Congress of the United States
Washington, DC 20510

April 11, 2022

Dennis J. Carlo
Chief Executive Officer
Adamis Pharmaceuticals Corporation
11682 El Camino Real, Suite # 300
San Diego, CA 92130

Dear Dr. Carlo,

Given our nation's alarming opioid overdose rates, we write to urge Adamis Pharmaceuticals Corporation to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent.[2] With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers.[3] Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who

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need it, as well as for first responders and other good Samaritans, and increase the supply in at-risk communities.

The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.[4, 5] Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Adamis will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Margaret Wood Hassan
United States Senator

Angus S. King, Jr.
United States Senator

Brian Fitzpatrick
Member of Congress

Joe Manchin III
United States Senator

Susan Collins
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Sheldon Whitehouse
United States Senator

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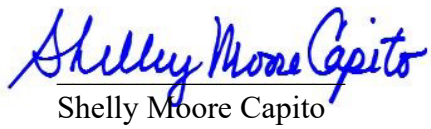
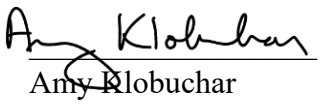


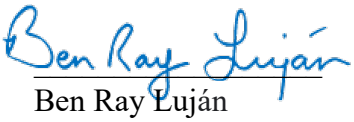
Shelly Moore Capito
United States Senator

Elizabeth Warren
United States Senator

Lisa Murkowski
United States Senator



Amy Klobuchar
United States Senator



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United States Senator

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Brian Schatz
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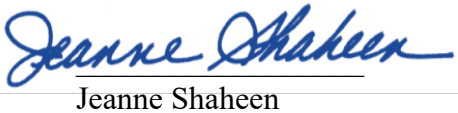
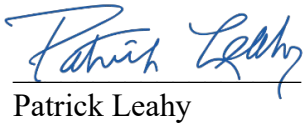


Jeanne Shaheen
United States Senator



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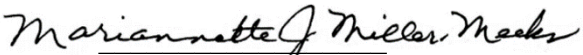

Mariannette J. Miller-Meeks, M.D.
Member of Congress

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Ayanna Pressley
Member of Congress

Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Douglas S. Boothe
Chief Executive Officer
Akorn
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Dear Mr. Boothe,

Given our nation's alarming opioid overdose rates, we write to urge Akorn to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent.[2] With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers.[3] Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who

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The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.[4, 5] Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Akorn will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

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Chairwoman
Committee on Oversight and Reform

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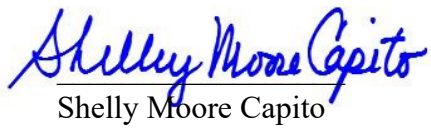

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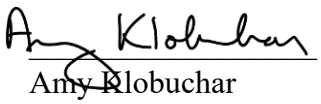

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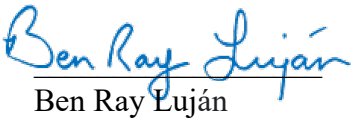
United States Senator



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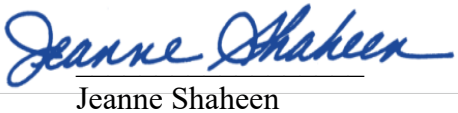

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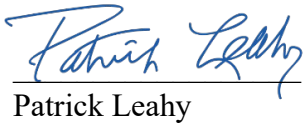
United States Senator



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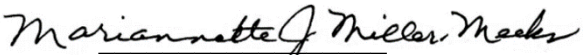

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Rashida Tlaib
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Ayanna Pressley
Member of Congress

Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Sven Dethlefs
Executive Vice President, North America
Teva Pharmaceuticals USA
400 Interpace Parkway, #3
Parsippany, NJ 07054

Dear Dr. Dethlefs,

Given our nation's alarming opioid overdose rates, we write to urge Teva to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent.[2] With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers.[3] Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who

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The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.[4, 5] Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Teva will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Margaret Wood Hassan
United States Senator

Angus S. King, Jr.
United States Senator

Brian Fitzpatrick
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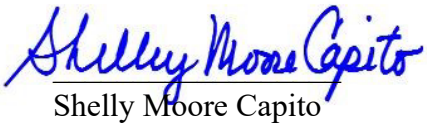

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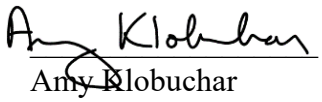

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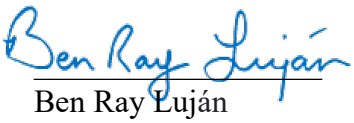

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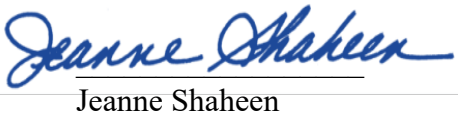

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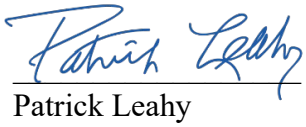

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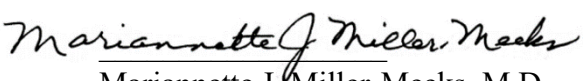

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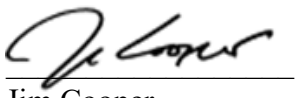

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Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Albert Bourla
Chief Executive Officer
Pfizer Inc.
235 East 42nd Street
NY, NY 10017

Dear Dr. Bourla,

Given our nation's alarming opioid overdose rates, we write to urge Pfizer to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

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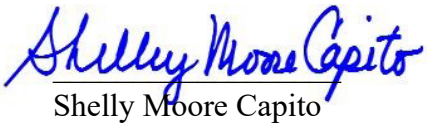

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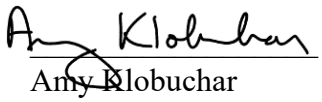

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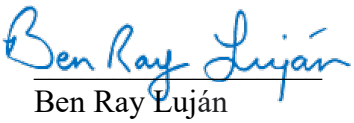

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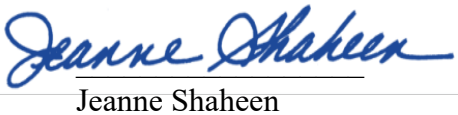

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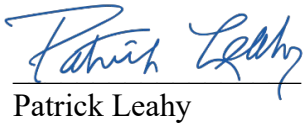
United States Senator

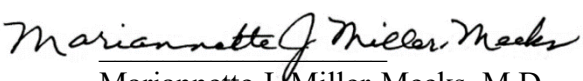


Patrick Leahy
United States Senator

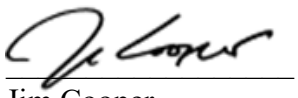
Mark DeSaulnier
Member of Congress

Peter Meijer
Member of Congress

Katie Porter
Member of Congress



Mariannette J. Miller-Meeks, M.D.
Member of Congress



Jim Cooper
Member of Congress

Congress of the United States
Washington, DC 20510

Peter Welch
Member of Congress

Alexandria Ocasio-Cortez
Member of Congress

Cori Bush
Member of Congress

Rashida Tlaib
Member of Congress

Ayanna Pressley
Member of Congress

Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Siggi Olafsson
Chief Executive Officer
Hikma Pharmaceuticals USA
200 Connell Drive, 4th Floor
Berkeley Heights, NJ 07922

Dear Mr. Olafsson,

Given our nation's alarming opioid overdose rates, we write to urge Hikma Pharmaceuticals to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent.[2] With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers.[3] Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who

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The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.[4, 5] Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Hikma Pharmaceuticals will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Margaret Wood Hassan
United States Senator

Angus S. King, Jr.
United States Senator

Brian Fitzpatrick
Member of Congress

Joe Manchin III
United States Senator

Susan Collins
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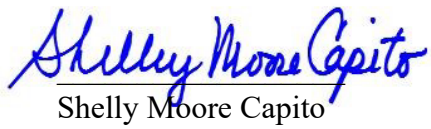

Shelly Moore Capito
United States Senator

Elizabeth Warren
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Lisa Murkowski
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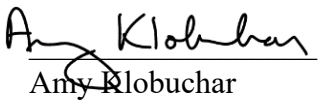

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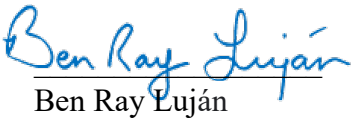

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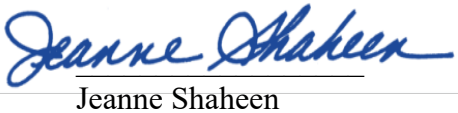
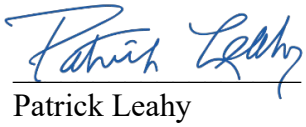


Jeanne Shaheen
United States Senator



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United States Senator

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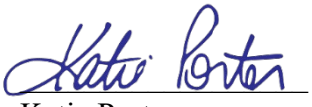
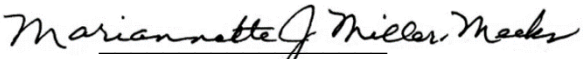
Member of Congress

Peter Meijer
Member of Congress



Katie Porter
Member of Congress



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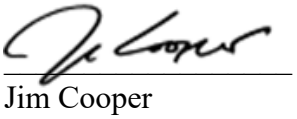

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Washington, DC 20510

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Rashida Tlaib
Member of Congress

Ayanna Pressley
Member of Congress

Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Jack Y. Zhang
Chief Executive Officer
Amphastar Pharmaceuticals
11570 6th St.
Rancho Cucamonga, CA 91730

Dear Dr. Zhang,

Given our nation's alarming opioid overdose rates, we write to urge Amphastar Pharmaceuticals to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent.[2] With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers.[3] Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who

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The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.[4, 5] Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Amphastar will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Margaret Wood Hassan
United States Senator

Angus S. King, Jr.
United States Senator

Brian Fitzpatrick
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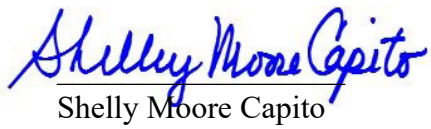

Shelly Moore Capito
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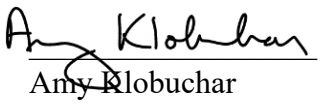

Amy Klobuchar
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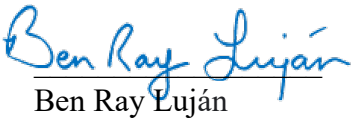

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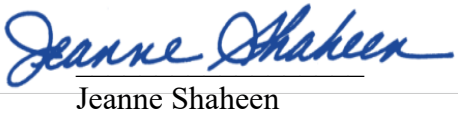
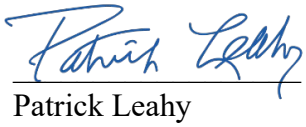


Jeanne Shaheen
United States Senator



Patrick Leahy
United States Senator

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Peter Meijer
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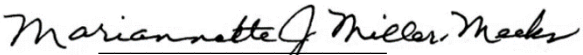

Mariannette J. Miller-Meeks, M.D.
Member of Congress

Jim Cooper
Member of Congress

Congress of the United States
Washington, DC 20510

Peter Welch
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Alexandria Ocasio-Cortez
Member of Congress

Cori Bush
Member of Congress

Rashida Tlaib
Member of Congress

Ayanna Pressley
Member of Congress

Jimmy Gomez
Member of Congress

Congress of the United States
Washington, DC 20510

April 11, 2022

Robert G. Kramer
Chief Executive Officer
Emergent Biosolutions
400 Professional Drive, Suite 400
Gaithersburg, MD 20879

Dear Mr. Kramer,

Given our nation's alarming opioid overdose rates, we write to urge Emergent to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths.[1] These trends show no signs of abating as overdose deaths continue to rise.

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We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

Tammy Baldwin
United States Senator

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

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United States Senator

Angus S. King, Jr.
United States Senator

Brian Fitzpatrick
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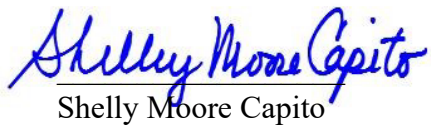

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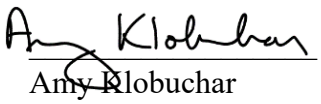

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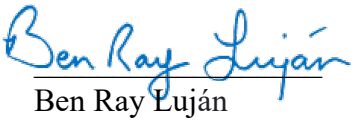

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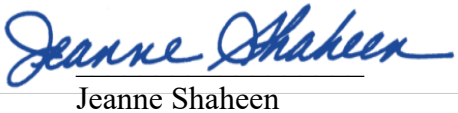

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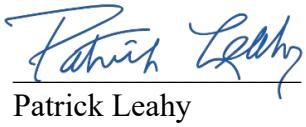

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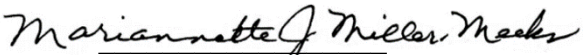

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