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United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

November 4, 2015

Scott Spencer
General Manager
Rodelis Therapeutics
72 Marietta St
Alpharetta, GA 30009

Dear Mr. Spencer:

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 Rodelis's recent acquisition of the rights to sell Seromycin (cycloserine), a drug used to treat dangerous multidrug-resistant tuberculosis, from the Chao Center for Industrial Pharmacy and Contract Manufacturing. The Committee also wishes to better understand Rodelis's subsequent decision to increase the price for 30 pills from \$500 to \$10,800, as well as Rodelis's eventual decision to return the rights to Seromycin to the Chao Center.

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



Claire McCaskill
Ranking Member
U.S. Senate Special Committee on Aging

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SCHEDULE A

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

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16. Any communications with the FDA relating to Seromycin; exclusive of documents responsive to Schedule A, Specifications 14 and 15, herein.
17. Any documents relating to Seromycin 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 Seromycin and Medicare or Medicaid; exclusive of documents responsive to Schedule A, Specifications 5, 6, and 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 Seromycin was 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 Rodelis reached the price for each country.
 - c. How the revenue, costs, and any discounts associated with international sales are accounted for within Rodelis.
2. State in detail any changes Rodelis has made, or plans to make, to Seromycin or the administration of the drug.
3. Identify the Rodelis employee responsible for setting the price of Seromycin.
4. Identify the names and addresses of all companies owned in whole or in part by Rodelis that were or are involved in the production, marketing, and sale of Seromycin and any of its components.
5. State the total expense to Rodelis related to the acquisition of Seromycin.
6. State in detail all known uses of Seromycin by medical professionals, including both on-label and off-label uses.
7. State in detail all known protocols, of which Seromycin 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.