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ONE HUNDRED TWELFTH CONGRESS

# Congress of the United States

## House of Representatives

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2157 RAYBURN HOUSE OFFICE BUILDING

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October 5, 2011

Mr. Steven Greenwald  
Chief Executive Officer  
PRN Pharmaceuticals  
11736 Parklawn Drive  
Rockville, MD 20852

Dear Mr. Greenwald:

I am writing to request documents relating to your company's purchases and sales of the drug fluorouracil, which is used to treat colon, stomach, breast, and pancreatic cancer and is in critically short supply, according to the Food and Drug Administration (FDA).<sup>1</sup>

The Committee is investigating "key areas related to drug safety."<sup>2</sup> Pursuant to this investigation, I have been working with a network of hospital, pharmacy, and government representatives to investigate the extent to which "gray market" middleman companies are making substantial profits by engaging in a form of drug speculation. There have been several reports describing this problem. For example:

- On August 23, 2011, Premier Healthcare Alliance issued a report examining more than 1,700 offers by 18 gray market companies for drugs in short supply sent to 42 acute care hospitals. Premier found that the average markup for these drugs was 650% and that the largest markups were for drugs for critical patients, such as those with cancer.<sup>3</sup>
- On August 25, 2011, the Institute for Safe Medication Practices issued the results of a survey of purchasing agents and pharmacists at more than 500 hospitals, reporting that

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<sup>1</sup> Food and Drug Administration, *Current Drug Shortages* (accessed Sept. 26, 2011) (online at [www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm](http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm)).

<sup>2</sup> House Oversight and Government Reform Committee, *Oversight Plan*, 112th Cong. (Feb. 10, 2011) (online at [http://oversight.house.gov/images/stories/112th\\_Oversight\\_Plan\\_02092011.pdf](http://oversight.house.gov/images/stories/112th_Oversight_Plan_02092011.pdf)).

<sup>3</sup> *Buyer Beware: Drug Shortages and the Gray Market*, Premier Healthcare Alliance (Aug. 23, 2011) (online at [www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf](http://www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf)).

more than half received solicitations from gray market companies on a daily basis, and “up to 12% of respondents reported awareness of a product authenticity issue, medication error, or adverse drug reactions associated with the use of gray market products in the past 2 years.”<sup>4</sup>

- On September 23, 2011, the Associated Press published the results of a review of industry reports and interviews with nearly two dozen experts about the current drug shortage and its impact on patients, hospitals, and the gray market. The review found that “a severe shortage of drugs for chemotherapy, infections and other serious ailments is endangering patients and forcing hospitals to buy life-saving medications from secondary suppliers at huge markups because they can’t get them any other way.”<sup>5</sup>

According to FDA, “in 2010 there was a record number of shortages and in 2011 FDA has continued to see an increasing number of shortages.”<sup>6</sup> According to Dr. James Speyer, the medical director of the New York University Langone Clinical Cancer Center, in August 2011 the Center was “cold out” of fluorouracil and “had over 30 patients who had their treatment delayed or changed” to another drug, which some patients had trouble tolerating.”<sup>7</sup>

During the course of our investigation, we have obtained internal documents indicating that your company may be charging prices that are many times higher than normal contract prices for critical drugs. For example, fluorouracil is manufactured by the following three U.S. companies: Mylan Institutional, APP, and Teva.<sup>8</sup> According to information obtained by my staff, a typical price for fluorouracil is approximately \$15. This price is based on negotiated contracts to purchase drugs with authorized manufacturers and distributors of the drug.

In contrast, however, documents we have obtained also indicate that an account representative from your company offered to sell fluorouracil for over \$350 per vial, more than 23 times a typical sales price. These documents do not disclose where your company obtained the drug or how much your company originally paid for it.

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<sup>4</sup> *Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis*, Institute for Safe Medication Practices (Aug. 25, 2011) (online at [www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3](http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3)).

<sup>5</sup> *Hospital Drug Shortages Deadly, Costly*, Associated Press (Sept. 23, 2011) (online at [http://abclocal.go.com/wpvi/story?section=news/national\\_world&id=8365402](http://abclocal.go.com/wpvi/story?section=news/national_world&id=8365402)).

<sup>6</sup> Food and Drug Administration, *Current Drug Shortages* (accessed Sept. 26, 2011) (online at [www.fda.gov/drugs/drugsafety/drugshortages/default.htm](http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm)).

<sup>7</sup> *U.S. Drug Shortage Could Threaten U.S. Health System*, ABC News (Sept. 23, 2011) (online at <http://abcnews.go.com/Health/CancerPreventionAndTreatment/drug-shortages/story?id=14593880&page=2>).

<sup>8</sup> Food and Drug Administration, *Current Drug Shortages* (accessed Sept. 26, 2011) (online at [www.fda.gov/drugs/drugsafety/drugshortages/default.htm](http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm)).

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Although it is possible that you have higher labor and equipment costs than other distributors, it is difficult to understand why your company would charge over \$350 per vial when a typical contract price for the drug is approximately \$15 per vial.

Fluorouracil is a critical drug used to treat colon, stomach, breast, and pancreatic cancer, and it is in desperately short supply. In order to determine why your company appears to be charging more than 23 times a typical contract price for this drug, please produce, for the time period from January 1, 2010, to the present, all documents, including e-mails, purchase orders, inventory lists, and other documents, relating to:

1. the identity of all companies and individuals from which your company purchased fluorouracil, the date of each purchase, the quantity of each purchase, and the price paid for each purchase;
2. the identity of all companies and individuals to which your company sold fluorouracil, the date of each sale, the quantity of each sale, and the price paid in each sale;
3. your company's handling, storage, and recordkeeping procedures for this drug;
4. your company's gross revenues, net profits, and the compensation of company executives; and
5. your company's costs for labor, equipment, and other costs for handling, storage, and delivery.

Please provide these documents by October 19, 2011. When producing documents to the Committee, please deliver them to the Minority Staff in Room 2471 of the Rayburn House Office Building and the Majority Staff in Room 2157 of the Rayburn House Office Building. If you have any questions, please contact Chris Staszak or Pamela Dooley at (202) 225-5051.

Sincerely,



Elijah E. Cummings  
Ranking Member

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