Congress of the United States
Washington, DC 20515

June 11, 2012

Senator Tom Harkin
Chairman
U.S. Senate Committee on Health, Education, Labor and Pensions

Representative Fred Upton
Chairman
U.S. House of Representatives Committee on Energy and Commerce

Senator Michael Enzi
Ranking Member
U.S. Senate Committee on Health, Education, Labor and Pensions

Representative Henry Waxman
Ranking Member
U.S. House of Representatives Committee on Energy and Commerce

Dear Chairman Harkin, Chairman Upton, Ranking Member Enzi, and Ranking Member Waxman:

For the past six months, we have been investigating why hospitals and other health care providers are having difficulty obtaining prescription drugs they need to treat critically ill patients suffering from cancer and other life-threatening conditions. In the course of this investigation, we have identified significant risks in the U.S. pharmaceutical distribution chain that make it difficult for health care providers to obtain safe and affordable drugs for their patients.

As you continue House-Senate negotiations on legislation to reauthorize programs within the Food and Drug Administration (FDA), we are writing to provide a short summary of our findings and to offer our assistance. We believe that the troubling information our investigation has brought to light about the "gray market" for short-supply prescription drugs can inform and improve your legislative work. In particular, we encourage you to consider whether legislative proposals to modify the current federal law on pharmaceutical supply chain security would adequately address the risks we have identified in our investigation.

Background on Gray Market Investigation

Last October, Congressman Cummings, Ranking Member of the House Committee on Oversight and Government Reform, launched this investigation by sending information request letters to five companies that were marketing prescription drugs to hospitals.[1] The letters asked for information about the companies' sales of five injectable drugs that were at the time facing

[1] House Committee on Oversight and Government Reform, Minority, *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&Itemid=107).

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national shortages, according to FDA.[2] All five drugs are used to treat critically ill patients, including cancer patients.[3]

At the time Ranking Member Cummings initiated this investigation, there were widespread reports that hospitals were facing significant challenges obtaining short-supply drugs for their critically ill patients. Hospitals and patient groups reported numerous examples in which patient care was compromised because hospitals could not obtain adequate supplies of these drugs through their normal distribution networks. They alleged that so-called "gray market" drug companies were taking advantage of these shortages to sell short-supply drugs to hospitals at exorbitant prices. In order to investigate these serious allegations, Ranking Member Cummings asked the five companies where they had obtained their supplies of the short-supply drugs and how much they were charging hospitals.

In December 2011, Senator Rockefeller, Chairman of the Senate Commerce Committee, and Senator Tom Harkin, Chairman of the Senate HELP Committee, joined Ranking Member Cummings in the investigation. Since that time, we have requested information—including drug pedigree information—from more than 50 prescription drug manufacturers, distributors, and pharmacies.[4] We have also consulted with a variety of industry experts, state and federal regulators, and other stakeholders about how prescription drugs are distributed, marketed, and sold.

Preliminary Findings

Although we intend to present the results of our investigation in an upcoming hearing, we would like to share with you several of our important preliminary findings. We believe these findings are directly relevant to the legislative proposals you are considering to amend current federal law on pharmaceutical supply chain security.

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[2] Center for Drug Evaluation and Research, Food and Drug Administration, Manual of Policies and Procedures, 6003.1 (defining 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 user level") (online at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM079936.pdf).

[3] The five drugs are: (1) cytarabine, which doctors use to treat leukemia in children and adults; (2) fluorouracil, which doctors use to treat colon, stomach, breast, and pancreatic cancer; (3) leucovorin, which doctors use to treat advanced colon cancer; (4) magnesium sulfate, which doctors use to prevent life-threatening seizures during pregnancy; and (5) paclitaxel, which doctors use to treat breast and ovarian cancer.

[4] On March 2, 2012, Chairman Rockefeller issued a Senate Commerce Committee subpoena to one drug distributor that refused to provide the requested information voluntarily.

We have found that many short-supply drugs do not reach health care providers through the typical process that policymakers and industry stakeholders present as the normative model for drug distribution: manufacturer to distributor to dispenser. Instead, we have found that these drugs are diverted into much longer "gray market" distribution networks in which a number of different companies buy, sell, and transfer the drugs.

As the drugs pass through these lengthier gray market distribution chains, they are marked up at each stage, resulting in prices that are often hundreds of times higher than the prices that hospitals and other health care providers normally pay. The markups we have observed bear little or no relation to the companies' cost of purchasing, shipping, or storing the drugs. Instead, they indicate that gray market "middlemen" companies are taking advantage of, and sometimes even exacerbating, the acute demand for short-supply drugs by charging health care providers exorbitant prices.

Our review also raises concerns about the business practices of companies involved in gray market distribution chains. We have identified multiple instances in which wholesalers obtained pharmacy licenses in order to obtain greater access to short-supply drugs, but then re-sold the drugs to other wholesalers rather than dispensing them to health care providers or patients. We have also identified pharmacies that do not appear to be complying with the terms of their state licenses, which require them to dispense all or most of their product to health care providers or patients.[5] Still other companies in these chains seem to function solely as drug brokers, diverting short-supply drugs from pharmacies to "downstream" gray market distributors.

Many of the purchases and sales within these chains do not appear to be arm's-length transactions. In some cases, the companies buying and selling drugs have common employees, common ownership, or family relationships. For example, in a letter we sent on March 21, 2012, we documented the case of a Maryland pharmacy and a New Jersey distributor that were owned by a husband and wife, Gabor Szilagyi and Marianna Pesti.[6] Ms. Pesti's pharmacy, Priority Healthcare, purchased short-supply cancer drugs and then sold them at a highly marked up price to Mr. Szilagyi's company, Tri-Med America, after which Mr. Szilagyi's company resold them to another gray market distributor. Both companies ceased operations after these abuses were revealed.[7]

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[5] *Local Pharmacy Faces a Barrage of Charges*, Bakersfield Californian (Mar. 22, 2012) (online at www.bakersfieldcalifornian.com/health/x560111673/Local-pharmacy-faces-a-barrage-of-charges).

[6] House Committee on Oversight and Government Reform, Minority, *Investigation of "Fake Pharmacies" Buying and Selling Shortage Drugs in the Gray Market* (Mar. 21, 2012) (online at http://democrats.oversight.house.gov/index.php?option=com_content&view=article&id=5647&Itemid=119).

[7] *See* State of New Jersey Department of Health and Senior Services, *Wholesale Drug Project Revocations and Suspensions* (online at

Our investigation has also raised concerns about whether drugs are being handled properly when they travel across the country through gray market distribution networks. Some businesses that take possession of these drugs do not appear to have the facilities or personnel necessary to handle the drugs properly according to their labels. Some companies seem to be little more than physical addresses to receive mail and packages.

For example, when inspectors from the Maryland Pharmacy Board visited Ms. Pesti's pharmacy during business hours in June 2010, the pharmacy was closed, and an employee of a neighboring business informed them that he often signed for the pharmacy's UPS packages because "no one is ever there."[8] Similarly, when a Senate Commerce Committee investigator recently visited the address of Investigational Drug Delivery, a New Jersey company involved in multiple gray market distribution chains, he found a small office suite with a sign on the door asking Federal Express and UPS to call a telephone number "and someone will be here within 5 minutes."[9]

Policy Considerations

As you continue your discussions about the security of the pharmaceutical distribution supply chain, we respectfully offer the following observations and recommendations, which are based on the documents and information we have obtained during our investigation.

Pedigrees Are an Important Tool for Security and Accountability. Many businesses that distribute drugs in the United States are required, either by state or federal law, to provide pedigrees to their customers. During this investigation, our staffs have reviewed scores of so-called "paper pedigrees" and used them to determine how drugs made the journey from manufacturer to patient. Although these documents are far from perfect, they are one of the few tools regulators and consumers currently have to reconstruct distribution chains and identify fraudulent or unsafe practices.

Preempting state pedigree laws without replacing them with a workable federal pedigree requirement will make it more difficult to determine who is handling drugs before they are

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http://nj.gov/health/foodanddrugsafety/rev_sus.shtml); Maryland Board of Pharmacy, *Establishment Verification* (online at https://license.mdbop.org/verification/veri/establishmentDetail.asp?PermitNo=PW0275).

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

[9] Notwithstanding that sign, the investigator found a tag on the company's door regarding a package that Federal Express had attempted to deliver when no one was there to receive it.

administered to patients. Today, policymakers and regulators have limited visibility into the gray market for prescription drugs. Without a pedigree requirement, we would have even less, and gray market drug companies would have even more opportunities to continue the risky, abusive practices we have identified in our investigation. We hope you agree that the pharmaceutical supply chain in the United States needs to be more secure and accountable, not less.

Serializing Drugs Does Not Replace Pedigrees. We understand that one proposal you are considering is to create a national "track and trace" system for prescription drugs. We understand the great value in assigning each manufactured drug a unique identifier, but this step alone does not ensure that consumers, regulators, or industry stakeholders know who has owned a drug or how the drug has been handled. Although a unique identifier may help determine whether a particular unit of a drug is "authentic," it does not prove that the drug has been handled by authorized, qualified distributors and dispensers.

The value of unique identifiers would be further diminished if downstream parties in the supply chain were not required to track the individual pharmaceutical units they buy and sell. The gray market drug transactions we have identified involve relatively small volumes of drugs, often five or ten units per transaction. If entities in the supply chain track products only at the aggregate "lot" level, the unique identifier would provide no information about who takes custody of these drugs after the lot is opened and individual units are distributed.

Higher Standards for Wholesaler Distributors. We are aware that you have been discussing strengthening federal standards for pharmaceutical wholesale distributors. We support this goal. Although there are many drug distributors that operate lawfully and responsibly, there are many others that do not have appropriate personnel or facilities to properly handle and safeguard prescription drugs. Many of the distribution businesses we have identified in our investigation appear to serve little purpose other than facilitating transactions during which gray market entities apply large markups.

In response to the findings of our investigation, last month Ranking Member Cummings introduced H.R. 5853, the Gray Market Drug Reform and Transparency Act of 2012, which includes proposals that would:

- prohibit wholesalers from buying drugs from pharmacies, a practice that has been abused by unscrupulous gray market wholesalers in order to obtain greater access to shortage drugs, charge excessive markups, and divert drugs away from patients who need them;

- establish a national wholesaler database of information to assist consumers, health care providers, and state regulators in identifying problems with companies distributing drugs in interstate commerce; and

- require that sellers provide price information to buyers of short-supply drugs that, although not disclosed to the government or the public, would provide buyers with greater information about the markups they are paying.

These provisions directly address some of the most serious problems we have documented in our investigation and would benefit patients who desperately need drugs facing critical national shortages.

Offer for Briefing

We strongly commend you for the comprehensive and bipartisan approach you have taken during these negotiations, and we stand ready to provide additional information that may assist you in your efforts. If you believe it would be helpful, our staffs can provide a briefing on the results of our investigation to date and answer any questions you may have about our findings. Thank you for your consideration.

Sincerely,

John D. Rockefeller IV
Chairman
Senate Committee on Commerce,
Science, and Transportation

Elijah E. Cummings
Ranking Member
House Committee on Oversight
and Government Reform

cc: The Honorable Kay Bailey Hutchison, Ranking Member
Senate Committee on Commerce, Science, and Transportation

The Honorable Darrell E. Issa, Chairman
House Committee on Oversight and Government Reform