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United States Senate

SPECIAL COMMITTEE ON AGING WASHINGTON, DC 20510-6400 (202) 224-5364

November 4, 2015

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CLAIRE McCASKILL, MISSOURI, RANKING MEMBER

Mr. J. Michael Pearson Chairman of the Board and Chief Executive Officer Valeant Pharmaceuticals International Inc. 400 Somerset Corporate Blvd. Bridgewater, NJ 08807

Dear Mr. Pearson:

The United States Senate Special Committee on Aging is conducting an investigation into the pricing of off-patent drugs in certain circumstances. We seek your cooperation with this investigation so that the Committee may better understand drug pricing and related regulatory and public policy concerns.

In particular, the Committee wishes to learn more about Valeant's recent acquisition of the rights to sell Isuprel and Nitropress, drugs used to treat cardiac arrests and Cuprimine, a drug used to treat Wilson's Disease. In particular, the Committee is interested in better understanding: (1) the increase in the price of Nitropress by 312% the same day that Valeant purchased the rights to Nitropress, from \$257.80 to \$805.61 per vial; (2) the increase in the price of Isuprel by 820% from \$4,489 for twenty-five 0.2 ml ampules to \$36,811; and (3) the increase in the price of Cuprimine by 2,949% from \$888 for one hundred 250 mg capsules to \$26,189.

In order to assist us in our investigation, we ask that you provide us with the documents set forth in Schedule A and the information set forth in Schedule B by December 2, 2015. Please submit the material responsive to this request as it becomes available, rather than waiting to provide it all at once. In order to facilitate this production, we request that Valeant schedule a time to meet and confer on the Request with Committee Staff as soon as it is practicable for you to do so.

The jurisdiction of the Special Committee on Aging is set forth in Section 104 of S. Res. 4, agreed to February 4, 1977.

We appreciate your attention to this matter. Should you have any questions, please do not hesitate to have your staff contact Samuel Dewey of the Majority Staff at (202) 224-2798, or Cathy Yu of the Minority Staff at (202) 224-7752. Please direct all official correspondence to the Committee's Chief Clerk, Matt Lawrence, at Matt_Lawrence@aging.senate.gov.

Sincerely,

Susan M. Collins

Chairman

U.S. Senate Special Committee on Aging

Claire McCaskill

Ranking Member

U.S. Senate Special Committee on Aging

Mr. J. Michael Pearson Chairman of the Board and Chief Executive Officer Valeant Pharmaceuticals International Inc. 400 Somerset Corporate Blvd. Bridgewater, NJ 08807

SCHEDULE A

- 1. Any analysis conducted by Valeant relating to the price of Nitropress, Isuprel, or Cuprimine.
- 2. Any analysis in Valeant's possession, custody, or control relating to the price of Nitropress, Isuprel, or Cuprimine; exclusive of documents responsive to Schedule A, Specification 1, herein.
- 3. Any communications with Valeant's Board of Directors relating to Nitropress, Isuprel, or Cuprimine.
- 4. Any documents generated by the Valeant Board of Directors relating to Nitropress, Isuprel, or Cuprimine.
- 5. Any projected or historical financial data relating to Nitropress, Isuprel, or Cuprimine, including, but not limited to, costs, revenues, profits, losses, and cash flows.
- 6. Any projected or historical financial data relating to Valeant's research and development from January 1, 2010, to present, including, but not limited to, research and development relating to Nitropress, Isuprel, or Cuprimine.
- 7. Any documents evaluating any product market that includes, directly or indirectly, Nitropress, Isuprel, or Cuprimine, regardless of the definition of the geographic market, including, but not limited to, analysis of barriers to entry thereto.
- 8. Any documents evaluating market share that includes Nitropress, Isuprel, or Cuprimine, or the market power of that market share, for any product market or geographic market; exclusive of documents responsive to Schedule A, Specification 7, herein.
- 9. Any communications with Marathon Pharmaceuticals relating to Nitropress, Isuprel or Cuprimine.
- 10. Any documents relating to Marathon Pharmaceuticals' sale of Nitropress, Isuprel or Cuprimine to Valeant.
- 11. Any contracts entered into by Valeant that are related to the production, marketing, and sale of Nitropress, Isuprel, or Cuprimine.
- 12. Any marketing or pricing plans prepared for, or being used in, the sale or advertisement of Nitropress, Isuprel, or Cuprimine, including all documents related thereto.

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- 13. Any documents relating to Patient Assistance Programs relating to Nitropress, Isuprel, or Cuprimine.
- 14. Any documents relating to the price of Nitropress, Isuprel, or Cuprimine that have been produced pursuant to an investigative inquiry by any federal, state, or local government entity.
- 15. Any analysis relating to Nitropress, Isuprel, or Cuprimine and any statute or regulation administered by the FDA.
- 16. Any communications with the FDA relating to Nitropress, Isuprel, or Cuprimine; exclusive of documents responsive to Schedule A, Specifications 14 and 15, herein.
- 17. Any documents relating to Nitropress, Isuprel, or Cuprimine and the Health Resources and Services Administration's 340B Drug Discount Program; exclusive of documents responsive to Schedule A, Specifications 13, 15, and 16 herein.
- 18. Any projected or historical financial data related to Nitropress, Isuprel, or Cuprimine and Medicare or Medicaid; exclusive of documents responsive to Schedule A, Specifications 5, 6, 14–17, herein.
- 19. Any documents notating, memorializing, or summarizing a communication, or a portion thereof, responsive to Schedule A, Specifications 3, 9, and 16, herein.

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SCHEDULE B

1. State:

- a. A list of all countries where Nitropress, Isuprel, or Cuprimine are sold (or are expected to be sold in the next two years from the date of this letter) and the corresponding price or planned price for each country.
- b. In detail, how Valeant reached the price for each country.
- c. How the revenue, costs, and any discounts associated with international sales are accounted for within Valeant.
- 2. State in detail any changes Valeant has made, or plans to make, to Nitropress, Isuprel, or Cuprimine or the administration of the drugs.
- 3. Identify the Valeant employee responsible for setting the price of Nitropress, Isuprel, or Cuprimine.
- 4. Identify the names and addresses of all companies owned in whole or in part by Valeant that are involved in the production, marketing, and sale of Nitropress, Isuprel, or Cuprimine and any of their components.
- 5. State the total expense to Valeant related to the acquisition of Nitropress, Isuprel, or Cuprimine.
- 6. State in detail all known uses of Nitropress, Isuprel, or Cuprimine by medical professionals, including both on-label and off-label uses.
- 7. State in detail all known protocols, of which Nitropress, Isuprel, or Cuprimine is a component, used by medical professionals, including both on-label and off-label uses.
- 8. For each discrete communication that did not occur via document, but which would have been responsive to Specifications 1–18 of Schedule A if made via document, state:
 - (a) The method of communication.
 - (b) The date and time of the communication.
 - (c) The author and addressee of the communication.
 - (d) The relationship of the author and addressee to each other.
 - (e) A general description of the communication.

Information responsive to this question should be produced in a native Excel file.