and Transportation, 112\textsuperscript{th} Cong.} 5-6 (2012), http://www.gpo.gov/fdsys/pkg/CHRG-112shrg79524/pdf/CHRG-112shrg79524.pdf. Drug Shortages included 70 drugs in 2006 and 231 as of November 2011. \textit{Drug Shortages: Why They Happen and What They Mean: Hearing Before the Committee on Finance United States Senate, 112\textsuperscript{th} Cong. 3} (2011) (statement of Dr. Kasey Thompson). Over eighty percent of the shortages include generic drugs used for chemotherapy, emergencies, anesthesia, and intravenous feeds, many of which are fundamental to the most routine surgeries. The FDA has named around 200 drugs in short supply. U.S. Department of Health & Human Services, \textit{Current Drug Shortage Index} (March 20, 2013), http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm50792.htm. In 2011, over 400 generic drugs were back ordered for at least five days, and in 2010 sterile injectables were reported “as most frequently being in short supply.” GREATER NEW YORK HOSPITAL ASSOCIATION, \textit{DRUG SHORTAGES, available at} http://www.gnyha.org/10824/File.aspx (hereinafter GNYHA).

On October 31, 2011, President Obama issued an executive order in an effort to address the proliferation of drug shortages. The executive order instructs the FDA to employ its existing authority and administrative tools “to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages” for drugs required in life support, sustainment, or debilitating diseases, “to expand its current efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes,” and to “communicate to the Department of Justice (DOJ) any findings that shortages have led market participants to stockpile the affected drugs . . . .”
shortages include problems of quality, delays in manufacturing, raw material shortages and business dynamics. Pharmacies and other health care providers fail to give

Friske, supra note 6, at 531 (quoting Exec. Order No. 13588, FR 682962011 WL 5190307 at 68295 (2011)). In 2011, CDER reported that 73% of the short listed drugs were sterile injectable. U.S. SENATE COMM. ON COMMERCE, SCI. & TRANSP., SHINING LIGHT ON THE “GRAY MARKET,” AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES 2 (July 25, 2012), available at http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=dcc81e66-09ae-4650-ab06-c590ae284c4e [hereinafter SHINING LIGHT ON THE GRAY MARKET]. The same year, the IMS found the largest number of reported drug shortages included sterile injectables used in chemotherapy for cancer patients. Id. Between the months of January and June of 2011, 99.5% of hospitals across the nation reported at least one serious drug shortage. Id. 58 Drug Shortages, FDA, http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm (last updated Oct. 9, 2013). Short-term drug supply may halt when a manufacturer shuts down production to look into a quality problem or improve and repair its facilities. SHINING LIGHT ON THE GRAY MARKET, supra note 57, at 3. When this happens, in the case of sterile injectables, it is hard for competitors to up production to fill the void because these drugs require special equipment and production processes. Id. In 2010 and 2011, the FDA looked into 127 reported drug shortages and found the shortages most commonly were caused by manufacturers shutting down their facilities to investigate drug quality issues. Id. Within the business dynamics of sterile injectable drugs, used for cancer treatment, Group Purchasing Organizations (GPOs) supply health care providers such as hospitals and physicians with drugs at a price after negotiating with the manufacturers. OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING AND EVALUATION, ASPE ISSUE BRIEF: ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES 5 (October 2011), available at http://aspe.hhs.gov/sp/reports/2011/drugshortages/ib.pdf [hereinafter ASPE]. Medicare reimburses health care providers for drugs used for qualifying patients under Part B and using the “Average Sales Price,” reimbursing health care providers for what they determine to be the average sales price. See SHINING LIGHT ON THE GRAY MARKET, supra note 57, at 4. For these reasons, the price of sterile injectables lacks elasticity and remains quite static, unable to account for increased demand and short supply. See ASPE, supra at 3-4. The production process for these drugs is complex and demanding as manufacturers must comply with Current Good Manufacturing Processes (CGMPs). Id. at 4. Drugs have a restricted shelf life and holding drugs in excess can make for costly waste. Id. In turn, manufacturers keep inventory as low as needed. Id. Raw materials required for production are hard to find and must also satisfy regulatory approval. Id. In addition, many GPO contracts with manufacturer’s include “failure to supply” clauses requiring the manufacturer to reimburse the GPO for the price difference negotiated for and the purchased price when there is a discrepancy due to short supply. Id. at 5. While these clauses are more frequently omitted from new contracts due to the current state of drug shortages, it remains that manufacturers operate with small profit margins. ASPE, supra at 5. These entities do not make the investments to increase capacity to meet the current demand for the above reasons and competitors have no financial incentive to break into the market. SHINING LIGHT ON THE GRAY MARKET, supra note 57, at 4. Some drug shortages result from scarcity of raw materials needed for the active pharmaceutical ingredient. See ASPE, supra at 2. Manufacturers often rely on only one supplier for these ingredients and finding another source when that supplier is short is difficult. Id. Any supplements must be approved by the FDA, which takes time. See id. at 4; see, e.g., 21 C.F.R. § 314.70 (a)(1)(i), (b)(1) (2008). It is important to note that “[a]bout half of the time manufacturers do not disclose the reason for a shortage,” and the causes for the current drug shortages are still being analyzed. Drug Shortages: Why They Happen
adequate notice to manufacturers when a shortage becomes imminent. Despite regulatory requirements, manufacturers often fail to give adequate notice of a shortage to the FDA and health providers. In addition, recent profit margin deterioration and the accrual of Current Good Manufacturing Practice (hereinafter “CGMP”) violations lead manufactures to feel forced to terminate production.


“(a) An applicant who is the sole manufacturer of an approved drug product must notify FDA in writing at least 6 months prior too discontinuance of manufacture of the drug if: (1) The drug product is life supporting, life sustaining or intended for use in the prevention of a serious condition . . . (b) Notifications required by [the above paragraph] of this section must be submitted to FDA either electronically or by phone according to instructions on FDA’s Drug Shortage Web site at: http://www.fda.gov/Drugs/DrugSafety/DrugShortages.”

Id. Discontinuance is defined as “a potential disruption in supply of the drug product, whether the interruption is intended to be temporary or permanent.” 21 C.F.R. § 314.8(b)(3)(ii)(d).


A drug or device shall be deemed to be adulterated-- (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture. (1) If it consists in whole
These shortages cause hospitals and physicians to ration their drug supplies by delaying treatment, or relying on alternative drugs such as gray products.\textsuperscript{62} Managing shortages depletes huge amounts of time and money on the part of providers needing to compensate for the missing drugs.\textsuperscript{63} Consequently, providers are coerced into paying

\begin{quote}

or in part of any filthy, putrid, or decomposed substance; or (2)\textsuperscript{A} if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act \textsuperscript{[21 USCS §§ 391 et seq.]} as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . . [T]he term “current good manufacturing practice” includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.


\textsuperscript{62} GNYHA, \textsuperscript{supra} note 57. In the face of drug shortages, providers may be forced to resort to practices of delaying treatment, or turn to less familiar drugs, both of which can cause negative health consequences for patients. \textit{Id.} In a survey conducted by the Institution for Safety Medication Practices in 2010, of over 1,800 healthcare providers, 84\% reported a lack of warning as to imminent shortages, and a large majority reported time and money lost to efforts attempting to manage the shortages. \textit{INSTITUTE FOR SAFE MEDICATION PRACTICES, DRUG SHORTAGES: NATIONAL SURVEY REVEALS HIGH LEVEL OF FRUSTRATION, LOW LEVEL OF SAFETY} (2010), available at http://www.ismp.org/newsletters/acute-care/articles/20100923.asp [hereinafter ISMP 2010]. The effort to compensate for drug shortages by hospitals reaches over $200 million each year. GNYHA, \textit{supra} note 57.

\textsuperscript{63} GNYHA, \textit{supra} note 57. ISMP’s report shows labor and financial resources otherwise spent on clinical duties are being used to search for alternative drugs. ISMP 2010, \textit{supra} note 62. In ISMP’s 2010 survey of 1,800 health care providers, 69\% reported spending substantial resources to acquire and make ready alternative products. \textit{Id.} Physicians and pharmacists reported having to investigate shortages and come up with a plan of resolve, hoarding medications that were short, finding an alternative, taking financial blows for buying drugs off contract, and high delivery costs for rushing products. \textit{Id.} The American Society of Health-System Pharmacists and the University of Michigan teamed up in a 2011 survey and concluded that the cost of drug shortage management amounts to $216 million in annual labor costs. \textit{See} Anne Polta, \textit{Shortages Are Often Costly for Hospitals}, \textit{WEST CENTRAL TRIBUNE}, (Nov. 7, 2011), available at
astronomical amounts in order to provide the necessary treatments. Providers in turn

http://www.wctrib.com/content/shortages-are-often-costly-hospitals. For example, the American Hospital Association polled its members and found that 92% of the hospitals bought more expensive drugs, and 85% ordered in bulk to have a robust and excessive inventory to manage and prepare for drug shortages. *Id.* The prices often cannot be handed off to patients because of already negotiated prices set by insurance contracts. *Id.* “Failure to supply” clauses in contracts between hospitals and wholesalers enable hospitals to recover some of the extra costs spent on alternatives to short supply drugs. *Id.*

See Jaimy Lee, *Providers fuel ‘gray market,’* MODERNHEALTHCARE.COM (September 5, 2011), http://www.modernhealthcare.com/article/20110905/MAGAZINE/309059980#. According to ISMP’s 2011 report, more than 13% of the 549 purchasing agents and pharmacists surveyed had received solicitations from gray market vendors who wanted to buy medically necessary medications in short stock, undoubtedly to sell to other hospitals in need. *Id.; ISMP 2011, supra* note 53. The director of pharmacy services at Carroll Hospital Center in Westminster, Maryland, for example, tells of receiving between five and ten calls a day offering drugs. *Lee, supra.* The hospital takes up the gray market offers “when ‘the benefit outweighs the risk.’” *Id.* The same director admits to buying injectable drugs normally priced at $2.73 a vial for $33.50 a vial. *Id.* In 2010, the shortage of cytarabine, a major leukemia drug, caused hospitals like Johns Hopkins to ration their supply while others turned patients away all together. Jennifer C. Dooren, *Shortage Worsens of Leukemia Drug,* WALL STREET JOURNAL (April 14, 2011), available at http://online.wsj.com/article/SB10001424052748704547804576261282159840442.html. In the spring of 2011, a doctor at the University of Texas M.D. Anderson Cancer Center in Houston reached out to doctors around the nation, asking them to tell their own stories in order to raise awareness of the growing shortage for the drug and its grave implications. *Id.* Doctors in thirty different states shared that patients with acute myeloid leukemia will die without the drug. *Id.* An FDA spokeswoman stated the “FDA understands that the cytarabine shortage is extremely serious, as it’s for adults and children with leukemia and there are no substitutes that can be used.” *Id.* The vice president of pharmacy services for Baptist Health System in San Antonio, Texas, admitted to buying gray goods at inflated prices claiming, “[w]e have no other choice . . . We have to take care of our patients.” Richard A. Marini, *Drug shortages, skyrocketing prices anger pharmacists,* MYSA.COM (May 3, 2011), http://www.mysanantonio.com/life/health/article/Drug-shortages-skyrocketing-prices-anger-1362707.php. In 2011, over a two week period, Premier healthcare alliance membership recorded 1,745 gray market offers from 42 of its acute care hospitals with an average price mark up of 650%. Coleen Cherici, et al., *Buyer beware: Drug shortages and the gray market,* 2 Aug. (2011), https://www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf. Premier’s respondents recorded gray market offers for Cytarabine, the drug vital to leukemia patients as discussed above, at prices marked up as high as 3,980%. *Id.* Gray marketers email and use fliers to advertise their products with language similar to: “We only have 20 of this drug left and quantities are going fast.” *Id.* at 3. George W. Sledge, M.D. of Indiana University’s Simon Cancer Center, told of his experience when informing a patient diagnosed with metastatic breast cancer that liposomal doxorubicin was short listed: “It was the only drug that was keeping her in remission, and then one day I had to tell her that the drug was no longer available.” Eric T. Rosenthal, *Frustration Over Gray-Market Drugs Lingers Throughout Nation,* 104 JNCI 4, 264 (2012), available at http://jnci.oxfordjournals.org/content/104/4/264.full.pdf+html. When a single dose was finally found, “Sledge admitted that he had no idea about the drug’s cost but was glad to have it for his patient.” *Id.*
compromise a drug’s safety and integrity in order to serve their patients’ needs.  

Neither providers nor patients have knowledge of how gray drugs are stored, handled, or whether they are expired, counterfeit or well below the standards of quality set by the FDA.  

As a result, the intersection of U.S. drug shortages and the gray market pose serious health risks to American consumers.  

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65 See Lee, supra note 64 (quoting distributor spokesperson). “Buying directly helps ‘ensure the safety and integrity of the product and the safety of the whole supply chain.’” Id. Angered and frustrated by the ability of gray-marketers getting a hold of unavailable drugs, Nicholas J. Petrelli, M.D. of the Helen V. Graham Cancer Center in Delaware states, “[i]f they are diluted, counterfeited, mislabeled, [or otherwise compromised], they could pose a danger to patients and practicing physicians.” Id. The Fox Chase Cancer Center in Philadelphia stands behind the notion that if they cannot be sure of the drug’s integrity they refuse to administer it to a patient. Shining Light on the “Gray Market”, An Examination of Why Hospitals are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages 6 (2012), DEMOCRATS.OVERSIGHT.HOUSE.GOV 6 (July 25, 2012), http://democrats.oversight.house.gov/uploads/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf.  

66 The CDER continues to monitor more than 10,000 drugs even after their approval into the market. Preceptors by Center/Office, FDA, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/ucm118070. Gray marketers, however, circumnavigate these protective safeguards by behaving outside the regulated chains of drug production, distribution and use. See A Review of FDA’s Approach to Medical Product Shortages, U.S. FOOD & DRUG ADMIN., 29 (Oct. 31, 2011), www.fda.gov/downloads/aboutfda/.../reports/ucm277755.pdf [hereinafter U.S. FOOD & DRUG ADMIN]. In an FDA workshop, the Executive Vice President & Chief Commercial Officer at APP Pharmaceuticals expressed his own bewilderment on how gray goods enter the supply chains. Transcript of Workshop, Drug Shortage Workshop, FOOD & DRUG ADMIN., CENTER FOR DRUG EVALUATION AND RESEARCH, 316-17 (Sept. 26, 2011). “We don’t know how it gets there either. We are perplexed as the customers are, the health care professionals are.” Id. In 2009, consumers informed the FDA the insulin they used was not controlling their blood sugar levels. It turned out they were using stolen insulin, which had most likely been poorly stored or handled, losing its efficacy. Cherici, supra note 61, at 4. Ten years ago, staff at a prominent Houston hospital stole oncology drugs and sold them into the gray market. Rosenthal, supra note 64, at 266. The drugs were later found in a parked and unrefrigerated truck. Id.  

67 U.S. FOOD & DRUG ADMIN., supra note 66; see also SETH E. LIPNER, THE LEGAL AND ECONOMIC ASPECTS OF GRAY MARKET GOODS 9 (1990). With the free riding practice of selling identical goods as those sold by full service providers comes an inherent failure to provide consumers with ancillary services such as instruction, maintenance, repair or warranty. Furthermore, the free rider sells the goods without ensuring the products quality, compromising on packaging, transportation, storage or inspections standards. Id. The FDA’s Center for Drug Evaluation and Research makes sure prescription and over the counter drugs are safe and effective, ensuring that the drugs benefits outweigh its risks. Tanner, supra note 3, at 274; see also Improving Public Health: Promoting Safe and Effective Drug Use, U.S. DEPT. OF HEALTH & HUMAN SERVS. (Aug. 2003), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/WhatWeDo/UCM121592.pdf.
B. Distribution Chains and Gray Links

Traditionally, a drug distribution change starts with a manufacturer, who then sells the drug to a wholesale disturber, who in turn sells to a hospital or pharmacy, which ultimately administers the drug to patients.\(^6\) Other authorized links are often part of the chain, including re-packagers and secondary distributors.\(^6\) Pursuant to federal law, "authorized distributors of record" are those that have "established an ongoing relationship to distribute" the drugs of a given manufacturer.\(^7\) Three national distributors, AmerisourceBergen, Cardinal Health and McKesson, comprise about 85% of the authorized distributors of record for drug manufacturers.\(^7\) Distributors are authorized by federal statute to buy drugs from manufacturers and send them to pharmacies, hospitals and other providers.\(^7\) Some authorization agreements require that the distributors only buy a manufacturer's drug directly from the manufacturer.\(^7\) Some primary wholesale distributors use similar restrictions in dealing with customers, requiring final dispensaries that administer directly to patients to guarantee that they will not redistribute the drugs into the "Secondary Market."\(^7\) The larger a supply chain becomes, the more vulnerable it becomes to gray good entry.\(^7\)

While state and federal law requires wholesalers and other drug distributing businesses to provide a pedigree documenting the drug's distribution route, manufactures and authorized distributors are exempt from such requirements.\(^7\)

\(^{68}\) See Shining Light on the Gray Market, supra note 57, at 7.

\(^{69}\) Id.


\(^{71}\) See Shining Light on the Gray Market, supra note 57, at 8.


\(^{73}\) See Shining Light on the Gray Market, supra note 57, at 9 (requiring Hospira to authorize its distributors to only buy its drugs directly from Hospira).

\(^{74}\) Id.

\(^{75}\) Id. The FDA reports that gray drugs are more likely to leak into a supply chain with multiple wholesalers. Id.; see Counterfeit Drug Task Force Report October 2003 — Background: Vulnerabilities in the U.S. Drug Distribution System, FDA http://www.fda.gov/Drugs/DrgSafety/ucm174479.htm (last visited November 1, 2013).

\(^{76}\) See 21 U.S.C. § 353(e)(1)(A) (2006). The law requires any person engaged in wholesale drug distribution that is not the manufacturer or authorized distributor to record and provide to the receiver of each distribution the identification of "each prior sale, purchase or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction." Id.; see Shining Light on the Gray Market, supra note 57, at 11, n.50. See e.g. Ariz. Rev. Stat. § 32-1984(A) (2012). "Each full service wholesale permittee must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs, including pedigrees for all prescription-only drugs that leave the normal distribution channel." Id. See also, e.g., Colo. Rev. Stat. § 12-42.5-131 (2013); Fla. Stat. § 499.01212(1) (2013); Wis. Stat. § 450.073(1) (2012).
2011, a Congressional investigation reached out to five gray market companies believed
to be aggressively marketing to hospitals that were in short supply of drugs to treat
cancer and pregnancy seizures.\textsuperscript{77} The pedigrees named 125 different companies that at
one time possessed one of the five short-supply drugs under investigation.\textsuperscript{78} The study
found that in 69\% of the 300 investigated distribution chains, prescription drugs had
been "leaked" into gray market chains, and had been sold again by wholesalers to other
gray market companies at large mark up prices.\textsuperscript{79}

C. Prescription Drug Amendment Act

In an effort to "increase safeguards to prevent the introduction and retail sale of
substandard, ineffective, and counterfeit drugs in the US supply chain," the FDA
implemented the Prescription Drug Amendment Act of 1987.\textsuperscript{80} In 1999, the FDA faced
criticism "raised by various stakeholders" because it defined an "ongoing relationship"

\textsuperscript{77} Senate Commerce Committee Report on Drug Shortages and the Gray Market "Where Have They All
commerce-committee-report-on-drug-shortages-and-the-grey-market-where-have-they-all-
gone.html. The investigation, opened by House Committee on Oversight and Government
Reform Ranking Member Elijah Cummings and joined by Senator John D. Rockefeller IV,
Chairman of the Senate Committee on Commerce, Science and Transportation, and Senator
Tom Harkin, Chairman of the Senate Health, Education, Labor, and Pensions Committee,
analyzed 300 paper pedigrees listing names of all entities that took possession of each drug and
the dates of their possession. Id.

\textsuperscript{78} Id.

\textsuperscript{79} Id. Twenty-five vials of flurouracil, a sterile injectable used to treat colon, stomach, breast and
pancreatic cancer, traveled from its manufacturer to seven other companies and pharmacies in
four different states before ending up at Sonoara Regional Hospital in 2011, all the while listed as
one of the FDA's short supply drugs. SHINING LIGHT ON THE GRAY MARKET, supra
note 57, at 12-13. The vials started at $7 each and by the end of the distribution chain sold for $600 each,
constituting an 8,741\% mark up. Id.

\textsuperscript{80} 21 C.F.R. § 203.2 (2013); CPG Sec. 160.900 Prescription Drug Marketing Act – Pedigree Requirements
CompliancePolicyGuidanceManual/ucm073857.htm (last visited November 1, 2013); 21 C.F.R. §
203.2 states:

The purpose of this part is to implement the Prescription Drug Marketing Act
of 1987 and the Prescription Drug Amendments of 1992, except for those
sections relating to State licensing of wholesale distributors (see part 205 of
this chapter), to protect the public health, and to protect the public against
drug diversion by establishing procedures, requirements, and minimum
standards for the distribution of prescription drugs and prescription drug
samples.

Id.
as one that "include[s] a written agreement between manufacturer and distributor." The "stakeholders" vowed to implement electronic pedigrees, but the practice was never widely adopted. In 2006, the FDA made effective the authorized distributor definition and the subsequent statutory provision that all "unauthorized distributors" must satisfy pedigree requirements that include, among other criteria, dosage, container size, date of each previous transaction, business name and addresses of all parties involved.

The FDA's distinction between authorized and unauthorized entities is not unchallenged. In 2006, the New York District Court refused to rule conclusively on the statute's constitutionality since the plaintiff filed a week before the statute took effect. The court did, however, acknowledge a substantial likelihood of success on the merits in

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Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Id.

82 FDA, CPG Sec. 160.900 Prescription Drug Marketing Act - Pedigree Requirements under 21 CFR Part 203, U.S. FOOD & DRUG ADMINISTRATION HOME PAGE (2010). In 2004, the California State Board of Pharmacy issued an e-pedigree requirement with a January 1, 2007 deadline, which was eventually delayed to allow the industry to further develop the necessary technology. Claire Swedberg, All Eyes on FDA for Drug E-Pedigree, RFID JOURNAL (April 10, 2008) http://www.rfidjournal.com/articles/view?4013/. An e-pedigree uses bar codes or microchip tracking devices to tag drugs throughout the supply chain. Id. The California Board of Pharmacy currently states that its e-pedigree requirements will take effect "on a staggered basis" from January 1, 2015 through July 1, 2017. CALIFORNIA STATE BOARD OF PHARMACY, California's E-Pedigree Law, CA.GOV, http://www.pharmacy.ca.gov/about/e_pedigree_laws.shtml. However, in Nevada a wholesaler must provide a statement of prior sales, identifying each sale and entity and “[the] information required . . . must be transmitted by electronic mail to the board or to a website established by the Board in a format required by the Board.” NEV. ADMIN. CODE § 639.603 (5) (2012). Other states allow either electronic or paper pedigrees. See, e.g., 225 ILL. COMP. STAT. ANN. 120/57 (a) (2007); IND. CODE § 25-26-14-8.7 (2006); NEB. REV. STAT. § 71-7455 (2) (2012). States have also included target dates for electronic implementation within their pedigree statutes. See S.D. CODIFIED LAWS § 36-11A-40 (2012); V.T.C.A., Health & Safety Code § 431.413 (e-1) (2007) (explaining “[t]he targeted implementation date may not be earlier than July 1, 2010”).


favor of the pharmaceutical companies' equal protection claim against the FDA. The court found a public interest in exempting "unauthorized wholesale distributors" from providing pedigree information in order to allow smaller distributors to provide drugs for their customers and stay in business. The court further noted that requiring pedigrees upon distribution would increase consumer costs in the form of insurance premiums and prescription drug prices.

IV. Navigating the Future: Drug Access and Drug Safety in a Prominent Gray Market

The current drug shortage, a grave situation with over 200 drugs on FDA's short supply list and an unyielding infiltration of gray goods, makes for a significant problem in need of resolve. In May of 2012, Congressman Elijah Cummings introduced the Gray Market Drug Reform and Transparency Act "[t]o prohibit wholesalers from purchasing prescription drugs from pharmacies, and to enhance information and transparency regarding drug wholesalers engaged in interstate commerce." Notably, the act would require each person engaged in wholesale distribution of interstate drug commerce to annually report their name, contact information, place of business and licensing information to each Secretary of State of each state in which that person conducts his or her business. The act also requires the Secretary of State for each state to establish a database containing all of the reported information of each wholesale distributor. The information would then be available on the FDA's website. In addition, the act amends the federal law requiring pedigrees of wholesale distributors to include, in addition to the names and entities of each prior sale, the price paid for each drug received if it is in shortage and listed on the FDA's short supply list. If passed, each Secretary of State will be able to verify that practicing wholesalers are licensed to distribute, and pharmacies and hospitals will be able to easily

85 Id. "[T]here is a substantial likelihood that the classification resulting in the disparate treatment of authorized and unauthorized wholesale distributors may be found unconstitutional." Id.
86 Id. at 292.
87 Id.
88 See Exec. Order No. 13588, 76 Fed. Reg. 68,295 at 68,295 (Oct. 31, 2011); see also supra text accompanying note 57. President Barack Obama ordered the FDA to use the full scope of its current authority to require notice of shortages for medically necessary drugs to sustain life and end disease. Id; see also supra text accompanying notes 57, 67.
90 Id. § 3(a)(1)(A).
91 Id. at § 3(a)(3)(B).
92 Id.
93 Id. at § 4(a)(1) (proposing to amend 21 U.S.C. 353(e)).
access this information. However, the bill arguably falls short of a comprehensive solution seeing as, even after checking on a wholesaler with the Secretary of State, providers would likely still pay the same outrageous prices for drugs they need to provide.

Consumers and patients alike remain vulnerable to domestic distribution of manufactured drugs that have leaked into the gray market and have potentially been mishandled or poorly stored. The cases interpreting the Lanham Act and utilizing the material difference standard demonstrates that the legislature and court system has made a sound effort toward protecting consumers from foreign imported gray goods with potential hazards. Trademark owners have found success by appealing to the court’s tendency to hold slight differences in the aggregate to create a material difference when goods similar in purpose and appearance are introduced into the same markets but intended for different ones. Trademark owner’s lack of quality control, as held by the courts as a material difference, has benefitted many aggrieved parties.

The FDA’s Prescription Drug Amendment Act requires unauthorized distributors to produce a written record identifying each prior sale, thus documenting

94. See id.
95. See Rosenthal, supra note 64. One doctor admits having no idea of the cost of a drug keeping his breast cancer patient in remission, but being happy to have found the dose for her. Id. at 264.
96. See Cherici, supra note 61. In one instance, insulin failed to control patients’ sugar levels, and investigation revealed the medication was stolen and likely tainted during handling and storage in the gray market. Id. at 4.
98. See Oswald, supra note 27. See, e.g., Hokto Kinoko Co. v. Concord Farms, Inc. 810 F.Supp.2d 1013 (C.D. Cal. 2011) (holding mushrooms grown for the United States materially different from those intended for Japan); Gamut Trading Co. v. U.S. Int’l Trade Comm’n, 200 F.3d 780-83 (Fed. Cir. 1999) (holding tractors made for Japan and those made for the United States materially different); Societe Des Produits Nestle, S.A. v. Casa Helvetia, Inc., 982 F.2d 642-44 (1st Cir. 1992) (holding chocolates intended for Venezuela materially different from those intended for Puerto Rico); Polymer Tech. Corp. v. Mimran, 975 F.2d 61-64 (2nd Cir. 1992) (holding contact solution meant for the professional market materially different from contact solution meant for the retail market); Original Appalachian Artworks, Inc. v. Granada Electronics, Inc., 816 F.2d 73 (2nd Cir. 1987) (holding dolls with adoptions papers and instructions in Spanish found materially different from those carrying English papers); see also supra text accompanying note 41 (explaining courts’ deference to the FDA).
However, without the court’s support, the effort to regulate gray drugs will remain futile, failing to achieve the comprehensive force of both the legislature and judicial systems that protected Trademark owners and consumers from the infiltration of internationally imported gray products. The New York District Court’s willingness to consider the FDA’s differentiation and treatment of “authorized” and “unauthorized distributors” as an equal protection violation, as seen in RxUSA Wholesale, Inc. v. Department of Health and Human Services, clearly frustrates the agency’s attempt to ensure that drugs are safe by the time they reach hospitals by requiring pedigrees documenting their route. The court speaks to a valid public policy of keeping small distributor’s in business given the current drug shortage and the need to provide drugs for patients, but fails to acknowledge a more holistic approach to the drug shortage as it intersects with the gray market. Patients are in need of lifesaving drugs that remain on the FDA’s shortage list but they are also vulnerable to unsafe drugs that have escaped the conventional distribution chains and wound up in the hands of gray vendors, unmonitored in their handling, storing and quality control of such drugs.

By requiring widespread use of pedigrees pursuant to the FDA’s Prescription Drug Amendment Act and Congressman Cummings’ Gray Market Drug Reform and Transparency Act, drug routes into the gray market will become transparent. With public information as to what entities and persons are handling the drugs before they

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100 See 21 C.F.R. 203.50(a) (2013):

Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug.

Id.

101 See discussion supra Part II. Due to little regulation at the hand of FDA’s soft reprimand and a market short on drugs, there is an infiltration of unauthorized and potential harmful gray pharmaceuticals. Id.

102 See RxUSA Wholesale, Inc. v. Dept. of Health & Human Servs., 467 F. Supp. 2d 285, 291 (E.D. NY 2006); see also supra note 82 and accompanying text. The New York District Court focused on public goals of enabling small distributors to stay in business and the threat of an increase in consumer costs if pedigrees were to be required. Id. at 292. The court failed to give adequate light to the FDA’s attempt to keep clean and safe the chains of distribution and the drugs that end up in the hands of patients. Id.

103 Id. at 292.

104 See discussion supra Part II (discussing distribution chains and the problem of prescription drugs being leaked into the grey market).

end up at dispensaries, the public will become more aware of the gray goods presence. This awareness can spur disapproval and eventually corrective action. Congress should enact a statute analogous to the Lanham Act, prohibiting any domestic distribution among the states bearing "the name or mark calculated to induce the public to believe that the article" originates from the original manufacturer, assuming that manufacturer is the trademark owner, or an authorized distributor. Aggrieved parties can use the wholesaler information kept with the Secretary of State as required by the Gray Market Drug Reform and Transparency Act to identify gray market perpetrators and bring a claim. Drug manufacturers could argue that gray distributors circulate drugs materially different from their own yet bearing the same trademark, thus violating a domestic form of the Lanham Act. If such distributors fail to adhere to the quality control standards of the manufacturer by deviating from storing and handling methods needed to maintain the drug's integrity, those drugs may prove to be materially different from those that do not seep into gray areas. Subtle differences in the aggregate, such as storing or handling below the standard of quality control by the original manufacturer or authorized distributors, will add up to a material physical difference, satisfying an analogous threshold as the Lanham Act parallel import cases previously discussed. The goal will be to prevent consumers, including patients and providers, from confusing gray goods not originating from monitored and conventional drug distribution chains from those originating from the shadows of the gray market. History shows that the legislature and courts have served a similar public policy through Trademark Law, and public safety and health demand they do it again.

106 See Dooren, supra note 64. In 2011, the Wall Street Journal reported a doctor's attempt to persuade other cancer doctors nationwide to share their stories in an attempt to raise awareness of a drug shortage. Id.
108 See discussion supra Part II (discussing pharmaceuticals in the grey market and FDA regulation).
111 See discussion supra notes 19-39 (discussing Lanham Act parallel import cases).
112 See discussion supra Part I and Part II. Part I considers the success both the legislature and the judicial branches reached using Trademark Law and the Lanham Act in curbing the importation of gray market imports into our markets. See discussion supra Part I. Part II addresses failure of both branches to work together to achieve similar success in protecting domestic distribution of gray pharmaceuticals made materially different from their counterparts by a lack of quality control in handling, storage and care. See discussion supra Part II.