## Congress of the United States Washington, DC 20515

March 21, 2012

Ms. Marianna Pesti Owner and President, Priority Healthcare LLC Mr. Gabor Szilagyi Manager, Priority Healthcare LLC 751 Elkton Blvd. Suite #1 Elkton, MD 21921

Mr. Gabor Szilagyi Owner Tri-Med America LLC 68 Colfax Ave. Clifton, NJ 07013

Dear Ms. Pesti and Mr. Szilagyi:

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 Ms. Pesti is the owner and operator of Priority Healthcare, while Ms. Pesti's husband, Mr. Szilagyi, is the manager of Priority Healthcare and the owner of Tri-Med America. The documents indicate that you obtained a license from the State of Maryland authorizing Priority Healthcare to sell pharmaceuticals to long-term care facilities and nursing homes, but rather than operating Priority Healthcare to purchase drugs in short supply, transfer them to Tri-Med America, and then sell them to other gray market distributors.

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

## **Priority Healthcare**

Maryland Board of Pharmacy records show that, on August 16, 2006, you obtained a pharmacy license for Priority Healthcare to serve long-term care facilities and nursing homes.<sup>1</sup> On June 18, 2010, however, the Board of Pharmacy conducted a routine inspection of Priority Healthcare and found numerous violations of Maryland state law.<sup>2</sup> The inspection revealed:

- 5. On the Respondent-Pharmacy's [Priority Healthcare's] Application for Pharmacy Permit, received by the Board on May 26, 2006, Ms. Pesti disclosed that Pharmacist A was employed as the Respondent-Pharmacy's full-time pharmacist. The application also stated that the Respondent-Pharmacy would be open for business Monday through Friday from 9:00 a.m. to 5:00 p.m.
- 7. On June 18, 2010 at 10:00 a.m., the Board's inspector and Pharmacist Compliance Officer ("Compliance Officer") arrived at the Respondent-Pharmacy's location in Elkton, Maryland to conduct a routine inspection.
- 8. The Respondent-Pharmacy was closed.
- 10. According to the staff and owner of a neighboring business ... there was seldom anyone present at Respondent-Pharmacy. ...
- 11. A 35-year employee of [the neighboring business], Witness A, who works Monday through Friday from 7:00 a.m. to 4:00 p.m. stated that he had never seen anyone at the Respondent-Pharmacy more frequently than "once every 6 business days at best." Witness A further stated that the United Parcel Service is often attempting deliveries and asking for a signature because "no one is ever there [at Respondent-Pharmacy]."
- 12. Witness A also stated that a man and woman, believed to be husband and wife, "show up every once in a while."
- 13. The owner of the property where Respondent-Pharmacy leases its space stated that he hadn't seen "the guy" (referring to Ms. Pesti's husband) in one to one-and-a-half years.<sup>3</sup>

 $^2$  Id.

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<sup>&</sup>lt;sup>1</sup> Maryland Board of Pharmacy, *Consent Order: In the Matter of Priority Healthcare, LLC* (Oct. 19, 2011) (online at

www.dhmh.state.md.us/pharmacy/docs/FormalOrders/P/Priority%20Healthcare,%20LLC%2010-19-11.pdf) (The license you obtain is also known as a "waiver pharmacy license").

On June 21, 2010, the Compliance Officer came back "during regular business hours to serve two subpoenas."<sup>4</sup> He found that Priority Healthcare "was closed and no one answered the door." He also "observed several pieces of mail with postmark dates ranging from June 14, 2010 to June 17, 2010 from McKesson Med/Surg, ConMed, Fisher Scientific, Hollister, Inc., BSN Medical, GSK Contract Operations, and Verizon."<sup>5</sup> After this second visit:

The Compliance Officer received a call from Gabor Szilagyi, who identified himself as the manager of Respondent-Pharmacy and husband of Ms. Pesti. ... Mr. Szilagyi asked that the Compliance Officer "come back tomorrow" because he didn't have childcare. The Compliance Officer stated that she would wait for him, and he estimated that he would arrive in two hours because he was in New Jersey.

When Mr. Szilagyi and Ms. Pesti arrived at Priority Healthcare later that day, Mr. Szilagyi reportedly stated:

The Respondent-Pharmacy is attempting to open an account with McKesson to purchase drugs, but "[McKesson] wanted a business plan ... and all of this stuff ... it's really difficult to get on with them;" ... Pharmacist A is at present at the Respondent-Pharmacy "most of the time, every day," but was on vacation that week.

In addition, during an interview with the Maryland Board of Pharmacy, the individual who you told the Board of Pharmacy was your pharmacist explained that he was not in fact serving this role:

- 20. Pharmacist A stated that he is employed as a "consultant" for the Respondent-Pharmacy and had only been to the Respondent-Pharmacy "three or four times" over a one year period. He further stated that he does not receive a salary from Respondent-Pharmacy, but his travel expenses are paid, in cash, if he has to visit the Respondent-Pharmacy.
- 21. Pharmacist A never dispensed any medications from the Respondent-Pharmacy. ...
- 22. According to Pharmacist A, he informed Mr. Szilagyi that he was unable to be at Respondent-Pharmacy every day.<sup>6</sup>

Based on these findings, and your failure to comply with their subpoena, the Maryland Board of Pharmacy concluded as a matter of law that you violated multiple provisions of

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

<sup>5</sup> Id.

 $^{6}$  Id.

Maryland law, including the provisions stating "that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation," that "a person may not hinder an inspection or an investigation," and that "a person may not obtain a license by making any false representation."<sup>7</sup>

## **Tri-Med America**

Documents obtained during the course of our ongoing investigation indicate that, throughout 2011, Priority Healthcare repeatedly purchased drugs in critically short supply. Rather than dispensing these drugs to patients in long-term care facilities and nursing homes in accord with Priority Healthcare's license, the documents indicate that Priority Healthcare sold these drugs to Tri-Med America, which later sold them to other gray market distributors.

For example, the documents indicate that on at least two different occasions in 2011, Priority Healthcare purchased fluorouracil, which is used to treat colon, stomach, breast, and pancreatic cancer, and magnesium sulfate, which is used to treat life-threatening seizures in pregnant women. Both drugs were and still are on the Food and Drug Administration's list of drugs in critically short supply.<sup>8</sup> The documents show that you transferred them to your other company, Tri-Med America, on the same day as the original purchase.

Under Maryland law, the sale of prescription drugs by a waiver pharmacy such as Priority Healthcare to a wholesaler generally requires a wholesaler license.<sup>9</sup> In New Jersey, wholesale distributors such as Priority Healthcare located outside of New Jersey need a wholesaler license to engage in wholesale distribution of prescription drugs.<sup>10</sup>

## **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 Priority Healthcare or Tri-Med America has operated at any time since January 1, 2010.

 $^{7}$  Id.

<sup>8</sup> Food and Drug Administration, *Current Drug Shortages* (online at www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm) (accessed Mar. 2, 2012).

<sup>9</sup> Code of Maryland Regulations 10.34.22.

<sup>10</sup> New Jersey Statutes 24:6B-15.

- 2. Copies of all the licenses under which Priority Healthcare or Tri-Med America has operated at any time since January 1, 2010.
- 3. Documents sufficient to show, aside from Priority Healthcare or Tri-Med America, 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 Priority Healthcare'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 Priority Healthcare took physical possession of the drug.
- 5. Documents sufficient to show each of Priority Healthcare'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 Tri-Med America'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 Tri-Med America took physical possession of the drug.
- 7. Documents sufficient to show each of Tri-Med America'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.
- 8. Documents sufficient to show for each drug Priority Healthcare or Tri-Med America took possession of, how they were stored, handled, and shipped to and from the companies.
- 9. A list of all pharmaceutical manufacturers for which Priority Healthcare or Tri-Med America 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