

Congress of the United States
Washington, DC 20515

December 16, 2016

Gary Ruckelshaus
Vice President and General Counsel
Heritage Pharmaceuticals Inc.
12 Christopher Way, Suite 300
Eatontown, New Jersey 07724

Dear Mr. Ruckelshaus:

Earlier this week, the Department of Justice filed charges against two of Heritage's former executives—CEO, Jeffrey Glazer and President, Jason Malek—for engaging in price fixing with two drugs, doxycycline hyclate and glyburide. According to charging documents, Mr. Glazer and Mr. Malek conspired to “allocate customers, rig bids, and fix and maintain prices for doxycycline hyclate sold in the United States” and “sold doxycycline hyclate in the United States and elsewhere at collusive and noncompetitive prices.”¹

We began investigating Heritage's pricing practices on October 2, 2014, when we sent a letter to Mr. Glazer raising concerns about the price of doxycycline hyclate and requesting information and documents relating to the company's sales and pricing of this drug.²

On October 23, 2014, you sent a letter responding to our request to Mr. Glazer, in your capacity as outside counsel at the law firm Blank Rome. The letter, which was signed by you, made the following assertion:

[A]fter a thorough examination of Heritage's sales records from April 30, 2013 (the first date that Heritage was authorized to begin selling its Doxycycline Hyclate DR product) to present, please be advised that Heritage has not seen any significant price increases for its Doxycycline Hyclate DR product in the United States market.³

¹ Information, 2-3 (Dec. 12, 2016), *U.S. v. Glazer*, E.D. Pa. (No. 2:16-cr-00506-RBS); Information, 2-3 (Dec. 13, 2016) *U.S. v. Malek*, E.D. Pa. (No. 2:16-cr-00508-RBS).

² Letter from Chairman Bernard Sanders, Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor, and Pensions, and Ranking Member Elijah Cummings, House Committee on Oversight and Government Reform, to Jeffery Glazer, CEO, Heritage Pharmaceuticals, Inc. (Oct. 2, 2014).

³ Letter from Gary J. Ruckelshaus, Blank Rome Counselors at Law, to Chairman Bernard Sanders, Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor, and Pensions, and Ranking Member Elijah Cummings, House Committee on Oversight and Government Reform (Oct. 23, 2014).

Your firm declined to provide any of the documents or information we requested concerning Heritage's pricing or sales of doxycycline hyclate. It now appears from publicly available information that you have joined Heritage as Vice President and General Counsel for the company.⁴

In light of these new criminal allegations against Mr. Glazer and Mr. Malek, and your new capacity as the company's chief legal officer, we are very concerned that you made these assertions to Congress on behalf of Heritage during the exact time period that its executives were engaged in a price fixing scheme to prevent competition from driving down prices of doxycycline hyclate, according to the Department of Justice.

If these allegations are true and Heritage executives sought to keep the price of doxycycline hyclate artificially high through price fixing and other anticompetitive arrangements, the company's assertions to Congress now seem disingenuous at best. According to a complaint filed by 20 states' attorneys general against Heritage and five other generic drug manufacturers, "As a result of the conspiracies enumerated herein, consumers nationwide paid more for numerous generic pharmaceutical drugs, including specifically Doxy DR [doxycycline hyclate] and Glyburide, than they otherwise would have in a competitive market, and the Defendants illegally profited as a result."⁵

In order to further investigate Heritage's actions regarding doxycycline hyclate, we request that you produce the following documents and information for the time period covering April 1, 2013 to the present:

- (1) all communications relating to our October 2, 2014, request and the response submitted on behalf of Heritage Pharmaceuticals on October 23, 2014, including all email communications, draft memoranda, and other internal communications;
- (2) all materials requested in our October 2, 2014, letter concerning the company's sales and pricing of doxycycline hyclate, including any cost estimates, profit projections, or other analyses; and
- (3) all communications, including email communications, analyses, presentations, or other materials that reference the current or future price of doxycycline hyclate and also reference any other manufacturer of doxycycline hyclate.

⁴ LinkedIn, Profile of Gary Ruckelshaus (online at www.linkedin.com/in/gary-ruckelshaus-8b755a6?authType=NAME_SEARCH&authToken=dUHQ&locale=en_US&trk=tyah&trkInfo=clickedVertical%3Amynetwork%2CclickedEntityId%3A19282315%2CauthType%3A_NAME_SEARCH%2Cidx%3A1-1-1%2CtarId%3A1481896566401%2Ctas%3Agary%20ruckelshau) (accessed Dec. 16, 2016).

⁵ Complaint, 5 (Dec. 14, 2016), *The State of Connecticut v. Aurobindo Pharma USA, Inc.*, D. Conn. (No. 3:16-cv-02056-VLB).

Mr. Ruckelshaus

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Please provide the requested documents and information by December 30, 2016. If you have any questions about this request, please contact Sophie Kasimow with Ranking Member Sanders' staff at (202) 224-5141 or Alexandra Golden with Ranking Member Cummings' staff at (202) 225-5051.

Sincerely,



Bernard Sanders
Ranking Member
Subcommittee on Primary Health
and Retirement Security,
Senate Committee on Health, Education, Labor
and Pensions



Elijah E. Cummings
Ranking Member
House Committee on Oversight and
Government Reform

cc: The Honorable Jason Chaffetz
Chairman, House Committee on Oversight and Government Reform.

The Honorable Michael B. Enzi
Chairman, Subcommittee on Primary Health and Retirement Security, Senate Committee
on Health, Education, Labor and Pensions.