Congress of the United States

Washington, DC 20510

March 2, 2015

Jack Y. Zhang, Ph.D. Chief Executive Officer Amphastar Pharmaceuticals, Inc. 11570 6th Street Rancho Cucamonga, CA 91730

Dear Dr. Zhang:

We are writing to request information regarding the increasing prices that your company has been charging for naloxone, an antidote used to treat the life-threatening effects of opiate overdoses.

Over the past several months, police departments, law enforcement agencies, and public health officials across the country have warned about the increasing price of naloxone, which they use to combat the scourge of heroin abuse. According to a report in the New York Times in November, "police and public health officials from New York to San Francisco are facing sticker shock: Prices for a popular form of the medication, naloxone, are spiking, in some cases by 50 percent or more."¹ This press report continued:

In Georgia, police officials have seen the price of a kit containing the drug rise to \$40 from \$22. Departments in New Jersey, where heroin addiction has ravaged small communities, are facing similar increases. In New York City, a spokeswoman for the Health Department said a more than 50 percent price increase for nasal naloxone has officials "concerned" over the future of its distribution programs.²

Some have suggested that these price increases coincide with an increasing number of large city police departments deciding to supply their officers with the drug. Chuck Wexler, the Executive Director of the Police Executive Research Forum, stated: "It's not an incremental increase. ... There's clearly something going on."³

¹ Naloxone, a Drug to Stop Heroin Deaths, Is More Costly, the Police Say, New York Times (Nov. 30, 2014) (online at www.nytimes.com/2014/12/01/nyregion/prices-increase-for-antidote-to-heroin-overdoses-used-by-police.html).

² Id.

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Earlier this month, the Attorney General of New York announced that your company would agree to reduce the price of naloxone by providing a rebate of \$6 per dose, which will automatically increase to match any future growth in wholesale prices, but this agreement applies only to sales to agencies within New York State.⁴ Although we are encouraged by your stated willingness to work with other states, it remains unclear why your company has not already lowered its prices in states other than New York.⁵

The rapid increase in the cost of this life-saving medication in such a short time frame is a significant public health concern. The Centers for Disease Control reported that opiate overdose deaths have more than tripled between 1999 and 2012.⁶ The Congressional Budget Office and the Government Accountability Office have explained that generic drugs provide tremendous cost savings to our health care system and to the federal government.⁷ Generics now account for 29 percent of pharmaceutical spending and 86 percent of drugs dispensed in the United States.⁸ As strong supporters of access to generic pharmaceuticals, we are concerned about the impact that these increases have on American taxpayers.

In order to evaluate the underlying causes of recent increases in the price of your company's drug, we request that you provide the following documents and information for the time period covering January 2012 to the present:

- (1) total gross revenues from the company's sales of this drug;
- (2) the dates, quantities, purchasers, and prices paid for all sales of this drug;
- (3) total expenses relating to the sales of this drug, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
- (4) sales contracts or purchase agreements for active pharmaceutical ingredients for this drug, including any agreements relating to exclusivity, if applicable;

⁵ FiercePharma, *Amphastar Pays Some Rebates After Price of Overdose Drug Doubles* (Feb. 18, 2015) (online at www.fiercepharma.com/story/amphastar-pays-public-agencies-rebates-after-price-overdose-drug-doubles/2015-02-18).

⁶ National Center for Health Statistics, *Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States 1999-2012* (Dec. 2014).

⁷ Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (July 2014); Government Accountability Office, *Drug Pricing: Research on Savings from Generic Drug Use* (Jan. 31, 2012) (GAO-12-371R).

⁸ IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare* (Apr. 2014).

⁴ Attorney General Eric T. Schneiderman, Press Release: A.G. Schneiderman Announces Agreement to Cut and Cap the Price of Heroin Overdose Antidote for All Agencies in New York State (Feb. 5, 2015).

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- (5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the price of this drug;
- (6) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of this drug; and
- (7) the identity of company official(s) responsible for setting the price of the drug over the above time period.

Please provide the requested documents and information by March 13, 2015. If you have any questions, please contact Kelly Christl of Ranking Member Cummings' staff at (202) 225-5051 or Sophie Kasimow of Ranking Member Sanders' staff at (202) 224-5141.

Sincerely,

Representative Elijah E. Cummings

Ranking Member Committee on Oversight and Government Reform United States House of Representatives Bef Sanders

Senator Bernard Sanders Ranking Member Subcommittee on Primary Health and Retirement Security Committee on Health, Education, Labor and Pensions United States Senate

cc: The Honorable Jason Chaffetz Chairman, House Committee on Oversight and Government Reform

The Honorable Lamar Alexander Chairman, Senate Health, Education, Labor and Pensions Committee

The Honorable Patty Murray Ranking Member, Senate Health, Education, Labor and Pensions Committee

The Honorable Michael B. Enzi Chairman, Subcommittee on Primary Health and Retirement Security