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SHORT-SUPPLY PRESCRIPTION DRUGS: SHINING A LIGHT ON THE GRAY MARKET

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

JULY 25, 2012

Printed for the use of the Committee on Commerce, Science, and Transportation

U.S. GOVERNMENT PRINTING OFFICE

79–524 PDF WASHINGTON : 2013

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ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

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SHORT-SUPPLY PRESCRIPTION DRUGS: SHINING A LIGHT ON THE GRAY MARKET

WEDNESDAY, JULY 25, 2012

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 2:35 p.m. in room SR–253, Russell Senate Office Building, Hon. John D. Rockefeller IV, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, U.S. SENATOR FROM WEST VIRGINIA

The CHAIRMAN. Good afternoon. This hearing will come to order, and it should be an interesting hearing. Others will be appearing, do not despair.

We are holding this hearing today because some, I would say, very unscrupulous people have figured out a way to make a quick buck at the expense of sick patients, hospitals, and, in the end, our entire health care system. For the past few years, hospitals all over the country have been struggling with the terrible problems of drug shortages: they don't have certain drugs when they need them.

The drugs that have been in short supply are not allergy drugs. They're not blood pressure pills. They tend to be cancer drugs, powerful drugs that doctors need to treat cancer patients and/or to perform surgery. These drugs, in their shortage, make it very difficult and sometimes impossible for doctors and for hospitals and nurses and other health care professionals to do their job, which is to care for us when we're critically ill.

A West Virginia hospital recently told me about two young ovarian cancer patients who traveled several hours to reach the hospital and start their treatment. When they arrived, the hospital had to send them home. The hospital had to send them home because it didn't have the needed drug. They didn't say it didn't exist. They just didn't have it.

The main purpose of this hearing today is not to talk about the causes of drug shortages on a general scale. There have been hearings in other committees about this issue. I know that the Food and Drug Administration and the drug industry are working hard to avert shortages, and I applaud them and urge them to keep up their work. There would be nothing more terrifying than to think about being in a hospital and needing a drug, and you can't get it, because somebody else is hoarding it and jacking up the price on it.

What we are here to talk about today are the opportunists who suddenly appear when drugs are in short supply. They are profiteers, people who exploit the misery of sick patients to make a quick buck. We usually call them gray market companies. There are other names that are ascribed to them, but we'll stick with gray market companies.

These gray market companies seem to know when drugs are in shortage—that is their leverage, their key to success—even before the hospitals know it. And they always seem to be able to get their hands on short-supply drugs, even when authorized prescription drug distributors don't have them in stock.

For the past few months, my friends, Senator Harkin, who I believe is coming, and Congressman Elijah Cummings, who I'm pretty sure is coming—he's running a meeting now but I think he wants to make a statement, and I want him to. I'm hopeful also that Senator Enzi might be here. He certainly is invited. We would be honored to have him. And myself—all of us have been investigating who these gray market companies are and where they're getting their drugs.

At this point, I ask unanimous consent to insert our staff report on this investigation into the record of this hearing.

What we have found is that our drug distribution system has weak points, and gray market companies know exactly how to exploit weak points. We have learned that there are people in the drug supply chain who ignore their professional and business obligations and sell their drugs to gray market companies instead of to doctors and to patients or hospitals. This is the report.

We have carefully mapped out dozens of cases where prescription drugs that should have been delivered to hospitals and administered to sick patients instead spent weeks circulating in the gray market. We're not sure about everything that happens to the drugs when they are being passed from hand to hand in the gray market, but here's one thing we do know. Every company in the chain charges a big markup.

By the time the gray market has done its work, a cancer drug that originally costs maybe $10 or $12 has become a drug that costs $500 or even $1,000. You're talking about markups of 1,000 percent or more. And the person who makes the drug, the distributor who distributes the drug, to the hospital who needs the drug—but in between is the gray market, these little boxes of people who are using shortages to drive up the cost of—the profit they can make.

This kind of price gouging is disgusting to me and, obviously, indefensible. Not even gray market companies themselves are willing to defend it. I invited the five companies we looked at in this investigation to testify at this hearing. They all declined my invitation, and that's because they all know what they're doing is wrong. I could subpoena them. We've subpoenaed some of their records, and maybe some day I'll subpoena them, just because I like to see people who don't do good things squirm.

We need to close down this gray market, I would suggest to you, and do a better job making sure that prescription drugs are safe and affordable. And that's what I look forward to talking about today.

[The information previously requested follows:]

"SHINING LIGHT ON THE GRAY MARKET"

An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages

Staff Report prepared for: Senator John D. Rockefeller IV, Chairman, Senate Committee on Commerce, Science, and Transportation, Senator Tom Harkin, Chairman, Senate Committee on Health, Education, Labor, and Pensions, Representative Elijah E. Cummings, Ranking Member, House Committee on Oversight and Government Reform—July 25, 2012

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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

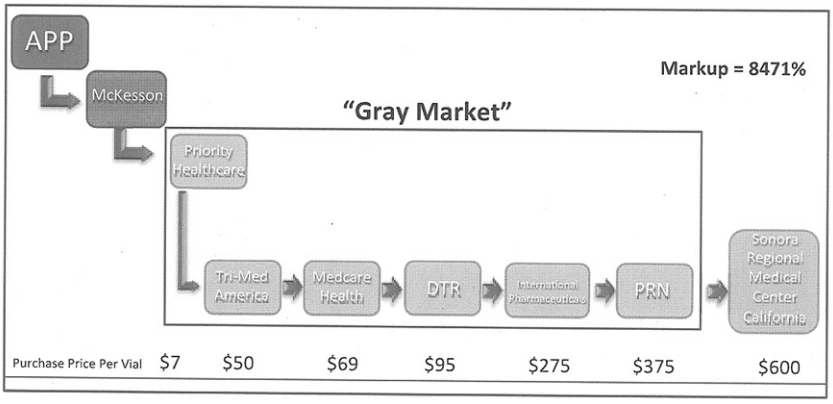
these offers. They have asked, "why the hospitals can't get these products but the 'scalpers' can."

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 percent) 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 percent, 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.

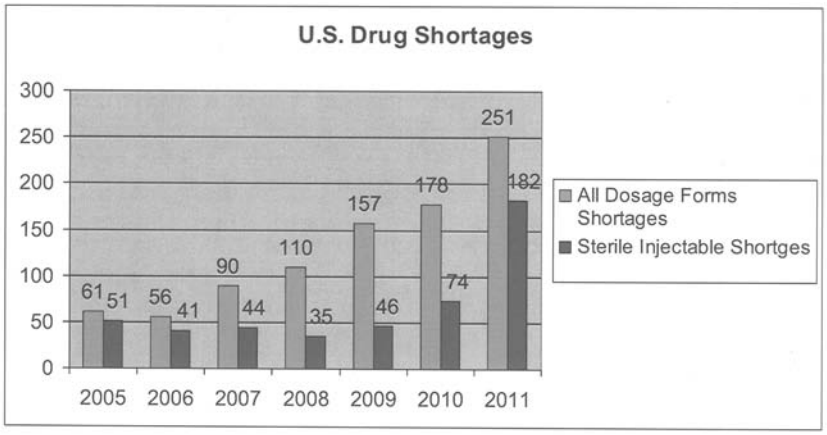
Gray Market Drugs Are Marked Up as They Quickly Pass from Owner to Owner. On average, the prescription drugs examined in this investigation were owned by three to four different gray market businesses before being sold to a hospital; most of the drugs traveled through the gray market in five days or 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."[1] 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.[2]

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 com-

[1] U.S. Food and Drug Administration, *A Review of FDA's Approach to Medical Product Shortages,* 8 (Oct. 31, 2011).

[2] *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).

plications caused by incorrect dosages.[3] 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.[4]

Of the 251 drug shortages the CDER reported in 2011, 182 of the shortages (73%) involved sterile injectables.[5] 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.[6] 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.[7]

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.[8] 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."[9]

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.[10] When drugs are unavailable, health care providers are sometimes forced to delay 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.[11]

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.[12] 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

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[3] David E. Golan, *et al., Principles of Pharmacology, 3rd Edition,* 30–31 (2012).

[4] *Id.*

[5] U.S. Food and Drug Administration, *supra* note 2, at 10.

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

[7] *Id.* at 3.

[8] *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).

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

[10] American Hospital Association, *AHA Survey on Drug Shortages* (July 12, 2011).

[11] *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.").

[12] Kaakeh, *supra* note 2, at 1818.

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.[13] In some cases, manufacturers stop or slow down production because they cannot obtain the Active Pharmaceutical Ingredients (API) they need to produce the drugs.[14]

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.[15] A Government Accountability Office (GAO) analysis of 15 drug shortages occurring in 2009 and 2010 found that 12 of the shortages were caused by "manufacturing problems."[16] Manufacturers themselves have reported to ASHP that the top reason for these shortages was "production-related issues and increased demand."[17]

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.[18] 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.[19]

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.[20] 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.[21]

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.[22]

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

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[13] 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).

[14] *Id.*

[15] *Id.*

[16] U.S. Government Accountability Office, *Drug Shortages: FDA's Ability to Respond Should be Strengthened,* 22–23 (Nov. 2011) (GAO–12–116).

[17] IMS Institute for Healthcare Informatics, *supra* note 6, at 9.

[18] 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.

[19] *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*).

[20] 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.

[21] 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").

[22] *Id.*

of the shortage cancer drug cytarabine for $995 per vial.[23] 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?[24]

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."[25] Hospital pharmacists also "reported feeling pressured by physicians and hospital administrators to purchase medications from the gray market."[26]

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,[27] others decided to buy drugs from gray market companies because, as one hospital pharmacist explained, "[w]e have no other choice . . . We have to take care of our patients."[28] 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.[29]

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."[30] 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.[31]

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,

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[23] *Drug Shortages, Skyrocketing Prices Anger Pharmacists,* San Antonio Express-News (May 3, 2011).

[24] *Id.*

[25] Institute for Safe Medication Practices, *supra* note 20.

[26] *Id.*

[27] *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.").

[28] 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").

[29] John VanEeckhout, *Financial Implications of the Drug Shortage Crisis,* Children's Hospitals Today (Winter 2012).

[30] 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).

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

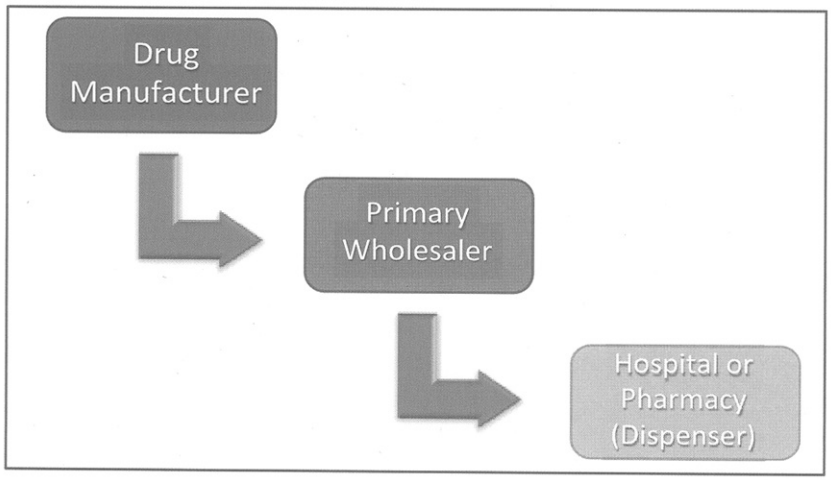
but the main thing is: If I can't be absolutely sure of the integrity of the drug, then I can't administer it to a patient."[32]

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."[33]

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.[34] 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 distributors of record" (ADR) for the manufacturers.[35] About 85 percent 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.[36] 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 "pri-

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

[33] *Short of Drugs, Hospitals Wary of 'Gray Market,'* St. Petersburg Times (Nov. 7, 2011).

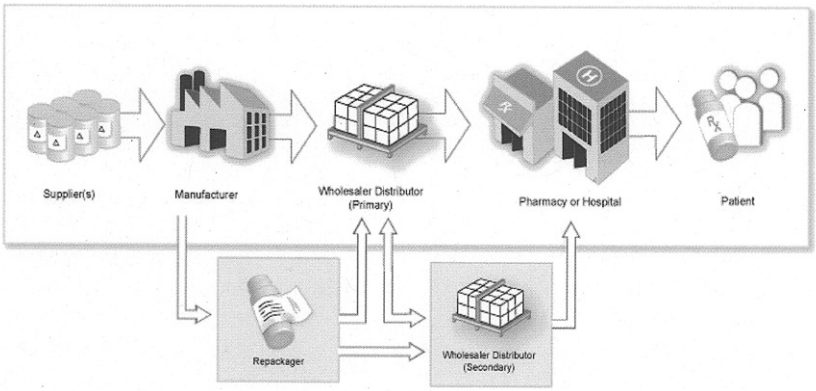
[34] "In the U.S., wholesale drugs in bulk containers are often repackaged into smaller containers prior to sale to an end user. Repackaging operations are performed by independent entities, wholesale distributors, or by distribution centers owned by large pharmacies." Food and Drug Administration, *Counterfeit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

[35] 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).

[36] 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*).

mary" distributors.[37] "Secondary" distributors are also sometimes ADRs, and they obtain access to drugs from primary distributors or other sources.[38] 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.[39] 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.[40]

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."[41]

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."[42] 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.[43] Another primary wholesale distributor typically requires its final dispenser customers to agree to use purchased

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[37] Healthcare Distribution Management Association, *HDMA Fact Sheet on PDMA* (online at *http://www.healthcaredistribution.org/press_room/pdma_facts.asp*).

[38] *Id.*

[39] 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).

[40] 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; 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.

[41] 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).

[42] Primary Wholesale Distributor, *Policy Statement on Secondary Market Sales.*

[43] Primary Wholesale Distributor, *Wholesaler Safe Product Practices.*

products for their "own use" and its secondary wholesaler customers to agree to sell purchased products only to final dispensers.[44]

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.[45] 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 have the legacy of the drug. It's not the same quality assurance and you don't know its authenticity."[46]

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.[47] 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.

	Manufacturers	Treatment	Distributor Receiving Information Request
Cytarabine	APP, Bedford, Hospira	Leukemia in children and adults	Allied Medical Supply, Inc., Miami, FL
Fluorouracil	APP, Mylan, Teva	Colon, stomach, breast, and pancreatic cancer	PRN Pharmaceuticals, Rockville, MD
Leucovorin	APP, Bedford, Teva	Advanced colon cancer	Premium Health Services Inc., Columbia, MD
Magnesium Sulfate	American Regent, APP, Hospira	Seizures during pregnancy	Reliance Wholesale, Inc., Miami, FL
Paclitaxel	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.[48] Since that time, the three Members of Congress have requested information from more than 50 prescription drug manufacturers, distributors, and pharmacies.[49] 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.[50]

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

[45] Food and Drug Administration, *Counterfeit Drug Task Force Report* (October 2003).

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

[47] 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).

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

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

[50] *See* 21 U.S.C. § 353(e)(1)(A). Drug manufacturers and authorized distributors of record are exempt from the Federal pedigree requirement.

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

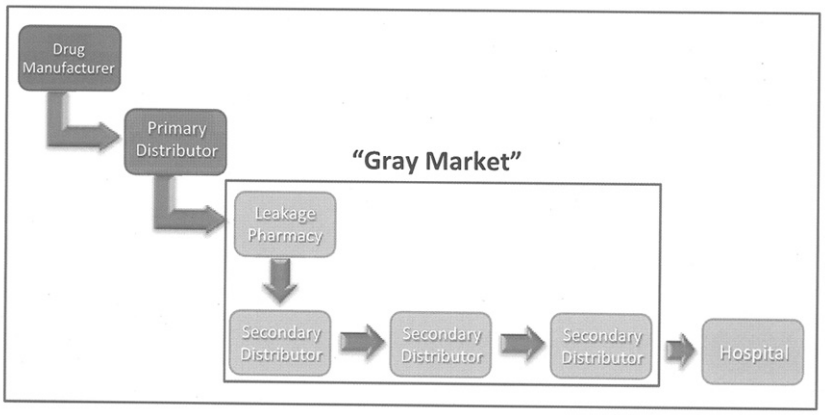
A. Exorbitant Prices Charged for Drugs in Gray Market

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.

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

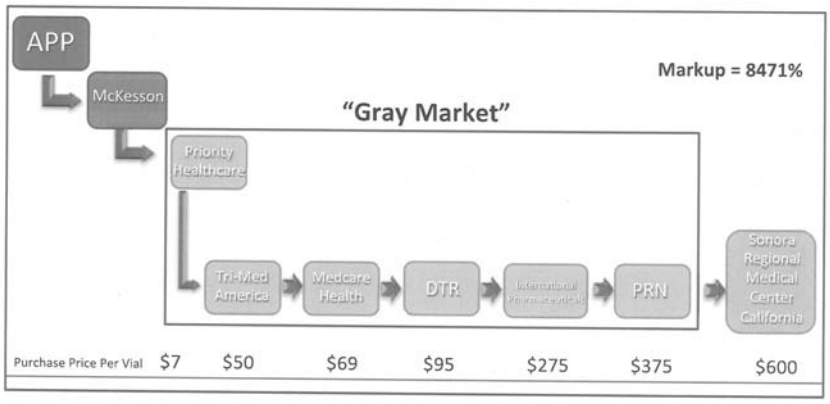


Figure V illustrates how 25 vials of fluorouracil, a sterile injectable drug used to treat colon, stomach, breast, and pancreatic cancer, traveled from its manufacturer, APP Pharmaceuticals, to Sonora Regional Medical Center in Sonora, California. At the time of these transactions, September 2011, fluorouracil 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.[51] 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%.[52]

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 Mis-

[51] See section II.B.4. of this report for further discussion of Priority Healthcare.

[52] 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.

sissippi 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.[53]

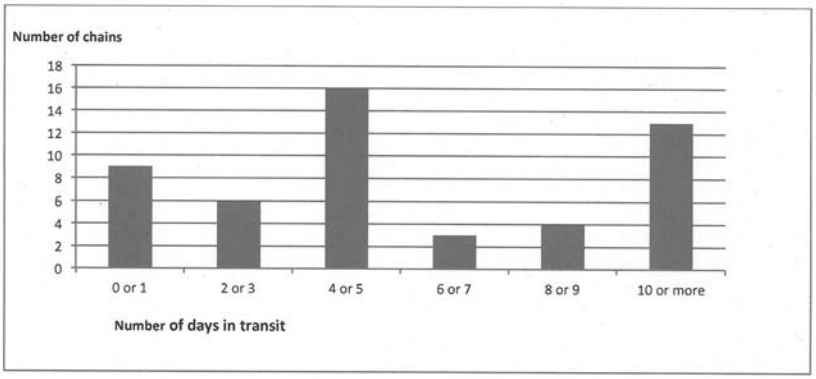
Exhibit III in the Appendix shows that price markups could be substantial even in cases where small numbers of gray market actors handled the drug. In the transaction shown there, 30 vials of paclitaxel, which is used to treat breast and ovarian cancer patients, were sold to the Heartland Regional Medical 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%.[54]

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.[55] In 13 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:

[53] 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).

[54] 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.

[55] 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."

- 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 percent) 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.[56] 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 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.[57] 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.

[56] 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.

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

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 percent of its products to a distributor business they also owned.[58] These sales appear to violate a Maryland law that requires pharmacies to obtain separate wholesaler licenses if they re-sell more than 5 percent of their products.[59] On April 10, 2012, HealthRite Pharmaceuticals informed the Maryland Board of Pharmacy that it had ceased operations.[60]

Similarly, a New Jersey pharmacy, Morningstar Pharmacy, reported that, from March 2011 to February 2012, all of its revenues came from re-sales,[61] which appears to violate New Jersey pharmacy laws. New Jersey law permits pharmacies to engage in "the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug for emergency medical reasons."[62]

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

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.[64] 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.[65]

For example, an e-mail from a pharmaceutical consultant to a pharmacy owner, dated June 13, 2011, states, "[w]e guarantee our Pharmacies 20 percent or more every time."[66] 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."[67]

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 be-

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[58] 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).

[59] 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").

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

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

[62] New Jersey Statutes § 24:6B–14.

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

[64] 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.

[65] 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.

[66] E-mail from broker to pharmacy owner (June 13, 2011).

[67] E-mail from broker to pharmacy owner (Aug. 19, 2011).

half.[68] 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 for him, and promised a 20 percent profit margin for doing the same.[69] 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."[70]

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."[71] 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."[72] 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.[73]

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.[74] As the document indicates, brokers sometimes placed orders directly using a pharmacy's account.[75] 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.[76] 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 purpose of reselling them to Priority Pharmaceuticals.[77] The distributors then distributed the drugs "to government hospitals and other health care facilities at" what the Board described as "exceedingly high markups."[78] The Board determined that the pharmacies violated the California Business and Professional Code by acting as "purchasing agents" for Priority Pharmaceuticals.[79]

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 ("Ardie" 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

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

[69] E-mail from pharmacist to House Committee on Oversight and Government Reform, Minority Staff (June 7, 2012).

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

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

[72] E-mail from broker to pharmacy owners (Sept. 22, 2011).

[73] 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).

[74] Fax from broker to pharmacy owner (Sept. 15, 2011).

[75] E-mail from pharmacy owner to House Oversight and Government Reform, Minority Staff (June 12, 2012).

[76] *Local Pharmacy Faces a Barrage of Charges,* The Bakersfield Californian (Mar. 22, 2012).

[77] *Id.*

[78] *Id.*

[79] *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).

- I will schedule a pick up 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]."[80] Metoprolol is a drug used to improve survival after a heart attack and in the treatment of heart failure.

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 percent to 35 percent of its annual 123,700 unit prescription drug sales volume.[81] Similarly, Harford Health Services, a Maryland company, purchased 25 percent of its $2 million prescription drug volume from pharmacies between March 2011 and February 2012.[82] During the same time frame, California-based Optimal Pharmaceuticals told investigators that it purchased 44% of its total volume from pharmacies.[83]

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.[84] State regulators in North Carolina found that, "International Pharmaceuticals and LTC Pharmacy willfully violated NC wholesaler prescription drug distribution laws,"[85] and LTC Pharmacy "is not an operating pharmacy."[86] Licenses for both companies have recently been surrendered or denied.[87] Figure VIII below shows photos that the North Carolina Board of Pharmacy Inspectors took of LTC Pharmacy.

[80] E-mail from broker to pharmacy owner (Jan. 20, 2012).

[81] 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).

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

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

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

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

[86] North Carolina Board of Pharmacy, *Miscellaneous Inspection Report* (Sept. 19, 2011).

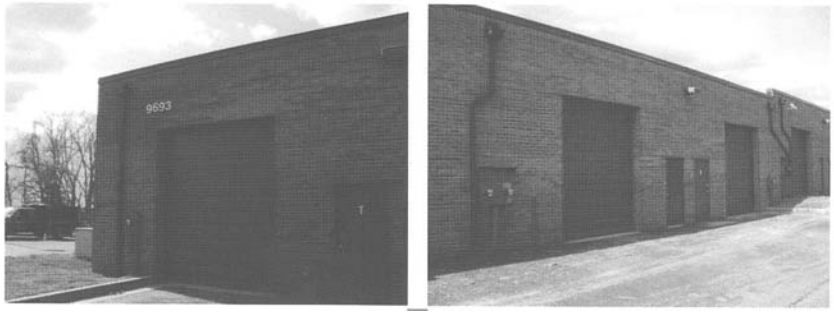
[87] E-mail from North Carolina Department of Agriculture and Consumer Services to former International Pharmaceuticals employee (Jan. 3, 2012).

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 Szilagyi, 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.[88] New Jersey officials have recently revoked Tri-Med America's license.[89] Maryland state regulators found that Priority Healthcare committed numerous violations of state law.[90] Priority Healthcare is no longer in business.[91]

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 same person and were located in the same industrial office complex.[92] Figure IX below shows photos of Columbia Med Services' location.

Figure IX—Photos of Columbia Med Services



[88] This transaction is also discussed in section II.A.1.

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

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

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

[92] *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).

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.[93] 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."[94] J&A voluntarily surrendered its pharmacy license in March 2012.[95]

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

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.[97] 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.[98] Nunzio Gallo was an owner or director of Avenel Pharmacy and Edison Pharmacy when the transactions occurred.[99]

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

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[93] North Carolina Department of Agriculture and Consumer Services, *Inspection Report* (Apr. 23, 2012).

[94] E-mail from North Carolina Board of Pharmacy to North Carolina Department of Agriculture and Consumer Services (Mar. 22, 2012).

[95] North Carolina Department of Agriculture and Consumer Services, *Inspection Report* (Mar. 28, 2012).

[96] 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).

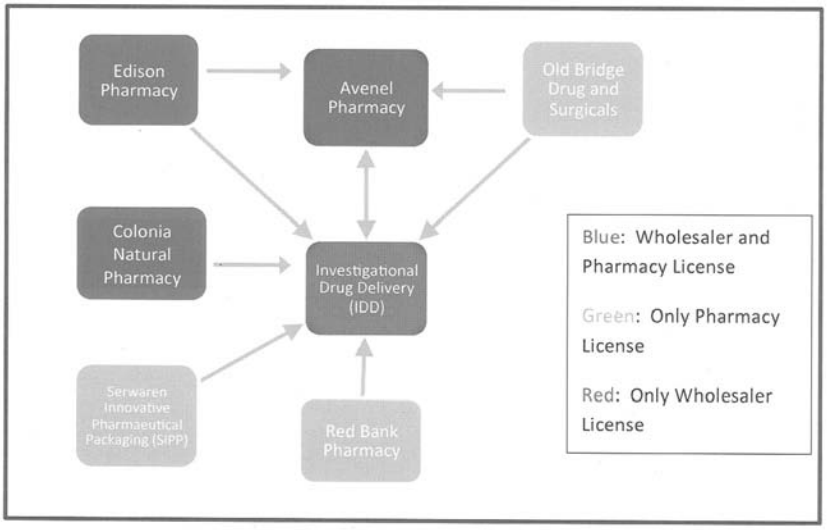
[97] Several pharmacies outside of this local area also sold drugs into this network through Avenel Pharmacy.

[98] *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 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).

[99] *Id.*

Discount Drugs and Medicine Centre Pharmacy.[100] 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."[101]

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



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.[102] 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."[103]

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.[104] His sentence is pending, and he has already agreed to a $489,000 forfeiture order.[105]

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."[106] As of March 2012, International Pharmaceuticals

[100] All of these listed pharmacies also held Kentucky wholesale distribution licenses.

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

[102] *United States v. Phillip Giannino,* Case No. 05–00315–16–CR–W–ODS (W.D. Mo. entered Dec. 15, 2009).

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

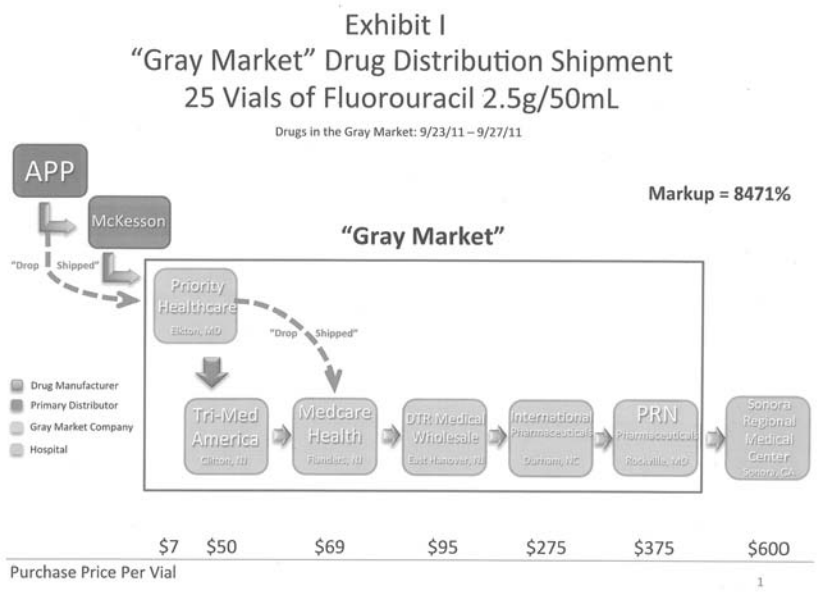
[104] The United States Attorney's Office, District of New Jersey, *Fourth Man Pleads Guilty in $40.8 Million Mortgage Fraud Scheme* (Aug. 16, 2011) (online at *www.justice.gov/usao/nj/Press/files/Williams,%20Michael%20Plea%20News%20Release.html*).

[105] 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).

period of time during 2011."[106] 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 business called "KY Meds" in Kentucky.[107] This company has already obtained wholesaler licenses in Kentucky as well as two other states.[108]

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.



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

[107] 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).

[108] 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).

Exhibit II
"Gray Market" Drug Distribution Shipment
Four Packs of Magnesium Sulfate SDV 50% 25x2mL

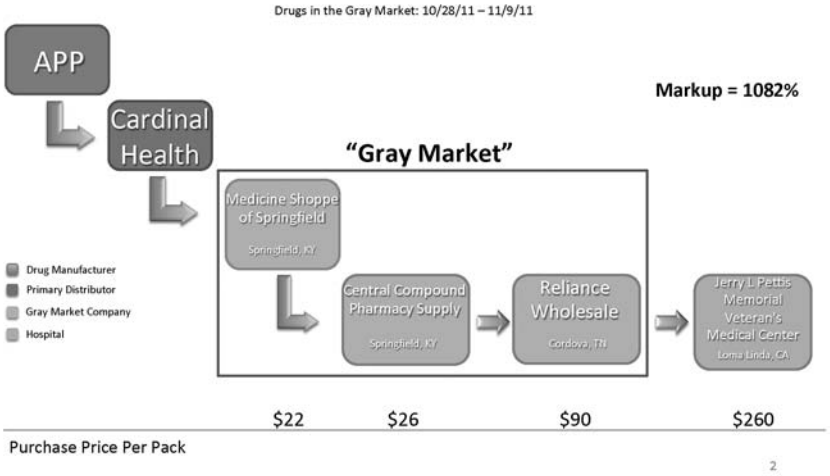


Exhibit III
"Gray Market" Drug Distribution Shipment
30 Vials of Paclitaxel 30mg/5mL

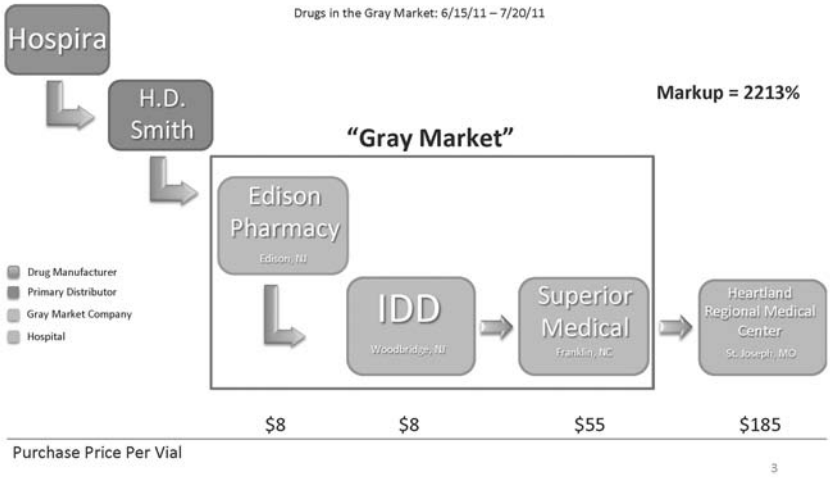


Exhibit IV
"Gray Market" Drug Distribution Shipment
Two Vials of Cytarabine 1gm

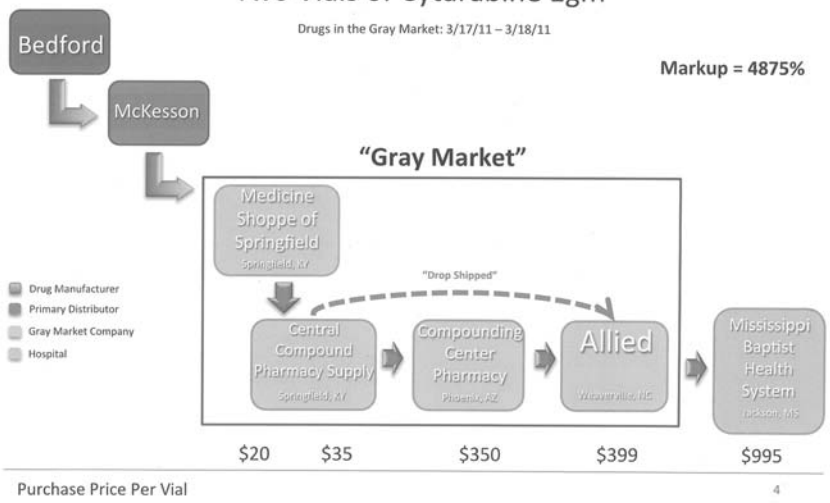
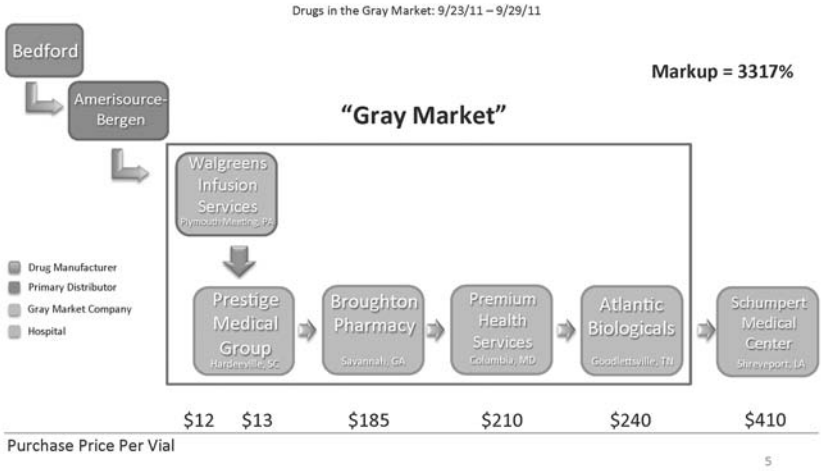


Exhibit V
"Gray Market" Drug Distribution Shipment
50 Vials of Leucovorin 200mg



PEDIGREE FOR EXHIBIT I

EXHIBIT VI

PREMIUM RX NATIONAL, LLC. DBA PRN PHARMACEUTICALS (Wholesaler's name)
PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

gend Drug Name, Strength, Dosage Form, Container Size: FLUOROURACIL 2.5 GM 50ML
his is a repackaged drug (requires repackager's pedigree information and
authentication of repackager's pedigree)
IDC (optional) 63323-0117-51

Reference* Number 8696
Document Type: INVOICE
Reference* Date 9/27/2011
(related to the sale by the wholesaler identified above)

Lot Number	Quantity	Unique Serial #
6101764	25	

OWNERSHIP HISTORY

Manufacturer's Name: APP
Manufacturer's Information for authentication:

1. Wholesaler that purchased from the MANUFACTURER or a REPACKAGER (which requires authentication)

Name: MCKESSEN DRUG
Address: 400 DELRAN PKWY
DELRAN NJ 08075
Date Purchased & Ref: 9/20/2011 PO: 3597974M5611
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 800[redacted]
Email address:
License / Permit Number:

PHYSICAL DISTRIBUTION HISTORY
(if different from the owner information)

Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

2. #1 Above SOLD TO:
Name: PRIORITY HEALTHCARE
Address: 751 ELKTON BLVD
ELKTON MD 21226
Date Purchased & Ref: 9/20/2011 PO: 3597974M5611
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 20[redacted]
Email address:
License: PW0275 12/31/2011

SHIPPED TO:
Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

3. #2 Above SOLD TO:
Name: TRIMED AMERICA LLC
Address: 68 COLFAX AVE
CLIFTON NJ 07013
Date Purchased & Ref: 9/22/2011 #1601
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 973[redacted]
Email address:
License / Permit Number:

SHIPPED TO:
Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

CONFIDENTIAL
PRN-H-000553

wear or affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, required.

Signature (authorized to bind the company) [redacted] Print Name and Title 9/27/2011 Date

* Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.

Page 1 of 3 pages.

PEDIGREE FOR EXHIBIT I

EXHIBIT VI

PREMIUM RX NATIONAL, LLC. DBA PRN PHARMACEUTICALS *(Wholesaler's name)*
PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

4. #3 Above SOLD TO:
Name: MEDCARE HEALTH OF NJ
Address: 186 GOLDMINE RD UNIT 3
FLANDERS NJ 07836
Date Purchased & Ref: 9/22/2011 #523
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 973[redacted]
Email address:
License / Permit Number: 5003651 1/3/2012

SHIPPED TO:
Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

5.
Name: DTR MEDICAL
Address: 15A MELANIE LN UNIT 3B
EAST HANOVER NJ 07936
Date Purchased & Ref: 9/23/2011 #7744
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 973[redacted]
Email address:
License / Permit Number: 5002938 1/31/2012

SHIPPED TO:
Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

6. #5 Above SOLD TO:
Name: INTERNATIONAL PHARMACEUTICALS
Address: 1518 PAGE ROAD UNIT 101
DURHAM NC 27703
Date Purchased & Ref: 9/23/2011 #43739
Print Name of Recipient: [redacted]
Signature of Recipient:
Name of Authenticator: [redacted]
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name: CUSTOMER SERVICE
Telephone Number: 919[redacted]
Email address:
License / Permit Number: 284 12/31/2011

SHIPPED TO:
Name:
Address:
Date Purchased & Ref *
Print Name of Recipient:
Signature of Recipient:
Name of Authenticator:
Signature of Authenticator:
To authenticate a subsequent transaction, contact:
Name:
Telephone Number:
Email address:
License / Permit Number:

CONFIDENTIAL
PRN-H-000554

swear or affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, as required.

Signature (authorized to bind the company) [redacted] Print Name and Title 9/27/2011 Date

* Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.

Page 2 of 3 pages.

PEDIGREE FOR EXHIBIT I

EXHIBIT VI

PREMIUM RX NATIONAL, LLC. DBA PRN PHARMACEUTICALS *(Wholesaler's name)*
PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

7. #6 Above SOLD TO: Name: PREMIUM RX NATIONAL Address: 11736 PARKLAWN DRIVE ROCKVILLE MD 20652 Date Purchased & Ref: 9/27/2011 #7322 Print Name of Recipient: [redacted] Signature of Recipient: Name of Authenticator: [redacted] Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: CUSTOMER SERVICE Telephone Number: 877[redacted] Email address: [redacted]@prnpharma.com License / Permit Number: D03137	SHIPPED TO: Name: Address: Date Purchased & Ref * Print Name of Recipient: Signature of Recipient: Name of Authenticator: Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: Telephone Number: Email address: License / Permit Number:
8. Name: SONORA REGIONAL MEDICAL CENTER Address: 1000 GREENLEY RD SONORA CA 95370 Date Purchased & Ref: 9/27/2011 #8696 Print Name of Recipient: Signature of Recipient: Name of Authenticator Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: CUSTOMER SERVICE Telephone Number: Email address: License / Permit Number: HSP40239 5/1/2012	SHIPPED TO: Name: Address: Date Purchased & Ref * Print Name of Recipient: Signature of Recipient: Name of Authenticator: Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: Telephone Number: Email address: License / Permit Number:
9. #8 Above SOLD TO: Name: Address: Date Purchased & Ref Print Name of Recipient: Signature of Recipient: Name of Authenticator: Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: Telephone Number: Email address: License / Permit Number:	SHIPPED TO: Name: Address: Date Purchased & Ref * Print Name of Recipient: Signature of Recipient: Name of Authenticator: Signature of Authenticator: *To authenticate a subsequent transaction, contact:* Name: Telephone Number: Email address: License / Permit Number:

CONFIDENTIAL
PRN-H-000555

swear or affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, . required.

[redacted]

Signature (authorized to bind the company) — Print Name and Title — 9/28/2011 Date

* Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.

Page 3 of 3 pages.

SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

From: [redacted]@prnpharma.com [mailto:[redacted]@prnpharma.com]
Sent: Wednesday, May 11, 2011 10:25 AM
To:
Subject: Happy Hump Day! Atropine, Acetylcyst 20%, CYTARABINE and Highest Selling Weekly Products

Good morning

I hope everyone is having a good stress free week! The American Regent plant shut down is still affecting most of you and we are working to help you find all of your "Hard to Find" products. This has been a busy week at PRN and there are numerous shortages and updates over the last day or so. I can still access a good portion of what is short in the market so please don't hesitate to ask!

I've listed the newest shorts and latest updates on the ASHP site for your review. I've also included a short list of the products I have access to this morning. It's a long email but I hope this is helpful to you.

As always, if there is a product that you need that is not listed please contact me, and I will find it for you!

Thanks,

[redacted]

Wednesday – May 11th, 2011

INCOMING:

41616-0931-44 Vecuronium #20 @ $105 eta today/tomorrow (D867)

SAMPLE SOLICITATIONS TO HOSPITALS **EXHIBIT VII**

AVAILABLE ETA FRIDAY/MONDAY:

Protamine 5ml 25 pack 0229-05 #20 pc $300 ea

Protamine 25ml 25 pack 0229-30 #40 pc $105 ea

Azithromyc adv 500mg 10 pack 0144-11 #15 pc $199 ea

Doxorubicin 50mg pfs 5046-01 #20 pc $195 ea

Mitomycin 5mg 20ml 0115-05 #24 Fl $135

Mitomycin 20mg 50ml 0108-11 #20 FL $164 ea

Venofer sdv 5ml 10 pack 2340-10 #15 pc $750 ea

Fluphenazine dec 25mg 5ml 0272-05 #30 pc $185 ea

Glycopyrol 5ml 25 pack 0016-54 #20 pc $85 ea

L-cysteine vl 50mg 10ml 10 pack 0004-02 #15 pc $105 ea

Atropine sulfate .4mg 1ml 25 pack 0401-25 #10 pc $105 Fl

Levophed 4ml 3375-04 #24 pc $245 ea

Ketorolac 30mg 25 pack 3795-49 #20 pc Fl $86.50 ea

Ketorolac 30mg 25 pack 3795-01 #20 pc $86.50 ea

Erythrocin 500mg adv 6476-44 #20 pc $235 ea

Digoxin amp .5mg 2ml 25 pack 1410-35 #20 pc $79 ea

Lanoxin amp .5mg 2ml 10 pack 0260-10 #9 pc in stock $75 ea

Hydroxyzine 50mg 1ml 25 pack 5601-25 #6 in stock $190 ea

Hydroxyzine 50mg 10ml 25 pack 5610-25 #10 pc $359 ea

Dex 10mg 1ml 25 pack 0367-25 #10 pc $115.50 ea

Folic acid 50mg 10ml 0184-10 #50 pc $65 ea 9-2012 dating

SAMPLE SOLICITATIONS TO HOSPITALS

EXHIBIT VII

Dex 4mg 30ml 0165-30 #80 pc $145 ea

Vecuronium 10ml 0931-44 #18 $105 ea in stock

Chorionic gonaditropin 10,000u 10ml 0025-10 #100 vials in stock $124 ea

Leuco 350's 0054-01 #40 pc $95 ea

Sod chl 40ml 25 pack 6660-75 #15 pc $120 ea

Labetolol 5mg 4ml 10 pack 2339-34 #30 pc $109 ea

Labetolol 5mg 20ml 2267-20 #50 pc $15.99 Fl

Neostigmine 5mg 10lml 10 pack 0382-10 #20 pc $185 ea

Neostigmin 1:1000 10 pack 0270-10 #15 pc $109

Neostigmine 1:2000 25 pack 0034-25 #4 pc in stock $305 ea

NEW SHORTAGES and UPDATES

Lorazepam Injection 2 mg/ml (updated 5/9/2011) Baxter has lorazepam 2 mg/mL, 10 mL vials (NDC 10019-0102-10) currently available for distribution. The 2 mg/mL, 1 mL vial presentation (NDC 10019-0102-01) will be on back order until the end of April. Bedford has all lorazepam injection presentations on long-term back order and the company cannot estimate a release date. Hospira has all presentations anticipated to be released in mid to late April, 2011. Please note that 2mg/ml 1 mL iSecure prefilled syringes (NDC 00409-1985-05) and 4mg/ml 1mLCarpuject syringes (NDC 0409-1539-31) are temporarily unavailable. Akorn has Lorazepam injection available.

Methylphenidate HCl (updated 5/10/2011) Sandoz is dealing with capacity constraints and receiving API orders. Expect sporadic backorders for the next couple of months. Mallinckrodt expects to have continued gradual improvement over the next two months, with full recovery by July 2011. UCB has all presentations of 5 mg IR available. All UCB presentations of 10 mg IR, 20 mg IR, and 20 mg ER, are out of stock. The out of stock tablets are expected to be on intermittent backorder until approximately May 20. Watson continues to have product available.

Amikacin Injection (updated 5/10/2011) Teva has amikacin 250 mg/mL 2 mL (NDC 00703-9032-03) and 4 mL (NDC 00703-9040-03) vials on allocation. If a pharmacy cannot obtain product from their wholesaler, please have the wholesaler contact Teva directly to place an emergency order. Bedford anticipates release of the 500mg and 1g presentations in late May. The 100mg presentation has been discontinued.

Amphetamine Mixed Salts, ER Capsules (updated 5/10/2011) Shire expects increased product

availability in May 2011. Teva has 20 mg and 30 mg market availability: approx 4/14/11. All other strengths market availability: approx 4/29/11. Global has all product strengths other than 25 mg are currently available on an allocated basis.

BICNU (Carmustine) Injection, 100 mg (NDC 00015-3012-60) ☐(5/10/2011) Bristol-Myers Squibb has BICNU injection on back order and the company estimates a release date of late-May 2011. Shortage due to Manufacturing delays at contract manufacturer.

Bumetanide Injection (updated 5/10/2011) Hospira is continuing to release the 0.25 mg/mL; 4 mL via NDC 0409-1412-04; 0.25 mg/.mL; 4 mL Novaplus vial NDC 0409-1412-49, the 0.25 mg/mL; 10 mL vial NDC 0409-1412-10; 0.25 mg.mL; and the 10 mL Novaplus vial NDC 0409-1412-50 as they become available. Hospira is continuing to produce and release product as it becomes available. Baxter has all bumetanide 0.25 mg/mL injections on back order. Bedford will have all presentations anticipated for release within the next 3-months.

Cisplatin injection 1 mg/mL solution (updated 5/10/2011) APP is continuing to allocate as releases occur: 50 mL vial (NDC 63323-0103-51), 100 mL vial (NDC 63323-0103-65) and 200 mL vial (NDC 63323-0103-64). Teva continues to release cisplatin injection 1 mg/mL solution. 50 mL vial (NDC 00703-5747-11) and 100 mL vial (NDC 00703-5748-11) as it becomes available. Bedford currently has all presentations discontinued.

Cytarabine Injection (powder for reconstitution) (updated 5/10/2011) Release of Bedford's 1g presentation is anticipated in early May; the 100 mg presentation in the next 3-months; the 500 mg presentation in the next 6-months. The 2g presentation has been discontinued. APP has been able to increase production to help address the shortage and estimates additional supplies to be released by end of April. Hospira will begin releasing additional lots of 100mg/ml 20ml vials on April 11, 2011.

Diltiazem Injection 5 mg/mL (updated 5/10/2011) Baxter is experiencing a back order situation on all codes and estimates the following product availability: 5 mL vial (NDC 10019-510-01) Additional product releases expected later this month and at the end of May.
10 mL vial (NDC 10019-510-02) - Product will be available end of May. 25 mL vial (NDC 10019-510-04) - Product releases expected by mid April and end of May. Product will be made available as it is released.

Hospira will have diltiazem 5 mg/mL 5 mL (NDC 00409-1171-01) and 5mg/ml; 10 mL vials (NDC 00409-1171-02) available late-April. The 100mg/ml ADD-Vantage vials (NDC 00409-4350-03) are on back order with an estimated release date of mid-April, 2011. Emergency supplies of the ADD-Vantage vials are available for direct orders. Bedford anticipates release of all presentations in the next 3 months.

Doxorubicin (adriamycin) lyophilized powder (updated 5/10/2011) Bedford anticipates release of all presentations in the next 6-months. Shortages due to manufacturing delays.

Doxorubicin Solution for Injection (updated 5/10/2011) APP is releasing the 2mg/ml 100 ml vials (NDC 63323-0101-61), the 2mg/ml 25 ml vials (NDC 63323-0883-30), and the 2mg/ml 5 ml vials (NDC 63323-0883-05) as it becomes available. Teva is releasing all strengths on allocation: Doxorubicin solution for injection, 2 mg/mL 5 mL vial (NDC 00703-5043-03) 25 mL vial (NDC 00703-5046-01) 100 mL vial (NDC 00703-5040-01). Bedford anticipates release of the 50mg presentation in the next 3months and release of the 10 mg, 25 mg, and 100 mg solutions in the next 6-months.

Etoposide solution for injection (updated 5/10/2011) Bedford anticipates release of 500 mg product in early May, 1g in the next 3-months, and 100 mg in the next 6-months. Teva has Toposar 20 mg/mL solution for

injection 5 mL vials (NDC 00703-5653-01) vials availalbe. The 25 mL and 50 mL vials are on back order. APP is releasing all etoposide solution for injection 20 mg/mL presentations as they become available. BMS has available Etopophos 100 mg powder for injection (NDC 00015-3404-20).

Haloperidol Decanoate Injection (updated 5/10/2011) Teva has all presentations on back order. Ortho-McNeil has Haldol Decanoate available in 50 mg/mL 1 mL ampoules in 3 count (NDC 00045-0253-03) presentations and 100 mg/mL 1 mL ampoules (NDC 00045-0254-14). APP has haloperidol decanoate available in 50 mg/mL 5 mL vials (NDC 63323-0469-05). 100 mg/mL 5 mL vials (NDC 63323-0471-05) and 100 mg/mL 1mL vials (NDC 63323-0471-01) and 50 mg/mL 1 mL vials (NDC 63323-0469-01) are being released as they become available. Bedford has all presentations of the Haloperidol Decanoate discontinued.

Leucovorin Calcium Lyophilized Powder for Injection (updated 5/10/2011) Bedford anticipates release of 200mg and 350mg lyophilized product in early May, 500mg liquid product in early May, and 100mg and 50mg lyophilized product in the next 3-months. Teva has leucovorin calcium lyophilized powder 100 mg and 350 mg vials on back order and the company does not anticipate release until April 2011. APP is currently back-ordered. Initial supplies are limited, however APP is continuing to produce and release leucovorin calcium lyophilized powder for injection (NDC# 63323-710-50 for the 200mg SDV and NDC# 63323-711-00 for the 500mg SDV).

Methylphenidate HCl (updated 5/10/2011) Sandoz says to expect sporadic backorders for the next couple of months. Mallinckrodt expects to have continued gradual improvement over the next two months, with full recovery by July 2011. UCB has all presentations of 5 mg IR available. All UCB presentations of 10 mg IR, 20 mg IR, and 20 mg ER, are out of stock. The out of stock tablets are expected to be on intermittent backorder until approximately May 20. Watson continues to have product available.

Norepinephrine Bitartrate Injection (updated 5/10/2011) Bedford anticipates release in the next 3-months. Levophed (Norepinephrine Bitartrate Injection) 1 mg/mL 4 mL ampules (NDC 0409-1443-04) and 4 mL vials (NDC 0409-3375-04) are available for direct order for customers in dire need, and the company expects continuous deliveries going forward, with recovery estimated to occur in 3Q 2011. Teva anticipates having product available again 4th quarter 2011. Sandoz, in conjunction with the FDA, is initiating a temporary importation of Norepinephrine Injection, to the United States market.

Thiotepa for Injection, Bedford 15 mg/mL vial (NDC 55390-0030-10) (updated 5/10/2011) Bedford anticipates release mid-May.

Vecuronium Injection (updated 5/10/2011) Bedford anticipates release of the 10mg product in early May and the 20mg product in the next 3-months. Sun Pharmaceutical Industries (Distributor: Caraco Pharmaceutical Labs, Ltd.) is continuing to release product as it becomes available. Vecuronium Bromide for Injection 10 mg 10 vials NDC 41616-0931-44 Vecuronium Bromide for Injection 20 mg 10 vials NDC 41616-0932-44. Teva has the 10mg/vial (NDC 00703-2914-03) and 20 mg/vial (NDC 00703-2925-03) on backorder. Hospira will be off-market for an undefined period.

Thanks,

[redacted]

[redacted]

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SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

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SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

From: [redacted]@prnpharma.com [mailto:[redacted]@prnpharma.com]
Sent: Wednesday, May 18, 2011 8:53 AM
To:
Subject: [redacted] from PRN (This weeks requests, a few offers & Discounted Inventory)

Good morning

I also wanted to include a list of our most requested products this week. Thanks

Wednesday, May 18th, 2011

Top requested Products

BICNU-- NDC#-00015-3012-60

CALCITRIOL INJECTION 1MCG/ML , 25X1ML 00517-0132-25

Calcium Gluconate 10% 10

CYANOCOBALAMIN : 00517-0031-25

Venofer sdv 2.5ml 10 pac 2325-10

Lidocaine 1% 10 mg/mL 2 mL vial (NDC 63323-0492-02)

Etoposide injection 100mg/5ml 55390-0291-01

SAMPLE SOLICITATIONS TO HOSPITALS **EXHIBIT VII**

Levophed 00409-3375-04

Protamine sulfate

Acetylsystein: 4 & 10ml

Papaverine 00517-4010-01

Hydralazine 20mg/ml 1ml vials

Atropine 00517-1010-25

Vasopressin/ Pitressin

VINCRISTINE: 00703-4412-11, 61703-0309-06, 61703-0309-16

Mulit trace 00517-6202-25

Methylene Blue 1% 00517-0310-10

Gentamicin

A few offers

L-cysteine vl 50mg 10ml 10 pack 0004-02 #15 pc $75 ea

Atropine sulfate .4mg 1ml 25 pack 0401-25 #20 pc $40 Fl in stock

Ketorolac 30mg 25 pack 3795-49 #20 pc Fl $46.50 ea

Acetylcysteine 20% 30ml	00409-3308-03	25 @ $165	eta Fri
Cytarabine 2gm	00409-3199-22	50 @ $169	eta Thurs
Dexamethasone 4mg 30ml	63323-0165-30	300 @ $95	eta Fri
Dexamethasone 10mg 1ml	00641-0367-25	100 @ $149	eta Thurs
Dexamthesone 10mg/ml 10x10ml	63323-0516-10	26 @$155	eta Fri
Diprivan 50ml	63323-0269-50	53 @ $415	eta Thurs
Diprivan 100ml	63323-0269-65	54 @ $475	eta Thurs
Furosemide 4ml	00409-6102-04	50 @ $55	eta Thurs
Furosemide 10ml	00409-6102-10	20 @ $49	eta Thurs
Gentamycin	00409-1207-03	60 @ $105	eta Thurs
Hydralazine 20mg 1ml	17478-0934-01	25 @ $323	eta Thurs
Indigo Carmin	17478-0508-01	4 @ $125	eta Thurs
Levophed	00409-3375-04	10 @ $179	eta Fri
Leucovorin 350	55390-0054-01	100@ $95	eta Thurs
Magnesium Sulfate 5yg	00409-1754-10	25 @ $235	eta Fri

SAMPLE SOLICITATIONS TO HOSPITALS **EXHIBIT VII**

Paperavine 30mg 10ml	00517-4010-01	50 @ $88	eta fri
Phenylephrine 1ml	10019-0163-12	11 @ $65	eta Fri
Phenylephrine 10ml	66758-0017-01	10 @ $63	eta Fri
Pitressin 20un 1ml	42029-0117-25	20 @ $235	eta Fri
Pot ace 20ml	00409-8183-01	15 @ $129	eta Thurs
Pot Ace 50ml	00409-3294-51	75 @ $99	eta Thurs
Sodium Phosphate 50ml	00517-3450-25	5 @ $227	eta Thurs
Vecuronium 10mg	41643-0931-44	40 @ $128	eta Thurs

Again this is a small part of what we have available. Please let me know what is on your short list and I'll do my best to get it for you.

Product Name	NDC	Qty	Exp Date	Price
Marcaine EPN .25% SDV	00409-1756-10	6	7/1/2012	$16.50
ALBUMIN 5% 250ML ZLB	44206-0310-25	20	11/11/2011	$28.50
CIPRO 500MG TAB 100	00172-5312-60	12	11/11/2011	$22.50
CIPRO 500MG TAB 100	00172-5312-60	12	11/1/2011	$22.50
CLINDAMYCIN PHOSPHATE 150MG/ML	00409-4052-01	5	11/1/2011	$75
DEXTROSE 25% SOLUTION INJ	00409-1775-10	5	9/1/2011	$15
ENLON-PLUS VL 10MG/ML 15ML	67457-0191-15	32	9/30/2011	$15
EPINEPHRINE SRN 1:10M 18GA X10	00409-4901-18	3	9/1/2011	$28.50
ERYTHROMYCIN 0.5 % O/O 50X1 GM	48102-0008-11	5	11/1/2011	$285
FOLIC ACID 5GM/ML, 10ML VL INJ	63323-0184-10	5	10/31/2011	$5
MITOMYCIN 40MG/100ML	55390-0253-01	2	10/1/2011	$95
PROCHLORPERAZINE EDISYLATE 10M	55390-0077-10	2	10/1/2011	$10
PROCHLORPERAZINE EDISYLATE 10M	55390-0077-10	2	10/1/2011	$10
TAMIFLU BLISTERPACK 75MG CAPS	00004-0800-85	71	11/1/2011	$65
TOBRAMYCIN SULF INJ 20MG/2ML F	00409-3577-01	8	11/1/2011	$28.50
VANCOMYCIN 1 GM F/T FTV	00409-6533-01	26	11/1/2011	$32.50
VANCOMYCIN 1 GM F/T FTV	00409-6533-01	1	11/1/2011	$32.50
VANCOMYCIN 1GM ADV	00409-6535-01	6	11/1/2011	$72.50
NIMBEX 2MG/ML MDV 10X10 ML	00074-4380-10	13	8/1/2011	$75
VITRASE OVINE 200U /ML VL 6X1.	67425-0002-10	1	8/1/2011	$85

[redacted]

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SAMPLE SOLICITATIONS TO HOSPITALS **EXHIBIT VII**

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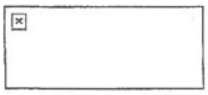

SAMPLE SOLICITATIONS TO HOSPITALS

EXHIBIT VII

From: [redacted] [mailto: [redacted] @premiumhealthservices.com]
Sent: Thursday, May 19, 2011 7:25 AM
To: [redacted]
Subject: Premium Health Services- Product Stock Update

12 Cyanoco (Vit B12) 1000mcg 30ml 5pk @ $175.00

15 Aminocaprioc 250mg/ml 20ml 25pks # 0517-9120-25 @ $95.00

5 Pot Ace 50ml NDC# 00517505425 @ $235.00

20 Cytarabine 2gm Vials @ $169.00

1 Mutitrace-4 3ml 25pk @ $195.00

8 Multitrace-5 1ml SDV 25pk @ $265.00

50 Vincasar 1mg/ml 1ml SDV @ $29.00

54 Glycopyrrolate 0.2mg/ml 1mL 25pk @ $55.00

8 Glycopyrrolate 0.2mg/ml 5ml 25pk @ $89.00

20 Phenylephrine 10mg/ml 1ml 25pk @ $127.00

20 Phenylephrine 10mg/ml 10ml Vial @ $89.00

25 Hydralazine 20mg 1ml (093401) @ $345.00

5 Acetylcysteine 20% 30ml 3pk 00517763003 @ $175.00

10 Neostigmine 1:2000 25pk @ $245.00

28 Ketorolac 30mg 1ml 25pk @ $61.00

50 Ketorolac 30mg 1ml 10pk @ $44.00

50 Furosemide 40mg 4ml 25pk @ $29.00

SAMPLE SOLICITATIONS TO HOSPITALS **EXHIBIT VII**

20 Enlon 10mg 15mL @ $125.00

46 Enlon Plus 10mg 15mL @ $99.00

57 Vecuronium 10mg 10pk @ $75.00

30 Leucovorin 350mg vials EA @ $79.00

50 Dexamethasone 4mg 30ml vials @ $68.00

40 Dexamethasone 10mg/1ml 1ml 25pk @ $125.00

24 Propofol 20ml 5pk @ $105.00

2 Propofol 50ml 20pk @ $525.00

10 Propofol 100ml 10pk @ $595.00

8 Acetazolamide 500mg SDV @ $49.00

BLOOD PRODUCTS

Gammagard Liq 5gm, 10gm, 20gm - Call for Availability

Gammagard Powder 5gm, 10gm - Call for Availability

Gamunex 5gm, 10gm, 20gm - Call for Availabilty

200 Albumin 25% 50ml @ $49.00

100 Albumin 25% 100ml @ $89.50

200 Albumin 5% 250ml @ $49.50

100 Albumin 5% 500ml @ $96.00

CLEARANCE ITEMS

75 Quelicin 20mg 10ml 25pk @ $50.00/pack

60 Clindamycin 600mg 4ml 25pk @ $60.00

20 Clindamycin 900mg 6ml vials 25pk @ $100.00

47 Epinephrine 1mg 10ml Syringe 10pk @ $18.00

143 Nalbuphine 10mg 1ml amp 10pk @ $16.66

30 Vancomycin 5gm BULK @ $24.50

50 Vancomycin 10gm BULK @ $49.00

36 Vancomycin 1gm ADV 10pk @ $60.00

SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

[redacted]
Premium Health Services
Area Manager
443-[redacted] (cell)
410-[redacted] (office)
877-[redacted] (toll-free)
www.rxphs.com

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SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

From: [redacted]@pmpharma.com [mailto:[redacted]@pmpharma.com]
Sent: Friday, April 29, 2011 12:20 PM
To:
Subject: American Regent - Affected products

Hello

I have put together a more accurate list of all the products affected by the Shirley NY plant being shut down (pasted under my signature). Thanks to all my clients who helped me put this together.

Our pricing and availability has been all over the place as you can imagine. Please take a look and give me a call or email with what you feel you may need me to look into.

I will of course supply you with the best pricing I can find. I hope this helps.

Also, I've got #44 Sodium Acetate 2mEq/mL, 50 mL vial (NDC 00409-3299-06) @$245.

Friday, April 29th, 2011

00517-7504-25	ACETYLCYSTEINE 100 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x4.000 ML) VIAL
00517-7510-03	ACETYLCYSTEINE 100 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (3x10.000 ML) VIAL/KIT
00517-7604-25	ACETYLCYSTEINE 200 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x4.000 ML) VIAL
00517-7610-03	ACETYLCYSTEINE 200 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (3x10.000 ML) VIAL/KIT
00517-7630-03	ACETYLCYSTEINE 200 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (3x30.000 ML) VIAL/KIT
00517-0401-25	ATROPINE SULFATE 0.4 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x1.000 ML) VIAL
00517-1010-25	ATROPINE SULFATE 1 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x1.000 ML) VIAL
00517-0720-01	BETAMET ACET/BETAMET NA PH 6 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (1x5.000 ML) VIAL
00517-0020-10	CAFFEINE CITRATED 60 MG/3 ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x3.000 ML) VIAL
00517-2502-10	CAFFEINE/SODIUM BENZOATE 250 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x2.000 ML) VIAL
00517-0132-25	CALCITRIOL 1MCG/ML AMPUL (ML) (25x1.000 ML) AMPUL
00517-2710-25	CALCIUM CHLORIDE 100 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-3900-25	CALCIUM GLUCONATE 100 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x100.000 ML) VIAL
00517-3950-25	CALCIUM GLUCONATE 100 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-0730-01	CLONIDINE HCL/PF 1000MCG/10 VIAL (SDV,MDV OR ADDITIVE) (ML) (1x10.000 ML) VIAL
00517-0731-01	CLONIDINE HCL/PF 5000MCG/10 VIAL (SDV,MDV OR ADDITIVE) (ML) (1x10.000 ML) VIAL
00517-6210-25	CUPRIC SULFATE 0.4 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-0031-25	CYANOCOBALAMIN (VITAMIN B-12) 1000MCG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x1.000 ML) VIAL
00517-0032-25	CYANOCOBALAMIN (VITAMIN B-12) 1000MCG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-0130-05	CYANOCOBALAMIN (VITAMIN B-12) 1000MCG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (5x30.000 ML) VIAL

SAMPLE SOLICITATIONS TO HOSPITALS EXHIBIT VII

00517-2064-25	CYSTEINE HCL 50 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-2050-05	CYSTEINE HCL 50 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (5x50.000 ML) VIAL
00517-0131-25	DEXPANTHENOL 250 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x2.000 ML) VIAL
00517-1905-25	DOPAMINE HCL 400 MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-1305-25	DOPAMINE HCL 800MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-9702-25	DROPERIDOL 2.5 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x2.000 ML) VIAL
00517-1130-05	EPINEPHRINE 1 MG/ML VIAL (5x30.000 ML) VIAL
00517-1071-25	EPINEPHRINE/PF 1 MG/ML AMPUL (ML) (25x1.000 ML) AMPUL
00517-8571-10	ETHYL ALCOHOL 98% AMPUL (ML) (10x1.000 ML) AMPUL
00517-8575-10	ETHYL ALCOHOL 98% AMPUL (ML) (10x5.000 ML) AMPUL
00517-4601-25	GLYCOPYRROLATE 0.2 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x1.000 ML) VIAL
00517-4602-25	GLYCOPYRROLATE 0.2 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x2.000 ML) VIAL
00517-4620-25	GLYCOPYRROLATE 0.2 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x20.000 ML) VIAL
00517-4605-25	GLYCOPYRROLATE 0.2 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-0901-25	HYDRALAZINE HCL 20 MG/ML VIAL (25x1.000 ML) VIAL
00517-4201-25	HYDROXYZINE HCL 25 MG/ML VIAL (25x1.000 ML) VIAL
00517-5601-25	HYDROXYZINE HCL 50 MG/ML VIAL (25x1.000 ML) VIAL
00517-5610-25	HYDROXYZINE HCL 50 MG/ML VIAL (25x10.000 ML) VIAL
00517-5602-25	HYDROXYZINE HCL 50 MG/ML VIAL (25x2.000 ML) VIAL
00517-0134-10	IRON DEXTRAN COMPLEX 50 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x1.000 ML) VIAL
00517-0234-10	IRON DEXTRAN COMPLEX 50 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x2.000 ML) VIAL
00517-2340-10	IRON SUCROSE COMPLEX 100 MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x5.000 ML) VIAL
00517-2340-25	IRON SUCROSE COMPLEX 100 MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-2310-05	IRON SUCROSE COMPLEX 100 MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (5x10.000 ML) VIAL
00517-1045-25	LEVOCARNITINE 200 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-5034-01	MAGNESIUM CHLORIDE 200 MG/ML VIAL (1x50.000 ML) VIAL
00517-2650-25	MAGNESIUM SULFATE 4 MEQ/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-6410-25	MANGANESE SULFATE 0.1 MG/ML VIAL (25x10.000 ML) VIAL
00517-8905-10	METHYLDOPATE HCL 250 MG/5ML VIAL (SDV,MDV OR ADDITIVE) (ML) (10x5.000 ML) VIAL
00517-0372-71	METHYLENE BLUE 1 % AMPUL (ML) (25x1.000 ML) AMPUL
00517-0373-70	METHYLENE BLUE 1 % AMPUL (ML) (25x10.000 ML) AMPUL
00517-0301-10	METHYLENE BLUE 1 % VIAL (SDV,MDV OR ADDITIVE) (ML) (10x1.000 ML) VIAL
00517-0310-10	METHYLENE BLUE 1 % VIAL (SDV,MDV OR ADDITIVE) (ML) (10x10.000 ML) VIAL
00517-1355-25	METOPROLOL TARTRATE 5 MG/5 ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-6610-25	MOLYBDENUM 25 MCG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-0033-25	NEOSTIGMINE METHYLSULFATE 1:1000 VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-0034-25	NEOSTIGMINE METHYLSULFATE 1:2000 VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-4810-25	NITROGLYCERIN 50 MG/10ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-0760-01	OFLOXACIN 0.3 % DROPS (1x5.000 ML) DROP BTL
00517-4010-01	PAPAVERINE HCL 30 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (1x10.000 ML) VIAL
00517-4002-25	PAPAVERINE HCL 30 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x2.000 ML) VIAL
00517-5024-25	POTASSIUM ACETATE 4 MEQ/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-2350-25	POTASSIUM PHOS,M-BASIC-D-BASIC 3MMOL/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-6510-25	SELENIUM 40MCG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x10.000 ML) VIAL
00517-3120-25	SOD/POT/MAG/CAL/CHLO/ACE/GLUC 25-40.6MEQ VIAL (SDV,MDV OR ADDITIVE) (ML) (25x20.000 ML) VIAL
00517-5023-25	SODIUM ACETATE 4 MEQ/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-2930-25	SODIUM CHLORIDE 4 MEQ/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x30.000 ML) VIAL
00517-3065-01	SODIUM MORRHUATE 50 MG/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (1x30.000 ML) VIAL
00517-3405-25	SODIUM PHOS,M-BASIC-D-BASIC 3MMOL/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x5.000 ML) VIAL
00517-3450-25	SODIUM PHOS,M-BASIC-D-BASIC 3MMOL/ML VIAL (SDV,MDV OR ADDITIVE) (ML) (25x50.000 ML) VIAL
00517-1019-05	SODIUM THIOSULFATE 10 % VIAL (SDV,MDV OR ADDITIVE) (ML) (5x10.000 ML) VIAL

I turn now to my esteemed Ranking Member, Senator Boozman, from the great state of Arkansas.

STATEMENT OF HON. JOHN BOOZMAN, U.S. SENATOR FROM ARKANSAS

Senator BOOZMAN. Thank you, Mr. Chairman, very much. And I appreciate your efforts and appreciate that of the staff working so hard in this particular area.

I agree with Chairman Rockefeller. It is indefensible that we have cancer patients that have to wait to get chemotherapy. No hospital should pay $1,000 for a drug that only costs a few bucks. But I think we are missing the bigger picture. Drug shortages are

the root of the problem. I hear about shortages all across Arkansas nearly every day. Shortages create significant problems.

This hearing is really about supply and demand. No one pays $250 for a loaf of bread. There are no 8,000 percent markups in a competitive market. In this investigation, four of the five cases involve generic injectable cancer drugs. These drugs are very inexpensive. Some cost $5 or $6. Some have been around for many, many years, and they save lives.

There should be no shortage of life-saving $6 drugs, period. But today, companies are producing dozens of these generic cancer drugs at or near a loss. This is the real danger. This is the real threat to patients. Artificial Medicare drug pricing caps have created this problem. Aggressive FDA oversight has exacerbated this problem. And Ezekiel Emanuel, President Obama's health advisor said, "the long-term solution is to make the production of generic cancer drugs more profitable."

We need to reform Medicare pricing and address the root of the problem. It's not a complicated problem. It's not an expensive problem. But it's a very, very serious problem.

Second, before we use this investigation as a justification for new Federal rules, I think we should stop and ask, are state pharmacy boards and regulators enforcing the laws on the books?

The fact is, people have oversight responsibilities under current law. There's no reason to expect people to comply with new layers of rules if they're violating the ones that currently exist.

Yes, we can create a new Federal agency. We can pass restrictions and burden manufacturers, distributors, and pharmacists with red tape. But, again, there's no substitute for people fulfilling their responsibilities. Shell pharmacies simply should not exist. If they do, someone is not doing their job.

In addition, as we talk about secondary distributors and reselling, there is a story that we should keep in mind, and I actually was part of this. In 2005, Hurricane Katrina hit New Orleans. It was a disaster in every sense of the word. Thirteen thousand evacuees were sent to Fort Smith, Arkansas. Many needed medical attention. Time was short, and the Federal Government was unresponsive.

Thankfully, a pharmacist named John Vinson coordinated an incredible emergency response. Community leaders, independent pharmacists, secondary distributors, chain pharmacies, and wholesalers all came together. It was all hands on deck. They aggregated, resold, and dispensed drugs. Their actions kept many out of the hospital, and they saved many lives.

As we move forward, let's not forget that secondary distributors and intermediary drug markets serve a critical role. In times of tightened supply and limited stockpiles, they help address gaps in the supply chain. Across Arkansas, we have compound pharmacists who register as distributors and pharmacists. They have been critical throughout the drug shortage emergency. Without them, doctors could not perform needed surgeries. In rural or neglected areas, distributors can plug holes in the system or address needs that may go overlooked.

Like nearly every industry, pharmacists also need backup options. They need tools to unload excess stock and flexibility to ad-

dress sudden spikes in demand. So, again, let's not forget the necessary role that distributors and pharmacists play.

Last, it's time we learn our lesson about healthcare consolidation. From the manufacturing plant through the distribution system, pharmacy, clinic, and hospital, we've seen so much consolidation. If we expect to meet the growing healthcare needs of every American, we need choices. Choices satisfy niche markets. Choices facilitate competition. Regulations that crowd out smaller actors eliminate choices. So we've got to move carefully.

Mr. Chairman, again, I thank you so much for your efforts in regard to bringing this important problem forward, and I really look forward to our witnesses today.

The CHAIRMAN. Thank you very much, Senator Boozman.

Actually, I'm looking at an interesting situation, because Elijah Cummings is doing exactly this kind of work in the House, and I'm looking at his name plate. But the Congressman is not here. So let's decide this is what we're going to do. I want, please, Virginia Herold, Dr. David Mayhaus, John Coster, John Gray, and Patricia Earl all to come forward and take a seat at the table.

Senator BOOZMAN. Mr. Chairman, as they come forward, can I ask that the hearing be kept open for 2 weeks for additional statements and questions for the record?

The CHAIRMAN. Absolutely.

Senator BOOZMAN. Thank you, Mr. Chairman.

The CHAIRMAN. And then I thought also if Senator Harkin comes—I've been to his committee on coal-related things, coal mine safety, and he has me sit at the dais. So I'm inviting him to sit at the dais. And I think if Senator Enzi comes, he should also sit at the dais and ask questions and stay as long as they want.

If Elijah Cummings comes—he's conducting a hearing and will be continuing to after he makes a statement. So I may have him come to the dais and just make his statement. But there's still plenty left to do.

So, Virginia Herold, let's start with you. You're the Executive Officer of the California Board of Pharmacy.

STATEMENT OF VIRGINIA HEROLD, EXECUTIVE OFFICER, CALIFORNIA BOARD OF PHARMACY

Ms. HEROLD. Chairman Rockefeller and members of the Committee, thank you for the invitation to come and speak before you today. I'm Virginia Herold. I'm the Executive Officer of the California State Board of Pharmacy.

The Board of Pharmacy in California licenses pharmacies, pharmacists, drug wholesalers. We are the largest regulator of pharmacists in the country. We have over 40,000 pharmacists licensed with us. Within the state of California, we have 6,200 community pharmacies, another 500 hospital pharmacies, and 500 wholesalers located within the state. We have another 700 wholesalers located out of state that are licensed to ship into California legally.

The Board's paramount mandate, which is expressly stated in California law, is consumer protection. So, above all else, that is our focus.

California state law provides the limited circumstances under which a pharmacy may provide prescription drugs to any entity.

You have a copy at the back of my testimony. One of the provisions provides that a pharmacy may furnish prescription drugs to another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of healthcare and only in quantities sufficient to alleviate the shortage. Violations can be charged up to $5,000 per occurrence. This would mean per invoice, for example.

In the fall of 2011, the Board initiated an investigation following a pharmacist's inquiry to the Board about the legality of the pharmacy ordering prescription drugs from another wholesaler in short supply. These sales would be initiated at the behest and solicitation of the second wholesaler who informed the pharmacy that the prescription drugs were declared as temporarily short. Thus it would be OK. We have a provision in California state law that very much limits when a pharmacy can sell drugs to a wholesaler.

The pharmacy's role would be to act as a purchasing agent for the wholesaler, purchasing drugs specifically on a list of prescription drugs in short supply that the wholesaler provided the pharmacy. The arrangement between the pharmacy and wholesaler was financial. The pharmacy would be paid an agreed amount, typically 10 percent over invoice plus shipping expenses.

As of today, the Board has identified cases in which 55 pharmacies purchased drugs in short supply for this one wholesaler on 514 occasions, totaling wholesale prices over $330,000. Each of the pharmacies and their pharmacists in charge have been cited and fined in various amounts up to $70,000 for violation of California law. Appeals of these citations and fines are currently pending, and the wholesaler has not yet had discipline completed. So we are still going through the process.

However, these actions and investigations are very important, we believe, to share with the Committee. And we are hoping and looking to the Committee as finding ways to secure additional means to provide safeguards into the supply chain.

The Board's investigations generally identified that, one, a pharmacy would be visited by a sales agent representative of the wholesaler, who explained the dire impact that the drug shortages presented to the patients and healthcare providers and stressed the inability of the wholesaler to obtain these drugs on its own. The soliciting wholesaler advised it was another source of pharmaceuticals for medical facilities and needed these medications.

Sales were triggered from a list that the wholesaler released each week to the pharmacies that was titled "Items We Are Looking For." The pharmacies involved were all independent community pharmacies. The drugs were principally medication that would be used by hospitals and rarely would be needed by community pharmacies.

The Board did not find cases where the pharmacies purchased drugs for their own patients as well. All drugs were purchased exclusively for the wholesaler, using the list. The pharmacies had no independent knowledge of the shortage. They would sometimes verify once they were told there was a shortage of the drug. But, generally, that shortage was made at the time of purchase from their primary wholesaler.

Some of the pharmacies seemingly circumvented the allocation that was set up by manufacturers by making multiple orders on the same day at different times so that they could maximize what they purchased. For example, one pharmacy ordered one drug 12 times in 1 day to maximize the amount purchased. Other times, very large orders were made. For example, we had another case where 30 boxes—each box had 25 units or vials—of a particular short-supply drug—were purchased, which is far in excess of what the community pharmacy would have ever needed, in fact, this particular drug is used in hospitals for infants. It's a very select drug.

Pharmacies were typically paid 10 percent over the invoice for the drugs they purchased for the wholesaler. However, the wholesaler also sought direct access to the pharmacy's primary wholesaler ordering systems, which was granted by 23 of the 55 pharmacies. This allowed the wholesaler to directly order the drugs it sought without the active involvement of the pharmacy. For this access, the pharmacy was paid 12 to 15 percent, a higher rate.

Several pharmacies also sold drugs in short supply to several other wholesalers, including several wholesalers out of California who are not licensed to do business in the state. The wholesaler made considerably more when it resold the short-supply drugs than the 10 to 15 percent it paid the pharmacy to obtain the drugs.

Some of the extreme examples include a Naval hospital that paid 6,246 percent markup for a drug over what——

Senator ROCKEFELLER. Could you repeat that?

Ms. HEROLD.—6,246 percent, and it was very much like the situation you gave. This was a drug that was $1.50 per container. They charged over a hundred and something dollars per vial for that. There was another hospital that had another drug that they paid over 1,200 percent markup to get the drug. So this was a distortion of the market allocation system that was set up to ensure everyone had fair access.

The wholesaler also resold over 10 percent of the short-supply drugs it had purchased to other wholesalers, not to pharmacies or healthcare providers. Hence, they're now reshipping the product throughout the supply chain. The Board also documented cases where the wholesaler resold the entire quantity it purchased from the pharmacy to another wholesaler.

The Board moved forward with these cases because instead of alleviating the shortage of drugs, the wholesaler instead removed more drugs from the availability in the legitimate supply chain which had allocations in place to most equitably distribute the product. We believe that it increased the shortage of the drugs and dramatically increased the cost of these drugs to other healthcare entities and thus to patients.

That concludes my remarks.

[The prepared statement of Ms. Herold follows:]

PREPARED STATEMENT OF VIRGINIA HEROLD, EXECUTIVE OFFICER, CALIFORNIA STATE BOARD OF PHARMACY

Dear Chairman Rockefeller, Ranking Member Hutchison and Committee Members:

Good afternoon.

I am Virginia Herold, Executive Officer of the California State Board of Pharmacy. It is a privilege to be given this opportunity to address the Committee on California's efforts to address some of the unethical and illegal behavior surrounding manipulation of prescription drug shortages by wholesalers and pharmacies, to the detriment of the public health. As I speak today, our investigations and resultant enforcement activities that I describe below are not yet fully completed.

The California State Board of Pharmacy licenses pharmacies, pharmacists, drug wholesalers and other entities that dispense, ship, transport or store prescription drugs and devices into, throughout and from California. The board is the largest licenser of pharmacies and pharmacists in the country—nearly 40,000 pharmacists, 6,200 community pharmacies and 500 wholesalers are located in California and licensed by the board. The board's paramount mandate, which is expressly stated in the California Business and Professions Code, is consumer protection.

California state law provides the limited circumstances under which a pharmacy may provide prescription drugs to any entity. One of the provisions provides that a pharmacy may furnish prescription drugs to another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous (or prescription) drug that could result in the denial of health care and only in quantities sufficient to alleviate the temporary shortage. Violations can be charged up to $5,000 per occurrence (*e.g.,* invoice). A copy of this code section is provided as an attachment to this testimony.

In the fall of 2011, the board initiated an investigation following a pharmacist's inquiry about the legality of the pharmacy ordering prescription drugs in short supply from its primary wholesaler, expressly for sale to another wholesaler. These sales would be initiated at the behest and solicitation of the second wholesaler, who informed the pharmacy that the prescription drugs were declared as temporarily short and thus these sales were legal.

The pharmacy's role would be to act as a purchasing agent for the wholesaler, purchasing drugs specifically on a list of prescription drugs in short supply that the wholesaler provided to the pharmacy. The arrangement between the pharmacy and wholesaler was financial: the pharmacy would be paid an agreed amount, typically 10 percent over invoice, plus shipping expenses.

The board initiated an investigation of the California wholesaler making this solicitation, which yielded hundreds of invoices from 55 California pharmacies that had sold prescription drugs in short supply to this wholesaler, at the wholesaler's request. The board next investigated each of the 55 pharmacies, interviewing the pharmacists-in-charge or others who had knowledge of the sales. Again, invoices were obtained from each pharmacy.

As of today, the board has identified cases in which 55 pharmacies purchased drugs in short supply for the wholesaler on 514 occasions, totaling wholesale prices of over $330,000. Each of the pharmacies and their pharmacist-in-charge have been cited and fined in various amounts up to $70,000 for violation of California law. Appeals of these citations and fines are currently pending. The wholesaler has not yet had discipline completed. Thus none of these actions and investigations is fully concluded. However, we are sharing this information to the Committee in hopes of securing enhanced ways to stop the practices identified by the board.

The board's investigations generally identified that:

1. A pharmacy would be visited by a sales agent/representative of the wholesaler, who explained the dire impact that drug shortages presented to patients and health care providers, and stressed the inability of the wholesaler to obtain these drugs on its own. This soliciting wholesaler advised that it was another source of pharmaceuticals for medical facilities, and needed these medications.
2. Sales were triggered from a list the wholesaler released each week to the pharmacies titled "Items we are looking for."
3. The pharmacies involved were all independent, community pharmacies.
4. The drugs were principally medication that that would be used by hospitals and rarely would be needed by community pharmacies. The board did not find cases where the pharmacies purchased drugs for their own patients needs'—all drugs were purchased exclusively for the wholesaler using the list.
5. The pharmacies had no independent knowledge of the shortage.

6. Some of the pharmacies seemingly circumvented the allocation system set up by manufacturers by making multiple orders on the same day at different times. For example, one pharmacy ordered acetylcysteine 12 times in one day to maximize the amount purchased. Other times, large orders were made (30 boxes of 25 vials of magnesium sulfate).
7. Pharmacies were typically paid 10 percent over invoice for the drugs they purchased for the wholesaler.
8. However, the wholesaler also sought direct access to the pharmacies' primary wholesaler ordering systems, which was granted by 23 pharmacies—allowing the wholesaler to directly order the drugs it sought without the active involvement of the pharmacy. For this access, typically the pharmacy was paid 12 to 15 percent over invoice.
9. Several pharmacies also sold drugs in short supply to other several other wholesalers, including several wholesalers out of California who were not licensed to do business in the state.

The wholesaler made considerably more when it resold the short supply prescription drug than the 10 to 15 percent it paid the pharmacy. Some of the extreme examples include:

1. Labetalol sold to a Naval hospital: 6,246 percent markup.
2. Leucovorin sold to a hospital: 996 percent markup.
3. Famotidine sold to a hospital in Georgia: 1240 percent markup.
4. Calcium gluconate sold to a hospital in Los Angeles: 441 percent markup.

The wholesaler also resold about10 percent of the short supply drugs it had purchased to other wholesalers, not to pharmacies or health care providers. These wholesalers were charged lower fees (*e.g.,* sometimes 40 percent over the price paid by the wholesaler). The board also documented cases where the wholesaler resold the entire quantity purchased to another wholesaler.

The board moved forward with these cases because instead of alleviating the shortage of these drugs, the wholesaler instead removed more drug from availability in the legitimate supply chain, which had allocations in place to most equitably distribute the product. We believe that it increased the shortage of the drugs and dramatically increased the cost of these drugs to other health care entities, and thus to patients.

This concludes my statement. Thank you again for this opportunity.

Attachment of Section 4126.5, California Business and Professions Code

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(*5*) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.*5* of the Government *Code*. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

The CHAIRMAN. You did OK.

Ms. HEROLD. I came in under 5 minutes, and I wasn't sure I'd do it. I talked as quickly as I could.

The CHAIRMAN. Thanks a lot. You did a good job.

At this point, I'd like to interrupt and have Chairman Tom Harkin, who is head of Labor, Education, Health, and several other things—chairs that committee—and he's very much involved in this, and I want him to—and if Mike Enzi comes, I hope—and Elijah Cummings is also coming a few minutes out.

But we welcome any words you have to say.

STATEMENT OF HON. TOM HARKIN,
U.S. SENATOR FROM IOWA

Senator HARKIN. Well, thank you, Mr. Chairman, and I thank the panel for letting me intervene at this moment. I'm sorry I'm a bit late in getting here.

But, first of all, I want to thank you, Chairman Rockefeller, for your great leadership in this area and for working with us on our committee and also with the House committee, also. This truly is a problem that cries out for something to be done. It's not just costs that I heard you commenting about on these huge markups. It's also about patient safety, too. How do we know just how safe some of these drugs are when they go through four or five or six different hands?

And we've had instances in our committee of people saying that expiration dates were changed. Different things were taken out of vials and put into other vials. So it has to do with safety, also.

Mr. Chairman, when we did the FDA reauthorization bill recently that the president just signed into law, we had great bipartisan agreement on the upstream side of the drug safety issue in terms of where the drugs come from to the manufacturer. And we gave the FDA a lot more authority to police that and to make sure that both the non-pill form type of drugs, the bulk drugs coming in, but also the finished drugs coming in were under heightened scrutiny from here on.

What we did not have bipartisan agreement on—general agreement on—was the downstream side, which you're looking at right here, and that is from the manufacturer on down to the patient, to the purchaser. And, hopefully, we can find agreement on how to move ahead. It's very complicated. I've looked at this in great detail. It's a very complicated issue, but that doesn't mean it's not solvable. It is solvable, and we just have to do it.

Just last week, the FBI and the U.S. Attorney in Manhattan charged 48 people in connection with a massive scheme in which crooks bought HIV/AIDS medications from Medicaid patients and then sold them to prescription drug wholesalers, who got the drugs back into the hands of pharmacies and patients. So a system where drugs sold for cash on street corners can make their way back to legitimate pharmacies—a system that is crying out for some kind of reform.

So your hearing today moves us a step forward. In that way, the work done by your committee, Chairman Rockefeller, and mine and Congressman Cummings', I believe, will better define the problem. And I'm committed to work with you, Mr. Chairman, and our rank-

ing members to practice and to get a system in there where—we've got the upstream, and now we have to make sure that we get this gray market thing out of the system so that we can keep the price of drugs down and also make sure they're safe for patients.

So thank you very much, Mr. Chairman. And I thank our panel for letting me intervene.

The CHAIRMAN. Thank you very much, Chairman Harkin.

Chairman Harkin and I came into the Senate the same year, and we're fairly inseparable.

Senator HARKIN. That was in the last century, wasn't it?

The CHAIRMAN. Yes, it was. All right.

Now, Dr. Mayhaus, I'm having a trauma over pronouncing your name correctly.

Dr. MAYHAUS. You are pronouncing it correctly—Mayhaus.

The CHAIRMAN. Good. OK. You are the Chief Pharmacy Director of the Cincinnati Children's Hospital Medical Center, where my wife and my children all got tested for allergies.

Dr. MAYHAUS. I hope they had a great experience.

The CHAIRMAN. Just a little plug.

Dr. MAYHAUS. OK. Good.

The CHAIRMAN. Please go ahead.

STATEMENT OF DR. DAVID MAYHAUS, CHIEF PHARMACY DIRECTOR, CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER; MEMBER, EXECUTIVE COMMITTEE, CHILDREN'S HOSPITAL ASSOCIATION PHARMACY FORUM

Dr. MAYHAUS. Chairman Rockefeller and members of the Committee, my name is David Mayhaus, and I am Chief Pharmacy Director at Cincinnati Children's Hospital Medical Center. I am grateful for the opportunity to speak to you today, not only on behalf of Cincinnati Children's, but also as a member of the Executive Committee for the Children's Hospital Association Pharmacy Forum.

My goal today is to describe the process Cincinnati Children's uses for managing drugs when they reach critical shortages and how these issues have impacted our pharmacy operations over the past 5 years.

Cincinnati Children's is a tertiary care research facility that was recently ranked third in the nation among all Honor Roll Hospitals in *U.S. News and World Report's* Best Children's Hospital ranking. Within Cincinnati Children's, the Division of Pharmacy is an extremely busy unit, dispensing approximately 7,500 doses per day. When there is a sudden drug shortage crisis, the impact can be felt throughout our entire system.

Today, at Cincinnati Children's, there are currently 30 drugs that we are actively managing on a daily basis. The buyers that work for me check our primary wholesaler or the manufacturer on a daily basis. We meet several times a day to discuss where we are and possible mitigation plans. Our buyers spend 30 percent of their time just dealing with drug shortages and trying to prevent Cincinnati Children's from experiencing a crisis.

As Chief Pharmacy Director, approximately 10 percent of my time is also dedicated to these issues, including what I am doing here today, appealing to you to assure an adequate supply of medi-

cations to our patients. Everything we do is in the best interest of our pediatric patients.

Once a drug is determined to be in shortage, our clinical pharmacists identify our utilization pattern and estimate the number of base supplies that we have in inventory. If the anticipated length of the shortage exceeds our current supply, we develop a mitigation plan which could include purchase of the gray market in extreme cases.

Our goal at this point is to extend the amount of inventory until the drug is released to the market. Work also begins at this stage with the impacted medical divisions to explore if various safe alternatives and treatments exist.

The vast majority of drugs purchased for Cincinnati Children's are from two primary wholesalers. At the point all inventory of the affected drug has been exhausted, regular wholesalers and manufacturers have no product, and the mitigation plan has run its course, Cincinnati Children's has in the past looked for alternative wholesalers for the product. Let me be clear. Cincinnati Children's only uses these alternative wholesalers as a last resort when it is determined that the absence of the drug could cause harm to one of our small patients.

In these extreme cases, Cincinnati Children's has very specific due diligence procedures for obtaining drugs from alternate wholesalers, which includes an examination of the drug pedigree. Over the past 12 months, Cincinnati Children's has purchased only nine out of the 2,800 different line item drugs from these alternative wholesalers.

As a medical team, it was determined that all these drugs were critical. In fact, three of them are drugs used to maintain life support during a code. Cincinnati Children's believed running out of the stock of these drugs was not an option and would have the potential to cause significant harm to our patients.

Critical chemotherapy drugs have been frequently reported in short supply. One specific example is when we needed to purchase a very important chemotherapy called Cytarabine that was in short supply. Cytarabine is used to treat acute lymphoblastic leukemia and is the drug our oncology division firmly believes has the most efficacy for treatment.

After careful consideration and the due diligence described above, and because there is no treatment alternative for this particular disease, Cincinnati Children's did, in fact, purchase this drug from alternative wholesalers. Because of this purchase, we did not run out of this important drug, and all the patients received all the appropriate doses.

It is a daily reality that our buyers in the division receive e-mails and phone calls from alternative wholesalers. It is our experience that the call activity increases when a new or critical drug goes into a shortage situation. The prices vary from wholesaler to wholesaler. Cincinnati Children's has had the experience of the price changing rapidly, even between phone calls, within the same alternative wholesaler, depending on the market activity and the critical nature of the drug.

These business practices are not the normal procedure for our primary wholesaler or any other of our activities within the prac-

tice of pharmacy. As you can surmise, it is also a fact that in all of our purchases through alternative wholesalers, Cincinnati Children's did, in fact, pay substantially more than our normal contracted price. In some cases, the price exceeded 35 times the normal pricing.

Finally, on behalf of my colleagues at the other children's hospitals across the country, I would like to conclude by thanking this committee for its efforts to gain a full understanding of the complexity of this issue. As Cincinnati Children's has seen over the past 5 years, the fragile nature of the pharmaceutical supply chain does have a direct correlation to the treatment of our patients. At Cincinnati Children's, safety is paramount, and there is nothing more important to the institution than making sure a child gets the right care in the appropriate setting with the very best quality and competency that can be delivered.

Thank you for allowing me to share our experiences with you today, and I would be happy to respond to questions later.

[The prepared statement of Dr. Mayhaus follows:]

PREPARED STATEMENT OF DR. DAVID MAYHAUS, CHIEF PHARMACY DIRECTOR, CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER; MEMBER, EXECUTIVE COMMITTEE, CHILDREN'S HOSPITAL ASSOCIATION PHARMACY FORUM

Chairman Rockefeller and members of the Committee, my name is David Mayhaus and I am the Chief Pharmacy Director at Cincinnati Children's Hospital Medical Center. I am grateful for the opportunity to speak to you today not only on behalf of Cincinnati Children's, but also as a member of the Executive Committee for the Children's Hospital Association Pharmacy Forum. My goal today is to describe the process Cincinnati Children's uses for managing drugs when they reach critical shortage and how these issues have impacted our pharmacy operations over the past five years.

Cincinnati Children's was recently ranked third in the Nation among all Honor Roll hospitals in U.S. News and World Report's Best Children's Hospitals ranking. Our institution is ranked in the top 10 for all of the pediatric specialties ranked. On the research side, Cincinnati Children's is one of the top two pediatric recipients of grants from the National Institutes of Health. In FY 2011 there were over 1 million patient encounters at Cincinnati Children's from 48 states and over 50 countries. Cincinnati Children's operates over 570 registered beds including a Heart Institute, a Perinatal Institute and a Cancer and Blood Disease Institute. Cincinnati Children's division of pharmacy is a large facility which dispenses approximately 7,500 doses per day. When there is a sudden drug shortage crisis the impact can be felt through our entire system.

Our division of pharmacy consists of 150 FTEs. Three of these FTE are pharmacy buyers. These buyers are responsible for managing the inventory of approximately 2800 line items of drugs. Over the past several years, more and more time has been dedicated to management of medications that are in short supply. Over time I have seen it grow to the point where today our buyers spend 30 percent of their day just dealing with drug shortages and trying to prevent Cincinnati Children's from experiencing a crisis. In addition to our drug buyers; clinical pharmacists and directors spend an inordinate portion of their time monitoring drug supply which can range from modification of therapy, to alternative medications. Our pharmacists have contacted manufacturers, wholesalers and alternative suppliers to get what we need. As Chief Pharmacy Director approximately 10 percent of my time is also dedicated to these issues including what I am doing today, appealing to you to assure adequate supply of medications for our patients.

Today at CCHMC there are currently 30 drugs being actively managed on a daily basis and approximately an additional 70 where there have been concerns about shortage in the recent past. The buyers who report to me check our primary wholesaler on a daily basis for the 30 drugs on the critical list. We meet informally several times a day as a group and discuss where we are and possible mitigation plans. As a pediatric institution, it is vitally important to continually monitor the drug shortage market and react quickly to the changes.

There are several mechanisms to determine new and ongoing drug shortages. The 3 most important are the American Society of Health-System Pharmacists (ASHP) website, The FDA website and the Children Hospital's Association's pharmacy directors and buyers list serve. Other less helpful mechanisms are the primary wholesaler and manufacturer notifications. It is the experience of Cincinnati Children's that these last two tend to be delayed in their announcement of shortages. For these reasons we applaud the Senate for their passage of the Senate Bill 3187, the FDA user fee legislation, which will create an early-warning notice system that will give providers like myself more timely notice ahead of a critical shortage.

Everything we do is in the best interest of our pediatric patients. Once a drug is determined in shortage, our clinical pharmacists identify our utilization pattern and an estimate for days supply is developed. If the anticipated length of the shortage exceeds our current supply, we meet to develop a mitigation plan which could include purchase from the gray market in extreme circumstances. Our goal at this point is to extend the amount of inventory until the drug is released to the market. Work also begins at this stage with the impacted medical divisions to explore if various safe alternatives in treatment exist. Mitigation plans could include: reducing the dosing guidelines within medical staff approval for the affected drug, changing the current distribution from readily available to pharmacy dispensed therefore maximizing product or changing to a similar drug in the pharmaceutical class. None of these decisions would be made without complete and thorough consultation with the medical team.

The vast majority of the drugs purchased from Cincinnati Children's are from two primary wholesale companies. At the point all inventory of the affected drug has been exhausted, regular wholesalers have no product and the mitigation plan has run its course, Cincinnati Children's has in the past looked to alternative wholesalers for product. Let me be clear, Cincinnati Children's only use these alternative wholesalers as a last resort when it is determines that the absence of the drug could cause harm to our patients.

In those situations where Cincinnati Children's decides to purchase a drug from an alternative wholesaler, we follow extensive due diligence procedures including checking the prescription drug pedigree.

Over the past 12 months Cincinnati Children's has purchased only 9 out of 2,800 different line item drugs from these alternative wholesalers. As a medical team it was determined that all of these drugs were critical and in fact three of them are drugs used to maintain life support during a code. Cincinnati Children's believes running out of stock of these drugs is not an option and would have had the potential to cause significant harm to our patients.

Critical chemotherapy drugs have been frequently reported to be in short supply. One specific example is approximately 18–24 months ago the institution needed to purchase a very important chemotherapy (Cytarabine) that was in short supply. Cytarabine is used to treat Acute Lymphoblastic Leukemia (ALL) and is the drug that our number three ranked oncology division firmly believes has the most efficacy for treatment. After careful consideration and the due diligence described above and because there is no treatment alternative for this particular drug, Cincinnati Children's did in fact purchase this drug from alternative wholesalers. Because of the purchase, we did not run out of this important drug and all patients received the appropriate dose.

It is a daily reality that the buyers in our division receive e-mails and phone calls from alternative wholesalers. It is our experience that the call activity increases when a new or critical drug goes into a shortage situation. The prices vary from wholesaler to wholesaler. Cincinnati Children's has had the experience of the price changing rapidly, even between phone calls, within the same alternative wholesaler depending on the market activity and the critical nature of the drug. These business practices are not the normal procedure for our primary wholesaler or for any other activity within the practice of pharmacy. As you can surmise, it is also a fact that in all of our purchases through alternative wholesalers, Cincinnati Children's paid substantially more than our normal contracted price. In some cases this price exceeded 35 times more than normal pricing.

Finally, on behalf of my colleagues at the other children's hospitals across the country, I would like to conclude by thanking this Committee for its efforts to gain a full understanding of the complexity of these issues. As Cincinnati Children's has seen over the past five years the fragile nature of the pharmaceutical supply chain does have a direct correlation to treatment for patients. At Cincinnati Children's safety is paramount and there is nothing more important to the institution than making sure a child gets the right care, in the appropriate setting with the very best quality and competence that can be delivered.

Thank you for allowing me to share our experiences with you today and I will be happy to respond to questions.

The CHAIRMAN. Thank you very much, Dr. Mayhaus. You spoke in a quiet manner, but your testimony was very potent.

And now I would once again call upon my colleagues and our witnesses to allow a very distinguished visitor, Elijah E. Cummings, who is Ranking Member of the Oversight and Government Reform Committee in the House, who has been working on this and so many other issues. We've done a number of things together, and we've been in each other's daises, so to speak. But he has something he would like to say on this, and I hope that my colleagues and the witnesses will listen carefully to what he has to say, because then he has to go right back and continue chairing a hearing.

STATEMENT OF HON. ELIJAH E. CUMMINGS, RANKING MEMBER, U.S. HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

Mr. CUMMINGS. Thank you very much Chairman Rockefeller and Ranking Member Hutchison and members of the Committee, and I thank you for inviting me to testify here today. Let me also extend my personal thanks to Chairman Rockefeller and Chairman Harkin and their staffs for their great work during this investigation and for their comprehensive report issued today.

If I may, I would like to focus briefly on why I launched this investigation and what we found so far and what we can do about it. I initiated this investigation last year after receiving a heartfelt letter from Brenda Frese. Brenda is the head coach of the women's basketball team at the University of Maryland, and these are pictures of Brenda and her son, Tyler.

Brenda wrote to me about a critical shortage in a drug called Cytarabine, which treats leukemia in children. Let me read what she wrote. "Without Cytarabine, many leukemia patients won't be cured and they will die. What makes this hit home even more for me and my family is that my 3-year-old son, Tyler, is a leukemia patient who has benefited from Cytarabine," end of quote.

As we began investigating this shortage, we found something very disturbing. Hospitals such as Johns Hopkins, the University of Maryland, and others told us that even though they could not get the drug from their authorized distributors, they were being inundated with phone calls, e-mails, and faxes from gray market companies offering the shortage drugs and others at highly inflated prices. They were outraged by this and so was I.

Based on the information provided by the hospitals, we started with five drugs facing critical shortages, and we identified five gray market companies marketing them at exorbitant prices. We asked these companies where they were getting these drugs and how much money they were making by selling them. Based on their initial responses, we expanded our investigation to cover 125 different companies, and we reviewed 300 different drug transaction chains.

The report issued today does a terrific job laying out the facts in detail. So let me highlight one example that illustrates our findings.

First, let me put up a chart that shows how things are supposed to work. Under normal circumstances, drugs go from manufactur-

ers to distributors to hospitals, pharmacies, or other healthcare providers that dispense them to patients. But that is not what happens in the gray market. In the gray market transactions, shortage drugs are being diverted into a much longer distribution chain.

Let me show you an example, the transaction involving Fluorouracil. This drug is used to treat various forms of cancer, including colon cancer, stomach cancer, breast cancer, and pancreatic cancer. As you can see, instead of the three stops, in this case there are nine. The main problem is that each one of these entities marked up the price of the drug. Let me show you how much.

This is the same chart now listing the prices for each transaction. The drug started at $7—listen to what I'm saying—$7 per vial when it was sold by the authorized distributor. It was later sold for $50, then $69, then $95, then $275, then $375. And, remember, it started at $7, and it was sold finally to a hospital at an astonishing $600. Something is wrong with that picture. That was for a single vial of this cancer drug, more than 85 times its initial price.

This was not an isolated incident. We found this same pattern with all the drugs we examined. This system makes absolutely no sense for patients who need these critical drugs or for hospitals that treat them. The current system allows this network of private companies to boost their profits, and for what? For doing nothing but charging offensively high prices, increasing the overall cost of our nation's healthcare system, and raising significant safety concerns as these drugs criss-cross the country with markups at every single stop.

So how could this happen? How do these gray market drug companies get their hands on these drugs when our hospitals cannot? And I guarantee you almost every single hospital in this country, if you ask them about it, will tell you they're experiencing the same thing.

The answer is through pharmacies. In more than two-thirds of the drug sale chains we examined, gray market companies were able to buy shortage drugs from entities with pharmacy licenses. In the same chain we have been discussing, you can see that the third company was a pharmacy named Priority Healthcare. Rather than dispensing the drug to patients, this pharmacy sold it to a gray market wholesaler called Tri-Med America, which then sold it down the line.

During our investigation, we discovered that Priority was actually a fake pharmacy. It sold all of its drugs to Tri-Med and none, absolutely none, to patients. We also discovered that the owner of the pharmacy was married to the owner of Tri-Med, the gray market wholesaler. State regulators found that the pharmacy committed numerous violations of state law, and the wholesaler's license has now been revoked.

Again, this was not an isolated incident. In North Carolina, for example, an individual named Jessica Hoppe set up two companies, LTC Pharmacy and International Pharmaceuticals, a pharmacy and wholesaler. But when state regulators went to inspect these companies, this is what they found. They reported that LTC Pharmacy, and I quote, "was not an operating pharmacy," and that, quote, "no dispensing has taken place since opening," end of quote.

Licenses for both companies have now been surrendered or denied. However, just last week, we learned that the owner has now opened a new company, just under a different name and in a different state.

Even legitimate pharmacies are being used by unscrupulous gray market companies to obtain access to shortage drugs. Gray market companies and their brokers have been approaching pharmacies, asking them to buy drugs on their behalf and promising big profits in return.

For example, an e-mail to one pharmacy said, and I quote, "We guarantee our pharmacies 20 percent or more every time," end of quote. Another e-mail encouraged a pharmacy to locate shortage drugs, saying, and I quote, "The more you find, the more you make," end of quote. Some gray market companies even dupe pharmacies into believing that buying shortage drugs for them would help needy patients obtain drugs faster. In fact, all they were doing is artificially driving up prices.

The good news is that there is something we can do about this, and we must do something about it. In May, I introduced legislation, and there are two provisions I would just like to highlight as I close.

First, my bill would prohibit wholesalers from buying drugs from pharmacies. There is no legitimate reason for wholesalers to do this, and this is how many shortage drugs are being diverted into the gray market.

Second, my bill would create a national wholesaler data base that would allow state boards of pharmacy to share information more easily. One of the biggest challenges state regulators face is monitoring enforcement actions in other states. We have already found examples of gray marketers being shut down in one state, only to open their doors in another.

Let me close by emphasizing again why this investigation is so very, very important. As Brenda Frese said to me in her letter last year, this is a matter of life and death. And nobody, absolutely nobody, should be allowed to profiteer at the expense of patients by jacking up the price of drugs in critically short supply.

We're talking about kids, with leukemia in some cases, children with life threatening illnesses. And these companies are taking advantage of them to boost their own bottom lines.

Again, I want to thank Chairman Rockefeller and Chairman Harkin, and I want to thank you for lending to us and helping us with your phenomenal staffs. They have been absolutely incredible, and we really do appreciate them. Without your direct involvement and your sustained leadership, there is absolutely no way we would have uncovered as much as we did during this investigation.

And I apologize because I have to run back to the House. I'm managing a bill. But, again, thank you and may God bless.

[The prepared statement of Mr. Cummings follows:]

PREPARED STATEMENT OF HON. ELIJAH E. CUMMINGS, RANKING MEMBER, U.S. HOUSE OF REPRESENTATIVES, COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

Chairman Rockefeller, Ranking Member Hutchinson, and Members of the Committee, thank you for inviting me to testify. Let me also extend my personal thanks to Chairman Rockefeller, Chairman Harkin, and their staffs for their great work during this investigation and for the comprehensive report issued today.

If I may, I would like to focus briefly on why I launched this investigation, what we have found so far, and what we can do about it.

[Figure 1: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure1%283%29.pdf*] I initiated this investigation last year after receiving a heartfelt letter, *http://democrats.oversight.house.gov/images/stories/freselettertocummings.pdf,* from Brenda Frese. Brenda is the head coach of the women's basketball team at the University of Maryland, and these are pictures of Brenda and her son Tyler. Brenda wrote to me about a critical shortage in a drug called cytarabine, which treats leukemia in children. Let me read what she wrote:

> Without cytarabine, many leukemia patients won't be cured and will die. What makes this hit home even more for me and my family is that my three year old son Tyler is a leukemia patient who has benefited from cytarabine.

As we began investigating this shortage, we found something very disturbing. Hospitals told us that even though they could not get the drug from their authorized distributors, they were being inundated with phone calls, e-mails, and faxes from gray market companies offering this shortage drug and others at highly inflated prices. They were outraged by this, and so was I.

Based on information provided by the hospitals, we started with five drugs facing critical shortages, and we identified five gray market companies marketing them at exorbitant prices. We asked these companies where they were getting these drugs, and how much money they were making by selling them. Based on their initial responses, we expanded our investigation to cover 125 different companies, and we reviewed 300 different drug transaction chains.

The report issued today does a terrific job laying out the facts in detail, so let me highlight one example that illustrates our findings.

[Figure 2: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure2%283%29.pdf*] First, let me put up a chart that shows how things are supposed to work. Under normal circumstances, drugs go from manufacturers to distributors to hospitals, pharmacies, or other health care providers that dispense them to patients. But that is not what happens in the gray market. In gray market transactions, shortage drugs are being diverted into much longer distribution chains.

[Figure 3: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure3%283%29.pdf*] Let me show you an example. This transaction involved fluorouracil, which is used to treat various forms of cancer, including colon, stomach, breast, and pancreatic cancer. As you can see, instead of three stops in this case, there were nine. The main problem is that each one of these entities marked-up the price of the drug.

[Figure 4: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure4%283%29.pdf*] Let me show you how much. This is the same chart, now listing the prices for each transaction. This drug started at $7 per vial when it was sold by the authorized distributor. It was later sold for $50 . . . $69 . . . $95 . . . $275 . . . $375 . . . In the end, it was finally sold to a hospital for an astonishing $600. That was for a single vial of this cancer drug—more than 85 times its initial price.

This was not an isolated incident. We found this same pattern with all of the drugs we examined. This system makes absolutely no sense for patients who need these critical drugs or for hospitals that treat them. The current system allows this network of private companies to boost their profits. And for what? For doing nothing but charging offensively high prices, increasing the overall costs to our Nation's health system, and raising significant safety concerns as these drugs crisscross the country with mark-ups at every stop.

So how could this happen? How do these gray market drug companies get their hands on these drugs when hospitals cannot? The answer is through pharmacies. In more than two-thirds of the drug sale chains we examined (69 percent), gray market companies were able to buy shortage drugs from entities with pharmacy licenses.

[Figure 5: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure5%283%29.pdf*] In the same chain we have been discussing, you can see that the third company was a pharmacy named Priority Healthcare. Rather than dispensing the drug to a patient, this pharmacy sold it to a gray market wholesaler called Tri-Med America, which then sold it down the line.

During our investigation, we discovered that Priority was actually a fake pharmacy. It sold all of its drugs to Tri-Med and none to patients. We also discovered that the owner of this pharmacy was married to the owner of Tri-Med, the gray market wholesaler. State regulators found that the pharmacy committed numerous violations of state law, and the wholesaler's license has now been revoked.

Again, this was not an isolated incident. In North Carolina, for example, an individual named Jessica Hoppe set up two companies—LTC Pharmacy and Inter-

national Pharmaceuticals, a pharmacy and a wholesaler. But when state regulators went to inspect these companies, this is what they found.

[Figure 6: *http://democrats.oversight.house.gov/images/stories/GrayMarketFigure6%283%29.pdf*] They reported that LTC Pharmacy was "not an operating pharmacy" and that "no dispensing has taken place since opening." Licenses for both companies have now been surrendered or denied. However, just last week, we learned that the owner has now opened a new company, just under a different name and in a different state.

Even legitimate pharmacies are being used by unscrupulous gray market companies to obtain access to shortage drugs. Gray market companies and their brokers have been approaching pharmacies, asking them to buy drugs on their behalf, and promising big profits in return. For example, an e-mail to one pharmacy said this: "We guarantee our Pharmacies 20 percent or more every time." Another e-mail encouraged a pharmacy to locate shortage drugs, saying this: "The more you find, the more you make."

Some gray market companies even duped pharmacies into believing that buying shortage drugs for them would help needy patients obtain drugs faster, when in fact all they were doing is artificially driving up prices.

The good news is that there is something we can do about this. In May, I introduced legislation, and there are two provisions I would like to highlight. First, my bill would prohibit wholesalers from buying drugs from pharmacies. There is no legitimate reason for wholesalers to do this, and this is how many shortage drugs are being diverted into the gray market.

Second, my bill would create a national wholesaler database that would allow state boards of pharmacy to share information more easily. One of the biggest challenges state regulators face is monitoring enforcement actions in other states. We have already found examples of gray marketers being shut down in one state only to open their doors in another.

Let me close by emphasizing again why this investigation is so important. As Brenda Frese said to me in her letter last year, this is a matter of life and death. Nobody should be allowed to profiteer at the expense of patients by jacking up the price of drugs in critically short supply. We're talking about kids with leukemia in some cases—children with life-threatening illnesses—and these companies are taking advantage of them to boost their bottom-line.

I would like to thank Chairman Rockefeller and Chairman Harkin once again, as well as your staffs. Without your direct involvement and your sustained leadership, there is no way we would have uncovered as much as we did during this investigation. Thank you.

The CHAIRMAN. Thank you very much, Congressman Cummings. You're a remarkable person, and we wish you well.

Again, I've never sort of done this before. So, again, I want to apologize to my colleagues that were all sort of looking at me in a slightly skeptical way. But, fortunately, we work on the seniority system here, so there's not much you can do about it.

[Laughter.]

The CHAIRMAN. However, now I want to go to John Coster, who is Senior Vice President of Government Affairs and Director of the NCPA, which is the National Community Pharmacists Association.

Please.

STATEMENT OF JOHN COSTER, PH.D., R.PH., SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS AND DIRECTOR, NCPA ADVOCACY CENTER, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Dr. COSTER. Chairman Rockefeller, Senator Boozman, members of the Senate Commerce Committee, I'm John Coster, Senior Vice President of Government Affairs for the National Community Pharmacists Association. I am also a licensed pharmacist in the states of New York, Maryland, and Virginia. Thank you for conducting this hearing and for allowing us to submit our views on this very important and timely issue.

NCPA represents the owners and operators of 23,000 independent community pharmacies in the United States. We appreciate your focusing this hearing on the issues surrounding the shortages of prescription drugs. While most of the drug shortages to date have been experienced by hospitals and other institutional settings for injectable and infusion drugs, many community pharmacies also experience daily shortages of vital prescription medications.

How do community pharmacies manage an inventory of thousands of drug products on their shelves and also handle drug shortages? Pharmacy inventory is a function of many factors, including local prescribing patterns and patient populations served. Pharmacies do their very best to efficiently manage their inventories because drug products are very expensive.

A typical independent community pharmacy has a great deal of capital invested in inventory items, likely hundreds of thousands of dollars. Over 90 percent of the average independent pharmacy's dollar inventory is tied up in prescription products. However, the last message a pharmacist wants to deliver to a patient standing at the counter is that their drug is not in stock or, worse, temporarily unavailable.

The relationship between community pharmacies and their wholesale distributors is one of critical importance to manage inventory and prevent shortages. Community pharmacists rely heavily on their wholesalers to ensure that they have the necessary access to virtually all medications at all times in order to ensure that their patients' needs are met.

Most community pharmacies rely on a primary wholesaler to meet the majority of their ongoing prescription drug needs. However, community pharmacies typically need to have at least one or more backup or secondary wholesalers that they can call upon in the event that there is a shortage.

Recently, there have been troubling reports of shell pharmacies, fake pharmacies, paper pharmacies that seem to have been established for the sole purpose of buying medications in short supply from primary wholesalers in order to sell them to unethical secondary wholesalers. NCPA condemns these activities and applauds the Committee for its investigative work in this area. No pharmacy, whether fake or legitimate, should be in the business of acting as a conduit to facilitate the activities of an illegitimate gray market. These few pharmacies cast a pall over all the good community pharmacies that do work in their communities.

It is our understanding that the Committee's investigation focuses mainly on injectable and infusion drugs that are not typically sold to or dispensed by community pharmacies. These aberrant purchases by these pharmacies should have been a warning signal to wholesalers selling these drugs that something could be wrong.

How was it that some of these pharmacies could open and operate in the first place? Typically, state boards conduct an onsite investigation of any new pharmacy. However, sometimes in certain situations boards may issue a temporary license with the permanent license withheld pending the results of an actual inspection.

Beyond the appreciated actions already taken by Congress to address drug shortages in the recently enacted FDA bill, Congress

continues to examine ways to further secure the supply chain. We support these discussions and want to continue to serve as a resource on the best way to achieve these objectives in a seamless, efficient, patient-oriented manner.

What practices do pharmacies currently use to address shortages of medications? First, it is in the normal course of business that community pharmacies return outdated or short-dated products to wholesalers or distributors. We need a way to do this in order to return product because of the significant amount of capital tied up in these returns.

Second, at times, where permitted by law, pharmacies do sell inventory to other pharmacies. For example, some state practice acts allow retail pharmacies to sell a small amount of their inventory in certain situations. Pharmacies will do this on occasion to alleviate temporary shortages.

Finally, some states permit appropriate licensed pharmacy sales to wholesalers. These sales are also permitted to alleviate a temporary shortage of drugs. In surveying our members, however, we have found very few that actually do this.

We want to work with the Committee to assure that community pharmacies can continue to manage their inventories while being able to meet their individual prescription drug needs. For example, we support the implementation of Federal standards for wholesale distributors. In addition, there should be greater emphasis on the importance for all participants in the supply chain to perform their due diligence with respect to business partners.

In conclusion, it is necessary for pharmacies to have options to address temporary shortages in the marketplace. We urge Congress to not take actions that might limit the ability of pharmacies to take care of their patients. The primary and secondary wholesale markets play an important role in ensuring that all patients have seamless access to virtually all products they require. Having said that, it is unethical for pharmacists to act as a conduit for the illegitimate gray market, which is contrary to the goals of providing the best patient care.

We appreciate the opportunity to provide our views to the Committee, and I look forward to answering any questions.

[The prepared statement of Dr. Coster follows:]

PREPARED STATEMENT OF JOHN COSTER, PH.D., R.PH., SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS AND DIRECTOR, NCPA ADVOCACY CENTER, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Chairman Rockefeller, Senator Boozman, and Members of the Senate Commerce Committee. I am John Coster, Ph.D., R.Ph., Senior Vice President of Government Affairs for the National Community Pharmacists Association. I am a licensed pharmacist in the states of New York, Maryland, and Virginia. Thank you for conducting this hearing and for allowing us to submit our views on this very important and timely issue. NCPA represents the owners and operators of more than 23,000 independent community pharmacies in the United States. Our members provide about 40 percent of all outpatient prescription drugs in the United States. We are also major providers of pharmacy services to long term care and assisted living facilities. Our members are also prevalent in urban and rural areas.

We appreciate your focusing this hearing on the issues surrounding the shortages of prescription drugs. While most of the drug shortages to date have been experienced by hospitals and other institutional settings for injectable and infusion drugs, many community pharmacies also experience daily shortages of vital prescription medications. In particular, recently there have been critical shortages of medications

to treat ADD and ADHD. The newly enacted FDA law will take important steps to help address these types of shortages, as well as require better coordination between FDA and the Drug Enforcement Administration (DEA) on determining and updating the quotas for the production of these medications. We appreciate the bipartisan steps that Congress took to address this shortage situation.

Pharmacies Rely on Combination of Wholesalers

How do community pharmacies manage an inventory of the thousands of drug products on their shelves and handle drug shortages? Pharmacy inventory is a function of many factors, including local prescribing patterns and the patient population served. Pharmacies do their best to efficiently and effectively manage their inventories because drug products are very expensive.

A typical independent community pharmacy has a great deal of capital invested in inventory items, likely hundreds of thousands of dollars. Over 90 percent of the average independent pharmacy's dollar inventory is tied up in prescription products. However, the last message a pharmacist wants to deliver to a patient standing at the counter is that their drug is not in stock, or worse, is temporarily unavailable.

The relationship between community pharmacists and their wholesale distributors is one of critical importance to manage inventory and prevent shortages. Community pharmacists rely heavily on their wholesalers to ensure that they have the necessary access to virtually all medications at all times in order to ensure that patient needs are met. Most community pharmacists rely on a primary wholesaler to meet the majority of their on-going prescription drug supply needs. However, community pharmacists typically need to have at least one or more "back-up" or secondary distributors that they can call upon in the event that their primary distributor for some reason cannot meet their needs at any particular time.

The term "primary wholesaler" generally describes entities that purchase the vast majority of their product directly from drug manufacturers. This market is highly concentrated, as the "big three" wholesalers generate approximately 85 percent of all revenues from pharmaceutical wholesaling in the United States. Most manufacturers typically limit the number of entities that they will sell to directly and most do not sell directly to smaller companies that are not interested in purchasing extremely large, bulk amounts

The term "secondary" wholesaler generally describes distributors that do not purchase the majority of their products directly from a pharmaceutical manufacturer. They often play an important role for patients and pharmacies by serving as a "back-up" source of supply to pharmacies who may use a primary wholesaler for their usual and expected day-to-day needs. They also provide necessary competition for the primary wholesalers which helps keep costs down.

Illicit Activities by "Shell" Pharmacies and Gray Market Distributors Unethical

Recently, there have been troubling reports of "shell pharmacies" or "paper pharmacies" that seem to have been established for the sole purpose of buying medications in short supply from primary wholesalers in order to sell them to seemingly unethical secondary wholesalers. NCPA condemns these activities and applauds the Committee for its investigative work in this area. No pharmacy should be in the business of acting as a conduit to facilitate the activities of an illegitimate gray market.

It is our understanding that the Committee's investigation focuses mainly on injectable and infusion drugs that are not typically sold to or dispensed by most community pharmacies. The aberrant purchases by these pharmacies should have been a strong warning signal to wholesalers selling these drugs to these pharmacies that something could be wrong.

How was it that these shell pharmacies could even open and operate in the first place? Typically, state boards of pharmacy conduct an on-site inspection of any new pharmacy; however, sometimes boards may issue a temporary license with the permanent license withheld pending the results of an actual inspection.

Efforts to Curb Unacceptable Practices Should Not Harm Patient Care

Beyond the actions already taken by Congress to address drug shortages in the recently-enacted FDA bill, Congress continues to examine ways to furthers secure the pharmaceutical supply chain. We support these discussions and want to continue to serve as a resource to Congress on the best ways to achieve these objectives in a seamless, efficient, patient-oriented manner. What current practices allow pharmacies to address shortages of medications to meet patient needs, while managing their inventory?

First, it is in the normal course of business that community pharmacies return outdated or short dated products to wholesalers or distributors, or products that

were sent to the pharmacy in error. Pharmacies need a way to return products because of the significant amount of pharmacy capital tied up in these returns. We appreciate that our business partners work with us on taking back these returns, and we urge Congress to continue to allow us to return these products.

Second, at times, where permitted by law, community pharmacies do sell pharmaceutical products to other pharmacies. For example, some state pharmacy practice laws allow retail pharmacies to sell a small amount of their inventory in certain situations. Pharmacies will do this on occasion to alleviate temporary shortages, to assure that patients are able to receive needed drugs, or to assure that "short dated" drugs will not be wasted before they expire. We believe that this is an appropriate practice. This helps to facilitate the functioning of the market and helps to assure timely and appropriate cost effective patient care. This is particularly important in rural areas where daily wholesaler deliveries may be more sporadic.

Finally, some states permit pharmacy sales to wholesalers. These sales are permitted to alleviate a temporary shortage of drugs. In surveying our members, however, we have found very few that hold both types of licenses. Having said that, we think that this situation contrasts with the unethical practices found by the Committee where a pharmacy was knowingly buying short supply inventory it knew it would not use and did not need, with the intended purpose of selling it into the illegitimate gray market.

However, one of the options discussed to address the issues identified by the Committee is a potential prohibition of pharmacies selling drug products to wholesalers. While this would appear to be a logical solution to the problem, we ask the Committee to carefully consider whether this option would have unintended consequences for patients.

Supply Chain Partners Need to Know Their Customers

We would want to work with the Committee to assure that community pharmacies can continue to manage their pharmaceutical inventories, while being able to meet the prescription drug needs of individual patients, including in shortage situations.

For example, NCPA supports the implementation of Federal standards for wholesale distributors, as well as a proposed lot-level tracking system for prescription drugs that will make it much easier to keep track of the purchase and sale of pharmaceuticals. Uniformly raising the bar for all entities that wish to engage in this line of business should provide a greater assurance for all participants in the supply chain that they are doing business with a legitimate entity.

In addition, there should be greater emphasis on the importance for all participants in the supply chain to also perform their "due diligence" with respect to their business partners. NCPA currently publishes a manual that provides assistance to pharmacists who are seeking to open their own pharmacy and a portion of this document deals with the selection of a wholesaler or wholesaler(s). The manual includes a list of questions that each pharmacy should ask before retaining the services of any wholesaler. Notably, NCPA also stresses the fact that every pharmacy needs to have more than one wholesaler "because no wholesaler can offer every product that you may need to stock."

In conclusion, it is necessary for pharmacies to have options to address temporary shortages in the marketplace. We urge Congress to not take actions that might limit the ability of pharmacies to take care of their patients. The primary and secondary wholesaler markets both play an important role in ensuring that all patients have seamless access to virtually any product that they may require.

Having said that, it is unethical for pharmacists to act as a conduit for the illegitimate gray market, which is contrary to the goal of providing the best patient care at the lowest cost. Problems or questionable practices should certainly be investigated and addressed, but any solution needs to be carefully tailored so that the pharmaceutical supply chain is not unduly disrupted and patients do not suffer due to shortages that may occur. We appreciate the opportunity to provide our views to the Committee and I look forward to answering any questions.

The CHAIRMAN. Thank you very much, Mr. Coster.

And now Mr. John Gray, who is President and CEO of Healthcare Distribution Management Association.

STATEMENT OF JOHN M. GRAY, PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)

Mr. GRAY. Thank you. Good afternoon, Chairman Rockefeller, Ranking Member Boozman, members of the Senate Commerce Committee. I'm John Gray, President and CEO of the Healthcare Distribution Management Association. I want to thank you for the opportunity to come here and provide an overview of the pharmaceutical distribution system with respect to the critically important issue of drug shortages.

We applaud the Committee's efforts to address the shortage issue and some of the resulting symptoms, including gray market diversion of products in short supply. For purposes of the discussion today, I'll reference a recent report from the Premier Healthcare Alliance that defines the gray market as a parallel market that is, quote, "unofficial, unauthorized, or unintended by the original manufacturer," end quote.

Given that context, and to distinguish HDMA members from the gray market, I'll share with you information about the primary pharmaceutical distribution industry. HDMA is the national association representing those primary healthcare distributors, which we consider the vital link between manufacturers and providers in our nation's healthcare system.

Approximately 90 percent of all pharmaceutical product sales in the United States today flow through HDMA's 34 distributor members. Each business day, HDMA member companies ensure that more than nine million prescriptions and healthcare products from more than 1,100 manufacturers are delivered safely and efficiently to nearly 200,000 healthcare providers, which include pharmacies, hospitals, nursing homes, clinics, and other healthcare entities. Our provider customers generally place orders for prescription medicines by 8 p.m. in the evening and receive deliveries from the distributors the next morning.

Wholesale distribution is defined as, quote "the distribution of prescription drugs to persons other than a consumer or a patient." HDMA members are these primary wholesalers. That is, our members are predominantly Authorized Distributors of Record, as designated by the pharmaceutical companies themselves. Our members purchase the majority of product directly from pharmaceutical manufacturers and sell only to appropriately licensed healthcare providers and entities.

In 1988, the Prescription Drug Marketing Act, PDMA, was enacted to increase safeguards in the drug distribution system by preventing the introduction and retail sale of substandard, ineffective, or counterfeit drugs. It has also helped define the pharmaceutical distribution industry as we know it today. Our distributor members operate in accordance with the requirements set forth in the PDMA as well as licensing rules and standards in all 50 separate states.

HDMA and its members are strong advocates for increased wholesale licensure standards and a uniform Federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, Federal pedigree, we believe, will be a major

tool and useful in discouraging gray market activities associated with drug products in short supply.

Effectively addressing the drug shortage problem is a difficult and complex challenge for the entire healthcare community, in large part because the shortage typically appears with little or no warning and often requires significant resources to manage. HDMA member companies are working hard to improve communications within our supply chain and, where possible, to mitigate the impact of these shortages.

Distributors do not manufacture the products, so we can do little about the root causes of the shortages. However, we do play an important role in helping coordinate and share information about the shortages when they arise. Distributors are typically notified of a shortage by a manufacturer or provider partner.

Once that information is received, our distributors communicate with their manufacturer partners about product availability to understand the scope and expected duration of the shortage. They then work as quickly as possible with customers to fill orders, to the extent they are able, based usually upon each customer's historical purchasing patterns. And, if necessary, distributors work with customers and the manufacturers to identify alternative product options.

HDMA, in collaboration with all its distributor members, manufacturers, and providers, recently completed voluntary industry guidelines on improving communications with the supply chain in the event of these kinds of shortages. We hope this effort, combined with the enhanced wholesale licensure standards and a uniform federal pedigree system, will contribute to the better management of product shortage issues in the future.

HDMA is committed as an organization to work with the Congress, all relevant regulatory agencies, and the entire supply chain to develop the necessary collaborative solutions that mitigate the impact of drug shortages and the impact that these have on the most important stakeholder, our patients.

I thank you again for the invitation to participate, and I look forward to the Committee's questions. Thank you very much.

[The prepared statement of Mr. Gray follows:]

PREPARED STATEMENT OF JOHN M. GRAY, PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

Good morning Chairman Rockefeller, Ranking Member Hutchison and Members of the Senate Commerce Committee. I am John Gray, president and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to provide an overview of the pharmaceutical distribution system with respect to the critically important issue of drug shortages.

We applaud the Committee's efforts to address the drug shortage issue and some of the resulting symptoms, including gray market diversion of products in short supply.

For the purposes of our discussion today I will reference a recent report from the Premier Healthcare Alliance that defines the gray market as *a* parallel market, "that is unofficial, unauthorized or unintended by the original manufacturer." Given that context, and to distinguish HDMA members from the gray market, I will share with you information about the primary pharmaceutical distribution industry.

HDMA is the national association representing America's primary healthcare distributors—the vital link between manufacturers and providers in our Nation's healthcare system. Approximately 90 percent of all pharmaceutical product sales in the United States flow through HDMA's 34 distributor members. Each business day,

HDMA member companies ensure that more than nine million prescription medicines and healthcare products from more than 1,100 manufacturers are delivered safely and efficiently to nearly 200,000 healthcare providers including, pharmacies, hospitals, nursing homes, clinics and other healthcare entities. Our provider customers generally place orders for prescription medicines by 8 p.m. in the evening and receive deliveries from their distributors the next morning.

Wholesale distribution is defined as the "distribution of prescription drugs to persons other than a consumer or patient." HDMA members are primary wholesalers, that is our members are predominantly Authorized Distributors of Record (ADRs), as designated by pharmaceutical manufacturers. Our members purchase the majority of product directly from pharmaceutical manufacturers and sell only to appropriately licensed healthcare providers and entities.

In 1988, the Prescription Drug Marketing Act (PDMA) was enacted to increase safeguards in the drug distribution system by preventing the introduction and retail sale of substandard, ineffective or counterfeit drugs. It also helped define the pharmaceutical distribution industry as we know it today. Our distributor members operate in accordance with the requirements set forth in the PDMA, as well as licensing rules and standards in all 50 states.

HDMA and its members are strong advocates for increased wholesaler licensure standards and a uniform Federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, Federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

Effectively addressing a drug shortage is a difficult and complex challenge for the entire healthcare community, in large part because a shortage typically appears with little or no warning and often requires significant resources to manage. HDMA member companies are working hard to improve communications within the supply chain and, where possible, to mitigate the impact of drug shortages. Distributors do not manufacture product and so can do little about the root causes of shortages. However, distributors do play an important role by helping to coordinate and share information about drug shortages when they arise.

Distributors are typically notified of a shortage by a manufacturer or provider partner. Once information is received, distributors communicate with their manufacturer partners about product availability to understand the scope and expected duration of any shortage. They then work as quickly as possible with their customers to fill orders, to the extent they are able, usually based upon each customer's historical purchasing patterns. If necessary, distributors work with customers and manufacturers to identify alternative product options.

HDMA, in collaboration with its distributor members, manufacturers and providers, recently completed voluntary industry guidelines on improving communication between supply chain partners in the event of a product shortage. We hope this effort, in conjunction with enhanced wholesale licensure standards and a uniform Federal pedigree system, will contribute to the better management of product shortage issues in the future.

HDMA is committed to working with the Congress, all relevant regulatory agencies and the entire supply chain to develop collaborative solutions that mitigate the impact drug shortages have on the most important stakeholder: the patient.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable to the Committee as it explores this important and timely topic.

The CHAIRMAN. Thank you very much, sir.

And, finally, Ms. Patricia Earl, who is the Industry Analyst for the National Coalition of Pharmaceutical Distributors.

STATEMENT OF PATRICIA EARL, INDUSTRY ANALYST, NATIONAL COALITION OF PHARMACEUTICAL DISTRIBUTORS (NCPD)

Ms. EARL. Great. It's great to be last. Good afternoon. I would first like to thank Chairman Rockefeller, Senator Boozman, and distinguished members of the Ccommittee for the Committee's strong leadership in addressing the critical problem of short-supply prescription drugs in the supply chain. I have submitted a more complete statement. But in this portion of my testimony, I would like to discuss the issues you have brought to light.

I have more than a quarter century of experience in the pharmaceutical supply chain and understand all sides of the distribution model. In addition to my experience in the distribution industry, I have served as an industry expert in Federal court proceedings involving supply chain practices.

I'm here today to represent the views of the National Coalition of Pharmaceutical Distributors, NCPD, and its members, which are predominantly small and independent pharmaceutical companies. I cannot emphasize enough the value that small, or secondary, pharmaceutical distributors bring to the healthcare system. These organizations are there when no one else is, in the middle of the night, on the weekends, and in remote parts of the country where no one else wants to deliver because it's not considered profitable.

As a result, small distributors help save lives every single day. They save lives by making it their business to ensure that quality medicines reach a patient in the safest, fastest, and most cost-effective way possible, no matter the time or location. Few others can say the same thing. Their value is so profound that we have e-mail after e-mail from customers, including the NIH, thanking them for the help that they have provided to find medicine or deliver it at the last minute to save a life and at a reasonable price, a function primary wholesalers are simply not geared to perform.

Despite their value, small secondary distributors have come under fire recently because few people really understand them or have the time to see where they fit in the supply chain. The arguments have ranged from accusations of price gouging to shifting product between multiple companies as a means to increase profit to working with fake pharmacies.

These allegations are not grounded in reality. What's more, these characterizations fail to reflect one basic fact of the market. There are thousands of small distributors that work with hospitals across the Nation. To remain competitive, they must comply with all laws, follow pedigree and handling requirements to the letter, and still offer an economical price point that allows for only a modest profit margin. If they do anything else, they run the risk of permanently losing a customer.

See, hospitals comparison shop. If they don't like a price offered by one company, they will call another. When it comes to working with secondaries, healthcare providers don't face the same restrictions they do with the big three wholesalers. They are free to move their accounts elsewhere. This is a reality that every small distributor out there is well aware of. And they know that if they were to engage in the types of activities you accuse them of, they would not be in business very long.

As you learn more about this industry which represents less than 1 percent of all drugs bought and sold across the nation, you will see that the activities being painted as nefarious actually have legitimate and reasonable explanations. On the subject of price gouging, or markups, secondary distributors pay the highest prices for drugs in the entire U.S. supply chain, sometimes as much as 91 percent more than one of the big three wholesalers would ultimately pay for the same product.

What's more, many people look at a pedigree and compare the cost the distributor paid for a drug to the price he sold it for and

assume the entire amount was pocketed as profit. That's the furthest thing from the truth. Pedigrees do not show how much was spent on things like shipping, which can be much more expensive than the drug itself if the hospital needs it delivered overnight.

On the subject of several companies being involved in the handling of a product, we are aware, Mr. Chairman, that you are in possession of a handful of pedigrees that show multiple distributors handled a product before it got to the patient. I do not know the circumstances that led to these situations, so I can't defend these pedigrees specifically. But what I can say is that these incidents are anomalies.

Our members work tirelessly to make sure that the route from the distributor to the customer is as straight as possible, because they want to get the product to those who need it as fast as possible, and because they know that they face stiff competition. Even when a drug is in short supply, more than one distributor can get it, and, as I said, hospitals comparison shop.

So for every one pedigree you find that shows multiple touch points, we have literally tens of thousands of pedigrees that show only one or two distributors were involved and with a nominal profit realized. In fact, one NCPD distributor handles 1.2 million pedigrees every year. The handful of pedigrees in your possession do not even equal one-tenth of 1 percent of the number of products he handles in one year.

Finally, on the subject of fake pharmacies, by law, pharmacies are allowed to sell a small portion, 5 percent or less, of their inventory to distributors as long as they comply with state regulatory requirements. In most cases, pharmacies take advantage of this law to sell drugs that will expire within 90 days that they do not believe they can dispense in that timeframe.

Instead of letting them go to waste, many pharmacies will sell the products to an authorized distributor, both small independent companies as well as large wholesalers. The authorized distributor, in turn, will sell it to a medical provider that can use it immediately. Ultimately, this practice is a win-win. Drugs don't go to waste. Pharmacies don't lose large quantities of money on products that are expiring, and providers are able to get pharmaceuticals at a discounted rate.

This is a legitimate and necessary practice and is not a fake pharmacy. Our members will not work with fake pharmacies or pharmacies that do not dispense drugs to patients and will report them to the proper authorities when they encounter them.

That ends my oral presentation, and I urge you to read the more comprehensive testimony that I submitted.

Thank you, Mr. Chairman, Senator Boozman, and members of this Committee.

[The prepared statement of Ms. Earl follows:]

PREPARED STATEMENT OF PATRICIA EARL, INDUSTRY ANALYST, NATIONAL COALITION OF PHARMACEUTICAL DISTRIBUTORS

Good afternoon, first I would like to thank Chairman Rockefeller, Ranking Member Hutchison and distinguished Members of the Committee for the Committee's strong leadership in addressing the critical problem of short-supply prescription drugs in the supply chain. The record shortage of drugs we are currently experiencing has had an adverse effect on the health and safety of communities across the country, and is a contributing factor to rising healthcare costs.

I am here today to represent the views that the National Coalition of Pharmaceutical Distributors (NCPD) and its members, which are predominantly small and independent pharmaceutical distributors, have regarding the distribution of short-supply prescription drugs and the role that the coalition's members play in distributing the drugs in the U.S. supply chain. The three key issues presented in this discussion are ones that NCPD believes the Committee has brought to light for this hearing.

I can offer this insight because I am an expert in the pharmaceutical distribution supply chain, having spent more than twenty-six years in the industry, working with large and small distributors as a senior executive on supply chain management as it relates to hospitals and group purchasing contracts, as well as running distribution centers. My background has resulted in me being called as an expert witness in Federal court cases

Introduction

In recent months, there has been a great deal of controversy and speculation swirling around the entire distribution chain offered by people who do not understand or have first-hand knowledge of how the health care supply chain fits together. The issues raised fit into three basic categories:

1. So-called "price gouging" or mark-ups
2. Several companies being involved in the handling of a product
3. Fake pharmacies

I will address each of these objections in turn, but I wanted to start by helping everyone here understand the various companies involved in supply chain management.

Drug sales and distribution is a complex market with many key players, including "primary" traditional wholesalers, who are members of HDMA, group purchasing organizations—otherwise known as (GPOs), and "secondary" distributors, members of NCPD. All play a vital role in ensuring that quality medicines reach a patient in the safest, fastest and most cost-effective way possible. Small distributors fill a gap in the market, offering versatility and flexibility that primary distributors can't provider while also serving less profitable rural regions of the country.

Role of Small Distributors—Filling A Gap

I cannot emphasize enough the value that small—or secondary—pharmaceutical distributors bring to the health care system. These organizations are there when no one else is—in the middle of the night, on the weekends and in remote parts of the country where no one else wants to deliver because it's not considered profitable. As a result, small distributors help save lives every single day. They save lives by making it their business to ensure that quality medicines reach a patient in the safest, fastest and most cost-effective way possible—no matter the time or location.

Few others can say the same thing.

Their value is so profound that we have e-mail after e-mail from customers—including the NIH—thanking them for the help they have provided to find medicine or deliver it at the last minute to save a life (and at a reasonable price)—a function primary distributors are simply just not geared to perform.

Our members do this work as part of long standing relationships they have with health care providers in which they fill in the gaps when the primary has a drug shortage. The secondary distribution industry primarily serves smaller medical facilities, doctor's offices and pharmacies, many of which are found in rural or other underserved locations around the country. As a practical matter, large distributors are organized to take advantage of volume sales; therefore, they set prohibitively high minimum monthly purchasing requirements for a health care provider to have an account with them and they organize their supply network around major population centers, where they are more likely to find facilities that meet their minimum requirements. They are not well suited to cost-effectively distribute medication to more remote locations.

This is where secondary distributors come in. Hospitals, health care centers and pharmacies in rural locations and those too small to meet the minimums of large distributors rely on secondary distributors to fill critical needs for life-saving medicine. What's more, every sector of the health care industry depends critically upon secondary distributors because they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply.

While they are crucial in getting life-saving drugs to critically ill patients, small distributors are on an individual basis, one of the smallest customers of "traditional" wholesalers. These same wholesalers do billions of dollars of sales to large hospitals, but will not supply smaller clinics and facilities. In addition, small distributors are

required to pay the highest acquisition cost offered in the U.S. supply chain, putting them at a competitive disadvantage.

Despite their value, small, secondary distributors have come under fire recently because few people really understand them or have taken the time to see where they fit in the supply chain. The arguments have ranged from accusations of price gouging to shifting product between multiple companies as a means to increase profits to working with fake pharmacies.

These allegations are little more than character assassinations and are not grounded in reality. What's more, these characterizations fail to reflect one basic fact of this market: There are thousands of small distributors that work with hospitals across the Nation. To remain competitive, they must comply with all laws, follow pedigree and handling requirements to the letter and still offer an economical price point that allows for only a modest profit margin. If they do anything else, they run the risk of permanently losing a customer.

That's because hospitals comparison shop. If they don't like a price offered by one company, they will call another.

This is a reality that every small distributor out there is well aware of. And they know that if they were to engage in the types of activities you accuse them of, they would not be in business very long.

As you learn more about this industry you will see that the activities you are trying to paint as nefarious actually have legitimate and reasonable explanations:

1. So-Called "Price Gouging" Or Mark-Ups

Drug prices are established on an intricate system that is far more complex than most free markets. Manufacturers set a number of price points for a product, including the Wholesale Acquisition Cost—or WAC—which is the lowest price at which a wholesaler or distributor can buy the product. As with many markets, hospitals and physicians can negotiate the price they are willing to pay for a drug. The more product a hospital or doctor expects to use, the more power they have in securing to negotiate a lower price. Neither large nor small distributors have the ability to influence drug price negotiations. To secure the best prices for patients, most hospitals belong to one of the major GPO's, which leverage the strength of the collective buying power of their members when negotiating contracts with manufacturers. GPOs require hospitals to adhere to specific rules, such as select a primary wholesaler—generally one of the Big3: McKesson, Cardinal or AmerisourceBergen—and if their primary does not have a drug, they are prohibited from using another primary. Instead, they must contact their second-line—or "secondary—distributor to supply their needs. Secondary distributors are able to work with all of the primary wholesalers, plus their network of small distributors to locate and secure drugs, even those that are in short-supply. Because small distributors are not restricted by GPO contracts, they are able to use avenues that hospitals cannot, such as large distributors that compete with the hospital's primary wholesalers.

Small distributors have been inaccurately portrayed when it comes to the price of products. As I noted before, secondary distributors pay the highest prices for drugs in the entire U.S. supply chain—sometimes as much as 91 percent more than one of the Big 3 would ultimately pay for the same product. What's more, many people will look at a pedigree and compare the cost a distributor paid for a drug to the price he sold it for and assume the entire amount was pocketed as profit. That's the furthest thing from the truth. The reality is that the pedigree does not show how much was spent on things like shipping, which can be much more expensive than the drug itself if the hospital needs it delivered overnight.

As I said before, every small distributor knows that the hospitals they work with are going to comparison shop. If a hospital doesn't like the price that one secondary distributor quotes to them, they will call another. Or, if they need it right away and can't risk losing it, they will buy it, but will find another secondary distributor to work with moving forward. When it comes to working with secondaries, health care providers do not face the restrictions they do with the Big 3. They are free to move their account elsewhere, so secondary distributors have to remain competitive and will often sacrifice their own profit margins to make sure they keep a customer.

2. Number of Companies Involved in Distribution of A Single Product

We are all aware, Mr. Chairman, that you are in possession of a handful of pedigrees that show multiple distributors handled a product before it made its way to a patient. While I cannot defend these pedigrees specifically because I do not know the circumstances that led to this situation, what I can say is that these incidents are anomalies. Our members work tirelessly to make sure that the route from distributor to customer is as straight as possible. No detours, no additional mark-ups, no changing of hands multiple times. Why? Because our members are concerned

about making sure the products get to those who need it as fast as possible, and because they know that they face stiff competition. Even when a drug is in a shortage situation, more than one distributor will still be able to get it, and hospitals comparison shop—looking for new ways to get the product at a lower price.

So, for every one pedigree you can find that shows multiple touch points, we have literally thousands of pedigrees that show a straight line in which only one or two distributors were involved with only a nominal profit realized. In fact, one distributor that I work with handles 1.2 million pedigrees every year—enough to stretch more than 680 miles if laid end-to-end. And that's just one distributor. The handful that you have shown would not even equal one-tenth of 1 percent of what the number of products he handles every single year.

His focus—and the focus of all of our members—is to provide much-needed products at the most competitive price they can while still making a modest profit. If they did anything else, they would be out of business very quickly.

3. Fake Pharmacies

Under law, pharmacies are allowed to sell a small portion—5 percent or less—of their inventory to distributors, as long as they comply with state regulatory requirements. In most cases, pharmacies take advantage of this law to sell drugs that will expire within 90 days that they do not believe they can dispense in that timeframe. Instead of letting them go to waste, many pharmacies will sell the products to an authorized distributor—both small, independent companies, as well as large wholesalers—at a discounted rate. The authorized distributor, in turn, will sell it to a hospital, medical clinic or physician office that can use it immediately.

Ultimately, this practice is a win-win—drugs don't go to waste, pharmacies don't lose large quantities of money on products that are expiring and providers are able to get pharmaceuticals at a discounted rate. This is a legitimate and necessary practice, and is not a fake pharmacy.

Unfortunately, there is a small group of people out there who have discovered this and have set up a few "fake pharmacies" across the Nation. Fake pharmacies are those that buy and sell pharmaceutical products, but do not actually dispense drugs to patients. Let's be clear here—dispensing pharmacies that exercise their right to sell a small portion of their inventories are legitimate. Only those that do not dispense drugs are fake pharmacies.

It is the position of the NCPD that fake pharmacies are detrimental to the integrity of the entire health care supply chain. The coalition and its member companies constantly looking for companies operating in the black market and report any company they believe is operating a fake pharmacy.

Further, it is the position of NCPD that legitimate pharmacies that sell a small portion of inventory into the supply chain are working to ensure that every drug in the supply chain is available to people in need and these operations should not be under scrutiny.

Role That NCPD Members Played In Distributing Short-Supply Drugs

Much activity has driven these secondary relationships that have been the realities for the pharmaceutical supply chain during this period of increasing short-supply of critical drugs. One of the practical circumstances that have fed the expansion of these relationships in the secondary distribution industry is the fact that this industry of small suppliers primarily serves as a safety-net or back-up supplier to all hospitals, both large and small in the U.S. Add to that, the fact that this industry is the primary supplier of all drugs to smaller medical facilities, doctor's offices and pharmacies. Despite their crucial role in getting life-saving drugs to critically ill patients, they are also on an individual basis, one of the smallest customers of the "traditional" wholesalers that do billions of dollars of sales to these large hospitals and are required to pay the highest acquisition cost offered in the U.S. supply chain. As a practical matter, every sector of the healthcare industry depends critically upon secondary distributors due to the fact that they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply.

During the protracted recent drug shortages, customers of the Big 3 wholesalers were placed on product rationing based upon historical purchase volumes. For the secondary distributors, who may by necessity have much smaller average monthly purchase volumes, this often meant receiving only a handful of items each month under rationing process—certainly not enough to satisfy the demands of the smaller facilities who depend upon the secondary distribution industry. Importantly, it also meant that secondary distributors were unable to meet the monthly purchasing minimums required to maintain a Big 3 account (not to mention those direct manufacturer accounts with similar minimums). The Big 3, other large ADR distributors and many manufacturers used the inability of secondary distributors to meet these

minimums as the justification for broadly terminating or closing secondary distributor's accounts during 2010, 2011 and 2012. The real impetus underlying these terminations, however, appeared to be a desire of these larger entities to distance themselves from the widespread negative publicity about secondary distributors that had been engendered by the media and other's false and misleading report alleging "price gouging."

Despite losing their primary Big 3 accounts, the primary customer base and their loyal, secondary customer base continued to need critical medications to treat their patients. As a result secondary distributors found themselves clamoring to develop new supplier relationships that could replace the loss of their Big 3 accounts and ensure that these medications continued to be available for the health and welfare of underlying patients. These practical realities, as much as anything, drove increasing use by the secondary distribution industry of accepting short-supply drugs from multiple distributor links reflected on a small number of pedigrees that have surfaced during this committee's investigations. However, given that these secondary suppliers do thousands for transactions per month leading to hundreds of thousands on annual basis, only a handful of these transactions seem to have been outside their normal distribution channels that in reality are pedigreed from the manufacturer . . . to an ADR wholesaler . . . to a distributor . . . to another distributor . . . and ultimately to the end dispenser.

Doing The Right Things

Many of the assertions made in recent reports include activities that are illegal and would cause a small distributor to lose its license, but more importantly would cause them to lose their loyal customers that support the business model of their entire segment.

The NCPD members have stayed in business for the last 20 to 30 years (and even longer for some) because they bring a valuable service to their loyal customers. They know if they are perceived as "price gougers" and "profiteers", they will not get repeat business and their goals depend on that customer coming back to them month-in and month-out, not just in times of drug shortages. Again as a practical analysis of this segment would show, primary wholesalers guarantee to supply 98 percent of the non-backordered products 98 percent of the time, not 100 percent. Therefore, the business model for secondary distributors depends on them doing the right things, at the right times and keeping their customers coming back every month.

If the implications that these companies routinely charge prices that are in excess of their usual and customary cost of the drugs plus a mark up that covers their higher cost of ordering, receiving, handling, packaging, shipping and special delivery that equates to their business model based on price gouging and profiteering, they would not have repeat customers—nor would NCPD be standing here today defending that practice.

What we are saying is that drug sales and distribution is a complex market with many key players and at times on the surface, an analysis will find the anomalies, the special circumstances where higher mark-ups were passed from one distributor to another or a cost averaging model is used to achieve an average net profit on all items in certain categories. These selected examples are just samplings that reflect an example of what happens in a situation where a reaction to supply and demand rarely has anything to do with suppliers taking advantage of customers, but more to do with reacting to market conditions that included rationing, loss of access to products from normal supply chain and finding a solution to getting a critically needed product to fill a high demand request of a hospital that had a patient in life-threatening situations.

NCPD represents the interests of small and independent reputable distributors. All member distributors go through a thorough background check and must meet all licensing standards. The NCPD and its members condemn all drug distribution activities conducted by "gray market' distributors including stealing and selling drugs, setting up "fake" pharmacies, buying back drugs and reselling them, stockpiling drugs that are needed, and gross "profiteering." The NCPD is actively and aggressively lobbying in support of the most comprehensive and stringent Federal pedigree standard for the industry. As part of this, the NCPD has pushed for enhanced licensure standards and penalties for all distributors who fail to comply with laws and standards.

The NCPD recommends that hospitals work with their trusted secondary distributor to fill needs that primary distributors may not be able to provide and to report offers from a distributor they do not know or medicine that is offered at priced well below or well above that offered by other distributors to regulatory agencies.

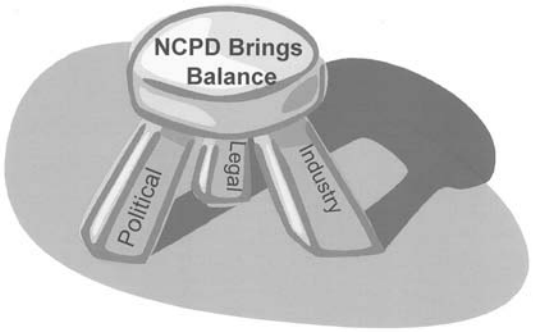
Thank you Mr. Chairman, Ms. Ranking Member and members of this committee.

Background Material
Independent Distributor Industry Survival Challenged
in 2012 by "Gray Market" Branding

United States Senate Commerce Committee
Hearing July 25, 2012

Prepared by Patricia Earl
NCPD Industry Consultant and
Secure Pharma Distributor Network
Principal and CEO

2006 National Coalition of Pharmaceutical
Distributors Stood up and Fought for Orphaned
Small Distributor 's Existence at FDA



Outreach for Industry, Policy Makers and Legal Protection

Who is the NCPD?

- Small, independent, reputable distributors that are regulated by the FDA, the DEA and every state in which we operate
- Produce pedigrees for all Rx products distributed
  - Range from 100,000 – 1,000,000 and more annually
- Engage in current good manufacturing practices
  - VAWD Certified through National Boards of Pharmacy
- Provide heightened product quality assurance
  - Follow same warehouse SOP and shipping as BIG3
- NCPD members adhere to bright, black and white regulations

Basic Principles of Supply and Demand

- The healthcare market is not immune to the basic principles of supply and demand. Supply represents how much the market can offer. The quantity supplied refers to the amount of a certain drug manufacturers are willing to supply when receiving a certain price. Price is a reflection of the supply and the demand. When there is a shortage, bad actors try to take advantage of the situation.
- NCPD members do not engage in price gouging behavior even though market conditions are ripe for it <u>because</u> they know it is inherently bad business to "gouge" customers that you want to come back and buy from you next week.
- You can't stay in business long unless your prices are fair and competitive and that is how NCPD members have done business with their long-standing relationships.

Small Distributors Act in a Clearinghouse Capacity to Fill the Gap for Shortages

- Dr. Scott Gottleib, former FDA Administrator gave supporting testimony in Senate Finance Hearing on 12/7/2011 that this industry has been providing a ***"clearinghouse to reallocate the finite stock of drugs remaining when manufacturer has no supply to ship."***
- They can react quickly when bottlenecks created by the largest distributors are not able to supply.
- Certainly, "big" has advantages for the system, but to unfairly drive small distributors out of the supply chain will hurt providers and patients given the fact that they have been the only reliable, licensed sources for reallocating product in many life-saving situations.

2011Pharmaceutical Distribution Channel

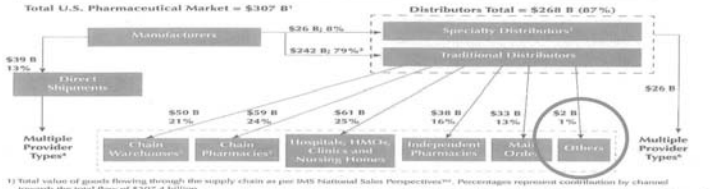
**See HDMA 2011-2012 Factbook & "The Role of Distributor in U.S. Healthcare Industry

Drug Distribution is a Complex Market with Many Key Players

Prescription pharmaceutical sales revenue moving through all distributors increased at a CAGR rate of 5 percent between 2006 and 2010. Significant growth in the generic and specialty drug segments drove this increase. The growth of the specialty segment,[a] at 69 percent CAGR, was particularly explosive — the fastest-growing category in pharmaceuticals. In fact, industry observers expect this to represent 50 of the top 100-selling drugs by 2016.[a] Generic drug sales revenue flowing through distributors grew at 5 percent rate, and this segment is expected to continue to grow — at an 8.6 percent CAGR between 2010-2014[10] — as more branded drug patents expire and additional demand shifts to generic products.

Figure 4 shows the multiple providers by sales volume that distributors serve in the healthcare supply chain.

FIGURE 4: Flow of U.S. Prescription Sales ($B) and Contribution by Channel (%) in 2010



1) Total value of goods flowing through the supply chain as per IMS National Sales Perspectives™. Percentages represent contribution by channel towards the total flow of $307.4 billion.
2) Total value of goods flowing through traditional distributors, *2011-12 HDMA Factbook* (Tables 1 and 3) — excludes all non-prescription products, and sales to other distributors.
3) Specialty distributors' sales and definition from Center for the Healthcare Supply Chain Research. *2010 Specialty Pharmaceuticals: Facts, Figures and Trends*, 2010.
4) Manufacturers ship directly to multiple provider types, including those served primarily by pharmaceutical distributors.
5) Chain pharmacies include national and regional drug store chains, mass merchandisers and food stores. Chain warehouses represent centralized warehouses for chain pharmacies.
6) Specialty distributors provide services to many provider types, including physicians' offices and clinics, home care providers, hospital pharmacies and specialty pharmacies.
Sources: Center for Healthcare Supply Chain Research. *2011-12 HDMA Factbook* (Tables 1, 3 and 109), IMS Health, Inc., Booz & Company analysis

[a] Specialty products are generally defined as products having four or more of the following characteristics: typically high cost ($600 or more per month); require special handling, storage and delivery; generally biologically derived; available in injectable, infused and occasionally oral forms; dispensed to treat individuals with chronic or rare diseases; have complex treatment regimes that require ongoing clinical monitoring and patient education; frequently have limited or exclusive product availability and distribution; used to treat therapeutic categories such as oncology, autoimmune/immune and inflammatory conditions.
[9] Walgreens Analyst Day report November 2010, IMS Health, Inc.
[10] Datamonitor, Global Generics report 2010.

THE ROLE OF DISTRIBUTORS IN THE U.S. HEALTHCARE INDUSTRY

See The Role of Distributors in U.S. Healthcare Industry, A 2011 study prepared Booz & Company, HDMA 2011-12 Factbook

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GRAY MARKET DRUG REFORM AND TRANSPARENCY ACT of 2012

- Drug distribution is a complex market with many key players. Secondary distributors fill a gap that the large distributors can't service.
- Service less profitable rural regions and smaller providers that the large players will not service (i.e. minimum $20,000 - $50,000 monthly).
- Are required to pay much higher prices than large distributors which often receive chargebacks and rebates under large GPO contracts.
- Small distributors are "blocked/restricted" by the manufacturers and the GPO's from selling these contract items at the exclusive, often artificially-loss leader contract pricing between GPO and selected partners.
- Comparing prices offered under GPO contracts to those offered by small distributors is like comparing Walmart to the corner mom-and-pop store.

What is NCPD Trying to Accomplish?

- NCPD supports federal pedigree legislation. Its members are the only companies required to authenticate drugs and pass pedigrees since 2006.
- Supports the serialization of drugs for national track and trace system both at lot level and with 2D bar codes. Many of its members serialize drugs today for tracking and billing purposes where distribution in small unit of use packs.
- Actively lobbying since 2006 in support of stringent federal licensure standards and penalties for those who fail to comply with laws and standards
- Condemns all activities by gray market including stealing and selling drugs, "fake pharmacies" buying back drugs and reselling them, stockpiling drugs that are needed and gross "profiteering."

Role of NCPD Member in Distributing Short-Supply Drugs

- Served as back-up, secondary, safety-net.
- Many drugs were being rationed by manufacturers and large wholesalers.
- Member buys from same wholesalers.
- They were rationed due to size and accounts closed by wholesaler due to negative publicity.
- They had to find new suppliers and use multiple distributors when purchasing product for hospitals.
- Accepted higher mark-ups on critical products in order to fill the immediate need of a hospital.

Pricing Perception is Not Reality

Small distributor does not "profiteer" and full analysis data will dispel claims that price gouging is normal business practice:

- Estimated revenues are about $13Mil.
- Average net operating income is about 7.5%
- Average products shipped are 144,000 units yr.
- Average products with pedigrees 144,000 yr.
- Average cost of drugs is approximately $90 unit.
- If mark-up was 200% per unit, would have net operating profits in excess of $20 Mil.
- None of NCPD members have reported net operating profits in excess of 10% of revenues. Many report losses.

NCPD Condemns Fake Pharmacies

- The NCPD does not support bad actors that create fake pharmacies in order to buy drugs from large wholesalers as a retail pharmacy and then resell the products as an intra-company transfer that re-distributes those same products into the U.S. supply chain.
- This is not a legitimate industry practice that is supported by the NCPD or its members.
- These incidents are not common practice and should not be used to punish the companies that do all the right things.

Pharmacy - Distributor Five Percent Rule

- State laws vary broadly in implementing 5% rule.
- Some states will allow a combo license – retail pharmacy/wholesale distributor license .
- NCPD and its members support all state laws and licensing provisions and adhere to them.
- Practical reality of the drug rationing situations during short-supply periods has driven some distributors to utilize the 5% rule to acquire drugs that were needed to meet their customer's needs in critical, life-threatening situations

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We Oppose a "One-Touch" System

- NCPD opposes a "One-Touch" system which would mandate that distributors only buy product from an original manufacturer, such as Pfizer, Teva or J&J etc.
- One-touch would prevent distributors from buying products from Authorized Distributors of Record such as AmerisourceBergen, Cardinal or McKesson because the product would be "touched twice" by two distributors before it was sold to a hospital, clinic or physician's office.
- NCPD members are small purchasers of pharmaceuticals and large manufacturers use the Authorized Distributor of Record (ADR) system to distribute products and require that small distributors purchase from an ADR.

Why Do We Oppose This System?

- This system will eliminate pharmaceutical distributors and, in turn, preclude small clinics and doctors' offices from buying necessary medication.
- Moreover, eliminating pharmaceutical distributors will add to the anti-competitiveness rampant in our health care market.
- It won't fix drug pricing concerns or cure the drug shortage.
- It would create an oligopoly, and you know happens to prices when that happens.

Drug Prices – Price Gouging False Allegations

- Premier Healthcare Alliance's Analysis "Navigating Drug Shortages in American Healthcare" March 20, 2011, Coleen Cherico, et al. leveled an accusation at "gray market" distributors (price gouging).
- As a result of this report and a follow up article, Buyer Beware Drug Shortages Opening Door to Price Gouging by Mike Alkire, Premier Inc. Oct. 15, 2011, "the secondary distributor industry is experiencing yet another unjustified attack on the business integrity of serving small, rural, underserved health care providers, just like them."
- It is disingenuous for Premier to attack secondary distributors, who must pay significantly higher prices for the same drugs that Premier's exclusive distributors get to sell at extraordinarily low contracted prices.

Drug Prices – Deeper Background

- Drug prices are established on an intricate system that is far more complex than most free markets
- Manufacturers set a number of price points for a product, including Wholesale Acquisition Cost (WAC) – lowest price a small distributor can buy the product
- GPO's leverage collective buying power when negotiating with the manufacturers
- Large distributors buy at WAC and sell at GPO contract then get reimbursed from manufacturers to make them whole in transactions
- Small distributors do not receive reimbursements from manufacturers or GPO pricing even if they sell same product to the exact same hospitals
- Loss leaders by GPO who benefits from system is distorting the market. Shortage appears, NCPD member fills need and the appearance is worse than reality

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Small Distributors Inaccurately Portrayed in Price Gouging Accusations…

- The Premier "study" unscrupulously implies that all small distributors are "gray market" because they charge exorbitant mark-ups. Premier omitted the fact that their own exclusionary contracts forced small distributors to pay the highest price from the manufacturers.

- The reality is that smaller pharmaceutical distributors in the U.S. are legitimate, licensed, and highly regulated secondary suppliers to hospitals that need expedited orders.

- In fact, these secondary suppliers have provided a "safety-net" for hospitals when the designated, exclusive primary wholesaler has run short of critical drugs. In other words, when a product is in short supply, secondary distributors fill orders at reasonable mark-ups that are negotiated with their long-standing customers, but without the advantage of the lower, negotiated GPO prices.

- Distributors want repeat business. If seen as gougers, would not get repeat orders. Normal course of business is modest mark-ups.

Premier Reports Uses Threat Tactics to End Business Relationships

- Small distributors buy up available supplies and offer to see them to end purchasers at significantly higher prices
- Going after secondary distributors, now labeled as "gray market" because they have been forced to deal with "hard-to-find" medications.
- They have been labeled "gray market" companies indicating that how they practice business is not illegal, but may have a questionable business model.
- Unsubstantiated accusations are that they hoard medications and prey on institutions desperate for these medications.
- By selling these short supply meds at an exorbitantly higher price than the usual contract price.
- Not the real story.

"Premier has not revised their numbers or provided their analysis"

- Premier submitted this statement on Nov. 29, 2011 to NCPD when asked to put out a corrected press release…
- "To compute the markups, we compared Premier's contracted price to the gray market price. In the case of Pharmaceutical Commerce, the reporter asked whether markups were still significant if they were compared to a vastly more expensive metric – the Wholesale Acquisition Cost (WAC). We were specifically asked if we still saw pricing gouging if we compared the gray market price to WAC. WE DID."
- Even using much high WAC price comparison, we found the gray market marking up propofol between 29% and 729%.
- Premier stated "We deliberately did not use WAC as the comparison in our report because hospitals do not pay WAC for drug products. The calculations in our report are more reflective of the added costs being passed to hospitals, consumers and other payors by the gray market."

Premier Intentionally Distorted Facts

- The failure to use WAC in the comparison is misleading because, as Premier knows since they created the policy, secondary distributors must pay the actual WAC price because of Premier's monopolistic, exclusive practices.
- To not acknowledge the fact that they ignored WAC is leaving out an important, critical element of the analysis. Secondary distributors must pay WAC and to ignore it is an intentional distortion the facts.
- It is disingenuous for Premier to attack small distributors, who must pay significantly higher prices for the same drugs that Premier's exclusive distributors get to sell at extraordinarily low contracted prices.

Effects of Anti-Competitive GPO Practice Lessening Competition

- Manufacturers bid low prices in exchange for sole source GPO awards
- One supplier then corners the market for multiple years of contracts
- Artificial price controls drive competition to discontinue that product
- Limited distribution conspires to drive drugs into commodity exchanges
- Artificially low pricing leads to unnecessary shortages

Propofol is the generic version of Diprivan, the anesthetic drug used in Hospital Operation Rooms

Price: When No-Adverse Market Supply Issue:	On Major GPO Contracts
Manufacturer **A** Published Wholesale Acquisition Cost (WAC)	$5.60
GPO Contract Price	**$0.48**
Discount off Published Wholesale Acquisition Cost (WAC)	$5.12
Percent Discount Savings	**91.43%**

Actual Pricing that a Small Distributor Pays for Propofol when Purchasing for Normal Supply

Price Between Two Distributor Trading Partners, i.e. an ADR to Distributor	No GPO Contract
The WAC Price to Authorized Distributors	$5.60
ADR Invoice Price to Small Distributor	**$6.60**
Cost Plus Invoice Price to Distributor	$1.00
Percent Markup on ADR to Distributor	**17.86%**

Selling Price that a Small Distributor Offers to Hospital at15% Markup on its Purchase Price

Price If Market Supply Channel is Disrupted:	Market Price
Small Distributor Acquisition Price from ADR	$6.60
Sell Price to Hospital - Non GPO Eligible	**$9.25**
Cost Plus Mark-up on Sale to Hospital	**$2.65**
Percent Markup on Small Distributor Price	**40.15%**

This Illustration Shows a 40% Markup to Cover the Costs of Picking, Packing, Handling and Shipping Transactions for Propofol… $2.65 for all services

Cost Impact on hospital pricing as reported to GPO:	On vs. Off Contract
GPO negotiated contract price on APP product	**$0.48**
Non-GPO authorized distributor sale at WAC+	**$9.25**
Additional Cost to Purchase Off-Contract Alternative	$8.77
Cost Impact for hospital reporting to GPO	1827%

Anti-Competitive Leveraging Disadvantage to Small Distributors

- Manufacturer limited contract price and chargebacks to GPO-designated Wholesaler ONLY.
- Manufacturer and ADR set price to small distributor.
- Manufacturer and GPO restrict contract pricing to ADR's only.
- Non-GPO sale is WAC plus reasonable mark-up by small distributor.
- May include higher mark-up% for UPS Overnight, special handling, hazardous, refrigerated.

Conclusion

- NCPD members abide by bright black and white regulations.
- We condemn “gray market” activities and “fake pharmacies” black market activities.
- NCPD members would like to have level playing field to access contract prices – especially in times or national shortages.
- We support the pedigree standard with enhanced licensure standards and penalties for distributors that fail to comply with laws and standards.

Thank you on behalf of NCPD for your time and efforts to listen to the small distributors

Prepared for NCPD by Industry Analyst:
Patricia Earl

About the Author

Patricia Earl, Principal and CEO, Secure Pharma Distributor Network leverages more than twenty six (26) years of senior executive pharmaceutical wholesale distribution industry experience, primarily at AmerisourceBergen to bridge large and small distributors issues and manufacturers to small distributors contracts.

As an industry veteran, she is recognized as an SME in her field and has served as an expert witness in recent federal court cases involving pharmaceutical wholesale distribution of counterfeit and adulterated drugs.

The CHAIRMAN. Thank you very much, Ms. Earl. And from my point of view, you represent the gray market. From your point of view, we're talking about just a few—I should tell you that we have at least 300 pedigrees in our possession, and there are plenty more where they came from.

Now, I want to—because we made life more difficult—to call first upon Senator Klobuchar and then Senator Lautenberg and then Senator Begich.

STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM MINNESOTA

Senator KLOBUCHAR. Very nice. Thank you, Mr. Chairman, and thank you to the witnesses here.

I got involved in this issue a few years ago and introduced the first bill on this in the Senate on drug shortage. We had only a few authors and got more and more support as we went on. Senator Harkin agreed to do a hearing, and I think from there, we were able to get the early notification requirements in place, and I thank those of you who helped us with that issue. And this really came from patients and pharmacists in my state—where we believe you should always have excellent medical care, in Minnesota—that came to me, and we were able to get this done.

But I thank the Chairman for continuing this fight and looking at this critical issue of the gray market, which is clearly a major part of the problem. It's bad enough that we have the shortages. It's even worse to think that there are people who are preying on those shortages and making money off of them.

So my first question is of you, Ms. Herold. Distributors and pharmacies all need to be licensed by the states that they practice in. These licenses dictate the rules by which these companies and providers practice. California is known to have one of the most stringent set of regulations when it comes to the prescription drug supply chain. Even with these rules, your testimony describes a situation where a wholesaler was able to recruit pharmacies to purchase drugs in short supply and then divert them into the gray market.

Is the investigation you described in your testimony an unfortunate anomaly, or is it a frequent occurrence? And how do you think we should fix this?

Ms. HEROLD. I most certainly hope it is not a frequent occurrence. The difficulty we have with 6,200 pharmacies in the state, 400 million prescriptions dispensed within the state during the course of a year, and 500 wholesalers, not to mention what's coming in from outside through mail order or other sources—it's a busy place. We only know what we know. And we exist for the bad 5 percent, let's say, that can't operate without having a regulator in the space to assure that they follow laws, behave themselves, and that the public safety is enhanced by the healthcare providers.

I don't know. I will tell you that we have—I believe it's three other investigations involving the very same thing. We did not find shell pharmacies in this case doing the kind of thing that your committee and Mr. Cummings has found. But we do have shell pharmacies that are bilking our state's Medicaid program for millions of dollars. And when they go out and do an audit—surprise, there's no pharmacy there. Now, where those drugs go, we don't know, either.

Senator KLOBUCHAR. Thank you. I appreciate that and your work.

Dr. Mayhaus, we have a hospital that spent in excess of $1.5 million in extra fees for short-supply products and during the last year had to assign three full time pharmacists to handle the sourcing, shortage guidelines, alternatives, and communications around the shortages. Can you talk about what you think this is costing your hospital?

Dr. MAYHAUS. I think we've spent about $100,000 only over the last year. We've been very good in being able to maintain an adequate supply of drugs. So from a dollar amount of cost of goods sold, it's only about that amount. We spend about 30 percent of our technician time in overtime to manage the drug shortage issue.

Senator KLOBUCHAR. Thank you. And as you know, we have such limited funds right now for care. I just don't think we should be spending it on that.

Ms. Earl, as with any industry, there are good actors and bad actors, and your testimony clearly defends the actions of the distributors. However, what we're trying to do is to figure out how to address the bad actors. We're clearly seeing, as Representative Cummings' chart showed and Senator Rockefeller's investigation has shown, that there are people that are gouging. How do you think we weed out the bad actors from the good actors and get at this problem?

Ms. EARL. You know, one of the aspects of our association, the National Coalition of Pharmaceutical Distributors, is our distributors that are part of our organization all are licensed by the States' Board of Pharmacies. They all work with the FDA if they need to and the DEA. There's a lot of regulations today that guide pharmacies and that could be used to weed out the bad actors.

We do not support the bad actors, you know, the fake pharmacies or anyone who does price gouge. We would just like the paint brush that has been brushed against all small distributors, secondary distributors, to basically take into effect that there are a lot of—you know, hundreds and thousands of small distributors that have been working for 20 years, that they——

Senator KLOBUCHAR. You do acknowledge, though, if we see a case of a 750 percent markup in cost that we have a problem.

Ms. EARL. Well, yes. I would say we have a problem. But I wouldn't say that just because you can look at a pedigree and an invoice that you have found the root of that problem. You know, we have distributors today that have given us some documentation on some of the pedigrees that—when a hospital calls them—and I will give you—you know, I will say thank you to Dr. Mayhaus. My children go to that hospital.

But yesterday or Monday, when we were on the phone for this hearing, getting ready for it, we had an e-mail come to five of our distributors that work with his hospital looking for pharmaceuticals, you know, on a secondary basis. And our distributors do that every day, and they do not price gouge, you know, in the routine normal business. Otherwise, they wouldn't have repeat customers, like Children's Hospital of Cincinnati, come looking for them.

However, there are a lot of complexities and abnormalities in the way drugs are priced and the cost of shipping to receive an order. The inbound shipping to get the order to be able to process it and ship it out overnight to a hospital is sometimes 100 percent or even more for that drug. And that's not taken into effect on a lot of the pedigrees that you're looking at, because you can't see the actual cost of the inbound freight.

Senator KLOBUCHAR. I have to turn my time over here to other people. But, I mean, clearly, there must be some problem here

when we're seeing these markups. Or you don't see a problem at all?

Ms. EARL. I see that there's a problem in the way that the system is designed today. First of all, for secondary distributors, for the small distributors, because of the price that they do have to pay, it is the highest price out there. You know, they don't have the advantage of being able to acquire and sell drugs at the lower price that Dr. Mayhaus's hospital is used to buying them at. So they've got to buy them at a much higher price. And then they've got to pay the cost of processing that drug and the freight to get it there, because it's——

Senator KLOBUCHAR. OK. I just think we are dealing with a lot more than the cost of the freight. And I will turn it over to my colleague.

Thank you.

The CHAIRMAN. Thank you, Senator Klobuchar.

Senator Lautenberg.

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM NEW JERSEY

Senator LAUTENBERG. Thanks, Mr. Chairman. When I think of the situation that's presented, it's the equivalent of having a gun pointed at a person and threatening their health at every turn and seeing, apparently, a network that prospers with this kind of activity.

Ms. Earl, in your written testimony, you claim that your members work tirelessly to make sure that the route from the distributor to the customer is as straight as possible. So you're saying that the price differentials are fair. But this investigation shows that drugs sometimes change hands half a dozen times before reaching patients. Some of these companies never sell drugs to hospitals or patients. They're effectively middle men. It's like a trading market.

How does having so many middle men benefit the patients?

Ms. EARL. I do want to say, you know, we do not support the multiple transactions where it goes through multiple distributors before it gets to the patient. In the norm, our distributors—you know, most of our pedigrees, the thousands of pedigrees that we have that are done, are usually between one or two. You'll see one or two distributors on there.

The multi-pedigrees that you're seeing now are anomalies. They're extreme cases. I saw the one that's up on the board there, and, you know, the first several distributors in there—where you've got five distributors in that chain outside of the manufacturer to the large wholesaler to the pharmacy, you know, they're not our members. They're not in our network.

So how that's getting into their hands—I think we do need to stop what's happening on the fake pharmacies, the shell pharmacies——

The CHAIRMAN. Then don't say they're anomalies. Cancer is an anomaly, but it hurts, and it costs, and people die. So be straight with us.

Excuse me, Senator Lautenberg.

Senator LAUTENBERG. That's all right, because the questions here are being raised. I mean, is the gray marketplace a legitimate part of a mechanism that sells material when they have it, and upping the price, gouging the price? I've learned in this committee that drugs can be marked up as much as 85 times their original price.

Is it your testimony that a markup of that magnitude is justified and appropriate?

Ms. EARL. I do not believe that a markup—I think that there's a lot more that goes into a markup than what you're seeing.

Senator LAUTENBERG. Such as?

Ms. EARL. A markup is not all profit. A lot of that markup is expense that is incurred to acquire that drug and ship that drug.

Senator LAUTENBERG. Well, then, they're part of a price-gouging ring. I mean, if you're saying divide it up enough and everybody gets a piece of it, that's not so bad. But it's what the final outcome is that's the distressing part of this.

Ms. EARL. Well, I didn't say divide it up and everybody should put a markup——

Senator LAUTENBERG. No, but I said it, because that's the way you frame it. You said that no one is making these gigantic profits, or you intimate that no one is getting these gigantic profits. But, nevertheless, there is this chain of people standing there, hands out, taking a little nip in part of this.

And so you have to make up your mind. Is it justifiable that at the end, the patient is there, begging for mercy, begging for life, and having to pay an outrageous price? Now, you may not think it's outrageous, but I think the chairman was very clear to say that it's outrageous to the person who is, in many cases, breathlessly awaiting the medication to arrive that they can afford.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Lautenberg.

Senator Begich to be followed by Senator Thune.

STATEMENT OF HON. MARK BEGICH,
U.S. SENATOR FROM ALASKA

Senator BEGICH. Thank you very much, Mr. Chairman.

And, Senator Klobuchar, to answer your question, in Alaska, our large medical hospital system has chosen to limit their activity, if at all, with the gray market. But it costs another $15 million for operations to deal with the pharmaceutical components of ensuring where they get it and all the things—so just to add that as part of your question to the individual here.

Ms. Earl, I'm struggling here with your testimony. Let me ask you this. If the Committee gave you the list of the 300 folks, companies, would you submit to us if any of those are your members? I know associations like to hold their membership lists. So if we give you a list, will you tell us if any of these are your members? Yes or no? It's not a complicated question.

Ms. EARL. I would ask my NCPD, and they would have to give us permission to do that.

Senator BEGICH. OK. Mr. Chairman, I'd want to put that on the record.

Second, have you ever, out of your association, kicked someone out for this type of activity?

Ms. EARL. I'm not aware.

Senator BEGICH. Have you ever kicked anyone out for any activities that might violate or come in question of their business practices?

Ms. EARL. I will tell you that before we take new members in, we do vet the new——

Senator BEGICH. That's not what I asked you.

Ms. EARL. I know that's not what you asked me.

Senator BEGICH. So of members that are part of your organization——

Ms. EARL. I am not aware that we have kicked any members out.

Senator BEGICH. So all your members are perfect.

Ms. EARL. No. I'm not saying all of our members are perfect.

Senator BEGICH. Can I ask you for the record—I've got limited time here, a very short time here. Can you provide to me or to the Committee, however it works here, anybody within your organization that has violated these types of issues—maybe law or ethically—that you just said this is not our practice—and submit that to the Committee so we can understand how your organization works?

Ms. EARL. I believe we have some members that would be willing to share with you. But we haven't seen the data, so I——

Senator BEGICH. Well, that's what I'm asking. Forget about the report. What I'm asking you—you understand the problem. You said here on the record that seldom do your folks have more than one or two stops to the customer. OK? I'll take you at that, and so show me the data. You must have lots of members who have never done this, so just show me that.

We're asking you now for the data, because you don't necessarily like this data. So I want your data to prove differently. OK? That's my question.

I don't know, Mr. Chairman. I'll just put that out there. I don't know what the right approach is.

Also, you made a comment, "We don't price gouge in the normal situation." Now, I'm assuming you meant you don't price gouge at all.

Ms. EARL. I meant we do not price gouge. It is not a practice of our members to price gouge. If they did, they would be out of business and they wouldn't, you know——

Senator BEGICH. Would they be out of your association?

Ms. EARL. If we had proof that they were price gougers.

Senator BEGICH. And let me just say this. As someone from Alaska, I understand shipping, you know. We're still not part of the United States for some reason for some companies. So I'd buy your argument for a certain point of the debate, but there's no way, because thanks to Congress, we have bypass now that gets to every village in our state at a reasonable rate to deliver products, especially pharmaceutical products. That's why bypass mail is in place.

So we are the most expensive place to get products to, and, you know, you're shipping—pharmaceuticals are easy to ship. And when you talk about overnight in the worse conditions and having to deliver it to the hardest places in the country, Alaska is it. So

I do not buy from a $7 product—and, again, this is one example—to $600. I mean, you have to agree that there is a reasonableness we have to have in the pricing of product. Yes?

Ms. EARL. Yes. I agree there's a reasonable——

Senator BEGICH. Do you believe in a standard—I don't know if this is the right question—but that we should be able to track the pedigree through an electronic system, like FedEx can track everything—I mean, the minute I place an order, within 15 seconds, I know where that order is, to the time it gets delivered to my door from a small company that I've ordered something from. Do you believe in that kind of tracking system?

Ms. EARL. Yes, we do. In fact, our association——

Senator BEGICH. So you support it.

Ms. EARL. Our association supports track-and-trace all the way down to the unit level, which Ginny's state is also supporting at this point. Yes, I do believe that electronic track-and-trace is important. Our association does.

Senator BEGICH. Mr. Chairman, I know my time is up here.

But I guess on the flip side, Ms. Earl, I do recognize there is a need for some of these distributors in small amounts, because the large ones do control a lot of the market. I understand that. And your pricing question—I would encourage you, as many groups that I have worked with—when I was mayor of Anchorage, small cities joined together to create co-ops to buy products at a higher volume, lower price. But put that aside. I recognize that there is a role.

But somehow we have to get at this, because, you know, you talk about people angry, when I caught onto this issue, it wasn't long—I mean, I don't know how many e-mails I've received from Alaskans about drug shortages and pricing of the drug shortages. And for people to take advantage of the situation is outrageous.

Now, maybe a small amount—the point is it's still happening, and we can argue at what degree it's happening. But we need to figure this out, because the supply chain of pharmaceutical goods for health is critical. So I'll just leave it at that.

Mr. Chairman, thank you very much for allowing me a few minutes here.

The CHAIRMAN. Thank you, Senator Begich.

Senator Thune.

STATEMENT OF HON. JOHN THUNE,
U.S. SENATOR FROM SOUTH DAKOTA

Senator THUNE. Thank you, Mr. Chairman.

This issue does seem to be quite wrapped up in the issue of drug shortages. And I serve on the Finance Committee with Senator Rockefeller, as well, and the Finance Committee held a hearing last fall on the topic of drug shortages. And one issue that came up was the current pricing structure in Medicare for injectable medications that uses average sales price. I'm wondering if anybody would like to comment about whether you think that drug shortage issues can be attributed in any way to the pricing structure within Medicare.

Dr. COSTER. Senator Thune, I can tell you from the community pharmacy perspective that those reimbursements for products both in Medicare and Medicaid come down. You tend to see some of the

suppliers get driven out of the market, because as the pressure is put on us, we try to put the pressure on them. And as they get driven out of the market because of the pricing pressures, you will see manufacturers leave the market, which may create a shortage situation.

So we do think reimbursement policy in Medicare and Medicaid can have a direct effect on, at least, pharmacies' abilities to buy certain medications, because if the manufacturers are not able to recoup some of their investments and maintain all the processes they need to comply with Federal regulations, they may just leave the market or go out of business. So we agree that reimbursement can have a direct impact on short-supply drugs.

Senator THUNE. And it also seems that part of the problem stems from questions about the supply chain, which you've mentioned. And I'm curious as to whether you could give your opinion on what measures might be taken to tighten that supply chain. Does anybody want to take a stab at that?

Ms. Herold?

Ms. HEROLD. In California, we have on the books—it will take effect in 2015 on a staggered basis out to 2017 and a half—an electronic pedigree requirement that must start with the manufacturer. Every change of ownership has to be certified into the electronic pedigree, and not only just the change of ownership. The seller certifies into the pedigree that it sold the product to the specific buyer. The buyer specifically certifies to the seller that it's buying the product. That's creating a chain of custody.

And, thus, when we, as a regulator, walk in and scan a product, we can see everywhere that product has been. And if there should be a gap in, suddenly, where the drug was acquired from, for example, we know that the point prior to that is where the introduction occurred. And so it allows us to police the distribution of drugs in California as well as across the nation, because Federal regulators are going to be looking at this, too, that they can use in investigations, because once that product goes across state lines, it's very difficult to track.

And there are rings of these things set up—much like what the FBI did in New York last week. Those products are moving from one location to another location, but almost always across multiple state lines. So it's virtually impossible to track them as a state regulator.

Senator THUNE. How many states have electronic pedigrees?

Ms. HEROLD. We are the only state that has the depth of the requirement that we have. And it is a complex process——

Senator THUNE. Process to get there?

Ms. HEROLD. Yes, it really is. But without that—you need to put the onus on each member of the supply chain to certify they are a legitimate and ethical buyer, and you do that every time you buy or sell a product, because without that, people will slip things in, and you won't be able to do anything about it. And, regrettably, it needs to be done at the unit level, much like the FedEx tracking is. You have to track every single one of those packages, or else you don't know where it is or where it's been.

Senator THUNE. Anybody else?

Mr. Gray?

Mr. GRAY. In our organization, we've been working with Ginny for six or 7 years back to the development of the California law and, most recently, at the direction of the Congress here, for a uniform Federal pedigree. Our position has been since the adoption of California that what we need is a Federal system. It's not enough to do something in California. Our members dealing in all 50 states need some consistency in the business process by which we ship drugs into every state.

And Florida, for example, has a completely different paper-based pedigree system, quite different from California's, but, nonetheless, it's a pedigree system. So we have been proponents of, hopefully, getting the Congress to approve a national uniform pedigree system and work out the technology requirements to do that.

But our members have been advocating this since 2004. And we got perilously close a month ago. We're not giving up the fight on this one yet. We think this can have a large impact, just as Ginny described, as far as how we can keep an eye on all six of those steps and know where these drugs have been and whose hands they've exchanged for security reasons as well as cost.

Senator THUNE. When did California put its pedigree system in?

Ms. HEROLD. Initially, 2004. Then it was pushed back with respect to implementation four times. It started in 2007. It was then moved via legislation to 2009. The Board pushed it to 2011, which it did. And then, finally, in 2008, the current dates were established on a staggered basis so the supply piece could come up in stages. As the product moves through the supply chain, each stage of that supply chain will have an opportunity to make sure their component in it is working.

Senator THUNE. Great. I see my time has expired.

Thank you, Mr. Chairman.

Senator BOOZMAN. Ms. Herold, I was impressed with your testimony. It sounds like you are doing your very best to police a very difficult situation. We appreciate the community pharmacies so much. In places like West Virginia and Arkansas and much of the country, that is the source of healthcare in very small communities. That's one of the most respected professions in the country.

We in Congress are at about 18 percent now. We've worked our way up from 12. So, again, we do appreciate it. This is an important hearing. But we shouldn't lose sight of that.

In your testimony, it sounds like the activities that were going on—and, again, I think Senator Rockefeller described them as despicable and things like that. We would all agree. But those were illegal under the current statutes that exist, weren't they? I mean, it sounded like you got very aggressive and moved on them.

Ms. HEROLD. Our first pedigree law in 2004 included the very provision that we're prosecuting these pharmacies and the wholesaler under—that you don't want a pharmacy in the business of wholesaling drugs. And when it gets over a nominal amount and very limited to address a specific shortage, they've crossed over, and profit becomes the motive, not healthcare. And when that occurs, that becomes a problem, and so we have—we are able to use that.

The problem is in some cases, it's the buyer, the hospital, pharmacy, that has to buy those drugs. It has no way of knowing where

that product has been. And we do not believe that a paper pedigree is a complete solution, because how do you know this piece of paper goes to that bottle?

Senator BOOZMAN. The pedigree—was that put in place for $2 injectables to treat cancer, or was that more put in place for the tremendous problem that we've got now with prescription pain killers and things like that?

Ms. HEROLD. It was actually put in place because patients would go to California pharmacies with a legitimate prescription and often for AIDS or cancer drugs and walk out with a fake drug, because the drug was very valuable. And we couldn't detect where this product came from with any certainty, and we couldn't prosecute at a level we needed to to ensure the safety of the California public. So every single product, whether it's $1 or $6,000 a dose—that product itself has to be pedigreed, with a few exceptions, but pretty much every single unit.

Senator BOOZMAN. Right. And, again, what I'm trying to do is get at the root of the problem, not to address, really, Dr. Mayhaus's problem so much of the $1 or $2 drugs that it seems like are so cheap now—they've been around forever—that it's simply—because of the fact that Medicare and, thus, insurance companies will only pay so much, it gets to the point it's not profitable to make them.

The other problem that I see is if we add another layer—and, again, you guys are doing such a good job in California, and we could encourage the other states. My fear is if we layer more regulation and more hassle on the pharmacists, that increases their cost to the point where they don't want to fool with them because they are such low priced drugs.

Dr. Mayhaus, when you get in these terrible situations, you know, where you're trying to supply medicines to your oncologists in treating these kids, when you reach out to people, what percentage do you feel like are people that are acting in good faith, you know, really busting their tails, trying to get out, to call around and see where the drugs are available, as opposed to the kind of people that we'd like to get rid of?

Dr. MAYHAUS. We would definitely prefer 100 percent of our drugs to come through our primary wholesaler. And as I stated in my testimony, when we determine there's a shortage and we run through our mitigation plan and there's no drug in the market, then we do sometimes call the alternative wholesalers to see if they have a market for that. But we have paid an exorbitant amount of money for some of those drugs.

The Cytarabine situation that I described earlier—our cost was about $12 through our buying group, and we did pay $966 for that. We bought six doses of that drug. It was for one particular patient, and if that patient would not have received Cytarabine, we believe that the outcome of that patient would have suffered.

Senator BOOZMAN. Again, I'm glad that you mentioned that story, because that highlights the terrible problem that we've got and the problem that you face. I guess what I'm wondering is if we get rid of all of the secondary folks, are you still going to face that problem or not?

Dr. MAYHAUS. I believe that the drugs will be available in the primary wholesaler. So if the drug is there, the primary wholesaler

or those distributors should have the drug and not the alternative wholesaler.

Senator BOOZMAN. So you feel like the alternative wholesalers are stocking the drug to the extent that it's causing a shortage.

Dr. MAYHAUS. I do not think that, no. I think the drug is short, and somehow they react to the market. I'm not sure how that happens, but they tend to get the drug sometimes before we even know there's a shortage. But they are not causing the shortage of the drugs, no.

Senator BOOZMAN. Good. And, again, I guess my point is that we can address this problem and we should. I'd like to see the state boards address it—and, again, the pedigrees—for lots of reasons, in the sense of the other problems that we're dealing with with prescription drugs, pain killers, you know, things like that, which would greatly help in that regard.

But I think we're misleading ourselves if we feel that dealing with the secondary issue, which needs to be dealt with for other reasons—to me, it's like a big football game. If West Virginia and Arkansas were playing, and we were both undefeated, you're going to have scalping because you're going to have a shortage of tickets.

So, hopefully, we can work together to make it such—if we can deal with this without overregulating—but also make it so that you're not put in a position where you've got some child that desperately needs care and you're faced with an $8 drug or whatever, paying $900 for it.

Thank you, Mr. Chair.

The CHAIRMAN. Thank you very much, Senator Boozman. Ms. Herold, you don't have this situation in California?

Ms. HEROLD. Actually, we do. But, as I said, we have not found the shell pharmacies operating in this realm, but, regrettably, we have pharmacies that are buying drugs at the behest of a secondary wholesaler. The pharmacy is buying the full allocation available to it from that wholesaler, and if it can, it will buy multiple times from that primary wholesaler so that it can maximize the amount of drug.

They were told in a face-to-face meeting with the sales agent from the wholesaler—and I can't call it anything else but a sales agent—that "we will pay you 10 percent over invoice, but you are helping alleviate a shortage. Patients are desperate, providers are desperate, and you can help."

The CHAIRMAN. But I'm reading here that you have a new law in California that will prevent these abuses.

Ms. HEROLD. It won't prevent them. It allows us to discipline when we identify them.

The CHAIRMAN. And when you discipline them, what does that mean?

Ms. HEROLD. Well, in this particular case, it means we cited and fined up to $70,000 the pharmacies, each, for their behavior. We cited and fined the pharmacists in charge, and, in many cases, they're going to be required to take a 20-hour ethics course so this does not occur. And with the wholesaler, that's still currently under investigation. We have not disciplined the wholesaler yet.

The CHAIRMAN. So whether it's an anomaly or not, if it's just 1 percent or 2 percent or 3 percent, whatever, you treat it seriously, and you find them and find ways to try to stop them.

Ms. HEROLD. I don't think we would become involved with a 1 percent or a 2 percent over invoice that they bought from the pharmacy and then——

The CHAIRMAN. No. I mean of the total pharmacy population.

Ms. HEROLD. Yes. We don't believe it's everyone.

The CHAIRMAN. I know it isn't everyone. But for those who it does affect, you have in whatever your new law is ways to find them and to discourage them from doing that, because they're often—the wife may be the distributor and the husband may be the pharmacist. Right?

Ms. HEROLD. We found exactly what your results of the Committee was in our investigations. And, early on, we reached out to Mr. Cummings, because at the same time he initiated his, we were doing ours, and we found pretty much the same thing. The only thing different was they were different players.

The CHAIRMAN. Very well. We are meant to have a vote starting now, which means we'd better head down.

Mr. Coster, you worked together with David Pryor, didn't you?

Dr. COSTER. I did, Senator, many years ago, and with many of your staff as well.

The CHAIRMAN. I did get a letter a week ago. I wrote him back two nights ago. He's well.

Dr. COSTER. He's doing well? Thank you.

The CHAIRMAN. Yes.

Dr. COSTER. He's a great man.

The CHAIRMAN. A great influence on my life.

I want to thank you all. One thing I regret about this hearing is that there was so much—so many questions were addressed to Ms. Earl, because it means that we didn't—I mean, for example, Dr. Mayhaus, there's a whole bunch of questions I would have liked to have asked you. And you don't really have a problem, so to speak. You always have what you need on hand, and that bears investigation, as to how you manage a hospital successfully like that.

But, anyway, hearings are what hearings are. And in this case, what we're trying to do—we're an oversight and investigations committee here, in terms of this particular hearing. And we're trying to root out bad behavior and disallow bad behavior. We've done that with the health insurance industry, and, as a result of that, they have now refunded about $4 billion of what they thought they could get away with charging to the premium payers.

So, anyway, that's what we do. And I very much appreciate you all taking the time to be here, and I'm sorry we didn't do the questioning more thoughtfully. No, that's not what I mean. Well, we'll leave it at that.

The hearing is adjourned.

[Whereupon, at 4:10 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF ALLAN COUKELL, DIRECTOR, MEDICAL PROGRAMS, PEW HEALTH GROUP, THE PEW CHARITABLE TRUSTS

Chairman Rockefeller, Ranking Member Hutchison, and members of the Commerce Committee, thank you for the opportunity to present testimony. I thank you for holding this hearing and for your efforts to reveal and address risks to our pharmaceutical supply.

Through research and analysis, the Pew Health Group seeks to improve the health and well-being of all Americans by reducing unnecessary risks to the safety of medical and other consumer products and supporting medical innovation.

The focus of my testimony today is the drug distribution system—the weaknesses in the system and the risks of counterfeit and stolen drugs.

In July of 2011, Pew released a report entitled "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs."[1] The report, which underwent extensive external review, was based upon information from regulatory and public documents, peer-reviewed journal articles and interviews with dozens of supply chain experts from numerous perspectives. It was informed by a two-day conference we hosted in March 2011 that included representatives of brand and generic pharmaceutical manufacturers, active drug ingredient makers, major and secondary pharmaceutical wholesalers, chain and independent pharmacies, consumer and health professional organizations, the U.S. Food and Drug Administration (FDA), state regulators and independent supply chain experts.

In our report we explain that numerous entities are involved in drug distribution, and the routes to market are not always simple. Drugs can be bought and sold by one wholesaler or by many before reaching a pharmacy. Drugs may be traded between distributors, and may travel back from distributors and pharmacies in local markets to major wholesalers through sales or returns before ultimately reaching patients. Some drugs travel through repackagers; some are transported by third-party logistics providers who do not actually purchase the drug; that is, the physical movement of drugs does not always conform to transfers of ownership, further complicating drug tracking. This potential for complexity is not inherently problematic, but absent sufficient safeguards bad actors are able to take advantage of weak links in the chain.

Risks to the Drug Distribution System

One of our key findings is that incidents of counterfeiting and drug diversion in this country—while thankfully far less common here than in other parts of the world—are a matter of serious concern.

Just last week, on July 17th, the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale criminal scheme to buy prescription drugs "on the street" from patients, re-package them and re-sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies.[2]

The scheme included medicines for HIV, schizophrenia, and asthma. If the patient labeling was apparent, the criminals would use solvents to remove it. If the medicine's label was damaged or said the drugs were expired, a new, fake label would be printed and applied.[3]

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[1] Pew Health Group. "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs." (2011) *http://www.prescriptionproject.org/after_heparin_report*.

[2] United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs. July 17, 2012. *http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html*. Accessed July 20, 2012.

[3] United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the

Continued

This scheme cost the Medicaid program an estimated half-billion dollars. But this crime is also a serious patient safety issue. Drugs were allegedly stored in inappropriate, sometimes egregious conditions. In some cases pills were removed from the bottles and handled loose[4]—creating a risk for contamination. Disturbingly, we do not know the frequency and extent of crimes like this, but numerous, similar examples have been brought to light over the past decade.

The United States currently has no national system to detect or prevent such incidents. The U.S. pharmaceutical distribution system is sometimes described as a "closed" system, meaning that it is not legal to import drugs that were not manufactured for the U.S. market. However, the system is not closed in the sense that we have over a thousand individual licensed wholesalers, large and small, providing multiple points of entry to the legitimate distribution system. Sometimes medicines are bought and sold numerous times before reaching a pharmacy. Today we have learned about cases where pharmacies are not the last stop in the supply chain, selling drugs to wholesalers for further distribution.

Legitimate companies—manufacturers, wholesalers, and pharmacies—work together to keep drug distribution safe, secure and efficient. But bad actors exist that are willing to take advantage of supply chain weaknesses for profit.

A few additional examples will help to illustrate the nature of the risks.

In another series of arrests this spring, the New York Attorney General announced that a pharmacy in New York had allegedly accepted bribes to purchase drugs sourced from the black market worth over $247 million from shell companies.[5]

Another threat is drug theft. In 2009, thieves stole a tractor-trailer containing 129,000 vials of insulin. This drug, which needs to be refrigerated, disappeared for a number of months before being sold back into distribution.[6] While most of the stolen drug was never recovered, the FDA has said that some of it was found at retail chain pharmacies in Texas, Georgia and Kentucky, having passed through the hands of licensed wholesalers in at least two other states.[7]

In another case, thieves stole $75 million worth of pharmaceuticals from an Eli Lilly warehouse in Connecticut. It was a sophisticated operation, the largest dollar-value loss from a warehouse in U.S. history.[8] The theft was in 2010. Just this spring, those stolen drugs were discovered stored in South Florida.[9] One investigator who spoke at the Pew conference and who is an expert in pharmaceutical distribution crime believes that a scheme of drug thieves is to steal the product then hold it, hidden, for a year or two, letting the alarm die down before selling it back in to the system.

Finally, we have incidents of outright counterfeits reaching unsuspecting American patients. This spring cancer patients in the U.S. were exposed to counterfeit Avastin®—a critical chemotherapy agent used to treat numerous types of the disease. In 2001, counterfeit Serostim®, a human growth hormone used to treat AIDS-related wasting, was found in at least seven states and passed through multiple

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Diversion and Trafficking of Prescription Drugs. July 17, 2012. *http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html.* Accessed July 20, 2012.

[4] United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs. July 17, 2012. *http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html.* Accessed July 20, 2012.

[5] New York State Office of the Attorney General. A.G. Schneiderman Announces Arrests In $274 Million Black Market Prescription Drug Operation. April 4, 2012. *http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-274-million-black-market-prescription-drug-operation.* Accessed July 20, 2012.

[6] U.S. Food and Drug Administration. Update to FDA Alert About Stolen Insulin. August 26, 2009. *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm180320.htm.* Accessed November 12, 2010.

[7] Ciolek, Michelle M., Special Agent, Office of Criminal Investigations, U.S. Food and Drug Administration. Affidavit in support of search warrant. July 21, 2009. *USA* v. *Altec Medical Inc. and RX Healthcare Inc.* Document number: 8:09–cr–00814–WMC.

[8] Forsaith, Chuck. Corporate Director, Supply Chain Security, Purdue Pharma L.P. "Cargo Theft." Presentation, 2010 PDA/FDA Pharmaceutical Supply Chain Workshop. Bethesda, MD. April 26–28, 2010.

[9] United States Attorney's Office, Southern District of Florida. Eleven Indicted in Pharmaceutical Thefts. May 3, 2012. *http://www.justice.gov/usao/fls/PressReleases/120503–01.html.* Accessed July 20, 2012.

wholesalers.[10] [11] [12] EMD Serono, the manufacturer of Serostim,® has since put in place a secured distribution program, with a unique serial number assigned to each vial that must be verified by the dispensing pharmacy.[13] It is an example of how drug distribution security can, and should, be improved.

Finally, your own investigation highlights the potential of the drug shortage crisis to exacerbate existing supply chain weaknesses. When a pharmacy or hospital can't obtain an essential drug from usual channels, they may purchase from unfamiliar sources. This supply chain flexibility is a good thing, and secondary wholesalers play an important role in optimizing distribution. But it also creates an opportunity for bad actors to introduce illegitimate product. We currently lack national standards for wholesaler licensure. Any such standards should address pharmacies that function as *de facto* wholesalers.

A National Serialization and Traceability System to Secure Distribution

The United States lacks strong uniform national standards for licensure of pharmaceutical wholesalers, and we lack a standard system for companies to keep track of our pharmaceuticals during distribution. There is currently no way to check whether an individual vial or bottle is authentic or counterfeit.

Some state laws exist. California has put in statute a comprehensive system that would require manufacturers to put a serial number on each bottle or vial, and would require wholesalers and pharmacies to check the drugs they buy and sell to ensure they are authentic. California's law is scheduled to come into effect three years from now. Despite the strength of the law, a patchwork of state requirements is not ideal either for companies or for consumers.

Congress is now considering Federal requirements for drug distribution security. However a national standard that preempts state laws like California's must not replace them with a weaker standard, especially one that would not prevent patients from receiving the kind of stolen and counterfeit drugs I have just described.

To protect patients, a system must include the following two components:

1. Unit-level Traceability

The key to improved security of drug distribution is knowing who handles the drugs as they move from manufacturer, through a succession of wholesalers, to the pharmacy or hospital and, ultimately, the patient.

Some have proposed a system to track drugs by the lot number, but a lot can contain numerous cases of many thousands of individual bottles or packs of vials. Each case or vial may be sold separately, and tracking by lot does not allow industry or regulators to ever know who bought and sold a given drug through distribution.

Maintaining data about lots *may* provide an *incremental* benefit over the status quo, but it would fail to catch unsafe drugs in many scenarios.

For example, if a bad-acting pharmacy agrees to sell expensive injectables out the back door to drug diverters, regulators that discover those drugs will not be able to tell where the vials left the legitimate system. They will only know the lot number—and this lot of drugs could have traveled through multiple distributors and reached multiple pharmacies.

Also, if part of a lot is stolen and illicitly reintroduced into commerce, a pharmacist or patient will have no way to tell if the product on their shelf is compromised. However if unit-level data is kept, specific stolen unit serials could be identified. Even if manufacturers are willing to recall an entire lot when only part is stolen, shortage situations create a compelling public health argument that recalls be as targeted as possible.

Today, some companies are required to track a drug's transaction history through paper "pedigrees". An electronic system would be a welcome replacement to this paper-based paradigm—Congress should certainly not replace pedigrees with a structure that does less to capture chain of custody than today's imperfect system.

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[10] Serono, Inc. Serostim [somatropin (rDNA origin) for injection]. Press Release, January 2001. *http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173895.htm.* Accessed February 17, 2011.

[11] Otto, Alex. Counterfeit Serostim Found Nationwide. *Pharmacy Today.* American Pharmacists Association. March 1, 2001. *http://www.medscape.com/viewarticle/406804.* Accessed October 13, 2010.

[12] *Dutchess Business Services Inc.* v. *Nevada State Board of Pharmacy.* No. 46345. September 11, 2008. *http://caselaw.findlaw.com/nv-supreme-court/1219556.html.* Accessed February 17, 2011.

[13] Williamson, Joyce P. Statement of Serono before the task force on drug importation. *http://archive.hhs.gov/importtaskforce/session2/presentations/Serono.pdf,* Accessed February 17, 2011.

2. Routine Checking to Identify Diverted and Counterfeit Drugs

Most stakeholders agree that drug packages should bear unique serial numbers. A key reason to do this is so that pharmacies and others who handle the drugs use the numbers to verify the authenticity of the drugs. However, Congress is considering a proposal that would not require these serials to be checked before a drug reaches a patient. This act of checking alone could have prevented the massive criminal recycling of government subsidized drugs—a serial number that has been retired because it has already reached a pharmacy would be caught on its second trip around. Without required checking, a criminal could sell a recycled drug or a counterfeit drug with a fake serial number, and no one would detect it. They could also sell thousands of fake vials with the exact same serial number—real or phony.

Pew supports required authentication of drug products by companies involved in distribution. Required checking would help ensure fake or otherwise flagged serials are caught, and not allowed to make it to patients. In addition to preventing crime, such a requirement would support enforcement of responsible purchasing by wholesalers and pharmacies

Conclusion

The risk of stolen or counterfeit products reaching and harming patients through the drug distribution system is small, but real. Recently, both the U.S. Counterfeit Pharmaceutical Inter-agency Working Group and the office of the U.S. Intellectual Property Enforcement Coordinator have recommended implementation of a track-and-trace system to secure drug distribution against counterfeits in separate March 2011 reports.[14] [15] The impending implementation of California's law creates momentum for a single national standard. We urge Congress to create a robust national system—one that protects patients today and provides the flexibility to ensure we can build upon it in the future.

Thank you, and I welcome your questions.

HEALTHCARE SUPPLY CHAIN ASSOCIATION
Washington, DC, August 2, 2012

Chairman JOHN D. ROCKEFELLER IV,
Committee on Commerce, Science, and Transportation,
Washington, DC.

Dear Chairman Rockefeller:

I am writing on behalf of the Healthcare Supply Chain Association (HSCA) to request that this correspondence be included in the record for the hearing held before your Committee on July 25, 2012. We applaud you for holding this important hearing and examining these so-called "gray market" drug companies that drive up the cost of short-supply prescription drugs. The hearing and corresponding staff report entitled, "Shining Light on the "Gray Market": An Examination of Why Hospitals Are Forced To Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages" provided valuable insight into why hospitals and other health care providers sometimes struggle to obtain short-supply prescription drugs they need to treat patients suffering from cancer and other life-threatening conditions.

We want to clear up any misstatements made by the witnesses for the National Coalition for Pharmaceutical Distributors attempting to blame Group Purchasing Organizations (GPOs). We also want to address any questions or misconceptions the reports mention of group purchasing organizations and the role they play in the supply chain may raise. Specifically, the report cites information from "some observers" that have linked "the broader business dynamics of the generic sterile injectable market to explain the recent shortages." These observers argue that the bargaining power of the GPOs and Medicare Part B reimbursements tied to the "Average Sales Price" cause manufacturers to operate with only very small profit margins." The facts are that GPOs have worked vigorously with hospitals, providers, manufacturers, distributors, the FDA, and Congress to bring critical issues related to drug shortages to light, to help find market-based solutions to managing and preventing shortages, and to help ensure that hospitals and patients have uninterrupted access to lifesaving drugs.

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[14] Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress. March 2011. *http://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf.* Accessed April 22, 2011.

[15] Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations. March 2011. *http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf.* Accessed April 22, 2011.

GPOs negotiate vigorously on behalf of our hospital members and clients. These negotiations are between extremely sophisticated parties, and while GPOs have continually demonstrated our success in lowering prices to bring savings to our members, clients and taxpayers, we do not have the ability—nor would it be in our interest—to force manufacturers into contracts that undermine their ability to deliver product. Drug companies regularly and quickly adjust pricing of GPO contracts when they experience shocks to production, and GPOs manage thousands of price changes annually, both increases and decreases. Drug shortages are a complex problem and one without an easy or overnight fix. GPOs are clearly part of the solution, and we support recent regulatory and legislative activities aimed at solving the drug shortage problems. As an industry, we are committed to mitigating this public health crisis.

In addition, we are concerned that the materials submitted by the witness for the National Coalition for Pharmaceutical Distributors to the Committee contain inaccuracies and statements that should not go unchallenged. We would like to clear up the record on a few key points. For example, it was stated that GPOs limit access for "small distributors or only contract with the "Big 3." In fact, GPOs contract with a range of distribution providers, including national, regional and family-owned businesses. Most GPOs have dozens of distributors on contract to provide members with maximum choice and flexibility. Also, any hospital can purchase off contract any time they choose—they often do so, especially in times of shortage. It is standard practice to include provisions in GPO contracts allowing any member to seek alternatives sources of supply in the instance of a product shortage.

GPOs have been at the forefront of advancing private sector solutions to drug shortages and seeking common-sense policy solutions. The market realities are that some drugs, particularly older, generally low margin generics, may only have 1 or 2 suppliers. The fact that GPOs only contract with 1–2 companies is not by choice. It's because that's all there is to work with. And if one of those companies experiences a problem, we all can see the results. Drug shortages are caused by a variety of reasons, but GPOs are not the problem but rather an important part of the solution.

The Healthcare Supply Chain Association is a broad-based trade association that represents 15 group purchasing organizations, including for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and healthcare provider alliances. The GPO industry stands ready to work with you and all parties to address today's drug shortages. I appreciate the opportunity to correct the record and to share our role in the healthcare delivery system. We are proud of the savings we achieve for our customers and the contribution we make toward containing costs in an unstable pharmaceutical market.

If you have any questions or would like additional information about GPOs, please do not hesitate to contact me. Thank you for your consideration of our comments.

Sincerely,

CURTIS ROONEY,
President,
Healthcare Supply Chain Association.

PREPARED STATEMENT OF MARK SNYDER, CHIEF EXECUTIVE OFFICER, SUPERIOR MEDICAL SUPPLY, INC.

Chairman Rockefeller, Ranking Member Hutchison, I thank you for the opportunity to submit written testimony for this hearing entitled: "Short-Supply Prescription Drugs: Shining a Light on the Gray Market." I commend the Senate Commerce, Science and Transportation Committee for conducting oversight of the important issues surrounding our pharmaceutical supply chain. The serious and protracted drug shortages plaguing this country are undoubtedly a tragedy from the perspective of the patient who cannot obtain critically necessary medication, and all healthcare stakeholders and policymakers who will need to work together to resolve these dangerous shortages in a fashion that can truly benefit *all* patients in every healthcare sector. I strongly support the Committee's effort to help ensure that patients receive the medication that they need and deserve. I offer this written testimony today to discuss the business practices of my company, Superior Medical Supply, Inc. (subsequently referred to as "Superior").

Background

Superior was formed in 2004 as a small family-held company to engage in nationwide wholesale pharmaceutical distribution. Superior suffered substantial losses in its first several years, due to the difficulty of establishing a competitive foothold in

the heavily-consolidated distribution industry. Early on, it became readily apparent that Superior, like most specialty distributors, could not offer competitive pricing in the large and lucrative hospital sector. Despite these competitive challenges, Superior has been able to establish a healthy customer base in its 8+ years as a specialty surgical distributor catering to the non-hospital sector. Because of this specialized customer base, Superior's single largest inventory component is injectable medications, especially sterile injectables used in the operating room, most of which are produced in a generic, non-branded form.

Today, Superior plays an important and indispensable role in the pharmaceutical supply chain primarily serving these smaller surgical facilities operating outside the hospital sector, including those facilities in more remote locations that are not well served by the larger primary distributors, including the Authorized Distributors of Record or "ADRs" for the drug manufacturers. Superior's business model focuses on providing pharmaceuticals to these smaller medical facilities that otherwise cannot acquire them in the primary distribution market. The necessity of the smaller more flexible wholesaler couldn't be more apparent than it is today, with monthly minimum purchasing requirements by the major wholesalers often exceeding $100,000/month for a direct account, thus excluding most smaller facilities from participation in these accounts.

As a specialty wholesaler, Superior currently serves hundreds of these small facilities as a primary—if not only—source of necessary medications, while also servicing thousands of other facilities, both large and small, as a supplemental or "secondary" source of supply. In many cases, Superior provides a very low volume of medications (such as one or two vials) to a facility in need, and necessarily incurs substantial overhead expenses in operating this low-volume, high-cost specialized service throughout the entire U.S. But, as noted, many of these smaller facilities necessarily depend upon the services of Superior and other specialty distributors to obtain their medications. If these smaller medical facilities and private physicians are to get the medications that they—and their patients—desperately need, secondary wholesalers like Superior must meet this demand.

Superior prides itself on offering its customers the most favorable pricing possible under then-prevailing market conditions. As a smaller distributor, however, Superior must pay a proportionally higher "Wholesaler Acquisition Cost" or "WAC" to acquire its pharmaceutical supplies than the larger wholesalers—and this is generally true regardless of whether acquired directly from the manufacturer itself, a large primary wholesaler, or another secondary wholesaler. Like many specialty distributors, simply Superior lacks the economy of scale to qualify for more favorable volume-based pricing from many drug manufacturers and larger wholesale distributors and ADRs. As a result of this market dynamic, Superior's customer pricing tends to be significantly higher than the larger wholesalers and ADRs even under normal market conditions where there are few critical drug shortages. The concentrated critical drug shortages, however, have made it more difficult and expensive for everyone to obtain their medications, including Superior's specialized customer base.

The medical and surgical facility customers of Superior definitely value the important service that they receive. Superior has a series of written customer testimonials which illustrate the strong regard that Superior is held in by its customers (sample testimonials can be viewed online at www.superiormedicalsupply.com). Some of these customer testimonials also highlight the difficulties faced by the customers who rely upon specialty distributors like Superior, including the escalating drug costs caused by these critical shortages. For example, as an attachment to this written testimony (Exhibit #1), I provide for the hearing record a recent testimonial from a surgery center in Casper, Wyoming, which both thanks Superior for its indispensable services but also bemoans the lack of better pharmaceutical availability and pricing to smaller facilities. I am attaching this exhibit for inclusion in the hearing record.

Drug Shortages

I described above how Superior's business model serves many smaller surgical facilities as a primary source of their pharmaceuticals, particularly sterile injectable medications used in virtually every operating room in this country. This means that Superior's customer base competes directly with the hospital sector for many of the same necessary OR drug supplies. To meet the needs of its specialized customer base, Superior has expended substantial time and resources in developing an extensive supply network that can offer its customers the best drug pricing possible under then-prevailing market conditions, particularly for generic injectables.

As manufacturer backorders and other shortages of pharmaceuticals have intensified, however, Superior has found it increasingly difficult, if not impossible, to locate certain medications at favorable wholesale prices through the customary channel of

the larger primary wholesalers, including ADRs. These large wholesalers operate on a "just in time" inventory system that maintains only about one (1) week of stock on hand, so that when a drug shortage strikes the market, their inventory is almost immediately exhausted by the sudden spike in demand. When this happens, Superior is forced to purchase these backordered pharmaceuticals at a much higher price on the open market, or in other words, from other secondary wholesalers who have them in stock at the time.

Thus, due to the Company's specialized customer base, the shortages that you are now investigating have placed Superior squarely in the "hard-to-find" or backorder drug market as a matter of necessity. According to a recent Health and Human Services report, "in 2010, there were 178 drug shortages. . . . Currently, shortages are concentrated in the area of sterile injectable drugs, 132 of which are now in shortage." Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Development, U.S. Department of Health and Human Services, *Economic Analysis of the Causes of Drug Shortages* at 2 (October 2011).

Thus, even though Superior's business model is not focused upon servicing the so-called "hard-to-find" drug market, our participation in this particular market has necessarily increased substantially because of the concentration of these shortages in sterile injectables. These critical drug shortages have been so protracted in the generic injectable market, in fact, that Superior is now forced to acquire most of its inventory on the open market from other secondary wholesalers, rather than through its direct accounts with drug manufacturers and ADR wholesalers at a more favorable wholesale pricing. This market reality prompted Superior to form its Backorder Management Division to offer expertise in this "hard-to-find" marketplace as a specialized customer service. This group is specifically tasked with locating and acquiring backordered pharmaceuticals that our customers need and cannot otherwise locate. Though important to our customers, this service has not supplanted our primary model of distribution to our smaller medical facility customer base.

It is important to note that this service is almost entirely reactive (not proactive). In response to customer requests, Superior expends substantial time and significant labor cost to locate the desired medications on the open market at the best price then available, but as a practical matter, this price point is always significantly higher than the price that would be paid under normal market conditions when Superior is able to obtain medications directly from the manufacturer or primary ADR wholesalers. Superior typically purchases these backordered medications only if the customer authorizes the particular purchase price. Superior typically receives hundreds of requests per week from both established and prospective customers desperately seeking these backordered medications.

As the success of this Division grew, so did our customer base. Through customer referrals, industry word of mouth, and an outreach program, many hospitals too began to find value in utilizing Superior to fill in the gaps of medications that they could not acquire though their primary wholesalers. Over the last several years, and as the shortages had worsened, the customer base of hospitals that utilized Superior in this supplemental or secondary capacity had grown to several hundred customers strong. However, with the widespread publicity focused on secondary distributors servicing hospitals, Superior and many other specialty wholesalers have found it necessary to pull back from servicing hospitals as a matter of business survival. Many specialty distributors around the country have suffered substantial lost business from this negative publicity, forcing many to lay off more than half of their staff members in order to survive. Superior has now reduced its hospital base to only a handful of preferred customers, and intends to ultimately cease all distribution into this sector to minimize further business losses. Superior is not alone. We now receive numerous calls daily from hospitals around the country desperately seeking drugs.

Although there are several drivers for drug shortages ranging from raw material deficiencies to manufacturing plant closures, the most prominent shortage type in Superior's experience revolves around regional shortages. As noted above, the large primary ADR wholesalers operate on "just in time" inventory systems that maintain minimal stock on hand at any given time. In the hospital sector, virtually every hospital belongs to a Group Purchasing Organization or "GPO," which obtains preferential "contract" drug pricing for its hospital members by leveraging their collective purchasing power and negotiating extremely favorable direct pricing from the drug manufacturers. The GPO product management and allocation systems are operated primarily by the largest wholesale distributors, which function by separate regional distribution centers ("DCs") spread across the country; each hospital member is typically assigned to a single regional DC to obtain their pharmaceuticals at the favorable GPO contract price This GPO distribution structure is fundamentally flawed due to the lack of flexibility caused by the restrictive pricing and distribution

structure that hospitals are held to under their GPO contracts. This often results in situations where a hospital customer is told that a particular medication is on "backorder" and unavailable, when in fact the same drug may be in stock in other regional DC's of the same primary distributor, and is almost always available from other wholesalers within the region, particularly secondary wholesalers.

In Superior's industry experience, these regional DCs of the largest distributors actually compete with each other intra-company, resulting in a real disincentive to cooperate with each other to alleviate these regional drug shortages. The typical policies of these largest distributors also tend to discourage and effectively penalize—through, for example, cost-prohibitive transfer or service "fees"—GPO hospital customers from acquiring products from another regional DC with product in stock. These situations result in a localized shortage to the hospital that cannot acquire pharmaceuticals through its GPO distributor, and must then go out on the open market to acquire these medications for its patients and necessarily pay a substantially higher price—often hundreds of times more—than the artificially low GPO contract price. This is where Superior and other secondary distributors typically enter the picture in servicing the hospital sector, performing a critical market reallocation function that the inflexibility of the GPO distribution system simply cannot accommodate. While hospitals must pay higher prices to acquire necessary medications from secondary distributors, there are undeniable benefits to the patients who avoid unnecessary suffering and death due to this critical role of distributors like Superior.

Congressional Investigation Into the Pricing of Paclitaxel

On October 5, 2011, Superior received letter from the Ranking Member of the House Oversight and Government Reform Committee, the Honorable Elijah Cummings (D–MD), requesting documents related to our purchase and sale of Paclitaxel. This drug is used to treat breast and ovarian cancer. A subsequent request for this information was made on December 15, 2011 by the following Members of Congress: Senator John Rockefeller, the Chairman of the Senate Committee on Commerce, Science, and Transportation; Senator Tom Harkin, the Chairman of the Senate Committee on Health, Education, Labor and Pensions; and Representative Cummings. We met repeatedly and worked cooperatively with the staff of these three committees, providing them with proprietary and confidential materials regarding these Paclitaxel transactions and Superior's standard business practices.

The greatest area of interest to the committees was the difference in the price Superior had paid to acquire the Paclitaxel and the price it charged when it subsequently sold the drug to its customers. In response to this inquiry, Superior provided data to the committees on its pricing structure and practices. Pursuant to this data, Superior showed that its average gross margin on all of its sales of Paclitaxel was less than 40 percent overall. The committees also expressed particular interest in the higher-priced sales of Paclitaxel. The data provided to the committees specifically showed that, for the Paclitaxel sales in the higher $500.00 range, the average gross sales margin in this price range was less than 25 percent. This data shows, importantly, that market supply and demand will tolerate only so high of drug prices, and that Superior actually makes less profit as a drug shortage worsens and market prices trend upward. In other words, because Superior's primary inventory component of sterile injectable medications has been the class of drugs most affected by the current shortages, these medications have been subject to greater price escalation caused by market supply and demand, resulting in lower operating revenues for Superior than during normal market conditions where few drug shortages exist.

I do not believe that these gross margins are excessive, unreasonable, unconscionable, or amount to "price gouging." This is particularly true given that these gross margins do not account for the substantial overhead costs of running a small business, paying employees, providing them with benefits like health insurance and retirement accounts, or even keeping the lights on in the office. As alluded to above, Superior's overhead costs are higher operating in this low-volume, high-cost "hard-to-find" marketplace, wherein Superior often provides a very low volume of necessary medication—sometimes only one or two vials—to a needy facility (as a practical matter, the high market prices of these "hard-to-find" drugs means that most customers purchase only the minimum amount of medication for their immediate patient needs). Since many sterile injectable medications are produced in glass vials, and sometimes must be kept refrigerated, there are also additional labor and packaging and shipping costs associated with the delivery of these particular drugs to customers. In general, Superior and other small specialty distributors must internalize substantial overhead costs in the form of labor expenses, pedigree authentication and compliance, packing materials, dry ice and other refrigerated packing materials and methods, as well as the high costs of maintaining a common carrier ac-

count (such as UPS or FedEx) to deliver numerous smaller shipments of critical medications across the U.S.

In fact, as shown to the investigating committees, Superior's costs are up substantially while annual revenues have decreased by several million dollars. If given a choice, Superior would strongly prefer not to have to operate in this difficult secondary market, and would gladly return to the normal market conditions that provide more stability and sustainability to its core business model. But Superior still prides itself on supplying its regular customers with all of the medications that their patients need, even if it makes for difficult operating conditions.

When looking at the gross margins on Paclitaxel, several key points must be considered. First, Paclitaxel represents a specialty drug with a need to immediately get it to customers, yet comply with the costly and time-consuming burdens of verifying/creating paper pedigrees, hand packaging glass vials (including, if applicable, additional refrigerated packing), delivering product safely and on time, and then invoicing the customer and subsequently collecting payment. Second, operating a small business in the pharmaceutical industry includes significant fixed overhead and operating costs, such as the following: licensing, insurance, bonds, compliance, pedigree, shipping, payroll, rent, utilities, and taxes, among other things To illustrate, Superior currently maintains 112 different licenses for its distribution operations, and each of these licenses must be annually renewed at substantial expense to Superior and other similarly situated small businesses, yet the costs of maintaining this licensure is roughly the same as expended by the largest wholesalers in this country.[1] Superior is just not big enough to recognize the "economies of scale" that its larger competitors enjoy, resulting in proportionally higher total operating costs for Superior and other small, specialty distributors.

Shipping is one of the particular areas where we find ourselves unable to compete. For example, as shown to the investigating committees, the annual cost to maintain Superior's UPS shipping account ranks second only to employee payroll as its largest annual operating expense. In contrast, the major wholesalers utilize their own internal carriers to deliver product to their customers. They have the luxury of placing their products in plastic totes with little to no packing material as these totes are not being handled through processing centers by common carriers. Each package that Superior ships to a customer must be meticulously packed, often times requiring each unit to be wrapped in bubble wrap, surrounded by paper or Styrofoam material, possibly packed in a manner to maintain adequate refrigeration conditions during shipment, and then placed inside a cardboard box, addressed and shipped. This sort of packaging "overkill" is costly but necessary to ensure that shipments of valuable medications reach the intended patient in time and intact.

Furthermore, even when Superior purchases products under a direct manufacturer or ADR contract, we pay significantly higher prices than larger wholesalers and other volume-based organizations like GPOs. To illustrate, there have been many instances in Superior's existence where, under normal market conditions, we have been able to acquire needed product cheaper on the open market from other wholesalers (even taking into account their additional markup) than we could pursuant to our direct accounts with drug manufacturers or ADR wholesalers. Available evidence suggests that while volume-based discounting is a standard practice in nearly every U.S. industry, drug manufacturers engage in more pronounced forms of price differentiation based on customer type, or "price discrimination,"[2] than in other industries. For example, the Minority staff of the House Committee on Government Reform in 1999 found that price differentials are far higher for drugs than they are for other consumer goods. According to their findings, the average price differential of the specific drugs evaluated was 134 percent, whereas the price differential for consumer goods in other industries was only 22 percent. Minority Staff, Special Investigations Division, Committee on Government Reform, U.S. House of Representatives at ii (November 9, 1999). Superior and other specialty distributors, and the small customers who critically depend upon them, can attest firsthand to the

[1] Under these licenses, Superior is accountable to the rules of numerous administrative agencies and bodies, including but not limited to the various state boards of pharmacy, the U.S. Drug Enforcement Administration, the U.S. Food and Drug Administration, the Federal Aviation Administration, the U.S. Department of Transportation, and others. The costs of complying with these multiple, and sometimes conflicting, laws and rules are extraordinary, including substantial employee training and monitoring expenses.

[2] Price Discrimination is defined as "the practice of charging different prices for the identical product to distinct buyers." *See* Ernst R. Berndt & Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets* at 29 (Harvard Research Working Paper Series, September 2010).

anti-competitive effects of the pronounced price differentials in the pharmaceutical industry.

Response to Release of Exhibits by the Senate Commerce Committee

The Senate Commerce Committee released five exhibits to the public on July 25, 2012. Exhibit III summarized a specific pedigree involving Paclitaxel and Superior's involvement in the distribution of this drug. This exhibit listed Heartland Regional Medical Center in St. Joseph, Missouri as the end user of Paclitaxel in this transaction. As a response to this release of information by the Senate Commerce Committee, I am attaching for inclusion in the hearing record as Exhibit #2 a customer testimonial from Heartland. Heartland is one of Superior's preferred hospital customers and we have enjoyed working closely with Heartland for many years to assist it in locating hard-to find drugs that it cannot acquire from its primary wholesaler. Attached to my written testimony is a customer testimonial that Heartland provided to Superior attesting to the excellent customer service, fair pricing, and overall professionalism of Superior as a specialty wholesaler. Heartland closes its testimonial with the following statement that really sums up the important service that we provide during times of shortage:

> "Superior offers fair pricing that is often better than other similar companies in this business, and they deliver fast and overnight if necessary. Superior Medical recently obtained a very important chemotherapy drug (paclitaxel) that Heartland could not obtain through any other sources. We would not have received the paclitaxel if not for Superior. Superior is able to help us find several different drugs that have been in very short supply recently. We will continue to use Superior Medicals services in the future."

This customer testimonial shows the close working relationship that many specialty distributors like Superior have with the individual hospital pharmacy buyers. These buyers are responsible for maintaining adequate pharmaceuticals to meet the needs of critical patients on a day-to-day basis. As a result, these buyers often have a unique perspective on the real value that specialty distributors can bring to the table in terms of industry knowledge, drug supply trends, inventory management, and meeting the immediate needs of the underlying patients. These hospital pharmacy buyers often have a markedly different perspective on the value of secondary distributors to the hospital sector, particularly during times of drug shortages, than do the hospital administrators or compliance officers who are not involved with the secondary distribution industry on a regular basis and, thus, often do not truly understand the unique value that specialty distributors like Superior can bring to the table for hospital purchasing departments.

Recommendations by Superior to Address Drug Shortages

Superior would like to offer a couple recommendations to address drug shortages.

1. Encourage the use of smaller distributors by the major wholesalers to help alleviate national and regional shortages, as well and to increase the availability of drugs to more remote or less populous regions of the U.S. Also increase the supply channels between the primary and secondary distribution industry so that our customers—and their patients—can readily obtain the critical drugs they need at more reasonable price points.
2. Pass new laws and/or administrative policies to lessen the anticompetitive effects of differential pricing in the pharmaceutical industry, and to level the playing field for the hundreds of small distributors like Superior and the small medical facilities that depend upon them for their critical drug supplies.
3. Implement a nationalized electronic pedigree system and openly support any effort to make this happen. As the current pedigree law was crafted to exempt 90–95 percent of the pharmaceutical wholesale transactions that occur daily, the unilateral burden of pedigree on the secondary distribution industry undercuts our ability to compete with larger wholesalers and offer better pricing to the customers who depend upon us. Because of the pedigree burden, specialty distributors like Superior must process mountains of paperwork each day, raising the cost of product that each pedigree-compliant company transacts in by adding hundreds of man-hours each week. Perhaps more importantly, absent a national pedigree system that applies to all stakeholders in the supply chain from top to bottom, this country cannot realize the Prescription Drug Marketing Act's original promise of a true closed system of drug distribution that can better ensure drug integrity and resulting patient safety.

4. Simplify the license structure for small business pharmaceutical suppliers. Superior maintains over 100 licenses between two distribution centers at a cost no different than what a $100 million company is required to pay. Also simplify the bonds required by the various state boards of pharmacy and other administrative agencies in order to be licensed in this industry. Superior would propose a uniform national bond requirement, with tiered-pricing according to the scale of each licensee. In this way, tiered licensing and bonding overhead costs would level the playing field for small distributors and the customers and their patients who depend upon us.

Conclusion

Thank you for the opportunity to provide written comments for this important hearing.

I understand the objective of the Committee is to better understanding the function of the secondary or specialty wholesalers and Superior does function in this capacity when necessary. However, Superior is genuinely more interested in operating in a market without shortages.

We believe that Superior helps represent an indispensable part of the pharmaceutical supply chain. Our job is to get the drugs to those medical and surgery facilities that desperately need them for their patients. Thanks again for this opportunity.

Enclosure of Exhibits

June 20, 2012

To Whom It May Concern:

It has come to our attention that there is a Congressional hearing coming up that is focused on the rural areas affected by the nation-wide drug shortages. We are writing this letter on behalf of our office only, but those around us have most certainly been affected by this situation as well.

Our doctors have the capability of using I.V. sedation for surgeries in an outpatient setting. While often times patients choose this option out of fear or anxiety associated with a surgery, we also have many patients that require sedation out of medical necessity, i.e. they are disabled, suffering from Alzheimer's or Dementia, etc. We have only a small number of Oral and Maxillofacial Surgeons in the state so we get patients referred to us daily that have to travel to our location for services. As a result of the drug shortages, we have been extremely close to running out of our supply of the medications needed for I.V. sedation on more than one occasion, which could have potentially lead to turning patients away.

Many patients in our area do not have a general Dentist they see on a regular basis because they live outside of city limits or simply cannot afford it so the only time they come in is if they are having a problem. If a patient has an infection or an abscess and is not treated in a reasonable amount of time, it can lead to emergency extractions or other health issues. If turned away from our office, these patients would most likely end up in a hospital or other type of emergency treatment facility. This is not solving the problem, but rather pushing it off onto someone else.

With that said, we were fortunate enough to find a couple of companies that still had or were able to get a supply of the drugs we were desperately seeking, particularly Midazolam, Fentanyl, and Valium at a time when our major suppliers were unable to. Superior Medical Supply was one of those companies. The cost was higher of course, but when it came down to making our patients as comfortable as possible or turning them away, we were willing to pay the higher cost to make it through until the major suppliers could fill our orders again.

We certainly appreciate them for the service they provided us when no one else could and for alleviating some of the stress that has been caused by the drug shortages. It is our hope that regulations will be put in place to prevent this from happening again. After all, the most important thing is patient care and whatever affects us most certainly affects them.

Sincerely,

Anna Ray
Office Manager
Wyoming Oral & Maxillofacial Surgery, P.C.

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WYOMS
The Implant Center

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AUG-08-2012 WED 10:29 AM FAX NO. EXHIBIT 2 . 01

HEARTLAND HEALTH

5325 Faraon Street St. Joseph, Missouri 64506
816.271.6000 tel

Our calling in life is life itself.

To whom it may concern,

Heartland Regional Medical Center in St. Joseph, Missouri is a 350 bed acute care area hospital, and includes over 30 physician clinics within a 50 mile radius.
Our relationship with Superior Medical Supply is very important to us here at the Heartland Pharmacy Department. During the past two years the drug shortages have increased tremendously, making many of the necessary life-saving medications harder to obtain, due to the many manufacturer interruptions.
Superior Medical has been able to obtain several key medications needed to provide continuous care to our patients, which is our top priority.
Heartland has worked with Superior Medical for approximately three years now, since I was introduced to their services at the annual National Pharmacy Purchasing Association convention. Superior is able to obtain and provide many medications that are on back-order or in short supply nationwide. We purchase from them almost weekly in order to maintain supply levels on items we are not able to obtain from our regular drug wholesaler or directly from the manufacturers.
Superior offers fair pricing that is often better than other similar companies in this business, and they deliver fast and overnight if necessary.
Superior Medical recently obtained a very important chemotherapy drug (paclitaxel) that Heartland could not obtain through any other sources. We would not have received the paclitaxel if not for Superior.
Superior is able to help us find several different drugs that have been in very short supply recently. We will continue to use Superior Medicals services in the future.

David Huntsman, CPhT
Pharmaceutical Buyer
Heartland Regional Medical Center
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816-271-6140
816-271-6845 fax

www.heartland-health.com

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. ROGER F. WICKER TO VIRGINIA HEROLD

Question. Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?

Answer. Actually, we see two questions in Senator Wicker's comment. We strongly believe that the questionable transactions involved in the gray market of prescription drugs in short supply that were highlighted by the Committee result from opportunists, and not health care providers, who see an opportunity to make a profit from a supply and demand inequity involving prescription medication. As such, the consequences of engaging in such activity should involve substantial fines or other financial sanctions that cannot be readily discharged. Additional, deterrent sanctions are needed when the transactions are committed by unlicensed entities selling and buying prescription drugs.

In 2004, California enacted changes to pharmacy law to stem one source of drug diversion—to prohibit a pharmacy from acting like a wholesaler, except in limited

circumstances. As a deterrent, the board was granted the extraordinary ability to issue fines at $5,000 per invoice, which correlates a higher fine which repeated involvement in performing prohibited acquisitions or sales. In our experience: pharmacies should be prohibited from engaging in wholesale transactions except in limited circumstances, and correspondingly wholesalers should be barred from buying from pharmacies except in rare circumstances (the latter provision we do not have in law currently).

The answer to the second question—how to tighten the supply chain against questionable transactions—we believe requires greater transparency in the supply chain, and specifically, the tracking of all sales transactions from the manufacturer to the purchaser (wholesaler, pharmacy) in a tamperproof manner. A purchaser needs to be able to review everyone who has owned the product before the sale. Because the supply chain is more of a network than a true chain, this is virtually impossible now to know where a drug has been before purchase.

If a purchaser has the information needed to track (in a tamperproof manner) the product back to the manufacturer, this will aid detection against the sudden, unauthorized entry into the supply chain of a product at a specific point. This is because such insertions would be traceable to a particular owner who did the insertion, and thus serve as a deterrent to unauthorized insertions of any product into the supply chain, making the pharmaceutical supply chain more secure. Such entries are not now readily detected.

In California, such a system is in place via the e-pedigree law, which will take effect on a staggered basis from 2015 through July 2017. The law will require electronic tracking of every owner of pharmaceutical product from the manufacturer to the dispenser.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. JOHN BOOZMAN TO VIRGINIA HEROLD

Question 1. Mr. Coster testified that, depending on state requirements, pharmacies may be allowed to open with a temporary license before regulators conduct an on-site inspection. When dealing with potentially lifesaving drugs that must be handled and stored properly, how does a state board determine whether a pharmacy can open without an on-site inspection? How long can a pharmacy operate without being inspected? If this practice was changed, would it prevent fake pharmacies from operating?

Answer. We had to change our practices in performing pre-opening inspection relatively recently, Since 2010 California now does pre-opening inspections of new non-chain store pharmacies before a pharmacy license is issued. This is a resumption of a requirement that was in effect until approximately 1996 for all pharmacies.

From approximately 1996 to 2010, California discontinued pre-opening inspections of all new pharmacies before a license was issued. During these years, the board viewed pre-opening inspections as providing little value where staff resources could be better deployed after the pharmacy was operating. Specifically, the inspection of a pharmacy before it operates, before it has been issued a license, and before it has been authorized to purchase drugs resulted in the board making visits to sites in pre-1995 inspections where there was little to inspect. Essential functions and operations could not be reviewed because the sites had not been operating, staff were not present and there were no records to review. Instead, the board opted to inspect the pharmacy after the first 120 days of operation, and where the board could cancel the license if there was no pharmacy present (pursuant to California law).

However in 2010, the board reinstituted pre-opening inspections of non-chain store pharmacies due to a flurry of fake pharmacies that once licensed, began to defraud MediCal or divert drugs. The resumption of these inspections has permitted the detection of truly fake pharmacies. The board will continue to conduct these pre-licensure inspections.

To additionally ensure the safety of the public, we also try to inspect pharmacies sometime after 120 days of operation to review their functioning.

Question 2. Does California have any compliance cost estimates for independent pharmacies for the new electronic tracking system?

Answer. No. The few pilots underway between manufacturers and wholesalers do not currently involve many pharmacies, perhaps because e-pedigree implementation for pharmacies will not occur for another five years (July 2017). We expect to see more involvement of community pharmacies in the future once the current pilots involving the manufacturer/wholesaler interface mature.

However, one area in which the board is cognizant of decreased costs is in the area of e-pedigree readers for the serialized product. In discussions with the supply

chain in 2008 and earlier, the supply chain was projecting readers would be required in a pharmacy in at least three different forms (RFID high frequency, RFID ultra-high frequency and 2-D bar code). Some of the readers then in use were bulky and expensive.

Today, we are aware that readers in cell phones are possible, which greatly reduces this cost component to pharmacies, as well as the size of the reader. Moreover, manufacturers are principally using 2-D bar codes to serialize their products, and RFID high frequency is disappearing for this purpose. We expect continual evolution in the technology in this area in the future.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. ROGER F. WICKER TO DR. DAVID MAYHAUS

Question. Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?

Answer.

a. I might recommend a look at the main business market of secondary distributors. Specifically, if their role is to provide pharmaceuticals to community pharmacies, then why do they need to purchase intravenous drugs and chemotherapeutic agent used exclusively in hospitals? There should be some kind of accountability from the manufacturer or primary wholesaler where the initial transaction took place to verify the legitimacy of the purchase of hospital used pharmaceuticals. Cincinnati Children's would not use the secondary wholesalers if the product was available through our primary. Some of our pedigrees have indicated that the initial distributer listed was a primary wholesaler. I was not aware that primary wholesalers sold drugs to secondary wholesalers. If there is a process to determine if the secondary wholesaler had a legitimate market for intravenous drugs used exclusively in hospitals, it may deter this type of transaction.

b. Limiting the number of wholesalers that can handle a pharmaceutical might be something to consider. As described in other's testimony, as the number of wholesalers involved with the drug increased, so did the price. Setting a limit of 2–3 distributors permitted on a pedigree may significantly curtail this activity.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. JOHN BOOZMAN TO DR. DAVID MAYHAUS

Question. How often do you turn down business offers from secondary distributors because you identify inaccurate, incomplete, or unsettling information in your procurement process?

Answer. The buyers at Cincinnati Children's decline the offers of approximately 90 percent of the calls they receive. The reasons are either they are not licensed as a wholesaler in Ohio, too high of price, or the secondary wholesaler wants a purchase order given to them without confirmation of the needed drug in supply. The issuance of a purchase order prior to providing firm confirmation the secondary wholesaler has the actual drug in supply is not normal pharmacy business practice of Cincinnati Children's.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. ROGER F. WICKER TO DR. JOHN COSTER

Question 1. Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?

Answer. There are a number of actions or measures that could be taken to tighten the supply chain. These could include making sure that all pharmacies must have an actual on-site inspection prior to being allowed to open. This would ensure that the pharmacy is, in fact, an operational and legitimate pharmacy and not a "shell" pharmacy. In addition, NCPA has gone on record in support of Federal standards for wholesaler licensure.

A number of years ago, there was a flurry of publicity around the fact that in many states, the licensure requirements necessary in order to operate as a drug wholesaler were not terribly consistent or robust. In response, many states took the necessary steps to tighten up or increase these requirements in order to provide a

greater degree of assurance that only legitimate entities were operating in this area. That being said, there are still some states in which the wholesaler licensure requirements are more rigorous than others. Uniform, Federal requirements for wholesaler licensure would create a consistently high standard for these entities across the country.

NCPA has also publicly stated its support for a lot-level form of tracking for prescription drugs that could be used in the event of a recall or to investigate suspect product. Such a system would make it much easier for each participant in the supply chain to keep track of exactly who products are purchased from and subsequently sold to. In addition, NCPA feels that there should be a greater emphasis on the importance of all participants in the supply chain to perform their due diligence with respect to their business partners.

Question 2. Is there a valid reason why a pharmacy may sell a small amount of his or her inventory to either another pharmacy or perhaps even to a wholesaler, and do the states address this issue in a consistent manner? In light of the types of activities we have heard about, should these practices be allowed to continue?

Answer. Many state pharmacy practice acts recognize the value of allowing pharmacies to sell small amount of his or her inventory to another pharmacy in order to alleviate temporary shortages. In addition, some states also permit appropriate licensed pharmacy sales to wholesalers as well to alleviate temporary shortages. In addition, a pharmacy may sell a product which is close to the expiry date to a wholesaler who has a client with an immediate need, to ensure that the product will not go to waste and can actually be used for patient benefit. This is also critical for small pharmacy owners due to the significant amount of capital that is tied up in inventory stock.

States do not address these issues in a uniform fashion. There are some states that specifically allow these types of sales or exempt these transactions from the state definition of wholesale distribution. There are other states that allow these types of sales but only in instances of the existence of an actual patient need or as long as a pharmacy does not sell over a certain percentage of their inventory. NCPA feels that greater clarity or consistency from state to state in how these types of transactions are allowed would certainly be helpful. No pharmacy, whether fake or legitimate, should be in the business of acting as a conduit to facilitate the activities of a gray market or placing specific orders with a primary wholesaler for the sole purpose of immediately selling to a secondary wholesaler.

NCPA does feel that pharmacies do need to have the option to engage in these types of sales in certain circumstances in order to address temporary shortages in the workplace and to respond to patient needs. We feel that any remedial action taken to prohibit the types of activities highlighted in the hearing should be narrowly tailored. We urge Congress to not take any overly broad actions that might limit the ability of pharmacists to take care of their patients or manage their inventories.

Question 3. Is there a valid role for secondary distributors in the market? If so, could you elaborate on ways in which your members utilize these entities?

Answer. Yes, NCPA feels that there is a valid role for secondary distributors in the market. Most community pharmacies rely on a primary wholesaler to meet the majority of their ongoing prescription drug needs. However, community pharmacies typically need to have at least one or more backup or secondary wholesalers that they can call upon in the event that there is a shortage. "Primary wholesaler" generally describes entities that purchase the vast majority of their product directly from drug manufacturers. This market is highly concentrated—the "big three" wholesalers generate approximately 85 percent of all revenues from pharmaceutical wholesaling in the United States. "Secondary" wholesaler generally describes distributors that do not purchase the majority of their products directly from a pharmaceutical manufacturer. Most manufacturers typically limit the number of entities that they will sell to directly and most do not sell directly to smaller companies that are not interested in purchasing extremely large, bulk amounts. Secondary wholesalers play an important role in the industry by serving as a "back-up" source of supply to pharmacies who may use a primary wholesaler for their usual and expected day-to-day needs and also provide necessary competition for the primary wholesalers which helps keep costs down. These entities also frequently specialize or focus on a subset of the market, such as a geographical region or specific product categories such as differing types of specialty drugs such as oncology or HIV.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. JOHN BOOZMAN TO DR. JOHN COSTER

Question 1. Do you think that a national pedigree or track and trace system would prevent nefarious activities by wholesalers or fake or real pharmacies with respect to the buying and selling of shortaged drugs?

Answer. It is important to recognize that no system, whether a national pedigree or track and trace system would solve all problems or "loopholes" that may exist in the pharmaceutical supply chain. NCPA favors a multi-pronged approach to bolstering the integrity of the supply chain including uniform, Federal licensure standards for wholesalers, cracking down on illegal Internet pharmacies as well as a lot-level form of tracking for prescription drugs that could be used in the event of a recall or to investigate suspect product. In addition, there needs to be a greater emphasis on each sector of the supply chain to thoroughly "vet" their trading partners—their suppliers and their customers.

Question 2. What track-and-trace system do small pharmacies support and why? How will such a system improve the supply chain?

Answer. NCPA supports a lot-level form of tracking for prescription drugs that could be used in the event of a recall or to investigate suspect product. This system, known as RxTEC, is the result of a year-long effort by a multi-stakeholder workgroup that sought to create a system that would recognize both tangible safety improvements and appropriate industry burden.

Implementation of this type of system would make it much easier for each participant in the supply chain to keep track of exactly who products are purchased from and subsequently sold to. NCPA does not at this time support the electronic tracking and tracing of prescription drugs at the unit level due to the costs of the hardware and software to small businesses that would be required to set up and maintain such a system as well as the significant time and labor costs associated with its implementation.

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION
Arlington, VA, August 31, 2012

Hon. JOHN D. ROCKEFELLER,
Committee on Commerce, Science, and Transportation,
Washington, DC.

Dear Chairman Rockefeller:

Thank you for the opportunity to testify before the Senate Committee on Commerce, Science and Transportation on July 25, 2012 at the hearing entitled "Short-Supply Prescription Drugs Shining a Light on the Gray Market." I have attached my response to the Questions for the Record forwarded to us by your staff.

As a result of the Commerce committee hearing and release of the *"Shining Light on the Gray Market"* report, we understand that responsible pharmacies are more acutely aware of the potential impact of drug shortages on patient health and may be ending their practices of reselling product, to the extent they had previously done so. While this is a very positive development, we are encouraging our members to remain vigilant for any change in tactics from gray market suppliers. These gray market entities may pursue other avenues to obtain drugs in short supply, such as through veterinary and dental providers.

In fact, the Federal Trade Commission is convening a workshop to examine certain veterinary drug prescribing and distribution practices, including instances in which "veterinarians purchase pet medications from manufacturers or authorized distributors and then resell some portion of their purchase to secondary suppliers for a profit." 77 Fed. Reg. 40,355, 40,356 (July 9, 2012).

Thank you for your leadership and we look forward to continuing to work with you and your staff on the important issue of drug shortages.

Sincerely,

JOHN M. GRAY,
President & CEO.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. ROGER F. WICKER TO JOHN M. GRAY

Question. Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?

Answer. HDMA and its members are strong advocates for increased wholesaler licensure standards and a uniform Federal pedigree system to enhance the safety and security of the pharmaceutical supply chain. In addition to fundamentally addressing counterfeit and diverted medicines, Federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

Further, HDMA supports a prohibition on wholesalers' purchasing prescription drugs from pharmacies. When HDMA members sell any drugs (regardless of their shortage status) to pharmacies or providers, it is with the intention that the product will be dispensed or administered to a patient in the usual course of pharmacy or medical practice.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. JOHN BOOZMAN TO JOHN M. GRAY

Question. According to Dr. Coster's testimony, the NCPA encourages pharmacists to conduct due diligence on potential wholesalers before engaging in business transactions. Has HDMA developed industry guidelines to assist primary distributors in vetting their customers?

Answer. In 2008, HDMA published the *Industry Compliance Guidelines: Reporting Suspicious Order and Preventing Diversion of Controlled Substances* (ICGs) (*http://www.healthearedistribution.oregov_affairs/pdf_controlled/20081113_ieg.pdf*).

These guidelines emphasize "Know Your Customer"—that is, obtaining and reviewing thorough background information about a distributor's prospective customers prior to doing business with them. The ICGs support due diligence efforts to provide assurance that pharmacy customers are appropriately licensed by state and Federal authorities and that these entities intend to dispense drug products for legally acceptable purposes.

The ICGs were specifically developed to help evaluate customer orders for controlled substances and report those that are "suspicious" to the Drug Enforcement Administration (DEA) as required under Federal law'.[1] These guidelines are also intended to aid distributors in evaluating and incorporating DEA interpretations of distributors' responsibilities for responding to ever-evolving changes in the diversion and illicit use of these much needed medications.

As important as it is for distributors to take responsibility to prevent diversion of controlled substances, it is equally important for all members of the supply chain (including manufacturers, dispensers, and prescribers) to take steps to help prevent drug abuse as well as preventing the diversion of product into the gray market.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. ROGER F. WICKER TO PATRICIA EARL

Question 1. Can you give us your opinion on what measures could be taken to tighten the supply chain or to prevent these types of "questionable" transactions from taking place?

Answer. Who is NCPD: Founded in 2006, the National Coalition of Pharmaceutical Distributors (NCPD) has represented and promoted the interests and priorities of small and independent pharmaceutical distributors before legislatures, regulatory organizations, industry partners and the community at large by advocating sound and responsible public policy. In this manner, NCPD is committed to preserve the well-being of its members; to ensure distribution system efficiency; and to strengthen the pharmaceutical supply chain to the greatest degree possible. Our members are regulated by the FDA, the DEA and every State Board of Pharmacy in which we operate. Our companies produce pedigrees, engage in current good manufacturing practices and provide heightened product quality assurance. NCPD members operate *inside* ordinary, lawful channels of distribution referred to as the authorized distribution networks.

Question 2. How did the "gray market" root causes emerge?

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[1] 21 C.F.R. § 1301.74(b).

Answer. Industry changes have placed medication in short supply. The FDA website provides frequently asked questions and answers. One noted question is this: What has caused drugs to be in short supply?" The FDA answered the question as follows:

> *"The major reason for these shortages has been quality/manufacturing issues. However there have been other reasons such as production delays at the manufacturer and delays companies have experienced receiving raw materials and components from suppliers. Discontinuations are another factor contributing to shortages. FDA can't require a firm to keep making a drug it wants to discontinue. Sometimes these older drugs are discontinued by companies in favor of newer, more profitable drugs. With fewer firms making older sterile injectable drugs, there are a limited number of production lines that can make these drugs. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities. This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs."*

The Staff Report prepared for Chairman John D. Rockefeller, IV, Chairman Tom Harkin and Representative Elijah E Cummings entitled "An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages" confirmed those root causes from the Committee's extensive examination of the authorized distribution networks.

Question 3. So what are the repercussions of drug shortages and what measures are needed to prevent these "questionable" gray market transactions?

Answer. Following shortages, supply and demand allowed for prices to increase. The healthcare market is not immune to the basic principles of supply and demand. Supply represents how much the market can offer. The quantity supplied refers to the amount of a certain good producers are willing to supply when receiving a certain price. The correlation between price and how much of a good or service is supplied to the market is known as the supply relationship. Price, therefore, is a reflection of supply and demand. When there is a short supply of drugs, as has been noted by the FDA, there is an opportunity for "bad actors" to take advantage of the system. NCPD members do not engage in pricing gouging behavior even though market conditions are ripe for it because they know it is inherently bad business to gouge customers that you want to come back and buy from you next week. Our members know you can't stay in business long unless your prices are fair and competitive and that is how NCPD members have done business with their long-standing relationships. Further, a typical hospital pharmacy purchaser has multiple backup small distributors from which to choose. As such, a secondary distributor will typically seek to offer the best price available to ensure that its hospital customer will continue to utilize its services in the future.

Congress is presently considering various legislative proposals intended to enhance the Federal government's ability to track and trace prescription drugs beginning with the manufacturer and continuing with every subsequent transaction until the product is ultimately provided to the patient or consumer NCPD supports Federal pedigree legislation that includes unit level track and trace mandates. Since 2006, its members are the only companies required to authenticate drugs and pass pedigrees. We support the serialization of drugs for national track and trace system both level and with 2D bar codes. Many of our members serialize drugs today for tracking and billing purposes where distribution in small unit of use packs. We support stringent Federal licensure standards and penalties for those who fail to comply with laws and standards. This concept—commonly referred to as "pedigree"—is considered critical to ensuring that misbranded, adulterated or counterfeit prescription products do not enter the pharmaceutical supply chain. NCPD has actively supported congressional efforts to reform Federal pedigree laws with more stringent and effective requirements for supply chain participants.

NCPD does not support the "shell pharmacies" or illegal wholesalers that divert drugs that would have gone directly from manufacturer to independent distributors and been available for normal distribution supply chain safety net. Plugging those holes with more stringent Federal licensure standards and penalties for failure to comply should be the most important measure to prevent these questionable transactions.

Rather than focusing on how the "bad apples" received the "leaked" product, a better solution for all normal trading partners in the ordinary, lawful channel of distribution would be to get product to the registered, licensed, compliant, traditional

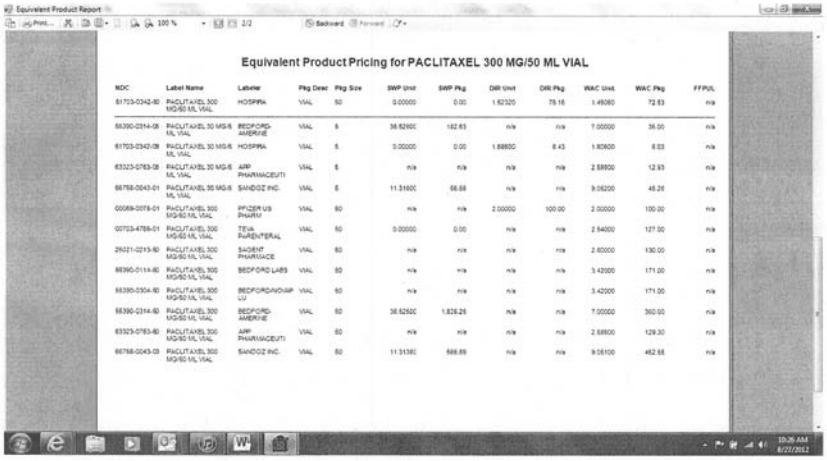
safety-net secondary distributors that have historically been able to redistribute short supply product without extraordinary measures of multiple distributors touching the products. Historically, secondary distributors have stepped in to fill the gap that the normal trading partners cannot because of their inability to handle the exceptions created by the current fragile supply chain. The solution to keeping the supply chain safe is to have all the "ordinary, lawful channels of distribution" have equal access to their fair share of the available inventory based on their customer's historical needs and not allow, such unlawful, fake pharmacies and their unlawful business partners sneak into the supply chain and siphon off the legitimate inventory to gain illegal and unlawful profits at the expense of everyone else.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. JOHN BOOZMAN TO PATRICIA EARL

Question. There are a number of price markups of critical, lifesaving drugs that have been uncovered during the course of this investigation. What would account for these significant markups? I understand that small distributors have to pay higher prices than those negotiated under GPO contracts, but will you explain how your members price their drugs? Putting shipping costs aside, can you explain why secondary wholesalers may charge more than $100 to pass along product to another entity in the distribution chain?

Answer. Analyzing prices of the drugs that were examined in the Staff Report, the first questions we have to ask is "Is the comparison apple to apples?" On page 10 of the report, it was stated that five prescription drugs were the focus of the examination. Those five drugs were all compared using the manufacturer—GPO—wholesaler "normal contract pricing" to establish the baseline for the mark-ups to the hospitals. As you have requested, we will do our response based on the industry standard, Wholesale Acquisition Cost, which is what a distributor will pay for the drug in the "authorized distribution network." It appears in the report, that these examinations make the assumption that all stakeholders track their purchases using the unique identifier, NDC number that is the manufacturer identification code for only one manufacturer's chemical entity for that drug. That NDC tracking process must be used to trace a drug transaction from the manufacturer to the normal trading partner and to the GPO hospital in order to process the GPO contract, file chargebacks and pay administration fees. Only the contract transactions must follow that specific NDC track for that one product and since many of our members are restricted from the GPO agreements, they are free to interchange competing manufacturer products under one Generic Sequence Number (GCN). The manufacturer wholesaler acquisition prices are published in three national data warehouses, First Data Bank (FDB), RedBook and MediSpan. These database files are used to set the WAC by NCPD members and many times are used in lieu of a company's actual acquisition price for single items.

As defined in FDB, the GCN Sequence number is a unique number representing a generic formulation. It is specific to the generic ingredients, route of administration, dosage form and strength. According to FDB, the GCN Sequence Number is the same across manufacturers and/or package sizes and therefore can be used to interchange equivalent products. As a consequence of our distributor members not being restrained in their inventory management systems to tracking by specific NDC numbers, they may set up a shelf-keeping-unit (SKU) system by GCN code in order to run all equivalent GCN products under one unique item number for the purpose of financial accounting and inventory valuation. They may create an SKU number that is proprietary to their company, *i.e.,* Paclitaxel 300mg and track that item by their SKU number. That SKU record will establish their base cost for purchasing and selling price algorithms based on the average costing or FIFO or LIFO cost of the drug. In these situations, they may have multiple manufacturers that make that same drug and sell in different package sizes and they all sell at a different manufacturer wholesaler acquisition price. Since our members do not have to follow the GPO process of selling only one specific manufacturer's NDC number at a pre-negotiated contract price, they can use the most recent published market price established for that item. Here is an example of that pricing comparison is the Paclitaxel 300mg 50ml Vial and its GCN equivalent of 5ml Vials that is listed in the First Data Bank and the Redbook data repositories.



Equivalent Product Pricing for PACLITAXEL 300 MG/50 ML VIAL

NDC	Label Name	Labeler	Pkg Desc	Pkg Size	SWP Unit	SWP Pkg	DIR Unit	DIR Pkg	WAC Unit	WAC Pkg	FFP/UL
61703-0342-50	PACLITAXEL 300 MG/50 ML VIAL	HOSPIRA	VIAL	50	0.00000	0.00	1.52320	76.16	1.45060	72.53	n/a
55390-0314-05	PACLITAXEL 30 MG/5 ML VIAL	BEDFORD-AMERINE	VIAL	5	36.52900	182.65	n/a	n/a	7.00000	35.00	n/a
61703-0342-09	PACLITAXEL 30 MG/5 ML VIAL	HOSPIRA	VIAL	5	0.00000	0.00	1.68600	8.43	1.60600	8.03	n/a
63323-0763-05	PACLITAXEL 30 MG/5 ML VIAL	APP PHARMACEUTI	VIAL	5	n/a	n/a	n/a	n/a	2.58600	12.93	n/a
66758-0043-01	PACLITAXEL 30 MG/5 ML VIAL	SANDOZ INC	VIAL	5	11.31600	56.58	n/a	n/a	9.05200	45.26	n/a
00069-0078-01	PACLITAXEL 300 MG/50 ML VIAL	PFIZER US PHARM	VIAL	50	n/a	n/a	2.00000	100.00	2.00000	100.00	n/a
00703-4788-01	PACLITAXEL 300 MG/50 ML VIAL	TEVA PARENTERAL	VIAL	50	0.00000	0.00	n/a	n/a	2.54000	127.00	n/a
25021-0213-50	PACLITAXEL 300 MG/50 ML VIAL	SAGENT PHARMACE	VIAL	50	n/a	n/a	n/a	n/a	2.60000	130.00	n/a
55390-0114-50	PACLITAXEL 300 MG/50 ML VIAL	BEDFORD LABS	VIAL	50	n/a	n/a	n/a	n/a	3.42000	171.00	n/a
55390-0304-50	PACLITAXEL 300 MG/50 ML VIAL	BEDFORD/DANP UJ	VIAL	50	n/a	n/a	n/a	n/a	3.42000	171.00	n/a
55390-0314-50	PACLITAXEL 300 MG/50 ML VIAL	BEDFORD-AMERINE	VIAL	50	36.52900	1,826.25	n/a	n/a	7.00000	350.00	n/a
63323-0763-50	PACLITAXEL 300 MG/50 ML VIAL	APP PHARMACEUTI	VIAL	50	n/a	n/a	n/a	n/a	2.58600	129.30	n/a
66758-0043-03	PACLITAXEL 300 MG/50 ML VIAL	SANDOZ INC	VIAL	50	11.31360	566.68	n/a	n/a	9.05100	452.55	n/a

As you can see, there are multiple manufacturer-specific generically equivalent products that have published Wholesale Acquisition Costs (WAC). If we look at four of these products to see the variance in the WAC for the purpose of establishing a market in-bound cost for a distributor to use as the competitive threshold to price the product when it is acquired from another trading partner, we will see that manufacturers have created wide variances in how they set their company's WAC and that there are wide spreads in the dollars and the percentage difference by manufacturer.

Drug Name: PACLITAXEL 300 MG/50 ML VIAL

NDC	MFG	Pkg Desc	Pkg Size	WAC Unit	WAC Pkg	Mark-Up $ over Lowest WAC	Mark-Up % over Lowest MFG WAC
61703–0342–50	Hospira	Vial	50	$1.45	$72.53	N/A	N/A
63323–0763–50	APP	Vial	50	$2.59	$129.30	$56.77	78.27%
55390–0314–50	Bedford	Vial	50	$7.00	$350.00	$277.47	382.56%
66758–0043–03	Sandoz	Vial	50	$9.05	$452.55	$380.02	523.95%

Drug Name: PACLITAXEL 300 MG/5 ML VIAL

NDC	MFG	Pkg Desc	Pkg Size	WAC Unit	WAC Pkg	Mark-Up $ over Lowest WAC	Mark-Up % over Lowest MFG WAC
61703–0342–09	Hospira	Vial	5	$1.61	$8.03	N/A	N/A
63323–0763–05	APP	Vial	5	$2.58	$12.93	$4.90	61.02%
55390–0314–05	Bedford	Vial	5	$7.00	$35.00	$26.97	335.87%
66758–0043–01	Sandoz	Vial	5	$9.05	$45.26	$37.23	463.64%

When our members purchase a Paclitaxel 300mg 50ml Vial or a 5ml Vial, they put in the market price of the product based on what the First Data Bank, Redbook or MediSpan has published as the WAC and if they have purchased two of the four above and the SANDOZ product was one of those two, their base cost for that product would be $452.00 not the $129.30 that APP had priced their lowest contract negotiated product. Therefore, when a hospital was quoted their price on the Paclitaxel 300mg 50ml Vial as a non-primary customer of our member, they would be priced on the highest WAC, unless they have a pre-negotiated supply agreement with our member for sell price based on actual cost.

This is a common practice in the "secondary distributor" industry because a hospital has committed to buy 100 percent of their contract items from the primary distributor –referred to in the report as "normal trading partners." Since a secondary distributor does not know what products, if any, or how much dollar volume that a hospital will purchase from them, they normally sell at a cost plus based on their market intelligence and that is based on the higher of published WAC or their Com-

mercial Price File established by their inventory and pricing guidelines. Our members receive letters from their customers like this one on a consistent basis:

> *"This is to say THANK YOU for all the vital service you have provided to our company. You play a critical role in my daily routine as I rely on your e-mails that contain drugs that I currently need and you are quick to act on it. You are a life saver as I have never been without in spite of the current drug shortages. You have fair prices and I have referred your company to many of my colleagues so they too can receive the vital service you provide. Thank you again for the great service and I will continue to look forward to doing business with you as always!" RN, CNOR Surgery Center Customer*

There are additional factors that determine the selling price mark-ups and they include higher costs of acquisition of these life-saving, critical short supply drugs. Some of our members have long-standing relationships with hospitals and clinics (like the one above) to be the last resort in finding a drug that is critical to saving a patient's life. In these extreme situations, our members use extraordinary measures to find those drugs by contacting other trusted suppliers that have assisted them in the past. These extreme situations can cost hundreds of dollars in operational, administrative and labor costs. Many times either experienced sales reps or customer service management will spend hours in tracking down and locating the available product. They negotiate the rapid response to expedite the drug to the hospital or clinic. They incur special handling costs, packaging and labeling materials for hazardous (oncology), breakables (injectables and liquids) and sensitive transporting (OMD guidelines) of the product to a viable shipper. There are incremental costs for all these activities that must go into the cost of processing the drug.

Lastly, our members are required by PDMA and state statutes to provide a readable pedigree document in these situations that may involve tracking transactions from the manufacturer to the dispensing customer. Pedigree documentation not only involves labor costs but also our members are required to pay a fee to the "normal trading partners" in order to get access to that pedigree. The cost to get pedigree documentation from the primary wholesalers is a fixed fee of $5,000 per month or $60,000 per year and that is for one pedigree or for many per month. Internal labor costs for pedigree administration carries an average cost of $60,000 or more to authenticate and pass pedigree on these items. Many of our members have invested in software systems that have a license fee that has to be paid for the service. If our members passed on the actual cost of that pedigree service on these transactions, it could easily add at least $100 per item just for the authentication documents. Because this is an arduous, labor intensive process, in many instances, our members lose money on these emergency, hard-to-find situations in order to keep a good customer and to save a patient's life.

As benchmark tools for our industry, we have prepared some financial analysis to show the economic impact of the small distributions and how it relates to the normal trading partners. Prescription drugs move though a very complex distribution model that has many players. These multiple providers each play an important role in getting the right drugs, to the right patient, at the right time. However, because of the sheer volume of over $307 Billion, according to the Center for Healthcare Supply Chain Research, 2011–2012 HDMA Factbook, each traditional distributor placed more than 385,000 orders for healthcare products in 2012 from an average of 1,100 manufacturers delivering drugs daily to over 200,000 providers across the U.S. While this provider network is vast, distributors were able to consistently provide services levels exceeding 95 percent while operating efficiently and keeping the cost of distributor low. These large, national distributors are able to offer economies of scale by aggregating volumes and inventory for both manufacturers and providers. This systems works for drug distribution in a fast and efficient manner at least 95 percent of the time, but for the balance of that 5 percent, a back-up, secondary distributor is called on to provide the same level of service that these primary companies provide.

Table 1.—Flow of U.S. Prescription Sales ($B) and Contribution by Channel (%) in 2010.

Total U.S. Pharmaceutical Market	Contribution by Channel ($)	Contribution by Channel (%)
Manufacturers	$307 B	100%
Traditional and Specialty Distributors	$268 B	87%
Direct to Chains, Mass Merchandisers and Food Stores	$39 B	13%
Total Generic and Brand Prescription Drugs Sold through Traditional Wholesalers to Following Providers:		
Chain Warehouses purchased from Wholesalers	$51 B	21%
Chain Pharmacies	$59 B	24%
Hospitals, HMO's, Clinics and Nursing Homes	$61 B	25%
Independent Community Pharmacies	$38 B	16%
Mail Order Pharmacies	$33 B	13%
Others (Distributors)	$2 B	1%

1. Total value of goods flowing through traditional distributors, as per IMS National Sales Perspectives. 2011–12 HDMA Factbook (Tables 1 and 3 and 109.)
2. Sources: Center for Healthcare Supply Chain Research, 2012–12 HDMA Factbook, IMS Health, Inc., Booz & Company Analysis, The Role of Distributors in the U.S. Healthcare Industry

NCPD members, small and independent distributors, have estimated that this market segment does less than one percent of the total goods flowing through this supply chain or approximately $2 Billion annually. It is often hard to understand where secondary distributors fit into the flow of prescription drugs in this supply chain and the role that NCPD members play every day in distributing prescription drugs to their small healthcare customers and as a second-line supplier to the largest providers listed in Table 1. Much activity has driven these secondary relationships that have been the realities for the pharmaceutical supply chain during this period of increasing short-supply of critical drugs. One of the practical circumstances that have fed the expansion of these relationships in the secondary distribution industry is the fact that this industry of small suppliers primarily serves as a safety-net or back-up supplier to all hospitals, both large and small in the U.S. Add to that, the fact that this industry is the primary supplier of all drugs to smaller medical facilities, doctor's offices and pharmacies. Despite their crucial role in getting life-saving drugs to critically ill patients, they are also on an individual basis, one of the smallest customers of the "traditional" wholesalers that do billions of dollars of sales to these large hospitals and are required to pay the highest acquisition cost offered in the U.S. supply chain. As a practical matter, every sector of the healthcare industry depends critically upon secondary distributors due to the fact that they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply.

Many manufacturers, hospitals, health care centers and pharmacies in rural locations and those too small to meet the minimums of large distributors rely on secondary distributors to fill critical needs for life-saving medicine. What's more, every sector of the health care industry depends critically upon secondary distributors because they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply. While they are crucial in getting life-saving drugs to critically ill patients, small distributors are on an individual basis, one of the smallest customers of "traditional" wholesalers. These same wholesalers do billions of dollars of sales to large hospitals, but will not supply smaller clinics and facilities. In addition, small distributors are required to pay the highest acquisition cost offered in the U.S. supply chain, putting them at a competitive disadvantage.

In spite of their proven value, small, secondary distributors have come under fire recently because few people really understand them or have taken the time to see where they fit in the supply chain. The arguments have ranged from accusations of price gouging to shifting product between multiple companies as a means to increase profits to working with fake pharmacies. These allegations are not grounded

in reality. What's more, these characterizations fail to reflect one basic fact of this market: There are thousands of small distributors that work with hospitals across the Nation. To remain competitive, they must comply with all laws, follow pedigree and handling requirements to the letter and still offer an economical price point that allows for only a modest profit margin. If they do anything else, they run the risk of permanently losing a customer. That's because hospitals comparison shop. If they don't like a price offered by one company, they will call another. This is a reality that every small distributor out there is well aware of. And they know that if they were to engage in the types of activities you accuse them of, they would not be in business very long. As you learn more about this industry you will see that the activities you are trying to paint as nefarious actually have legitimate and reasonable explanations:

So-Called "Price Gouging" Or Mark-Ups

Drug prices are established on an intricate system that is far more complex than most free markets. Manufacturers set a number of price points for a product, including the Wholesale Acquisition Cost—or WAC—which is the lowest price at which a wholesaler or distributor can buy the product. As with many markets, hospitals and physicians can negotiate the price they are willing to pay for a drug. The more product a hospital or doctor expects to use, the more power they have in securing to negotiate a lower price. Neither large nor small distributors have the ability to influence drug price negotiations. To secure the best prices for patients, most hospitals belong to one of the major group purchasing organizations—GPO's, which leverage the strength of the collective buying power of their members when negotiating contracts with manufacturers. GPOs require hospitals to adhere to specific rules, such as select a primary wholesaler—and if their primary does not have a drug, they are prohibited from using another primary. Instead, they must contact their second-line—or "secondary—distributor to supply their needs. Secondary distributors are able to work with all of the primary wholesalers, plus their network of small distributors to locate and secure drugs, even those that are in short-supply. Because small distributors are not restricted by GPO contracts, they are able to use avenues that hospitals cannot, such as large distributors that compete with the hospital's primary wholesalers.

Small distributor companies measure key profitability by comparing income and expenses, which are significantly higher than the large traditional wholesalers because they do not have the depth, breadth and economies of scale that the larger companies can spread expenses across billions of dollars in pharmaceutical revenues. In fact, the small and independent distributors are very similar in size and scope to the small, independent, community pharmacies that are members of the National Community Pharmacy Association. We have used the data from the HDMA Factbook and the 2011 NCPA Digest to compare and contrast the revenues, gross profit margins, operating expenses and net operating incomes of these three industries.

Table 2.—Industry vs. Small Distributor. Percentage of Revenues, Expenses, Gross Margins and Net Margins

Proforma Categories	HDMA industry Avg.—Wholesalers [1]	Avg. %	NCPA Industry Avg.—Small Pharmacy [2]	Avg. %	NCPD Small Distributors Avg.	Avg. %
Revenues						
Rx Sales Per Location	$2,615,865,364	100.00%	$3,698,748	100.00%	$7,500,000	100.00%
Cost of Goods Sold	$2,528,757,047	96.67%	$2,812,250	76.00%	$5,625,000	75.00%
Gross Margin $ Sales After All Discounts	$87,108,317	3.33%	$886,498	24.00%	$1,875,000	25.00%
Gross Margin % After All Discounts	3.33%		23.97%		25.00%	
Expenses						
Payroll Expense	$15,845,003	18.19%	$110,812	12.50%	$215,625	11.50%
Payroll Taxes, Workers Comp, Empl. Benefits	$3,188,164	3.66%	$17,730	2.00%	$37,500	2.00%

Table 2.—Industry vs. Small Distributor. Percentage of Revenues, Expenses, Gross Margins and Net Margins—Continued

Proforma Categories	HDMA industry Avg.—Wholesalers [1]	Avg. %	NCPA Industry Avg.—Small Pharmacy [2]	Avg. %	NCPD Small Distributors Avg.	Avg. %
Total Payroll Expenses	$19,033,167	21.85%	$128,542	14.50%	$253,125	13.50%
Administrative Expense	$409,409	0.47%	$0	0.00%	$0	0.00%
Sales and Marketing Expense	$226,482	0.26%	$4,432	0.50%	$8,438	0.45%
Buying Expense	$17,422	0.02%	$0	0.00%	$0	0.00%
Insurance	$0	0.00%	$2,659	0.30%	$9,375	0.50%
Supplies, Storage and Ship Containers, Packing, Labels	$0	0.00%	$4,432	0.50%	$12,188	0.65%
Postage	$0	0.00%	$886	0.10%	$3,563	0.19%
Shipping and Delivery	$261,325	0.30%	$3,546	0.40%	$12,188	0.65%
Information and Technology	$182,927	0.21%	$3,546	0.40%	$5,625	0.30%
Rent	$130,662	0.15%	$10,638	1.20%	$71,250	0.95%
Utilities amd Telephone	$0	0.00%	$3,546	0.40%	$9,375	0.50%
Contract and Chargeback	$17,422	0.02%	$0	0.00%	$0	0.00%
Pedigree Authentication	$0	0.00%	$0	0.00%	$42,188	2.25%
Licensure, Bonds and Compliance	$0	0.00%	$0	0.00%	$15,000	0.80%
Other Operating Expense	$0	0.00%	$23,935	2.70%	$28,125	1.50%
Total Operating Expense (includes some lines not broken out separately above)	$31,247,820	1.19%	$776,737	21.00%	$1,668,000	22.24%
Net Operating Income [3]	$55,860,497	2.13%	$110,962	3.00%	$207,000	2.76%

[1] Center for Healthcare Supply Chain Research 2011–2012 HDMA Factbook (Pg. 19–24, 51).
[2] National Community Pharmacy Association 2011 NCPA Digest Sponsored by Cardinal Health.
[3] Center for Healthcare Supply chain Research 2011–2012 HDMA Factbook (Table 20).

Small distributors are very competitive with their pricing for products and services particularly geographically—close proximity to their distribution centers. For extreme situations where FedEx Air overnight deliver is provided, they face the possibility of the shipping, handling, packaging and related delivery costs to be more expensive than the actual drug itself. Many members have reported that the large distributors have discounts of 80 percent or more off delivery schedules. Patient safety is their first concern when requested to ship an emergency drug. Consistent temperature, humidity and quality control is vital for a critical, life-saving drug to be delivered to provide immediate benefits to a patient. They have experienced high quality warehouse advocates that provide excellent quality control when a hospital expects reliable, safe and secure drugs to be delivered just-in-time to save a patient. This manual processing from the receipt to the delivery of the emergency drug falls outside the normal cost of the division.

Small distributors have been inaccurately portrayed when it comes to the price of products. As I noted before, secondary distributors pay the highest prices for drugs in the entire U.S. supply chain—sometimes as much as 91 percent more than one of the traditional wholesalers would ultimately pay for the same product.

What's more, many people will look at a pedigree and compare the cost a distributor paid for a drug to the price he sold it for and assume the entire amount was pocketed as profit. That's the furthest thing from the truth. The reality is that the pedigree does not show how much was spent on things like shipping, which can be much more expensive than the drug itself if the hospital needs it delivered overnight.

Every small distributor knows that the hospitals they work with are going to comparison shop. If a hospital doesn't like the price that one secondary distributor quotes to them, they will call another. Or, if they need it right away and can't risk losing it, they will buy it, but will find another secondary distributor to work with moving forward. They are free to move their account elsewhere, so secondary distributors have to remain competitive and will often sacrifice their own profit margins to make sure they keep a customer.

Question 1a. How does our pricing work and does it contributes to the "questionable" gray market activities?

Answer. Pharmaceutical pricing is complex and difficult to understand; because of this the investigative reports and "gray market" reports have unfairly and incorrectly discounted the value of small pharmaceutical distributors that operate inside of authorized distribution networks. Let's talk about the layers of this business and the service each layer provides.

(1) Drug manufacturers discover patent, study, create, market and sell various drugs. Manufacturers build a service fee into their product price to recoup their cost.

(2) Authorized Distributors of Record's (ADRs) negotiate with drug manufacturers in order to buy large quantities of drugs at extremely low prices. ADRs buy from multiple manufacturers. When a hospital wants to buy certain drugs and does not want to be constrained by manufacturer product lines, they buy from ADRs. The best ADRs have strong negotiating power allowing them to offer low prices and multiple manufacturer product portfolios to customers. ADRs build a service fee into their price to account for their negotiation and marketing work.

(3) Pharmaceutical Distributors such as our NCPD members buy bulk product from manufacturers and ADRs. Some of us just sell the product in its original container. Others re-package and/or re-label product in accordance with current good manufacturing procedures and are regulated by the FDA and DEA. When product is repackaged from bulk bottles and placed into individual count bottles, many FDA quality regulations are mandatory. These quality regulations are not applicable to pharmacies, such as those referred to in the report entitled "Shining Light on the Gray Market" prepared and presented July 25, 2012 at the Senate Committee on Commerce, Science, and Transportation. *Also, our companies service locations with little to no buying power. Many rural area clinics and doctor's offices, for example, are precluded from buying manufacturer direct or from an ADR because they do not purchase sufficient quantities of product. Our companies cater to these clients and ensure that they receive quality, safe products; we are an integral part of the supply chain. Pharmaceutical Distributors build a service fee into their price to account for their operational, administrative and labor costs for sourcing, purchasing, regulatory compliance to pedigree, storage, handling, special packaging, labeling, quality checking, marketing and distribution services. Higher costs are incurred for special situations that involve life-saving, critical, short supply drugs.*

(4) The service provided by each layer is necessary and an increased price is a necessary corollary arising from the layers; each layer must be compensated for their service.

(5) So why are the reports saying that pharmaceutical distributors are price gougers? Despite the fact that pharmaceutical distributors provide quality, necessary services, the media has skewed the world's view of pharmaceutical distributors. For instance, Premier Healthcare Alliance report published in 2011 incorrectly calculated the percent markup charged by small distributors overstating the high-end by 3,804 percentage points or 521 percent. "Many people mistakenly believe that distributors that deal in medicines have greater negotiating power than they really do. This isn't like a car dealership, where people generally don't have to pay MSRP because of dealer incentives and rebates. In health care, small distributors must pay what's called a Wholesale Acquisition Cost that is many times greater than what the GPOs have negotiated. When you compare the cost a small distributor must pay for a medicine to the final price it charges a hospital, you find that the gross profit margin

is often in a very reasonable range. It is not the 1,400 percent markup you find when you compare to GPO numbers—a practice that is misleading and doesn't represent the complexities of the health care market. GPOs have created a market that is anticompetitive and exclusionary, which actually leads to shortages and higher prices on alternative products in times of market disruptions. The fact that the numbers in the original report were so drastically miscalculated indicates that it is another unjustified attack on the business integrity of small distributors. It was disingenuous for Premier Purchasing Partners who created and understand the system better than anyone, to point their fingers at small distributors, which must pay significantly higher prices for the same products to serve health care providers.

(6) Stories about a few "bad actors, fake pharmacies and fake distributors" have tainted the gray market debate. During 2005 and 2006, rogue companies in Florida took advantage of a flawed regulatory system and introduced counterfeits and unsafe practices into the U.S. pharmaceutical supply chain. NCPD was founded to represent the wellbeing and interests of reputable small distributors. We worked to help enact Federal legislations to revamp the Nation's chain of custody laws for drugs. A new system was put in place to make sure that our supply chain was safe from the criminals that could open a storefront, buy drugs off the street and resell them without any regard for patient safety or regulations. In order to fix the system, we need to look at all the links in the system, the manufacturers who bid for contracts and cannot supply, the traditional wholesalers who have a fragile supply chain with just-in-time inventory and no safety stock, and especially the group purchasing organizations that are protected by anti-kickback and safe harbor exemptions which create a smokescreen intended to prevent simple comparisons of GPO vs. non-GPO prices. As a knee jerk reaction to fix that 2005–2006 crisis and to make sure that we put some standards into place, we saw the manufacturers, the traditional wholesalers and the group purchasing organizations tighten their relationships.

(7) The FDA instituted the pedigree requirements that any distributor that did not buy from the manufacturer direct would have to create a pedigree record and authenticate that chain of custody all the way back to the manufacturer. The manufacturers then exempted Authorized Distributors of Record from the pedigree statutes. Manufacturers subjectively terminated all secondary distributors' direct accounts unless the distributor was a member of the legacy association, HDMA, representing large, traditional, full-line distributor and manufacturers. HDMA, at that time, decided to pare down their membership to only the top 20–30 distributors that could meet their stringent financial requirements. The group purchasing organizations pared down their list of authorized distributors to the ones with direct contracts with manufacturers. The traditional wholesaler's, who had done business with the smaller distributors over the last 20 some years, were given fee for services and inventory management agreements from the manufacturers and from their GPO partners. All three of the large wholesalers then blocked sales to the secondary distributors because they would lose their rights to purchase hospitals products and to sell into the large GPO members hospitals. Small independent distributors were essentially denied access, restricted, blocked and tackled from every direction, and the only source of product suppliers that they could buy from were small manufacturers that could not play in the GPO contracts, small generic manufacturers that could not win the large GPO contracts, (note that many of those suppliers went out of business or picked up new products that did not compete with the GPO manufacturers) thus leaving no safety net suppliers for products in the supply chain. The secondary distributors were on an island and their only source of support and trading partners were each other. They have seen millions of dollars evaporate off their shelves and balance sheets. Secondary distributors, by comparison, are often family-owned businesses. The companies try to obtain their products from the manufacturer, where permitted, and use a traditional wholesaler that is an ADR and from other trusted, well-known distributors, just like them. Secondary distributors, so called because they fill a need when a hospital's primary wholesaler cannot fill it, are a beneficial, integrated and official part of the authorized distribution network. They are required to pay much higher prices than traditional distributors, are excluded from GPO contracts, and restricted from filing for chargeback differentials with the manufacturer when a hospital has a GPO contract and buys off-contract with a secondary distributor. Their customers understand they will not get the GPO pricing, but know the service may help,

or even save a patient. They are the safety-net in the market, ensuring quality medications reach a patient in the safest, fastest and most cost-effective way possible.

Question 2. You state in your written testimony that NCPD members report fake pharmacies they uncover. How often do you come across these fake or "shell" pharmacies? Is action taken to shut them down when reported?

Answer. As we stated earlier in this response, NCPD represents and promotes the interests and priorities of small and independent pharmaceutical distributors before legislatures, regulatory organizations, industry partners and the community at large by advocating sound and responsible public policy. In this manner, NCPD is committed to preserve the well-being of its members; to ensure distribution system efficiency; and to strengthen the pharmaceutical supply chain to the greatest degree possible.

NCPD was founded in 2006 as a voluntary, horizontal, member-directed association that succeeds in differentiating the participants by a common set of guiding principals for self-governance. New members are accepted after being vetted by a membership steering committee. The criteria for vetting a new member may include, but is not be limited to:

- Do they meet all industry regulatory standards for licensing and business practices?
- Do they adhere to provisions of Prescription Drug Marketing Act for handling, packaging, storage, and shipping of drugs?
- Are they in full compliance with all governing federal, state and local laws?
- Provides pedigree and authenticates its inventory according to state statutes.
- Approved through VAWD certification, when applicable to business model.
- Follows cGMP guidelines from FDA in packaging, mail order and covered facilities.
- Employs mutual-nondisclosure agreements to meet anti-trust thresholds.
- Does business only with other licensed distributors or that meet their stringent customer inspection and monitoring policies.
- Have Standard Operating Procedures for diversion control and suspicious ordering reporting.
- Have rigorous governance policies in place to ensure internal and external practices for fair treatment of customers and employees.
- Legal aspects of the association will be carefully monitored by Board. When pricing and group purchasing are discussed, we abide by the provisions of Robinson-Patman Act and other anti-trust regulations pertaining to competitive activities.
- Member companies are independent of other member companies in all other respects—and transactions are strictly confidential.
- All member's business information, volumes, pricing, and supplier information are kept confidential.
- Members must approve release of any information.
- NCPD recognizes that most aspects of the supplier/member relationship remain under the individual member's full control.

In addition to the criteria above that we may use to evaluate and approve new members, each of our members has their own due diligence process when they accept new customers. That process follows certain specific PDMA, DEA and State Board of Pharmacy licensing criteria whereby the customer:

- If a Retail Pharmacy, Physician Office or Healthcare Clinic, it meets all DEA and state licensing and regulatory practices.
- Requires a physical inspection of pharmacy sites.
- If a Distributor, adheres to provisions of Prescription Drug Marketing Act for packaging, storage, and shipping and other applicable requirements.
- Is in full compliance with all governing federal, state and local laws.
- Provides pedigree and authenticates its inventory according to state statutes.
- Approved through VAWD certification, when applicable to business model.
- Follows cGMP guidelines from FDA in packaging, mail order and covered facilities.

As we said above, NCPD is a voluntary, member-directed association and is not a regulatory enforcement agency. However, NCPD does provide our members with

the most recent Federal, State and local legislative and regulatory updates to keep them up-to-date on the best practices of the industry. We have Annual Meetings to educate members on current trends and regulatory practices. When we receive notices of a counterfeit, adulteration, fake pharmacy or any unlawful or illegal activity that affects our membership, we have an immediate notification process in place to make sure the information gets to the NCPD members and, if applicable to the regulatory agencies involved.

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