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Nicole Rende

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PHARMACEUTICAL PRICE GOUGING: THE NEED FOR DIRECT REGULATION ON THE GRAY MARKET

NICOLE RENDE[†]

I. INTRODUCTION

Imagine you are walking home after a long, tiring day at work—your feet dragging, your body aching. Just that morning, you went to the pharmacy and picked up your pill to treat a disease you have been fighting for quite some time. This disease is the result of a weakened immune system from yet another life-threatening disease you have. That one, single, small pill costs what one month’s worth of groceries would cost for your family of four. Both you and your spouse work low income jobs, living paycheck to paycheck. Exhausted, you walk into your small apartment and see no one is home yet. You foolishly open the fridge just to see that it contains nothing.

You sit on the couch and turn on CNBC where you witness a CEO of one of these drug companies being questioned by Congress. You had no idea why the price of your pill went from just thirteen dollars to around seven hundred dollars.¹ You quickly realize that the CEO is being questioned on the reasoning behind his increase in the price of the one small pill you took that morning. The tiny pill that you need to save your life. You stare blankly at the television as the CEO continuously repeats with a smirk, “On advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your

[†]J.D. 2018, St. John’s University School of Law.

¹ See The Young Turks, *Price Gouging Drug CEO Claims He’s The Good Guy*, YOUTUBE (Sept. 22, 2015), <https://www.youtube.com/watch?v=WVlgveDesEY>; CNBC, *Turing CEO Martin Shkreli Talks 5,000% Drug Price Hike (Full Interview)*, YOUTUBE (Sept. 23, 2015), <https://www.youtube.com/watch?v=L-U1MMa0SHw> (explaining that the CEO of Turing Pharmaceuticals abruptly raised the price as a business decision without considering any consequences to patient health).

question,” to every single simple question he is asked.² You sit there watching, as your hope for answers dwindles and all you are left with are more questions . . . why *is he doing* this, how *can this happen*, why *does* it happen . . . but all you can do is sit there, without any answers to explain your empty fridge. Defeated. Hopeless.

There are other victims of pharmaceutical price gouging. Price gouging in the medical industry has become an increasing problem for the working poor and the middle class in the United States.³ Price gouging is a problem for the working poor because medicine that was once affordable for this group of people is no longer affordable.⁴ More importantly, patients of failing to terminal health are unable to afford life-saving medications. These drugs did not increase in price by accident. The price of life-saving drugs was increased because of the underlying problem of price gouging by pharmaceutical companies.

Price gouging “refers to the practice of raising the prices of goods, services, or commodities” to a level much higher than is reasonably fair, exploiting certain groups of people that cannot afford the goods so much so that it becomes unethical.⁵ Price gouging has become an issue in the pharmaceutical market. Pharmaceutical companies have recently been acquiring each other,⁶ making the market for medical supplies and medication a market of limited options. There are fewer companies, manufacturers, and suppliers of life-saving drugs,⁷ which creates

² CNBC, *Martin Shkreli Testifies Before Congress: Full Testimony*, YOUTUBE (Feb. 4, 2016), https://www.youtube.com/watch?v=LPIQ_gyiHag.

³ See Sreedhar Potarazu, *Rising cost of prescription drugs threatens health care gains*, CNN (Aug. 26, 2015, 7:29 AM), <http://www.cnn.com/2015/08/26/opinions/potarazu-drug-price-hikes/>; *Who are the working poor in America?*, UC DAVIS CENTER FOR POVERTY RESEARCH, <http://poverty.ucdavis.edu/faq/who-are-working-poor-america> (last visited Feb. 23, 2017) (“The ‘working poor’ are people who spend 27 weeks or more in a year in the labor force either working or looking for work but whose incomes fall below the poverty level. . . In 2014, the working poor as a fraction of all people in the labor force for 27 weeks or more were: 11.7% Black, 11.7% Hispanic/Latino, 5.5% White, 4.3% Asian[,] 7.2% women, 5.5% men[,] 18.3% with less than a high school diploma[,] 8.3% high school graduates with no college education[, and] 2% with a bachelor’s degree or higher.”).

⁴ See Potarazu, *supra* note 3.

⁵ *Price Gouging*, LEGAL DICTIONARY, <https://legaldictionary.net/price-gouging/> (last visited Feb. 24, 2017).

⁶ Makarand Jawadekar, *Mergers and Acquisitions in the Pharma Industry*, ELSEVIER (Feb. 8, 2017), <https://pharma.elsevier.com/pharma-rd/mergers-acquisitions-pharma-industry/>.

⁷ See *id.*

an environment ripe for monopoly.⁸ Due to lack of competition, some entities completely control the supply of a life-saving drug so that price gouging can easily occur.⁹ In addition to the decrease in the number of medical suppliers, the drug quantities themselves are in shortage.¹⁰ The demand for the life-saving drugs is increasing while the supply of the drugs is decreasing. Unethical officers of pharmaceutical companies are taking advantage of this situation by buying the small supply of highly important life-saving drugs at the expense of patients in an indirect, unregulated way: the gray market.¹¹

The gray market is an “unofficial, unauthorized, and unintended distribution network through which secondary wholesalers buy and sell medications at inflated prices.”¹² The normal distribution network is manufacturer to distributor to dispenser chain, whereas gray market entities negatively influence this network by buying and reselling drugs countless times before eventually selling the drugs to the dispensing entity.¹³ The gray market, originating as a network through which individuals and companies could buy and sell counterfeit, substandard, and ineffective medications, became “an avenue for opportunists to profit from the national drug shortage crisis.”¹⁴ Pharmaceutical companies that participate in the gray market are raising prices of life-saving drugs to extremely high rates because of the lack of adequate federal regulation on medication prices.

Although there has been some state and federal legislation regulating the pharmaceutical market generally, there is still too much leeway for companies to get around these regulations

⁸ A monopoly is a business term for when there is an “exclusive ownership through legal privilege, command of supply, or concerted action.” *Monopoly*, WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/monopoly> (last visited Feb. 24, 2017).

⁹ See Sean Williams, *These 3 Pharmaceutical Companies Control Roughly Half of All Cancer Drug Sales*, THE MOTLEY FOOL (Jan. 25, 2015, 8:03 AM), <https://www.fool.com/investing/general/2015/01/25/these-3-pharmaceutical-companies-control-roughly-h.aspx>.

¹⁰ See U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES (2013) [hereinafter STRATEGIC PLAN].

¹¹ See *Short-Supply Prescription Drugs: Shining A Light on the Gray Market*: Hearing Before the Comm. on Com., Sci., and Transp., 112th Cong. 9 (2012) [hereinafter *Short-Supply Prescription Drugs*].

¹² Brittany Mahugh, *Lost in the Gray: Navigating the Problem of Pharmaceuticals in the Gray Market*, 25 A.B.A. HEALTH. L. 1, 1 (2013).

¹³ See *id.*

¹⁴ *Id.* at 3.

because they affect the gray market only indirectly.¹⁵ There is no legislation directed at the gray market itself, and the indirect regulations on the gray market are not a means of effective enforcement on the gray market.¹⁶

The underlying issue of price gouging in the medical industry has multiple parts that are currently not being entirely addressed. The relationship between the national drug crisis, the pharmaceutical gray market, and the pharmaceutical price gouging practices generates a domino effect of causally linked sequences of occurrences with price gouging being the final piece of the domino linkage chain. The national drug crisis is at the beginning of the domino linkage chain with price gouging of pharmaceuticals at the end. The gray market is a major piece in the middle of this chain allowing the drug prices to increase without any regulation. Regulating the gray market would put a gaping hole in the domino sequence and make price gouging less likely.

This Note proposes federal legislation that will ultimately shut down the Pharmaceuticals gray market. The federal government should directly regulate the gray market and the price gouging mechanisms used. Congress should pass the Fair Accountability and Innovative Research Drug Pricing Act of 2016,¹⁷ currently

¹⁵ See *id.* at 7. The difference between direct legislation and indirect legislation, as it appears in this Note, in terms of the gray market, is that direct legislation includes language pertaining to the gray market. Meanwhile indirect legislation includes legislation that may focus on the drugs or the national drug crisis rather than the gray market distribution and the entities involved in that distribution.

¹⁶ These laws are ineffective and weak because they address the wrong aspects of the pharmaceutical market if the goal is regulating the gray market. For example, the Prescription Drug Marketing Act (PDMA) and Counterfeit Drug Task Force prevents the introduction of counterfeit drugs and regulates the amount and which type of counterfeit drugs are being introduced but do not prevent drugs from being distributed through the gray market. The FDA's Office of Criminal Investigation punishes violators of the Food, Drug, and Cosmetic Act, and the Federal Anti-Tampering Act which both oversee the safety of food, drugs, and cosmetics but do not regulate the resale and distribution of drugs on the gray market. See Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988).

¹⁷ Fair Accountability and Innovative Research Pricing Act of 2016, H.R.6043, 114th Cong. (2016). This bill amends the Public Health Service Act to require manufacturers of certain drugs and biological products to report to the Department of Health and Human Services (HHS) price increases that result in a 10% or more increase in the price of a drug over a 12-month period. Reports are required for prescription drugs and drugs commonly administered in hospitals, except vaccines, drugs for rare conditions, and drugs with annual sales for Medicare and Medicaid enrollees of less than \$1. Manufacturers that do not submit a required report are subject to a civil penalty. The Inspector General of HHS must review

proposed. This Act will increase price transparency and provide a civil penalty for wrong doers. In addition to the passage of this Act, there needs to be a direct attack on the gray market by creating an act that does not allow companies to participate in these distributions and ultimately form monopolies. This act needs to prevent the bulk of the sale distributions of these life-saving drugs going to specific entities; it could be a continuation of the provisions first drafted in the Gray Market Reform Act introduced in the 112th Congress.¹⁸ The companies that are involved in gray market activity should also be criminally punished for the lives they are affecting. In order for these new regulations to succeed and be enforceable, there should be a separate committee created that specifically addresses all gray market activities. A new committee solely focused on the pharmaceutical gray market will finally give the government a fighting chance to put an end to this social injustice. This committee could be given the power to enforce any new legislative provisions with necessary fines and punishments.

Direct legislation can address the gray market problems in a way that creates difficulties for companies to avoid the regulations. With the proposed provisional acts in place and a committee in place to enforce serious punishments, there would be an increased awareness of the gray market issues and a “watchdog” in place with effective means to put a stop to the companies trying to continue participation in the gray market for profit at the expense of the public.

Part II of this Note discusses the national drug shortage crisis,

drug price information to determine compliance. Collected penalty funds must be used to carry out activities related to this reporting requirement and to improve consumer and provider information about drug value and drug price transparency. *Id.*

¹⁸ Gray Market Drug Reform and Transparency Act of 2012, H.R. 5853, 112th Cong. (2012). This act amends the Federal Food, Drug, and Cosmetic Act to: (1) make it a prohibited act and a misbranding for a wholesale distributor of prescription drugs to purchase or receive a prescription drug from a pharmacy or a pharmacist; (2) require annual reporting by wholesale distributors of prescription drugs; (3) require the Secretary of Health and Human Services (HHS) to establish and maintain a national database of information reported by wholesale distributors of prescription drugs and to require such database to include information on actions taken by states against wholesale distributors (e.g., disciplinary actions and license revocations); (4) require the Secretary to assess and collect fees from wholesale distributors of prescription drugs; and (5) require wholesale distributors of prescription drugs to provide to recipients of a prescription drug in shortage the sales price for such drug at the time of its sale and at the time of any prior sale of such drug when it was in shortage. *Id.*

a normal medication distribution chain, and the gray market and its medication distribution network and issues. It also addresses the effect of price gouging on the working poor and how some pharmaceutical companies are creating monopolies and utilizing gray market distribution channels to take advantage of the situation by price gouging drugs. Examples of pharmaceutical companies taking advantage of the national drug crisis are exposed and analyzed. In Part III, this Note examines some of the indirect legislation and regulation on price gouging in pharmaceuticals in response to the emergence of the gray market. It addresses why the current legislation does not effectively regulate the gray market.

Part IV then describes the proposed legislation in the recent Congresses, demonstrating how the government is beginning to take action to increase the regulation on the gray market. Finally, Part V of this Note proposes a solution to the gray market problem and, as a result, price gouging in the pharmaceutical industry, using current proposed legislation and a call for a direct federal act that prevents manufacturers, distributors, pharmacies, and drug companies from participating in the gray market and its unfair practices by implementing criminal charges and civil penalties for violators. This proposal also suggests that a new executive committee be created so that this issue is continually being addressed in an effective way. This committee would enforce the new federal legislation being proposed in this Note.

II. BACKGROUND

To understand price gouging in the pharmaceuticals market, this section explains the major underlying causes: (1) the national drug shortage problem and (2) the medical distribution market and how it is affected by the emergence of the gray market. Moreover, this section discusses the gray market's history and the economic and patient safety issues it causes.

A. National Drug Shortage

A drug "currently in shortage," as defined by the FDA, is "[a] situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the

current or projected demand at the user level.”¹⁹ Drug shortages are caused by product quality concerns, discontinuation of product lines, changes in supply and demand, raw material shortages, and manufacturing problems.²⁰

Between 2000 and 2004, the United States healthcare system suffered irregular medication shortages.²¹ In 2005, these shortages became an increasingly widespread problem throughout the country;²² shortages of more than sixty “medically necessary” drugs were reported in the FDA Drug Shortage Index.²³

The shortages increased substantially to 251 in 2011.²⁴ In 2012, despite the fact that there were fewer new shortages, “more than 300 shortages remained active at the end of 2012”²⁵ and approximately 100 new medication shortages were reported by the

¹⁹ *Frequently Asked Questions about Drug Shortages*, FDA.GOV, <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm> (last updated July 5, 2018).

²⁰ See STRATEGIC PLAN, *supra* note 10, at 11-12. According to Figure 2 in the Strategic Plan for Preventing and mitigating Drug Shortages, the causes of drug shortages from most influential to least are as follows: (1) Quality: Facility Remediation Efforts, (2) Quality: Product Manufacturing Issues, (3) Discontinuation of Product, (4) Raw Materials (API) Shortage, (5) Other Component Shortage, (6) Increased Demand, and (7) Loss of Manufacturing Site. When a manufacturer experiences a discontinuance or interruption in manufacturing, a shortage of the particular drugs that the manufacture makes will experience a shortage if there is no other manufacturer to make that particular drug to fill the recent void in addition to making up any loss that already occurred. Product disruptions also occur when there is “a natural disaster or other unexpected event not within a manufacturer’s control, or a business decision to permanently discontinue production of a drug” due to the unprofitability of that specific drug. However, the primary factor that leads to disruptions in manufacturing and inevitably a drug shortage, is failure in product or facility quality. “In 2012, for example, based on information collected from manufacturers, [the] FDA determined that the majority of production disruptions (66%) resulted from either (1) efforts to address product-specific quality failures (31%, labeled Quality: Manufacturing Issues in Figure 2) or (2) broader efforts to remediate or improve a problematic manufacturing facility. Quality or manufacturing concerns can involve compromised sterility, such as roof leakage; mold in manufacturing areas; or unsterilized vials or containers to hold the product—issues that could pose extreme safety risks to patients.” *Id.*

²¹ See Mahugh, *supra* note 12, at 3.

²² KEVIN HANINGER, AMBER JESSUP & KATHLEEN KOEHLER, OFFICE OF SCIENCE AND DATA POLICY, U.S. DEP’T OF HEALTH & HUMAN SERVS., ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES 3, 16 (2011) [hereinafter ECONOMIC ANALYSIS].

²³ U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., A REVIEW OF FDA’S APPROACH TO MEDICAL PRODUCT SHORTAGES 14-15 (2011) [hereinafter FDA’S APPROACH]. The recent increase in drug shortages affects 93% of drugs the FDA deems “medically necessary.” *Id.*

²⁴ U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., PERMANENT DISCONTINUANCE OR INTERRUPTION IN MANUFACTURING OF CERTAIN DRUG OR BIOLOGICAL PRODUCTS; PROPOSED RULE 6 (2011).

²⁵ STRATEGIC PLAN, *supra* note 10, at 8.

FDA.²⁶ “Analysis of the data from [Center for Drug Evaluation and Research’s] drug shortage database shows that the number of new shortages significantly decreased, from 117 in 2012 to 44” in both 2013 and 2014 and, “[a]s of September 30, 2015, 22 new drug shortages have been identified.”²⁷ In the beginning of 2015, the “FDA was notified of 131 potential shortage situations by 47 different manufacturers.”²⁸ New drug shortages are decreasing; however, once a drug is in short supply, the “shortage” lasts a considerable amount of time.²⁹

Despite so many drug shortages in recent years, manufacturers have yet to increase production of these life-saving medications,³⁰ even with the shortages resulting in “significant and life threatening consequences” for patients.³¹ Most of these drug shortages are concentrated in life-saving medications and generic sterile injectables, which are commonly used in “cancer treatment, anesthesia, emergency treatments, and nutritional therapies.”³²

To address the drug shortage problem, the Federal Government has been attempting to focus on manufacturers with current legislation requiring notice of a shortage, but the “FDA receiving advance notice of shortages fails to address the underlying causes.”³³ Although, 47 manufacturers notified the government of potential shortages in 2015, there are fewer than 47 manufacturers that are actually manufacturing the drugs in

²⁶ Thomas Sullivan, *Prescription Drug Shortages: Crisis Abating- Still Need for Pricing Reform*, POL’Y & MED., <http://www.policymed.com/2012/12/prescription-drug-shortages-are-becoming-persistent-in-us.html> (last updated May 6, 2018).

²⁷ U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS, *THIRD ANNUAL REPORT ON DRUG SHORTAGES FOR CALENDAR YEAR 2015*, 8 (2015) [hereinafter *THIRD ANNUAL REPORT*].

²⁸ *Id.* at 4.

²⁹ STRATEGIC PLAN, *supra* note 10, at 8. “The number of new drug shortages quadrupled from approximately 60 in 2005 to more than 250 in 2011. These statistics reflect the number of new shortages reported in a given year, but because shortages typically continue for extended amounts of time, the actual number of shortages at a given point in time is likely to be higher.” This means that once a drug is in shortage, it is difficult to fix the problem for that particular drug. In order to get a drug off of a “shortage”, raw materials, manufacturing, and supply all need to increase in amount and quality of multiple facilities need to improve substantially. *Id.*

³⁰ Stacey B. Lee, *The Drug Shortage Crisis: When Generic Manufacturers “Just Say No”*, 93 OR. L. REV. 355, 358 (2014).

³¹ Mahugh, *supra* note 12, at 3.

³² *Id.*

³³ Lee, *supra* note 30, at 358.

shortage.³⁴ The FDA does not focus on the very few manufacturers that are strictly manufacturing the life-saving drugs and instead are focusing on manufacturers as a whole.³⁵

Moreover, the drug shortage problem is one of the main causes of price gouging in the pharmaceutical market.³⁶ The supply and demand relationship in the lifesaving pharmaceutical industry is far from a traditional supply and demand relationship. The pharmaceutical market, in this regard, has a demand-supply inflexibility; any change in supply or demand can cause a shortage of a medication.³⁷ The only way that demand would change would be if there was an increase in the amount of people getting a certain illness or a certain allergy that needs the life-saving drugs. Patients are constrained in their demand position once they have the sickness because there is no choice but to deal with the amount of supply offered.³⁸ Additionally, for these drugs, demand “is often unaffected by changes in price” because the necessity for the drugs is too important; patients’ lives are controlled by manufacturers because the demand is controlled by one’s health conditions instead of one’s preference in a low price.³⁹

To meet any increase in demand for life-saving drugs, pharmaceutical companies just increase production, using current

³⁴ THIRD ANNUAL REPORT, *supra* note 27, at 4. For example, the EpiPen, one of the main life-saving drugs that are being egregiously increased in price, is an injectable. The “injectable market is highly concentrated with seven manufacturers producing the vast majority of all the drugs . . . the majority of production of a given sterile injectable is done by three or fewer manufactures.” Lee, *supra* note 30, at 364.

³⁵ See FDA’S APPROACH, *supra* note 23, at 3. The FDA conducted a review of medical product shortage activities in four product Centers in FDA and talked to external stakeholders in the drug arena to understand their perspectives on the current drug shortage problem. Based on these conversations, a review of published and unpublished information on drug shortages, and analyses of existing or newly created databases, this report concludes that the problem of medical product shortages is complex and stems from economic, legal, regulatory, policy, and clinical decisions that are deeply interconnected. *Id.*

³⁶ See Kate H. Gamble, *Obama Ordering FDA to Help Reduce Drug Shortages*, PHARMACY TIMES (Oct. 30, 2011), <https://www.pharmacytimes.com/news/obama-ordering-fda-to-help-reduce-drug-shortages>.

³⁷ *Id.* Because there are so few of these manufacturers producing the lifesaver drugs, the supply end of the supply and demand relationship is the controller of the relationship and creates an environment for drugs to easily fall short in supply. *Id.*

³⁸ See Mahugh, *supra* note 12, at 3. When specific medications are not in supply, some patients turn to alternative drugs. These alternative drugs, although sometimes effective, are not always as effective as the preferred, unaffordable or unavailable drug. Sometimes these alternatives create “significant side effects” and further issues with other medications patients might be taking. *Id.*

³⁹ Lee, *supra* note 30, at 366.

manufacturing infrastructure without expanding.⁴⁰ However, this means that “any need for facility repairs or equipment maintenance could cripple a manufacturer’s ability to maintain sufficient output levels to prevent a shortage” because these manufacturers have not undergone any updated changes to their facilities since the 1960s.⁴¹

Additionally, these companies will produce just enough or even less than the actual demand requires so that their inventory will not suffer any consequences, like overstock, in the attempt to avoid wasting products or resources.⁴² If companies did expand the infrastructure, in addition to increasing production, the companies would produce an excess of drugs and would be able to store them effectively for longer periods of time. However, “[d]rugs have a limited shelf life and holding excess inventory is costly,” so “manufacturers face an asymmetry of incentives: there is little cost . . . of producing too little of one drug . . . but a potentially high cost of producing too much of that drug.”⁴³ There is very little incentive to overproduce the drugs because of the cost it takes to overproduce and store the surplus of the drugs. This makes it almost impossible for the supply to ever be in excess enough to flood the market and deal with a major increase in demand without experiencing shortages.

Ultimately, the problem of drug shortages is the root of an extended chain of issues that lead first to the existence of the gray market and then to the ability of drug companies to price gouge. In order to address the injustice of price gouging groups of people who cannot afford the drugs and the legal issues of the gray market, the drug shortage is the underlying cause that needs to be addressed.⁴⁴ However, addressing the drug shortage issues is not the only way to address price gouging.⁴⁵ The gray market and its

⁴⁰ *Id.* at 365. Expanding both infrastructure and production together will meet the demand of these lifesaving drugs.

⁴¹ *Id.*

⁴² ECONOMIC ANALYSIS, *supra* note 22, at 6.

⁴³ *Id.* at 4-6.

⁴⁴ A solution to the drug shortage is not within the scope of this Note. However, the drug shortage problem was discussed here for necessary context to understand price gouging and the gray market.

⁴⁵ The problem can also be addressed through legislation.

The federal government has already passed legislation to address the drug shortage crisis, but failed to adequately resolve the gray-market

distribution differs greatly from a Normal Drug Distribution. This is another issue to address as a major cause of price gouging.

B. Pharmaceutical Markets

Previously mentioned was a discussion of the national drug crisis and how it affects the pharmaceutical market in general. To address the issue of price gouging in the pharmaceutical market, there are a lot of moving parts to consider, including the normal medical distribution chain, the emergence of the gray market and its history, and the issues that the gray market poses. The relationship between the national drug crisis, the pharmaceutical gray market, the infiltration by gray market companies, and the pharmaceutical price gouging generates a domino effect of causally linked sequences of occurrences with price gouging being the ending piece of the domino linkage chain.

a. Normal Medical Distribution

Normal drug distribution chains include manufacturers, wholesale distributors, and dispensers.⁴⁶ The process begins with manufacturers, who then sell the drug to a wholesale distributor, who in turn sells to a hospital or pharmacy, which ultimately administers the drug to patients.⁴⁷ Federal statutes authorize distributors to buy medications from manufacturers and send them to pharmacies, hospitals, and other non-patient entities.⁴⁸ Primary wholesale distributors buy drugs directly from manufactures.⁴⁹ Then the primary wholesale distributors sell

problem. While reducing shortages of medications will likely reduce some of the gray market presence, it will not solve the problem of gray market companies profiting at the suffering of sick patients and desperate healthcare providers; nor will it solve the patient safety concerns associated with gray market distribution.

Mahugh, *supra* note 12, at 2.

⁴⁶ *Id.* at 3.

⁴⁷ See *Short-Supply Prescription Drugs*, *supra* note 11, at 8. “Authorized distributors of record” are also allowed in these chains but need to prove that they “established an ongoing relationship to distribute” the drugs of a given manufacturer. *Id.* at 9; see also 21 U.S.C. § 353(d)(4) (2018). These “authorized distributors” are usually re-packagers and secondary wholesalers. Mahugh, *supra* note 12, at 3-4.

⁴⁸ 21 U.S.C. § 353(c)(3)(B)(iii). Subparagraph (B)(iii) permits “a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control”

⁴⁹ Mahugh, *supra* note 12, at 4.

those drugs directly to pharmacies and hospitals.⁵⁰ Secondary wholesale distributors do the same thing as primary wholesale distributors except that they buy their drugs from the primary wholesalers.⁵¹ When a drug is distributed through the entire normal drug distribution chain (through one or more wholesalers), it arrives at the dispensing hospital or pharmacy ready to be sold to a patient.⁵²

Unfortunately, this normal distribution chain does not always happen for certain life-saving drugs. When there is a predicted drug shortage, a different, more skewed medical distribution is created by entities taking advantage of the short supply. This skewed medical distribution is called the gray market.

b. The Emergence of the Gray Market in Pharmaceuticals

While a normal distribution network produces a chain that follows a manufacturer to distributor to dispenser path, this distribution network gets destroyed when there is a leakage in the chain, allowing for gray market entities to infiltrate the chain and therefore create the gray market. This section explains the pharmaceutical gray market piece of the domino effect, elaborating on what the gray market is and how companies are promoting this market. In addition, this section discusses the economic problems, the patient safety risks, and the drug quality risks that are directly related to the existence of the gray market.

i. History of the Gray Market

The pharmaceutical gray market is an “unofficial, unauthorized, and unintended distribution network through which secondary wholesalers buy and sell medications at inflated prices.”⁵³ For numerous years, gray markets have existed in several different forms in various industries. When a distributor

⁵⁰ *Id.*

⁵¹ *Id.* This happens very infrequently; however, there are some benefits in selling to secondary wholesale distributors. For example, if a manufacturer or primary wholesaler is overstocked in a particular drug, secondary wholesale distributors buy the surplus and save those entities from keeping the drugs too long. Drugs do not last in inventory forever. Also, secondary distributors can help in smaller, low volume transactions and sell to a remote, more specific population. The secondary distributors can spread the drug sales to entities that would not normally be in contact with the primary wholesalers. *Id.* at 4.

⁵² *Id.* at 5.

⁵³ *Id.* at 1.

buys a manufacturer's goods internationally and imports them into the United States or buys them cheap domestically and competes with the other domestic goods—often times at cheaper prices—it is called a gray market.⁵⁴ The pharmaceutical drug gray market is filled with opportunists that price gouge the drugs, “taking full advantage of the low supply and high demand” relationship that resulted from the national drug crisis that began in 2000,⁵⁵ becoming “an avenue for opportunists to profit from the national drug crisis.”⁵⁶ The national drug crisis creates an environment that forces hospitals to choose alternative treatment, if available, and more egregiously, choose which patient will receive available medications.⁵⁷ In a skewed life-saving drug supply-demand relationship, the gray market is often times the only distribution available: a doctor's last resort.

A gray market medication distribution chain differs from a normal drug distribution chain because it has a “leak” in its chain; “one of the entities within the normal distribution network fails to follow the authorized and intended steps.”⁵⁸ Although secondary wholesalers can be helpful at times, “wholesalers create vulnerabilities in the links of the chain when they sell to other wholesalers, enabling drugs to disperse out of the legitimate supply and into the gray market.”⁵⁹ The wholesalers do this to make a profit off of the drug.⁶⁰

There is no surplus of the drug that the wholesalers sell to other wholesalers; they resell the drugs in order to increase the profits made off of a particular drug due to unaffected high demand.⁶¹

⁵⁴ Jevan Jammal, *The Gray Market Infiltration of a Vulnerable United States Health Care*, 9 J. HEALTH & BIOMEDICAL L. 553, 553 (2014).

⁵⁵ *Id.* at 554.

⁵⁶ Mahugh, *supra* note 12, at 3.

⁵⁷ *See id.*

⁵⁸ *Id.* at 5.

⁵⁹ Jammal, *supra* note 54, at 564.

⁶⁰ *See Short-Supply Prescription Drugs*, *supra* note 11, at 2. The FDA reports that gray drugs are more likely to leak into a supply chain with multiple wholesalers. For example, “the shipment of 25 vials of a chemotherapy drug called fluorouracil in September 2011 [had a] leakage point [at a] Maryland pharmacy called Priority Healthcare. Instead of dispensing the drug to patients, the owner of this company, Marianna Pesti, sold the vials to a New Jersey distributor called Tri-Med America, which was owned by Ms. Pesti's husband, Gabor Szilagyi. The drugs were sold five more times before reaching their end user, a hospital in California.” *Id.* at 4.

⁶¹ *Id.* Selling to wholesalers even when there is not a surplus sometimes helps companies make a profit because a secondary wholesaler will pay more for the drugs to

Gray market companies sit back and watch the drug distributions and the reports on the scarcity of drugs. Once there is a leak in the chain of a drug in shortage being sold, they pounce by offering high prices to wholesalers in order to be the highest bidder for that particular drug, so that they can create a monopoly of a life-saving drug.⁶² Once the drugs are bought and sold by multiple companies, they are eventually sold to a dispensing entity at an egregiously high price.⁶³ The final price on gray market-traded drugs may be hundreds of times higher than the price that the manufacturer originally received from selling the product.⁶⁴

Pharmacies are also partially to blame for empowering the gray market. Licensed and unlicensed pharmacies are used as purchasing agents for gray market companies; some pharmacies that participated in a 2011 survey stated that they were contacted to buy medications in short supply on the gray market companies' behalf.⁶⁵ Companies do this to avoid detection in the rare case that there are pedigree systems.⁶⁶ In addition, some companies went as far as lying to the pharmacies by saying that the drugs would be distributed to hospitals for free in order to curb the drug shortages.⁶⁷ Gray market companies and second wholesalers would pay the pharmacies 12-15 percent more than the price the pharmacies would pay for the drugs and then the entities would

make the drugs available to areas that are not near any other wholesaler or dispensing entity. In addition, wholesalers can increase the price to an amount that a secondary wholesaler will agree to in order to cover costs knowing that the secondary wholesaler will be able to find gray market companies to buy the drugs. *Id.*

⁶² Mahugh, *supra* note 12, at 1.

⁶³ See *Short-Supply Prescription Drugs*, *supra* note 11, at 4. In 2011, a Congressional investigation by Representative Elijah Cummings, Senator John D. Rockefeller IV, and Senator Tom Harkin, reached out to five gray market companies believed to be aggressively marketing to hospitals that were in short supply of drugs to treat cancer. Pedigrees named 125 different companies that at one time possessed one of the five short-supply drugs under investigation. *Id.* at 3. The study found that in 69% of the 300 investigated distribution chains, prescription drugs had been "leaked" into gray market chains, and had been sold again by wholesalers to other gray market companies at large mark up prices. *Id.* at 4. Additionally, gray market companies heavily advertise and market to the dispensing entities to buy the drugs quickly. An example of such language is: "We only have 20 of this drug left and quantities are going fast." *Id.* at 7 n.21.

⁶⁴ See *id.* at i-ii.

⁶⁵ See *id.* at 16.

⁶⁶ *Id.* at 92.

⁶⁷ *Id.* at 17.

charge 40 percent more for the drugs when selling them to other dispensing entities such as other pharmacies and hospitals.⁶⁸

For example, companies like Mylan and Turing Pharmaceuticals are just two companies in the limelight for these behaviors. The following examples show how the existence of the gray market can result in an insanely high increase in the price of life-saving drugs.

Recently, Mylan, the company that produces the EpiPen,⁶⁹ is alleged to be gouging consumers with a retail price of \$608 dollars per two-pack.⁷⁰ This is a 500% increase from the original price.⁷¹ In an interview, Mylan's CEO, Heather Bresch, tried to justify the price increase by mentioning discounts for patients.⁷² Bresch's interview ultimately showed that her justifications for the price increase were weak.⁷³

Additionally, Turing Pharmaceuticals is another company that has price gouged life-saving drugs like, Daraprim.⁷⁴ The company received the selling rights for Daraprim from Impax, a California

⁶⁸ Mahugh, *supra* note 12, at 5-6. Companies would market these medications to hospitals and other dispensing entities in an aggressive way and portray the drug as a "must have" before the price would go up. *Id.* at 6.

⁶⁹ The EpiPen Auto-Injector "is a disposable, pre-filled automatic injection device that administers epinephrine in the event of a severe allergic reaction." *How to Use EpiPen*, EPIPEN, <http://www.epipen.ca/en/about-epipen/how-to-use?user=consumers> (last visited Feb. 25, 2017).

⁷⁰ Dan Mangan & Anita Balakrishnan, *Mylan CEO Bresch: 'No one's more frustrated than me' about EpiPen price furor*, CNBC (Aug. 25, 2016), <http://www.cnn.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html>.

⁷¹ The Associated Press, *New York attorney general investigates EpiPen manufacturer*, NCPRO.ORG (Sept. 7, 2016), <https://www.northcountrypublicradio.org/news/story/32519/20160907/new-york-attorney-general-investigates-epipen-manufacturer>.

⁷² See Melody Petersen, *Mylan CEO blames rising cost of the EpiPen on 'opaque' industry pricing*, LA TIMES (Sept. 21, 2016, 3:55 PM), <http://www.latimes.com/business/la-fi-mylan-ceo-20160921-snap-story.html>; Associated Press, *Mylan to launch a cheaper, generic version of EpiPen*, LA TIMES (Aug. 29, 2016, 2:35 PM), <http://www.latimes.com/business/la-fi-mylan-new-epipen-20160829-snap-story.html>.

Tyrone Gayle, a Hillary Clinton spokesman, was quoted saying during Clinton's campaign that "discounts for selected customers without lowering the overall price of EpiPens are insufficient, because the excessive price will likely be passed on through higher insurance premiums." Mangan, *supra* note 70.

⁷³ See Petersen, *supra* note 72.

⁷⁴ See Kevin McCoy, *Former Shkreli firm responsible for 5,000% drug hike sued*, USA TODAY, <https://www.usatoday.com/story/money/2016/05/02/former-shkreli-pharma-firm-sued/83820888/> (last updated May 2, 2016, 3:04 PM) ("Daraprim is used to treat toxoplasmosis, a potentially life-threatening illness that afflicts those with AIDS, cancer or other conditions that weaken the immune system.").

company, in August 2015.⁷⁵ Martin Shkreli, the CEO of Turing Pharmaceuticals, raised the per-pill cost of Daraprim 5,000% from \$13.50 to \$750 in 2015.⁷⁶ The price increase created tremendous turmoil in the media and “generated complaints from patients, health industry experts and presidential candidates.”⁷⁷ Shkreli was questioned by the media and Congress about the increase in price.⁷⁸ Shkreli told the media that Daraprim, the once unprofitable drug, was now profitable under his Turing leadership, but pled the fifth when questioned by Congress.⁷⁹ With no straight answers on the price gouging activities, Shkreli resigned from Turing in December.⁸⁰

In addition to the above practices, these companies that buy the drugs eventually have a monopoly on specific drugs.⁸¹ They buy up an entire supply or nearly almost an entire supply of the drug to have complete control, resulting in dispensing entities having no other choice but to buy from them.⁸² Thus, the gray market and its players are free to continue its practices.

ii. Issues with Drug Shortages and the Gray Market

The gray market poses many issues for dispensing entities and, ultimately, patients. For health care, the gray market creates tensions between access, quality of care, and high costs.⁸³ There is a lack of transparency in distribution networks as there are constant investigative failures in revealing who gets the drugs and from where.⁸⁴ This lack of transparency creates an environment that leads to endless, unregulated gray market activity, which

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ See *id.*; Ariana Eunjung Cha, *CEO Martin Shkreli: 4,000 percent drug hike is ‘altruistic,’ not greedy*, WASHINGTON POST (Sept. 22, 2015), <https://www.washingtonpost.com/news/to-your-health/wp/2015/09/22/turing-ceo-martin-shkreli-explains-that-4000-percent-drug-price-hike-is-altruistic-.../1/3/?noredirect=on>.

⁷⁹ See McCoy, *supra* note 74; Cha, *supra* note 78.

⁸⁰ McCoy, *supra* note 74.

⁸¹ See Joshua Gregg, *The Implications, Negative Health Effects, Legal Issues, and Potential Solutions Associated with the Shortage of Essential Drugs in the U.S. Medical Care Market*, 25 ALB. L.J. SCI. & TECH. 381, 384 (2015).

⁸² Mahugh, *supra* note 12, at 3.

⁸³ Jammal, *supra* note 54, at 562.

⁸⁴ *Id.* at 564 n.55.

then results in economic hardships and health risks for patients, in addition to poor drug quality in the life-saving drugs.⁸⁵

1. *ECONOMIC PROBLEMS*

Price gouging occurs easily when gray market companies can participate in gray market distribution chains.⁸⁶ Price gouging concerns arise because the gray market allows the medications to pass through so many entities.⁸⁷ When healthcare providers are faced with life and death situations daily, some hospitals resort to purchasing life-saving drugs on the gray market at “exorbitant prices.”⁸⁸ The expensive gray market resales do not seem to be slowing down any time soon, making the end prices extremely unaffordable for the last buyers, which are usually the dispensing entities and patients.⁸⁹

A study by Premier Healthcare Alliance researched 416 different medications that were used to treat emergencies and serious conditions, such as cancer and infectious disease; the study concluded that these medications had an average markup of 650 percent above the original market price.⁹⁰ Even more appalling are the markup prices of the most critical medications—averaging 1,721 percent to 4,533 percent above the original price.⁹¹ Some companies have even marked up the prices as much as 5,000 percent or more without any repercussions from regulating authorities.⁹² Finally, one study concluded that the average

⁸⁵ *See id.* at 567-69.

⁸⁶ *See* Mahugh, *supra* note 12, at 1-2.

⁸⁷ *See id.*

⁸⁸ Lee, *supra* note 30, at 362.

⁸⁹ *See* Mahugh, *supra* note 12, at 6-7. Insurance companies are also affected by the increased prices of the lifesaving drugs. Insurance companies could cover the cost of some drugs, depending on the insurance company and the plan coverage. However, this coverage might come at a cost of high premiums to the insured. While this is certainly a significant concern, this Note does not discuss the role insurance companies play in the price of these drugs resulting from gray market practices. *See* Potarazu, *supra* note 3.

⁹⁰ Mahugh, *supra* note 12, at 6; Lee, *supra* note 30, at 362-63.

⁹¹ Coleen Cherici, Patrick McGinnis & Wayne Russell, BUYER BEWARE: DRUG SHORTAGES AND THE GRAY MARKET, PREMIER HEALTHCARE ALLIANCE 2 (Aug. 2011), <http://www.anco-online.org/GrayMarketAnalysis-Premier.pdf>.

⁹² *Id.* at 3.

markup was 650 percent while another found that most medical markups were around 900 percent.⁹³

These egregiously high markups affect most of the patients that are in need of the medications because the medications are unaffordable. CNN reporter, Sreedhar Potarazu, reported “[b]ased on a recent survey by Consumer Reports, 33% of Americans” were paying an additional \$39 out of pocket for regular prescriptions drugs they needed.⁹⁴ The working poor and the middle class are struggling in a more egregious way: “For low-income and many fixed-income Americans, paying the rising cost of prescription drugs” and life-saving drugs forces them to cut back on daily expenses like groceries or rent payments.⁹⁵ According to the Consumer Reports survey, seven percent of people said that due to these increased prices, they had to skip a mortgage payment.⁹⁶ Additionally, the survey reported that one out of four people were unable to pay their medication bills and had to stop getting their prescriptions filled.⁹⁷ Due to the egregiously high prices, the working poor and the middle class in America have no choice but to make immense sacrifices in their daily lives or, even worse, stop treatment and risk poor health.

Not being able to afford medications is not the only consequence of high prices. Eventually, patient safety and the quality of the drugs are also impacted by the high prices.

2. *PATIENT SAFETY*

Gray market pharmaceuticals also have negative effects on patient health and safety in the United States.⁹⁸ First, quantity needs are not being fulfilled. “According to an AHA survey, seventy-eight percent of respondents reported rationing or

⁹³ Mahugh, *supra* note 12, at 6; *Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis*, INST. FOR SAFE MEDICATION PRACS. 5 (Aug. 25, 2011), <http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=3>.

⁹⁴ Potarazu, *supra* note 3, at 2.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ Jammal, *supra* note 54, at 553.

restricting drugs.”⁹⁹ When there is no alternative to a life-saving drug, one physician stated, “I guess patients just have to die.”¹⁰⁰

Second, another related concern is the use of alternative medications that are inferior, compromised, or ineffective.¹⁰¹ Providers are prescribing second-line alternatives because of the unavailability of life-saving treatments.¹⁰² In the same AHA survey, sixty-nine percent of respondents indicated that patients received a less effective drug after turning to the gray market due to shortages, and thirty-five percent reported that patients that were given those alternative treatments “have experienced adverse outcomes.”¹⁰³ In another study, “[t]welve percent reported side effects or other problems attributable to drugs supplied by the gray market.”¹⁰⁴

3. POOR DRUG QUALITY

“In addition to paying exorbitant prices, hospitals acquiring drugs through the gray market have no guarantee of the drug’s quality.”¹⁰⁵ “[D]rugs sold through the gray market may be diluted, expired, contaminated, or relabeled with the wrong information,”¹⁰⁶ or “improperly repackaged, re-labeled, and possibly stored under unsuitable conditions, as well as replaced by counterfeits, compromising their integrity and safety.”¹⁰⁷ Because drugs in the gray market are not being regulated, they may be unsafe even if they are being labeled and sold as the same drug purchased through the regular market.

Because the national drug crisis affects the pharmaceutical market and has enabled the gray market to proliferate, Americans, particularly the working poor and middle class, are

⁹⁹ AHA SURVEY ON DRUG SHORTAGES, AM. HOSP. ASS’N at 9 (July 12, 2011), www.aha.org/content/11/drugshortagesurvey.pdf.

¹⁰⁰ Lee, *supra* note 30, at 362.

¹⁰¹ See AHA SURVEY ON DRUG SHORTAGES, *supra* note 99, at 8.

¹⁰² Lee, *supra* note 30, at 361.

¹⁰³ *Id.* at 362.

¹⁰⁴ *Id.* at 363.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ Thomas A. Hemphill, *Should the FDA Regulate Drug ‘Gray Markets?’*, CATO INST., Fall 2015, at 3, <http://object.cato.org/sites/cato.org/files/serials/files/policy-report/2015/9/regulation-v38n3-6.pdf>.

experiencing the many negative consequences.¹⁰⁸ These negative consequences include economic concerns, patient safety risks, and compromised drug quality.¹⁰⁹ These consequences are normally addressed with legislation and regulations to control the pharmaceutical market; however, these laws do not include language pertaining to the gray market, and therefore they only indirectly affect it and do not directly address these issues.¹¹⁰

III. INDIRECT LEGISLATION AND REGULATION ON THE GRAY MARKET CURRENTLY IN PLACE

In the United States, all food, drugs, cosmetics, and medical devices are regulated under the authority of the Food and Drug Administration (“FDA”).¹¹¹ The FDA was created by the government in response to the pressing need to address the public’s safety with respect to its food and drugs.¹¹²

Legislation concerning the normal drug distribution is thorough; however, these acts that regulate the normal drug distribution fail to fully address the gray market problem, having only an indirect effect on the gray market.¹¹³ This section discusses the current federal legislation and regulations addressing pharmaceutical drugs, including the Prescription Drug Marketing Act, the FDA’s Office of Criminal Investigation, the Federal Trade Commission Act, Executive Order No. 13,588, and the Food and Drug Administration Safety and Innovation Act. However, because the legislation only indirectly effects the gray market, most of these laws fail to regulate the pharmaceutical market properly.¹¹⁴ This section also includes a discussion of the lack of state legislation and regulation.

¹⁰⁸ See Potarazu, *supra* note 3.

¹⁰⁹ See *supra* part (II)(B)(b).

¹¹⁰ See Mahugh, *supra* note 12, at 1, 7-8.

¹¹¹ *What does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated Aug. 22, 2018).

¹¹² See *When and why was FDA formed?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/transparency/basics/ucm214403.htm> (last updated Aug. 22, 2018).

¹¹³ See Mahugh, *supra* note 12, at 1, 7-8. Indirect legislation and regulation refer to current legislation and regulations that do not address the gray market specifically, but that do address other aspects of the pharmaceutical market.

¹¹⁴ See Mahugh, *supra* note 12, at 1, 7-8.

A. Federal Legislation and Attempts at Attacking the Gray Market

a. Prescription Drug Marketing Act (PDMA) and Counterfeit Drug Task Force

One of the FDA's first attempts to address price gouging was in the 1980s "in response to companies and individuals buying and selling counterfeit medications through unauthorized gray market distribution channels," but it had no means of enforcement.¹¹⁵ In 1987, the FDA implemented the Prescription Drug Amendment Act of 1987 ("PDMA") to "increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the US supply chain."¹¹⁶ In addition to the Act, the FDA created a Counterfeit Drug Task Force to evaluate the problem of the gray market, mainly focusing on the counterfeit drugs at the time and how the government should try and find a solution to the increase in counterfeit drugs.¹¹⁷

The idea of pedigree systems was a result of the increase in counterfeit drugs.¹¹⁸ Although pedigree systems would have been helpful to the Counterfeit Drug Task Force, they were mentioned

¹¹⁵ Mahugh, *supra* note 12, at 7.

¹¹⁶ Prescription Drug Amendment Act of 1987, 21 C.F.R. § 203 (2018); *Prescription Drug Marketing Act of 1987*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentsToTheFDCAct/PrescriptionDrugMarketingActof1987/ucm2005644.htm> (last updated Mar. 29, 2018); 21 C.F.R. § 203.1 (2018) ("This part sets forth procedures and requirements pertaining to the importation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples"); 21 C.F.R. § 203.2 (2018) ("The purpose of this part is to implement the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see part 205 of this chapter), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.").

¹¹⁷ See Marvin M. Goldenberg, *New FDA Initiatives in Response To the Problem of Counterfeit Drugs*, 30(3) PHARMACY & THERAPEUTICS 166, 166, 171-72. https://www.ashp.org/news/2003/08/20/fda_launches_new_initiative_to_battle_counterfeit_drugs.

¹¹⁸ *Counterfeit Drug Task Force Report 2006 Sections I and II: Introduction and Background*, U.S. FOOD & DRUG ADMIN. (Sept. 10, 2009), <https://wayback.archiveit.org/7993/20170114034344/http://www.fda.gov/Drugs/DrugSafety/ucm172773.htm>.

Pedigree systems identify what exactly is being bought and sold. See Prescription Drug Amendment Act of 1987, 21 C.F.R. § 203 (2018).

but never put in place in 1987; these pedigree papers would be provided to the purchasers of these drugs with information regarding the prior sale or trade of the drug dating back to the manufacturer.¹¹⁹ Stricter, more accurate pedigree systems, although more costly to companies and entities, could provide information for regulation enforcers.¹²⁰ In 2006, the FDA amended the act to include a definition of an “authorized distributor” and the subsequent statutory provision that all unauthorized distributors must satisfy pedigree requirements that includes, among other criteria, dosage, container size, date of each previous transaction, business name and addresses of all parties involved.¹²¹ When pharmaceutical companies challenged the additional provision about unauthorized distributors in court, the “court found that providing pedigree information upon distribution would increase consumer costs in the form of insurance premiums and prescription drug prices,” ruling in favor of the companies and not requiring a pedigree system.¹²² Ultimately, the PDMA and the task force did not have the adequate funds or government support to regulate the gray market properly.

b. FDA’s Office of Criminal Investigation

In addition to the PDMA, the FDA also employs its Office of Criminal Investigations to examine violations of federal statutes, such as the Food, Drug, and Cosmetic Act and the Federal Anti-

¹¹⁹ 21 C.F.R. § 203 (“The PDMA states that an authorized distributor of record is a distributor that has an ‘ongoing relationship’ with a manufacturer to distribute that manufacturer’s drug. However, the PDMA does not define ‘ongoing relationship.’”). This makes it easier to detect distributors that are not common in addition to also detecting the more common distributors that participate in price gouging.

¹²⁰ *See id.*

¹²¹ *See id.* §203.50. This requirement reaches the entities that are not approved by the FDA. Essentially, making it a requirement for any entity to report information to close any transparency gaps. *See also* Jammal, *supra* note 54, at 574-76.

¹²² *RxUSA Wholesale, Inc. v. Dep’t of Health and Human Servs.*, 467 F. Supp. 2d 285, 292 (E.D.N.Y. 2006), *aff’d*, 285 F. App’x 809, 809 (2d Cir. 2008); Jammal, *supra* note 54, at 570 (“The court . . . acknowledge[d] a substantial likelihood of success on the merits in favor of the pharmaceutical companies’ equal protection claim against the FDA. The court found a public interest in exempting ‘unauthorized wholesale distributors’ from providing pedigree information in order to allow smaller distributors to provide drugs for their customers and stay in business.”).

Tampering Act.¹²³ Both of these acts oversee the safety of food, drugs, and cosmetics and the tampering of any consumer products that can be harmful to the public.¹²⁴ These acts are a step in the right direction to regulate the gray market because they are attempting to address the patient safety and drug quality issues the gray market creates. However, they are not as effective as intended because the “FDA exercises direct authority over the approval and manufacture of drugs, while the states have primary authority over distribution, repackaging, dispensing, returns and disposal of medicines. And most states don’t have the authority, resources or knowledge to regulate and monitor the industry.”¹²⁵ The problems that result from the gray market often happen in the distribution chain, which is normally regulated by state law, so the Federal Government struggles to be an influential regulator at times over these matters.

c. Obama’s Executive Order

On October 31, 2011, in response to increasing drug shortages, President Obama issued an executive order that directed the FDA to use its existing authority “to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages” of life-saving drugs.¹²⁶ The order provides that the FDA and the Department of Justice work together to see if entities are hoarding medications during the drug shortages.¹²⁷ The executive order also required the FDA “to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes” and to “communicate to the Department of Justice (DOJ) any findings that shortages have led market participants to stockpile the affected drugs.”¹²⁸ This executive order is directed at the gray market because it tries to determine the new entities

¹²³ See *About OCI*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/CriminalInvestigations/ucm550316.htm> (last updated Mar. 12, 2018); Mahugh, *supra* note 12, at 7.

¹²⁴ Federal Anti-Tampering Act, 18 U.S.C. § 1365 (2018); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, 331 (2018).

¹²⁵ Mahugh, *supra* note 12, at 8.

¹²⁶ Exec. Order No. 13,588, 76 Fed Reg. 68,295 (Oct. 31, 2011).

¹²⁷ See *id.*; Mahugh, *supra* note 12, at 8.

¹²⁸ 76 Fed Reg. 68,295 (2011).

entering the distribution chain.¹²⁹ Additionally, it indirectly addresses gray market concerns by focusing on the drug crisis by determining what drugs are falling subject to shortages before it becomes a big enough problem for the drugs to enter the gray market.¹³⁰ However, the executive order's only enforceable power involves "further investigation, not concrete regulation."¹³¹

d. Food and Drug Administration Safety and Innovation Act

In July 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act ("FDASIA") into law.¹³² This Act was aimed at the drug crisis problem instead of the gray market problem; it expands the scope of drug shortage reporting requirements.¹³³ The Act amended the existing Food, Drug, & Cosmetic Act drug shortage notification requirements and adds new notice provisions.¹³⁴ Notice requirements will apply to all manufacturers of medically important, approved and unapproved drugs.¹³⁵ All manufacturers, within six months of the drug actually falling into short supply, must report if a medication is likely to become permanently wiped out and the reasons behind the shortage or depletion.¹³⁶

In addition, the FDA's responsibilities pertaining to the public are expanded by this act because the FDA is required to create a process for public entities that will make it easier to report such important facts regarding drugs.¹³⁷ The FDA is also obliged to annually report to Congress which drugs are anticipated to have

¹²⁹ *See id.*

¹³⁰ *See* Mahugh, *supra* note 12, at 8.

¹³¹ *Id.*

¹³² Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012).

¹³³ *See id.* The act was an extension of Obama's executive order in regard to the reporting requirements. *See* Mahugh, *supra* note 12, at 8.

¹³⁴ Food and Drug Administration Safety and Innovation Act, §§ 715, 1002; Lee, *supra* note 30, at 380 ("Title X of the Act: (1) expands drug supply disruption and reporting requirements, (2) directs the FDA to take specific actions to prevent or mitigate shortages, (3) creates a mechanism for tracking drug shortage data and sharing that information with key stakeholders, and (4) establishes a task force to analyze the causes of drug shortages and devise strategic plans that address the shortages. . . . Title X also expands the scope of drugs subject to shortage notification to include drugs used during emergency medical care or surgery.").

¹³⁵ §§ 1001, 1002.

¹³⁶ § 1001.

¹³⁷ *See id.* FDA also must maintain a publicly available list of drugs shortage. *Id.*

shortages; the report includes a plan describing ways to prevent the drug shortage or mitigate the drug shortage of a particular drug.¹³⁸ The FDA should not take any enforcement action that could have an adverse impact on a drug's supply center before sending a warning to the supply chain; the impact of a warning letter, according to this Act, can sometimes be a sufficient way to prevent the continued bad faith practices before taking any enforcement action.¹³⁹

FDASIA, however, is not directed at the gray market because, even though fixing the national drug crisis issue would eventually destroy the gray market by making more life-saving medications available in the normal distribution channel, addressing the national drug crisis is an entirely separate issue on its own and will not directly impact the gray market immediately.¹⁴⁰ The distribution chain and the leakage points are the major contributing factor to the success of the gray market.¹⁴¹ The national drug crisis simply creates an environment for the entities to participate in the gray market; a shortage of drugs cannot be repaired overnight. To cease gray market operation more quickly, more regulation needs to be directed at the distribution itself.

e. Federal Trade Commission

In an attempt to create enforceable regulations, senators started to request that the FTC get involved to prevent unfair practices by gray market participants.¹⁴² Involvement included examining the behaviors of the gray market companies and entities involved with the gray market to see if there were any violations of the Federal Trade Commission Act.¹⁴³ The Federal Trade Commission Act is

¹³⁸ *Id.*; Mahugh, *supra* note 12, at 8.

¹³⁹ *See* § 1003; Lee, *supra* note 30, at 376-77 ("As part of addressing issues raised in FDA warning letters, all of the recipients temporarily halted production. When explaining these concurrent production stoppages to Congress, the FDA stated that they were voluntary manufacturer decisions. However, given the explicit threat contained in FDA warning letters ('[f]ailure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction'), the 'voluntariness' of such action is questionable. By February 2012, fifty-eight percent of the drugs in short supply were manufactured by one or more of the facilities that had received a warning letter from the FDA and were undergoing remediation efforts.").

¹⁴⁰ *See* Mahugh, *supra* note 12, at 8.

¹⁴¹ *See id.* at 5-6.

¹⁴² Lee, *supra* note 30, at 399.

¹⁴³ *Id.*

an important statute and is empowered to do many helpful things relating to federal trade:

[It] is the primary statute of the Commission. Under this Act, as amended, the Commission is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; (c) prescribe rules defining with specificity acts or practices that are unfair or deceptive, and establishing requirements designed to prevent such acts or practices; (d) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce; and (e) make reports and legislative recommendations to Congress and the public.¹⁴⁴

Essentially, the FTC could prevent and investigate any unfair methods of competition and conduct investigations on entities relating to entities engaged in commerce and then suggest legislation to Congress.¹⁴⁵ With this power, the FTC could have some impact, preventing certain entities from participating in the gray market. The senators wanted the FTC to look into the healthcare delivery system and the effect the gray market was having on the access to lifesaving drugs.¹⁴⁶ The FTC has done some investigations, but none have been reported to the public.¹⁴⁷

The FTC, although a body of government that can make a difference, only investigates and studies the gray market but does not take action against the gray market and its unethical practices.

¹⁴⁴ Federal Trade Commission Act, 15 U.S.C. §§ 41-58 (2018); *Federal Trade Commission Act*, FED. TRADE COMM'N, <https://www.ftc.gov/enforcement/statutes/federal-trade-commission-act> (last visited Sept. 19, 2018).

¹⁴⁵ See 15 U.S.C. § 57b.

¹⁴⁶ Lee, *supra* note 30, at 399.

¹⁴⁷ See Patricia Earl & Phillip L. Zweig, *Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-Dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage*, CARE & COST (Feb. 14, 2012), <http://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/>; Lee, *supra* note 30, at 399.

B. State Legislation and Attempts at Attacking the Gray Market

States are attempting to address the gray market by determining who the true underlying entities are in the gray market distribution. States are attempting to regulate certain aspects relating to the gray market, such as wholesalers, but they are not regulating the distribution of the drugs which is another big aspect of the gray market as well.¹⁴⁸ States are focusing on their pharmacies and wholesalers by implementing state pedigree systems in order to slow the gray market down and provide a more concrete way for legitimate drugs to be bought;¹⁴⁹ pedigree systems require a record of what the drug is and where it was made with all of the buyers listed.¹⁵⁰ Having a list of all of this information will make the gray market more transparent and easier to target for regulators.

“While state and federal law requires wholesalers . . . to provide a pedigree documenting the drug’s distribution route, manufacturers and authorized distributors are exempt from such requirements.”¹⁵¹ California is making manufacturers equally accountable to report information on a pedigree system.¹⁵² California implemented an electronic pedigree system about a decade ago, but it only has started being used and put into effect.¹⁵³ Although states have the legislative power to affect the distribution of these drugs, they do not.¹⁵⁴ This further shows why federal legislation is needed.

¹⁴⁸ NAT’L ALLIANCE FOR MODEL ST. DRUG LAWS, DRUG PEDIGREE REQUIREMENTS FOR PHARMACIES AND WHOLESALERS STATE STATUTES (2010), <http://www.namsdl.org/library/3B95E55C-1C23-D4F9-74025D5E2B9B3371/>.

¹⁴⁹ *See id.*

¹⁵⁰ *See supra* note 121.

¹⁵¹ Jammal, *supra* note 54, at 570.

¹⁵² Stephen Barlas, *California e-Pedigree Rules Pose Challenges for Pharmacies*, 33(6) PHARMACY AND THERAPEUTICS, 360, 360 (2008).

¹⁵³ CAL. BUS. & PROF. CODE § 4163.5 (2011) (repealed 2015). Pedigree systems can affect the gray market because the companies will be identified more easily by the FDA in addition to there being more of a warning as to what target drugs the gray market will turn to next.

¹⁵⁴ The states that are trying to address the issue are not succeeding.

Four states - Arkansas, Kentucky, Maine, and Texas - have enacted laws restricting the price gouging behaviors by putting a cap on price increases for medication or medical supplies during declared emergencies. Other states have laws addressing price gouging for goods generally during declared emergencies. However, laws addressing price-gouging behaviors only during declared emergencies do not

IV. CURRENT PROPOSED LEGISLATION

Although current legislation does not directly affect the gray market, some proposed legislation would reduce the negative effects that the existence of the gray market creates.¹⁵⁵ The 112th and 113th Congresses proposed legislation to address the gray market problems.¹⁵⁶ These laws propose to prohibit secondary wholesalers from buying drugs from pharmacies, hold wholesalers accountable for their actions, increase reporting requirements, and make price gouging illegal during a time of shortage.¹⁵⁷ While these proposed regulations will have an impact on the gray market and price gouging, they fall short of being effective because they promote, at times, too much regulation on the wholesalers and did not have enough support in Congress to be passed.¹⁵⁸

A. *112th Congress*a. Gray Market Drug Reform (Transparency Act of 2012)

This act, referred to the Committee on Energy and Commerce, was introduced to the House of Representatives in May 2012 by Representative Cummings.¹⁵⁹ However, this act was not introduced in the 113th Congress or the 114th Congress.¹⁶⁰ This act essentially amends the Federal Food, Drug, and Cosmetic Act by “prohibit[ing] a secondary wholesaler from purchasing or receiving a prescription medication from a pharmacy or a pharmacist.”¹⁶¹ In addition, it would increase reporting requirements for those entities that are involved with any type of drug distribution, call for a national wholesaler distributor

address the gray market problems during drug shortages, unless federal or state governments decide to declare drug shortages emergencies.

Mahugh, *supra* note 12, at 8.

¹⁵⁵ Gray Market Drug Reform and Transparency Act of 2012, H.R. 5853, 112th Cong. (2012).

¹⁵⁶ *Id.*; Gray Market Drug Reform and Transparency Act of 2013, H.R. 1958, 113th Cong. (2013).

¹⁵⁷ H.R. 5853; H.R. 1958.

¹⁵⁸ H.R. 5853; H.R. 1958.

¹⁵⁹ H.R. 5853; Mahugh, *supra* note 12, at 9.

¹⁶⁰ H.R. 5853; Mahugh, *supra* note 12, at 9.

¹⁶¹ H.R. 5853; Mahugh, *supra* note 12, at 9. Pharmacies that sell back to wholesalers are a part of the problem that creates the leakage in the distribution chain of the gray market. Mahugh, *supra* note 12, at 5.

database, and collect fees from the distributors.¹⁶² “Notably, the act would require each person engaged in wholesale distribution of interstate drug commerce to annually report their name, contact information, place of business and licensing information to each state’s Secretary of State in which that person conducts his or her business.”¹⁶³ This would help enforcement groups identify the trouble makers in the gray market that are increasing the prices with every sale.¹⁶⁴ The act would also require that information regarding short supply medication prices be reported and have a detailed history of that short supply of the particular drug.¹⁶⁵

However, the bill does have some weaknesses. Even if the Secretary of State checks on the wholesalers, the same outrageous prices for drugs needed for patients would remain constant because it just requires reporting the information but does not prohibit price increases.¹⁶⁶ Another reason this act was not reintroduced into recent Congresses was because it prohibited secondary wholesalers from buying medications from pharmacies.¹⁶⁷ A complete ban, although perhaps somewhat effective in preventing distribution chain leaks, would hinder the benefits that secondary wholesalers provide in their role in the supply-distribution chain.¹⁶⁸ However, even though the act does not directly prohibit price gouging, it would make it very possible for law makers and the government to spot who the gray market companies are and how they are getting access to these drugs before any price gouging activities happen.¹⁶⁹ The act makes it easy for the government to identify illegitimate behaviors of gray market companies and regulate the market.¹⁷⁰

¹⁶² H.R. 5853. The database would have collections of the reported data and information on actions against wholesale distributors by state governments. Mahugh, *supra* note 12, at 9. The fee collection will also give the government more funds to increase its enforcement power. *Id.*

¹⁶³ Jammal, *supra* note 54, at 573. All the reported information would be available on the FDA’s website for anyone to observe. *Id.* See also H.R. 5853 § 3(a).

¹⁶⁴ See Jammal, *supra* note 54, at 573; H.R. 5853.

¹⁶⁵ H.R. 5853.

¹⁶⁶ Jammal, *supra* note 54, at 574.

¹⁶⁷ H.R. 5853 § 1(a).

¹⁶⁸ Mahugh, *supra* note 12, at 9.

¹⁶⁹ See *id.*

¹⁷⁰ *Id.*

b. Protecting Patients and Hospitals from Price Gouging Act

In September 2012, Senator Schumer introduced, in the Senate, the second proposed federal bill attempting to attack the gray market.¹⁷¹ This act was referred to the Committee on Health, Education Labor and Pensions, but it was not reintroduced in the 113th Congress.¹⁷² This act would have made price gouging of prescription drugs during a time of shortage an illegal activity.¹⁷³ Wholesale distributors would be held accountable if they charged “unreasonably excessive” prices for short supply drugs.¹⁷⁴ The accountability that distributors would be subjected to could include imprisonment up to 3 years, fines up to \$500,000, or a combination of both.¹⁷⁵ Unfortunately, even with the potential benefits that this act could create, it was not passed.

B. *114th Congress’ Fair Accountability and Innovative Research Act*

The Fair Accountability and Innovative Research Drug Pricing Act of 2016 was introduced in the 114th Congress by Representative Schakowsky.¹⁷⁶ It was referred to the House of Energy and Commerce.¹⁷⁷ This bill requires manufacturers of certain drugs to report price increases that result in a “10 percent or more” increase in the price of a drug “over a 12-month period.”¹⁷⁸ A civil penalty is given to manufacturers that do not submit a required report.¹⁷⁹ “[T]he Inspector General of the Department of Health and Human Services shall annually review” drug price information to determine compliance, and any collected penalty fees go towards improving the thoroughness of the reported information and price transparency.¹⁸⁰ The Fair

¹⁷¹ *Id.*; see also Protecting Patients and Hospitals From Price Gouging Act, S. 3622, 112th Cong. (2012).

¹⁷² S. 3622.

¹⁷³ *Id.* § 2(b).

¹⁷⁴ *Id.* §§ 3, 5.

¹⁷⁵ S. 3622 § 5.

¹⁷⁶ Fair Accountability and Innovative Research Pricing Act of 2016, H.R.6043, 114th Cong. (2016).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* § 1(b).

¹⁷⁹ *Id.* § 39900(b).

¹⁸⁰ *Id.* § 39900(e).

Accountability and Innovative Research Act, if passed, will be the only recent act that addresses proper price increase reporting requirements and will be a great start to shutting down the gray market.

The proposed laws address very specific groups participating in the gray market. Some of them only address one type of group that is involved in the gray market and price gouging. Additionally, the current laws in place are geared more towards awareness and lack any enforcement power. The pharmaceutical gray market is not regulated. Proponents of regulating it often struggle to gain support because of the *laissez-faire* attitude of American business. Many Americans prioritize profits and economic gain. Lobbyists will support big business.

The gray market also may not be regulated because of the lack of resources to investigate the issue, identify the issue, and enforce the punishment of such a big issue. Gray market price gouging has multiple moving parts; thus, it needs a solution that attacks the multiple moving parts.

This Note calls for three proposed acts to be passed because they address each group that participates in the gray market from a different angle. This Note suggests that all the acts be passed together as one act or all three separately with a committee alongside the legislation to be the enforcing agent.

V. PROPOSAL

Pharmaceutical price gouging is difficult to regulate. The gray market and gray market companies are major factors controlling the price of life-saving pharmaceuticals. Attempting to regulate the gray market will, at the very least, prevent the resale of the drugs and regulate one of the channels that creates an environment for entities to price gouge. Because states are ill-equipped to handle an issue of this magnitude, this Note proposes federal intervention. Picture a one-way bridge with two lanes. One lane is the gray market channel, and the other is the price gouging companies' monopoly channel. The beginning of the bridge is the national drug crisis, and the end of the bridge is the price gouged life-saving pharmaceuticals. This Note proposes to shut down the gray market channel lane. The gray market companies and pharmaceutical companies will still be able to have

a monopoly on some of the life-saving drugs; however, the normal market will fix that issue itself. So, just as shutting one lane down would increase the traffic in the other lane and make it more difficult to get to the other side of the bridge, shutting down the gray market would increase the drug supply in the regular market and make it more difficult to price gouge. Competitors can more easily compete with these companies with the decrease in the number of resales in the gray market.

For example, recently, CVS has announced that it is introducing a generic EpiPen that is only five dollars more than the original hundred-dollar price for a two pack from Mylan.¹⁸¹ With more companies, like CVS, entering the market, companies that are price gouging will be forced to decrease their prices in order to stay competitive.¹⁸² Companies will no longer be able to hoard a supply of a life-saving drug while increasing the price because they will have to worry about staying competitive with rival companies.¹⁸³

The gray market is the connecting piece from the national drug crisis to price gouging by companies that monopolize life-saving drugs. Regulating the gray market will make it more difficult for companies to price gouge because the prices will not be resold multiple times at higher and higher prices.

Considering the number of players involved with the gray market and price gouging, a solution to the problem should be a multi-step process. First, there should be legislation to address the manufacturers. The manufacturers are the beginning of the drug distribution chain in the gray market, and there are few manufacturers in the market for life-saving drugs.¹⁸⁴ By first regulating the manufacturers and the prices they set by giving them a price range in which the drugs can be set, there would be more control in the beginning stages of drug distribution. Next, there should be legislation to address the wholesalers and distributors.¹⁸⁵ Wholesalers and distributors are the entities in a

¹⁸¹ Ben Popken, *Cigna Changes to Cheaper Generic EpiPen, CVS Cuts Rival's Prices*, NBC NEWS (Jan. 12, 2017, 4:05 PM), <http://www.nbcnews.com/business/consumer/cigna-drops-name-brand-epipen-while-cvs-offers-generic-100-n706171>.

¹⁸² *See id.*

¹⁸³ *See id.*

¹⁸⁴ *See supra* notes 7, 35.

¹⁸⁵ *See supra* Part III. This Note mentioned earlier that laws governing wholesalers and distributors in pharmaceutical markets are controlled by state law; however, presumably when drugs are sold, they are sold across state borders, making the regulation

drug distribution chain that cause a leakage and allow drugs to enter the gray market. Having regulation that directly addresses the actions of these specific entities will solve issues regarding the re-distribution of drugs and, therefore, make it more difficult for entities and companies to price gouge. Lastly, there should be legislation to address the drug companies (the companies that are the actual manufacturers themselves and the companies that just buy and sell the drugs) that are participating in the gray market and egregiously increasing the price of drugs in the final step of drug distribution. All of these types of laws should be enacted together (or in quick succession) to affect all the players at once. Alternatively, if passing three separate acts in such a short amount of time is unrealistic, a new single law that encompasses regulation of the three different groups should be passed. In addition to the legislation, there should also be a committee created strictly for the purposes of regulating and enforcing the new legislation. Specifically, the committee should focus only on the gray market and price gouging.

The Federal Government should directly regulate the gray market and the price gouging mechanisms used. The Fair Accountability and Innovative Research Drug Pricing Act of 2016 should be passed in its entirety the way it is currently drafted.¹⁸⁶ The reporting provisions and the civil remedy provisions in the act would be a great start in addressing the gray market issues.¹⁸⁷ The Act addresses manufacturers as persons who control the price of medications initially, and requires drug price transparency.¹⁸⁸ This act is directed at the manufacturers that set the price of the drug in the beginning but does not mention distribution or price fixing afterwards.¹⁸⁹

In order to address the wholesalers and distributors involved in the gray market, an act introduced in the 112th Congress, The Gray Market Drug Reform and Transparency Act of 2012, should

of distributors and wholesalers subject to federal law under the Commerce Clause. In addition, the proposed federal legislation had provisions governing both wholesalers and distributors, implying that the legislators presume they have jurisdiction over this matter. This Note will adopt that presumption as well.

¹⁸⁶ Fair Accountability and Innovative Research Pricing Act of 2016, H.R.6043, 114th Cong. (2016).

¹⁸⁷ *See id.*

¹⁸⁸ *See id.*

¹⁸⁹ *See id.*

be passed.¹⁹⁰ This Act addresses the stage of the gray market that involves the leakage of the chain.¹⁹¹ This Act would increase reporting requirements and prohibit a secondary wholesaler from purchasing or receiving a prescription medication from a pharmacy or a pharmacist.¹⁹² Because the regulations on the secondary wholesalers received some pushback when first proposed, a modified version would be required. The Act should be modified to restrict the amount of buy back rather than prohibit buy back. This might meet less resistance, but it would still allow for control of the quantity of drugs that the wholesalers buy back.

Moreover, the Protecting Patients and Hospitals From Price Gouging Act should be passed to address the wholesalers and the gray market companies that are involved in gray market activities.¹⁹³ This act also addressed the stage of the gray market that involved the leakage of the chain.¹⁹⁴ This is when the price of drugs keeps getting multiplied. After a wholesaler sells to another wholesaler, or other entity, the price keeps increasing, forcing the last entity to make the price extremely high in order to make a profit for the business to stay afloat. To address this, the Act would have made it illegal for wholesalers to price gouge prescription drugs during a time of shortage. This Note proposes that all of the aspects of this law be applied to the gray market companies that price gouge in addition to the wholesalers. Wholesale distributors would be held accountable if they charged “unreasonably excessive” prices for short supply drugs.¹⁹⁵ The accountability that the distributors would be subjected to could include imprisonment up to 3 years or fines of \$500,000, or a combination of both.¹⁹⁶ This proposal suggests that this fine be increased to \$800,000 per serious violation. This Act incentivizes companies, wholesalers, and distributors to not participate in the gray market because if caught, they would pay fines and company

¹⁹⁰ Gray Market Drug Reform and Transparency of 2012, H.R. 5853, 112th Cong. (2012).

¹⁹¹ *See id.*

¹⁹² *Id.*

¹⁹³ Protecting Patients and Hospitals from Price Gouging Act, S. 3622, 112th Cong. (2012).

¹⁹⁴ *See id.*

¹⁹⁵ *Id.* § 4.

¹⁹⁶ *Id.* § 5.

executives could face time in prison. The Act would deter those entities willing to engage in these faulty practices of price gouging.

These new laws or single law should also have additional provisions that directly attack the gray market and gray market companies that are participating in price gouging. The Federal Government needs to prevent the monopoly from happening on these “medically necessary” drugs before the companies can even have exposure to them. There needs to be added provisions to the above acts that prevent the sale of these life-saving drugs in bulk to specific entities. The new provision can set a maximum number of drugs that one company can buy from a wholesaler or distributor and a restriction on how much a company can hold of a particular life-saving drug. This can be difficult, especially if a limited amount of companies sell a certain type of drug. However, if there is at least some regulation regarding the amount of a particular drug that a company can hold onto at a given time, it could prevent a company that resells the drug from having a complete monopoly on a specific drug. Although this can also have a negative effect by perhaps deterring manufacturers from producing large quantities of drugs, the right amount of drug production can be part of a solution. All of these laws should be combined into one law or all passed at the same time with the additional provisions above.

Additionally, a committee should be made solely for the purpose of regulating gray market activities and pharmaceutical price gouging. Multiple committees are being appointed the task of trying to solve a price gouging or pharmaceutical drug problem. There is no streamlined focus that one committee is giving to the issue of the gray market alone. Creating a committee that is solely focused on the gray market will make the workload manageable and increase the man power for the specific issue. This committee can be part of the FDA: the newly created committee can be a subcommittee with its own tasks but will also report to the FDA and its overarching regulations. The committee should include people that are knowledgeable in the field and are also qualified government officials that know the process of enforcing regulations.

Arguably, some committees cannot keep up with the work they are supposed to address because of lack of resources. To make sure

the above proposed legislation is enforceable, a new committee will ensure the attention that this social injustice deserves.

VI. CONCLUSION

In order to shut down the gray market, multiple issues need to be addressed. The gray market is not a single problem that can be fixed with one step. The gray market and its effects on price gouging of life-saving drugs is just one part of what seems to be a domino effect. The national drug crisis leads to an environment where a gray market can exist, making entities able to take advantage of other entities and patients in the effort of making a profit. From here, price gouging becomes the last inevitable step along the domino effect making the gray market a connecting domino piece between the national drug crisis and price gouging of lifesaving pharmaceutical drugs. The national drug crisis is a cause of the gray market while price gouging is a direct result of the gray market; it is an endless cycle. To break this endless cycle, it needs to be addressed at all angles, at the same time. The national drug crisis is most likely the hardest issue to address. Drug shortages will persist due to uncontrollable causes, such as limited raw materials. However, shutting down the gray market will shut down a major price gouging mechanism used to take advantage of dispensing entities.

Although this Note addresses a serious issue in the pharmaceutical industry that most of society would support, lobbyists in support of the price gouging companies and the price gouging companies themselves would not support regulating the gray market. Companies are making profits off of drugs that used to be unprofitable, and there are lobbyists that are supportive of these companies. However, with recent news creating public awareness of this issue, the support in fixing the problem can overcome its opponents. Proponents of regulating the gray market will bring enough support to want to create a solid solution.

Ultimately, direct federal legislation can be the start of seeing the gray market diminish. Some proposed legislation should be passed with the additional provisions that will fill unanswered gaps. A separate committee for the gray market would be helpful in taking on such a daunting task. However, this social injustice has lasted way too long, and it affects a big sector of the United

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States population. The issue of price gouging medications needs to be resolved in a direct and meaningful way: by shutting down the gray market.