

# **SHINING LIGHT ON THE “GRAY MARKET”**

## **AN EXAMINATION OF WHY HOSPITALS ARE FORCED TO PAY EXORBITANT PRICES FOR PRESCRIPTION DRUGS FACING CRITICAL SHORTAGES**

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## **EXECUTIVE SUMMARY**

This investigation has examined a group of companies that buy and sell prescription drugs that hospitals and other health care providers urgently need to treat their sick patients. Operating outside of authorized distribution networks, these “gray market” companies take advantage of drug shortages to charge exorbitant prices for drugs used to treat cancer and other life-threatening conditions. These companies’ questionable business practices put patients at risk and cost the United States health care system hundreds of millions of dollars each year.

### **The Role of Gray Market Companies in Drug Shortages**

Over the past several years, a growing number of prescription drugs sold in the United States have experienced supply shortages. Because these shortages have been most severe among a group of injectable drugs used to treat patients with cancer and other serious illnesses, they have had a particularly serious impact on hospitals. Hospitals across the country have struggled to provide appropriate care to their patients and have spent hundreds of millions of dollars managing the administrative and clinical problems drug shortages cause.

During drug shortages, hospitals are sometimes unable to buy drugs from their normal trading partners, usually one of the three large national “primary” distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage drugs for prices that are often hundreds of times higher than the prices they normally pay. Hospital pharmacists have been both angered and confused by these offers. They have asked, “why the hospitals can’t get these products but the ‘scalpers’ can.”

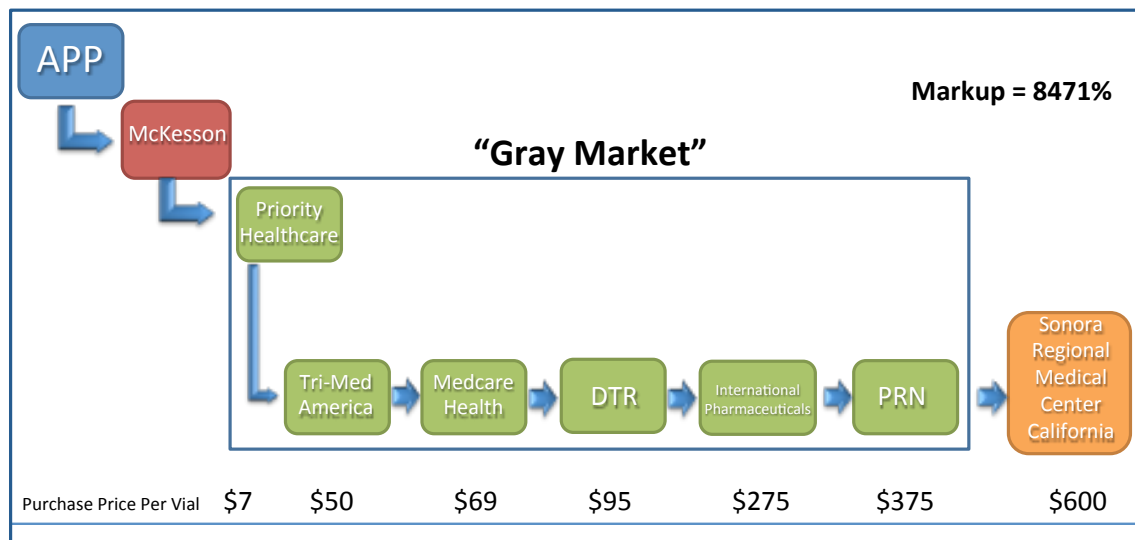
### **Gray Market Drugs “Leak” Out of Authorized Distribution Chains**

The drug “pedigree” documents reviewed in this investigation show that some short-supply injectable drugs do not reach health care providers through the manufacturer-wholesaler distributor-dispenser chain that policymakers and industry stakeholders present as the typical model for drug distribution. Instead, these drugs “leak” into longer gray market distribution networks, in which a number of different companies – some doing business as pharmacies and some as distributors – buy and re-sell the drugs to each other before one of them finally sells the drugs to a hospital or other health care facility.

In more than two-thirds (69%) of the 300 drug distribution chains reviewed in this investigation, prescription drugs leaked into the gray market through pharmacies. 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. The

wholesalers in turn sold the drugs – usually at significant markups – to other gray market companies.

In the drug chain illustrated below, which documents the shipment of 25 vials of a chemotherapy drug called fluorouracil in September 2011, the leakage point was 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.



### Gray Market Companies Aggressively Mark Up Drug Prices

As the drugs pass through these gray market distribution chains, they are significantly marked up, sometimes to prices that are hundreds of times higher than the prices that hospitals and other health care providers normally pay. The markups in these chains often bear no relation to the companies’ cost of purchasing, shipping, or storing the drugs. Instead, they reflect an intent to take advantage of the acute demand for short-supply drugs by charging health care providers exorbitant prices.

In the example above, each company in the chain marked up the vials by large margins, two by more than 100%, even if they never took physical custody of the vials or only held them for a short time. The hospital that purchased the drug ended up paying \$600 per vial for a drug that a pharmacy had purchased for \$7 per vial. Hospitals purchase short-supply drugs at these exorbitant prices because, as one hospital explained, “We have no other choice ... We have to take care of our patients.”

Other significant findings of this investigation are:

***“Fake Pharmacies” Acquire Prescription Drugs from Authorized Distributors and then Sell Them Into the Gray Market.*** The investigation has identified a number of businesses holding pharmacy licenses that do not dispense drugs, but instead appear to operate for the sole purpose of acquiring short-supply drugs that can be sold into the gray market.

***“Drug Brokers” Recruit Pharmacies to Purchase Drugs for the Gray Market.*** Some gray market wholesalers gain access to shortage drugs by recruiting pharmacies to act as their purchasing agents.

***Gray Market Business Practices Are Widespread.*** Pedigree and price information collected for five different short-supply injectable drugs, documenting the activities of 125 different companies, showed similar patterns of leakage and aggressive gray market price markups. For all five drugs, units normally costing \$10 to \$20 were regularly marked up to prices of \$200 or more while they traveled through the gray market.

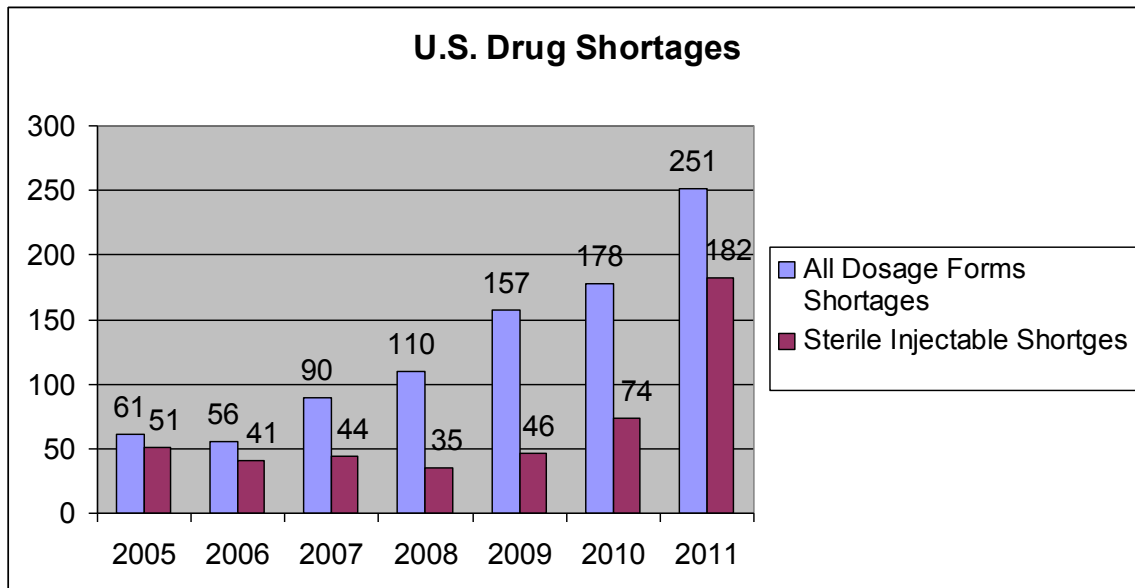
***Gray Market Drugs Are Marked Up as They Quickly Pass from Owner to Owner.*** On average, the prescription drugs examined in this investigation were owned by three to four different gray market businesses before being sold to a hospital; most of the drugs traveled through the gray market in five days or less.

***Gray Market Companies Sometimes Charge Hospitals Significantly Different Prices for the Same Drug Product on the Same Day.*** Gray market companies sold units of the exact same drug product to different hospitals on the same day at significantly different prices. On the same day, for example, a gray market company sold a drug to a U.S. military hospital for \$315 per unit, and sold the exact same drug product to another hospital for \$215 per unit.

## I. THE GROWING SHORTAGES OF DRUGS USED TO TREAT CRITICALLY ILL PATIENTS

The Food and Drug Administration (FDA) defines a drug shortage as “a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level.”<sup>1</sup> Federal government officials and health care professionals have observed a growing rate of shortages in recent years. According to drug shortage tracking conducted by the FDA’s Center for Drug Evaluation and Research (CDER) and the American Society of Health-System Pharmacists, drug shortages more than quadrupled between 2005 and 2011. For example, CDER reported that drug shortages increased from 61 in 2005 to 251 in 2011.<sup>2</sup>

Figure I – FDA Count of U.S. Drug Shortages



The rising number of drug shortages has been concentrated primarily in the area of generic sterile injectable drugs, liquids packaged in sterile glass vials that are “parenterally” administered to the body through syringes or an intravenous (i.v.) administration set. Drugs administered in this manner reach their target treatment area more quickly than oral drugs, but also carry greater risks of infection and complications

<sup>1</sup> U.S. Food and Drug Administration, *A Review of FDA’s Approach to Medical Product Shortages*, 8 (Oct. 31, 2011).

<sup>2</sup> *Id.* at 9 (2005-10 shortage numbers). See also U.S. Food and Drug Administration, *Overview: U.S. Drug Shortage Trends, Reasons for Drug Shortages, FDA’s Role, View of the Future*, 10 (July 2012) (2011 shortage numbers). ASHP defines a drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent,” Rola Kaakeh, et al., *Impact of Drug Shortages on U.S. Health Systems*, Vol. 68 *American Journal of Health-Systems Pharmacy*, 1811 (Oct. 1, 2011).

caused by incorrect dosages.<sup>3</sup> Administering a drug intravenously usually requires a trained health care professional who can carefully monitor the dosage and the patient's reaction to the drug.<sup>4</sup>

Of the 251 drug shortages the CDER reported in 2011, 182 of the shortages (73%) involved sterile injectables.<sup>5</sup> An October 2011 analysis of short-supply drugs conducted by the IMS Institute for Healthcare Informatics also found that most of the reported shortages involved generic sterile injectable drugs. The largest number of drugs in this group (20) were sterile injectables used in chemotherapy treatment for cancer patients.<sup>6</sup> In its report, IMS noted the group of patients who were most directly affected by these shortages:

The drug shortage problem is almost entirely affecting generic injectable drugs, which means that the impacted patients are mostly acute care patients being treated by providers in hospitals and out-patient facilities. Of the total generic injectable market, half are on the shortages list.<sup>7</sup>

The sterile injectables in shortage have also included frequently-used items such as anesthetics for surgery, "crash cart" drugs used in emergency rooms, and electrolytes for intravenous feeding.<sup>8</sup> A representative of the American Society of Health-System Pharmacists recently commented that the shortages have "the potential to affect almost every patient that comes into a hospital."<sup>9</sup>

#### **A. The Impact of Drug Shortages on Patients and Hospitals**

According to many health care professionals, the recent widespread shortage of sterile injectable drugs has had a serious impact on patients suffering from cancer and other life-threatening conditions. Nearly all hospitals across the country (99.5%) reported experiencing at least one serious drug shortage from January to June 2011.<sup>10</sup> When drugs are unavailable, health care providers are sometimes forced to delay

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<sup>3</sup> David E. Golan, et al., *Principles of Pharmacology*, 3<sup>rd</sup> Edition, 30-31 (2012).

<sup>4</sup> *Id.*

<sup>5</sup> U.S. Food and Drug Administration, *supra* note 2, at 10.

<sup>6</sup> IMS Institute for Healthcare Informatics, *Drug Shortages: A Closer Look at Products, Suppliers, and Volume Volatility*, 7 (Nov. 2011).

<sup>7</sup> *Id.* at 3.

<sup>8</sup> *See, e.g.*, Senate Committee on Health Education Labor & Pensions, *Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions*, 112th Cong. (Dec. 15, 2011) (written statement of Sherry Glied, Ph.D., Assistant Secretary for Planning and Evaluation, Department of Health and Human Services).

<sup>9</sup> *Waning Cancer Drug Supplies a Growing Concern at St. Jude Children's Research Hospital*, The Commercial Appeal (Mar. 25, 2012).

<sup>10</sup> American Hospital Association, *AHA Survey on Drug Shortages* (July 12, 2011).

treatments or procedures, or to make the difficult choice to use an alternative treatment. Either choice can lead to negative consequences. Delaying treatment can allow conditions to worsen or can even lead to death, while alternative therapies may be less effective than shortage drugs or may cause more significant side effects.<sup>11</sup>

Hospitals also spend a significant amount of money and administrative resources managing drug shortages. A 2011 American Society of Health-System Pharmacists (ASHP) report estimated that drug shortages cost hospitals more than \$400 million a year, including the higher costs that hospitals pay to purchase shortage drugs and the cost of labor that is dedicated to managing the shortages.<sup>12</sup> Increased labor costs associated with drug shortages include time that pharmacists, physicians, nurses, and other staff spend searching for shortage drugs or alternative treatments. Some hospitals have dedicated staff members to managing shortages on a full-time basis.

## **B. The Causes of Drug Shortages**

Policymakers have offered a number of different explanations for why drug shortages occur. The short-term supply of a drug may drop because a manufacturer shuts down a production line to investigate a quality problem, or upgrade or repair its facilities. In the case of sterile injectables, which are usually manufactured by only two or three companies and require specialized equipment and processes, it is difficult for competitors to quickly increase their production to make up for this lost production.<sup>13</sup> In some cases, manufacturers stop or slow down production because they cannot obtain the Active Pharmaceutical Ingredients (API) they need to produce the drugs.<sup>14</sup>

According to an FDA review of 127 drug shortages reported in 2010 and 2011, the most common cause for shortages was manufacturers' decisions to shut down facilities to address drug quality problems.<sup>15</sup> A Government Accountability Office (GAO) analysis of 15 drug shortages occurring in 2009 and 2010 found that 12 of the

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<sup>11</sup> See, e.g., Senate Committee on Health Education Labor & Pensions, *Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions*, 112th Cong. (Dec. 15, 2011) (statement of Dr. John Maris, Chief of the Division of Oncology, Children's Hospital of Philadelphia); Senate Committee on Finance, *Drug Shortages: Why They Happen and What They Mean*, 112th Cong. (Dec. 7, 2011) (statement of Dr. Patrick Cobb, Oncologist, Frontier Cancer Center, Billings, MT); *Chemotherapy Shortage Prevents Patients from Getting Treatment*, The Daily Oklahoman (Aug. 26, 2011) (quoting Erin Fox, Pharm.D, Manager, Drug Information Service, University of Utah Hospitals and Clinics, on the difficulty of using alternative treatments during drug shortages: "That's what makes a chemo shortage very difficult. These aren't easy drugs to switch out like Legos.").

<sup>12</sup> Kaakeh, *supra* note 2, at 1818.

<sup>13</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Office of Science and Data Policy, *ASPE Issue Brief: Economic Analysis of the Causes of Drug Shortages* (Oct. 2011).

<sup>14</sup> *Id.*

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



shortages were caused by “manufacturing problems.”<sup>16</sup> Manufacturers themselves have reported to ASHP that the top reason for these shortages was “production-related issues and increased demand.”<sup>17</sup>

Other observers have pointed to the broader business dynamics of the generic sterile injectable market to explain the recent shortages. They argue that the strong bargaining power of group purchasing organizations (GPOs) and Medicare Part B reimbursements tied to the “Average Sales Price” cause manufacturers to operate with only very small profit margins.<sup>18</sup> According to these observers, manufacturers do not make the investments necessary to increase their capacity to produce the drugs, and potential competitors have no financial incentive to enter the market, because they have little or no ability to raise the prices of their products.<sup>19</sup>

### C. The Appearance of Gray Market Companies

As a growing number of sterile injectable drugs went into short supply in 2010 and 2011, hospitals around the country began receiving increasing numbers of telephone, fax, and e-mail solicitations from “gray market” drug companies.<sup>20</sup> These companies claimed to have supplies of short-supply drugs that the hospitals could not obtain through their normal distribution channels. The companies’ offers generally mentioned the fact that the drugs were in short supply and often suggested that their supplies were very limited.<sup>21</sup>

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<sup>16</sup> U.S. Government Accountability Office, *Drug Shortages: FDA’s Ability to Respond Should be Strengthened*, 22-23 (Nov. 2011) (GAO-12-116).

<sup>17</sup> IMS Institute for Healthcare Informatics, *supra* note 6, at 9.

<sup>18</sup> Group purchasing organizations, or “GPOs,” are organizations that act as purchasing intermediaries between medical product vendors and the hospitals, pharmacies, and other health care providers that are members of the GPOs. Among other things, GPOs negotiate the prices for which drug manufacturers sell prescription drugs to GPO members. Typically, drug manufacturers ship their products to wholesalers who then sell the drugs to health care providers at GPO-negotiated prices.

<sup>19</sup> *See e.g.*, Senate Committee on Finance, *Drug Shortages: Why They Happen and What They Mean*, 112th Cong. (Dec. 7, 2011) (statement of Rena M. Conti Ph.D., Assistant Professor of Health Policy and Economics, University of Chicago); *See also* Ali Yurukoglu, *Medicare Reimbursement and Shortages of Sterile Injectable Pharmaceuticals* (National Bureau of Economic Research, Working Paper No. 17987 at 7) (April 2012) (online at [http://www.nber.org/papers/w17987.pdf?new\\_window=1](http://www.nber.org/papers/w17987.pdf?new_window=1)).

<sup>20</sup> Institute for Safe Medication Practices (ISMP) Medication Safety Alert, *Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche during the Drug Shortage Crisis* (Aug. 25, 2011). More than half of respondents reported daily solicitations.

<sup>21</sup> Premiere Healthcare Alliance, *Buyer Beware: Drug Shortages and the Gray Market* (Aug. 2011) (quoting one solicitation as stating “[w]e only have 20 of this drug left and quantities are going fast”).

The gray market companies appeared to be taking advantage of supply shortages to sell the drugs at prices much higher than hospitals paid their normal suppliers. An analysis by the Premier Healthcare Alliance of 636 solicitations made to hospitals in early 2011 found that gray market companies were selling short-supply drugs at prices that were on average 650% higher than the prices hospitals paid for the drugs through their group purchasing agreements. In some cases, companies were selling the drugs at markups as high as 3,000% to 4,000% over their typical contract prices.<sup>22</sup>

In May 2011, for example, Mark Richerson, the pharmacy director of Christus Santa Rosa Health Care in San Antonio, Texas, reported that Allied Medical Supply, a gray market company based in Miami, had offered to sell him 2-gram vials of the shortage cancer drug cytarabine for \$995 per vial.<sup>23</sup> The hospital's normal average purchase price for the drug was \$15.76 per vial. Mr. Richerson told the San Antonio Express-News:

I don't understand this shortage, and it makes me angry because the drug is unavailable for patients who need it... What I want to know is, how did these distributors get this drug when no one else has it, and what is the basis for their pricing? Isn't this kind of price gouging illegal?<sup>24</sup>

Many hospital pharmacists and purchasing agents like Mr. Richerson were frustrated and angered by gray market solicitations. When the Institute for Safe Medication Practices (ISMP) surveyed a large group of hospitals in July and August 2011, it received hundreds of comments complaining about the gray market solicitations and asking "why hospitals can't get these products, but the 'scalpers' can."<sup>25</sup> Hospital pharmacists also "reported feeling pressured by physicians and hospital administrators to purchase medications from the gray market."<sup>26</sup>

Choosing between having no supply of a drug or purchasing the drug at an exorbitant price from an unknown gray market company raised difficult ethical and business questions for hospitals. While some hospitals set policies to buy drugs only through their regularly trusted networks,<sup>27</sup> others decided to buy drugs from gray market companies because, as one hospital pharmacist explained, "[w]e have no other

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<sup>22</sup> *Id.*

<sup>23</sup> *Drug Shortages, Skyrocketing Prices Anger Pharmacists*, San Antonio Express-News (May 3, 2011).

<sup>24</sup> *Id.*

<sup>25</sup> Institute for Safe Medication Practices, *supra* note 20.

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

<sup>27</sup> See, e.g., Eric T. Rosenthal, *Frustration Over Gray-Market Drugs Lingers Throughout Nation*, Journal of the National Cancer Institute (Feb. 22, 2012) ("Our pharmacy purchasing department receives [gray market] solicitations every day, but we disregard them all. We have a very conservative, black-and-white approach and will not use any drugs that come from outside our regular wholesalers or manufacturers.").

choice... We have to take care of our patients.”<sup>28</sup> According to a report in a recent newsletter of the National Association of Children’s Hospitals and Related Institutions (NACRI):

Some children’s hospitals refuse to deal with the gray market in any capacity. Others only purchase from gray market distributors when they’ve exhausted all other outlets for access to a drug critical in a life-threatening situation for a patient and if the pedigree contains documented proof of origin and transfer. There are risk management and quality and efficacy issues in addition to the exorbitant cost of gray market drugs. The astronomical cost of the gray market cannot be passed on to the patient or payer, so it must be absorbed by the hospital.<sup>29</sup>

Many hospitals and other stakeholders expressed concern about the safety of drugs purchased from gray market companies because they did not understand how gray market vendors obtain short-supply prescription drugs. During a recent FDA workshop on drug shortages, an executive of drug manufacturer APP Pharmaceuticals explained, “we don’t know how it gets there either. We’re as perplexed as the customers are, the health care professionals are.”<sup>30</sup> A representative of the University of Utah Health System explained during the workshop why it had implemented a policy not to purchase prescription drugs from gray market vendors:

Now we feel like there are very significant safety issues with these products. We don’t know where they’ve come from. We don’t know if they’ve stored [sic] properly, so it’s been our hospital’s policy not to purchase from these companies, and we have not ever purchased from those companies.<sup>31</sup>

The Fox Chase Cancer Center in Philadelphia will not purchase prescription drugs in the gray market for the same reason: “It’s not because of the cost issues, but the main thing is: If I can’t be absolutely sure of the integrity of the drug, then I can’t administer it to a patient.”<sup>32</sup>

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<sup>28</sup> San Antonio Express-News, *supra* note 23. See also *Shortages Are Often Costly for Hospitals*, West Central Tribune (Nov. 17, 2011) (quoting the pharmacy director at Rice Memorial Hospital in Willmar, Minnesota as saying that the hospital tries to avoid purchasing prescription drugs from secondary wholesalers “if at all possible” and has only made such purchases “on occasion where there literally were no other options”).

<sup>29</sup> John VanEeckhout, *Financial Implications of the Drug Shortage Crisis*, Children’s Hospitals Today (Winter 2012).

<sup>30</sup> Transcript of Workshop, Food and Drug Administration, Center for Drug Evaluation and Research, *Drug Shortage Workshop* (Sept. 26, 2011) at 316-17 (statement of Scott Meacham, Executive Vice President & Chief Commercial Officer, APP Pharmaceuticals).

<sup>31</sup> *Id.* at 69 (statement of Erin R. Fox, Pharm.D, Manager, Drug Information Service University of Utah Hospitals & Clinics).

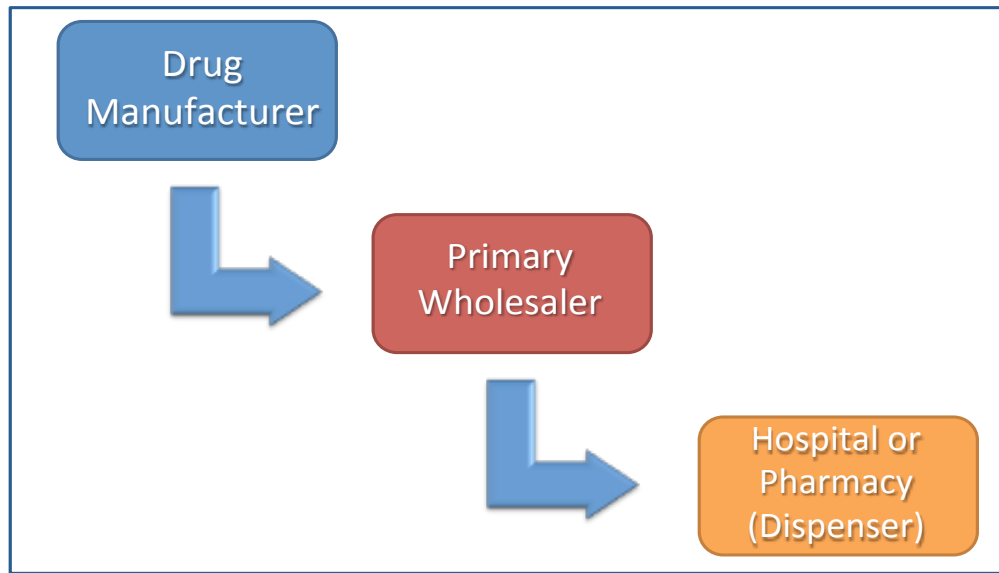
<sup>32</sup> Jaimy Lee, *Providers Fuel Gray Market: Some Sell While Others Buy During Drug Shortage*, Modern Healthcare (Sept. 5, 2011).

Some hospital pharmacists believe that gray market wholesalers contact them to learn which drugs the hospitals are having trouble acquiring so that the gray market wholesalers can quickly attempt to buy quantities of those drugs. A drug buyer at All Children’s Hospital in St. Petersburg, Florida, explained, “[t]hey will ask you, ‘What are you having a hard time getting?’” She said that answering the question is “the worst thing you can do, because then they will go and buy it all up from the manufacturers.”<sup>33</sup>

**D. How Drug Distribution Chains Typically Work**

A typical drug distribution chain has three elements: (1) a manufacturer, which creates and sells a prescription drug to (2) a wholesale distributor, which then sells the drug to (3) a hospital or pharmacy, which dispenses it to patients. (See Figure II).

*Figure II – Commonly Understood Drug Distribution Model*



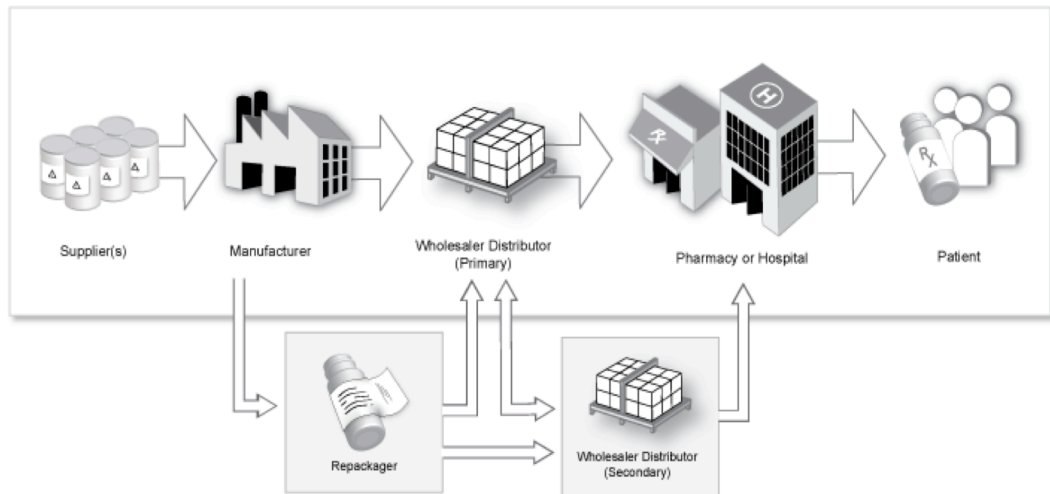
In some cases, additional authorized parties might be involved in these chains. Drug manufacturers sometimes sell their products to “repackagers,” before the drugs are distributed.<sup>34</sup> In addition, large “primary” distributors sometimes sell drugs to “secondary” distributors, which then sell the drugs to pharmacies or hospitals. Such sales to secondary distributors comprise only a small percentage of primary distributors’ sales. Distributors that have an ongoing relationships with manufacturers serve as “authorized

<sup>33</sup> *Short of Drugs, Hospitals Wary of ‘Gray Market,’* St. Petersburg Times (Nov. 7, 2011).

<sup>34</sup> “In the U.S., wholesale drugs in bulk containers are often repackaged into smaller containers prior to sale to an end user. Repackaging operations are performed by independent entities, wholesale distributors, or by distribution centers owned by large pharmacies.” Food and Drug Administration, *Counterfeit Drug Task Force Report* (October 2003).

distributors of record” (ADR) for the manufacturers.<sup>35</sup> About 85% of all revenues in the wholesale market are generated by three national distributors –AmerisourceBergen, Cardinal Health, and McKesson – that serve as ADRs for many manufacturers.<sup>36</sup> Distributors that predominantly buy prescription medicines from the manufacturers and predominantly distribute them directly to health care providers such as hospitals and pharmacies are called “primary” distributors.<sup>37</sup> “Secondary” distributors are also sometimes ADRs, and they obtain access to drugs from primary distributors or other sources.<sup>38</sup> Figure III shows the FDA’s illustration of a typical distribution chain.

*Figure III – FDA Drug Distribution Model*



Distributors and pharmacies play distinct roles in the distribution chain and are subject to different regulatory and licensing requirements. Under federal law, distributors have the authority to purchase drugs from manufacturers and deliver them to pharmacies, hospitals, and other parties that are not patients.<sup>39</sup> Pharmacies are the end point of the chain, responsible for dispensing the drug in a manner that is consistent with the appropriate treatment of a patient.<sup>40</sup>

<sup>35</sup> Authorized distributors of record are “distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products.” 21 U.S.C. § 353(e)(3)(A).

<sup>36</sup> Pew Charitable Trusts, Pew Health Group, *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*, 63 (July 12, 2011) (online at <http://www.pewhealth.org/reports-analysis/reports/after-heparin-85899367953>).

<sup>37</sup> Healthcare Distribution Management Association, *HDMA Fact Sheet on PDMA* (online at [http://www.healthcaredistribution.org/press\\_room/pdma\\_facts.asp](http://www.healthcaredistribution.org/press_room/pdma_facts.asp)).

<sup>38</sup> *Id.*

<sup>39</sup> Under federal law, the wholesale distribution of drugs is defined as the “distribution of drugs...to other than the consumer or patient.” 21 U.S.C. § 353(e)(3)(B).

<sup>40</sup> According to the Model Pharmacy Act, the “Practice of Pharmacy” means “the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders;

In addition to the obligations that come with their licenses as distributors or pharmacies, companies involved in drug distribution chains often also have contractual obligations to their trading partners. Most large distributors purchase drugs from manufacturers pursuant to ADR agreements, which sometimes restrict the distributors' freedom to buy and sell the drugs. The drug manufacturer Hospira, for example, requires its ADRs to commit that "they will purchase Hospira products directly from Hospira, and only sell Hospira products to end users of our products."<sup>41</sup>

Primary wholesale distributors commonly place similar "own use" restrictions on their customers. For example, one of the primary wholesale distributors requires most of its customers that hold themselves out as "Final Dispensers," such as pharmacies, to certify "that they do not and will not redistribute prescription pharmaceuticals purchased from [that primary wholesale distributor] into the Secondary Market."<sup>42</sup> The same primary wholesale distributor also requires its secondary wholesaler customers to sell to "Final Dispensers" the pharmaceutical products they purchase from that primary wholesale distributor.<sup>43</sup> Another primary wholesale distributor typically requires its final dispenser customers to agree to use purchased products for their "own use" and its secondary wholesaler customers to agree to sell purchased products only to final dispensers.<sup>44</sup>

Ensuring that drugs pass through as few hands as possible on their way to patients helps to ensure the integrity and safety of the drug supply chain. According to the FDA, counterfeit drugs are most likely to be introduced as part of a drug supply chain involving multiple wholesalers.<sup>45</sup> Dr. Michael Link, Immediate Past President of the American Society of Clinical Oncology, has expressed the same concern about drugs that pass through multiple gray market vendors, "[i]t's not just the price gouging and taking advantage of patients, it's also the idea that when you buy gray market drugs it doesn't

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participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and administration of immunizations." National Association of Boards of Pharmacy, Model State Pharmacy Act § 104.

<sup>41</sup> Letter from Brian J. Smith, Senior Vice President, General Counsel and Secretary, Hospira, to Senate Commerce Committee Chairman Rockefeller, Senate Health, Education, Labor, and Pensions Committee Chairman Harkin, and House Oversight and Government Reform Committee Ranking Member Cummings (Jan. 5, 2012).

<sup>42</sup> Primary Wholesale Distributor, *Policy Statement on Secondary Market Sales*.

<sup>43</sup> Primary Wholesale Distributor, *Wholesaler Safe Product Practices*.

<sup>44</sup> E-mail from Primary Wholesale Distributor to Senate Committee on Commerce, Science, and Transportation Staff (July 19, 2012).

<sup>45</sup> Food and Drug Administration, *Counterfeit Drug Task Force Report* (October 2003).

have the legacy of the drug. It's not the same quality assurance and you don't know its authenticity."<sup>46</sup>

**E. Background on Congressional Investigation**

In October 2011, House Committee on Oversight and Government Reform Ranking Member Elijah Cummings opened this investigation by sending information request letters to five gray market companies that were aggressively marketing five prescription drugs to hospitals that were at the time in short-supply, according to the FDA.<sup>47</sup> Four of the drugs are used to treat various forms of cancer, and one is used to treat seizures during pregnancy. The letters asked the companies where they had obtained the short-supply drugs they were offering for sale and how much they were charging hospitals for the drugs.

	<b>Manufacturers</b>	<b>Treatment</b>	<b>Distributor Receiving Information Request</b>
<b>Cytarabine</b>	APP, Bedford, Hospira	Leukemia in children and adults	Allied Medical Supply, Inc., Miami, FL
<b>Fluorouracil</b>	APP, Mylan, Teva	Colon, stomach, breast, and pancreatic cancer	PRN Pharmaceuticals, Rockville, MD
<b>Leucovorin</b>	APP, Bedford, Teva	Advanced colon cancer	Premium Health Services Inc., Columbia, MD
<b>Magnesium Sulfate</b>	American Regent, APP, Hospira	Seizures during pregnancy	Reliance Wholesale, Inc., Miami, FL
<b>Paclitaxel</b>	APP, Bedford, Hospira, Sagent, Sandoz, Teva, Pfizer (started in 2012)	Breast and ovarian cancer	Superior Medical Supply, Inc., Superior, CO

In December 2011, Senator John D. Rockefeller IV, Chairman of the Senate Committee on Commerce, Science, and Transportation, and Senator Tom Harkin, Chairman of the Senate Health, Education, Labor, and Pensions Committee, joined Ranking Member Cummings in the investigation.<sup>48</sup> Since that time, the three Members of Congress have requested information from more than 50 prescription drug

<sup>46</sup> Eric T. Rosenthal, *The 'Gray Market' Raises Concerns about Cost, Safety, Ethics*, Journal of the National Cancer Institute (Feb. 8, 2012).

<sup>47</sup> U.S. House Committee on Oversight and Government Reform Democrats, *Cummings Investigates Potential Prescription Drug Price Gouging* (Oct. 5, 2011) (online at [http://democrats.oversight.house.gov/index.php?option=com\\_content&view=article&id=5445:gray-market&catid=146:democratic-agenda&Itemid=107](http://democrats.oversight.house.gov/index.php?option=com_content&view=article&id=5445:gray-market&catid=146:democratic-agenda&Itemid=107)).

<sup>48</sup> Senate Committee on Commerce, Science, and Transportation, *Senate Chairmen Join Cummings' Investigation of "Gray Market" Drug Companies* (Dec. 15, 2011).

manufacturers, distributors, and pharmacies.<sup>49</sup> Staff has also talked to a large number of industry experts, regulators, and stakeholders about how short-supply prescription drugs are distributed, marketed, and sold.

A key source of information in this investigation has been “drug pedigree” documents, which record the distribution route a drug has traveled since it left the manufacturer. Many businesses that distribute drugs in the United States are required, either by state or federal laws, to provide these pedigrees to their customers.<sup>50</sup>

Congressional investigators carefully studied 300 of these “paper pedigrees,” which list the names of all parties that purportedly took possession of the drug and the dates of their possession. The 300 pedigrees show 125 different companies that were involved in selling short-supply prescription drugs. Staff used the pedigrees to reconstruct how and when drugs entered gray market distribution chains and contacted companies listed in the pedigrees to collect information regarding the prices for which they purchased and re-sold the drugs. Staff obtained specific information from the companies listed on 58 of the pedigrees, including the prices for which they purchased and sold the drugs and the dates they possessed them.

## **II. FINDINGS**

### **A. Exorbitant Prices Charged for Drugs in Gray Market**

Documents obtained during the investigation demonstrate that drug wholesalers often charge exorbitant prices to health care providers for drugs facing critical national shortages that are used to treat cancer and other life-threatening illnesses. These inflated prices are often the result of unnecessarily long distribution chains that include significant markups at almost every level.

#### **1. Significant Markups Throughout Gray Market Distribution Chains**

The short-supply generic injectable drugs examined in this investigation did not reach doctors and patients through the typical distribution chain model described above. Instead of following the distribution route policymakers and industry stakeholders expect them to follow, these drugs were diverted into longer “gray market” distribution networks in which a number of different companies bought, sold, and transferred them.

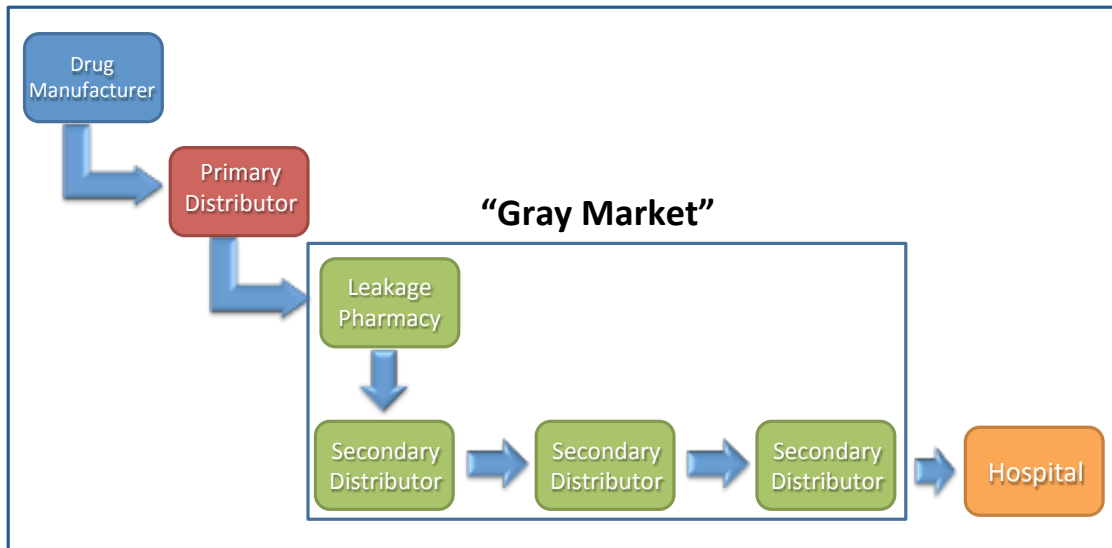
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<sup>49</sup> Senator Rockefeller issued a Senate Commerce Committee subpoena to one company, Superior Medical Supply, that refused to respond voluntarily to an information request.

<sup>50</sup> See 21 U.S.C. § 353(e)(1)(A). Drug manufacturers and authorized distributors of record are exempt from the federal pedigree requirement.



Figure IV – “Gray Market” Drug Distribution Model



As Figure IV demonstrates, the drugs were not dispensed directly to the hospitals, but instead “leaked out” of their authorized distribution chains and were bought and sold by additional companies before reaching the hospitals. As they traveled through these longer gray market chains, the drugs were marked up to prices that were often hundreds of times higher than the prices the hospitals and other health care providers normally paid for them.

Figure V – “Gray Market” Shipment of 25 Vials of 2.5g/50mL Vials of Fluorouracil

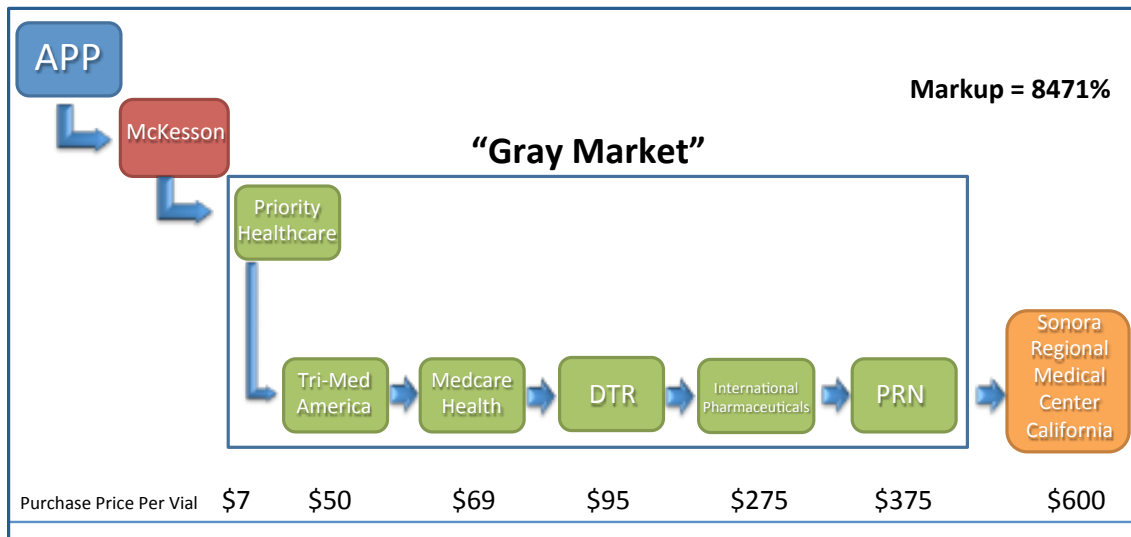


Figure V illustrates how 25 vials of fluorouracil, a sterile injectable drug used to treat colon, stomach, breast, and pancreatic cancer, traveled from its manufacturer, APP Pharmaceuticals, to Sonora Regional Medical Center in Sonora, California. At the time of these transactions, September 2011, fluorouracil was on the FDA’s list of shortage drugs.

On September 20, 2011, the primary distributor, McKesson, sold the vials to Priority Healthcare, a pharmacy that was then licensed in Maryland.<sup>51</sup> Instead of dispensing the drug to a doctor treating cancer patients, on September 22, 2011, Priority sold the vials to a New Jersey distributor called Tri-Med America, which in turn sold the vials to DTR, another New Jersey distributor. In total, eight companies in four different states took ownership of the drug before a gray market distributor sold it to the California hospital on September 27, 2011.

As Figure V shows, there were significant price markups at each level of this gray market distribution chain. McKesson originally sold the vials to Priority Healthcare for \$7 per vial. As they moved through the gray market distribution chain, the vials increased in price to \$600 per vial, about 85 times their initial price, at an increase of 8,471%.<sup>52</sup>

## **2. Similar Results Found for All Five Shortage Drugs Examined**

The pedigree and price information that was collected on the five sterile injectable drugs that were the subject of this investigation show a similar pattern. In almost all instances, the drugs were sold by a primary distributor to a buyer that the primary distributor expected to act as a dispenser, at prices that reflected the negotiated rates of manufacturers, distributors, and dispensers. Instead of dispensing the drugs to doctors and patients, however, the expected dispensers re-sold the drugs to gray market companies, which marked up the drugs to exorbitant prices before selling them to hospitals. In other words, gray market companies diverted part of the existing scarce supply of drugs, and then sold it back to legitimate end users at highly inflated prices.

The price markups examined in the course of this investigation bear little or no relation to the companies' costs of purchasing, shipping, or storing the drugs. Instead, they reflect an intent to take advantage of the acute demand for short-supply drugs by charging health care providers exorbitant prices. The appendix to this report provides examples of gray market distribution chains through which each of the five drugs traveled to hospitals in 2011.

Exhibit IV in the Appendix for example, documents how two vials of cytarabine, a sterile injectable drug used to treat leukemia patients, were marked up by almost 4,900% by a succession of gray market distributors before being sold to the Mississippi

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<sup>51</sup> See section II.B.4. of this report for further discussion of Priority Healthcare.

<sup>52</sup> Gray market drug distributors sometimes cite shipping costs as one of the reasons they mark up the per unit price of the drugs they sell. But in many transactions examined in this investigation, the gray market companies billed shipping as a separate line item cost on their invoices. The shipping costs varied, but generally were less than \$100 per invoice. In some transactions, the gray market companies never took physical possession of the drugs and instead arranged for drugs to be "drop shipped," directly from the company from which they purchased the drugs, to the customer to which they sold them.

Baptist Health System for \$995 per vial on March 18, 2011. Allied Medical Supply, the gray market company that sold the vials to the hospital, had purchased the vials two days earlier for \$399 per vial. Allied added \$596 to the cost of each vial before selling them to Mississippi Baptist Health System.<sup>53</sup>

Exhibit III in the Appendix shows that price markups could be substantial even in cases where small numbers of gray market actors handled the drug. In the transaction shown there, 30 vials of paclitaxel, which is used to treat breast and ovarian cancer patients, were sold to the Heartland Regional Medical Center in St. Joseph, Missouri on July 20, 2011 for \$185 per vial. The New Jersey pharmacy that leaked these vials into the gray market had purchased them on June 15, 2011 for \$8 per vial from the drug wholesaler H.D. Smith. The two gray market parties that handled the vials before they were sold to the hospital – a New Jersey distributor called Investigational Drug Delivery (IDD) and a Colorado distributor called Superior Medical Supply – marked them up by \$177 per vial, or 2,213%.<sup>54</sup>

### **3. Additional Information on Gray Market Chains**

As part of the investigation, congressional investigators carefully analyzed 58 drug distribution chains from beginning to end; these “vertical reviews” included establishing purchase and sale prices for all of the individual transactions within the 58 chains. Some of the most significant results of this analysis were the following:

- In more than half of the transactions, prices for the drugs increased by \$200 per unit or more while traveling through the gray market. In six chains, the price increase was \$500 or more per unit. The largest increase was \$975 per unit.
- On average, drugs traveling through these gray market chains were owned by three to four separate business entities before reaching the hospital or provider that administered the drugs to a patient.
- Most of the drugs traveling through the gray market (60.8%) were sold to hospitals within five days or less after they entered the gray market.<sup>55</sup> In 13

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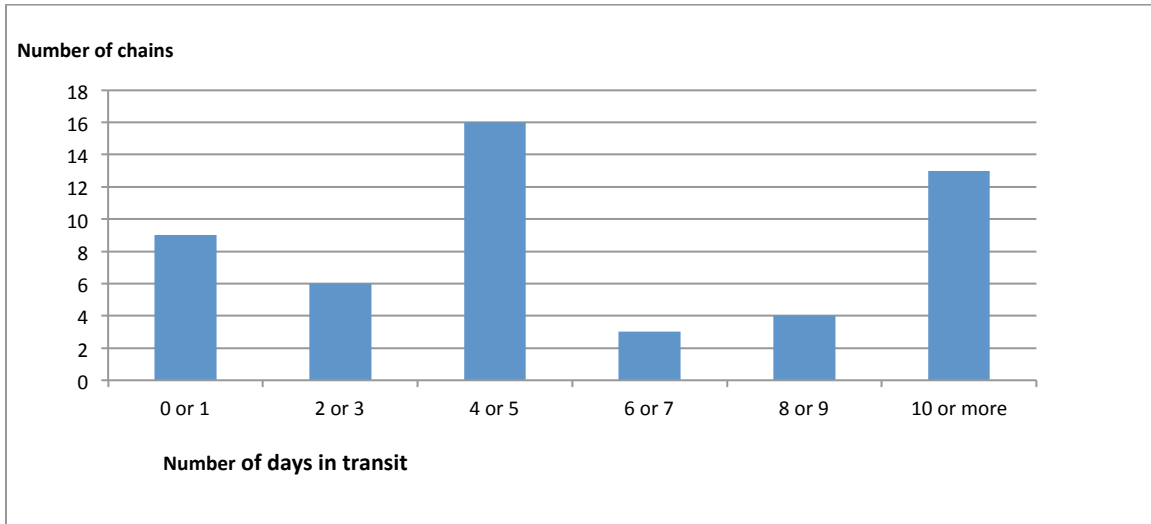
<sup>53</sup> Allied may have been able to charge such a high markup for cytarabine while the drug was in shortage, in part, because there is no alternative drug for treating the form of leukemia known as acute myeloid leukemia. *Shortage Worsens of Leukemia Drugs*, Wall Street Journal (Apr. 14, 2011).

<sup>54</sup> As discussed below in section II.B.5., Edison Pharmacy and IDD share common ownership. The common ownership likely explains why Edison Pharmacy was willing to “sell” paclitaxel to IDD without marking the price up. As discussed in Section II.B.6., the owner of IDD pleaded guilty to federal criminal charges in 2011.

<sup>55</sup> Staff were able to determine the number of days during which the drugs traveled through the gray market in 51 of the 58 drug distribution chains that were part of the “vertical review.”

chains, the drugs remained in the hands of gray market companies longer than 10 days.

*Figure VI – Distribution of Number of Days in the Gray Market, from Authorized Distributor to Hospital or Provider’s Office*



The drug distribution chains that congressional investigators examined also showed that gray market wholesalers sometimes sold units of the exact same drug to different hospitals on the same day at significantly different prices. For example:

- Reliance Wholesale charged Madigan Army Medical Center in Washington \$315 per unit for a magnesium sulfate product when it charged Twin Cities Community Hospital in California \$215 per unit for the same product. Reliance Wholesale had purchased the magnesium sulfate for \$100 per unit.
- Reliance Wholesale charged the VA Medical Center-Reno \$450 per unit for a magnesium sulfate product when it charged Sacred Heart-St. Mary’s Hospital in Wisconsin \$349 per unit. Reliance Wholesale had paid \$245 per unit for the product.
- Superior Medical Supply charged Children’s National Medical Center in Washington, DC, \$400 per vial for a paclitaxel product when it charged Heartland Regional Medical Center in Missouri \$325 per vial for the same product. Superior had purchased the product for \$200 per vial.

The hospitals that purchased short-supply drugs through the 300 gray market chains staff reviewed include a range of small and large hospitals, urban and rural hospitals, for-profit hospitals, and military, veteran, and other nonprofit hospitals located in all regions of the United States. To estimate the financial impact that gray market purchases have on hospitals, congressional investigators compared actual gray market prices for one form of

each of the five drugs reviewed to hospitals' contract price for the same drug product. The per-unit costs in the gray market were dramatically higher than the hospitals would have incurred to purchase the same drugs from their primary wholesale distributors:

- Staff's analysis revealed that hospitals overspent nearly \$750,000 on over 2,100 units of the five prescription drugs examined as a result of purchasing the drugs from the gray market instead of their normal distributors. The more than 2,100 units included in this analysis are just a fraction of the total number of drug units that were sold in the 300 gray market chains.
- For example, hospitals that usually pay \$12 to purchase a 2 g, 20 mL vial of the cancer drug cytarabine instead paid an average of \$736 per vial to purchase that product in the gray market.
- Instead of paying \$9 per 500 mg/mL, 2 mL vial package of magnesium sulfate, hospitals paid an average of \$307 per package to purchase them on the gray market.

## **B. How Drugs Enter the Gray Market**

Based on a review of documents obtained during the investigation, it appears that shortage drugs are leaking into the gray market primarily through entities that hold pharmacy licenses. It also appears that gray market drug companies are taking advantage of a patchwork of inconsistent state regulations to obtain drugs through questionable and sometimes illegal means.

### **1. Drugs Entering Gray Market Primarily Through Pharmacies**

In more than two-thirds (69%) of the 300 short-supply drug distribution supply chains reviewed in this investigation, the drugs entered the gray market through pharmacies. These pharmacies purchased their drugs from manufacturers' ADRs, but instead of dispensing the drugs in accordance with their state laws, their professional duties, and their contractual obligations, these pharmacies re-sold the drugs to wholesalers.<sup>56</sup> The wholesalers in turn sold the drugs – usually at significant markups – to other gray market entities. The pharmacies do not appear to have had any other reason for purchasing these drugs – all of which are predominantly used by health care professionals in a hospital setting – than to sell them into the gray market.

For example, in the distribution chain involving fluorouracil illustrated in Exhibit I of the Appendix and described in Section II.A.1 above, a company called Priority Healthcare, which held a pharmacy license issued by the State of Maryland, was the first entity to purchase the drug from the authorized primary distributor, McKesson. Rather

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<sup>56</sup> The pharmacies that purchased drugs from ADRs and sold them to secondary distributors included members of the independent pharmacy networks of each of the three national primary distributors.

than selling the drug to a health care provider or to patients, Priority Healthcare sold it to a gray market wholesaler, Tri-Med America, at a significant markup.<sup>57</sup> In addition to the manufacturer, seven entities owned the drug before a gray market distributor finally sold it to a medical center for \$600 per vial.

## **2. Some Pharmacies Selling Their Entire Inventories into Gray Market**

Evidence that some pharmacies are selling short-supply injectable drugs to gray market wholesalers suggests that these pharmacies are not complying with their states' pharmacy laws that limit re-sales. Some states allow pharmacies to re-sell portions of their inventories in emergency circumstances, while other states permit up to 5% of pharmacies' annual sales to come from re-selling their drugs. The parameters of these exceptions rules vary from state to state. Some states' rules appear to be intended to resolve local supply problems by allowing pharmacies to sell drugs to each other, while other states' rules may permit pharmacies to re-sell their drugs to wholesalers.

Documents obtained during the investigation indicate that some pharmacies are clearly exceeding these limited re-sale exceptions. For example, in a letter to Ranking Member Cummings, the owners of a Maryland pharmacy called HealthRite Pharmaceuticals reported that from March 2011 to February 2012, the pharmacy sold 100% of its products to a distributor business they also owned.<sup>58</sup> These sales appear to violate a Maryland law that requires pharmacies to obtain separate wholesaler licenses if they re-sell more than 5% of their products.<sup>59</sup> On April 10, 2012, HealthRite Pharmaceuticals informed the Maryland Board of Pharmacy that it had ceased operations.<sup>60</sup>

Similarly, a New Jersey pharmacy, Morningstar Pharmacy, reported that, from March 2011 to February 2012, all of its revenues came from re-sales,<sup>61</sup> which appears to violate New Jersey pharmacy laws. New Jersey law permits pharmacies to engage in

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<sup>57</sup> As noted in section II.B.4. below, a husband-wife team owned both Tri-Med America and Priority Healthcare.

<sup>58</sup> Letter from Mackie A. Barch, Managing Director of HealthRite Pharmaceuticals to Ranking Member Elijah E. Cummings, House Oversight and Government Reform Committee (Apr. 20, 2012).

<sup>59</sup> Code of Maryland Regulations 10.34.22.02(23) (defining a "wholesale distributor" as "[a] retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the retail pharmacy's annual sales").

<sup>60</sup> E-mail from Maryland Board of Pharmacy to House Committee on Oversight and Government Reform, Minority Staff (Apr. 25, 2012).

<sup>61</sup> E-mail from Alton Chatmon, Owner, Morning Star Pharmacy, to House Committee on Oversight and Government Reform, Minority Staff (Apr. 17, 2012).

“the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug for emergency medical reasons.”<sup>62</sup>

In addition, some pharmacies appear to sell to wholesalers portions of their inventories that exceed the 5% thresholds. For example, B&C Health, a Maryland pharmacy, reported that 21% of its gross sales came from drug sales to wholesalers.<sup>63</sup>

### **3. Using Pharmacies as Purchasing Agents for Shortage Drugs**

Documents obtained during the investigation indicate that wholesalers and independent brokers often approached pharmacies and convinced them to purchase shortage drugs on their behalf, promising significant profits.<sup>64</sup> Twenty-one of the 25 pharmacies that responded to requests for information about their purchases and sales of shortage drugs stated that wholesalers or brokers representing wholesalers had asked them to purchase shortage drugs for them.<sup>65</sup>

For example, an e-mail from a pharmaceutical consultant to a pharmacy owner, dated June 13, 2011, states, “[w]e guarantee our Pharmacies 20% or more every time.”<sup>66</sup> Another e-mail from an outside buyer to a pharmacy owner on August 19, 2011, stated, “please look at your distributor site as soon as you can for these items. The more you find, the more you make.”<sup>67</sup>

Pharmacy owners told congressional investigators that brokers sometimes approached them directly to try to convince them to buy shortage drugs. One pharmacy owner stated that a broker came into her pharmacy and conducted “a presentation and provided credentials” to convince her to buy shortage drugs on his behalf.<sup>68</sup> Another pharmacist told investigators that a broker approached the pharmacist at a trade show, introduced the pharmacist to other pharmacy owners that had purchased shortage drugs

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<sup>62</sup> New Jersey Statutes § 24:6B-14.

<sup>63</sup> Letter from Prince Dennis, Owner, B&C Health Services, to House Committee on Oversight and Government Reform, Minority Staff (Mar. 27, 2012).

<sup>64</sup> According to a 2011 survey of hospital pharmacists, “[m]ore than 13% of respondents reported receiving solicitations, mostly weekly, from gray market vendors who wanted to purchase vital medications in short supply from the hospital, presumably to sell to other hospitals at steeply inflated prices. Institute for Safe Medication Practices, *supra* note 20.

<sup>65</sup> Three pharmacies refused to respond to this information request: PMO Pharmacy of Pearl, Mississippi, Polk’s Discount Drugs of Brandon, Mississippi, and Ranch Pharmacy of Scottsdale, Arizona.

<sup>66</sup> E-mail from broker to pharmacy owner (June 13, 2011).

<sup>67</sup> E-mail from broker to pharmacy owner (Aug. 19, 2011).

<sup>68</sup> E-mail from pharmacy owner to House Committee on Oversight and Government Reform, Minority Staff (Apr. 14, 2012).

for him, and promised a 20% profit margin for doing the same.<sup>69</sup> Other pharmacy owners who sold drugs to wholesalers were motivated by the desire to alleviate shortages. For example, the president of one pharmacy told investigators that his pharmacy was “approached by a wholesaler/distributor ... with the idea to redistribute the pharmaceuticals to vendors and pharmacies in need.”<sup>70</sup>

Brokers and consultants who convinced pharmacists to purchase shortage drugs on their behalf established close relationships with routine contact. One pharmacist informed investigators that pharmacists were placed on e-mail distribution lists “sometimes twice a day” circulating “a list of drugs they are looking for.”<sup>71</sup> One such e-mail from a broker to a pharmacist dated September 22, 2011, directed the pharmacist as follows, “[p]lease check your distributors as soon as possible and let me know what’s available how much and the price.”<sup>72</sup> Attached to the e-mail was a spreadsheet that contained a list of drugs. According to the Drug Information Service at the University of Utah, virtually all of the drugs listed in the spreadsheet were in short supply as of that date.<sup>73</sup>

Figure VII is a “protocol” document obtained during the investigation that guides a pharmacy owner through the purchase and subsequent sale of shortage drugs to gray market drug companies.<sup>74</sup> As the document indicates, brokers sometimes placed orders directly using a pharmacy’s account.<sup>75</sup> In addition, brokers created invoices for the pharmacies to facilitate the shipping process.

According to a report in the Bakersfield Californian, the 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 named Priority Pharmaceuticals and, in some instances, other distributors.<sup>76</sup> According to the Board, the pharmacies received lists of drugs that Priority Pharmaceuticals wanted them to order and used their “ordering ability with a [primary] wholesaler to purchase [the] drugs” for the

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<sup>69</sup> E-mail from pharmacist to House Committee on Oversight and Government Reform, Minority Staff (June 7, 2012).

<sup>70</sup> E-mail from pharmacy owner to House Committee on Oversight and Government Reform, Minority Staff (May 22, 2012).

<sup>71</sup> E-mail from pharmacy owner to House Committee on Oversight and Government Reform, Minority Staff (Mar. 29, 2012).

<sup>72</sup> E-mail from broker to pharmacy owners (Sept. 22, 2011).

<sup>73</sup> E-mail from Erin Fox, Manager of the University of Utah Drug Information Service, to House Committee on Oversight and Government Reform, Minority Staff (July 22, 2012).

<sup>74</sup> Fax from broker to pharmacy owner (Sept. 15, 2011).

<sup>75</sup> E-mail from pharmacy owner to House Oversight and Government Reform, Minority Staff (June 12, 2012).

<sup>76</sup> *Local Pharmacy Faces a Barrage of Charges*, The Bakersfield Californian (Mar. 22, 2012).



purpose of reselling them to Priority Pharmaceuticals.<sup>77</sup> The distributors then distributed the drugs “to government hospitals and other health care facilities at” what the Board described as “exceedingly high mark-ups.”<sup>78</sup> The Board determined that the pharmacies violated the California Business and Professional Code by acting as “purchasing agents” for Priority Pharmaceuticals.<sup>79</sup>

*Figure VII: Protocol for Brokers’ Use of Pharmacies as Purchasing Agents*

Below is the proper protocol for the entire operation

- I will place an order via log-in or drop ship ("Ardio" will be the PO name)
- When the product arrives, immediately send me the invoice/packing slip with lot #, exp date, and your pharmacy cost via fax or email (remember time is of the essence)
- Within a couple hours I will send a PO & Fed Ex Label for the product via fax or email
- I will schedule a pick up with Fed Ex and verify this with my contact at the pharmacy
- The pharmacy will then make sure the product is packed properly, place the pre-paid label on the box, and make sure it ships. If a Packing Slip is provided, place the packing slip in the box with the product. The Purchase Order will stay at the pharmacy.

Documents obtained during the investigation also reveal that brokers and consultants monitor the release of new drug shipments from manufacturers and their distributors. For example, on January 20, 2012, one broker sent an e-mail indicating that a new batch of metoprolol had been released, and asked various pharmacies to buy up the shortage drug, “we jsut [sic] found some it’s been a release find it get sale it [sic].”<sup>80</sup> Metoprolol is a drug used to improve survival after a heart attack and in the treatment of heart failure.

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<sup>77</sup> *Id.*

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

<sup>79</sup> *See, e.g.,* California Department of Consumer Affairs, Board of Pharmacy, Citation and Fine, Citation Number CI 2011 49887, Medical Arts Pharmacy, Phy 45941 (citing and fining Medical Arts Pharmacy for acting as a purchasing agent for Priority Pharmaceuticals, Dubin Medical, Gulf Coast Pharmaceuticals, and Vital Healthcare); California Department of Consumer Affairs, Board of Pharmacy, Citation and Fine, Citation Number CI 2011 49813, Los Altos Pharmacy at El Camino Hospital, Phy 50153 (citing and fining Los Altos Pharmacy at El Camino Hospital for acting as a purchasing agent for Priority Pharmaceuticals).

<sup>80</sup> E-mail from broker to pharmacy owner (Jan. 20, 2012).

Wholesalers operating in the gray market purchased a significant portion of prescription drugs through pharmacies. For example, Vital Healthcare, a gray market company based in Georgia, estimated that it uses brokers to locate approximately 25% to 35% of its annual 123,700 unit prescription drug sales volume.<sup>81</sup> Similarly, Harford Health Services, a Maryland company, purchased 25% of its \$2 million prescription drug volume from pharmacies between March 2011 and February 2012.<sup>82</sup> During the same time frame, California-based Optimal Pharmaceuticals told investigators that it purchased 44% of its total volume from pharmacies.<sup>83</sup>

#### **4. Establishing Fake Pharmacies**

Documents obtained during the investigation identified numerous entities that appear to have established “fake pharmacies” to gain greater access to shortage drugs. After obtaining these drugs, the “pharmacies” typically did not dispense the drugs to patients pursuant to their pharmacy licenses, but instead sold them to wholesalers they also owned or in which they had interests.

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. Jessica Hoppe owned both companies. Between May 23, 2011 and Sept. 19, 2011, a quarter of the prescription drug products invoiced to International by LTC were on the FDA shortage list as of April 2012.<sup>84</sup> State regulators in North Carolina found that, “International Pharmaceuticals and LTC Pharmacy willfully violated NC wholesaler prescription drug distribution laws,”<sup>85</sup> and LTC Pharmacy “is not an operating pharmacy.”<sup>86</sup> Licenses for both companies have recently been surrendered or denied.<sup>87</sup> Figure VIII below shows photos that the North Carolina Board of Pharmacy Inspectors took of LTC Pharmacy.

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<sup>81</sup> Letter from J. Patrick Connell, Ellis, Painter, Ratterree & Adams LLP, representing Vital Healthcare to Minority Staff, House Committee on Oversight and Government Reform (May 31, 2012).

<sup>82</sup> Letter from Jose Torres, Harford Health Services, Inc., to Senate Committee on Commerce, Science, and Transportation, Majority Staff (June 11, 2012).

<sup>83</sup> E-mail from Ismail Kabook, Optimal Pharmaceuticals, to House Committee on Oversight and Government Reform, Minority Staff (May 29, 2012).

<sup>84</sup> E-mail from North Carolina Department of Agriculture and Consumer Services to Minority Staff, House Committee on Oversight and Government Reform (June 12, 2012).

<sup>85</sup> E-mail from North Carolina Department of Agriculture and Consumer Services to former International Pharmaceuticals employee (Jan. 3, 2012).

<sup>86</sup> North Carolina Board of Pharmacy, *Miscellaneous Inspection Report* (Sept. 19, 2011).

<sup>87</sup> E-mail from North Carolina Department of Agriculture and Consumer Services to former International Pharmaceuticals employee (Jan. 3, 2012).

*Figure VIII –Photos of LTC Pharmacy Taken by North Carolina Board of Pharmacy Inspectors*



Priority Healthcare and Tri-Med America: A husband and wife team, Marianna Pesti and Gabor Szilagy, established a pharmacy and a wholesale company. On multiple occasions, the couple purchased the cancer drug fluorouracil, transferred it to their own wholesaler, and then sold it to another gray market drug company at significant markups, sometimes on the same day as the original purchase. Exhibit I in the Appendix illustrates one such transaction.<sup>88</sup> New Jersey officials have recently revoked Tri-Med America's license.<sup>89</sup> Maryland state regulators found that Priority Healthcare committed numerous violations of state law.<sup>90</sup> Priority Healthcare is no longer in business.<sup>91</sup>

Columbia Med Services and Columbia Medical Distributors: Columbia Med Services, a pharmacy in Maryland, transferred short-supply drugs without a wholesaler license to Columbia Medical Distributors, a wholesaler in Maryland, which then sold them into the gray market. The companies were owned by the

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<sup>88</sup> This transaction is also discussed in section II.A.1.

<sup>89</sup> State of New Jersey Department of Health and Senior Services, *Wholesale Drug Project Revocations* (online at [http://nj.gov/health/foodanddrugsafety/rev\\_sus.shtml](http://nj.gov/health/foodanddrugsafety/rev_sus.shtml)) (accessed June 7, 2012).

<sup>90</sup> Maryland Board of Pharmacy, *Consent Order: In the Matter of Priority Healthcare, LLC* (Oct. 19, 2011) (online at <http://www.dhmv.maryland.gov/pharmacy/docs/FormalOrders/P/Priority%20Healthcare,%20LLC%2010-19-11.pdf>).

<sup>91</sup> Maryland Board of Pharmacy, *Establishment Detail* (online at <https://license.mdbop.org/verification/veri/establishmentDetail.asp?PermitNo=PW0275>) (accessed June 10, 2012).

same person and were located in the same industrial office complex.<sup>92</sup> Figure IX below shows photos of Columbia Med Services' location.

*Figure IX – Photos of Columbia Med Services*



J&A Pharmaceutical Services and North, Inc.: J&A Pharmaceutical Services, a pharmacy in North Carolina, sold drugs without a wholesaler license to North, a licensed wholesaler. Both entities were located at the same address and had the same owner.<sup>93</sup> The North Carolina Board of Pharmacy found that J&A Pharmaceutical Services “ordered numerous injectable medicals, also found on the FDA Drug Shortage List, with no records of dispensation for any of them from June 2011 through December 2011.”<sup>94</sup> J&A voluntarily surrendered its pharmacy license in March 2012.<sup>95</sup>

HealthRite Pharmaceuticals and AmeriSure Pharmaceuticals: According to its owner, AmeriSure Pharmaceuticals “was established and licensed under Maryland law to act as a wholesaler for any drug procured by HealthRite,” a pharmacy licensed in Maryland. Both companies were owned by the same

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<sup>92</sup> See Maryland Secretary of State, Articles of Incorporation for a NonStock Corporation (filed Aug. 5, 2005) (listing Brenda Marshall as the incorporator for Columbia Med Services, LTD at 9693 Gerwig Lane Unit 1R, Columbia MD 21046); Maryland Secretary of State, Articles of Organization of Columbia Medical Distributors, LLC (filed Jan. 22, 2002) (listing Brenda Lee Marshall as the initial member of Columbia Medical Distributors at 9687-C Gerwig Lange, Columbia, MD 21045).

<sup>93</sup> North Carolina Department of Agriculture and Consumer Services, *Inspection Report* (Apr. 23, 2012).

<sup>94</sup> E-mail from North Carolina Board of Pharmacy to North Carolina Department of Agriculture and Consumer Services (Mar. 22, 2012).

<sup>95</sup> North Carolina Department of Agriculture and Consumer Services, *Inspection Report* (Mar. 28, 2012).

individual and were located in the same address. HealthRite informed Ranking Member Cummings that the company sold all of its drugs to AmeriSure.<sup>96</sup>

## **5. Common Ownership and Shared Employees**

Pedigree chains reviewed in this investigation reveal that groups of companies routinely worked together to procure shortage drugs. In some cases, these business dealings were not arms-length transactions because the companies had common owners or shared employees.

For example, a network of seven companies in New Jersey all located within a 30-mile radius routinely worked together to obtain and sell drugs that were in short supply. Companies with pharmacy licenses – Avenel Pharmacy, Old Bridge Drug and Surgicals, Red Bank Pharmacy, Sewaren Innovative Pharmaceutical Packaging (SIPP), Colonia Natural Pharmacy, and Edison Pharmacy – used their pharmacy licenses to obtain shortage drugs from various ADRs.<sup>97</sup> As Figure X illustrates, rather than dispensing these drugs to patients, the pharmacies sold the shortage drugs to one of the network’s wholesalers, Avenel Pharmacy or Investigational Drug Delivery (IDD), which operated as the network hub. These wholesalers then re-sold the shortage drugs to other secondary wholesalers at a markup. Exhibit III in the Appendix shows how 30 vials of the cancer drug paclitaxel traveled through this network and were later sold to a hospital in Missouri.

Hank Incognito was an owner, officer, and/or director of four of these companies, IDD, Avenel Pharmacy, SIPP, and Edison Pharmacy, at the time of the transactions examined in this investigation.<sup>98</sup> Nunzio Gallo was an owner or director of Avenel Pharmacy and Edison Pharmacy when the transactions occurred.<sup>99</sup>

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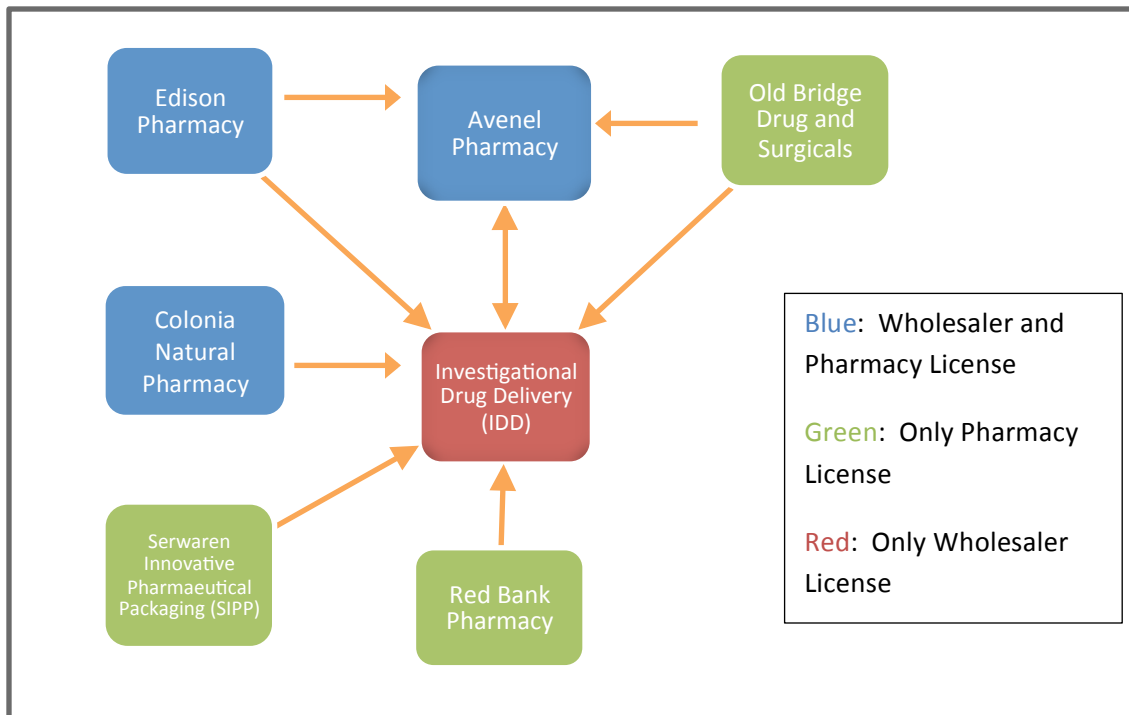
<sup>96</sup> Letter from Mackie A. Barch, Managing Director of HealthRite Pharmaceuticals, to Ranking Member Elijah E. Cummings, House Committee on Oversight and Government Reform (Apr. 20, 2012).

<sup>97</sup> Several pharmacies outside of this local area also sold drugs into this network through Avenel Pharmacy.

<sup>98</sup> See New Jersey Department of the Treasury, Division of Revenue, Certificate of Formation for Investigational Drug Delivery Limited Liability Company (filed Jan. 14, 2011) (listing Hank Incognito and Stephen F. Corba, Jr. as members/managers); New Jersey Certificate of Incorporation for Avenel Pharmacy, Inc. & Registration of Alternate Name of Avenel Pharmacy, Inc., d/b/a Avenel Surgical & Pharmaceuticals (filed July 7, 2003 & July 7, 2010) (listing Hank Incognito as president and director & Nunzio Gallo as director); New Jersey Department of the Treasury, Division of Revenue, Certificate of Formation for Investigational Drug Delivery Limited Liability Company (filed Jan. 14, 2011) (listing Hank Incognito and Stephen F. Corba as members/managers); New Jersey Department of the Treasury, Division of Revenue, Certificate of Formation for Sewaren Innovative Pharmaceutical Packaging Limited Liability Company (filed Feb. 4, 2011) (listing Hank Incognito as authorized representative); New Jersey Certificate of Incorporation for N G H I, Inc. & New Jersey Department of the Treasury, Division of Revenue, Renewal Notice and Filing Form for Alternate Business Name for N G H I, Inc., d/b/a Edison Pharmacy (filed Dec. 19, 2003 & Dec. 29, 2003) (listing Hank Incognito as director & Nunzio

The investigation also uncovered a network of Kentucky pharmacies that purchased shortage drugs for the same Kentucky wholesaler. In this case, a licensed wholesaler, Central Compound Pharmacy Supply, routinely purchased drugs from local pharmacies – Bluegrass Pharmacy, the Medicine Shoppe of Springfield, Hurst Discount Drugs and Medicine Centre Pharmacy.<sup>100</sup> Gary Smith signed pedigree documents for these pharmacies and identified himself as the “compliance manager” for the pharmacies. Central Compound Pharmacy Supply’s website identifies Gary Smith as part of its “team.”<sup>101</sup>

Figure X – Network of New Jersey Companies that Sell Shortage Drugs



Gallo as owner & director); *Service a Priority at Edison Pharmacy*, Courier News (June 6, 2011) (identifying Hank Incognito and Nunzio Gallo as the co-owners of Avenel Pharmacy and Edison Pharmacy).

<sup>99</sup> *Id.*

<sup>100</sup> All of these listed pharmacies also held Kentucky wholesale distribution licenses.

<sup>101</sup> Central Compound Pharmacy Supply website, *Meet The Team!* (online at <http://centralpharmacysupply.com/career.html>) (accessed July 22, 2012).

## 6. Wholesalers Handling the Drugs Have Disciplinary or Licensing Problems

Some of the pedigree chains congressional investigators examined include secondary distributors whose owners have a history of disciplinary actions.

For example, Alliance Wholesale Distributors of Richton Park, Illinois purchased and sold cytarabine and leucovorin. Phil Giannino, its owner, was sentenced in federal court in late 2009 for conspiracy to defraud the United States by distributing diverted pharmaceutical drugs. The court ordered him to pay almost \$4 million in restitution.<sup>102</sup> Based on this conviction, Illinois revoked Mr. Giannino's pharmacist license and Alliance Wholesale Distributors' drug distributor license in 2011, stating that, "Giannino is prohibited from being employed or otherwise working for an Illinois wholesale drug distributor in any capacity."<sup>103</sup>

Stephen F. Corba, Jr., a managing member of Investigational Drug Delivery (IDD), was involved in the purchase and sale of magnesium sulfate and paclitaxel. In August 2011, Mr. Corba pleaded guilty to conspiracy to commit wire fraud and conspiracy to commit money laundering in a \$40 million mortgage fraud case.<sup>104</sup> His sentence is pending, and he has already agreed to a \$489,000 forfeiture order.<sup>105</sup>

It is difficult for state regulatory agencies to stay abreast of disciplinary actions, revocations, and non-renewals of wholesalers entities operating in other states. For example, the state of North Carolina chose not to renew the wholesaler license for International Pharmaceuticals in December 2011 as a result of the company "willfully violat[ing] NC wholesale prescription drug distribution laws for an extended period of time during 2011."<sup>106</sup> As of March 2012, International Pharmaceuticals still had active wholesaler licenses in at least 23 other states; these other state licenses referenced the company's primary license in North Carolina. In addition, the owner and sales manager of International Pharmaceuticals and LTC Pharmacy recently opened a new wholesaler

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<sup>102</sup> *United States v. Phillip Giannino*, Case No. 05-00315-16-CR-W-ODS (W.D. Mo. entered Dec. 15, 2009).

<sup>103</sup> Illinois Department of Financial and Professional Regulation, News (Apr. 28, 2011) (online at [http://www.idfpr.com/Forms/DISCPLN/1103\\_dis.pdf](http://www.idfpr.com/Forms/DISCPLN/1103_dis.pdf))

<sup>104</sup> The United States Attorney's Office, District of New Jersey, *Fourth Man Pleads Guilty in \$40.8 Million Mortgage Fraud Scheme* (Aug. 16, 2011) (online at [www.justice.gov/usao/nj/Press/files/Williams,%20Michael%20Plea%20News%20Release.html](http://www.justice.gov/usao/nj/Press/files/Williams,%20Michael%20Plea%20News%20Release.html)).

<sup>105</sup> Defendant's Plea Agreement, *United States v. Stephen F. Corba, Jr.*, Case No. 1:11-cr-00523-JEI-1 (D.N.J. May 13, 2010).

<sup>106</sup> E-mail from North Carolina Department of Agriculture and Consumer Services to former International Pharmaceuticals employee (Jan. 3, 2012).

business called “KY Meds” in Kentucky.<sup>107</sup> This company has already obtained wholesaler licenses in Kentucky as well as two other states.<sup>108</sup>

## **CONCLUSION**

This investigation has found that gray market companies that operate outside of authorized distribution networks take advantage of drug shortage situations to charge exorbitant prices for drugs used to treat cancer and other life-threatening conditions. Gray market drugs leak out of authorized distribution chains, often through pharmacies that sell to wholesale distributors, and are sold to end users at aggressively marked-up prices. The questionable business practices of the distributors and pharmacies engaged in gray market sales result in higher health care costs and potential risks to patients.

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<sup>107</sup> Commonwealth of Kentucky Articles of Incorporation for KY Meds Inc. (filed Jan. 10, 2012) (listing Jennifer Colon, former Sales Manager for International Pharmaceuticals, as the President and Owner); E-mail from Jessica Hoppe, Sales Manager for KY Meds Inc., to pharmacy owner (July 13, 2012).

<sup>108</sup> Kentucky Board of Pharmacy, License Verification Details; Ohio Board of Pharmacy, License Center; and Pennsylvania Department of Health, Drug Device and Cosmetic Program Public Lookup (July 16, 2012).