

Congress of the United States

WASHINGTON, DC 20510

March 3, 2022

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases

Dear Dr. Califf and Dr. Fauci:

We are writing regarding a recent report of a physician practicing in Texas who has used a treatment—ZYESAMI—under the Right to Try Act to save COVID-19 patients’ lives.¹ Our understanding is the drug manufacturer, NRx Pharmaceuticals, applied for three Emergency Use Authorization’s (EUA) with the Food and Drug Administration (FDA) for ZYESAMI. NRx submitted its most recent EUA application on January 4, 2022 but the FDA has not yet granted this authorization. However, we are told the FDA refuses to review the data until the completion of clinical trials later this year.² We write to request information on the FDA’s review of ZYESAMI, as well as other information about treatment options for Americans suffering from COVID-19. We also wanted to share the stories of three individuals that credit ZYESAMI with saving their lives.

According to the physician, more than 20 patients suffering respiratory failure from COVID-19 received ZYESAMI as authorized under Right to Try.³ It is our understanding the patients received ZYESAMI after prior administration of remdesivir did not improve the patients’ conditions.⁴ All the patients were at the very end stage of COVID and were not expected to recover. Upon receiving ZYESAMI, no serious adverse events associated with use were reported and 16 of the 20 patients left the hospital.⁵ According to the physician, patients with ARDS normally have a 40 percent mortality rate.⁶ With ZYESAMI, the mortality rate decreased to roughly 10 percent.⁷

We are grateful to hear of patients successfully receiving lifesaving treatment under Right to Try. However, we are concerned that the FDA, National Institute of Allergy and Infectious Diseases (NIAID) and other public health agencies are not doing all they can to make this promising treatment available to Americans suffering from COVID-19. Almost a year ago, Dr.

¹ Nanette Holt, *New Drug for Seriously Ill COVID-19 Patients Shows Promise Under Right to Try Act*, Epoch Times (Jan. 31, 2022), available at https://www.theepochtimes.com/new-drug-for-seriously-ill-covid-19-patients-shows-promise-under-right-to-try-act_4247983.html.

² Phone call between clinical trial physician and Sen. Ron Johnson staff (Feb. 8, 2022).

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

Fauci touted ZYESAMI as a promising treatment for COVID-19.⁸ However, the drug remains largely unavailable, and we are told FDA refuses to review the data of NRx's EUA until the National Institute of Health (NIH) completes clinical trials of ZYESAMI later this year.⁹

Two years into a pandemic and with a death toll exceeding a reported 900,000 Americans, it is unacceptable that the FDA and NIAID are needlessly delaying a treatment for late-stage COVID-19 with a remarkable track record of success. This bureaucratic dragging of your feet appears in stark contrast to the expedited review of other treatments like remdesivir, Molnupiravir, Paxlovid and the COVID-19 vaccines. The FDA's disparate review processes for different treatments that appears to favor large manufacturers is troubling.

To better understand the FDA's decisions regarding an EUA for ZYESAMI, we respectfully request the following information:

1. Please provide a timeline of FDA and NIAID actions to review ZYESAMI as an emergency treatment for COVID-19.
2. Please provide documentation of any communications between FDA or NIAID and physicians or hospitals that are utilizing ZYESAMI under Right to Try.
3. Has the FDA ever accepted the data of ongoing clinical trials when issuing an EUA for a treatment for COVID-19? If so, please provide the treatment and its EUA.
4. Please explain why the FDA refuses to review ZYESAMI data until completion of a clinical trial.
5. For COVID patients that received remdesivir and steroids but did not recover, what is the FDA and NIAID's current treatment recommendation?

Please provide this material as soon as possible but no later than 5:00 p.m. on March 17, 2022. Thank you for your attention to this urgent matter.

Sincerely,



Ron Johnson
United States Senator



Ted Cruz
United States Senator

⁸ *Press Briefing by White House COVID-19 Response Team and Public Health Officials.* (2021, April 23). The White House. <https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/23/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-31/>.

⁹ *Supra* note 2.

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Andy Biggs
Member of Congress



Chip Roy
Member of Congress

cc: The Honorable Xavier Becerra
U.S. Department of Health and Human Services

Acting Director Lawrence A. Tabak, D.D.S., Ph.D.
U.S. National Institute of Health

Patient Stories using ZYESAMI under Right to Try

Joel Webb

Texas

- Three friends were given remdesivir. Their organs shut down and they died. Joel did not want to go to hospital because he believed it was a death ticket.
- Joel had a prescription for HCQ and IVM but was so nauseous he couldn't keep the medicine down.
- His symptoms worsened so he went to the ER.
- He was admitted to Texas Frisco hospital.
- 100 percent of his lungs had shattered glass.
- Was told he was too far gone for remdesivir but offered an experimental treatment (ZYESAMI) for ARDS.
- Joel initially refused the treatment but symptoms worsened so agreed to take ZYESAMI on the evening of the third day in the hospital.
- Was told by doctor he would be intubated the next day if symptoms did not improve.
- After receiving ZYESAMI, almost instantaneous benefit to breathing.
- Next day symptom severity decreased.
- Checked out 4 days later.

Mark A. Akins

Florida

- Mark's mother is a 75 year old former respiratory therapist with multiple comorbidities (obese, heart disease, kidney failure, diabetes).
- She was admitted to Piedmont Hospital in Jasper, GA with onset COVID pneumonia.
- Upon admission to the hospital, she was given one round of remdesivir and treated with corticosteroids. Mark refused additional doses of remdesivir due to his mother's prior kidney issues.
- On day three, her condition worsened and she was given Ativan.
- Because she is a retired respiratory therapist, she had made a decision on admission for a do not ventilate order.
- Physicians told her she was out of options and had a 50 percent chance of survival after Ativan treatment.
- Mark and his sister researched ZYESAMI.
- Mark inquired about the treatment to the hospital, signed the Right to Try paperwork on Friday and was told the treatment would arrive within 24 hours.
- By Sunday, the treatment had not arrived so Mark sent a LinkedIn message to the drug manufacturer on Super Bowl Sunday. The CEO called within 45 minutes to say the hospital had not submitted all the paperwork but he would expedite the treatment.
- One hour later the paperwork was finalized.

- Mark was told the closest manufacturing facility was 4 hours away in West Columbia, South Carolina. Mark drove to pick up treatment and the next day his mother began the three day intravenous treatment.
- 36 hours after the final ZYESAMI treatment, Mark's mother was fully recovered.
- Nursing staff told Mark's mother it was a miracle and Mark completely credits ZYESAMI for the recovery.

Michael J. Tuttle

Maryland

- Michael's wife was hospitalized with COVID.
- She received remdesivir but it did not work.
- Michael's wife was on a ventilator and the physician gave an end of life talk.
- Michael asked about ZYESAMI but the hospital opposed the treatment.
- Michael continued to request the treatment and the hospital continued to refuse the treatment.
- The hospital finally agreed to allow ZYESAMI and the treatment was shipped through private delivery to the hospital.
- Before the first infusion was complete, Michael's wife's condition was improving.
- Michael's wife is now in a rehab facility to repair muscle deterioration from her 60 days in the hospital.
- She is eating regular food and excited to go home tomorrow, March 4, 2021.
- Michael stated ZYESAMI saved his wife's life.