

United States Senate

WASHINGTON, DC 20510

September 13, 2018

Nirmal Mulye, Ph.D.
Chairman of the Board and Chief Executive Officer
Nostrum Laboratories, Inc.
1370 Hamilton Street
Somerset, NJ 08873

Dear Dr. Mulye:

We write to request information concerning price increases Nostrum Pharmaceuticals, LLC, has applied to nitrofurantoin oral suspension, a generic pharmaceutical product used to treat bladder infections. Nitrofurantoin is manufactured by Nostrum Laboratories, Inc., a subsidiary of Nostrum Pharmaceuticals with facilities in Kansas City, Missouri.

A recent report in the *Financial Times* asserts that Nostrum Pharmaceuticals raised the price of a bottle of nitrofurantoin by more than 400% from \$474.75 to \$2,392 in August 2018.¹ This is a shocking price increase for a generic antibiotic that was first approved by the FDA in 1953. According to the report, this sudden price spike followed a decline in the drug's availability in the consumer market and raised the price of your product to slightly below the price of its brand competitor.² Nitrofurantoin is a gold standard treatment that appears on the World Health Organization's list of essential medicines, and recent supply shortages have made access to this medicine even more difficult for those in need.³

In defending Nostrum's pricing action, you argued that FDA fees, which you claimed are tantamount to "highway robbery," had resulted in lost profits.⁴ Astonishingly, according to this report, you also flatly argued that "it is a moral requirement to make money when you can...to sell the product for the highest price" and compared your decision to increase the price for nitrofurantoin to that of an art dealer who sells "a painting for half a billion dollars."⁵ Troublingly, you also defended former Turing Pharmaceuticals CEO Martin Shkreli, claiming "that when he raised the price of his drug he was within his rights because he had to reward his shareholders. [...] If he's the only one selling [the lifesaving medication Daraprim] then he can make as much money as he can."⁶

In November 2015, we launched a bipartisan investigation into sudden price spikes of decades old off-patent drugs from several companies, including Turing Pharmaceuticals, and

¹ *Pharma Chief Defends 400% Drug Price Rise as a "Moral Requirement," Financial Times* (Sept. 11, 2018) (www.ft.com/content/48b0ce2c-b544-11e8-bbc3-ccd7de085ffe).

² *Id.*

³ World Health Organization, *WHO Model List of Essential Medicines* (Mar. 2017) (<http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1>).

⁴ *Pharma Chief Defends 400% Drug Price Rise as a "Moral Requirement," Financial Times* (Sept. 11, 2018).

⁵ *Id.*

⁶ *Id.*

released a report detailing our findings in December 2016.⁷ We concluded that Mr. Shkreli's "investor-driven strategy" for Turing created "turmoil" for the vulnerable patient population dependent on Daraprim, causing some patients to experience treatment interruptions or delays and causing others to forego their medication entirely.⁸ Ultimately, we found Mr. Shkreli's business model threatened "the health of individuals who discover that drugs they need are unaffordable and difficult to access."⁹ In the pharmaceutical industry—as opposed to the luxury art market—pricing decisions can have a devastating impact on patients and their families that can literally amount to a matter of life or death.

To aid us in understanding recent pricing decisions Nostrum has implemented for its nitrofurantoin product, please provide the following documents and information:

1. A description of the financial and non-financial factors contributing to your decision to increase the price of your nitrofurantoin product, including the role of any actual or potential supply shortages;
2. Total gross revenue from the company's sales of nitrofurantoin to date;
3. Total expenses relating to the company's sales of nitrofurantoin, including the specific expenses relating to manufacturing, marketing, and advertising efforts, as well as the purchase of active pharmaceutical ingredients for nitrofurantoin;
4. Any analyses the company has conducted or commissioned relating to the August 2018 price increase or future price increases for nitrofurantoin, including any cost estimates, profit projections, or other analyses relating to current and future sales of nitrofurantoin;
5. Any company documents evaluating any product market that includes nitrofurantoin directly or indirectly;
6. A list of other antibiotic products the company considers competitor products for its nitrofurantoin product, if any;
7. The costs the company incurred in reformulating its nitrofurantoin product in response to FDA impurities rules;

⁷ Senate Special Committee on Aging, *Collins, McCaskill Open Senate Investigation into Rx Drug Pricing, Announce Intention to Hold Hearings* (Nov. 4, 2015) (www.aging.senate.gov/press-releases/collins-mccaskill-open-senate-investigation-into-rx-drug-pricing-announce-intention-to-hold-hearings); Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (Dec. 21, 2016) (www.mccaskill.senate.gov/imo/media/doc/Senate-Aging-Report-Sudden-Price-Spikes-in-Off-Patent-Prescription-Drugs.pdf).

⁸ Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (Dec. 21, 2016).

⁹ *Id.*

8. The amount and purpose of any fees the company has paid to FDA, as well as an explanation of the financial impact of these fees; and
9. A description of any "market conditions" that could lead to further price increases for the company's nitrofurantoin product.

Please provide your responses as soon as possible, but in no event later than September 28, 2018. If you have any questions related to this request, please contact [REDACTED] of Senator McCaskill's staff at [REDACTED] or [REDACTED] of Senator Collins' staff at [REDACTED]. Please send any official correspondence relating to this request to [REDACTED].

Sincerely,



Claire McCaskill
Senator



Susan M. Collins
Senator