U.S. Sen. Johnson: Leads colleagues in demanding answers from Dr. Califf and Dr. Fauci

Posted on Tuesday, Mar 8, 2022

WASHINGTON — Last week, U.S. Sen. Ron Johnson (R-Wis.), along with U.S. Sen. Ted Cruz (R-Texas), U.S. Rep. Andy Biggs (R-Ariz.) and U.S. Rep. Chip Roy (R-Texas), sent a letter to the U.S. Food and Drug Administration (FDA) Commission Dr. Robert Califf and the Director of the National Institute of Allergy and Infectious Diseases (NIAID) Dr. Anthony Fauci seeking answers to why certain drugs used in the treatment of COVID-19 have not received Emergency Use Authorization (EUA). The treatment, ZYESAMI has successfully saved the lives of more than 20 COVID-19 patients under the Right to Try Act.

The members wrote, "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."

Nearly a year ago, Dr. Fauci touted ZYESAMI as a promising treatment for COVID-19. However, the drug appears no closer to receiving FDA approval. Meanwhile, treatments including remdesivir, Molnupiravir, Paxlovid and the COVID-19 vaccines were fast tracked to approval.

The members are seeking an explanation for the delayed review process and favoritism shown by federal health agencies for large drug manufacturers.

Read more about the letter in The Blaze.

The full text of the letter can be found here and below:

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.

According to the physician, more than 20 patients suffering respiratory failure from COVID-19 received ZYESAMI as authorized under Right to Try.[3] At the end of the letter, we included the stories of three individuals that credit ZYESAMI with saving their lives. 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. 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,