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ONE HUNDRED SEVENTEENTH CONGRESS

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Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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January 19, 2022

Dr. Janet Woodcock
Acting Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

We write to inquire about the numerous stalled Emergency Use Authorization (EUA) applications for lifesaving COVID-19 therapeutics and treatments at the U.S. Food and Drug Administration (FDA). Operation Warp Speed enabled the FDA to grant EUA for three COVID-19 vaccines in record time. Unfortunately, since those vaccines were approved, the Biden Administration has *not* encouraged or focused on quickly developing and distributing COVID-19 therapeutics.[1] As health officials have confirmed the vaccine does not protect against infection from Omicron, it is critically important we develop viable therapies and treatments.

On March 31, 2020, the FDA created the Coronavirus Treatment Acceleration Program to use every tool at the agency's disposal to determine which therapeutics are safe and effective for use against COVID-19.[2] Yet, the American Rescue Plan passed in March 2021, allocated less than 1 percent of the $1.9 trillion to developing therapies.[3] As of January 19, 2022, the FDA has reviewed over 470 trials of potential COVID-19 therapeutics.[4] To date, the FDA has approved just seven COVID-specific therapeutics for emergency use and fully approved one treatment.[5]

Even worse, it appears the Biden Administration is consistently behind the curve every step of the way on responding to COVID-19—including purchasing those few treatments that have been approved. As the *Wall Street Journal* editorial board concluded on January 12, 2022:

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[1] Matthew Childs, *Biden's Operation Snail Speed on Covid Therapies*, THE WALL ST. J. (Jan. 12, 2022).
[2] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Continues to Accelerate Development of Novel Therapies for COVID-19 (Mar. 31, 2020).
[3] Matthew Childs, *Biden's Operation Snail Speed on Covid Therapies*, THE WALL ST. J. (Jan. 12, 2022).
[4] *Coronavirus Treatment Acceleration Program*, U.S. FOOD & DRUG ADMIN. (last visited Jan. 13, 2022).
[5] *Emergency Use Authorization,* U.S. FOOD & DRUG ADMIN. (last visited Jan. 13, 2021). The seven COVID-specific treatments include are (1) GlaxoSmithKline/Vir Biotechnology (sotrovimab), (2) Eli Lilly (bamlanivimab with etesevimab), (3) Regeneron (casirivimab and imdevimab), (4) convalescent plasma, (5) Actemra (tocilizumab), (6) Evusheld (tixagevimab and cilgavimab), and (7) Pfizer's Paxlovid (nirmatrelvir and ritonavir). The fully approved therapy is Remdesivir.

"Having more therapies this winter would have reduced the burden on hospitals and might have saved thousands of lives."[6]

The Trump Administration's Operation Warp Speed accelerated vaccine development and production by placing advance orders so a supply would be available as soon as the FDA approved a vaccine.[7] President Biden has failed to do the same for treatments leaving Americans with a very minimal supply of effective treatments at a time when we need them most. For instance, the orders placed by the Biden Administration for monoclonal antibodies and antivirals in the last two weeks will likely not be delivered until after the Omicron peak.[8] That is unacceptable.

To help the Committee better understand the status of the rapid and safe approval of viable EUA therapeutic and treatment applications, please provide the following documents and information no later than February 2, 2022:

1. The total number of EUA applications for treatments and therapeutics for COVID-19 the FDA has received to date;

2. The total number of EUA applications for treatments and therapeutics for COVID-19 that have been rejected and the reasons why those applications were rejected;

3. A list of pending EUA applications, including the current stage of each of the EUA applications for COVID-19 treatments and therapeutics; and

4. The anticipated approval date for the next treatment or therapeutic for COVID-19.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

Jody Hice
Ranking Member
Subcommittee on Government Operations

[6] Matthew Childs, *Biden's Operation Snail Speed on Covid Therapies*, THE WALL ST. J. (Jan. 12, 2022).
[7] *Id.*
[8] *Id.*

Glenn S. Grothman
Ranking Member
Subcommittee on National Security

Michael Cloud
Ranking Member
Subcommittee on Economic and Consumer Policy

Ralph Norman
Ranking Member
Subcommittee on Environment

Nancy Mace
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Jim Jordan
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Bob Gibbs
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Pete Sessions
Member of Congress

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Andy Biggs
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Scott Franklin
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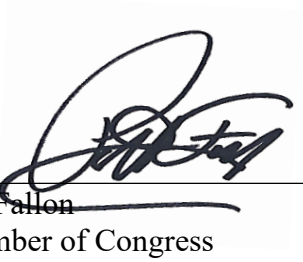
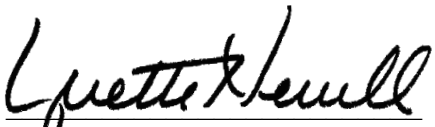
Member of Congress



Pat Fallon
Member of Congress



Yvette Herrell
Member of Congress

Byron Donalds
Member of Congress

cc: The Honorable Carolyn Maloney, Chairwoman
Committee on Oversight and Reform

The Honorable Gerald E. Connolly, Chairman
Subcommittee on Government Operations

The Honorable Stephen F. Lynch, Chairman
Subcommittee on National Security

The Honorable Raja Krishnamoorthi, Chairman
Subcommittee on Economic and Consumer Policy

The Honorable Ro Khanna, Chairman
Subcommittee on Environment

The Honorable Jamie Raskin, Chairman
Subcommittee on Civil Rights and Civil Liberties