

**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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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<sup>1</sup> Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 (Nov. 17, 2021), [https://www.cdc.gov/nchs/pressroom/nchs\\_press\\_releases/2021/20211117.htm](https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm)

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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.<sup>4, 5</sup> 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.

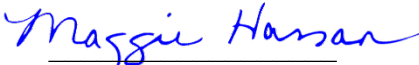
Sincerely,



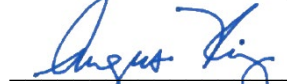
Tammy Baldwin  
United States Senator



Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform



Margaret Wood Hassan  
United States Senator



Angus S. King, Jr.  
United States Senator



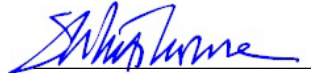
Brian Fitzpatrick  
Member of Congress



Joe Manchin III  
United States Senator



Susan Collins  
United States Senator



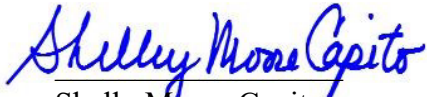
Sheldon Whitehouse  
United States Senator

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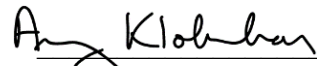
Shelly Moore Capito  
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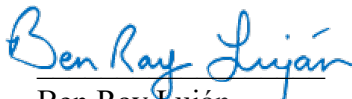
Elizabeth Warren  
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Lisa Murkowski  
United States Senator



Amy Klobuchar  
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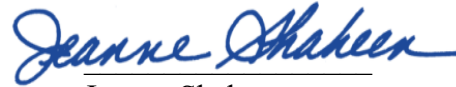
Edward J. Markey  
United States Senator



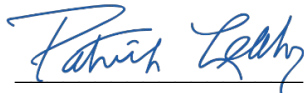
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United States Senator



Brian Schatz  
United States Senator



Jeanne Shaheen  
United States Senator



Patrick Leahy  
United States Senator



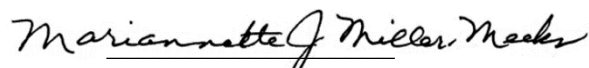
Mark DeSaulnier  
Member of Congress



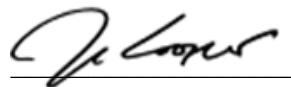
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Member of Congress



Katie Porter  
Member of Congress



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

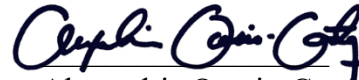


Jim Cooper  
Member of Congress

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Peter Welch  
Member of Congress



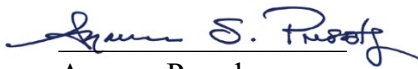
Alexandria Ocasio-Cortez  
Member of Congress



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

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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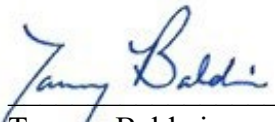
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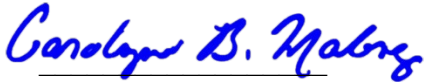
need it, as well as for first responders and other good Samaritans, and increase the supply in at-risk communities.

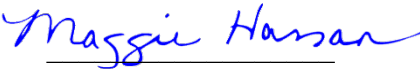
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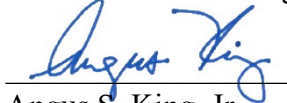
We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.


Sincerely,


  
\_\_\_\_\_  
Tammy Baldwin  
United States Senator

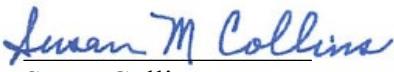
  
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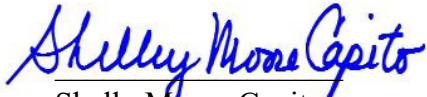
  
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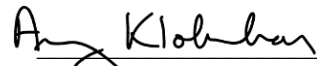
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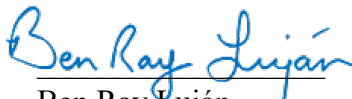
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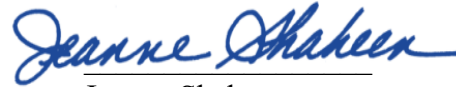
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Brian Schatz  
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Patrick Leahy  
United States Senator



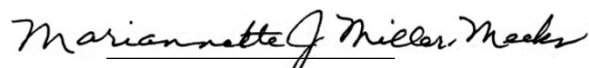
Mark DeSaulnier  
Member of Congress



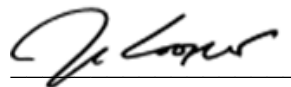
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Member of Congress



Katie Porter  
Member of Congress



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

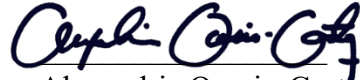


Jim Cooper  
Member of Congress

Congress of the United States  
Washington, DC 20510



Peter Welch  
Member of Congress



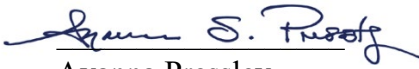
Alexandria Ocasio-Cortez  
Member of Congress



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

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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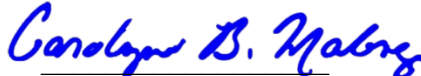
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We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.


Sincerely,




Tammy Baldwin  
United States Senator



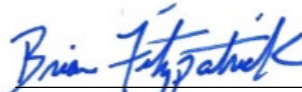
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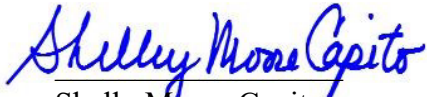
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United States Senator

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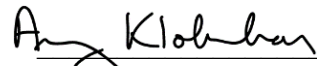
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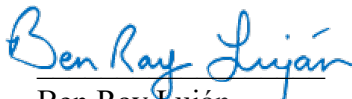
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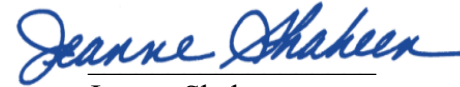
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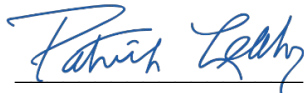
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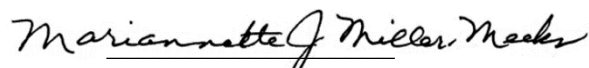
Mark DeSaulnier  
Member of Congress



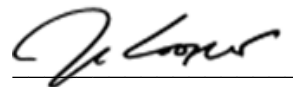
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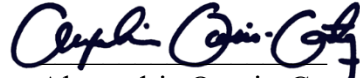


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Peter Welch  
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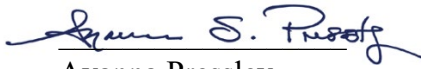
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Cori Bush  
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Rashida Tlaib  
Member of Congress



Ayanna Pressley  
Member of Congress



Jimmy Gomez  
Member of Congress

**Congress of the United States**  
Washington, DC 20510

April 11, 2022

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.<sup>1</sup> These trends show no signs of abating as overdose deaths continue to rise.

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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.<sup>3</sup> 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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<sup>1</sup> Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 (Nov. 17, 2021), [https://www.cdc.gov/nchs/pressroom/nchs\\_press\\_releases/2021/20211117.htm](https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm)

<sup>2</sup> Walley A Y, et al. Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis *BMJ* 2013; 346 :f174 doi:10.1136/bmj.f174

<sup>3</sup> "Plan N: The Case for Over-The-Counter Naloxone," Health Affairs Blog, July 2, 2021.

**Congress of the United States**  
Washington, DC 20510

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

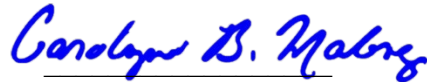
The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.<sup>4, 5</sup> Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, Emergent 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.

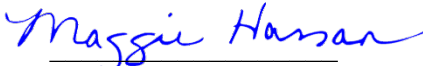
Sincerely,



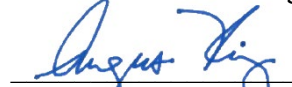
Tammy Baldwin  
United States Senator



Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform



Margaret Wood Hassan  
United States Senator



Angus S. King, Jr.  
United States Senator



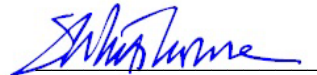
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Member of Congress



Joe Manchin III  
United States Senator



Susan Collins  
United States Senator



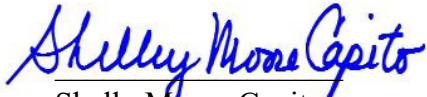
Sheldon Whitehouse  
United States Senator

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<sup>4</sup> <https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose>

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Washington, DC 20510



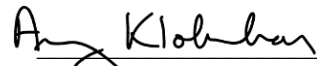
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United States Senator



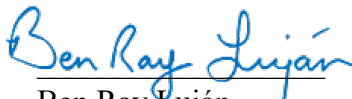
Elizabeth Warren  
United States Senator



Lisa Murkowski  
United States Senator



Amy Klobuchar  
United States Senator



Ben Ray Luján  
United States Senator



Richard Blumenthal  
United States Senator



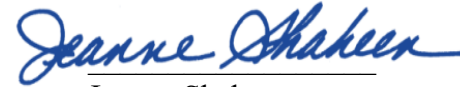
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United States Senator



Sherrod Brown  
United States Senator



Brian Schatz  
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Jeanne Shaheen  
United States Senator



Patrick Leahy  
United States Senator



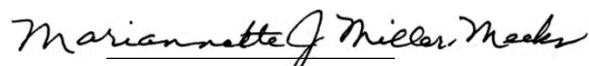
Mark DeSaulnier  
Member of Congress



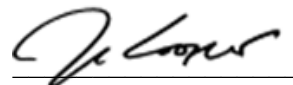
Peter Meijer  
Member of Congress



Katie Porter  
Member of Congress



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

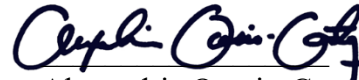


Jim Cooper  
Member of Congress

Congress of the United States  
Washington, DC 20510



Peter Welch  
Member of Congress



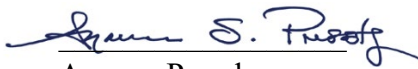
Alexandria Ocasio-Cortez  
Member of Congress



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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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**Congress of the United States**  
Washington, DC 20510

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.<sup>4, 5</sup> 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  
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Washington, DC 20510



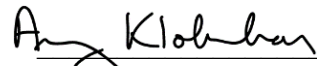
Shelly Moore Capito  
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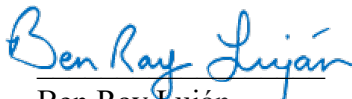
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Lisa Murkowski  
United States Senator



Amy Klobuchar  
United States Senator



Ben Ray Luján  
United States Senator



Richard Blumenthal  
United States Senator



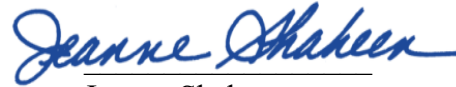
Edward J. Markey  
United States Senator



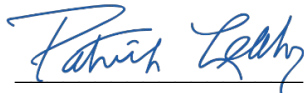
Sherrod Brown  
United States Senator



Brian Schatz  
United States Senator



Jeanne Shaheen  
United States Senator



Patrick Leahy  
United States Senator



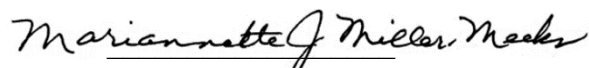
Mark DeSaulnier  
Member of Congress



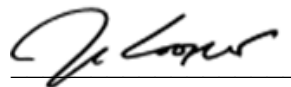
Peter Meijer  
Member of Congress



Katie Porter  
Member of Congress



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

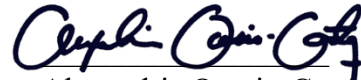


Jim Cooper  
Member of Congress

Congress of the United States  
Washington, DC 20510



Peter Welch  
Member of Congress



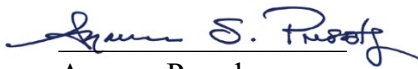
Alexandria Ocasio-Cortez  
Member of Congress



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

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.

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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Congress of the United States  
Washington, DC 20510

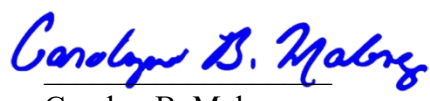
need it, as well as for first responders and other good Samaritans, and increase the supply in at-risk communities.

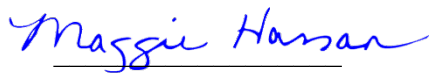
The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the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

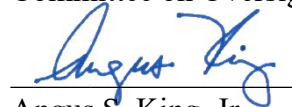
We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,


  
Tammy Baldwin  
United States Senator

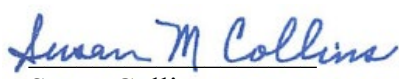
  
Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform

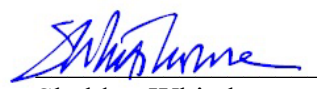
  
Margaret Wood Hassan  
United States Senator

  
Angus S. King, Jr.  
United States Senator

  
Brian Fitzpatrick  
Member of Congress

  
Joe Manchin III  
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Congress of the United States  
Washington, DC 20510



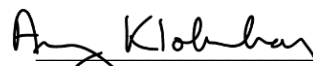
Shelly Moore Capito  
United States Senator



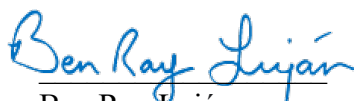
Elizabeth Warren  
United States Senator



Lisa Murkowski  
United States Senator



Amy Klobuchar  
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Ben Ray Luján  
United States Senator



Richard Blumenthal  
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Edward J. Markey  
United States Senator



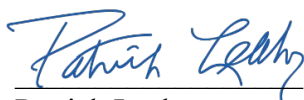
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United States Senator



Brian Schatz  
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Jeanne Shaheen  
United States Senator



Patrick Leahy  
United States Senator



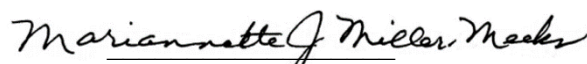
Mark DeSaulnier  
Member of Congress



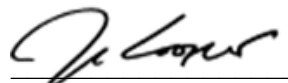
Peter Meijer  
Member of Congress



Katie Porter  
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Member of Congress

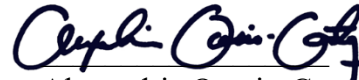


Jim Cooper  
Member of Congress

Congress of the United States  
Washington, DC 20510



Peter Welch  
Member of Congress



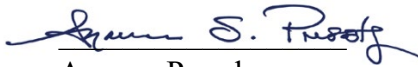
Alexandria Ocasio-Cortez  
Member of Congress



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

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.<sup>1</sup> These trends show no signs of abating as overdose deaths continue to rise.

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<sup>2</sup> Walley A Y, et al. Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis *BMJ* 2013; 346 :f174 doi:10.1136/bmj.f174

<sup>3</sup> "Plan N: The Case for Over-The-Counter Naloxone," Health Affairs Blog, July 2, 2021.

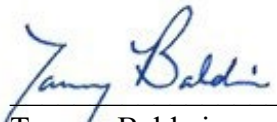
Congress of the United States  
Washington, DC 20510

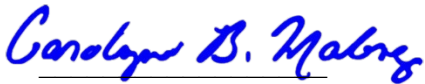
need it, as well as for first responders and other good Samaritans, and increase the supply in at-risk communities.

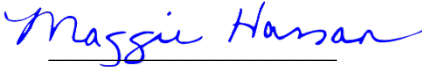
The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone.<sup>4, 5</sup> 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.

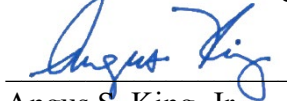
We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

  
\_\_\_\_\_  
Tammy Baldwin  
United States Senator

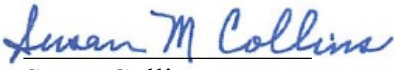
  
\_\_\_\_\_  
Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform


  
\_\_\_\_\_  
Margaret Wood Hassan  
United States Senator

  
\_\_\_\_\_  
Angus S. King, Jr.  
United States Senator

  
\_\_\_\_\_  
Brian Fitzpatrick  
Member of Congress

  
\_\_\_\_\_  
Joe Manchin III  
United States Senator

  
\_\_\_\_\_  
Susan Collins  
United States Senator


  
\_\_\_\_\_  
Sheldon Whitehouse  
United States Senator

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<sup>4</sup> <https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose>

<sup>5</sup> <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over>

Congress of the United States  
Washington, DC 20510



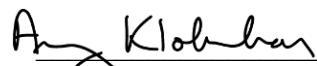
Shelly Moore Capito  
United States Senator



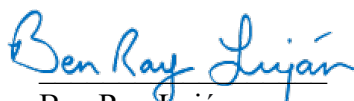
Elizabeth Warren  
United States Senator



Lisa Murkowski  
United States Senator



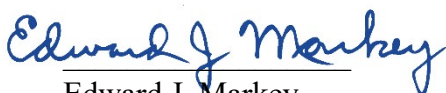
Amy Klobuchar  
United States Senator



Ben Ray Luján  
United States Senator



Richard Blumenthal  
United States Senator



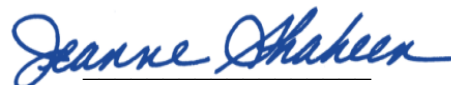
Edward J. Markey  
United States Senator



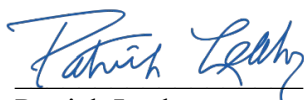
Sherrod Brown  
United States Senator



Brian Schatz  
United States Senator



Jeanne Shaheen  
United States Senator



Patrick Leahy  
United States Senator



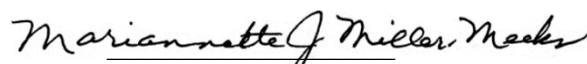
Mark DeSaulnier  
Member of Congress



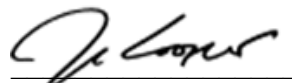
Peter Meijer  
Member of Congress



Katie Porter  
Member of Congress



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

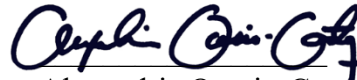


Jim Cooper  
Member of Congress

Congress of the United States  
Washington, DC 20510



Peter Welch  
Member of Congress



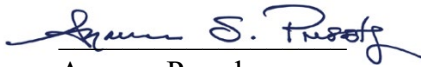
Alexandria Ocasio-Cortez  
Member of Congress



Cori Bush  
Member of Congress



Rashida Tlaib  
Member of Congress



Ayanna Pressley  
Member of Congress



Jimmy Gomez  
Member of Congress