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United States Senate

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

November 4, 2015

BILL NELSON, FLORIDA ROBERT P. CASEY, JR., PENNSYLVANIA SHELDON WHITEHOUSE, RHODE ISLAND KIRSTEN E. GILLIBRAND, NEW YORK RICHARD BLUMENTHAL, CONNECTICUT JOE DONNELLY, INDIANA ELIZABETH WARREN, MASSACHUSETTS TIM KAINE, VIRGINIA

Mr. Stephen Aselage Chief Executive Officer Retrophin, Inc. 12255 El Camino Real, Suite 250 San Diego, CA 92130

Dear Mr. Aselage:

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 Retrophin's license of the rights to sell Thiola, a drug used to treat kidney disease, from Mission Pharmacal Company, and Retrophin's subsequent decision to increase the price of Thiola from \$1.50 to \$30 per tablet.

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 you 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

Suran M. Collins

Claire McCaskill Ranking Member

U.S. Senate Special Committee on Aging

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SCHEDULE A

- 1. Any analysis conducted by Retrophin relating to the price of Thiola.
- 2. Any analysis in Retrophin's possession, custody, or control relating to the price of Thiola; exclusive of documents responsive to Schedule A, Specification 1, herein.
- 3. Any communications with Retrophin's Board of Directors relating to Thiola.
- 4. Any documents generated by the Retrophin Board of Directors relating to Thiola.
- 5. Any projected or historical financial data relating to Thiola, including, but not limited to, costs, revenues, profits, losses, and cash flows.
- 6. Any projected or historical financial data relating to Retrophin's research and development, including, but not limited to, research and development relating to Thiola.
- 7. Any documents evaluating any product market that includes, directly or indirectly, Thiola, regardless of the definition of the geographic market, including, but not limited to, analysis of barriers to entry thereto.
- 8. Any documents evaluating any market share that includes Thiola, 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 Mission relating to Thiola.
- 10. Any documents relating to Mission's sale of Thiola to Retrophin.
- 11. Any contracts entered into by Retrophin that are related to the production, marketing, and sale of Thiola.
- 12. Any marketing and pricing plans prepared for, or being used in, the sale or advertisement of Thiola, including all documents related thereto.
- 13. Any documents relating to Patient Assistance Programs relating to Thiola.
- 14. Any documents relating to the price of Thiola that have been produced pursuant to an investigative inquiry by any federal, state, or local government entity.
- 15. Any analysis relating to Thiola and any statute or regulation administered by the FDA.
- 16. Any communications with the FDA relating to Thiola; exclusive of documents responsive to Schedule A, Specifications 14 or 15, herein.

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- 17. Any documents relating to Thiola and the Health Resources and Services Administration's 340B Drug Discount Program; exclusive of documents responsive to Schedule A, Specifications 13, 15, or 16, herein.
- 18. Any projected or historical financial data related to Thiola and Medicare or Medicaid; exclusive of documents responsive to Schedule A, Specifications 3, 8, or 14–17, herein.
- 19. Any documents notating, memorializing, or summarizing a communication, or a portion thereof, responsive to Schedule A, Specifications 3, 9, or 16, herein.

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SCHEDULE B

1. State:

- a. A list of all countries where Thiola is sold (or is 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 Retrophin reached the price for each country.
- c. How the revenue, costs, and any discounts associated with international sales are accounted for within Retrophin.
- 2. State in detail any changes Retrophin has made, or plans to make, to Thiola or the administration of the drug.
- 3. Identify the Retrophin employee responsible for setting the price of Thiola.
- 4. Identify the names and addresses of all companies owned in whole or in part by Retrophin that are involved in the production, marketing, and sale of Thiola and any of its components.
- 5. State the total expense to Retrophin related to the acquisition of Thiola.
- 6. State in detail all known uses of Thiola by medical professionals, including both on-label and off-label uses.
- 7. State in detail all known protocols, of which Thiola 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.