



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

January 18, 2016

Jason Shandell
President, Amphastar Pharmaceuticals, Inc.
11570 Sixth Street
Rancho Cucamonga, CA 91730

Re: Extension of Naloxone Payment Agreement

Dear Mr. Shandell:

The Office of the New York Attorney General ("NYAG") and Amphastar Pharmaceuticals, Inc. ("Amphastar") entered into a one-year agreement, effective January 27, 2015, that reduces the net price New York public agencies pay for naloxone, a vital drug that counteracts overdoses from heroin and other opiates (the "Agreement"). For reference, the Agreement follows this letter as **Exhibit A**.

The Agreement has ensured that New York public agencies, including NYAG, through the Community Overdose Prevention ("COP") program, as well as the New York State Department of Health, the New York City Health Department, and others, can continue to access naloxone to save lives. The key terms of this Agreement are due to expire on January 27, 2016.

In recognition of the ongoing public health crisis related to heroin and opiate abuse, and the success of this Agreement to date, NYAG and Amphastar wish, and through this letter agree, to extend the Agreement's terms by one (1) *additional* year. Specifically, the parties hereby agree to amend the Agreement by striking Paragraph 5, titled "Term and Termination," and replacing Paragraph 5 with the following language:

5. Term and Termination. This Agreement shall apply to Syringes purchased within **two (2) years** following the Effective Date of this Agreement (the "Term"). Following the payment of all Payment Amounts accrued during the Term and submitted for reimbursement pursuant to paragraph 3 or paragraph 4 above, this Agreement shall terminate ("Termination"), except for paragraphs 6 through 14, which shall survive Termination.

Except for the replacement of Paragraph 5 noted above, this letter does not amend or otherwise alter any other provisions of the Agreement, which remain in full effect.

(continued on next page)

By countersigning below, the parties acknowledge and affirm that this letter constitutes a valid and binding agreement.

Signed:



Simon G. Brandler
Senior Advisor & Special Counsel, NYAG

Countersigned:



Jason Shandell
President, Amphastar

EXHIBIT A

PAYMENT AGREEMENT

This payment agreement (the "Agreement") is made as of the 27th day of January, 2015 (the "Effective Date") by and between Amphastar Pharmaceuticals, Inc., a Delaware Corporation, with its principal offices and place of business at 11570 6th Street, Rancho Cucamonga, California 91730, U.S.A. ("Amphastar") on the one hand, and the Office of the Attorney General of the State of New York, with offices at 120 Broadway, New York, New York 10271, U.S.A. ("NYAG"), on the other hand, each of Amphastar and NYAG a "Party," and together, the "Parties."

RECITALS

WHEREAS, New York and other states are confronting a profound public health challenge, as the number of heroin and opioid-related deaths continues to increase;

WHEREAS, with proper, timely administration, the generic drug naloxone reverses the effects of an overdose of heroin or another opioid, acting as an antidote and saving lives;

WHEREAS, NYAG established the Community Overdose Prevention Program, which sought to prevent avoidable opioid-related deaths by covering the costs of naloxone and associated training for law enforcement agencies in New York;

WHEREAS, the State of New York, local governments in New York, and associated public entities, including but not limited to the State Department of Health ("DOH"), the City of New York ("NYC"), and the governments of individual New York counties, likewise established programs to respond to the heroin and opioid epidemic by distributing, purchasing, or funding the purchase of naloxone;

WHEREAS, Amphastar raised prices for its current naloxone products in fall 2014 ("Naloxone");

WHEREAS, NYAG transmitted a letter to Amphastar, dated December 1, 2014, expressing concern that the increase in Naloxone pricing could adversely affect access to the drug in New York State;

WHEREAS, Amphastar transmitted a response letter to NYAG's letter on or about December 3, 2014, maintaining that its pricing of Naloxone is based upon legitimate and lawful business factors;

WHEREAS, in a mutual good faith effort to amicably resolve NYAG's stated pricing concerns, the parties have engaged in discussions regarding Amphastar's Naloxone pricing; and

WHEREAS, Amphastar and NYAG each believe that the obligations imposed by this agreement are beneficial to the public and will improve access to Naloxone, and will potentially save lives.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. **Payment Amount.** Amphastar shall make a payment ("Payment") in the amount of \$6.00 (the "Payment Amount") for each Amphastar Naloxone Syringe (a "Syringe") where either (a) the purchase price of the Syringe was reimbursed by a government or public entity in New York ("NY Agency"), including but not limited to NYAG, DOH, or NYC; or (b) an NY Agency purchased the Syringe and where that NY Agency will receive no reimbursement for the costs of that Syringe from any other NY Agency. Amphastar shall pay the Payment Amount associated with a given Syringe regardless of whether the Syringe was purchased directly from Amphastar or from a third party.

2. **Payment Increase.** Notwithstanding paragraph 1, in the event Amphastar increases its wholesale acquisition cost ("WAC") of a Naloxone Syringe ("WAC Increase"), Amphastar shall increase the Payment Amount by the actual dollar amount of the WAC increase to offset any increase in the Syringe price. However, in no event shall the Payment Amount be reduced.

3. **Payment Procedures.** An NY Agency seeking Payments under this Agreement shall submit to Amphastar a written accounting certifying the number of Naloxone Syringes purchased or reimbursed by the NY Agency during a given quarter, i.e., a three (3) month time period (a "Certified Request"), within sixty (60) business days of the conclusion of the quarter. This Certified Request shall include paid invoices or other reasonably adequate documentation of the number of Syringes purchased. Amphastar shall pay the total accrued Payment Amounts to the submitting NY Agency within ninety (90) business days of receipt of a Certified Request. Amphastar shall mail a report to NYAG each quarter listing each NY Agency that submitted a Certified Request to Amphastar and the total Payment Amounts disbursed to each such NY Agency.

4. **Special Payment Procedures.** Notwithstanding paragraph 3, in the event more than ten (10) separate NY Agencies submit Certified Requests to Amphastar in a given quarter, Amphastar shall collect all Certified Requests it receives and forward them in a single submission to NYAG. Within sixty (60) days of receiving these Certified Requests from Amphastar, NYAG shall consolidate them into a single Certified Request ("Consolidated Request") and submit this Consolidated Request to Amphastar on behalf of all NY Agencies seeking Payments that quarter. Within sixty (60) business days of receipt of the Consolidated Request, Amphastar shall pay the total accrued Payment Amounts reflected in the Consolidated Request to NYAG. NYAG shall thereafter disburse Payments to NY Agencies as required.

5. **Term and Termination.** This Agreement shall apply to Syringes purchased within one (1) year following the Effective Date of this Agreement (the "Term"). Following the payment of all Payment Amounts accrued during the Term and submitted for reimbursement pursuant to paragraph 3 or paragraph 4 above, this Agreement shall terminate ("Termination"), except for paragraphs 6 through 14, which shall survive Termination.

6. **Liability Exclusion.** Except as otherwise may be stated herein, Amphastar's liability under this Agreement is limited to payment of the Payment Amount for Syringes purchased during the Term, and Amphastar otherwise shall assume no further liability pursuant to this Agreement, including liability for damages of any type (including direct, indirect, and consequential damages). Except as provided in paragraph 7 below, however, nothing in this Agreement shall be construed to alter or limit Amphastar's existing legal obligations or liabilities, including but not limited to those arising from the manufacture or marketing of Naloxone.

7. **Assurance of Discontinuance.** NYAG finds the financial relief and other obligations set forth in this agreement to be in the public interest, accepts the terms of this Agreement in lieu of

commencing any legal proceeding, and hereby agrees not to take legal action against Amphastar or any of its Affiliates, predecessors, successors, parents, subsidiaries, assigns, agents, administrators, attorneys, directors, shareholders, officers, employees, or representatives in connection with its 2014 pricing of Naloxone. For the avoidance of doubt, nothing in this Agreement shall be construed as an admission or concession by Amphastar of any liability in connection with its pricing of Naloxone prior to the Effective Date.

8. **Disclaimer.** Amphastar expressly disclaims any endorsement or promotion of off-label use by NYAG and/or any NY Agency of any of Amphastar's products, including Amphastar's Naloxone.

9. **Amendment.** Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

10. **Severability.** Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

11. **Governing Law.** This Agreement shall be governed by and interpreted under the laws the State of New York without regard to its conflict or choice of law provisions. Amphastar agrees not to raise or interpose in any way their state of incorporation as a defense on grounds of personal jurisdiction as to any cause of action, claim, or argument arising from the enforcement of this Agreement by NYAG or any NY Agency.

12. **Third Party Beneficiaries.** The Parties agree that any NY Agency purchasing Naloxone during the Term constitutes an intended third-party beneficiary of this Agreement.

13. **Entire Agreement.** This Agreement includes all exhibits attached hereto and constitutes the entire agreement by and between the Parties as to the subject matter hereof. This Agreement supersedes and replaces in its entirety all prior agreements, understandings, letters of intent, and memoranda of understanding by and between the Parties hereto, in either written or oral form.

14. **Counterparts; Electronic or Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

Amphastar Pharmaceuticals, Inc.

By: _____

Name: _____

Title: _____

Jason Shandell

President

Eric T. Schneiderman
Attorney General of the State of New York

By: _____

Name: _____

Title: _____

Simon G. Brandler

Senior Advisor & Special Counsel