

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051

<http://oversight.house.gov>

May 13, 2015

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you very much for speaking with me about the Committee's investigation of the increasing price of certain generic and other drugs. I appreciate the manner in which you and I have been able to work together constructively, and I thank you again for considering my proposals. As you requested, this letter sets forth ideas for hearings and requests for documents to further this investigation.

At the beginning of this Congress, our Committee voted unanimously to adopt an oversight plan that includes a commitment to investigate increases in the prices of certain drugs:

The Committee will examine the causes and effects of critical pharmaceutical drug shortages, recent increases in the price of certain generic drugs, and the policies and procedures in place to protect the public from the outbreak of dangerous or deadly diseases.¹

On February 27, my staff submitted several proposals for hearings important to Democratic Members—including a hearing on drug price increases. Later that day, your staff indicated that they had gone over these proposals with you and that you agreed in concept with all of them, although they also stated that you might suggest adjustments to some of the proposed witnesses.

In order to move this process forward, I am setting forth in this letter several specific steps we can take in the coming days.

¹ House Committee on Oversight and Government Reform, Oversight Plan for the 114th Congress (Feb. 11, 2015).

Price Increases for Isuprel and Nitropress

Isuprel and Nitropress are drugs used by doctors to treat abnormal heart rhythms, congestive heart failure, and hypertensive episodes. In 2013, the unit prices of these medicines, which were manufactured by Hospira, were \$38 and \$45, respectively. In December of 2013, these drugs were purchased by a company known as Marathon Pharmaceuticals, and this company increased the prices of both drugs to more than \$200 per unit. Then, in February of this year, Marathon sold these drugs to another company known as Valeant, and this company increased the prices again to more than \$1,200 per unit and \$600 per unit, respectively.

These price increases appear to have no bearing on the costs the companies incurred to produce them. As a result of these price increases, hospitals and other providers have warned that increasingly large portions of their budgets will now have to be diverted to cover the increased costs of these drugs.

To understand the reasons behind these price increases and their effects on providers, I propose a hearing with the following witnesses:

- **F. Michael Ball**
CEO of Hospira
- **Jeffery Aronin**
CEO of Marathon Pharmaceuticals
- **Michael Pearson**
CEO of Valeant Pharmaceutical International
- **Gerard Anderson Ph.D.**
Director, Center for Hospital Finance and Management
Johns Hopkins Bloomberg School of Public Health
- **Erin Fox, Pharm.D.**
Director, Drug Information Service
University of Utah Health Care

In addition, attached are draft letters to Marathon and Valeant requesting documents relating to their decisions to increase the prices of these drugs.

Price Increases for Naloxone

Over the past year, police departments, law enforcement agencies, and public health officials across the country have warned about the increasing price of naloxone, which they use to combat the scourge of heroin abuse. According to a report in the *New York Times* in November, “police and public health officials from New York to San Francisco are facing sticker

shock: Prices for a popular form of the medication, naloxone, are spiking, in some cases by 50 percent or more.”²

The manufacturer of naloxone, a company known as Amphastar, agreed to reduce the price of this drug in New York after the state Attorney General wrote to the company warning about the public health and budgetary effect of the price increases. The company agreed to reduce the price of naloxone by providing a rebate of \$6 per dose.

In order to understand whether other states could obtain similar reductions in the price of this drug, I propose a hearing with the following witnesses:

- **The Honorable Eric Schneiderman**
Attorney General, State of New York
- **The Honorable Sean Reyes**
Attorney General, State of Utah
- **The Honorable Brian E. Frosh**
Attorney General, State of Maryland
- **Jack Y. Zhang, Ph.D.**
CEO, Amphastar Pharmaceuticals
- **Chuck Wexler**
Executive Director
Police Executive Research Forum
- **Sharon Stancliff, M.D.**
Medical Director
Harm Reduction Coalition
- Representative from Utah Department of Health
- Representative from Maryland Department of Health and Mental Hygiene

Request for Information from CMS

Finally, also attached is a draft letter to the Centers for Medicare and Medicaid Services at the Department of Health and Human Services requesting information regarding the Average Manufacturer Price for drugs that have increased in price, according to National Average Drug Acquisition Cost data. Manufacturers already provide this data on a quarterly basis, but the Department has indicated that it will produce this information only in response to a request from the Committee.

² *Naloxone, a Drug to Stop Heroin Deaths, Is More Costly, the Police Say*, New York Times (Nov. 30, 2014) (online at www.nytimes.com/2014/12/01/nyregion/prices-increase-for-antidote-to-heroin-overdoses-used-by-police.html).

I hope these proposals and the attachments to this letter provide enough specific information for the Committee to proceed on this investigation. As I mentioned when we spoke, this is one of my highest priorities because it affects our constituents in every single congressional district. Thank you again for your consideration, and please contact me or my staff if you have any questions or if we can provide any additional information.

Sincerely,

A handwritten signature in blue ink that reads "Elijah E. Cummings". The signature is written in a cursive, flowing style with a large loop at the end of the last name.

Elijah E. Cummings
Ranking Member

May xx, 2015

Jeffrey S. Aronin
Chairman and Chief Executive Officer
Marathon Pharmaceuticals, LLC
1033 Skokie Boulevard
Northbrook, IL 60062

Dear Mr. Aronin:

We are conducting an investigation into the recent price increases for drugs used to treat common medical conditions to life-threatening illnesses. As part of this investigation, we are writing to your company to request information about the prices it charged for two drugs, Isuprel and Nitropress, which are used by doctors to treat abnormal heart rhythms, congestive heart failure, and hypertensive episodes.

According to data provided by the Healthcare Supply Chain Association, the average prices charged for these drugs have increased by as much as 391% for Isuprel and 388% for Nitropress from November 2012 to September 2014. Over that time period, the average market price went up by as much as \$3,573 for Isuprel and \$171 for Nitropress.¹

In order to evaluate the underlying causes of these price increases, we request that you provide the following documents and information for the time period covering December 2013 to February 10, 2015:

- (1) total gross revenues from the company's sales of these drugs;
- (2) the dates, quantities, purchasers, and prices paid for all sales of these drugs;
- (3) total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;

¹ Healthcare Supply Chain Association, *Survey of Group Purchasing Organizations* (Oct. 2013 to Apr. 2014) (HSCA surveyed the average costs paid by four GPOs from October 2013 to April 2014. One GPO provided percentage increases rather than price increases, so the average reflects additional price data not captured by the average market price increase. One GPO provided price information for January 2013 to April 2014.).

- (4) sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;
- (5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the price of these drugs;
- (6) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
- (7) prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest price; and
- (8) the identity of company official(s) responsible for setting the price of these drug over the above time period.

Please provide the requested documents and information by [May xx, 2015].

The Committee on Oversight and Government Reform is the principal investigative committee in the U.S. House of Representatives. Pursuant to House Rule X, the Committee has authority to investigate "any matter" at "any time."

If you have any questions about this request, please contact Sean Hayes with the majority staff at (202) 225-5074 or Kelly Christl with the minority staff at (202) 225-5051. Thank you for your attention to this important matter.

Sincerely,

Jason Chaffetz
Chairman

Elijah E. Cummings
Ranking Member

May xx, 2015

Michael Pearson
Chairman and Chief Executive Officer
Valeant Pharmaceutical International, Inc.
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807

Dear Mr. Pearson:

We are conducting an investigation into the recent price increases for drugs used to treat common medical conditions to life-threatening illnesses. As part of this investigation, we are writing to your company to request information about the prices it charges for two drugs, Isuprel and Nitropress, which are used by doctors to treat abnormal heart rhythms, congestive heart failure, and hypertensive episodes.

Your company recently purchased these two drugs from Marathon Pharmaceuticals. According to press reports, your company increased the prices of these two drugs by 525% and 212% on the day your company bought the rights to these drugs.¹

In order to evaluate the underlying causes of these price increases, we request that you provide the following documents and information:

- (1) total gross revenues from the company's sales of these drugs;
- (2) the dates, quantities, purchasers, and prices paid for all sales of these drugs;
- (3) total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
- (4) sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;
- (5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the price of these drugs;

¹ *Pharmaceutical Companies Buy Rivals' Drugs, Then Jack up the Prices*, Wall Street Journal (Apr. 26, 2015).

- (6) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
- (7) prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest price; and
- (8) the identity of company official(s) responsible for setting the price of these drug over the above time period.

Please provide the requested documents and information by [May xx, 2015].

The Committee on Oversight and Government Reform is the principal investigative committee in the U.S. House of Representatives. Pursuant to House Rule X, the Committee has authority to investigate "any matter" at "any time."

If you have any questions about this request, please contact Sean Hayes with the majority staff at (202) 225-5074 or Kelly Christl with the minority staff at (202) 225-5051. Thank you for your attention to this important matter.

Sincerely,

Jason Chaffetz
Chairman

Elijah E. Cummings
Ranking Member

May xx, 2015

The Honorable Marilynn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Tavenner:

Historically, generic drugs have helped millions of Americans who rely on prescription pharmaceuticals to manage their health needs, and they have resulted in huge savings for consumers and taxpayers. However, recent cost increases are now preventing some patients from getting the drugs they need.

For example, according to National Average Drug Acquisition Cost (NADAC) data, the average price for a 2 mg tablet of Albuterol Sulfate, which is used to treat asthma and other lung conditions, was 11 cents in November 2012. By December 2014, 2014, the average price had increased to \$3.83 per tablet, representing a 3,381% price increase.

We are writing to request that you provide to the Committee by [May xx, 2015], the quarterly Average Manufacturer Price data at the National Drug Code level from January 2010 to the present for the drugs listed in the Attachment to this letter, which have all increased in price according to NADAC data analyzed by the Congressional Research Service.

The Committee on Oversight and Government Reform is the principal investigative committee in the U.S. House of Representatives. Pursuant to House Rule X, the Committee has authority to investigate “any matter” at “any time.”

If you have any questions about this request, please contact Sean Hayes with the majority staff at (202) 225-5074 or Kelly Christl with the minority staff at (202) 225-5051. Thank you for your attention to this important matter.

Sincerely,

Jason Chaffetz
Chairman

Elijah E. Cummings
Ranking Member

ATTACHMENT

Albuterol Sulfate 4mg tablet	Fluconazole 150 mg tablets
Albuterol Sulfate 2mg tablet	Fluconazole 100 mg tablet
Amitriptyline Hydrochloride 150 mg tablet	Fluconazole 50 mg tablet
Amitriptyline Hydrochloride 100 mg tablet	Glycopyrrolate 0.2 mg/ml, 20 ml vial
Amitriptyline Hydrochloride 75 mg tablet	Glycopyrrolate 0.2 mg/ml, 5 ml vial
Amitriptyline Hydrochloride 50 mg tablet	Glycopyrrolate 0.2 mg/ml, 2 ml vial
Amitriptyline Hydrochloride 25 mg tablet	Glycopyrrolate 0.2 mg/ml, 1 ml vial
Amitriptyline Hydrochloride 10 mg tablet	Isoproterenol 1 mg/5ml vial
Atenolol & Chlorthalidone 100-25 mg tablet	Isoproterenol 0.2 mg/ml vial
Atenolol & Chlorthalidone 50-25 mg tablet	Levothyroxine Sodium 300 mcg tablet
Benazepril-Hydrochlorothiazide 20-25 mg tablet	Levothyroxine Sodium 200 mcg tablet
Benazepril-Hydrochlorothiazide 20-12.5 mg tablet	Levothyroxine Sodium 175 mcg tablet
Benazepril-Hydrochlorothiazide 10-12.5 mg tablet	Levothyroxine Sodium 150 mcg tablet
Benazepril-Hydrochlorothiazide 5-6.25 mg tablet	Levothyroxine Sodium 137 mcg tablet
Captopril 100 mg tablet	Levothyroxine Sodium 125 mcg tablet
Captopril 50 mg tablet	Levothyroxine Sodium 112 mcg tablet
Captopril 25 mg tablet	Levothyroxine Sodium 100 mcg tablet
Captopril 12.5 mg tablet	Levothyroxine Sodium 88 mcg tablet
Clomipramine Hydrochloride 75 mg capsule	Levothyroxine Sodium 75 mcg tablet
Clomipramine Hydrochloride 50 mg capsule	Levothyroxine Sodium 50 mcg tablet
Clomipramine Hydrochloride 25 mg capsule	Levothyroxine Sodium 25 mcg tablet
Desonide 0.05% ointment	Methotrexate Sodium 2.5 mg tablet
Desonide 0.05% cream	Mirtazapine 45 mg tablet
Desonide 0.05% lotion	Mirtazapine 30 mg tablet
Digoxin 250 mcg tablet	Mirtazapine 15 mg tablet
Digoxin 125 mcg tablet	Mirtazapine 7.5 mg tablet
Divalproex Sodium ER 500 mg tablet	Neostigmine Methylsulfate 1:1000 vial
Divalproex Sodium ER 250 mg tablet	Neostigmine Methylsulfate 1:2000 vial
Doxazosin Mesylate 8 mg tablet	Nitroprusside Sodium 25 mg/ml 2 ml (50 mg) vial
Doxazosin Mesylate 4 mg tablet	Pravastatin Sodium 80 mg tablet
Doxazosin Mesylate 2 mg tablet	Pravastatin Sodium 40 mg tablet
Doxazosin Mesylate 1 mg tablet	Pravastatin Sodium 20 mg tablet
Doxycycline Hyclate 100 mg capsule	Pravastatin Sodium 10 mg tablet
Doxycycline Hyclate 100 mg tablet	Prednisolone Acetate 1% eye drop
Doxycycline Hyclate 50 mg capsule	Prednisone 50 mg tablet
Enalapril Maleate 20 mg tablet	Prednisone 20 mg tablet
Enalapril Maleate 10 mg tablet	Prednisone 10 mg tablet
Enalapril Maleate 5 mg tablet	Prednisone 5 mg tablet
Enalapril Maleate 2.5 mg tablet	Prednisone 2.5 mg tablet
Fluorometholone 0.1% drops	Prednisone 1 mg tablet
Fluconazole 200 mg tablet	Prednisone 10 mg tab dose pack
	Prednisone 5 mg/5 ml solution
	Procainamide Hydrochloride 100 mg/ml 10 ml vial

Procainamide Hydrochloride 500 mg/ml
2 ml vial

Tetracycline 500 mg capsule

Tetracycline 250 mg capsule

Tizanidine Hydrochloride 6 mg tablet

Tizanidine Hydrochloride 4 mg tablet

Tizanidine Hydrochloride 2 mg tablet

Ursodiol 500mg tablet

Ursodiol 300mg tablet

Ursodiol 250 mg tablet