

Congress of the United States
Washington, DC 20515

March 21, 2012

Ms. Jessica Hoppe
President and Owner, LTC Pharmacy, Inc.
1618 Page Road Extension, Unit 101-B
President and Owner, International Pharmaceuticals, Inc.
1618 Page Road Extension, Unit 101-A
Durham, NC 27703

Dear Ms. Hoppe:

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 that show that two companies you own and control, LTC Pharmacy and International Pharmaceuticals, have been involved in multiple transactions for short-supply cancer drugs. Both of these companies have been located in the same building in Durham, North Carolina.

Based on our own investigation and the results of investigations undertaken by the North Carolina Board of Pharmacy, we have serious concerns about these companies’ business practices. Although LTC Pharmacy obtained a license from the State of North Carolina to sell pharmaceuticals to long-term care facilities and infusion clinics, its main purpose instead appears to have been to purchase drugs in short supply, and then transfer them to your other company, International Pharmaceuticals, which in turn would sell them to other gray market distributors.

We are writing to request more information about how these companies bought and sold short-supply drugs.

LTC Pharmacy

According to North Carolina Board of Pharmacy records, on May 2, 2011, you obtained a license for LTC Pharmacy to serve long-term care facilities and infusion clinics.¹ On September 19, 2011, however, the North Carolina Board of Pharmacy inspected LTC Pharmacy and concluded that it “is not an operating pharmacy.”² Board of Pharmacy investigators reported as follows:

Pharmacist manager is not at present at Pharmacy 35 hours a week. ... Staff has indicated no dispensing has taken place since opening. [R]ather orders being placed by the pharmacy are transferred to International Pharmaceuticals for wholesale distribution. The Pharmacy is acting as a wholesaler/Distributor w/out a license to do so.³

As a result of these findings, on October 26, 2011, the pharmacist you hired to operate LTC Pharmacy admitted that “she committed acts that give the Board sufficient cause to revoke her license to practice pharmacy in North Carolina.”⁴ She voluntarily surrendered the permit to operate LTC Pharmacy on September 20, 2011.⁵

International Pharmaceuticals

Documents obtained during our ongoing investigation indicate that, throughout 2011, LTC Pharmacy repeatedly purchased drugs in critically short supply. Rather than distributing the drugs to long-term care facilities or infusion clinics pursuant to LTC Pharmacy’s license, the documents indicate that LTC Pharmacy instead transferred the drugs to your other company, International Pharmaceuticals, a licensed pharmaceutical wholesaler, which then sold these drugs to other gray market distributors.

For example, the documents indicate that on six different occasions from June to September 2011, you used LTC Pharmacy 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

¹ North Carolina Board of Pharmacy, *Voluntary Surrender of Permit for Cause* (Sept. 20, 2011); North Carolina Board of Pharmacy, *2011 Application for Registration and Permit to Conduct a Pharmacy* (Mar. 24, 2011) (also known as a “waiver pharmacy license”).

² North Carolina Board of Pharmacy, *Miscellaneous Inspection Report* (Sept. 19, 2011).

³ *Id.*

⁴ North Carolina Board of Pharmacy, *Voluntary Surrender of License for Cause* (Oct. 26, 2011).

⁵ North Carolina Board of Pharmacy, *Voluntary Surrender of Permit for Cause* (Sept. 20, 2011).

Administration's list of drugs in critically short supply.⁶ The documents indicate that rather than selling these drugs to long-term care facilities and infusion clinics in accord with LTC Pharmacy's license, you transferred them to your other company, International Pharmaceuticals, within days of the original purchase.

Table A: Transfers of Fluorouracil from LTC Pharmacy to International Pharmaceuticals

Date of Transfer to LTC Pharmacy	Date of Transfer to International Pharmaceuticals	Date of Sale by International Pharmaceuticals
June 15, 2011	June 15, 2011	June 16, 2011
July 19, 2011	July 20, 2011	July 20, 2011
August 24, 2011	August 25, 2011	August 29, 2011
September 7, 2011	September 8, 2011	September 7, 2011*
September 8, 2011	September 8, 2011	September 12, 2011
September 8, 2011	September 8, 2011	September 12, 2011

* International Pharmaceuticals may have dated its invoice before it obtained the drugs from LTC Pharmacy, or LTC Pharmacy may have dated its invoice after it transferred the drugs to International Pharmaceuticals.

According to the North Carolina Board of Pharmacy, investigators received information that LTC Pharmacy was "located in the back of International Pharmaceuticals."⁷ Under North Carolina law, the sale of prescription drugs to wholesalers requires a wholesaler license,⁸ and wholesalers are prohibited from buying prescription drugs from sources other than those with appropriate licenses to sell drugs in North Carolina.⁹

On November 3, 2011, North Carolina officials informed you that they would no longer allow International Pharmaceuticals to operate as a wholesale prescription drug distributor because it was improperly purchasing drugs from LTC Pharmacy, which did not have a license to sell drugs to wholesale distributors.¹⁰ The officials issued a notice stating that they planned to

⁶ Food and Drug Administration, *Current Drug Shortages* (online at www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm) (accessed Mar. 2, 2012).

⁷ North Carolina Board of Pharmacy, Office of Investigations and Inspections, *Complaint* (Sept. 15, 2011).

⁸ North Carolina General Statutes § 106-145.3.

⁹ Rule 02 North Carolina Administrative Code 09M.0103.

¹⁰ Letter from Director, Food and Drug Protection Division, North Carolina Department of Agriculture and Consumer Services, to Jessica Hoppe, President, International Pharmaceuticals, Inc. (Nov. 3, 2011).

“deny any further renewal of the license of International Pharmaceuticals” because of “the purchasing of prescription drugs from an unlicensed source,” namely LTC Pharmacy.¹¹

On December 12, 2011, one of your former employees applied for a license in North Carolina to operate as a pharmaceutical wholesaler.¹² North Carolina officials rejected this application, concluding as follows:

[Y]our affiliation with International Pharmaceuticals and your responsibilities with International Pharmaceuticals as sales representative/sales manager/office manager is of great concern to us; International Pharmaceuticals and LTC Pharmacy willfully violated NC wholesaler prescription drug distribution laws for an extended period of time during 2011, resulting in the denial of a wholesale license renewal for International Pharmaceuticals and the voluntary surrender of the pharmacy license for LTC Pharmacy.¹³

Although International Pharmaceuticals no longer holds a prescription drug wholesaler license in North Carolina, it appears that the company may have active wholesaler licenses in at least 23 other states.¹⁴ Although these out-of-state licenses reference your company’s primary location in North Carolina, it is unclear whether you have notified those states that North Carolina refused to renew International Pharmaceuticals’ license.

¹¹ *Id.*

¹² North Carolina Department of Agriculture and Consumer Services, *License Application for Wholesale Prescription Drug Distributors* (Dec. 12, 2011).

¹³ Email from North Carolina Department of Agriculture and Consumer Services to Former International Pharmaceuticals Employee (Jan. 3, 2012).

¹⁴ Including Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Missouri, New York, Ohio, Pennsylvania, Tennessee, Texas, Washington, West Virginia, and Wyoming.

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:

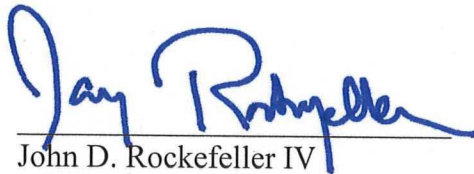
1. Documents sufficient to show all the physical locations where LTC Pharmacy or International Pharmaceuticals has operated at any time since January 1, 2010.
2. Copies of all the licenses under which LTC Pharmacy or International Pharmaceuticals has operated at any time since January 1, 2010.
3. Documents sufficient to show, aside from LTC Pharmacy or International Pharmaceuticals, 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 LTC Pharmacy's 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 LTC Pharmacy took physical possession of the drug.
5. Documents sufficient to show each of LTC Pharmacy's 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 International Pharmaceuticals' 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 International Pharmaceuticals took physical possession of the drug.
7. Documents sufficient to show each of International Pharmaceuticals' 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 LTC Pharmacy or International Pharmaceuticals took possession of, how they were stored, handled, and shipped to and from the companies.

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9. A list of all pharmaceutical manufacturers for which LTC Pharmacy or International Pharmaceuticals 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



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