

## “SOLE SOURCE” PROCUREMENT JUSTIFICATION

Sole source purchases are goods and services available from only one vendor. There may be just one vendor because of patents or copyrights or simply because the vendor is the only one which supplies the good or service. Using Department must provide a written explanation as to why only this particular product/service is acceptable and why no other will be suitable or acceptable to meet the need. A quote must accompany this form.

Department name: Health and Human Service

1. Name of product or service: NARCAN Nasal Spray \$125,000
2. Name of product manufacturer: Adapt Pharma, Inc.
3. Name of “sole” product supplier or service provider: Adapt Pharma, Inc.
4. Describe in general terms the product/service you are requesting and the intended application.

DAC-HHS would like to purchase a nasal administration non-assembly naloxone treatment unit to dispense to none traditional first responders. Naloxone is a drug that blocks or reverses the effects of opioids overdose in emergency situations. DAC-HHS has received funding by the Substance Abuse and Mental Health Services Administration (SAMHSA) to purchase, store, and distribute naloxone throughout Doña Ana County. SAMHSA mandates the use of a naloxone device that is approved by the Food and Drug Administration (FDA).

5. Describe the unique features/capabilities/characteristics that distinguish it from other products/services.

NARCAN (nasal spray) is a needle-free device which is ready-to use, this product requires no assembly or priming unlike other naloxone delivery methods. There are no needles which make it easy to use by non-traditional first responders. Given the risk of blood borne pathogens the nasal delivery method reduces the chance of these types of exposures because individuals administering the drug do not have to inject the naloxone into the user. Narcan is the only Food and Drug Administration approved device for nasal administration of naloxone.

6. How did you determine there was only one source for the product or service? Provide information on the research that was performed to locate suppliers for this product(s) or service(s). (Please furnish names, addresses and other documentation).

DAC-HHS researched products online and contacted the following pharmaceuticals companies; Adapt Pharma, Amphastar Pharmaceuticals, Kaléo Pharma, Mylan N.V., and Pfizer Pharmaceuticals.

**Adapt Pharma** (Tele: 1-844-232-7811) offers a product with no assembly, no priming, or no injection required when administering naloxone. Adapt Pharma delivers naloxone treatments in a ready to use out of the package nasal spray.

**Kaléo Pharma** (Tele: 1-804-545-6360), 111 Virginia St, Richmond, VA 23219, offers an auto-injector naloxone delivery system, contacted vendor to confirm they do not offer nasal delivery naloxone applications. **Amphastar Pharmaceuticals, Inc.** (Tele: 1-800-423-4136), 11570 6<sup>th</sup> Street Rancho Cucumonga, California 91730, contacted vendor to confirm they do not offer nasal delivery naloxone application. **Pfizer Pharmaceuticals** (tele: 1-800-533-4535), 235 East 42<sup>nd</sup> Street NY, NY 10017, contacted vendor to confirm they do not offer a nasal delivery naloxone application. **Mylan N.V.** (tele: 1-800-533-4535), 1000 Mylan Blvd Canonsburg, PA 15317, contacted vendor to confirm they do not offer a nasal delivery naloxone application.

7. What product supplier or service provider has your Department used until now to satisfy similar requirements?

Our department submitted a sole source justification for purchased NARCAN in the past.

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Signature of Department Head Date

(Attach Quote and Use Additional Sheets As Necessary)

\*\*This form is used by Purchasing Department to determine if a "Sole Source" procurement criterion is met. Completing this form does not guarantee approval of this type of procurement.



Date February 22, 2018

To Whom It May Concern:

This letter identifies Adapt Pharma as the sole manufacturer of NARCAN® (naloxone HCl) Nasal Spray. Upon approval of the product, the following Press Release was issued:

On November 19, 2015 – Adapt Pharma announced that the U.S. Food and Drug Administration (FDA) has approved NARCAN® Nasal Spray for the emergency treatment of known or suspected opioid overdose. NARCAN® Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. NARCAN® Nasal Spray requires no assembly or priming prior to use.

**ABOUT NARCAN® NASAL SPRAY**

NARCAN® Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN® Nasal Spray is not a substitute for emergency medical care. Always seek emergency medical assistance in the event of a suspected, potentially life-threatening opioid emergency after administration of the first dose of NARCAN nasal spray.

If the desired response is not obtained after 2 or 3 minutes, administer an additional dose of NARCAN® Nasal Spray using a new NARCAN® Nasal Spray. If the patient responds to NARCAN® Nasal Spray and relapses back into respiratory depression before emergency assistance arrives, administer an additional dose and continue surveillance of the patient. If there is still no response and additional doses are available, administer additional doses of NARCAN® Nasal Spray every 2 to 3 minutes using a new NARCAN® Nasal Spray with each dose until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Please see Indications and Important Safety Information below.  
Please see Full Prescribing Information and Instructions for use by clicking [here](#) or by calling 844-4-NARCAN.

**Indication and Important Safety Information- Professional**

**INDICATIONS**

NARCAN® (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency



treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN® Nasal Spray is not a substitute for emergency medical care.

#### **IMPORTANT SAFETY INFORMATION**

NARCAN® Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the development of opioid withdrawal.

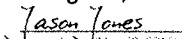
Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Regards,

  
Jason Jones,

Director of Trade and Distribution



U.S. Media: Christy Maginn, Burson-Marsteller  
T: 646-280-5210; email: [Christy.Maginn@bm.com](mailto:Christy.Maginn@bm.com)

**NARCAN® (NALOXONE HYDROCHLORIDE) NASAL SPRAY APPROVED BY  
U.S. FOOD AND DRUG ADMINISTRATION**

*First Ready-To-Use Needle-free Nasal Spray Treats Opioid Overdose Emergency*

Dublin, Ireland -- November 19, 2015 – Adapt Pharma Limited ([www.adaptpharma.com](http://www.adaptpharma.com)) announced today that the U.S. Food and Drug Administration (FDA) has approved NARCAN® (naloxone hydrochloride) Nasal Spray for the emergency treatment of known or suspected opioid overdose.

For more than 40 years, naloxone has been trusted by healthcare providers for reversing the effects of opioid overdose, but until today, it was FDA approved only as an injection.

NARCAN Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. NARCAN Nasal Spray requires no assembly or priming prior to use. Adapt Pharma is committed to affordable and transparent pricing of NARCAN Nasal Spray. Group purchasers, such as law enforcement, fire fighters, first-responders, departments of health, local school districts, colleges and universities, and community-based organizations that order directly from Adapt Pharma, are eligible for a discounted **Public Interest Price** of **\$37.50 per 4mg NARCAN Nasal Spray device** (\$75 for a carton containing 2 devices of NARCAN Nasal Spray 4mg).<sup>1</sup>

We are delighted to have reached agreement with the **Clinton Health Matters Initiative**, an initiative of the Clinton Foundation, our first partner in establishing this discounted **Public Interest Price approach**. We expect to announce additional partnerships soon. To learn more, group purchasers may call 844-4-NARCAN (844-462-7226) or email [customerservice@adaptpharma.com](mailto:customerservice@adaptpharma.com). For individuals with health insurance coverage, NARCAN Nasal Spray is expected to have broad coverage with affordable co-pays.

NARCAN Nasal Spray can be administered in an emergency by family members, caregivers or others to reverse the effects of opioid overdose until help arrives. An opioid overdose may cause brain damage or death, so NARCAN Nasal Spray should be administered as quickly as possible if a patient is unresponsive and an opioid overdose is suspected, even when in doubt.

In the United States, opioid overdose related deaths are growing and claimed almost 24,500 lives in 2013, or an average of one life every 21 minutes.<sup>2</sup> The majority of those deaths involved prescription opioids<sup>3</sup> and happened in people's homes.<sup>4</sup>

In response, momentum to increase access to naloxone is building. In October, President Obama included a call to make naloxone more readily available as part of a major initiative to address the nation's opioid epidemic.<sup>5</sup> Major medical groups, including the American Medical Association and American Academy of Family Physicians, have also called for increased access to naloxone.<sup>6</sup>

“Opioid overdose is responsible for the deaths of thousands of Americans in communities throughout the country, leaving a trail of devastation for friends and families,” said **Seamus Mulligan, Chairman and CEO of Adapt Pharma**. “NARCAN Nasal Spray a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. This new device makes naloxone readily available for emergency use by a friend, family member or caregiver, as well as offering an alternative treatment option for first-responders and healthcare providers. It gives new hope to those concerned about the potentially fatal effects of opioid overdose.”

Anyone who uses prescription opioids for the long term management of chronic pain, or those who take heroin, are potentially at risk of experiencing a life-threatening or fatal opioid overdose where breathing and heart beat slow or stop.<sup>7</sup> Prescription opioids include morphine, codeine, methadone, oxycodone (e.g. OxyContin®, Percocet®), hydrocodone (e.g. Vicodin®, Lortab®), fentanyl (e.g. Duragesic®, Fentora®), hydromorphone (e.g. Dilaudid®, Exalgo®), oxymorphone (Opana® ER), and buprenorphine (Subutex®, Suboxone®). Illicit opioids include heroin and increasingly heroin/fentanyl mixes.

“Overdoses can potentially occur anytime and anywhere opioids are being used. That is why expanding access to naloxone, which can rapidly reverse an overdose, is being encouraged by several professional organizations,” said **Dr. Anita Gupta**, a board-certified anesthesiologist, pharmacist and pain specialist. “By making naloxone available and easy to use for anyone taking an opioid, as well as their family members and loved ones, we may be able to decrease needless opioid overdose deaths.”

“After my son’s passing, I made a vow to him that I was going to save a life in his name,” said **David Humes**, who lost his 24-year-old son, Gregory, to an accidental heroin overdose in May 2012. “Since then, I have been a passionate advocate for the broader distribution and use of naloxone. I believe the approval of additional opioid overdose treatment options, like NARCAN Nasal Spray, may greatly increase access to this potentially lifesaving medication. Expanding access to naloxone became my path toward fulfilling my vow to my son and helping to prevent a similar heartbreak for other parents.” Adapt Pharma collaborated with the National Institutes on Drug Abuse (NIDA) on the development of NARCAN Nasal Spray, which received Fast Track Designation and a Priority Review by the FDA.

Adapt Pharma originally licensed the project from Lightlake Therapeutics, Inc. It is available in a carton containing two blister packages, each with a single NARCAN Nasal Spray containing a single 4 mg dose of naloxone hydrochloride intranasal spray.

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#### **AVAILABILITY OF NARCAN NASAL SPRAY**

Once launched, in early 2016, we expect NARCAN Nasal Spray will be available at retail pharmacies.

Qualifying group purchasers may source NARCAN Nasal Spray directly from wholesalers and distributors. To place a pre-order immediately or for assistance in sourcing NARCAN Nasal Spray please contact Adapt Pharma's dedicated Customer Service Team at 844-4-NARCAN (844-462-7226) or email [customerservice@adaptpharma.com](mailto:customerservice@adaptpharma.com)

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#### **ABOUT ADAPT PHARMA**

Adapt Pharma Limited is a privately-held pharmaceutical company committed to positively impacting the lives of patients. Adapt Pharma's strategy is to identify, evaluate, selectively acquire and enhance the value of late stage development, and FDA approved, pharmaceutical products. Adapt Pharma's company headquarters is in Dublin, Ireland and its U.S. headquarters is in Radnor, Pennsylvania. For more information, please visit [www.adaptpharma.com](http://www.adaptpharma.com).

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- <sup>1</sup> Access to Public Interest Price is restricted to qualifying entities and subject to terms and conditions.
  - <sup>2</sup> Centers for Disease Control and Prevention: NCHS Data Brief Number 190, March 2015 <http://www.cdc.gov/nchs/data/databriefs/db190.htm#ref2>
  - <sup>3</sup> Ibid
  - <sup>4</sup> CDC Wonder Database Multiple Cause of Death MCD - ICD-10 Codes: T40.1 (Heroin), T40.2 (Other opioids), T40.3 (Methadone), T40.4 (Other synthetic narcotics) 2013
  - <sup>5</sup> The White House Office of the Press Secretary. FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use. 2015. Available at: <https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector>
  - <sup>6</sup> American Medical Association. The American Medical Association Task Force to Reduce Prescription Opioid Abuse. 2015. Available at: <http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-task-force.page>
  - <sup>7</sup> Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.