United States Senate WASHINGTON, DC 20510

May 10, 2018

Mr. Robert DiCrisi Chief Executive Officer NextSource Pharmaceuticals 4300 SW 73rd Avenue, Suite 108 Miami, Florida 33155

Dear Mr. DiCrisi:

We write to express concern about reports that the price of the potentially lifesaving cancer drug has ballooned by 1,400 percent since NextSource Pharmaceuticals acquired the product in 2013 and to call on your company to lower the price immediately for all Americans who rely on this critical cancer therapy.

As you know, lomustine is commonly used to treat brain tumors and Hodgkin lymphoma. Recent government-funded studies suggest that the drug can significantly prolong survival in patients with certain brain tumors. Yet, the skyrocketing prices for this drug—from around \$50 per capsule in 2013 to nearly \$800 per capsule at the beginning of 2018—has placed a significant financial strain on health care providers, patients, and their families nationwide. In fact, the Wall Street Journal recently reported that NextSource raised the price of lomustine to \$922 per capsule in February 2018—representing a 52 percent price increase since August 2017 alone. 2

We are troubled that these exploitative pricing practices follow a disturbing trend of systematic price increases by pharmaceutical companies on decades-old, lifesaving off-patent drugs. These actions have resulted in delayed treatment and extreme financial burden for many families that have already been stricken by severe, life-threatening illnesses.

We ask that you respond to the following inquiries regarding why a drug that has been on the market for nearly four decades has now been placed out of reach for many consumers by May 25, 2018:

1. What are the specific factors that led NextSource to increase the price of lomustine by 52 percent since August 2017?

https://www.wsj.com/articles/drug-price-hike-sparks-senate-probe-1522677600

¹ Berr, Jonathan. "Price of 40-year-old cancer drug hiked 1,400% by new owners." *CBS New*, https://www.cbsnews.com/news/cancer-drug-lomustine-price-hiked-1400-percent-by-new-owners/
² Loftus, Peter. "Drug Price Hike Sparks Senate Probe." *The Wall Street Journal*,

2. NextSource has pointed to "product development costs" as a contributing factor towards the pricing of lomustine.³ Please provide a list of these development costs. How have they have contributed to a more safe or effective product for consumers?

3. NextSource also claims that offering lomustine "at a significantly reduced cost to uninsured patients and patients who lack the resources to pay for the product...represent a substantial cost to the company." Please provide a detailed description of all patient

assistance programs offered for this product.

4. NextSource has suggested that the price of lomustine is related to an increase in Food and Drug Administration (FDA) user fees, but FDA user fees decreased during the time in which NextSource acquired the product and raised the price by nearly 1,400 percent. Specifically, prescription drug user fees were lower during fiscal year (FY) 2017 than any year since FY 2013.5 To address this disparity, please provide documentation regarding how much NextSource paid in FDA user fees annually since acquiring lomustine in 2013.

In light of the urgent need for this potentially lifesaving product and its history of availability at a much lower price, we call on you to immediately lower the price of lomustine to guarantee continued patient access. We hope we can work together to bring this product within reach of cancer patients who need it across the country.

Sincerely,

RICHARD BLUMENTHAL

United States Senator

AMY KLOBUCHAR United States Senator

United States Senator

³ "A STATEMENT REGARDING MEDIA COVERAGE OF GLEOSTINE® (LOMUSTINE)." NextSource Biotechnology, LLC.http://www.nextsourcepharmaceuticals.com/press/Statement-Media-Coverage-Gleostine.aspx

⁴ Id. ⁵ "PDUFA User Fee Rates Archive." United States Food and Drug Administration, https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm152775.htm