Congress of the United States Washington, DC 20515

March 21, 2012

Ms. Brenda Marshall President, Columbia Med Services 9693 Gerwig Lane, Suite R President, Columbia Medical Distributors 9687 Gerwig Lane, Suite C Columbia, MD 21046

Dear Ms. Marshall:

For the past several 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 serious diseases. When these providers are unable to obtain these drugs directly from drug manufacturers or authorized wholesalers, they sometimes purchase them from so-called "gray market" drug distributors at prices that are far higher than they would pay through normal distribution channels. We are deeply troubled that these gray market distributors appear to be benefiting at the expense of seriously ill patients and the health care professionals who care for them.

As part of our investigation, we have obtained documents showing that two companies you own and control, Columbia Med Services and Columbia Medical Distributors, have been involved in multiple transactions for short-supply cancer drugs. Both of these companies have been located in the same industrial office complex in Columbia, Maryland. Based on our investigation, we have serious concerns about these companies' business practices. We are writing to request more information about how these companies bought and sold short-supply drugs.

According to Maryland Board of Pharmacy records, on February 7, 2002, you obtained a license for your company, Columbia Medical Distributors, to operate as a pharmaceutical wholesaler.¹ On July 28, 2005, you obtained a license for your other company, Columbia Med Services, to operate as a pharmacy to serve patients in long-term care facilities.²

² Maryland Board of Pharmacy, *Establishment Detail* (accessed Mar. 1, 2012); Maryland Department of Assessments & Taxation, *Corporate Charter Approval Sheet* (online at http://sdatcert3.resiusa.org/ucc-charter/ViewDoc.asp?Film=B 00839&Folio=0615&Pages=0002&Date=08 03 2005&Ack=1000361991725544&Domain=Charter&ID=D10789790&Name=COLUMBIA

¹ Maryland Board of Pharmacy, *Establishment Detail* (accessed Mar. 1, 2012).

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Documents obtained during the course of this investigation indicate that throughout 2011, Columbia Med Services repeatedly purchased drugs in critically short supply. Rather than using those drugs to serve patients in long-term care facilities pursuant with Columbia Med Services' license, the documents indicate that Columbia Med Services instead transferred the drugs to your other company, Columbia Medical Distributors, which then sold these drugs to other gray market distributors.

For example, the documents indicate that on four different occasions from August to September 2011, you used Columbia Med Services to purchase fluorouracil, which is used to treat colon, stomach, breast, and pancreatic cancer, and which was and still is on the Food and Drug Administration's list of drugs in critically short supply.³ In each of these cases, the documents indicate that rather than dispensing these drugs to patients in long-term care facilities, Columbia Med Services transferred them to your other company, Columbia Medical Distributors, within days of the original purchase.

Date of Transfer to Columbia Med Services	Date of Transfer to Columbia Medical Distributors	Date of Sale by Columbia Medical Distributors	
August 24, 2011	August 25, 2011	August 25, 2011	
September 6, 2011	September 8, 2011	September 8, 2011	
September 6, 2011	September 8, 2011	September 8, 2011	
September 22, 2011	September 23, 2011	September 23, 2011	

Table A:	Transfers of	Fluorouracil	from	Columbia	Med	Services	to Columbia
Medical I	Distributors						

Under Maryland law, the sale of prescription drugs by a waiver pharmacy such as Columbia Med Services to a wholesaler such as Columbia Medical Distributors generally requires a wholesaler license—a license that Columbia Med Services did not have at the time of these sales.⁴

MED SERVICES, LTD.&source=1) (accessed Mar. 1, 2012) (also known as a "waiver pharmacy license").

³ Food and Drug Administration, *Current Drug Shortages* (online at www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm) (accessed Mar. 2, 2012).

⁴ Code of Maryland Regulations 10.34.22.

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On March 8, 2012, Congressman Cummings' staff personally visited your offices and noted that they both appear to have been vacated recently. An employee working for a business located next door informed the staff that he rarely saw anyone in the offices of Columbia Medical Distributors.

Request for Documents and Information

To help us understand how your companies acquired short-supply drugs and how much your companies profited from their sale, we request that you provide the following information:

- 1. Documents sufficient to show all the physical locations where Columbia Med Services or Columbia Medical Distributors has operated at any time since January 1, 2010.
- 2. Copies of all the licenses under which Columbia Med Services or Columbia Medical Distributors has operated at any time since January 1, 2010.
- 3. Documents sufficient to show, aside from Columbia Med Services or Columbia Medical Distributors, the names, assumed names, or fictitious business names and addresses and states of licensure of all other pharmacies, pharmaceutical wholesalers, or other drug-related companies in which you had a financial interest or held a position at any time since January 1, 2010.
- 4. Documents sufficient to show each of Columbia Med Services' purchases of pharmaceuticals during 2011, including, for each purchase, the date of the purchase, the identity of the seller, and the national drug code, the drug name, the lot number, the quantity, and the per-unit cost of each drug purchased, as well as whether Columbia Med Services took physical possession of the drug.
- 5. Documents sufficient to show each of Columbia Med Services' sales of pharmaceuticals during 2011, including, for each sale, the date of the sale, the identity of the purchaser, and the national drug code, the drug name, the lot number, the quantity, and the per-unit price of each drug sold.
- 6. Documents sufficient to show each of Columbia Medical Distributors' purchases of pharmaceuticals during 2011, including, for each purchase, the date of the purchase, the identity of the seller, and the national drug code, the drug name, the lot number, the quantity, and the per-unit cost of each drug purchased, as well as whether Columbia Medical Distributors took physical possession of the drug.

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- 7. Documents sufficient to show each of Columbia Medical Distributors' sales of pharmaceuticals during 2011, including, for each sale, the date of the sale, the identity of the purchaser, and the national drug code, the drug name, the lot number, the quantity, and the per-unit price of each drug sold.
- 8. Documents sufficient to show for each drug Columbia Med Services or Columbia Medical Distributors took possession of, how they were stored, handled, and shipped to and from the companies.
- 9. A list of all pharmaceutical manufacturers for which Columbia Med Services or Columbia Medical Distributors currently serves or has served as an authorized distributor of record.

We request that you provide this information by April 11, 2012. Please contact John Williams at (202) 224-1300, Beth Stein at (202) 224-2931, and Ellen Zeng at (202) 225-5051 to arrange for the production of the requested documents.

Sincerely,

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

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Tom Harkin Chairman Senate Committee on Health, Education, Labor, and Pensions

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 Michael B. Enzi, Ranking Member Senate Committee on Health, Education, Labor, and Pensions

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