

# THE IMPLICATIONS, NEGATIVE HEALTH EFFECTS, LEGAL ISSUES, AND POTENTIAL SOLUTIONS ASSOCIATED WITH THE SHORTAGE OF ESSENTIAL DRUGS IN THE U.S. MEDICAL CARE MARKET

*Joshua Gregg\**

## ABSTRACT

Today, health care organizations are experiencing unprecedented shortages in many life-saving drugs due to a variety of causal factors. In essence drugs that were once easily obtained are not available through the drug manufacturers commonly used by nearly every healthcare organization in America. The most concerning shortages are of drugs used to treat virulent and potentially terminal diseases such as cancer and AIDS. For diseases like this, if the affected patients do not receive the necessary treatment for their conditions within a certain window of time their chances of death are much greater. The implications of these shortages are somewhat startling. At any given time, severely ill patients may die, not because doctors did not know how to help them, but because the means for doing so were simply not available. Aside from the obvious health issues this problem poses, it also implicates a variety of legal and ethical issues. Of primary concern for this article are the parallel (or gray) markets that have developed in response to the drug shortages. The companies that participate in these parallel markets are run by profit-hungry individuals who have legally questionable access to supply leakages of drugs; essentially these suppliers obtain the drugs at the original market price, hoard them until a period when the shortage is at its worst, and then sell them at prices often thousands of times greater than the original prices. Because health care organizations are desperate

---

\* B.A., Sienna College; M.B.A., Union University; J.D., Albany Law School.

to obtain these drugs for their patients, they have no choice but to pay the prices set by the suppliers.

This current state is unacceptable in a country that arguably offers some of the most sophisticated medical care in the world. Furthermore, in an era where access to health care has become a primary concern to both the populace and the policy makers in Washington D.C., distribution chains that limit the availability of drugs to those who need them are completely counter to the goal of broadening access to care.

At this point, the issue of drug shortages presents a very new problem for the U.S. medical system, and therefore the literature on the topic is sparse at best. Currently, legal papers addressing the issue are largely limited to historical analyses of drug shortages. This article will build on that base, and seek go beyond it by looking at some of the implications and legal issues inherent in the drug shortage crisis.

This article will be divided into five main sections. The first portion will address some of the history behind the drug shortage crisis, including some of its causes and most notable effects. The second section will discuss legitimate marketing and sales by exploring applicable federal and state law, including regulations promulgated by the Centers for Medicare & Medicaid Services (hereinafter CMS). This section will also look at the legal status of gray market drug suppliers. The discussion of their legal status of will largely be based on state licensure laws, as currently there is a notable lack of federal law addressing parallel drug markets. The third section will address the gray market for prescription drugs specifically and will outline how gray marketers operate, and the means through which they obtain their drug. The fourth section will consider the many negative effects that gray-market suppliers of drugs have on the U.S. medical system will be considered; this will serve as primary support for this article's thesis that the parallel market for drugs (at least for drugs in short-supply) must be banned. The fifth section will serve to look at potential solutions for addressing drug shortages and the gray market. Specifically it will analyze proposed legislation at the federal level aimed at curbing the drug shortage problem, and will discuss some of the ways this law might be improved to bring about the most positive result.

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 383**

TABLE OF CONTENTS

I.	INTRODUCTION .....	384
A.	A Brief Synopsis of Current Drug Shortages & the Historical Origins of the Problem.....	386
B.	The Causes of the Drug Shortage.....	387
1.	Supply Side Cause One: Environmental Factors Affecting Production .....	388
2.	Supply Side Cause Two: FDA Regulations and their Impact on Drug Shortages.....	390
3.	Demand Side Cause One: Medicare Reimbursement .....	395
4.	Demand Side Cause Two: Parallel Markets.....	396
C.	The Consequences & Negative Effects of the Drug Shortage.....	398
1.	Effect One: Exacerbation of Patient Illness.....	398
2.	Effect Two: Gray Market Suppliers and Increases in the Cost of Medication .....	401
3.	Effect Three: Limitations on Medical Research ....	402
II.	LEGITIMATE MARKETING & THE LAWS REGULATING THE DISTRIBUTION OF PRESCRIPTION DRUGS.....	403
A.	Chains of Distribution.....	403
B.	Legal Requirements Imposed on Parties in the Course of Wholesale Distribution.....	405
1.	FDA Regulation of Re-sale .....	405
2.	State Statutes Regulating Re-sale .....	407
3.	Other Legal Consideration .....	410
III.	THE OPERATIONS OF THE GRAY MARKET .....	412
A.	Obtaining the Drugs .....	412
1.	Pharmacies .....	413
2.	Pharmacies as Drug Brokers.....	413
3.	Fake Pharmacies.....	414
B.	Obtaining Drugs through Illicit Channels.....	416
1.	Comparing the Gray Market with the Black Market: Is Gray the New Black?.....	418
2.	Drug Counterfeiting.....	424
IV.	THE ETHICALLY & LEGALLY QUESTIONABLE PRACTICE OF PRICE GOUGING BY GRAY MARKET DRUG SUPPLIERS ...	426
A.	Price Gouging: What is it? .....	427
B.	Price Markups/Gouging in the Secondary Drug Market .....	428
1.	Price Gouging Laws on the State Level.....	431

2. Price Gouging Laws on the Federal Level.....	433
C. Should Markups on Drugs in Short Supply be Considered Price Gouging and Made Illegal?.....	433
V. POTENTIAL SOLUTIONS TO THE DRUG SHORTAGE PROBLEM & THE GRAY MARKET.....	437
A. FDA Reform—In Terms of Reducing the Time it Takes to Approve New Drugs.....	437
1. FDA Regulatory Changes.....	438
2. The Hatch-Waxman Act.....	440
B. Increasing Medicare Payments for Generic Drugs....	441
C. Curbing the Operational Ability of Gray Market Suppliers.....	443
D. H.R. 5853: The Bill Aimed at Eliminating Gray Market Intermediaries.....	444
1. Banning the Re-sale of Prescription Drugs.....	444
2. Reporting Requirements for Wholesalers.....	446
3. Pricing for Drugs; Work with the Senate to Integrate the Anti-Price Gouging Law into the Bill.....	451
4. Require a Comprehensive Drug Pedigree for Every Drug that is Sold.....	452
VI. CONCLUSION.....	453

## I. INTRODUCTION

Imagine that your mother has recently been diagnosed with a mid-to-late stage cancer. Despite the cancer's progression, the oncologist remains optimistic, and a treatment regimen is begun. After a few weeks of treatment your mother's tumor begins to shrink, and it seems that her chances of beating the cancer are great. A few days before the next scheduled treatment however, a call comes from the hospital that "Taxol," the drug being used to treat the cancer, is not available, and your mother's treatment must be postponed. A similar call comes prior to the next scheduled treatment. At this point the oncologist begins to worry, and switches your mother to another drug in order to prevent the progression of her condition. The doctors do not consider this new drug as effective as Taxol, but it is the best alternative to doing nothing at all. The treatment begins thusly. At your mother's next screening, the doctors discover not only that the cancerous tumor has grown, but also that the cancer has spread. Over the

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 385**

next several weeks the treatments continue, but your mother's condition continues to worsen. Eventually, your mother dies, a result that you certainly did not expect based on her initially positive prognosis. This account was the actual experience of one Liz Chandler, whose mother died after being a victim of a drug shortage.<sup>1</sup>

In recent years, both the scale and negative effects of the problem have grown exponentially. Drugs that were once commonplace and easily obtained at a low price are now in short supply; furthermore, the drugs that can be obtained must be procured at great cost to the health care provider. This cost in turn is ultimately borne by the individual patient on to whom it is passed, by the provider. Given the relatively recent development of the problem, governmental efforts to stymie it have been insufficient and ineffective at best. In addition, as is the case whenever there is a great need for any commodity, opportunists have entered the picture and have cornered the market for many drugs. With this monopoly power, they are able to charge lucrative prices. These drug suppliers are often referred to as gray market providers or as operators of the parallel market for drugs.

The primary focus of this article will be on these gray marketers. The goal for this article is to show that gray marketers should be banned from the drug market due to the negative effects they have on both the patients and the doctors in the system. Some of the primary means through which these suppliers cause harm will be discussed in detail, as well as the reasons why their business should be made illegal. Last, the article will address potential solutions for curbing the drug shortage problem, as eliminating drug shortages would invariably eliminate gray marketers of drugs. Before that, however, the article will discuss the historical development of short-supply drugs and the parallel market for them.

As was noted above, the goal of this article is to argue that gray marketers of short supply drugs cannot be allowed to continue operating because of their negative impact on the U.S. health system. Among other things, gray marketers are "price-gouging": selling short-supply drugs at exorbitant prices.

---

<sup>1</sup> This story was first posted on <http://stopdrugshortages.org> on January 4, 2012; however, the article is no longer available online and could not be readily located.

Furthermore, there is evidence that they are engaged in the distribution of counterfeit drugs. These counterfeit drugs are at the very least dangerous because they substitute for needed medicinal treatment, and at worst they are proven killers. Yet regulators who seek to shut gray marketers down face potential problems. First, despite the gray market's reputation for price gouging in the short-supply drug market, as parallel suppliers gray marketers serve as one of the only means of obtaining cheaper drugs that are not in short supply from Canada. For this reason, parallel suppliers have widespread support. Second, any action taken against these drug suppliers may be viewed as a governmental infringement on free enterprise, which in a supposedly free market is never taken kindly. Accordingly, a blanket ban on gray market drug sales is not the answer; such a move would have highly negative social and political repercussions.

Concern about gray marketers of prescription drugs has only recently come into the public eye, and relatively few authors have addressed the topic in detail. Furthermore, both case law and legislative action are largely non-existent. Thus, this article's legal analysis is derived largely from related topics about which there is existing law and legal analysis.

*A. A Brief Synopsis of Current Drug Shortages & the Historical Origins of the Problem*

The Food and Drug Administration (FDA) defines a drug shortage as existing when "the total supply of all clinically interchangeable versions of a FDA-regulated drug is inadequate to meet the current or projected demand at the patient level."<sup>2</sup> According to the American Society of Health-System Pharmacists, 206 drugs are in short supply in the United States today.<sup>3</sup> This list of drugs is composed largely of what are referred

---

<sup>2</sup> Sharona Hoffman, *The Drugs Stop Here: A Public Health Framework to Address the Drug Shortage Crisis*, 67 FOOD & DRUG L.J. 1, 2 (2012); see also CTR. FOR DRUG EVALUATION & RESEARCH, MANUAL OF POLICIES AND PROCEDURES (MAPP) 4190.1, at 12 (Rev. 2, Sept. 2014) [hereinafter MAPP 4190.1], available at <http://www.fda.gov/downloads/AboutFDA/CentersOfTices/CDER/ManualofPoliciesProcedures/UCM079936.pdf> (describing a drug shortage as "[a] period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug").

<sup>3</sup> *Drug Shortages: Current Drugs*, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, <http://www.ashp.org/Drugshortages/Current/?sort=2> (last visited Apr. 15, 2015).

to as generic “sterile injectables,” which are delivered via syringe rather than in tablet form.<sup>4</sup> As implied, the drugs typically in the shortest supply are generic drugs rather than name brands that still have patent protection (which makes sense given the higher profits associated with brand names).<sup>5</sup> Sterile injectables represent treatment methodologies for some of the most virulent and deadly diseases today (i.e., cancer and AIDS); as such, their shortage poses a significant threat to some of the nation’s sickest patients.<sup>6</sup> For a number of years now the drug market has been experiencing such shortages, and as time has passed the numbers of drugs in short-supply has steadily increased.<sup>7</sup> According to policy researchers, “the number of drugs in short supply in 2010 was almost triple that of 2005.”<sup>8</sup> According to various sources, drug shortages first began occurring in the mid-to-late 1990s.<sup>9</sup> When the problem first appeared, shortages were sporadic and not widespread.<sup>10</sup> The exact reasons for the exacerbation of the problem are unclear; it seems logical to surmise, however, that environmental factors leading to drug shortages have become more prevalent. If so, an effective analysis of the history of drug shortages should start with its causes.

### B. *The Causes of the Drug Shortage*

The factors responsible for drug shortages are many and varied. Several, however, are likely, the most significant. Like any other commodity market, the market for drugs follows the

---

<sup>4</sup> JOHN R. GRAHAM, THE SHORTAGE OF GENERIC STERILE INJECTABLE DRUGS: DIAGNOSIS AND SOLUTIONS 2 (2012), available at <http://forum.educationreport.org/archives/2012/s2012-04SterileInjectables.pdf>.

<sup>5</sup> *Examining the Increase in Drug Shortages: Hearing Before the Subcomm. on Health of the H. Committee on Energy and Commerce*, 112th Cong. 5 (2011) (statement of Hon. Frank Pallone, Jr., Rep. N.J.), available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Final-Transcript-Health-Examining-Increase-in-Drug-Shortages-2011-9-23.pdf>.

<sup>6</sup> *Id.* at 6 (statement of Hon. Henry A. Waxman, Rep. Cal.).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> See Hoffman, *supra* note 2, at 2 (stating that serious drug shortages emerged in 1999); see also JoAnn Grif Alspach, *Is the Drug Shortage Affecting Patient Care in Your Critical Care Unit?*, 32 CRIT CARE NURSE 8, 8 (Feb. 2012), available at <http://ccn.aacnjournals.org/content/32/1/8.full> (stating that drug shortages started in the 1990’s).

<sup>10</sup> See Alspach, *supra* note 9, at 8 (stating that shortages used to be sporadic).

economic principles of supply and demand.<sup>11</sup> Accordingly, many experts divide the causes for the shortage into two distinct categories: (1) demand-side factors and (2) supply-side factors.<sup>12</sup> These terms are often used in economic analyses to describe the causes for inflation. Put succinctly, demand-side inflation occurs when consumers' demand outpaces supply, thereby leading producers of commodities to raise their prices; supply-side inflation occurs when producers of goods have the ability to raise prices due to market power.<sup>13</sup> The application of these terms to drug shortages is especially fitting since one of the primary results of the drug shortage is that the price of many drugs increases exponentially.<sup>14</sup> Let us first consider some of the supply-side factors to which drug shortages have been attributed.

### 1. Supply Side Cause One: Environmental Factors Affecting Production

Many environmental factors could and do lead to drug shortages. A principal environmental factor is manufacturing difficulties.<sup>15</sup> Manufacturing issues can come in several forms; one involves the availability of ingredients used to make the drugs.<sup>16</sup> According to several authors, most U.S. drug manufacturers import the majority of drug ingredients from outside the U.S.<sup>17</sup> As a result, many events, such as natural disasters or political unrest, may disrupt the supply chain for these ingredients.<sup>18</sup> Accordingly, access to essential ingredients may at any time be cut off. This type of scenario has occurred many times, but one of the most recent examples is the earthquake and resultant tsunami that occurred in Japan in

---

<sup>11</sup> Joey Mattingly, *Understanding Drug Pricing*, 37 U.S. PHARMACIST: GENERIC DRUG Rev. 40, 40 (June 2012), available at <http://www.uspharmacist.com/content/s/216/c/34894>.

<sup>12</sup> See GRAHAM, *supra* note 4, at 4–6 (discussing demand and supply side causes of the drug shortage problem).

<sup>13</sup> VANITA AGARWAL, *MACROECONOMICS: THEORY AND POLICY* 295 (Pearson 2010) (defining of supply-side and demand-side inflation).

<sup>14</sup> Alspach, *supra* note 10, at 9.

<sup>15</sup> Hoffman, *supra* note 2, at 4.

<sup>16</sup> *Id.*

<sup>17</sup> See *id.* (“According to one estimate, the U.S. imports approximately eighty percent of raw materials used in pharmaceutical products.”).

<sup>18</sup> See Graham, *supra* note 4, at 4 (discussing physical factors influencing the production of drugs).

2011.<sup>19</sup> Specifically, this natural disaster caused a notable shortage in the drug potassium iodide, which is used to mitigate the negative effects of exposure to radioactive iodine (specifically cancer).<sup>20</sup> According to reports, multiple pharmaceutical companies in the U.S. ran out of potassium iodide when supplies diminished due to the increased demand for the drug in Japan and, in all likelihood, the destruction of pharmaceutical plants there.<sup>21</sup>

In addition to experiencing difficulties obtaining raw materials, manufacturers may at times cease production in order to tweak drugs for quality purposes.<sup>22</sup> According to the FDA, this occurs regularly:

In 2010, a majority of the drugs in shortage had quality and manufacturing problems. Some of these quality problems included the presence of particulates, microbial contamination, and newly identified impurities in sterile injectables. Companies sometimes voluntarily stop production or suspend production of critical drugs when manufacturing problems occur so that they can resolve the root cause of product-quality problems. Some of these issues are complex, and companies may need to take substantial amounts of time to correct the underlying cause of the problem.<sup>23</sup>

As will be noted shortly, on top of the voluntary shutdowns

---

<sup>19</sup> See Tricia Meyer, *The Anatomy of Drug Shortages*, 27 ASPF NEWSLETTER 7, 8 (2012), available at [http://www.apsf.org/newsletters/pdf/spring2012v11\\_051512.pdf](http://www.apsf.org/newsletters/pdf/spring2012v11_051512.pdf) (“The earthquake in Japan has contributed to circumstances leading to several potential shortages.”).

<sup>20</sup> See Jeffrey Young & Michelle Fay Cortez, *Japan Nuclear Meltdown Risk Spurs Shortage at U.S. Radiation-Drug Makers*, BLOOMBERG BUSINESS (Mar. 16, 2011, 3:14 AM), <http://www.bloomberg.com/news/2011-03-15/japan-nuclear-meltdown-risk-spurs-shortage-at-u-s-radiation-drug-makers.html> (discussing the effects of the Japanese earthquake on drug suppliers); see also *Frequently Asked Questions on Potassium Iodide (KI)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismAndDrugPreparedness/ucm072265.htm> (last updated Oct. 27, 2014) (discussing the cancer prevention properties of potassium iodide).

<sup>21</sup> See Young & Cortez, *supra* note 20 (discussing the high demand of potassium iodine after Japan’s earthquake to prevent the accumulation of radioactive iodine in the thyroid for those victims surrounding damaged nuclear plants); see also Jinichi Mori et al., *Drug Shortages After the Eastern Japan Earthquake: Experiences in a Tertiary Referral Center*, 46 DRUG INFO. J. 607, 609 (2012) (outlining the destruction of Japan’s manufacturing institutions after the earthquake).

<sup>22</sup> See GRAHAM, *supra* note 4, at 4.

<sup>23</sup> Jouhayna Saliba, *The Problem With Drug Shortages: The FDA Response*, MEDSCAPE (Nov. 3, 2011), <http://www.medscape.com/viewarticle/752440>.

that occur, manufacturers are sometimes forced to cease production by regulatory agencies like the FDA.<sup>24</sup>

Despite their potential for disrupting drug production, it is unclear how these factors may have changed or worsened sufficiently to bring about the dire state of affairs seen in the drug market today. Thus, although physical factors may well bear some responsibility for drug shortages, the primary supply-side factor for the shortages may well be regulatory bodies.

## 2. Supply Side Cause Two: FDA Regulations and their Impact on Drug Shortages

The Food and Drug Administration was officially formed in 1930 pursuant to the Pure Food and Drugs Act<sup>25</sup> in an effort to ensure that food and drug packages contained what they said they did.<sup>26</sup> Essentially the goals of the organization were to prevent negative health impacts on individuals who consumed mislabeled drugs, to ensure that the drugs actually did what they were supposed to, and also to regulate the testing of drugs and chemical ‘additives’ in food.<sup>27</sup> Over time the FDA’s role in drug development has increased significantly.<sup>28</sup> This has led to an extensive approval process through which any new drug must pass in order to make it onto the market.<sup>29</sup> Objectively speaking, this approval process can take quite a bit of time; in fact it could take nearly twenty years for a drug to reach the market under extreme circumstances.<sup>30</sup> That it is difficult for new drugs to

---

<sup>24</sup> GRAHAM, *supra* note 4, at 5.

<sup>25</sup> Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>26</sup> *History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated Mar. 23, 2015).

<sup>27</sup> John P. Swann, *FDA’s Origins*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last updated June 23, 20104).

<sup>28</sup> See Michael R. Ward, *Drug Approval Overregulation*, 15 REG. 47, 47–53 (1992), available at <http://www.cato.org/sites/cato.org/files/serials/files/regulation/1992/10/reg15n4e.html> (indicating that “[t]here is, however, evidence to suggest that U.S. drug approval standards have become more stringent than is socially optimal. Industry studies show not only a dramatic increase in the stringency of the FDA’s drug regulation but also a net effect that harms consumers”).

<sup>29</sup> *Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm> (last updated Oct. 27, 2014).

<sup>30</sup> *The Drug Development and Approval Process*, FDAREVIEW.ORG,



An Overview of the Drug Development Process						
Preclinical	Clinical				Approval	Market
Toxicology	Investigational New Drug Application	Phase I safety	Phase II safety dosing efficacy	Phase III safety efficacy side effects	New Drug Application	Phase IV / Postmarket surveillance
Expenses		\$15.2 million	\$23.4 million	\$86.5 million		
Time		21.6 months	25.7 months	30.5 months		
1 to 6 years	6 to 11 years				0.6 to 2 years	11 to 14 years
Overall probability of success						
		30%	14%	9%	8%	
Conditional probability of success						
	40%	75%	48%	64%	90%	
Sources: Dimasi, Hansen, and Grabowski (2003). <sup>32</sup>						

**Table 1. An Overview of the Drug Development Process**

The length of the approval process for drugs exacerbates the drug shortages because it prevents drug manufacturers from developing substitutes for the drugs in short-supply quickly enough to preclude a potential shortage.<sup>33</sup> The purpose of this lengthy approval period is to weed out drugs that might cause harm; in fact it is estimated that FDA approval times are far longer than those of regulatory agencies in other countries.<sup>34</sup> It would seem however, that by trying to avoid negative health impacts to individuals from poisonous drugs, FDA officials are

<sup>32</sup> *The Drug Development and Approval Process*, *supra* note 30, at fig. 1.

<sup>33</sup> STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 112TH CONG., REP ON FDA'S CONTRIBUTION TO THE DRUG SHORTAGE CRISIS 14 (Comm. Print 2012) [hereinafter DRUG SHORTAGE CRISIS], available at <http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-Report-FDAs-Contribution-to-the-Drug-Shortage-Crisis.pdf>.

<sup>34</sup> *Id.* at 15.

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 393**

causing deaths by preventing life-saving drugs from reaching the market in a timely manner. The reasons why the FDA uses process that is far longer than other regulatory agencies around the world are unclear. However, a 2012 House report hypothesized the following stating:

Many FDA experts believe the incentives of FDA officials to be risk-averse and focus on avoiding Type I errors [“FDA allowing a harmful drug”] relative to avoiding Type II errors [“FDA disallowing beneficial drugs”] to be a large part of the problem. For example, when FDA allows a harmful drug, victims are identifiable and will likely cause shame and embarrassment for the agency. However, the victims who never gain access to drugs which are never developed are not identifiable.<sup>35</sup>

In other words, the policy seems to be in place more so because the agency wants to maintain its reputation, than to promote the health of the populace.

The negative effects associated with this policy are most prominent when it comes to the production of generic drugs, which serve as cheaper substitutes for name brand drugs.<sup>36</sup> The facts indicate that the FDA takes an exorbitant amount of time to approve these drugs;<sup>37</sup> this in turn renders manufacturers unable to stem a shortage with a substitute within a reasonable amount of time.<sup>38</sup> The issue is that generics, as their name implies, are drugs that are based on the same chemical compositions as their brand name predecessors.<sup>39</sup> The brand name drugs have already been through the FDA approval process and have been proven to be safe and effective; it seems logical, therefore, that when the same drug is manufactured under a different name, the approval process would be accelerated.<sup>40</sup> Clearly, however, this is not the case:

The Generic Pharmaceutical Association reports that there is now a backlog of about 1,400 unapproved filings for generics at the

---

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 7.

<sup>37</sup> See GRAHAM, *supra* note 4, at 4 (discussing the slowness of generic drug approvals).

<sup>38</sup> MAPP 4190.1, *supra* note 2, at 11.

<sup>39</sup> See GRAHAM, *supra* note 4, at 2 (addressing the differences between the drug makers that invent the drugs and generic drug makers).

<sup>40</sup> Dennis S. Fernandez & James T. Huie, *Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity*, FERNANDEZ & ASSOCS. L.L.P., available at <http://www.iploft.com/PTO-FDA.pdf> (last visited Apr. 15, 2015).

FDA . . . Median review and approval times have slowed to nearly 21 months, far worse than the legislatively mandated six months. In 2005, the backlog was much smaller — only 891 applications — and the median time to approval was 16.3 months.<sup>41</sup>

The American Society of Health-System Pharmacists, in conjunction with other organizations, in its recent Drug Shortages Summit, pointed to this regulatory morass as being a significant contributor to the shortages seen in the market today for many generic drugs.<sup>42</sup> In fact, the summit concluded that the cost and complexity of bringing a new drug to the market may in fact serve as a disincentive for manufacturers to even produce the drug.<sup>43</sup>

The regulatory arena can also lead to other problems. In some instances, the requirements for the production of a drug (as published by the United States Pharmacopeia) are subject to change because of perceived quality issues, be they actual or superficial.<sup>44</sup> The following quote is indicative of this:

Another contributing cause to drug shortages may be the availability of improved assays and other technologies that have resulted in issuance of new product specifications (e.g., revised United States Pharmacopeia [USP] standards for assessing heparin potency). In addition, when one manufacturer submits revised standards that are accepted by USP, other companies are required to meet the new specifications.<sup>45</sup>

While improving quality standards is certainly not a bad thing, meeting these new specifications requires manufacturers to cease production often for extended periods of time, thereby making short supplies of drugs even shorter.<sup>46</sup> In addition, for generic drugs, the costs associated with compliance with the new standards could be higher than the profits realized by the sale of the drug.<sup>47</sup> In cases like this, manufacturers will often simply opt

---

<sup>41</sup> GRAHAM, *supra* note 4, at 4.

<sup>42</sup> AM. SOC'Y OF HEALTH-SYS. PHARMACISTS ET AL., DRUG SHORTAGES SUMMIT SUMMARY REPORT 3 (2010) [hereinafter DRUG SHORTAGES SUMMIT REPORT], available at <http://www.ashp.org/drugshortages/summitreport>.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> See MAPP 4190.1, *supra* note 2, at 11 (discussing the cost of producing generic drugs); see also DRUG SHORTAGES SUMMIT REPORT, *supra* note 42, at 6 (indicating that several factors, which may include “insufficient profit margins and product liability concerns” can result in market withdrawal of certain

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 395**

to leave the market for the drug by ceasing their production of it.<sup>48</sup> Indeed, when changes are made to benefit patients, they may indeed have the opposite effect.<sup>49</sup> It should be noted that regulation is only one means through which the cost of production might increase, and is therefore not the only reason that manufacturers might leave the market.<sup>50</sup>

### 3. Demand Side Cause One: Medicare Reimbursement

Of all the people in the United States who rely on drugs on a daily basis, the elderly are undoubtedly the largest group.<sup>51</sup> The Medicare program, which Congress created in 1965, is the principal source of health insurance for those over age sixty-five; part D of that program was established more recently to provide Medicare beneficiaries with a source of payment for prescription drugs.<sup>52</sup> The Medicare Modernization Act (MMA) of 2003 amended Part D; in its present form, Part D forces drug companies to accept a lower level of compensation than they would otherwise seek in order to remain as providers in the Part D market.<sup>53</sup> The MMA served to reduce the proportion of cost borne by Medicare for drugs purchased by the elderly, thereby making it more difficult for drug companies to raise their prices.<sup>54</sup>

---

drugs).

<sup>48</sup> See MAPP 4190.1, *supra* note 2, at 11 (explaining that insufficient generation of income will prompt a manufacturer to discontinue production of a generic drug).

<sup>49</sup> See Ward, *supra* note 28 (explaining for example, that when the FDA mandates that certain drugs be available only by prescription, there may be adverse health consequences regarding consumers because as a result of the mandate, consumers may choose not to seek treatment at all, or use more powerful, possibly toxic, and less effective nonprescription drugs).

<sup>50</sup> See DRUG SHORTAGES SUMMIT REPORT, *supra* note 42, at 6 (explaining that a manufacturer's decision to discontinue a product has a plurality of underlying factors, for example, whether the complexity of manufacturing newer drugs causes resources to shift away from other products).

<sup>51</sup> Arvind Modawal, *Prescription Medication in the Elderly*, NET WELLNESS: CONSUMER HEALTH INFO., <http://www.netwellness.org/healthtopics/aging/faq16.cfm> (last updated Dec. 15, 2000).

<sup>52</sup> See generally David Pratt, *The New Medicare Part D Prescription Drug Benefit*, 17 ALB. L. J. SCI. & TECH. 337 (2007) (describing the implementation of the Medicare Program and the subsequent implementation of Part D).

<sup>53</sup> See generally DRUG SHORTAGE CRISIS, *supra* note 33, at 4 (discussing the effects of the MMA on manufacturers).

<sup>54</sup> See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2066, 2077 (codified as

At times the level of compensation is so low that manufacturers leave the market altogether.<sup>55</sup>

#### 4. Demand Side Cause Two: Parallel Markets

This factor may be viewed both as a cause and an effect of the drug shortage problem; it will be the primary focus of this article. In terms of causality, parallel or gray-marketers stockpile drugs that are in the highest demand by buying them from health care providers/intermediaries or directly from the manufacturers.<sup>56</sup> Gray marketers are opportunists who take advantage of existing or predicted shortages.<sup>57</sup> They buy up what little of a drug that is available, thereby making it nearly impossible for providers to obtain supplies.<sup>58</sup> As a preliminary matter, it is important to

---

amended at 42 U.S.C. § 1395w-102 (2012)) (indicating the following: “[t]he coverage provides benefits, after the part D eligible individual has incurred costs . . . for covered part D drugs in a year equal to the annual out-of-pocket threshold . . . , with cost-sharing that is equal to the greater of—(I) a copayment of \$2 for a generic drug or a preferred drug that is a multiple source drug . . . and \$5 for any other drug; or (II) coinsurance that is equal to 5 percent.”); *see also* DRUG SHORTAGE CRISIS, *supra* note 33, at 4 (“Manufacturers are reluctant to raise prices above what Medicare reimburses providers who administer them.”).

<sup>55</sup> *See* MAPP 4190.1, *supra* note 2, at 11 (discussing the effects of Medicare’s low level of compensation for generics).

<sup>56</sup> *See id.* at 9 (explaining that gray markets are created when distributors purchase remaining supplies of products and resell them to health care providers at a price which may be up to one-thousand times the original price of the products). Some may wonder why health care providers or other entities would sell their supplies to the gray market. The answer lies in the economics of the shortage; if a provider or other intermediary has a large stockpile of a drug which is not being used, and people are willing to pay hundreds of times its original cost, the entity could potentially realize a large profit. *See Short-Supply Prescription Drugs: Shining a Light on the Gray Market: Hearing Before the S. Comm. on Commerce, Sci., & Transp.*, 112th Cong. 15 (2012) (statement of Hon. John D. Rockefeller IV, Sen. W. Va.), *available at* <http://www.gpo.gov/fdsys/pkg/CHRG-112shrg79524/html/CHRG-112shrg79524.htm> (giving an example of a company with a pharmacy license who sold a drug to the gray market wholesaler at a significant markup).

<sup>57</sup> *See* Thomas Sullivan, *Senate Commerce Committee Report on Drug Shortages and the Gray Market “Where Have They All Gone,”* POL’Y & MED. (Aug. 28, 2012, 05:22 AM), <http://www.policymed.com/2012/08/senate-commerce-committee-report-on-drug-shortages-and-the-grey-market-where-have-they-all-gone.html> (indicating that gray market companies may even contact hospitals to know as soon as possible of which drugs there are shortages).

<sup>58</sup> *See id.* (explaining that health care providers, like hospitals, are left with no other choice but to purchase from the gray market).

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 397

understand what exactly parallel/gray marketers are generally, as well as what they do and how they do it. When the reader thinks of parallel trade, knockoff goods may come to mind; in the case of the gray market, however, the majority of the goods are actually genuine.<sup>59</sup> Gray markets exist for a wide variety of goods, not simply pharmaceuticals.<sup>60</sup> Gray marketers experience success primarily because they are selling the same goods as the actual manufacturers, but at a lower price.<sup>61</sup> Manufacturers tend to dislike gray marketers because of the stiff competition created by their lower prices.<sup>62</sup> But because of the shortages created (or exacerbated) by the gray marketers of prescription drugs, this gray market is notorious for price gouging. In cases where a shortage exists, gray marketers will often increase the prices for whatever good is most needed at the time.<sup>63</sup> For example, during the aftermath of Hurricane Sandy, gray marketers who were selling gas at exorbitant prices suddenly popped up.<sup>64</sup> As an NBC News report noted: “[s]horter but persistent lines at gas stations in the Northeast and sporadic closures have led to a gray market for fuel on Craigslist, with prices for delivery of a five-gallon container ranging from thirty to one hundred dollars Tuesday.”<sup>65</sup> Such is the case for the gray markets dealing in short-supply

---

<sup>59</sup> See Nancy T. Gallini & Aidan Hollis, *A Contractual Approach to the Gray Market*, 19 INT'L REV. L. & ECON. 1, 1 (1999) (“[G]ray marketers counter that the goods are genuine and that consumers benefit from the additional competition.”).

<sup>60</sup> See *id.* at 2 (indicating for example that there is a gray market for cars); see also *What is Gray Market?*, NIKON, [http://support.nikonusa.com/app/answers/detail/a\\_id/331/~what-is-gray-market%3F](http://support.nikonusa.com/app/answers/detail/a_id/331/~what-is-gray-market%3F) (last updated June 21, 2013) (describing the commonplace of gray market photographic equipment showing up in the photographic and consumer markets).

<sup>61</sup> See Gallini & Hollis, *supra* note 59, at 2 (indicating the cheaper prices of the gray market: “[t]his property right may be undermined by gray markets, which arise when the retail price in a country is higher than the wholesale price in a second country plus shipping costs. The gray good is typically sold in direct competition with the authorized distributor through a discount store without warranties or other services.”).

<sup>62</sup> *Id.*; see also *What is the Gray Market?*, WISEGEEK, <http://www.wisegeek.org/what-is-the-gray-market.htm> (last visited Apr. 15, 2015) (describing how authorized agents are financially affected by the gray market when they lose business to the unauthorized sellers).

<sup>63</sup> See, e.g., *Gas Shortages Lead to Gray Market Even as Lines Shrink*, NBC RIGHT NOW (Nov. 7, 2012, 9:13 AM), <http://www.nbcrightnow.com/story/20028383/gas-shortages-lead-to-gray-market-even-as-lines-shrink>.

<sup>64</sup> *Id.*

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

drugs, and as will shortly be seen, their prices serve as one of the primary justifications for forcing them out of the market altogether.<sup>66</sup>

These causes are representative of what experts have deemed to be the most likely sources of drug shortages, but are not comprehensive. Next, this article takes a brief look at some of the effects of drug shortages.

### *C. The Consequences & Negative Effects of the Drug Shortage*

The effects of drug shortages are many, and none of them are pleasant or positive. Nearly all implicate some level of harm for the patient, and all of them limit the effectiveness and efficiency of the U.S. medical system. The following represent a few of those effects.

#### 1. Effect One: Exacerbation of Patient Illness

The story told at the beginning of this article was true. The patient died because a drug shortage forced doctors to use a less effective drug for treatment.<sup>67</sup> Stories like hers have become commonplace. Drug shortages make illnesses more difficult to treat.<sup>68</sup> Examples include: “1) Adverse effects of therapeutic alternatives [to the drug in short-supply]; 2) Compromise or delay in medical treatment of procedures; 3) Failure to treat and progression of disease; and 4) Medication errors . . .”<sup>69</sup> Each could have highly negative health effects on a patient.

In 2012, the *New England Journal of Medicine* published an article chronicling the negative effects of a drug shortage on the treatment of childhood leukemia.<sup>70</sup> Mechlorethamine, one of the

---

<sup>66</sup> Jennifer Lubell, *Lawmakers Hear Evidence of Gray Market in Shortage Drugs*, AM. MED. NEWS (Aug. 20, 2012), <http://www.amednews.com/article/20120820/government/308209957/4/>.

<sup>67</sup> See *supra* note 1 and accompanying text.

<sup>68</sup> HemOnc Today, *Drug Shortages Threaten Patient Health and Safety*, HEALIO (Aug. 10, 2011), <http://www.healio.com/hematology-oncology/practice-management/news/print/hematology-oncology/%7B1eaebf7d-cbe6-4067-945c-9d8552a851f5%7D/drug-shortages-threaten-patient-health-and-safety>.

<sup>69</sup> DEREK TEMPLET & ANNE ELISE RIDER, THE TALL TALE OF DRUG SHORTAGES: CLINICAL IMPLICATIONS OF DRUG SHORTAGES FOCUS ON SEDATION AND ONCOLOGY 7 (2012), available at <http://www.cc.utexas.edu/pharmacy/divisions/pharmacorounds/templet02-24-12.pdf>.

<sup>70</sup> Monika L. Metzger et al., *The Impact of Drug Shortages on Children with Cancer — The Example of Mechlorethamine*, 367 NEW ENG. J. MED. 2461 (2012),

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 399**

most proven and highly effective means of treating leukemia,<sup>71</sup> fell into short-supply in 2009, forcing oncologists to find and use a substitute.<sup>72</sup> The substitute selected was cyclophosphamide, which was used as such for an extended period of time.<sup>73</sup> Wanting to discover the efficacy of the substitute, the doctors performed a study in which they mapped the survival rates of the patients using the substitute drug versus those that had the original. The results were shocking, to say the least:

In this retrospective comparison, we discovered that treatment with cyclophosphamide was significantly less effective . . . among [c]hildren with Hodgkin's Lymphoma [t]reated with the [o]riginal Stanford V Regimen with Mechlorethamine, as [c]ompared with [t]hose [t]reated with a [m]odified Stanford V Regimen with Cyclophosphamide. We can think of no credible explanation for this dramatic difference in event-free survival other than the drug substitution, since careful analysis of our data demonstrated that patients in the cyclophosphamide cohort did not have more unfavorable clinical features than those in the mechlorethamine cohort.<sup>74</sup>

As can be seen, the death rate of patients treated with a substitute was notably higher than the death rate of those treated with the short-supply drug.<sup>75</sup> This study is the first to document the negative effects of the drug shortage on patients with virulent diseases.<sup>76</sup> As time passes we can only anticipate that such statistics will become more prevalent.

When a drug runs short doctors are forced to find alternatives to the treatment that would have been given.<sup>77</sup> Essentially, doctors have to use a higher level of discretion in treating the patient, and oftentimes are forced to use trial and error in order to find something that is effective in addressing the patient's condition.<sup>78</sup> This opens the door for error and in turn the

---

available at <http://www.nejm.org/doi/full/10.1056/NEJMp1212468>.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> Chelsea Conaboy, *Human Toll Emerging in Shortage of Some Cancer Drugs*, BOS. GLOBE, Dec. 27, 2012, <http://www.bostonglobe.com/lifestyle/health-wellness/2012/12/27/drug-shortage-linked-increased-chance-relapse-childhood-cancer/9eoABZJMtCqK0BBaR3YEpl/story.html>.

<sup>77</sup> HemOnc Today, *supra* note 68.

<sup>78</sup> *Id.*

potential for patient harm. Clayton Christiansen and his fellow authors have noted that the more routinized the treatment of a disease becomes, the less room there is for error.<sup>79</sup> He breaks medicine into two types, intuitive and rules-based.<sup>80</sup> Intuitive chronic disease care is defined as “care for conditions that can be diagnosed only by their symptoms and only treated with therapies whose efficacy is uncertain. By its very nature, intuitive medicine depends upon the skill and judgment of capable but costly physicians.”<sup>81</sup> When intuitive medicine is applied, disease treatment is highly reliant on physician expertise, and there can be a large amount of ‘small-area-variation’ both in the way care is delivered and also in the health outcomes of the patients.<sup>82</sup> On the other hand, rules-based medicine is that which is proven to be effective for a disease whose causes and effects are fully understood.<sup>83</sup> Treatment is simple for a rules-based disorder because trial and error has already occurred, and doctors know exactly what treatment works, thereby eliminating the triage that is often characteristic of intuitive medicine.<sup>84</sup> But a drug shortage may take a disease for which a standardized (i.e. rules-based) effective treatment exists and force doctors to find a new or less effective (i.e. intuitive) treatment.<sup>85</sup> In some cases this substitution can prove harmful for patients, who, without the standardized effective

---

<sup>79</sup> See CLAYTON CHRISTIANSEN ET AL., *THE INNOVATOR’S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE* 45 (2009) [hereinafter *THE INNOVATOR’S PRESCRIPTION*] (describing “empirical medicine” in the middle of an intuitive medicine-precision medicine spectrum as “pattern recognition” that creates consistent outcomes).

<sup>80</sup> *Id.* at 44.

<sup>81</sup> *Id.*

<sup>82</sup> See *id.* (“By its very nature, intuitive medicine depends upon the skill and judgment of capable but costly physicians.”); see also LEIYU SHI & DOUGLAS A. SINGH, *ESSENTIALS OF THE U.S. HEALTH CARE SYSTEM* 290 (3d ed. 2013) (describing small-area variations as physician behavior that accounts “for wide variations in treatment patterns for similar patients” and that does not have “appreciably better outcomes”).

<sup>83</sup> *THE INNOVATOR’S PRESCRIPTION*, *supra* note 79, at 44.

<sup>84</sup> See *id.* at 46 (discussing how treatment for a rule based disorder is extremely effective once developed).

<sup>85</sup> See Rachel Fields, *7 Serious Effects of Anesthesia Drug Shortages on Surgery Centers*, BECKER’S ASC REV. (Feb. 9, 2012), <http://www.beckersasc.com/anesthesia/7-serious-effects-of-anesthesia-drug-shortages-on-surgery-centers.html> (discussing how short supplies of drugs force doctors to resort to the use of substitute drugs that are less effective).

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 401

treatment, may die or suffer side effects caused by the substituted drug.<sup>86</sup> In other words, despite doctors careful assessment of a patient, if there is a shortage, physicians may be prompted to try drugs as a last ditch effort that may in fact lead to the patients harm.<sup>87</sup>

## 2. Effect Two: Gray Market Suppliers and Increases in the Cost of Medication

The gray market might be viewed both as a cause and an effect of drug shortages. On the one hand, were it not for drug shortages, the gray-market would not exist; but on the other, gray marketers make the shortages far worse than they otherwise would be.<sup>88</sup> In essence, gray marketers buy up a large part of the remaining supplies of a short-supply drug.<sup>89</sup> This in and of itself is not the problem. The problem is that the gray marketers effectively corner the market, which gives them the ability to charge whatever prices they want, often *one-thousand* times greater than the original price.<sup>90</sup> Doctors and patients are willing to pay these exorbitant prices because without the drugs, the patients will inevitably die. The inflated prices not only prevent many patients from receiving needed treatment, but also undoubtedly raise the cost of health care.<sup>91</sup> Gray marketers therefore engage in a form of price gouging that for all intents and purposes is completely legal in America today.

The costs associated with drug shortages are not limited to the high prices charged by the gray marketers. For example,

---

<sup>86</sup> HemOnc Today, *supra* note 68.

<sup>87</sup> See Fields, *supra* note 85.

<sup>88</sup> C. Lee Ventola, *The Drug Shortage Crisis in the United States: Causes, Impacts and Management Strategies*, 36 PHARMACY & THERAPEUTICS 740, 750 (2011).

<sup>89</sup> See Linda A. Johnson, *Lawmakers: Fake Pharmacies Price Gouging On Drugs*, MANUFACTURING.NET (Mar. 22, 2012, 9:18 AM), <http://www.manufacturing.net/news/2012/03/lawmakers-fake-pharmacies-price-gouging-on-drugs> (indicating that gray marketers purchase short supply drugs).

<sup>90</sup> See *id.* (discussing the exorbitant prices charged by gray marketers); see also Kevin Born, *Time and Money: An Analysis of the Legislative Efforts to Address the Prescription Drug Shortage Crisis in America*, 33 J. LEGAL MED. 235, 239 (2012) (discussing how once the gray marketers corner the market, they sell the short-supply drugs at exorbitant prices).

<sup>91</sup> *Health Care and the 2004 Elections: Health Care Costs*, KAISER FAM. FOUND. (Sept. 1, 2004), <http://kff.org/health-costs/issue-brief/health-care-and-the-2004-elections-health-2/>.

hospitals that need to anticipate and prepare for drug shortages<sup>92</sup> might need to hire physician employees whose only jobs are to detect and guard against shortages.<sup>93</sup> Having employees devoted only to doing such work would increase hospital costs significantly without altering the revenue stream.<sup>94</sup> The higher prices paid for drugs and the associated employment costs are therefore the primary means through which the drug shortage increases hospitals' costs.<sup>95</sup>

### 3. Effect Three: Limitations on Medical Research

The last effect that will be noted here is on medical research. The goal of medical research is to determine what treatments are most effective for a particular disease; more often than not medical researchers rely on the use of drugs.<sup>96</sup> Obviously, drugs must be available for researchers to test them:

Shortages of cancer drugs are having an impact on studies sponsored by the NIH [National Institutes of Health] National Cancer Institute (NCI). While there have been periodic shortages of different cancer drugs over the past several years, nothing to date has approached the scale of the current shortages of chemotherapy drugs. We are now facing shortages of several

---

<sup>92</sup> See, e.g., Erin R. Fox, *Preparing For and Managing Drug Shortages*, 3(7) PHARMACY PURCHASING & PRODUCTS (2006), available at [http://www.pppmag.com/article\\_print.php?articleid=52](http://www.pppmag.com/article_print.php?articleid=52) (discussing the importance of effective drug shortage management for “[h]ospitals with a significant amount of automation . . .”).

<sup>93</sup> See Fields, *supra* note 85 (explaining how to address the potential for a drug shortage).

<sup>94</sup> See Born, *supra* note 90, at 239–40 (indicating that: “[h]ospitals and providers often must pay higher prices for alternative medications during a shortage. . . . A Premier survey estimated that drug shortages cost the American health care system \$200 million a year. Moreover, there are significant labor costs associated with shortages.”).

<sup>95</sup> Press Release, Am. Soc’y of Health-Sys. Pharmacists, *Drug Shortages Harming Patients, Increasing Costs to Hospitals* (July 11, 2011), <http://www.ashp.org/menu/AboutUs/ForPress/PressReleases/PressRelease.aspx?id=646>.

<sup>96</sup> See *Examining The Increase In Drug Shortages: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 112th Cong. 18–20 (2011) (statement of Howard K. Koh, Assistant Sec’y for Health, U.S. Dep’t Health & Human Servs.), available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Final-Transcript-Health-Examining-Increase-in-Drug-Shortages-2011-9-23.pdf> (outlining how “drug shortages create significant difficulty and disruptions for medical researchers and the patients they treat”).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 403**

generic cancer drugs that are widely used in treatment and are essential for clinical research.<sup>97</sup>

This of course could be especially damaging to the development of substitutes for drugs in short-supply; if there is no means through which comparisons can be made, how will researchers know if a new drug has value? Aside from the negative implications for the development of new drugs, this problem could have a negative impact on patients participating in the studies. Indeed, the patients may end up receiving sub-par treatment, which could ultimately lead to their deaths.<sup>98</sup> Such then are some of the effects of drug shortages on the U.S. healthcare system.

## II. LEGITIMATE MARKETING & THE LAWS REGULATING THE DISTRIBUTION OF PRESCRIPTION DRUGS

In order to better grasp the legal status of what gray market drug suppliers are doing, it is beneficial to consider the rules and regulations by which a legally operated drug distributor must abide. The following will consider some of the state licensure laws regulating drug distributors, as well as some of the more expansive federal laws designed to regulate prescription drug transactions.

### A. *Chains of Distribution*

In looking at the legitimate distribution of drugs, one of the most basic things to consider is how prescription drugs get from the manufacturer to the end user. The question is what does a completely legitimate drug distribution chain look like? To be clear, the reason why gray market drug suppliers have been viewed as legally questionable is not because they exist as a fundamentally non-legitimate stopping point for a drug in the chain of distribution. Gray market drug suppliers are more often than not organized as drug wholesalers, which entities are common in the prescription drug industry.<sup>99</sup> Their legitimacy is

---

<sup>97</sup> *Id.* at 19.

<sup>98</sup> *See id.* at 15–16 (explaining that drug shortages can be “life-threatening” because they can “impact . . . clinical decision-making” and “significantly affect patient outcomes”).

<sup>99</sup> Adam J. Fein, *2011 MDM Market Leaders: Top Pharmaceutical Wholesalers*, MOD. DISTRIBUTION MGMT. (May 26, 2011), [http://www.mdm.com/2011\\_pharmaceutical\\_mdm-market-leaders](http://www.mdm.com/2011_pharmaceutical_mdm-market-leaders).

called into question because of the means through which they obtain the drugs.<sup>100</sup> The idea is that as soon as they obtain the drugs illegitimately the entities cease to be an acceptable stopping point for the prescriptions.

In considering the legitimate distribution chain, the drug first starts off with the manufacturer. The manufacturer is the entity that designs the drug, patents it, and ultimately makes it.<sup>101</sup> Drug manufacturers are divided into two categories, brand name producers and generic producers.<sup>102</sup> No matter if the drug is generic or brand name, the distribution chain can sometimes end here, as in some cases manufacturers will actually distribute the product themselves.<sup>103</sup> However, the more typical situation is that the drugs are sold from the manufacturer to a wholesaler. According to a 2005 report, “Some wholesalers sell to a broad range of potential clients while others specialize in sales of particular products (e.g., biologic products) or sales to particular types of customers (e.g., nursing homes).”<sup>104</sup> After leaving the wholesaler, the drugs typically go to a pharmacy, and then from there they go directly to the patient (or rather they are supposed to).<sup>105</sup> As will be discussed, this is often the stage at which gray marketers come in. Rather than selling the drugs to patients, pharmacies may actually sell the drugs to a gray market wholesaler. This of course is outside of the legitimate supply chain, and is the type of thing that regulators are seeking to eliminate.

---

<sup>100</sup> U.S. SENATE, SHINING LIGHT ON THE “GRAY MARKET”: AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES 17 (2012) [hereinafter SHINING LIGHT ON THE “GRAY MARKET”], *available at* [http://www.commerce.senate.gov/public/?a=Files.Serve&File\\_id=678f675c-c7a4-4ecd-9cba-8b47c90ec7b3](http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=678f675c-c7a4-4ecd-9cba-8b47c90ec7b3).

<sup>101</sup> KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 4 (2005), *available at* <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.

<sup>102</sup> *Id.*

<sup>103</sup> *See id.* (indicating that manufactures may sell directly to pharmacies and hospitals).

<sup>104</sup> *Id.* at 8.

<sup>105</sup> *Id.*

*B. Legal Requirements Imposed on Parties  
in the Course of Wholesale Distribution*

One of the major shortcomings of the laws that are currently regulating the distribution of pharmaceuticals is that although drug sales occur on a national level, the laws are published by individual states; the result is that there are variations among the laws and many loopholes through which suppliers can slip.<sup>106</sup> Federal law, though it exists, is less than effective because it has loopholes designed to prevent its application to pharmacies in wholesale situations (presumably because it assumes that inter-pharmacy sales are the only wholesale transactions a pharmacy would make).<sup>107</sup> These facts are the primary reasons why a comprehensive law regulating the gray market is needed.

In any case, one of the primary claims against gray market drug suppliers is that while they often obtain licenses from their state governments to act as drug intermediaries, they consistently fail to act within the bounds of their licenses.<sup>108</sup> Gray market suppliers typically are licensed as wholesalers, and as such may buy and sell prescription drugs in a specified way and through specified channels.<sup>109</sup> The problem is gray marketers often fail to abide by these regulations, and indeed induce other entities (most notably pharmacies) to violate their own licenses. The following will discuss some of these issues, and will describe the legal requirements for drug wholesalers at the state and federal levels.

1. FDA Regulation of Re-sale

Currently, the distribution of prescription drugs is regulated at the federal level by the Prescription Drug Marketing Act (PDMA).<sup>110</sup> This statute was enacted in 1988, and according to

---

<sup>106</sup> See generally NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, DRUG PEDIGREE REQUIREMENTS FOR PHARMACIES AND WHOLESALERS: STATE STATUTES (2011), available at <http://www.namsdl.org/library/3B92E7EB-1C23-D4F9-74FDA698C8658EB4/> (analyzing various state regulations pertaining to the distribution of pharmaceutical drugs).

<sup>107</sup> See SHINING LIGHT ON THE "GRAY MARKET," *supra* note 100, at 17 (discussing violations of licensure agreements by gray market drug suppliers).

<sup>108</sup> *Id.* at 26.

<sup>109</sup> Michael Tomsic, 'Gray Market' Companies Take Advantage of Drug Shortages, WFAE 90.7 (Mar. 19, 2013, 10:18 PM), <http://www.wfae.org/post/gray-market-companies-take-advantage-drug-shortages>.

<sup>110</sup> Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat.

the FDA, “[t]he legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs.”<sup>111</sup> In other words, the purpose of laws that limit the re-sale of drugs is to maintain their viability; many drugs need to be maintained in a very specific environment that may be compromised once they leave the ordinary supply chain.<sup>112</sup>

The PMDA is codified in part in 21 U.S.C. § 331.<sup>113</sup> After its passage into law, the FDA proceeded to publish regulations that enforced it; they can be found primarily in 21 C.F.R. § 203 and § 205.<sup>114</sup> The portions of the regulations most relevant for wholesalers are §§ 203.20 through 203.23 and the entirety of § 205.<sup>115</sup> The former sections discuss the re-sale restrictions, while § 205 discusses the licensing requirements by which states must abide.<sup>116</sup> Of primary importance here is § 203 discussing the re-salability of drugs. It is important to define re-sale at this point for clarification purposes. In the sense that the term is used here, re-sale implies that the drugs have reached the final point of distribution (i.e. a pharmacy or a healthcare provider), and the intermediary, rather than selling the drugs to the consumer, sells them to another intermediary.<sup>117</sup> This adds an extra step to the distribution process.

The PDMA prohibits the re-sale of prescription drugs in the majority of cases, leaving only a few exceptions.<sup>118</sup> Quoting from the § 203.20, “no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was: (a) [p]urchased by a public or private hospital or other health care

---

95 (1988) (codified as amended in scattered sections of 21 U.S.C.).

<sup>111</sup> *Prescription Drug Marketing Act of 1987*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/> (last updated Aug. 19, 2013).

<sup>112</sup> COLEEN CHERICI ET AL., BUYER BEWARE: DRUG SHORTAGES AND THE GRAY MARKET 4–5 (Aug. 2011), <http://www.chcablog.com/wp-content/uploads/2011/08/Gray-Market-Analysis-David-Edit.pdf>.

<sup>113</sup> 21 U.S.C. § 331(t) (West, Westlaw through P.L. 113-294 approved 12/19/2014).

<sup>114</sup> 21 C.F.R. §§ 203, 205 (2014).

<sup>115</sup> *Id.* §§ 203.20–.23, 205.

<sup>116</sup> *Id.*

<sup>117</sup> See 21 U.S.C. § 353(c)(3)(A) (indicating the restrictions on re-sale).

<sup>118</sup> Robert T. Angarola & Judith E. Beach, *The Prescription Drug Marketing Act: A Solution in Search of A Problem?*, 51 FOOD & DRUG L.J. 21, 22 (1996).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 407**

entity; or (b) [d]onated or supplied at a reduced price to a charitable organization.”<sup>119</sup> As laws go this seems fairly straightforward. It seems to indicate that entities at the end of the distribution chain cannot re-sell their drug supply into the market. If this was all the law said, gray market drug sales would be explicitly illegal. The law however, has exceptions. Most notably, the following:

For purposes of this paragraph, the term “entity” does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term “emergency medical reasons” includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.<sup>120</sup>

Prima facie, this exception makes the prosecution of any gray market transaction quite difficult. Additionally the law contains multiple loopholes that further limit the ability of prosecutors to bring a case against gray marketers under the law.<sup>121</sup> In any case this is the extent of the law regulating the re-sale of prescription drugs at the federal level.

## 2. State Statutes Regulating Re-sale

The regulations codified in 21 C.F.R. § 205 require that every wholesale distributor of prescription drugs be licensed at the state level.<sup>122</sup> In light of this, and the fact that the PMDA is largely useless in regulating the re-sale of prescription drugs by wholesalers; this regulation is left primarily to the individual states.<sup>123</sup> These laws apply both to the gray marketers

---

<sup>119</sup> 21 C.F.R. § 203.20.

<sup>120</sup> 21 U.S.C. § 353(c)(3)(B).

<sup>121</sup> See *Civil Resource Manual 113. The Prescription Drug Marketing Act*, U.S. DEPT JUST. [hereinafter *Civil Resource Manual 113*], available at [http://www.justice.gov/usao/eousa/foia\\_reading\\_room/usam/title4/civ00113.htm](http://www.justice.gov/usao/eousa/foia_reading_room/usam/title4/civ00113.htm) (last visited Apr. 15, 2015) (“The provision, however, contains a host of exemptions, and further defines ‘health care entity’ to exclude ‘a wholesale distributor of drugs or a retail pharmacy licensed under State law.’ Due to the statute’s complexity and potential loopholes, prosecution of institutional diversion cases under the PDMA has been rare.”) (internal citation omitted).

<sup>122</sup> 21 C.F.R. § 205.

<sup>123</sup> See NAT’L ASS’N OF BDS. OF PHARMACY, WHOLESAL DRUG DISTRIBUTION: PROTECTING THE INTEGRITY OF THE NATION’S PRESCRIPTION DRUG SUPPLY 3 (2013), available at [http://www.nabp.net/system/rich/rich\\_files/rich\\_files/000/000/064/original/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-](http://www.nabp.net/system/rich/rich_files/rich_files/000/000/064/original/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-)

themselves as well as to the entities from whom the drugs are purchased. The reason for this is that both sides of the transaction ultimately are selling/buying large quantities of drugs as neither manufacturers nor end users.<sup>124</sup> This in essence classifies their activity as wholesaling and as such, state laws regulating drug wholesaling are applicable to both parties.

The state laws regulating wholesaling as it applies to re-sale by intermediaries can be broken into two broad categories according to the 2012 House report on the gray market:<sup>125</sup> “[s]ome states allow pharmacies to re-sell portions of their inventories in emergency circumstances, while other states permit up to 5 percent of pharmacies’ annual sales to come from re-selling their drugs. The parameters of these exceptions rules [sic] vary from state to state.”<sup>126</sup> As it turns out, some states actually have combined the two categories when defining what is appropriate for pharmacies. The following is an excerpt from North Carolina’s law defining wholesaling:

The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. Emergency medical reasons include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage when the gross dollar value of the transfers does not exceed five percent (5%) of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12-consecutive-month period.<sup>127</sup>

This law, as can be seen allows a pharmacy to resell its drug supply to another pharmacy in order to mitigate supply shortages that are occurring in the community.<sup>128</sup> The law is

---

prescription-drug-supply.pdf (explaining that despite PDMA, in the early 2000’s counterfeit drugs reappeared in the supply chain, and after meeting resistance, PDMA requirements were delayed; as a result, states developed their own pedigree programs).

<sup>124</sup> See DANIEL E. HARMON, *NEW MEDICINES: ISSUES OF APPROVAL, ACCESS, AND PRODUCT SAFETY* 20 (Rosen Publ’g Grp. 2009) (“Wholesalers are go-betweens, buying large quantities of medications from drugs manufacturers, then distributing and selling them to drugstore chains, independent pharmacies, hospitals, and clinics.”).

<sup>125</sup> SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 17.

<sup>126</sup> *Id.*

<sup>127</sup> N.C. GEN. STAT. ANN. § 106-145.2(10)(e) (West 2014).

<sup>128</sup> See SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 17 (indicating that “[s]ome states’ rules appear to be intended to resolve local supply problems by allowing pharmacies to sell drugs to each other . . .”).

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 409

clearly not intended to give pharmacies the ability to make the re-sale of drugs the primary source of their income, rather its primary goal is to ensure that consumers do not suffer when drugs are in short-supply. Another state law addressing the same issue is Virginia's:

A permitted pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as wholesale distributors when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances do not exceed five percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy . . . .<sup>129</sup>

This law is more lenient than the one from South Carolina, as it allows wholesaling activities by pharmacies strictly for the purposes of turning a profit, so long as that profit is limited to five percent of annual sales. Despite the differences between the statutes, if a pharmacy re-sells more than 5 percent of gross annual sales, states require the pharmacy to be fully licensed as a wholesaler.<sup>130</sup>

Gray market suppliers are largely licensed as such, and are therefore technically permitted to act as wholesalers when they re-sell drugs.<sup>131</sup> This, however, does not give them the ability to purchase the drugs without restriction (at least in some states). For example, Nebraska's statute says:

No wholesale drug distributor . . . shall knowingly purchase or receive any prescription drug from any source other than a person or entity licensed under the Wholesale Drug Distributor Licensing

---

<sup>129</sup> VA. CODE ANN. § 54.1-3435.02(A) (West 2014).

<sup>130</sup> See 21 C.F.R. § 205.2 (2014) (setting forth the implementation of the PDMA); GA. CODE ANN. § 26-4-115(a) (West 2014) ("All persons, firms, or corporations, whether located in this state or in any other state, engaged in the business of selling or distributing drugs at wholesale in this state, in the business of supplying drugs to manufacturers, compounders, and processors in this state, or in the business of a reverse drug distributor shall biennially register with the board as a drug wholesaler, distributor, reverse drug distributor, or supplier."); see also C. RICHARD ALLEN, GA. DRUGS & NARCOTICS AGENCY, ALERT: DRUG WHOLESALERS ARE ATTEMPTING TO BUY DRUGS FOR EMERGENCY MEDICAL REASONS, available at [https://gbp.georgia.gov/sites/gbp.georgia.gov/files/related\\_files/document/Drug%20Wholesalers%20Alert.pdf](https://gbp.georgia.gov/sites/gbp.georgia.gov/files/related_files/document/Drug%20Wholesalers%20Alert.pdf) (last visited Apr. 15, 2015) (alerting pharmacies of wholesalers asking pharmacies to resell excess drugs, and clarifying that reselling to wholesalers is illegal).

<sup>131</sup> See Tomsic, *supra* note 109 (discussing gray marketers' status as wholesalers).

Act except transfers for emergency medical reasons . . . the gross dollar value of which shall not exceed five percent of the total prescription drug sales of the transferor or transferee holder of a pharmacy license . . . .<sup>132</sup>

Under this statute, a gray market drug supplier would be guilty of violating the law if it purchased drugs from a pharmacy that was re-selling more than five percent of its drugs without a wholesaler's license. The reality is that not all states have laws that parallel Nebraska's; thereby what may be illegal in one state may technically be legal in another. This makes prosecution of these transactions nearly impossible. Controlling gray market drug transactions would become far easier if one law, such as the PDMA, was the only law used to regulate the gray market. Such then is a brief look at the laws regulating re-sale and wholesaling at the state and federal levels.

### 3. Other Legal Consideration

As already noted, gray marketers use legally questionable means in obtaining the drugs that they sell.<sup>133</sup> Similar to the means they use to obtain the drugs, gray market suppliers themselves exist in what can only be viewed as a 'legally questionable state.'<sup>134</sup> To further complicate the matter, in some cases gray marketers are actually a source of lower prices for drugs to consumers; for this reason there is popular support for their continued existence.<sup>135</sup> In other words, gray marketers may have access to cheaper drugs sold in countries like Canada; they then sell these drugs in the U.S. at a slight markup that is still cheaper than the regular price.<sup>136</sup> This type of situation does not

---

<sup>132</sup> NEB. REV. STAT. ANN. § 71-7454(1) (West 2014).

<sup>133</sup> See discussion *supra* Part I.B.4 (explaining effects of gray market supplier activities).

<sup>134</sup> See, e.g., Tomsic, *supra* note 109 ("LTC Pharmacy . . . was buying drugs in short supply and selling them to a wholesaler a few feet away. And those two companies had the exact same owner. The pharmacy had to shut down and the wholesaler's license wasn't renewed . . . Ragan said the only thing illegal about what they did was this: the pharmacy acted like a wholesaler without having a wholesaler's license.").

<sup>135</sup> See, e.g., Soumaya Bandyopadhyay, *The Internet And Gray Marketing*, 9 INT'L BUS. ECON. RES. J. 95, 96 (2010) ("11 percent of Americans have reported obtaining less-expensive prescription drugs from other countries, mostly over the internet[,] . . . mainly because . . . of high prescription drug prices in the United States.").

<sup>136</sup> *Id.*

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 411

reflect price gouging because the drugs involved are not in short supply. Because of the cost benefits to people with chronic disorders who need a large supply of prescription drugs, both the current and last Presidents of the United States appear(ed) to support the existence of gray marketers operating in this capacity.<sup>137</sup> “The lawmakers have been trying to show their constituencies, particularly the senior citizens, that they are sensitive to rising healthcare costs. Legislative action in the United States has so far mainly targeted the so called “rogue” online pharmacies—Websites that sell unapproved drugs . . . without a proper prescription.”<sup>138</sup> This situation presents a clear conundrum. On the one hand, when there is a shortage, gray marketers exacerbate the shortage and increase the costs of drugs immensely. On the other hand, in non-shortage situations, gray marketers serve to offer the public a lower priced prescription drug option and therefore have public support. Addressing the former problem then, would require the ability to distinguish between the activities of gray marketers. Without such discrimination, there is no doubt that public outcry would result from laws barring gray marketers operation. Any plan aimed at preventing drug shortages and the gray marketers that spring up in their wake, should make a distinction between these two ‘types’ of gray marketers and should ensure that those entities that reduce drug prices be allowed to exist.

At this point there do not seem to be any laws strictly prohibiting the operations of gray market drug suppliers.<sup>139</sup> Granted, there are laws that regulate gray marketers of other goods,<sup>140</sup> but these laws do not prohibit their sale, rather they simply set guidelines within which gray marketers must operate.<sup>141</sup> No such laws specifically target the sale of gray market drugs. Despite this void, many states have established “drug pedigree” laws, which serve to ensure that end users of a drug know how many times a drug changed hands and essentially prevent adulterated drugs from being sold on the

---

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at 96–97.

<sup>139</sup> See Tomsic, *supra* note 109 (explaining that legality of gray market activities is not easily determined, and indicating that many people feel there are insufficient federal laws addressing the gray market).

<sup>140</sup> See, e.g., CAL. CIV. CODE ANN. § 1797.81 (West 2014) (laying out the requirements for the sale of gray market goods in the state of California).

<sup>141</sup> *Id.*

market.<sup>142</sup> According to a relatively recent article, however, there is no evidence that these types of laws have served to make business more difficult for gray marketers.<sup>143</sup> It seems that laws addressing the gray market for drugs are largely limited to regulating and not barring their operations.<sup>144</sup> In a recent quote, Elijah Cummings, the Congressman who ordered the investigation into the gray market, said the following of its current legal status: “[i]f it’s not illegal, we need to make it illegal.”<sup>145</sup> This quote is indicative of the fact that the legal status of gray marketers across the United States is confusing even to lawmakers. What is clear is that at this time, there is no body of law that specifically targets the activities of gray markets.

### III. THE OPERATIONS OF THE GRAY MARKET

A closer look into the gray market distribution of drugs must consider in detail how gray market drug suppliers do business, specifically how they obtain and distribute the drugs. Because of the relative “newness” of these entities, many states do not yet have laws specifically addressing their activities or the legality of them.

#### A. *Obtaining the Drugs*

One of the most persistent questions involves how the gray marketers obtain the drugs in such large quantities that they are essentially able to corner the market. Theoretically, if these supply chain holes for vital injectable drugs could be eliminated, the problem might go away. At this point, nearly all of the

---

<sup>142</sup> See IND. CODE ANN. § 25-26-14-8.7(a)(1) (West 2014) (“As used in this chapter, ‘pedigree’ means a statement or record in a written or an electronic form that is approved by the board, that: (1) records each wholesale distribution of a legend drug from the sale by the manufacturer that leaves the normal distribution chain of custody and that includes information designated by the board through rules for each transaction . . .”).

<sup>143</sup> Jaimy Lee, *Laws Fail to Slow Gray Market: Concerns Raised over Secondary Drug Distributors*, MOD. HEALTHCARE, Oct. 3, 2011, <http://www.modernhealthcare.com/article/20111003/MAGAZINE/310039886>.

<sup>144</sup> See discussion *supra* Part II.B (summarizing the legal requirements imposed on the distribution of pharmaceuticals).

<sup>145</sup> Editorial, *‘Gray-market’ Drug Network Adds to Health Costs, Patients’ Anguish*, HERALD-DISPATCH, July 30, 2012, <http://www.herald-dispatch.com/opinions/x324218723/Editorial-Gray-market-drug-network-adds-to-health-costs-patients-anguish>.

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 413**

information regarding this topic is limited to a 2012 investigative House of Representatives study spearheaded by Elijah Cummings [hereinafter “House Committee”].<sup>146</sup>

**1. Pharmacies**

The House Committee’s 2012 study found that a majority of the supply leakage into the gray market comes from actual pharmacies whose operators choose to sell their drugs at a higher price to gray marketers, rather than health care providers.<sup>147</sup> “Instead of dispensing the drugs in accordance with their professional duties, state laws, and the expectations of their trading partners, these pharmacies re-sold the drugs to gray market wholesalers. Some pharmacies sold their entire inventories into the gray market.”<sup>148</sup> In fact, the study estimated that nearly seventy percent of gray market drugs are obtained from pharmacies.<sup>149</sup> The re-sale of drugs by pharmacies outside of the supply chain is legally questionable both in many states and at the federal level as can be seen from the discussion of state laws above. If a pharmacy is to re-sell drugs into the market at a value of more than five percent of its annual sales, it is a violation of many states’ laws.<sup>150</sup>

**2. Pharmacies as Drug Brokers**

Aside from having pharmacies simply sell them their own short-supply drugs, gray marketers will also use pharmacies as brokers of the drugs.<sup>151</sup> Typically, the gray marketer promises a pharmacy significant profit for assistance in their quest to obtain the short-supply drugs.<sup>152</sup> In many cases it actually works, as many pharmacies comply with their requests.<sup>153</sup> As noted above, the re-sale of drugs by pharmacies to intermediaries and

---

<sup>146</sup> SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100.

<sup>147</sup> *Id.* at i–ii.

<sup>148</sup> *Id.* at i.

<sup>149</sup> *Id.*

<sup>150</sup> See discussion *supra* Part II.B.2 (analyzing different states’ pharmaceutical laws).

<sup>151</sup> See Sullivan, *supra* note 56 (discussing the findings of the congressional committee).

<sup>152</sup> See SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 18–19 (explaining the means through which gray market dealers convince pharmacies to buy them drugs).

<sup>153</sup> *Id.*

distributors who do not comply with state regulations is prohibited in many states.<sup>154</sup> Though slightly different, it would seem that acting as a purchasing agent for a gray marketer is viewed as similarly illegal.<sup>155</sup> In reality though, that may be a misperception. The House Committee cited a California example:

[T]he California Board of Pharmacy recently cited more than 50 pharmacies for acting as purchasing agents for gray market companies. The Board cited the pharmacies for unlawfully selling short-supply prescription drugs to a San Diego-based drug distributor . . . . The Board determined that the pharmacies violated the California Business and Professional Code by acting as “purchasing agents” . . . .<sup>156</sup>

Despite indications that the pharmacist’s actions were illegal, there is no mention of the law that was violated, nor any indication that the defendant was actually convicted of violating a law. According to the news article cited by the House Committee, the illegality of the pharmacist’s actions involving the gray market wholesaler had not been established at the time the article was written, nor is there any indication that they were established after the article was written.<sup>157</sup> It would seem that the pharmacist’s actions merely had the appearance of being illicit, but in actuality were not. This analysis is supported by the fact that there is currently no law in California specifically prohibiting the sale of short-supply drugs to a licensed wholesaler. In any case, these are two of the ways gray market dealers use legal pharmacies in obtaining their supply of drugs.

### 3. Fake Pharmacies

Although the majority of drugs are obtained through regular pharmacies that are appropriately licensed and do business as such, gray marketers also obtain drugs through fake pharmacies that are established with the sole purpose of securing drugs in

---

<sup>154</sup> See discussion *supra* Part II.B.2 (describing different states’ regulations involving the re-sale of drugs to intermediaries).

<sup>155</sup> See SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 18–20 (discussing how the use of pharmacies as purchasing agents for short-supply prescription drugs is deemed to be unlawful).

<sup>156</sup> *Id.* at 19–20.

<sup>157</sup> Kellie Schmitt, *Local Pharmacy Faces a Barrage of Charges*, BAKERSFIELD CALIFORNIAN, Mar. 22, 2012, <http://www.bakersfieldcalifornian.com/health/x560111673/Local-pharmacy-faces-a-barrage-of-charges>.

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 415

short-supply.<sup>158</sup> These “pharmacies” obtain the necessary licenses, but instead of the drugs going directly to health care providers, they are immediately transferred to gray marketers.<sup>159</sup> These “pharmacies” are virtually shell corporations that, although having a physical location, do not perform any of the functions of an actual pharmacy.<sup>160</sup> The physical location serves as a front of legitimacy; in many cases these fake pharmacies buy the drugs and resell them in the same day.<sup>161</sup> Furthermore, the secondary buyer or the wholesaling company is often owned by the same individual(s) who owns the fake pharmacy.<sup>162</sup> Such a fake pharmacy in North Carolina was shut down for violations of state laws:

LTC Pharmacy and International Pharmaceuticals: LTC Pharmacy, a pharmacy in Durham, North Carolina, purchased drugs in short supply and transferred them to International Pharmaceuticals, a wholesaler located in the same building, which then sold them into the gray market. . . . State regulators in North Carolina found that, “International Pharmaceuticals and LTC Pharmacy willfully violated NC wholesaler prescription drug distribution laws,” and LTC Pharmacy “is not an operating pharmacy.” Licenses for both companies have recently been surrendered or denied.<sup>163</sup>

There do not seem to be any laws specifically prohibiting the operation of these fake pharmacies. Most laws regulating pharmaceutical distribution that could be used against these entities largely revolve around licensure and compliance with pharmacy board regulations. If the pharmacy has complied with state licensure laws, as most of them apparently do, they remain technically legal operations.<sup>164</sup> Theoretically, fake pharmacies

---

<sup>158</sup> SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 21.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 21–24.

<sup>161</sup> *Id.* at iii, 21–22.

<sup>162</sup> *Today: ‘Fake Pharmacies’ Ascend as Drug Wholesalers* (NBC television broadcast July 4, 2012), available at <http://www.pharmpro.com/videos/2012/07/fake-pharmacies-ascend-drug-wholesalers>.

<sup>163</sup> SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 21.

<sup>164</sup> See Linda A. Johnson, *Lawmakers: Fake Pharmacies Price Gouging on Drugs*, USA TODAY (Mar. 21, 2012, 2:39 PM), <http://usatoday30.usatoday.com/news/health/story/health/story/2012-03-21/Lawmakers-Fake-pharmacies-price-gouging-on-drugs/53687688/1> (“Three of the targets are individuals believed to have obtained licenses to operate both a pharmacy and a prescription drug wholesale business — solely to make money by taking advantage of the growing drug shortage crisis that’s disrupting hospital and other patient care.”).

could be in violation of the Prescription Drug Marketing Act, which prohibits the re-sale of drugs purchased by health care entities, but because of the loopholes in the law, no one can be sure.<sup>165</sup> Given this, the way these fake pharmacies are being caught and convicted of illegal activity is by finding them guilty of violating the terms of their licensing agreements.<sup>166</sup> For example, a fake pharmacy operating in Maryland (Priority Healthcare) was found in violation of its license for failing to have a pharmacist on the premises, which according to state law is a prerequisite for operating such a facility.<sup>167</sup> New York State has a similar law: “[e]very pharmacy shall be under the immediate supervision and management of a licensed pharmacist at all hours when open. No pharmacist shall have personal supervision of more than one pharmacy at the same time.”<sup>168</sup> Additionally fake pharmacies could be prosecuted for violating state laws preventing pharmacies from wholesaling. The key however is actually catching these entities because their disguises allow them to hide in plain sight. The best way to target the operation of fake pharmacies would be to pass a law specifically prohibiting their operation, but as things currently stand, no such law exists.

### *B. Obtaining Drugs through Illicit Channels*

Another method by which gray marketers obtain drugs is through collusion with Medicaid recipients.<sup>169</sup> In a relatively recent case coming out of New York City, gray marketers contacted Medicaid recipients who were afflicted with diseases like HIV/AIDS and purchased their prescriptions from them.<sup>170</sup> After purchasing the prescriptions, the suppliers re-sold them to

---

<sup>165</sup> *Civil Resource Manual 113*, *supra* note 121.

<sup>166</sup> SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 21.

<sup>167</sup> Consent Order at 7, Priority Healthcare, LLC, No. PI-10-042 (Md. State Bd. of Pharmacy Oct. 19, 2011), *available at* <http://www.dhmf.maryland.gov/pharmacy/docs/FormalOrders/P/Priority%20Healthcare,%20LLC%2010-19-11.pdf>.

<sup>168</sup> N.Y. EDUC. LAW § 6808(2)(e) (McKinney 2014).

<sup>169</sup> See Adam J. Fein, *Gray Market Drug Recycling for Fraud and Profit*, DRUG CHANNELS (July 24, 2012), <http://www.drugchannels.net/2012/07/grey-market-drug-recycling-for-fraud.html> (indicating that a scheme in which Medicaid recipients and gray-market drug suppliers colluded to obtain short-supply drugs, was uncovered in the Manhattan area).

<sup>170</sup> *Id.*

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 417**

pharmacies at a premium rate.<sup>171</sup> Diversions such as this cost taxpayers millions of dollars,<sup>172</sup> and as the prices of drugs in short supply increase, they are bound to become more frequent.<sup>173</sup> As the prices increase, people who have access to short-supply drugs stand to make great profits by re-selling them.<sup>174</sup>

This practice has come to be known as “drug diversion” (impliedly because drugs are removed from a strictly legal channel and brought into a legally questionable one).<sup>175</sup> The diverted drugs are removed from the legitimate supply chain and eventually end up back in the hands of legitimate health care entities after passing through a chain of intermediaries.<sup>176</sup> The practice of obtaining drugs through diversion is viewed as the least savory means the gray marketers use to obtain drugs and is in fact a federal crime.<sup>177</sup> According to FDA Associate Commissioner John Taylor, “[d]rug diversion is a serious crime that corrupts the integrity of the pharmaceutical distribution system, thereby placing the public health in jeopardy.”<sup>178</sup> The reason why drug diversion is so risky has to do with the drug’s place of origination. When a secondary drug supplier obtains the

---

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> See Gabriel Levitt & Sam Werbalowsky, *High Drug Prices Fuel Medicaid Fraud and U.S. Drug Safety Problems*, PHARMACYCHECKER BLOG (July 31, 2012), <http://pharmacycheckerblog.com/high-drug-prices-fuel-medicaid-fraud-and-u-s-drug-safety-problems> (discussing how higher drug prices created a black market for Medicaid patients, pharmacies, and end-users to buy and sell prescription drugs).

<sup>174</sup> See *id.* (explaining that Medicaid patients are willing to sell shortage drugs “because it [is] highly profitable, despite consequences to their own health”). It should also be noted that when a gray market supplier engages in behavior such as this, it ceases to be a gray market supplier and becomes black market supplier, since such activities are highly illegal. See *id.* (discussing how shortage drugs “made their way through a black market to a supply chain of ‘collectors’ and ‘aggregators’, eventually working their way into wholesale companies and pharmacies . . .”).

<sup>175</sup> U.S. FOOD & DRUG ADMIN., FDA PRELIMINARY REPORT: REVIEW OF COUNTERFEIT AND DIVERSION CRIMINAL CASE INFORMATION § 4.1.3 (Sept. 2011) [hereinafter FDA PRELIMINARY REPORT], available at <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM272150.pdf>.

<sup>176</sup> *Id.*

<sup>177</sup> *Illegal, Possibly Unsafe Drugs Sold in 80 Pharmacies Nationwide: United States v. Ocak*, 21 No. 4 ANDREWS PHARMACEUTICAL LITIG. REP. 9 (May 25, 2005), available at 2005 WL 1225456, at \*1.

<sup>178</sup> *Id.*

drugs initially from a pharmacy, the drugs typically have not departed from the typical supply chain.<sup>179</sup> Presuming that all regulations were followed in the manufacture and transport of the drugs, it is unlikely that they are contaminated or expired.<sup>180</sup> The same is not true if the drugs are obtained from a patient to whom they have already been prescribed, if they are drug samples, or if they are stolen.<sup>181</sup> The following quote taken from a CNN News story concerning the Medicaid drug diversion scheme is indicative of the danger: “[p]eople with real ailments were induced to sell their medications . . . rather than take them as prescribed, while end-users of the diverted drugs were getting second-hand medicine that may have been mishandled, adulterated, improperly stored, repackaged and expired.”<sup>182</sup> In other words, drugs that were once good are not as easily trusted once they have been in an individual’s possession.

Because of the danger posed by secondary market drugs obtained through these means, the FDA is seeking to crack down on gray marketers that use these means to obtain drugs. In one successful crackdown, Altec Medical, an Easley-based gray marketer, pleaded guilty of engaging in a large-scale drug diversion scheme.<sup>183</sup> In any case, of all the means gray marketers use to obtain drugs, this is the only one that is explicitly labeled as illegal.

#### 1. Comparing the Gray Market with the Black Market: Is Gray the New Black?

The black market could be thought of as the ‘underground’

---

<sup>179</sup> FDA PRELIMINARY REPORT, *supra* note 175, § 4.1.3.

<sup>180</sup> *See id.* §§ 4.1.2, 4.1.3 (explaining that when drugs are taken out of the supply chain, there is no way to monitor how they were handled in transport and whether transportation conditions could have ruined their quality and safety).

<sup>181</sup> *See* Jason Evans, *Easley Company Pleads Guilty to Grey Market Drug Scheme*, EASLEY PATCH (Aug. 12, 2012), <http://easley.patch.com/articles/easley-company-pleads-guilty-to-grey-marker-drug-scheme> (noting that drugs which are diverted by individuals from lawful channels “could be expired, become contaminated, or have their mechanisms of action altered”) (internal quotations omitted).

<sup>182</sup> Chris Boyette, *New York Authorities Charge 48 in Massive Medicaid Fraud*, CNN (July 18, 2012, 7:34 AM), <http://www.cnn.com/2012/07/18/justice/new-york-drug-scheme/index.html> (quoting Janice K. Fedarczyk, FBI assistant director) (internal quotations omitted).

<sup>183</sup> Evans, *supra* note 181.

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 419

version of an eBay, where a person with the right connections is able to purchase anything from Cuban cigars to other human beings. For the purposes of this article though, the area of primary concern is the sale and trade of medical services and supplies. First off, consider the organ trade.

The market for human organs is booming;<sup>184</sup> individuals who have sufficient funding and who need transplants are generally able to find donors.<sup>185</sup> In a world where there is clearly an organ shortage,<sup>186</sup> this secondary market might seem highly beneficial, in that it might save a life that otherwise would have been lost. Why then is this secondary market illegal? The answer is twofold. First, there are clear problems in both where and from whom the organs are obtained as well as the means used to obtain them.<sup>187</sup> Second, the effects on the individuals receiving organs may not always be as beneficial as they might appear.<sup>188</sup>

First, consider how black market dealers obtain organs. The black market distributors are often able to purchase organs from the donors,<sup>189</sup> however if this means is not available, they may use coercion.<sup>190</sup> The reason why the purchase of organs has been

---

<sup>184</sup> See Tom Scheve, *How Organ Donation Works*, HOWSTUFFWORKS, <http://science.howstuffworks.com/life/human-biology/organ-donation7.htm> (last visited Apr. 15, 2015) (describing black market activities in South Africa, the US, and other countries).

<sup>185</sup> See *id.* (explaining how South African, Israeli, and American organ brokers sold human organs on the black market to patients and research facilities).

<sup>186</sup> See Robert Ainley, *Organ Transplantation: A Model Law Approach to Combat Human Trafficking and Transplant Tourism*, 13 OR. REV. INT'L L. 427, 434 (2011) ("Since the 1980s, increasing shortages in organs globally has developed into a major problem for most countries.").

<sup>187</sup> See Brian Handwerk, *Organ Shortage Fuels Illicit Trade in Human Parts*, NAT'L GEOGRAPHIC (Jan. 16, 2004), [http://news.nationalgeographic.com/news/2004/01/0116\\_040116\\_EXPLorgantrafficking.html](http://news.nationalgeographic.com/news/2004/01/0116_040116_EXPLorgantrafficking.html) (explaining that for example, organs may be illegal trafficking rings, wherein donors from poor neighborhoods are flown to other countries to go into surgery).

<sup>188</sup> See Geraldine Leung, *Fun, Sun, Get a Surgery Done! The Growing Trend of Transplant Tourism*, ISSUES BERKLEY MED. J. (Spring 2006), [https://www.ocf.berkeley.edu/~issues/articles/13.2\\_Leung\\_G\\_Fun\\_Sun.html](https://www.ocf.berkeley.edu/~issues/articles/13.2_Leung_G_Fun_Sun.html) (indicating that black market donations often involve inadequate post-operative care for both the donor and the recipient; the recipient may not receive the right dose of immunosuppressant medication).

<sup>189</sup> See Scheve, *supra* note 184 (discussing where organs are obtained).

<sup>190</sup> Elizabeth Pugliese, *Organ Trafficking and the TVPA: Why One Word Makes A Difference in International Enforcement Efforts*, 24 J. CONTEMP. HEALTH L. & POL'Y 181, 185 (2007) ("Unlike the 'Baby Parts' myth, there are

banned in many countries is because organ donors are often taken advantage of by the traffickers.<sup>191</sup> In some cases the donors are paid abysmally low prices for their organs (prices that for them might seem high based on their standard of living).<sup>192</sup> In other cases they are promised jobs in other countries, but instead of getting the job their organs are taken from them under threat of death.<sup>193</sup> The reason that the practice is illegal then, is to prevent harm to people who donate their organs.<sup>194</sup> Furthermore, the purchase of human organs is viewed as unethical in the international community, lending a further reason for prohibiting it.<sup>195</sup>

The second reason why black market organ sales are prohibited is the potential negative effects on people receiving the organs.<sup>196</sup> Organ transplantation is under the best of circumstances a risky business. Black market organ transplants make the operations even riskier.<sup>197</sup> In many cases the transplants occur in ‘makeshift’ operating rooms that are prone

---

real cases of people being tricked into selling their organs through various stratagems. The Uzbek authorities broke up an organ trafficking ring in 2001. One victim had been promised a job in Canada. His body was found in his hometown; he never even left the country. During the course of the investigation, the authorities found the passports of over sixty people who had been reported missing and over £6000 that was believed to be the proceeds from organ sales.”).

<sup>191</sup> Handwerk, *supra* note 187.

<sup>192</sup> *See id.* (“‘They said that they received about \$800 a kidney, which for them is a year’s salary,’ Ling told *National Geographic News*. ‘It’s a decent amount of money to them, but of course when it runs out they can’t sell more organs.’”); *see also* Simon Robinson, *India’s Black Market Organ Scandal*, *TIME* (Feb. 1, 2008), <http://www.time.com/time/world/article/0,8599,1709006,00.html> (giving an example of a black market organ transplant ring in India which, when busted by police, revealed that doctors were paying donors only \$1,000 and then selling the organs for up to \$37,500).

<sup>193</sup> *See* Ainley, *supra* note 186, at 443 (discussing how ‘donors’ have their organs taken at gunpoint in India).

<sup>194</sup> *See id.* (explaining that the lack of strict international legal frameworks prompts organ traffickers to take advantage of donors).

<sup>195</sup> *See* EA Friedman & AL Friedman, *Payment for Donor Kidneys: Pros and Cons*, 69 *KIDNEY INT’L* 960, 960–61 (2006), *available at* <http://www.nature.com/ki/journal/v69/n6/pdf/5000262a.pdf> (describing the widespread global condemnation of selling organs).

<sup>196</sup> *See* Leung, *supra* note 188 (discussing the potential for negative effects on organ recipients).

<sup>197</sup> *See* Ainley, *supra* note 186, at 440 (indicating that donors participating in illicit organ donation often face medical complications and infectious diseases).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 421**

to being non-sterile and lack appropriate medical equipment.<sup>198</sup> In addition, the organs themselves often have not been properly vetted, and in some cases their previous owners may have had deadly diseases.<sup>199</sup> The following quote is representative of the harm that may result to people receiving organs on the black market:

Preliminary research with patients who received [illicit] transplantation procedures found high occurrences of botched procedures and infections, including hepatitis B, fungal sepsis, and HIV. Due to substandard medical practices, patient and graft survival rates are considerably lower. Finally, medical records for these patients are often incomplete or unobtainable, further complicating follow-up treatment and placing the public at risk.<sup>200</sup>

There is a high level of risk both for organ donors and recipients. In an effort to maintain the health of the populace, the United States government has banned black market organ transactions.<sup>201</sup>

This discussion was intended to show that the black market often causes harm to both organ donors<sup>202</sup> and recipients,<sup>203</sup> the reality is that these characteristics are not unique to the black market, and may in fact be shared by the gray market.

Similar to the black market, gray market drug suppliers consistently utilize legally questionable means of obtaining their drugs. Given that investigators have only recently begun to look into gray marketers, the exact scale of their illicit activities is

---

<sup>198</sup> See Scheve, *supra* note 184.

<sup>199</sup> See Caroline Logan, *Kidney Bank: Illegal Organ Trade in Nepal*, BORGEM MAG. (July 5, 2014), <http://www.borgenmagazine.com/kidney-bank-illegal-organ-trade-nepal/> (providing an example of a population with living conditions leading to organ disease, the people of the population being scammed into donating their organs).

<sup>200</sup> Ainley, *supra* note 186, at 439–40.

<sup>201</sup> See National Organ Transplant Act § 301(a), 42 U.S.C. § 274e(a) (2012) (“It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”).

<sup>202</sup> See Andy Henion, *Black Market for Organs Takes Toll on Poor*, FUTURITY (Mar. 13, 2012), <http://www.futurity.org/health-medicine/black-market-for-organs-takes-toll-on-poor/> (describing that many donors don’t get the money they are initially promised for their organs, and often face serious health problems after making a donation).

<sup>203</sup> See *supra* notes 196–200 and accompanying text (explaining the circumstances faced by black market organ recipients).

unclear.<sup>204</sup> Gray market suppliers consistently induce otherwise law-abiding pharmacies to break the law by paying them to sell their supplies of drugs.<sup>205</sup> In addition to the fact that both markets use untoward means of obtaining their product, both often cause harm to the people from whom they receive the products. In the black market, people whose organs have been removed often suffer life-long problems as a result.<sup>206</sup> In the same way, when gray marketers engage in drug diversion,<sup>207</sup> they buy the prescription drugs of sick individuals who may need the drugs to survive. In the 2012 bust of the New York City drug diversion ring, gray market players induced Medicaid recipients to sell their HIV drugs.<sup>208</sup> Though there is currently a lack of data on the issue, the individuals who sold their medication could have seen a worsening of their condition (i.e. going from HIV to full-blown AIDS).<sup>209</sup>

The second characteristic shared by the black and gray markets are that they often sell substandard products.<sup>210</sup> Black-market organs are often infected by disease,<sup>211</sup> and gray-market drugs suffer from a similar problem. Drugs must be maintained in a controlled environment in order to maintain their viability.<sup>212</sup>

---

<sup>204</sup> See SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 16 (surmising how drugs enter the gray market based upon a 2012 study).

<sup>205</sup> See *supra* notes 152–53 and accompanying text.

<sup>206</sup> See Henion, *supra* note 202 (stating that black market donors can be “plagued with serious health problems that prevent them from working, and cause them shame and depression”) (internal brackets omitted).

<sup>207</sup> Eric Palmer, *Company Convicted in Gray Market Distribution Scheme*, FIERCEPHARMA (Aug. 20, 2012), <http://www.fiercepharma.com/story/company-convicted-gray-market-distribution-scheme/2012-08-20>.

<sup>208</sup> See Boyette, *supra* note 182 (discussing what types of medication were purchased back from the Medicaid patients).

<sup>209</sup> See, e.g., Nat’l Inst. of Health, *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, AIDS INFO, <http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/458/plasma-hiv-1-rna—viral-load—and-cd4-count-monitoring> (last updated May 1, 2014) (noting that a person with HIV should be regularly repeating an ARV regimen, which suppresses the AIDS virus).

<sup>210</sup> See Ainley, *supra* note 186, at 439–40 (discussing the negative effects on patients who engaged in “transplant tourism”); see also Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279, 287 (2006) (indicating that counterfeit drugs enter the drug market through gray marketers).

<sup>211</sup> See *supra* notes 199–200 and accompanying text.

<sup>212</sup> Mary Shomon, *Warning: Hot Temperatures May be Hazardous to Your Drugs*, ABOUT.COM, <http://thyroid.about.com/od/thyroiddrugstreatments/a/drugs>

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 423**

If stored incorrectly, they may deteriorate.<sup>213</sup> As noted by one commentator, “[t]he gray market includes legitimate product, but you can’t be certain how it was handled during distribution, . . . [y]ou don’t know for sure if proper temperature, humidity, or other factors that impact efficacy have been maintained.”<sup>214</sup>

In the drug diversion bust that occurred in New York City, officials found “more than \$16 million worth of prescription drugs—33,000 bottles and more than 250,000 loose pills, ‘kept in uncontrolled and sometimes egregious conditions’ by some of the suspects.”<sup>215</sup> Clearly there is a chance that the drugs that are sold by gray marketers may be contaminated, thereby rendering them potentially harmful to those who receive them.<sup>216</sup> A 2011 study found the following:

Up to 12% of respondents reported awareness of a product authenticity issue, medication error, or adverse drug reactions associated with the use of gray market products in the past [two] years. Most cited errors associated with using a different strength of a product than usual stock, issues with improper storage of drugs that must be refrigerated, sale of recalled or stolen products, illegal importation of pharmaceuticals, questionable chain of custody, and sale of counterfeit products and placebos.<sup>217</sup>

As can be seen then, both the black and the gray markets often deal in products that could lead to the harm of the end users.

---

insummer.htm (last updated Dec. 16, 2014); see also Liz Szabo, *Drug Shortages Lead to Price Gauging*, USA TODAY (Aug. 7, 2011), <http://usatoday30.usatoday.com/news/health/healthcare/health/healthcare/story/2011/08/Drug-shortages-lead-to-price-gouging/50028148/1> (“Buying from unauthorized dealers can put patients at risk by circulating counterfeit or stolen medications, Alkire says. These drugs also may not have been stored and handled properly, which can render some medications ineffective or even dangerous, he says.”).

<sup>213</sup> Shomon, *supra* note 212.

<sup>214</sup> Kurt Ullman, *Drug Diversion Concerns on the Rise*, RHEUMATOLOGIST (Sept. 2012), [http://www.the-rheumatologist.org/details/article/2543951/Drug\\_Diversion\\_Concerns\\_on\\_the\\_Rise.html](http://www.the-rheumatologist.org/details/article/2543951/Drug_Diversion_Concerns_on_the_Rise.html).

<sup>215</sup> See Boyette, *supra* note 182.

<sup>216</sup> *Id.*

<sup>217</sup> See *Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis*, INST. FOR SAFE MEDICATION PRAC. (Aug. 25, 2011) [hereinafter *Gray Market, Black Heart*], <http://www.ismp.org/newsletters/acutecare/showarticle.asp?id=3>.

## 2. Drug Counterfeiting

The previous section was meant to show that the black and gray markets are not dissimilar, and if the actions of black market traders are viewed as harmful to society, so too should the actions of gray marketers of drugs. In fact, there is convincing evidence indicating that the gray market is in fact becoming more black than gray,<sup>218</sup> given some of the methods that have been used of late in obtaining and distributing drugs.

An activity that is measurably worse than drug diversion is drug counterfeiting. Quoting from the World Health Organization:

In accordance with Black's law dictionary, the term "counterfeit drug" may be used to describe a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original.<sup>219</sup>

The issue with this practice is obvious; if a doctor prescribes a counterfeited drug to a sick patient the drug could at least have no beneficial effect and at worst make the patient sicker or kill them.<sup>220</sup> The best example of harm being done to patients through these counterfeit drugs can be seen in third-world countries, where because of the low prices, these drugs are rampant.<sup>221</sup> The effects in these countries have been devastating;

---

<sup>218</sup> Liang, *supra* note 210, at 287 (discussing the fact that counterfeited drugs go through multiple gray market wholesalers prior to reaching pharmacies).

<sup>219</sup> *General Information on Counterfeit Medicines: Definition*, WORLD HEALTH ORG., <http://www.who.int/medicines/services/counterfeit/overview/en/> (last visited Apr. 15, 2015).

<sup>220</sup> See *General Information on Counterfeit Medicines: Factors Encouraging Counterfeiting of Drugs*, WORLD HEALTH ORG., <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> (last visited Apr. 15, 2015) ("The use of [counterfeit] drugs can prolong treatment periods as patients may not respond as quickly as they should and exacerbate conditions being treated. Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and may have a deleterious effect on a wide section of the population. In extreme cases, counterfeit drugs may even cause death.").

<sup>221</sup> See Amy M. Bunker, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 493, 497 (2007) (discussing the widespread presence of counterfeit drugs in many third-world countries); see also *Tackling Pharmaceutical Counterfeits: Beyond Packaging*, PHARMACEUTICAL-TECHNOLOGY.COM (Sept. 28, 2012), <http://www.pharmaceutical-technology.com/features/featuretackling->

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 425

in fact many have died because of the toxic ingredients contained in some of the drugs.<sup>222</sup> Although the risk of death is notably less within the United States, not all Americans have gone unscathed, as there have been isolated incidents of death across the country.<sup>223</sup>

In any case, the black market is largely responsible for the distribution of these drugs, and the fake drug industry is one of the most lucrative ventures in that they engage.<sup>224</sup> According to a report from the World Health Organization, it was estimated that “sales of counterfeit drugs represent between \$32 billion and \$35 billion annually . . . .”<sup>225</sup> A large portion of the profits no doubt stem from the fact that these drugs are so cheap to manufacture.<sup>226</sup> Indeed, the low cost of these drugs is quite possibly the reason why gray marketers of drugs are beginning to enter the industry.<sup>227</sup>

According to an expert in the field, the gray market is responsible for a large part of the counterfeit drug problem in the United States.<sup>228</sup> The reality is that nearly ten percent of the drugs sold in the U.S. drug market today go through multiple wholesalers before reaching their final destination (i.e. a pharmacy), as opposed to the other ninety percent that typically go through only one wholesaler (i.e. Amerisource Bergen, Cardinal Health, and McKesson Corporation).<sup>229</sup> It is further suggested that because of the various state laws that govern drug distribution, there are plenty of loopholes for gray marketers to slip through and bring these fake drugs into the market.<sup>230</sup> Quoting from Brian Liang: “[t]his highly convoluted gray market

---

pharmaceutical-counterfeits-beyond-packaging.

<sup>222</sup> See, e.g., Bunker, *supra* note 221, at 497 (describing tragic events in Nigeria and Brazil attributed to toxic ingredients in the drugs).

<sup>223</sup> *Id.* at 498.

<sup>224</sup> Nayanah Siva, *Tackling the Booming Trade of Counterfeit Drugs*, 376 LANCET 1725, 1725 (2010), available at [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(10\)62118-6.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(10)62118-6.pdf).

<sup>225</sup> Liang, *supra* note 210, at 285.

<sup>226</sup> *Intellectual Property Theft: Get Real, Counterfeit Drugs, Fake Drugs Are Bad Medicine*, NAT'L CRIME PREVENTION COUNCIL, <http://www.ncpc.org/topics/intellectual-property-theft/counterfeit-drugs-1> (last visited Apr. 15, 2015).

<sup>227</sup> *Id.*

<sup>228</sup> See Liang, *supra* note 210, at 287 (outlining the gray market system in the United States and the problems associated).

<sup>229</sup> *Id.*

<sup>230</sup> *Id.* at 287–88.

allows parties peddling fake drugs to slip their products into the distribution chain, and ultimately, into the patient who buys and takes the tainted medication.”<sup>231</sup> There is no denying that gray market drug suppliers are indeed becoming involved in counterfeit drugs. In fact, in early 2012 a gray marketer was caught and convicted of distributing a counterfeit chemotherapy drug known as Avastin®.<sup>232</sup>

The distribution of counterfeit drugs seems to be yet another reason why gray marketers of drugs should simply be banned from the U.S. drug market. According to one commentator:

Counterfeit, gray, and substandard drugs pose an unequivocal threat to the public health of North Americans. The US Food and Drug Administration (FDA) reports the number of counterfeit drug investigations have grown almost ten-fold in the last five years. Although the Agency estimates that less [than one] percent of drugs on the US market fall into one of these illicit categories, this could still mean that there is as much as a 1-in-100 chance of obtaining an illicit product.<sup>233</sup>

Not only are gray marketers profiteering off the drugs that they sell, but there is not even a guarantee that the drugs are real!<sup>234</sup>

#### IV. THE ETHICALLY & LEGALLY QUESTIONABLE PRACTICE OF PRICE GOUGING BY GRAY MARKET DRUG SUPPLIERS

As demonstrated previously, gray market drug sales are not yet explicitly illegal.<sup>235</sup> Gray market drug suppliers are governed by a veritable hodgepodge of federal and state statutes, thereby making it a relatively simple matter slip through legal loopholes.<sup>236</sup> The legal status of gray marketers is currently in a

---

<sup>231</sup> *Id.* at 288.

<sup>232</sup> Christopher Weaver et al., *Drug Distributor Is Tied to Imports of Fake Avastin*, WALL ST. J. (Mar. 7, 2012, 10:01 AM), <http://www.wsj.com/articles/SB10001424052970203370604577261343974214110>.

<sup>233</sup> BRIAN D. FINLAY, COUNTERFEIT DRUGS AND NATIONAL SECURITY 10 (Stimson Ctr. 2011), *available at* [http://www.stimson.org/images/uploads/research-pdfs/Full\\_-\\_Counterfeit\\_Drugs\\_and\\_National\\_Security.pdf](http://www.stimson.org/images/uploads/research-pdfs/Full_-_Counterfeit_Drugs_and_National_Security.pdf).

<sup>234</sup> *Id.*

<sup>235</sup> See Jason Kane, *Drug Prices Soar as Hospital Suppliers are Forced into 'Gray Market'*, PBS NEWSHOUR (Aug. 29, 2011, 5:18 PM), <http://www.pbs.org/newshour/rundown/drug-prices-soar-as-pharmacists-are-forced-into-gray-market/>.

<sup>236</sup> Anna Yukhananov, *'Fake Pharmacies' Tied to Drug Shortages in United States*, GLOBE & MAIL (Mar. 21, 2012, 1:01 PM), <http://www.theglobeandmail.com>

state of limbo such that their activities appear illicit but not necessarily illegal. This section will explore some of these operations in some more detail and will identify the double standards in state and federal law with respect to price gouging.

A. *Price Gouging: What is it?*

The next highly negative aspect of the gray market involves price gouging. Gray market drug suppliers are able to corner the market for drugs that are in short supply; this allows them to charge virtually any price that they see fit for the drugs.<sup>237</sup> This section of the article will look at the history of price gouging, the reasoning for prohibiting it in other cases, and the application of these reasons to the sale of prescription drugs.

Price gouging put succinctly is something vendors do when they find that there is particularly high demand for their product and that people's willingness to pay is as high as their demand.<sup>238</sup> Put into economic terms, price gouging occurs when vendors perceive that they have market power (i.e., in the form of an oligopoly). The U.S. government defines price gouging as follows: "[p]rice gouging occurs when a business charges more for goods or services than the regular selling price. Some businesses may practice price gouging during times of emergency, such as natural disasters."<sup>239</sup> Take for example the sale of gas during the Hurricane Sandy disaster in New York. During the hurricane, multiple refineries on the Jersey Shore were damaged, thereby placing a severe strain on the supply of gas in the area.<sup>240</sup> New

---

mail.com/life/health-and-fitness/fake-pharmacies-tied-to-drug-shortages-in-united-states/article535044 ("The findings illuminate gaps in the patchwork of state legislation that governs this sometimes shady network of pharmaceutical distribution known as the 'grey market' . . . [a]nd state officials are sometimes a step behind new scams – hobbled by tight budgets, slow bureaucracies and inefficient communication with fellow regulators in other jurisdictions.").

<sup>237</sup> See *id.*

<sup>238</sup> *Price Gouging*, FUNDAMENTALFINANCE.COM, <http://economics.fundamentalfinance.com/price-gouging.php> (last visited Apr. 15, 2015).

<sup>239</sup> *Price Gouging*, CIVIC AGENCY, <http://www.usa-faq.civicagency.org/answers/10259> (last updated Nov. 11, 2011).

<sup>240</sup> See Agustino Fontevicchia, *Gasoline Futures Spike But Prices at the Pump Hold Steady as East Coast Refineries Remain Offline*, FORBES (Oct. 31, 2012, 2:41 PM), <http://www.forbes.com/sites/afontevicchia/2012/10/31/hurricane-sandy-splits-energy-markets-as-gasoline-spikes-on-refinery-outages> (discussing the destruction of refineries); see also Winnie Hu, *New York City Will Keep Gas Rationing Until Week's End*, N.Y. TIMES, Nov. 18, 2012,

York State has laws that prevent price gouging during emergencies.<sup>241</sup> Despite these laws, many gas stations in the area raised the prices of their gasoline, engaging in what could have been construed as price gouging.<sup>242</sup> While the given example focuses strictly on a natural disaster, any event or series of events that places a strain on the market for a good or service can lead to price gouging.

*B. Price Markups/Gouging  
in the Secondary Drug Market*

Price gouging occurs in the secondary drug market on a regular basis, as gray market suppliers routinely charge exorbitant prices for their wares.<sup>243</sup> The magnitude of these price hikes is in fact quite shocking. First, as was just seen, price gouging in gasoline sales routinely follows some form of natural disaster that places a stricture on the supply of fuel.<sup>244</sup> The situation that sets the scene for price gouging in the secondary drug market is slightly different, in that it is largely ‘man-made.’<sup>245</sup> The strain on the market therefore comes from drug manufacturers either ceasing or reducing production of a drug.<sup>246</sup> In the case of many short-supply drugs, the factor that allows the gray marketers to charge such high prices is that the drugs are lifesaving, and without them, patients will die.<sup>247</sup> In light of the

---

<http://www.nytimes.com/2012/11/19/nyregion/new-york-to-extend-gas-rationing-through-friday.html>.

<sup>241</sup> N.Y. GEN. BUS. LAW § 396-r (McKinney 2014).

<sup>242</sup> *Consumers Complain of Post-Sandy Price Gouging at Many Area Gas Stations*, CBS N.Y. (Nov. 7, 2012, 6:10 PM), <http://newyork.cbslocal.com/2012/11/07/consumers-complain-of-post-sandy-price-gouging-at-many-area-gas-stations>.

<sup>243</sup> See generally Erin R. Fox et al., *ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems*, 66 AM. J. HEALTH-SYST. PHARM. 1399, 1401 (2009), available at [http://www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP\\_shortage\\_guide09.pdf](http://www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP_shortage_guide09.pdf) (indicating that exorbitant prices are being charged for shortage drugs by nontraditional distributors).

<sup>244</sup> *Price Gouging*, *supra* note 239.

<sup>245</sup> See Erin R. Fox et al., *supra* note 243, at 1400–01.

<sup>246</sup> See DRUG SHORTAGES SUMMIT REPORT, *supra* note 42, at 5 (discussing drug production stoppages and shortages).

<sup>247</sup> See generally Ken Alltucker, *U.S. Facing Cancer-Drug Shortage: Ariz. Doctors Rationing Supplies; FDA Allowing India Imports*, ARIZ. REPUBLIC (Feb. 22, 2012, 11:40 PM), <http://www.azcentral.com/business/articles/2012/02/22/20120222us-facing-cancer-drug-shortage.html> (stating that the reason why high prices for drugs have been tolerated is that these drugs are lifesaving).

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 429

high level of necessity associated with receiving these drugs, patients' willingness to pay is much greater than it otherwise would be.

To put the scale price gouging on the drug market into perspective, the gasoline example is an effective baseline. The New Jersey price gouging statute says:

"Excessive price increase" means a price that is excessive as compared to the price at which the consumer good or service was sold or offered for sale by the seller in the usual course of business immediately prior to the state of emergency. A price shall be deemed excessive if: (1) The price exceeds by more than 10 percent the price at which the good or service was sold or offered for sale by the seller in the usual course of business immediately prior to the state of emergency . . . .<sup>248</sup>

Taking this analogy further, the average gas price in Trenton, New Jersey prior to Hurricane Sandy was approximately \$3.72.<sup>249</sup> Noting that the law specifies that more than ten percent of the pre-disaster price is considered price gouging, a price of \$4.10 would technically be considered price gouging (a \$0.38 increase).<sup>250</sup> Given a fifteen-gallon tank of gas, this translates into a \$6.00 increase per tank. For New Jersey, this price is considered exorbitant and unfair and violations of the law are met with harsh penalties. In fact, in the wake of Hurricane Irene a New Jersey gas station caught increasing its prices more than the allowed ten percent was fined \$50,000.<sup>251</sup>

Given the current lack of legislation dealing with price gouging on the drug market, the reader might be led to believe that the price increases are simply not as bad. Shockingly, this is not the case. In fact the price increases seen in the drug market are far greater than those seen with gasoline sales.<sup>252</sup> Drug markups by

---

<sup>248</sup> N.J. STAT. ANN. § 56:8-108 (West 2014).

<sup>249</sup> Eliot Caroom, *Gas Prices Down in N.J. as Hurricane Sandy Approaches*, STAR-LEDGER, Oct. 26, 2012, [http://www.nj.com/news/index.ssf/2012/10/gas\\_prices\\_down\\_in\\_nj\\_as\\_hurri.html](http://www.nj.com/news/index.ssf/2012/10/gas_prices_down_in_nj_as_hurri.html).

<sup>250</sup> N.J. STAT. ANN. § 56:8-108.

<sup>251</sup> See John Carney, *Is Price Gouging Reverse Looting?*, CNBC (Oct. 31, 2012, 3:40 PM), <http://www.cnbc.com/id/49622944> (discussing the exorbitant price increases following Hurricane Sandy).

<sup>252</sup> Compare SHINING LIGHT ON THE "GRAY MARKET," *supra* note 100, at 11–13 (stating that drug prices have increased enormously), with Alan Neuhauser, *Gas Prices on the Rise, But No Need For Alarm*, U.S. NEWS & WORLD REP. (Feb. 2, 2015, 4:40 PM), <http://www.usnews.com/news/blogs/data-mine/2015/02/02/gas-prices-on-the-rise-but-no-need-for-alarm> (stating that gas prices have been

gray marketers are in fact rarely small.<sup>253</sup> As was just demonstrated, New Jersey considers a ten percent increase in price to be exorbitant, but in the secondary drug market price increases of several thousand percent are seen regularly!<sup>254</sup> A 2011 survey of health care providers regarding drug shortages found the following:

[T]he recent Premier survey . . . identified an average mark-up of 650% from the contract price, with higher mark-ups for some critical care drugs, oncology drugs, and anesthetics. For example, those who responded to the Premier survey reported more than a 4,000% mark-up for labetalol and more than a 3,000% mark-up for cytarabine, dexamethasone injection, leucovorin, and propofol during April 2011. . . . Our survey respondents also provided examples of exorbitant mark-ups when purchasing products from the gray market during the past 2 years, including . . . a supply of propofol that cost \$25,000 instead of \$1,500 (1,567% mark-up).<sup>255</sup>

The drug prices in the secondary market show no signs of slowing their upward climb.<sup>256</sup> Given the magnitude of the price increases, coupled with the fact that consumer willingness to pay stems from individual health emergencies, there is no denying that what the gray market is doing is indeed price gouging.<sup>257</sup> Granted, the value of lifesaving drugs is greater than gasoline, but prices over *one-thousand* times the normal price are simply unreasonable.<sup>258</sup> The question therefore becomes why, if there are strict laws against minor price gouging in non-lifesaving situations, are states not making an effort to control price gouging in the drug market?

---

falling for a substantial period of time).

<sup>253</sup> *Gray Market, Black Heart*, *supra* note 217.

<sup>254</sup> *See id.* (providing an example where hospitals and community hospitals reported a 4000 percent markup).

<sup>255</sup> *Id.*

<sup>256</sup> *See id.* (noting that the study occurred over a two year period, implicitly indicating that there was no decrease in price).

<sup>257</sup> *See* Bruce Buckley, *Price Gouging: A Black Mark On Gray-Market Distributors*, 39 PHARMACY PRAC. NEWS (Oct. 2012), *available at* [http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Policy&d\\_id=51&i=October+2012&i\\_id=894&a\\_id=21937](http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Policy&d_id=51&i=October+2012&i_id=894&a_id=21937) (discussing an example where a hospital consumer had no choice but to pay for the exorbitantly priced drugs).

<sup>258</sup> *See id.* (“We know these secondary wholesalers are not buying it for prices that our big wholesalers pay,” he said, but he questioned why prices were “30, 40, 50 times more than our acquisition costs.”) (quoting Dr. David Mayhaus, Chief Pharmacy Dir., Cincinnati Children’s Hosp. Med. Ctr.).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 431****1. Price Gouging Laws on the State Level**

States have seemingly ignored price gouging in the secondary drug market in their laws addressing price gouging. The laws that exist focus only on the price gouging that occurs in the wake of a natural disaster or other emergency. This section will look at the laws in some more detail, and will discuss any progress that has been made toward ending drug price gouging. This will include some analysis of proposals that are currently passing through legislative bodies.

At this point thirty-four states and the District of Columbia have passed laws specifically directed at preventing price gouging.<sup>259</sup> Clear common threads run through all of them:<sup>260</sup> nearly every anti-price gouging law requires an officially declared state of emergency in order to be applicable to whatever industry is being regulated.<sup>261</sup> Furthermore, the majority of the laws apply to sales of petroleum and little else.<sup>262</sup> Since most price gouging laws require that a state of emergency be declared before they apply, and since no such emergency exists when drug shortages occur, these statutes cannot be applied to the drug market.<sup>263</sup> Two notable exceptions to the general pattern of price gouging laws come out of Maine and Michigan.<sup>264</sup> The Maine Statute says:

Whenever it appears upon due inquiry and consultation with the Attorney General that an abnormal market disruption exists or that there is a substantial likelihood that an abnormal market disruption is imminent, the Governor may, in the Governor's sole discretion and after considering whether the declaration of an abnormal market disruption itself will disrupt supplies for affected necessities, declare an abnormal market disruption.<sup>265</sup>

The use of the term "abnormal market disruption" leaves the statute far more open ended than others that can apply only in a

---

<sup>259</sup> Michael Giberson, *List of Anti-Price Gouging Laws*, KNOWLEDGE PROBLEM (Nov. 3, 2012), <http://knowledgeproblem.com/2012/11/03/list-of-price-gouging-laws>.

<sup>260</sup> See generally AM. BAR ASS'N, SUMMARY OF STATE "PRICE GOUGING" STATUTES AND REGULATIONS 1-4 (2006), available at <http://apps.americanbar.org/antitrust/at-committees/at-fe/pdf/programs/spring-06/price-gouging-statutes.pdf> [hereinafter SUMMARY OF STATE "PRICE GOUGING"] (listing the various state law prohibitions on price gouging during states of emergency).

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

<sup>264</sup> *Id.* at 3.

<sup>265</sup> ME. REV. STAT. ANN. tit.10, § 1105 (West 2014).

state of emergency.<sup>266</sup> Furthermore, the Maine statute applies to necessities: “food for human or animal consumption; pharmaceutical products, including prescription medications; wearing apparel; shoes; building materials; gas and electricity for light, heat and power; ice; fuel of all kinds . . . .”<sup>267</sup> Maine’s price gouging law is among those more recently passed; that fact might account for the legislature’s recognition of a price gouging problem in the secondary drug market.<sup>268</sup> Although several state price gouging laws were passed after the Maine law, none address overpriced pharmaceuticals in a similar manner.<sup>269</sup>

Two other state’s anti-price gouging laws do contain references to pharmaceuticals but again, the laws only apply during a declared state of emergency or disaster.<sup>270</sup> Although this is better than nothing, it does not adequately address the problem. Michigan’s price gouging law is slightly better than others in that it is more open-ended and allows more price hikes to be considered price gouging. Its law is worded as follows: “[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful and are defined as follows: . . . Charging the consumer a price that is grossly in excess of the price at which similar property or services are sold.”<sup>271</sup> In any case, the majority of current state price gouging laws are inadequate for the purposes of controlling price gouging in the secondary drug market.<sup>272</sup> Most of the laws are worded in a way that precludes application to drug prices, and are therefore an ineffective means of addressing the problem.<sup>273</sup> As one author so astutely puts it, “Maine currently has [the] strictest form of price controls on prescription drugs, yet even there, the exact legal definition of price-gouging remains ambiguous—a logistical

---

<sup>266</sup> *Id.*; see also Justin Schuster, *America’s Drug Problem*, POLITIC (Feb. 11, 2013), <http://thepolitic.org/price-gouging-and-the-prescription-drug-gray-market> (indicating that Maine has the most expansive anti-price-gouging statute in the nation).

<sup>267</sup> ME. REV. STAT. ANN. tit.10, § 1105 (emphasis added).

<sup>268</sup> *Id.*

<sup>269</sup> See D.C. CODE § 28-4102 (2014) (failing to specify pharmaceuticals); see also R.I. GEN. LAWS ANN. § 30-15-9 (West 2014); OR. REV. STAT. ANN. § 401.960 (West 2014).

<sup>270</sup> See IDAHO CODE ANN. § 48-603 (West 2014); R.I. GEN. LAWS ANN. § 30-15-9.

<sup>271</sup> MICH. COMP. LAWS ANN. § 445.903 (West 2014).

<sup>272</sup> Schuster, *supra* note 266.

<sup>273</sup> *Id.*

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 433

nightmare when it comes to prosecuting exorbitant prices. Crafting a national definition for price gouging is a daunting endeavor . . . .”<sup>274</sup> Such then is the situation at the state level.

## 2. Price Gouging Laws on the Federal Level

Despite the presence of multiple state statutes dealing with price gouging, no such law has been passed at the federal level.<sup>275</sup> In 2007, a bill was introduced in the House of Representatives that was aimed at preventing post natural disaster price gouging.<sup>276</sup> The bill however was not passed.<sup>277</sup> It was later reintroduced in 2009, where it again died before reaching the Senate.<sup>278</sup> It appears however, that the price gouging issue in the drug market is gaining recognition in Washington as a bill was introduced in 2012 that dealt specifically with it.<sup>279</sup> This bill will be discussed in the following section.

### *C. Should Markups on Drugs in Short Supply be Considered Price Gouging and Made Illegal?*

As noted, the current price gouging laws largely do not apply to gray market price gouging.<sup>280</sup> This represents a severe problem in the U.S. health care system, especially at a time when patient access to care is a primary focus in healthcare reform.<sup>281</sup> While making a profit from one’s sales is an important part of the capitalist ideal, the gray market takes this concept too far.<sup>282</sup>

In September 2012, Senator Charles Schumer (D-N.Y.) introduced a bill that would make price gouging in the secondary

---

<sup>274</sup> *Id.*

<sup>275</sup> *Id.*

<sup>276</sup> Federal Price Gouging Prevention Act, H.R. 1252, 110th Cong. (2007).

<sup>277</sup> *H.R. 1252 (110<sup>th</sup>): Federal Price Gouging Prevention Act*, GOVTRACK.US, <http://www.govtrack.us/congress/bills/110/hr1252> (last visited Apr. 15, 2015).

<sup>278</sup> *H.R. 2129 (111<sup>th</sup>): Federal Price Gouging Prevention Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/111/hr2129> (last visited Apr. 15, 2015).

<sup>279</sup> See discussion *infra* Part IV.C.

<sup>280</sup> See *supra* note 263 and accompanying text.

<sup>281</sup> See Andis Robeznieks, *Doctors, Over-Extended, Worried About Patient Access, New Study Finds*, MOD. HEALTHCARE (Sept. 16, 2014), <http://www.modernhealthcare.com/article/20140916/NEWS/309169963>.

<sup>282</sup> See Taryn Tawoda, *Anesthesia Shortage Led to 7 Patient Deaths, ASA Survey Says*, ASC REV. (Apr. 17, 2012), <http://www.beckersasc.com/anesthesia/anesthesia-shortage-led-to-7-patient-deaths-asa-survey-says.html> (indicating that multiple patients have lost their lives because of the drug shortage).

drug market a federal crime.<sup>283</sup> According to GovTrack.us, however, the actual bill died after being referred to the Committee on Health, Education, Labor, and Pensions.<sup>284</sup> While this implies a setback, the bill's sponsors are not precluded from reintroducing it in a different form, and in this situation, that could very well occur.

According to the bill, if a shortage is recognized, the President would have the authority to declare that such a shortage exists, and that will essentially activate the law.<sup>285</sup> Once such a shortage has been declared it will be illegal for anyone to sell the drug at an excessive price.<sup>286</sup> The bill states in relevant part:

If the President issues an Executive order under paragraph (1), it shall be unlawful for any person to sell vital drugs at a price that is unreasonably excessive and indicates that the seller is taking unfair advantage of the circumstances related to a market shortage to unreasonably increase prices during such period.<sup>287</sup>

If this bill were reintroduced and enacted, it would effectively cripple the gray market for drugs, as these suppliers would no longer have an incentive to continue their operations. One can only hope that an updated version of the bill is reintroduced in the near future, as without federal legislation, price gouging in the drug market will undoubtedly continue to occur.

Even in a free-market economy, charging a premium on life-saving goods to patients who would be terminally ill without them, is ethically questionable.<sup>288</sup> Many writers have pontificated on this matter; where they come down on the issue typically depends on their political and economic leanings.<sup>289</sup> Writers fall into two camps; one argues that price gouging should be illegal because access to drugs should be more of a right than a privilege.<sup>290</sup> The second views any price controls seeking to

---

<sup>283</sup> Protecting Patients and Hospitals From Price Gouging Act, S. 3622, 112th Cong. (2012)

<sup>284</sup> S. 3622 (112<sup>th</sup>): *Protecting Patients and Hospitals From Price Gouging Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/112/s3622> (last visited Apr. 15, 2015).

<sup>285</sup> See S. 3622 § 4(a)(1).

<sup>286</sup> *Id.* § 4(a)(2).

<sup>287</sup> *Id.*

<sup>288</sup> Ian Maitland, *Priceless Goods: How Should Life-Saving Drugs Be Priced?*, 12 BUS. ETHICS Q. 451, 455–56 (2002).

<sup>289</sup> See Carney, *supra* note 251 (providing an example of a writer discussing how political views and views on free-markets steer opinions on price gouging).

<sup>290</sup> See Maitland, *supra* note 288, at 460 (discussing where the responsibility

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 435

eliminate price gouging as an unnecessary governmental control of the free market economy.<sup>291</sup> The majority of arguments against regulating price gouging, however, are focused on the drug manufacturers themselves and typically indicate that when manufacturers are free to set prices innovation and new drug research is stimulated.<sup>292</sup> This Article does not argue the validity of this point; concededly if price regulation of drug manufacturing were to occur it could undoubtedly have negative effects on the innovation of life-saving drugs. In fact, regulating the manufacturers themselves would likely serve to exacerbate the shortages that cause price-gouging in the first place. As is indicated here:

Price controls notoriously create shortages because they take away incentives to invest in producing more of an existing product and/or in developing new products. As surely as rent control leads to shortages of rental units and price controls on gasoline lead to long lines of cars at the pumps, so price controls on drugs will slow the development of new drugs.<sup>293</sup>

The question then becomes, what deleterious effects could prohibiting price gouging on the part of gray market middlemen have on the drug market? In reality these drug suppliers add no value at all to the drugs that they sell nor do the high prices they receive serve to stimulate innovative behavior on the part of manufacturers. Therefore, there does not seem to be any argument against regulating the prices that they charge. In other words, if the free market nature of the transaction is not imparting a benefit to society, but rather is harming it, the ethics of gray market price gouging become highly suspect.<sup>294</sup> In essence gray market price gouging is on the same level as the gas station proprietor that charges extra for gas after a devastating storm. Neither practice rewards innovation nor reimburses costs of creating a benefit to consumers; rather, both line the pockets of the business owners.

---

for drug availability falls under the assumption that access to needed drugs is a right).

<sup>291</sup> *Id.* at 471.

<sup>292</sup> *See id.* (suggesting that the incentive of profitability facilitates the productivity of the market to create required medicines).

<sup>293</sup> *Id.* at 458.

<sup>294</sup> *See generally id.* (arguing that companies should be left alone to charge market prices since drug makers are under pressure to reasonably price medicines).

Lawmakers across the U.S. have recognized that allowing suppliers of everyday goods to profit from a state of emergency is objectionable.<sup>295</sup> Indeed there is some evidence that lawmakers are expanding the scope of current regulation to apply to the medical industry.<sup>296</sup> For example, a San Francisco based hospital-owner was caught overcharging uninsured patients for services rendered, but settled before the case could go to trial.<sup>297</sup> According to an article documenting the price gouging, “[t]he suit claimed that the San Francisco-based healthcare provider . . . routinely charged uninsured patients as much as five times the amount paid by private insurers and government programs for the same services.”<sup>298</sup> Similar cases against pharmaceutical companies also exist.<sup>299</sup> These cases were not brought based on statutes specifically targeting price gouging, rather they were typically brought based on Consumer Fraud and Deceptive Practices statutes.<sup>300</sup> In any case, given the attention that is being paid to price gouging in other areas both inside and outside of the healthcare industry, the lack of legislative action focusing on gray-market price-gouging is somewhat confusing.

As can be seen, there is a clear double standard in state laws dealing with price gouging. The purpose of price gouging laws is to eliminate unethical price hikes during emergencies, but states have seemingly ignored the drug industry where the price hikes

---

<sup>295</sup> See Giberson, *supra* note 259 (listing states that have enacted anti-price-gouging statutes).

<sup>296</sup> See Michael Giberson, *The Problem with Price Gouging Laws*, 34 REG. 1, 48, 50 (2011) available at <http://object.cato.org/sites/cato.org/files/serials/files/regulation/2011/4/regv34n1-1.pdf> (indicating that California for example has put a law in place which prohibits charging more than ten percent higher than pre-declared state of emergency price for goods and services including medical supplies).

<sup>297</sup> Associated Press, *Hospital Firm to Settle Lawsuit*, L.A. TIMES, June 16, 2006, <http://articles.latimes.com/2006/jun/16/business/fi-catholic16>.

<sup>298</sup> *Id.*

<sup>299</sup> See, e.g., *Clark v. TAP Pharm. Prods., Inc.*, 798 N.E.2d 123, 126 (Ill. App. Ct. 2003) (discussing the suit of a pharmaceutical company for overcharging people for a drug).

<sup>300</sup> See *id.* (explaining that plaintiff in this case alleged that a fraudulent marketing and sales tactic which resulted in himself and many others overpaying for a prescription drug used to treat prostate cancer was a violation of Illinois’s Consumer Fraud and Deceptive Business Practices Act). See generally 815 ILL. COMP. STAT. 505/1 (West 2014) (setting forth protections of consumers against fraud and unfair competition).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 437**

are greatest and the emergency is the life or death of the patients.<sup>301</sup> It is clear is that if the ability to price gouge were taken away from gray marketers, a large part of drug shortage crisis could be rectified as gray marketers would no longer have the ability to exacerbate drug shortages.

V. POTENTIAL SOLUTIONS TO THE DRUG SHORTAGE  
PROBLEM & THE GRAY MARKET

This section deals with some of the means that for addressing the root causes of the drug shortage. Eliminating the root cause of drug shortages may eliminate gray market suppliers. Primarily these means will be the following: 1) reforming the FDA drug approval process; 2) continuing to develop failsafe methods of ensuring that the FDA has forewarning of shortages; 3) incentivizing manufacturers to continue producing generics; and 4) increasing the amount Medicare and Medicaid pay for generics. Lastly, and most importantly, this section will consider the means of addressing the gray market's exacerbation of drug shortages.

A. *FDA Reform—In Terms of Reducing the Time  
it takes to Approve New Drugs*

The FDA has played a significant part in the drug shortage crisis.<sup>302</sup> If the FDA approach to drug approval was reformed, it might limit the ability of gray marketers to peddle drugs as it would serve to eliminate a primary cause of drug shortages themselves. The FDA's extensive vetting process for new drugs makes it extraordinarily difficult for new drugs to enter the market.<sup>303</sup> Aside from the hoops it forces manufacturers to jump through to get new drugs onto the market, the FDA has sought to redouble its efforts to find drug manufacturers who are noncompliant with relatively obscure laws and force them to comply.<sup>304</sup> According to a 2012 House of Representatives report,

---

<sup>301</sup> See Associated Press, *Hospital Drug Shortages Deadly, Costly*, ATHENS BANNER-HERALD, Sept. 23, 2011, [http://onlineathens.com/stories/092311/bre\\_889515423.shtml](http://onlineathens.com/stories/092311/bre_889515423.shtml) (indicating that only three states have enacted laws which are specific to price-gouging involving medicine).

<sup>302</sup> See discussion *supra* Part I.B.

<sup>303</sup> See discussion *supra* Part I.B.

<sup>304</sup> See SHINING LIGHT ON THE "GRAY MARKET," *supra* note 100, at 16 (explaining that the number of warning letters sent by the FDA to

in a large majority of cases, once these manufacturers receive letters from the FDA informing them of their failure to comply and instructing them to remedy the noncompliance, they are forced to reduce production or cease production altogether.<sup>305</sup> In addition, not only has the FDA sent these letters to hundreds of manufacturers, but the agency has sent them all out virtually at the same time.<sup>306</sup> This, as would be expected, has led to widespread production decreases of generic sterile injectables, and it is maintained that such action is one of the primary causes of the drug shortage crisis.<sup>307</sup> According to the House Committee on Oversight and Government Reform:

[T]he number of drugs in shortage that are produced in at least one facility undergoing remediation efforts has grown. Of the 219 drugs listed on the ASHSP shortage list as of February 21, 2012, at least 128 (58% of all drugs on the shortage list) were being produced by at least one facility undergoing FDA remediation.<sup>308</sup>

Facts like these make it hard to argue that the FDA's stringent standards are not a large part of the current drug shortage crisis.

#### 1. FDA Regulatory Changes

What things might be done to ensure that the FDA itself is not contributing to the problem? The first thing would be to reduce the amount of time it takes for a drug to get approved, that in turn would allow substitutes for short-supply drugs to be produced and put on the market faster. In 1992, the FDA came out with what is referred to as the Accelerated Approval Program.<sup>309</sup> This program was intended to expedite the approval of drugs that served to provide a treatment benefit to patients that existing medications either failed to provide or failed to

---

manufacturers has increased).

<sup>305</sup> *Id.*

<sup>306</sup> *See id.* (indicating that that in one year alone the amount of letters sent increased by 42 percent, and that “[a]s a result of the FDA’s intensified inspection and compliance efforts to ‘facilitate prompt corrective action,’ four of America’s five largest manufacturers of generic injectable products have taken unprecedented and *simultaneous* remediation efforts”).

<sup>307</sup> *Id.* at 18.

<sup>308</sup> *Id.*

<sup>309</sup> *Transcript: Accelerated Approval Program Video*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm313852.htm> (last updated Aug. 1, 2012).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 439**

provide as well.<sup>310</sup> Experts in the field (primarily legislative officials) are seeking to have this process applied to drugs in short-supply that may allow acceptable alternatives to be introduced to the market prior to the occurrence of a shortage.<sup>311</sup>

Addressing the stringent regulatory inspections and compliance requirements requires only a common sense approach. Two possible solutions come immediately to mind to prevent compliance proceedings from causing drug shortages. The first is to stagger compliance proceedings such that major drug suppliers are not all forced to decrease drug production at the same time. In other words, rather requiring the whole manufacturing community to comply with standards at the same time, they could implement the new requirements in waves. This approach would be valuable in cases where the drugs, as they currently existed, were not threatening the lives of patients. Using something like this would prevent an entire industry of drug producers from ceasing the production of a drug, and would thereby mitigate if not prevent some shortages. According to a 2012 House of Representatives report:

One obvious question that FDA should answer is why nearly all of America's major producers of generic injectable medications were essentially required to remediate facilities at the same time. It was this simultaneous remediation that reduced available capacity at these facilities by 30% relative to capacity in 2009. For facilities with genuine manufacturing problems, it would have been more prudent to focus on directing facilities to make targeted improvements under close supervision of the FDA. Such a targeted approach would have significantly diminished the public health crisis the country is facing from the abundant number of drug shortages.<sup>312</sup>

Clearly, addressing the inefficiencies with the regulatory process would have positive implications for reducing the number of avoidable drug shortages.

The second option is to 'expedite' regulatory proceedings. In

---

<sup>310</sup> See *id.* (explaining that unmet medical needs arises where no therapy exists, or where a less toxic therapy is sought; for these unmet needs acceleration of approval is warranted).

<sup>311</sup> See *Fact Sheet: Drug Products in Shortage in the United States*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/ucm313121.htm> (last updated July 23, 2012) (discussing legislation aimed towards proactively preventing drug shortages).

<sup>312</sup> SHINING LIGHT ON THE "GRAY MARKET," *supra* note 100, at 18.

2011, President Obama issued Executive Order number 13,588.<sup>313</sup> This executive order was issued as a presidential response to the drug shortage crisis. In the order, the President instructs the FDA to:

[E]xpand its current efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes, whenever it determines that expedited review would help to avoid or mitigate existing or potential drug shortages. In prioritizing and allocating its limited resources, the FDA should consider both the severity of the shortage and the importance of the affected drug to public health.<sup>314</sup>

Presumably increasing the speed with that regulatory proceedings occur would allow manufacturers to get back on track with production much more quickly. This would limit the time production of a short supply drug had to stop, and would hopefully mitigate the shortage in the long run.

## 2. The Hatch-Waxman Act

Another area that experts point to as a means of decreasing the occurrence of drug shortages is The Hatch-Waxman Act,<sup>315</sup> which regulates the approval process for generic drugs.<sup>316</sup> The Hatch-Waxman Act served to establish what is known as the Abbreviated New Drug Application.<sup>317</sup> With these applications, “[g]eneric drug applications are termed ‘abbreviated’ because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. . . . [i]nstead, generic applicants must scientifically

---

<sup>313</sup> Reducing Prescription Drug Shortages, 76 Fed. Reg. 68295 (Oct. 31, 2011).

<sup>314</sup> *Id.* at 68296.

<sup>315</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (West, Westlaw through P.L. 113-296 approved 12/19/2014)).

<sup>316</sup> *Id.* §§ 101–04, 98 Stat. at 1585–97; *see also* Bruce A. Chabner, *Drug Shortages—A Critical Challenge for the Generic-Drug Market*, 365 NEW ENG. J. MED. 2147, 2148 (2011), *available at* <http://www.nejm.org/doi/pdf/10.1056/NEJMp1112633> (discussing the role of the Hatch-Waxman Act in the generic-drug industry).

<sup>317</sup> *See Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics> (last visited Apr. 15, 2015) (explaining that the Hatch-Waxman Act permits the FDA to give approval for generic drugs sans clinical trials).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 441**

demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).<sup>318</sup> Once these applications are approved, the manufacturer is free to begin selling the drugs on the market. What inevitably happens once the drugs reach the market is that they take away market share from the brand name drug on which the generic was based (because of the lower prices). Obviously, once demand for the brand name drug decreases, the brand name manufacturer will slow production to match the decreased demand. This is where the shortage problem begins. If the generic drug producer does not anticipate demand for the new drug appropriately, or reduces production because of cost, a shortage will develop. One of the major problems with generics is that oftentimes the cost of production is greater than the profits realized.<sup>319</sup> For this reason, after a time, many suppliers of generics tend to either produce less of the drugs or stop producing them altogether.<sup>320</sup>

Amendments to the Hatch Waxman Act have been proposed that would curb this sort of occurrence.<sup>321</sup> A possible solution to this problem would be to force generic drug applicants to forecast the demand for their drug prior to approval and establish a means for satisfying that demand.<sup>322</sup> In addition, an incentive plan would be established whereby producers who actually met the demand effectively would be given preferential treatment on their next Abbreviated New Drug Application.<sup>323</sup> If such a program was established, and was to work effectively, it would eliminate the occurrence of some of the generic drug shortages that occur.

*B. Increasing Medicare Payments  
for Generic Drugs*

The Medicare Modernization Act (MMA)<sup>324</sup> has also contributed

---

<sup>318</sup> *Id.*

<sup>319</sup> See DRUG SHORTAGE CRISIS, *supra* note 33, at 4 (“[T]he Committee has learned that manufacturers are losing money producing generic injectable oncology drugs.”).

<sup>320</sup> See *id.*

<sup>321</sup> See Chabner, *supra* note 316, at 2149 (stating that amendments have been proposed to the Hatch-Waxman Act).

<sup>322</sup> See *id.* (discussing projections of drug demand and plans for meeting the demand).

<sup>323</sup> *Id.*

<sup>324</sup> Medicare Prescription Drug, Improvement, and Modernization Act of

to drug shortages because it decreases the prices Medicare recipients pay for drugs and thereby decreases the incentive for manufacturers to produce them:<sup>325</sup>

By reducing profit margins and establishing a fixed percent mark-up, the new payment system implicitly favors high cost brand name drugs over generics. As physicians switch towards higher cost drugs, manufacturers may respond by sacrificing the production of cheaper generic drugs in favor of more lucrative options, thereby causing generic drug shortages.<sup>326</sup>

Prior to the institution of the MMA, providers were reimbursed for the drugs they prescribed on an Average Wholesale Price basis.<sup>327</sup> This system essentially amounted to a retrospective payment system and allowed for exorbitant fees to be charged to Medicare.<sup>328</sup> Because of these costs, the MMA instituted a new payment system based on the Average Selling Price that greatly reduced the amount Medicare paid out for drug sales.<sup>329</sup> This change decreased payments so much that it served to disincentivize the production of some generics altogether, thereby leading to the drug shortages that are seen today.<sup>330</sup>

In light of this, in order to effectively prevent the negative effects that Medicare is having on generic drug production, it would seem that the payment system needs to be altered in a way that would not only prevent overcharging, but would also prevent undercharging. One way to do this would be to eliminate the Average Selling Price (ASP) method altogether and put a system in place that allows producers to make a profit that is within reason. If the payment system does not allow for a profit,

---

2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

<sup>325</sup> See DRUG SHORTAGE CRISIS, *supra* note 33, at 4 (discussing how the MMA has decreased the prices that Medicare recipients pay for drugs, causing manufacturers to lose money).

<sup>326</sup> Mireille Jacobson et al., *Prescription Drug Shortages: Reconsidering the Role of Medicare Payment Policies*, HEALTH AFFAIRS BLOG (May 29, 2012), <http://healthaffairs.org/blog/2012/05/29/prescription-drug-shortages-reconsidering-the-role-of-medicare-payment-policies>.

<sup>327</sup> Kathryn Nix, *How Medicare Price Controls Have Contributed to Drug Shortages*, HERITAGE FOUND. (Dec. 21, 2011), <http://www.heritage.org/research/reports/2011/12/how-medicare-price-controls-have-contributed-to-drug-shortages>.

<sup>328</sup> See *id.* (stating that the average wholesale price increased, which is the price that Medicare payments were based on).

<sup>329</sup> *Id.*

<sup>330</sup> *Id.*

producers will have no incentive to produce the drugs, and Medicare will continue to lead to drug shortages.

*C. Curbing the Operational Ability of  
Gray Market Suppliers*

Of primary importance to this discussion are the contributions the gray market has made to the drug shortage crisis. In a drug shortage, gray marketers are able to buy up supplies that they hoard until they can charge an exorbitant price.<sup>331</sup> In many cases these actions make treatment for the terminally ill nearly impossible.<sup>332</sup> If it were not for these parallel market companies, short-supply drugs could be more effectively rationed, thereby mitigating the effects of the shortages on patients to an extent. In a 2011 interview, Elijah Cummings said: “[w]hen you take a drug that is a life saving type drug and deprive a child or anybody else of that drug by hoarding it and jacking up the price as much as 5,000 times - as far as I am concerned - that is criminal.”<sup>333</sup> The FBI appears to have adopted his attitude, as resources indicate that it has begun investigating gray marketers of drugs.<sup>334</sup> If in fact this investigation goes somewhere, and gray market drug sales are illegalized, a significant step will be taken toward eliminating the drug shortage problem. Finding a way to stop these entities will be easier said than done, however. Gray market suppliers are prima facie legal, given that the majority of them are licensed.<sup>335</sup>

A further wrinkle is that the gray market actually has a high level of support in some circles (i.e. when these suppliers bring drugs in from Canada, thereby making prices cheaper).<sup>336</sup> In light

---

<sup>331</sup> NAT'L ASS'N OF BDS. OF PHARMACY, *supra* note 123, at 6.

<sup>332</sup> See Armen Keteyian, “Gray Market” Companies Exploit, Profit From Short Supply of Life-Saving Drugs, CBS NEWS (Oct. 13, 2011, 12:00 AM), [http://www.cbsnews.com/8301-31727\\_162-20120140-10391695.html](http://www.cbsnews.com/8301-31727_162-20120140-10391695.html) (discussing the difficulties of treating the terminally ill since the drugs that they require have been made exorbitantly expensive by the gray marketers).

<sup>333</sup> *Id.*

<sup>334</sup> See *id.* (explaining that the FBI has begun investigating gray market drug suppliers).

<sup>335</sup> See Tomsic, *supra* note 109 (discussing the typical process of a gray market supplier obtaining a license).

<sup>336</sup> See Mike Masnick, *Canadian Pharmacies React to US Gov't Taking \$500 Million from Google Over Their Ads*, TECHDIRT (Sept. 1, 2011, 5:49 AM), <https://www.techdirt.com/articles/20110830/17182115744/canadian-pharmacies-react-to-us-govt-taking-500-million-google-over-their-ads.shtml> (stating that

of all this, effectively preventing the operations of the gray market will not only be difficult but banning the gray market altogether may not be the most politically popular move. The best way to stop the gray market from exacerbating drug shortages would be to pass a law against drug price gouging, or one that prohibits the purchase of short-supply drugs by anyone other than healthcare providers.

*D. H.R. 5853: The Bill Aimed at Eliminating Gray Market Intermediaries*

After commissioning the Congressional investigation of the gray market, and discovering the deleterious effects that it has on health care providers and seriously ill patients, Congressman Elijah Cummings wrote a bill aimed at controlling the problem.<sup>337</sup> This bill sought to amend select portions of Federal Food Drug and Cosmetic Act, in an effort to curb the ability of gray market drug suppliers to operate.<sup>338</sup> This section of the article will evaluate that bill in detail and suggest improvements.

1. Banning the Re-sale of Prescription Drugs

Prima facie, current laws are insufficient to prevent the re-sale of drugs by gray marketers. H.R. 5383's primary amendment to existing law was to place a blanket restriction on the re-sale or wholesaling of prescription drugs by pharmacies. As was discussed at length earlier, the majority of drugs that gray marketers peddle come from pharmacies that agree to sell them rather than keep the drugs in the legitimate supply chain.<sup>339</sup> As was noted by the House Report, there is a "patchwork of inconsistent state regulations" that limit re-sales.<sup>340</sup> The preceding quote is referring to state laws that regulate drug wholesaling by supply chain intermediaries. The current state of those laws explained as follows, "[t]here are provisions in state

---

there is a high level of support for drugs imported from Canada at a reasonable price).

<sup>337</sup> Gray Market Drug Reform and Transparency Act, H.R. 5853, 112th Cong. (2012).

<sup>338</sup> *Id.*

<sup>339</sup> See SHINING LIGHT ON THE "GRAY MARKET," *supra* note 100, at 16–17 (discussing the means through which drugs are obtained by gray market drug suppliers).

<sup>340</sup> *Id.* at 16.

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 445

laws in which pharmacies can wholesale up to five percent of their product. The intent was that, if you have a situation where a pharmacy runs short on a product, they can buy it from another pharmacy or wholesaler for that patient.”<sup>341</sup> The purpose of these laws is to mitigate the effects of a drug shortage by allowing pharmacies to sell to each other.<sup>342</sup> There is not, however, any limitation on who or what entities these sales can be made to, and in many cases pharmacies are taking advantage of the law by selling to the gray market, a party to whom the laws were not originally intended to apply to.

Federal law also addresses the re-sale of drugs by health care intermediaries in the Prescription Drug Marketing Act;<sup>343</sup> because of the exemptions for pharmacies however, its applicability is largely nullified.<sup>344</sup>

In light of this *mélange* of ineffective laws, many pharmacy owners are swayed by the money promised by gray marketers, and therefore often sell their short-supply drugs. Because of the ability of pharmacies to skirt the current law, the only means of ending sales to gray marketers is to put a blanket ban on such transactions.<sup>345</sup> This was in fact the primary goal of H.R. 5853; it states:

(a) Prohibited Act.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“(aaa) The purchase or receipt by any person required to report under section 510(b)(3) (relating to wholesale distributors of prescription drugs) of any drug subject to section 503(b)(1) from a pharmacy or pharmacist, except that this paragraph does not apply to the return of a drug to the wholesale distributor from which the particular drug was purchased.”<sup>346</sup>

A federal law addressing this issue is much needed. The

---

<sup>341</sup> *Federal Legislation Needed to Stop Gray Market Wholesaler Activity Related to Drug Shortages*, NAT’L ASS’N OF BOARDS OF PHARMACY (Aug. 22, 2012, 3:24 PM), <http://www.nabp.net/news/federal-legislation-needed-to-stop-gray-market-wholesaler-activity-related-to-drug-shortages>.

<sup>342</sup> *Id.*

<sup>343</sup> Prescription Drug Marketing Act (PDMA) of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (codified as amended in scattered sections of 21 U.S.C.).

<sup>344</sup> See Angarola & Beach, *supra* note 118, at 22–23, 37 (discussing the loopholes in the PDMA).

<sup>345</sup> Gray Market Drug Reform and Transparency Act, H.R. 5853, 112th Cong. § 2 (2012).

<sup>346</sup> *Id.*

inconsistencies among state laws are largely responsible for gray market drug suppliers remaining technically legal. They operate across state lines, thereby making it impossible to shut them down completely. In other words, if a gray marketer is prosecuted for a violation of law in one state, it does not preclude its continued operation in any other state. If the laws were uniform across the country (as H.R. 5853 aimed to make it), the prosecution and/or regulation of gray marketers would become far easier.

## 2. Reporting Requirements for Wholesalers

Currently lacking in the drug industry is both a comprehensive list of the entities, which serve as drug wholesalers in the market, and a uniform set of reporting requirements that would require entities to report that they do business with these wholesalers. The lack of these tools makes gray market transactions harder to regulate. If there is no way of determining what entities are engaged wholesale transactions, there is no way of finding out which entities are actually gray marketers. A law that required pharmacies to report each time they made a wholesale transaction would enable regulators not only to create comprehensive lists of wholesalers, but would also give them the ability to investigate suspicious transactions. H.R. 5853 sought to give regulators the ability to use these tools:

(3) On or before December 31 of each year, every person engaged in the wholesale distribution in interstate commerce of drugs subject to section 503(b)(1) shall report to the Secretary such person's name, contact information for such person's principal officer (or the designee thereof), such person's places of business, such person's licensing information (including the type of license and expiration date) for each State in that such person is so engaged, and such other information as the Secretary deems appropriate.<sup>347</sup>

This provision, if passed along with the rest of the law, would have allowed a regulatory body to be better able to investigate suspicious transactions and may have helped to prevent gray marketers from acting as wholesalers. Presumably, these reporting requirements would have allowed regulators to immediately determine which entities were failing to meet state licensure requirements or blatantly violating another law. This would have hopefully enabled regulators to immediately prevent

---

<sup>347</sup> *Id.*

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 447

at least some portion of gray marketers from continuing their operations.

While this provision would have been very helpful in removing blatant violators of the law from the market, it failed to consider the fact that most gray-market drug wholesalers are fully licensed as such by their respective states.<sup>348</sup> If the gray marketers are not explicitly violating a law or at least engaging in something that is at least questionable, it would have made it difficult for regulators to discover which entities were operating on the gray market and which were not. To make matters worse, it is estimated that there are nearly 6,000 registered wholesalers in the U.S.<sup>349</sup> Given the number of wholesalers and the fact that most gray marketers have the prima facie appearance of legitimacy, actually discovering gray marketers could be a costly undertaking. There are two things that could be added to this bill to address this problem. The first would be a requirement that all wholesaling entities be accredited by an outside body that would ascertain whether they were legitimate. The second would be the establishment of a federal licensing or accreditation system that would exist in addition to those that exist at the state level.<sup>350</sup>

Consider first the accreditation option. Accreditation is a process whereby an independent body looks at a firm in detail and determines if it is legitimate.<sup>351</sup> Typically, the accreditation body queries the wholesaler for information that allows it to determine whether the wholesaler is compliant with state/federal laws, and whether the organization is actually operating as a wholesaler.<sup>352</sup> The accreditation board most frequently used is

---

<sup>348</sup> See generally SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 26 (displaying how most drug wholesalers have licenses).

<sup>349</sup> *Drug Wholesalers Industry Overview*, HOOVERS, <http://www.hoovers.com/industry-facts.drug-wholesalers.1493.html> (last visited Apr. 15, 2015).

<sup>350</sup> Contrary to popular belief, the FDA does not license drug distributors/wholesalers. Licensing requirements for these entities are left largely up to the discretion of individual states. See *Verify Wholesale Drug Distributor Licenses*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/ucm281446.htm> (last updated Sept. 23, 2014) (providing links to U.S. state licensing authority databases of wholesale drug distributors).

<sup>351</sup> See *Criteria*, NAT'L ASS'N OF BOARDS OF PHARMACY, <http://www.nabp.net/programs/accreditation/vawd/criteria> (last visited Apr. 15, 2015) (listing the criteria used by the NABP for accrediting wholesale drug distributors).

<sup>352</sup> *Id.*

known as The National Association of Boards of Pharmacy (NABP). This organization has established its own set of accreditation criteria that wholesalers must comply with to obtain accreditation.<sup>353</sup> The accreditation itself is known as VAWD, which stands for “Verified-Accredited Wholesale Distributor.”<sup>354</sup> These criteria are quite detailed and would undoubtedly be quite effective in preventing illegitimate drug wholesalers from operating. This methodology of ensuring wholesaler legitimacy has been endorsed by multiple states and is currently required by three, namely Wyoming, North Dakota, and Indiana.<sup>355</sup> The effectiveness of this system is exemplified by the number of states that have adopted it, and are continuing to adopt and require it.<sup>356</sup>

Another advantage of requiring an accreditation board is that there is no cost to the government as the wholesalers bear the cost of the accreditation.<sup>357</sup> According to one commentator, “it puts the financial burden for being surveyed on the companies going through VAWD accreditation. Most states do not charge to conduct inspections. Given today’s economic situation, many states are seeking to cut costs, and thus, VAWD will play a bigger role.”<sup>358</sup> One of the problems with H.R. 5853 was that it necessarily implicated far more cost than the fees and revenue it would have generated to pay for the programs.<sup>359</sup> By requiring wholesalers to be accredited, the federal government could avoid taking on the costs associated with the initiatives that House Bill 5833 sought to put in place. Furthermore, the federal government could use the NABP to create the proposed list of wholesalers and thereby avoid the cost of using federal employees. This option would provide an optimum means of certifying that wholesalers were legitimate.

---

<sup>353</sup> See *id.* (discussing the organization’s accreditation criteria).

<sup>354</sup> *Id.*

<sup>355</sup> See *id.* (detailing the accreditation criteria for wholesaler legitimacy); see also CHERICI ET AL., *supra* note 112, at 5 (discussing the value of accreditation boards).

<sup>356</sup> Rob Wright, *VAWD: Impossible for Virtual Manufacturers in Maryland?*, LIFE SCI. LEADER (Jan. 12, 2011), <http://www.lifescienceleader.com/doc/vawd-impossible-for-virtual-manufacturers-0001>.

<sup>357</sup> *Id.*

<sup>358</sup> *Id.*

<sup>359</sup> See Gray Market Drug Reform and Transparency Act of 2012, H.R. 5853, 112th Cong. § 3 (2012) (discussing fees that would have been assessed and collected in order to cover the cost of the initiatives in the bill).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 449**

Second, consider the federal licensing or accreditation option. This option would necessarily involve more cost than accreditation, but would be similarly as effective. The Congressional report on the gray market found that, despite disciplinary actions in one state, gray marketers are not precluded from obtaining licenses and operating in others.<sup>360</sup> Creating one licensing system with uniform requirements and regulations would go far in ensuring that entities that had disciplinary actions pending against them would not be able to operate in other states. Granted, this might implicate Tenth Amendment issues of state sovereignty, but there is no doubt that such a system would serve to eliminate some of the problems with having individual state licensing boards. This federal licensing/accreditation process would optimally require that all wholesaling entities in the U.S. report to a designated regulatory body on a yearly basis. At that time the entity would have to prove that they were a legitimate pharmaceutical intermediary, not established merely to retain short supply drugs and game the system. This of course would have to be proven by hard data that would unequivocally prove the veracity of their statements. Only if the entities could prove this would they be given the right to engage in wholesaling. The database that House Bill 5853 sought to establish would have served to support this endeavor in that it would have enabled regulators to determine throughout the year whether or not legally licensed/accredited entities were violating the terms of their license.

One potential model for the database would be the National Practitioner Data Bank (NPDB). This is a system that was established in the late 1980s in an effort to track physicians accused and found guilty of malpractice.<sup>361</sup> The way this data bank works is that every time an insurer makes a malpractice payment on behalf of a physician, that payment is reported to the databank.<sup>362</sup> In addition to collecting data on malpractice, the data bank also keeps records of any disciplinary actions against

---

<sup>360</sup> See SHINING LIGHT ON THE “GRAY MARKET,” *supra* note 100, at 26–27 (discussing gray market supplier’s ability to operate in multiple states unhindered by disciplinary action in one or more states).

<sup>361</sup> U.S. Dep’t of Health & Human Servs., *Health Care Organizations, Reporting, DATA BANK NAT’L PRAC.*, <http://www.npdb.hrsa.gov/hcorg/whatYouMustReportToTheDataBank.jsp> (last visited Apr. 15, 2015).

<sup>362</sup> 42 U.S.C. § 11131(a) (2012).

physicians by state governing boards, and adverse actions against the physicians by regulatory bodies that set standards for care in the practice of medicine (i.e., the American Medical Association).<sup>363</sup> If these entities fail to provide information to the databank per the requirements, they can be assessed a monetary fine.<sup>364</sup> Pursuant to the law, the following pieces of information must be reported to the NPDB:

- (1) the name of any physician or licensed health care practitioner . . . ,
- (2) the amount of the payment,
- (3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,
- (4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and
- (5) such other information as the Secretary determines is required . . . .<sup>365</sup>

If the federal government could establish a database like the NPDB for wholesalers, it might be very effective in creating a list of distributors, as well as in regulating gray marketers. In this case, rather than having insurers and regulatory boards report to the data bank, the pharmacies that engaged in a wholesale transaction could be forced to do the reporting. For example, the reporting requirements for the wholesaler databank might be as follows: (1) the name of the wholesaler, (2) the wholesaler's license number, (3) the type of drug purchased and whether it was in short supply, and (4) the percentage of the pharmacy's total profits that the sale composed. By creating a database like this, federal regulators might be able to discern buying patterns in wholesalers that would allow them to discern who was operating on the gray market.

---

<sup>363</sup> See *The Nation: Data Bank to List Incompetent Doctors*, L.A. TIMES, Sept. 26, 1988, [http://articles.latimes.com/1988-09-26/news/mn-1909\\_1\\_national-practitioner-data-bank](http://articles.latimes.com/1988-09-26/news/mn-1909_1_national-practitioner-data-bank) (discussing that state medical boards and licensed health professionals are required to report misconduct to the data bank); see also John Ensslin, *National Practitioner Data Bank Restricted: How You Can Help*, FREEDOM OF THE PREZ (Oct. 10, 2011), <http://blogs.spjnetwork.org/president/2011/10/10/national-practitioner-data-bank-restricted-how-you-can-help> (reporting how the data bank tracks disciplinary actions against health care professionals).

<sup>364</sup> See *The Nation: Data Bank to List Incompetent Doctors*, *supra* note 363 (indicating that noncompliant organizations must pay fines).

<sup>365</sup> 42 U.S.C. § 11131(b).

**2015] THE SHORTAGE OF ESSENTIAL DRUGS 451****3. Pricing for Drugs; Work with the Senate to Integrate the Anti-Price Gouging Law into the Bill**

House Bill 5853 would also have promoted price transparency in the drug market. It would have required every wholesaler to provide the end buyer with information regarding the drug's original price (i.e., when it was purchased from the manufacturer).<sup>366</sup> The bill would have required a wholesaler to disclose "the amount paid for such drug by the person receiving it if such drug is in shortage at the time of the sale, and the amount paid for such drug for any prior sale that occurred at a time when such drug was in shortage . . . ."<sup>367</sup> This would have been an important step in preventing the occurrence of price gouging, but may not have been enough in the grand scheme of things. For example, what is to stop a gray market supplier from submitting a fraudulent document indicating the drug's original price? For this reason, it would seem that the bill should have had stricter regulations about price gouging. One potential solution to this problem is to integrate some of the portions of Senate Bill 3622 into House Bill 5853. Senate Bill 3622 sought to create a federal law that would have prevented drug prices from increasing over a certain level during the time of a shortage.<sup>368</sup> This bill unfortunately died in committee.<sup>369</sup> However, the language of the bill prevented drug wholesalers from over-charging for any drug in short-supply.<sup>370</sup>

According to the bill, "it shall be unlawful for any person to sell vital drugs at a price that is unreasonably excessive and indicates that the seller is taking unfair advantage of the circumstances related to a market shortage to unreasonably increase prices during such period."<sup>371</sup> Wording a bill like this would make it more effective at preventing price gouging than would a general rule forcing wholesalers to provide buyers with information on the drug's original price.<sup>372</sup> So long as the drug

---

<sup>366</sup> Gray Market Drug Reform and Transparency Act of 2012, H.R. 5853, 112th Cong. (2012).

<sup>367</sup> *Id.* § 4(a)(1).

<sup>368</sup> Protecting Patients from Price Gouging Act, S. 3622, 112th Cong. (2012).

<sup>369</sup> *S. 3622 (112th): Protecting Patients and Hospitals From Price Gouging Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/112/s3622> (last visited Apr. 15, 2015).

<sup>370</sup> S. 3622.

<sup>371</sup> *Id.* § 4(a)(2).

<sup>372</sup> *Compare id.* ("[I]t shall be unlawful for any person to sell vital drugs at a

buyer knew the drugs' original price and there was language defining what price hikes were unreasonable, it would be a fairly simple matter to determine whether price gouging was occurring. If an updated version of House Bill 5853 were to include provisions similar to those in Senate Bill 3622, it would serve to address the void that currently exists with respect to federal and state law regulating drug price gouging.

#### 4. Require a Comprehensive Drug Pedigree for Every Drug that is Sold

Although the House Bill 5853 addressed situations in which gray market wholesalers obtained their drugs from pharmacies or other healthcare entities, it did not address those situations where they obtained the drugs through diversion (i.e., from Medicaid recipients) or from counterfeiters. While this practice is already illegal, it is hard to determine when it is occurring. One of the means of addressing this problem would be through the establishment of a comprehensive federal drug pedigree system. According to the Prescription Drug Marketing Act:

A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription 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.<sup>373</sup>

Such a system would give care providers a means of determining the exact source of the drugs that they are purchasing, and would serve to prevent counterfeited or diverted drugs from entering the market. According to the FDA, there is currently a pedigree system in place in the United States; however, it would appear that the current system is rendered ineffective by the many loopholes and exceptions it contains.<sup>374</sup>

---

price that is unreasonably excessive . . .”), with H.R. 5853 § 4(a)(1)(requiring wholesalers to report “the amount paid for such drug by the person receiving it . . . and the amount paid for such drug for any prior sale that occurred . . .”).

<sup>373</sup> CPG Sec. 160.900 *Prescription Drug Marketing Act—Pedigree Requirements under 21 CFR Part 203*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm073857.htm> (last updated Mar. 20, 2015).

<sup>374</sup> See *id.* (discussing the background of drug pedigree requirements and

## 2015] THE SHORTAGE OF ESSENTIAL DRUGS 453

What is clear is that this law does not effectively replace the “patchwork of state-run pedigree systems”<sup>375</sup> that currently exists. In fact, one of the suggested regulations for House Bill 5853 was a new comprehensive pedigree system; however, for unstated reasons, the pedigree system did not make it into the bill.<sup>376</sup> If a future version of House Bill 5853 were to contain a pedigree system it would be greatly beneficial, and would serve to replace the current system.<sup>377</sup>

House Bill 5853 was introduced into the House of Representatives in May of 2012 and referred to a Committee, but unfortunately, it has died.<sup>378</sup> Given the importance of this bill, one can only hope that the legislators reintroduce it in the current session of Congress. If House Bill 5853 or an amended version were to be passed into law, it would have a significant impact on gray marketers’ ability to obtain drugs.

## VI. CONCLUSION

As things currently stand, drug shortages are an unfortunate reality for the U.S. health system. These shortages lead to increased wait times for treatment and, at times, patient harm. Regrettably, there is no clear cut means of addressing the root causes of the problem without a major system overhaul; indeed this is likely what will eventually happen, but in the short term there does not seem to be an end in sight. While drug shortages are likely to remain with us for some time, there is nothing prohibiting lawmakers from addressing correctable contributory factors that make shortages measurably worse. The gray market is one of these factors. As was demonstrated throughout this

---

suggesting new enforcement protocol to effectively prosecute violations).

<sup>375</sup> Alexander Gaffney, *Legislators: To Help Alleviate Drug Shortages, Establish Track and Trace Provisions*, REG. AFF. PROFS. SOC’Y (June 13, 2012), <http://www.raps.org/focus-online/news/news-article-view/article/1752/legislators-to-help-alleviate-drug-shortages-establish-track-and-trace-provisio.aspx>.

<sup>376</sup> *Id.*

<sup>377</sup> As a further note, if an accreditation system were to be adopted, it would prevent the need for such a program, as drug pedigree is one of the things the NABP looks at in accrediting wholesalers. See *Criteria*, *supra* note 351 (“The Wholesale Distributor is establishing and maintaining inventories and records of all transactions . . . [t]hese records shall include: (a) Pedigrees for all Drugs that are distributed . . .”).

<sup>378</sup> *H.R. 5853 (112<sup>th</sup>): Gray Market Drug Reform and Transparency Act of 2012*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/112/hr5853> (last visited Apr. 15, 2015).

narrative, the gray market operates a parallel market for drugs. This market preys on the desperation of what otherwise would be terminally ill patients by taking advantage of their willingness to pay and increasing the prices for life saving drugs to ridiculous levels. Their ability to do this hinges on the fact that gray marketers snatch up most of what is left of a short supply drug, thereby creating market power for themselves. These actions prevent the drugs from getting to most patients who need them, and require those that do get them to pay prices that are oftentimes thousands of times higher than the original price. All told, the activities of the gray market serve to exacerbate an already unfortunate situation.

Gray market drug sales implicate a variety of ethical and legal issues. For example, price gouging is an activity that is illegal in many states subsequent to a natural disaster; the logic being that making desperate people pay extra for necessities is morally wrong. Despite this attitude, there are no laws specifically preventing price hikes in the drug market. In addition to price-gouging terminally ill patients, gray marketers at times peddle either counterfeit or expired drugs; this has highly negative implications for patient health. Selling drugs like these is highly illegal; the problem is that it is extraordinarily difficult to prove when it occurs. One thing becomes clear from all of this: namely, that gray marketers add no value to drug market transactions and, in fact, may harm end users of drugs. It is therefore abundantly clear that gray marketers must be prohibited from dealing in short supply drugs.

There is currently a veritable *mélange* of laws governing the drug trade, but because of the lack of uniformity, gray marketers are able to avoid the appearance of wrongdoing and are rarely prosecuted. Laws have been proposed at the federal level that seek to address this problem, but as yet have not met with success. There is, however, a general consensus among lawmakers that something must be done to prevent the operations of gray marketers. Just how and when this will occur remains unclear. When it finally does occur, it will serve as a step in the right direction toward the ultimate goal of eliminating drug shortages.