JOHN McCAIN, ARIZONA ROB PORTMAN, OHIO RAND PAUL, KENTUCKY JAMES LANKFORD, OKLAHOMA MICHAEL B. ENZI, WYOMING JOHN HOEVEN, NORTH DAKOTA STEVE DAINES, MONTANA CLAIRE McCASKILL, MISSOURI THOMAS R. CARPER, DELAWARE JON TESTER, MONTANA HEIDI HEITKAMP, NORTH DAKOTA GARY C. PETERS, MICHIGAN MARGARET WOOD HASSAN, NEW HAMPSHIRE KAMALA D. HARRIS, CALIFORNIA

CHRISTOPHER R. HIXON, STAFF DIRECTOR MARGARET E. DAUM, MINORITY STAFF DIRECTOR

United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS WASHINGTON, DC 20510–6250

August 2, 2017

Seamus Mulligan Chief Executive Officer Adapt Pharmaceuticals 100 Matsonford Road Building 4, Suite 201 Radnor, PA 19087

Dear Mr. Mulligan:

In June 2016, as Ranking Member of the U.S. Senate Aging Committee, I wrote to pharmaceutical manufacturers, including Adapt Pharmaceuticals, regarding the sudden spike in prices for the opioid overdose reversal drug naloxone and the steps manufacturers have taken to ensure state and local communities have access to this lifesaving product. In my letter, I stressed the importance of equipping first responders and others on the front lines of the U.S. opioid epidemic with naloxone. In a survey the Harm Reduction Coalition conducted in 2014, for example, community organizations reported that layperson administration of naloxone—distributed in 150,000 kits—had resulted in 25,000 opioid reversals since 1996. More recently, a project manager for the Missouri Opioid-Heroin Overdose Prevention and Education Project (MO-Hope Project) reported in November 2016 that he had "already seen tremendous success with the naloxone program that the St. Louis County Police Department has implemented, saving dozens of lives in just a few months." To further this progress, I strongly supported the Comprehensive Addiction and Recovery Act of 2016, which included provisions to help rural communities obtain naloxone.

¹ Letter from Chairman Susan Collins and Ranking Member Claire McCaskill to Seamus Mulligan, Chief Executive Officer, Adapt Pharmaceuticals (June 03, 2016).

² Center for Disease Control and Prevention, *Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons* — *United States, 2014* 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

³ More Missouri Police and Fire Departments Getting Heroin Antidote, St. Louis Post-Dispatch (Nov. 29, 2016) (www.stltoday.com/news/local/crime-and-courts/more-missouri-police-and-fire-departments-getting-heroin-antidote/article_e02e69c8-8dce-54f5-8acd-a57844e52335.html).

⁴ Comprehensive Addiction and Recovery Act, Pub.L.No.114-198 (2016).

Seamus Mulligan August 2, 2017 Page 2

More than 600 community-based programs operating across 30 states and the District of Columbia provide naloxone to laypersons such as families and friends. Additionally, over 900 law enforcement departments across the country are equipped with naloxone kits to use when responding to emergencies. These departments often look to community-based organizations for training on how to administer naloxone and for donations to reduce the costs of purchasing the drug. MO-HOPE Project, for example, offers free training on proper naloxone deployment and relies on donations to provide Narcan nasal spray to law enforcement officers in the eastern region of Missouri.

However, the rise in costs associated with acquiring naloxone has caused significant accessibility issues for those on the front lines of this epidemic. Law enforcement departments in states without sufficient community resources, for example, could potentially pay between \$22 and \$60 per naloxone kit, depending on the specific form of naloxone used. Any additional rise in price could create further obstacles for departments and community-based organizations seeking to meet community demand.

As Congress works toward implementing commonsense solutions to address the opioid epidemic, cooperation between government entities and the pharmaceutical industry in promoting the availability of naloxone will play a critical role. In your response to my June 2016 letter, you emphasized the willingness of Adapt Pharmaceuticals to raise awareness of opioid addiction and to increase access to naloxone within U.S. communities. ¹¹ To help me better understand your efforts in this area; please provide responses to the information requested below:

⁵ Center for Disease Control and Prevention, Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

⁶ North Carolina Harm Reduction Coalition, Home Page (<u>www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/</u>)(accessed June 22, 2017).

⁷ Harm Reduction Coalition, *Training Law Enforcement to Identify Overdose and Use Naloxone*, (http://harmreduction.org/overdose-prevention/training-law-enforcement-to-identify-overdose-and-use-naloxone/) (accessed June 22, 2017).

⁸ MO-HOPE Project, Home Page (http://mohopeproject.org/)(accessed June 22, 2017).

⁹ See As Opioid Epidemic Worsens, the Cost of Waking Up From an Overdose Soars, CNBC (Jan. 4, 2017) (www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html); Local Police, EMS Agencies Feel Effect of Rising Naloxone Prices, Charleston Gazette-Mail (Sept. 4, 2016) (www.wvgazettemail.com/news-health/20160904/local-police-ems-agencies-feel-effect-of-rising-naloxone-prices).

¹⁰Bureau of Justice Assistance, Office of Justice Programs, National Training and Technical Assistance Center, Tools and Resources, Naloxone Toolkit, Acquiring Naloxone (bjatraning.org/tools/naloxone/Acquiring-Naloxone)(accessed June 22, 2017).

¹¹ Letter from Seamus Mulligan, Chairman and CEO, Adapt Pharmaceuticals to Chairman Susan Collins and Ranking Member Claire McCaskill (June 23, 2016).

- Please provide details concerning the administration of your naloxone donation program, including the years in which the program has operated, the number of naloxone units donated per year, how law enforcement organizations and community groups can request naloxone units; and how Adapt Pharmaceuticals otherwise identifies potential recipients of naloxone;
- Please provide copies of any contracts or other forms Adapt Pharmaceuticals has employed governing its relationship with recipients of donated naloxone products;
- 3. Please provide a list of all parties to which Adapt Pharmaceuticals has donated naloxone products, including the amount of product requested, the amount of product donated, and the year or years in which Adapt Pharmaceuticals made the donation;
- 4. Please provide a list of all parties to which Adapt Pharmaceuticals has provided coupons for rebates on naloxone products, including the amount of the rebate provided and the year or years in which Adapt Pharmaceuticals provided the coupons;
- 5. Please describe the training Adapt Pharmaceuticals provides to recipients of donated naloxone products, if any; and
- Please describe plans Adapt Pharmaceuticals has made to prevent product shortages from limiting its ability to meet its commitments to law enforcement organizations and community groups.

Please provide your responses as soon as possible, but no later than August 23, 2017. If you have any questions, please contact Phylicia Woods of the Committee staff at (202) 224-2627. Please send all official correspondence relating to this request to Amanda Trosen@hsgac.gov.

Sincerely,

Claire McCaskill Ranking Member

La Caslia

ce: Ron Johnson Chairman JOHN MCCAIN, ARIZONA ROB PORTMAN, OHIO RAND PAUL, KENTUCKY JAMES LANKFORD, OKLAHOMA MICHAEL B. ENZI, WYOMING JOHN HOEVEN, NORTH DAKOTA STEVE DAINES, MONTANA CLAIRE McCASKILL, MISSOURI THOMAS R. CARPER, DELAWARE JON TESTER, MONTANA HEIDI HEITKAMP, NORTH DAKOTA GARY C. PETERS, MICHIGAN MARGARET WOOD HASSAN, NEW HAMPSHIRE KAMALA D. HARRIS, CALIFORNIA

CHRISTOPHER R. HIXON, STAFF DIRECTOR MARGARET E. DAUM, MINORITY STAFF DIRECTOR

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510–6250

August 2, 2017

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

Dear Dr. Zhang:

In June 2016, as Ranking Member of the U.S. Senate Aging Committee, I wrote to pharmaceutical manufacturers, including Amphastar Pharmaceuticals, regarding the sudden spike in prices for the opioid overdose reversal drug naloxone and the steps manufacturers have taken to ensure state and local communities have access to this lifesaving product. In my letter, I stressed the importance of equipping first responders and others on the front lines of the U.S. opioid epidemic with naloxone. In a survey the Harm Reduction Coalition conducted in 2014, for example, community organizations reported that layperson administration of naloxone—distributed in 150,000 kits—had resulted in 25,000 opioid reversals since 1996. More recently, a project manager for the Missouri Opioid-Heroin Overdose Prevention and Education Project (MO-Hope Project) reported in November 2016 that he had "already seen tremendous success with the naloxone program that the St. Louis County Police Department has implemented, saving dozens of lives in just a few months." To further this progress, I strongly supported the Comprehensive Addiction and Recovery Act of 2016, which included provisions to help rural communities obtain naloxone.

Letter from Chairman Susan Collins and Ranking Member Claire McCaskill to Jack Y. Zhang, Ph.D., Chief Executive Officer, Amphastar Pharmaceuticals (June 3, 2016).

² Center for Disease Control and Prevention, *Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons* — *United States, 2014* 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

³ More Missouri Police and Fire Departments Getting Heroin Antidote, St. Louis Post-Dispatch (Nov. 29, 2016) (www.stltoday.com/news/local/crime-and-courts/more-missouri-police-and-fire-departments-getting-heroin-antidote/article_e02e69c8-8dce-54f5-8acd-a57844e52335.html).

⁴ Comprehensive Addiction and Recovery Act, Pub.L.No.114-198 (2016).

Jack Y. Zhang, Ph.D. August 2, 2017 Page 2

More than 600 community-based programs operating across 30 states and the District of Columbia provide naloxone to laypersons such as families and friends. Additionally, over 900 law enforcement departments across the country are equipped with naloxone kits to use when responding to emergencies. These departments often look to community-based organizations for training on how to administer naloxone and for donations to reduce the costs of purchasing the drug. MO-HOPE Project, for example, offers free training on proper naloxone deployment and relies on donations to provide Narcan nasal spray to law enforcement officers in the eastern region of Missouri.

However, the rise in costs associated with acquiring naloxone has caused significant accessibility issues for those on the front lines of this epidemic. Law enforcement departments in states without sufficient community resources, for example, could potentially pay between \$22 and \$60 per naloxone kit, depending on the specific form of naloxone used. Any additional rise in price could create further obstacles for departments and community-based organizations seeking to meet community demand.

As Congress works toward implementing commonsense solutions to address the opioid epidemic, cooperation between government entities and the pharmaceutical industry in promoting the availability of naloxone will play a critical role. In your response to my June 2016 letter, you emphasized the willingness of Amphastar Pharmaceuticals to raise awareness of opioid addiction and to increase access to naloxone within U.S. communities. ¹¹ To help me

⁵ Center for Disease Control and Prevention, Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

⁶ North Carolina Harm Reduction Coalition, Home Page (<u>www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/</u>)(accessed June 22, 2017).

⁷ Harm Reduction Coalition, *Training Law Enforcement to Identify Overdose and Use Naloxone*, (http://harmreduction.org/overdose-prevention/training-law-enforcement-to-identify-overdose-and-use-naloxone/) (accessed June 22, 2017).

⁸ MO-HOPE Project, Home Page (http://mohopeproject.org/)(accessed June 22, 2017).

⁹ See As Opioid Epidemic Worsens, the Cost of Waking Up From an Overdose Soars, CNBC (Jan. 4, 2017) (www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html); Local Police, EMS Agencies Feel Effect of Rising Naloxone Prices, Charleston Gazette-Mail (Sept. 4, 2016) (www.wvgazettemail.com/news-health/20160904/local-police-ems-agencies-feel-effect-of-rising-naloxone-prices).

¹⁰Bureau of Justice Assistance, Office of Justice Programs, National Training and Technical Assistance Center, Tools and Resources, Naloxone Toolkit, Acquiring Naloxone (bjatraning.org/tools/naloxone/Acquiring-Naloxone) (accessed June 22, 2017).

¹¹ Letter from Jack Y. Zhang, Ph.D., Chief Executive Officer, Amphastar Pharmaceuticals, to Chairman Susan Collins and Ranking Member Claire McCaskill (June 8, 2016).

Jack Y. Zhang, Ph.D. August 2, 2017 Page 3

better understand your efforts in this area; please provide responses to the information requested below:

- Please provide details concerning the administration of your naloxone donation program, including the years in which the program has operated; the number of naloxone units donated per year, how law enforcement organizations and community groups can request naloxone units, and how Amphastar Pharmaceuticals otherwise identifies potential recipients of naloxone;
- Please provide copies of any contracts or other forms Amphastar Pharmaceuticals has employed governing its relationship with recipients of donated naloxone products;
- Please provide a list of all parties to which Amphastar Pharmaceuticals has donated naloxone products, including the amount of product requested, the amount of product donated, and the year or years in which Amphastar Pharmaceuticals made the donation;
- Please provide a list of all parties to which Amphastar Pharmaceuticals has provided coupons for rebates on naloxone products, including the amount of the rebate provided and the year or years in which Amphastar Pharmaceuticals provided the coupons;
- Please describe the training Amphastar Pharmaceuticals provides to recipients of donated naloxone products, if any; and
- Please describe plans Amphastar Pharmaceuticals has made to prevent product shortages from limiting its ability to meet its commitments to law enforcement organizations and community groups.

Please provide your responses as soon as possible, but no later than August 23, 2017. If you have any questions, please contact Phylicia Woods of the Committee staff at (202) 224-2627. Please send all official correspondence relating to this request to Amanda Trosen@hsgac.gov.

Sincerely,

Claire McCaskill Ranking Member

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cc: Ron Johnson Chairman MARGARET E. DAUM, MINORITY STAFF DIRECTOR

JOHN McCAIN, ARIZONA JOHN McCAIN, ARIZONA
ROB PORTMAN, OHIO
RAND PAUL, KENTUCKY
JAMES LANKFORD, OKLAHOMA
MICHAEL B. ENZI, WYOMING
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COMMITTEE ON CHRISTOPHER R. HIXON, STAFF DIRECTOR HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

United States Senate

August 2, 2017

Spencer Williamson President and CEO Kaléo Pharma 111 Virginia Street, Suite 300 Richmond, VA 23219

Dear Mr. Williamson:

In June 2016, as Ranking Member of the U.S. Senate Aging Committee, I wrote to pharmaceutical manufacturers, including Kaléo Pharma, regarding the sudden spike in prices for the opioid overdose reversal drug naloxone and the steps manufacturers have taken to ensure state and local communities have access to this lifesaving product. In my letter, I stressed the importance of equipping first responders and others on the front lines of the U.S. opioid epidemic with naloxone. In a survey the Harm Reduction Coalition conducted in 2014, for example, community organizations reported that layperson administration of naloxonedistributed in 150,000 kits—had resulted in 25,000 opioid reversals since 1996.2 More recently, a project manager for the Missouri Opioid-Heroin Overdose Prevention and Education Project (MO-Hope Project) reported in November 2016 that he had "already seen tremendous success with the naloxone program that the St. Louis County Police Department has implemented, saving dozens of lives in just a few months." To further this progress, I strongly supported the Comprehensive Addiction and Recovery Act of 2016, which included provisions to help rural communities obtain naloxone.4

¹ Letter from Chairman Susan Collins and Ranking Member Claire McCaskill to Spencer Williamson, President and CEO, Kaléo Pharma (June 03, 2016).

² Center for Disease Control and Prevention, Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

³ More Missouri Police and Fire Departments Getting Heroin Antidote, St. Louis Post-Dispatch (Nov. 29, 2016) (www.stltoday.com/news/local/crime-and-courts/more-missouripolice-and-fire-departments-getting-heroin-antidote/article e02e69c8-8dce-54f5-8acda57844e52335.html).

⁴ Comprehensive Addiction and Recovery Act, Pub.L.No.114-198 (2016).

Spencer Williamson August 2, 2017 Page 2

More than 600 community-based programs operating across 30 states and the District of Columbia provide naloxone to laypersons such as families and friends. Additionally, over 900 law enforcement departments across the country are equipped with naloxone kits to use when responding to emergencies. These departments often look to community-based organizations for training on how to administer naloxone and for donations to reduce the costs of purchasing the drug. MO-HOPE Project, for example, offers free training on proper naloxone deployment and relies on donations to provide Narcan nasal spray to law enforcement officers in the eastern region of Missouri.

However, the rise in costs associated with acquiring naloxone has caused significant accessibility issues for those on the front lines of this epidemic. Law enforcement departments in states without sufficient community resources, for example, could potentially pay between \$22 and \$60 per naloxone kit, depending on the specific form of naloxone used. Any additional rise in price could create further obstacles for departments and community-based organizations seeking to meet community demand.

As Congress works toward implementing commonsense solutions to address the opioid epidemic, cooperation between government entities and the pharmaceutical industry in promoting the availability of naloxone will play a critical role. In your response to my June 2016 letter, you emphasized the willingness of Kaléo Pharma to raise awareness of opioid addiction and to increase access to naloxone within U.S. communities. To help me better understand your efforts in this area; please provide responses to the information requested below:

⁵ Center for Disease Control and Prevention, Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

⁶ North Carolina Harm Reduction Coalition, Home Page (<u>www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/</u>)(accessed June 22, 2017).

⁷ Harm Reduction Coalition, *Training Law Enforcement to Identify Overdose and Use Naloxone*, (http://harmreduction.org/overdose-prevention/training-law-enforcement-to-identify-overdose-and-use-naloxone/) (accessed June 22, 2017).

^{&#}x27;8 MO-HOPE Project, Home Page (http://mohopeproject.org/)(accessed June 22, 2017).

⁹ See As Opioid Epidemic Worsens, the Cost of Waking Up From an Overdose Soars, CNBC (Jan. 4, 2017) (www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html); Local Police, EMS Agencies Feel Effect of Rising Naloxone Prices, Charleston Gazette-Mail (Sept. 4, 2016) (www.wvgazettemail.com/news-health/20160904/local-police-ems-agencies-feel-effect-of-rising-naloxone-prices).

¹⁰Bureau of Justice Assistance, Office of Justice Programs, National Training and Technical Assistance Center, Tools and Resources, Naloxone Toolkit, Acquiring Naloxone (bjatraning.org/tools/naloxone/Acquiring-Naloxone)(accessed June 22, 2017).

¹¹ Letter from Spencer Williamson, President and CEO, Kaléo Pharma, to Chairman Susan Collins and Ranking Member Claire McCaskill (June 23, 2016).

- Please provide details concerning the administration of your naloxone donation program, including the years in which the program has operated; the number of naloxone units donated per year, how law enforcement organizations and community groups can request naloxone units, and how Kaléo Pharma otherwise identifies potential recipients of naloxone;
- 2. Please provide copies of any contracts or other forms Kaléo Pharma has employed governing its relationship with recipients of donated naloxone products;
- 3. Please provide a list of all parties to which Kaléo Pharma has donated naloxone products, including the amount of product requested, the amount of product donated, and the year or years in which Kaléo Pharma made the donation;
- Please provide a list of all parties to which Kaléo Pharma has provided coupons for rebates on naloxone products, including the amount of the rebate provided and the year or years in which Kaléo Pharma provided the coupons;
- 5. Please describe the training Kaléo Pharma provides to recipients of donated naloxone products, if any; and
- Please describe plans Kaléo Pharma has made to prevent product shortages from limiting
 its ability to meet its commitments to law enforcement organizations and community
 groups.

Please provide your responses as soon as possible, but no later than August 23, 2017. If you have any questions, please contact Phylicia Woods of the Committee staff at (202) 224-2627. Please send all official correspondence relating to this request to Amanda Trosen@hsgac.gov.

Sincerely,

Claire McCaskill Ranking Member

La Caplita

cc: Ron Johnson Chairman JOHN MCCAIN, ARIZONA ROB PORTMAN, OHIO RAND PAUL, KENTUCKY JAMES LANKFORD, OKLAHOMA MICHAEL B. ENZI, WYOMING JOHN HOEVEN, NORTH DAKOTA STEVE DAINES, MONTANA CLAIRE McCASKILL, MISSOURI THOMAS R. CARPER, DELAWARE JON TESTER, MONTANA HEIDI HEITKAMP, NORTH DAKOTA GARY C. PETERS, MICHIGAN MARGARET WOOD HASSAN, NEW HAMPSHIRE KAMALA D. HARRIS. CALIFORNIA

CHRISTOPHER R. HIXON, STAFF DIRECTOR MARGARET E. DAUM, MINORITY STAFF DIRECTOR

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510–6250

August 2, 2017

Ian C. Read Chief Executive Officer Pfizer, Inc. 235 East 42nd Street New York, NY 10017

Dear Mr. Read:

In June 2016, as Ranking Member of the U.S. Senate Aging Committee, I wrote to pharmaceutical manufacturers, including Pfizer, regarding the sudden spike in prices for the opioid overdose reversal drug naloxone and the steps manufacturers have taken to ensure state and local communities have access to this lifesaving product. In my letter, I stressed the importance of equipping first responders and others on the front lines of the U.S. opioid epidemic with naloxone. In a survey the Harm Reduction Coalition conducted in 2014, for example, community organizations reported that layperson administration of naloxone—distributed in 150,000 kits—had resulted in 25,000 opioid reversals since 1996. More recently, a project manager for the Missouri Opioid-Heroin Overdose Prevention and Education Project (MO-HOPE project) reported in November 2016 that he had "already seen tremendous success with the naloxone program that the St. Louis County Police Department has implemented, saving dozens of lives in just a few months." To further this progress, I strongly supported the Comprehensive Addiction and Recovery Act of 2016, which included provisions to help rural communities obtain naloxone.

¹ Letter from Chairman Susan Collins and Ranking Member Claire McCaskill to Ian C. Read, Chief Executive Officer, Pfizer, Inc. (June 3, 2016).

² Center for Disease Control and Prevention, *Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014* 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm)

³ More Missouri Police and Fire Departments Getting Heroin Antidote, St. Louis Post-Dispatch (Nov. 29, 2016) (www.stltoday.com/news/local/crime-and-courts/more-missouri-police-and-fire-departments-getting-heroin-antidote/article_e02e69c8-8dce-54f5-8acd-a57844e52335.html).

⁴ Comprehensive Addiction and Recovery Act, Pub. L. No. 114-198 (2016).

Ian C. Read August 2, 2017 Page 2

More than 600 community-based programs operating across 30 states and the District of Columbia provide naloxone to laypersons such as families and friends.⁵ Additionally, over 900 law enforcement departments across the country are equipped with naloxone kits to use when responding to emergencies.⁶ These departments often look to community-based organizations for training on how to administer naloxone and for donations to reduce the costs of purchasing the drug.⁷ MO-HOPE Project, for example, offers free training on proper naloxone deployment and relies on donations to provide Narcan nasal spray to law enforcement officers in the eastern region of Missouri.⁸

However, the rise in costs associated with acquiring naloxone has caused significant accessibility issues for those on the front lines of this epidemic. Law enforcement departments in states without sufficient community resources, for example, could potentially pay between \$22 and \$60 per naloxone kit, depending on the specific form of naloxone used. Any additional rise in price could create further obstacles for departments and community-based organizations seeking to meet community demand.

As Congress continues to work toward implementing commonsense policy solutions to address the opioid epidemic, cooperation between government entities and the pharmaceutical industry in the provision of naloxone will play a critical role. In your response to my June 2016 letter, you emphasized the willingness of Pfizer to raise awareness of opioid addiction and to increase access to naloxone within U.S. communities. Specifically, you discussed the launch

⁵ Center for Disease Control and Prevention, Morbidity Mortality Weekly Report: Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014 64(23); 631-635 (June 19, 2015) (online at www.cdc.gov/innwr/preview/mmwrhtml/imm6423a2.htm)

⁶ North Carolina Harm Reduction Coalition, Home Page (<u>www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/</u>) (accessed June 22, 2017).

⁷ Harm Reduction Coalition, *Training Law Enforcement to Identify Overdose and Use Naloxone*, (http://harmreduction.org/overdose-prevention/training-law-enforcement-to-identify-overdose-and-use-naloxone/) (accessed June 22, 2017).

⁸ MO-HOPE Project, Home Page (http://mohopeproject.org/) (accessed June 22, 2017).

⁹ See As Opioid Epidemic Worsens, the Cost of Waking Up From an Overdose Soars, CNBC (Jan. 4, 2017) (www.cnbc.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html); Local Police, EMS Agencies Feel Effect of Rising Naloxone Prices, Charleston Gazette-Mail (Sept. 4, 2016) (www.wvgazettemail.com/news-health/20160904/local-police-ems-agencies-feel-effect-of-rising-naloxone-prices).

¹⁰ Bureau of Justice Assistance, Office of Justice Programs, National Training and Technical Assistance Center, Tools and Resources, Naloxone Toolkit, Acquiring Naloxone (www.bjatraning.org/tools/naloxone/Acquiring-Naloxone) (accessed June 22, 2017).

¹¹ Letter from Ken W. Cole, Senior Vice President, U.S. Government Relations, Pfizer Inc., to Chairman Susan Collins and Ranking Member Claire McCaskill (June 24, 2016).

Ian C. Read August 2, 2017 Page 3

of Pfizer's *Naloxone Access Program*—a new program that will donate up to 1 million naloxone hydrochloride injection to groups such as nonprofit organizations, community clinics, and health departments and provide \$1 million in opioid overdose grants across five states. ¹² To help the Committee better understand your efforts in this area; please provide responses to the information requested below:

- 1. Please describe the current status of Pfizer's *Naloxone Access Program* and the company's plans for administering the program;
- 2. Please provide a list of the parties requesting naloxone under the *Naloxone Access Program*, including the number of units each party has requested and the number of units Pfizer has provided in response;
- 3. Please provide copies of any contracts or other forms Pfizer has employed governing its relationship with recipients of donated naloxone products;
- 4. Please explain how Pfizer will administer state grants under the *Naloxone Access Program*, including the procedures by which states will apply criteria for selecting participants, grant renewal procedures, and guidelines for the distribution of grant money within states; and
- 5. Please provide copies of any contracts or other forms Pfizer has employed governing its award of state grants under the *Naloxone Access Program*.

Please provide your responses as soon as possible, but no later August 23, 2017. If you have any questions, please contact Phylicia Woods of the Committee staff at (202) 224-2627. Please send all official correspondence relating to this request to Amanda_Trosen@hsgac.gov.

Sincerely,

Claire McCaskill Ranking Member Dulca 2

cc: Ron Johnson Chairman