FDA Approves Controversial Remdesivir COVID Treatment for Infants and Young Children

As if the U.S. Food and Drug Administration (FDA) couldn't sink further into the pit of ridiculous decisions it has made in the name of "COVID-19," the agency on Monday expanded approval of remdesivir to include patients who are 28 days or older, weigh at least 7 pounds and test positive for the virus.

To be eligible for treatment, the FDA said children must be hospitalized or have mild to moderate COVID and a high risk for progressing to severe disease even if they are not hospitalized.

Remdesivir is the first FDA-approved COVID treatment for pediatric patients under the age of 12 – although there are safer, less expensive and more effective drugs that could be approved that do not make pharmaceutical companies billions of

dollars.

The drug, made by Gilead Sciences and sold under the brand name Veklury, is given as an injection and had been previously approved to treat certain adults and patients 12 and older who weighed at least 88 pounds.

“As COVID-19 can cause severe illness in children, some of whom do not currently have a vaccination option, there continues to be a need for safe and effective COVID-19 treatment options for this population,” Dr. Patrizia Cavazzoni, director of the FDA’s Center for Drug Evaluation and Research, said in a news release. “Today’s approval of the first COVID-19 therapeutic for this population demonstrates the agency’s commitment to that need.”

The agency wrote that expanding remdesivir’s availability for certain pediatric age groups was supported by several “phase 3 clinical trials in adults.”

It also cited a clinical study of only 53 pediatric patients who were at least 28 days old and weighed at least 7 pounds, or 3 kilograms, “with confirmed SARS-CoV-2 infection and mild, moderate or severe COVID-19,” according to the FDA.

“Patients in this pediatric phase 2/3 trial received Veklury for up to 10 days. The safety and pharmacokinetic results from the phase 2/3 study in pediatric subjects were similar to those in adults,” the agency added.

Remdesivir is associated with severe side effects including liver injury, kidney failure, allergic reaction, shortness of breath, fever, swelling, nausea or death.

Even the World Health Organization recommends against the use of remdesivir for COVID-19, saying as early as November 2020 there wasn’t enough evidence to support its use.

Fauci and top officials altered clinical trial to make remdesivir look effective

If using an adult clinical trial and only one small pediatric study of only 53 patients to justify approval for the younger age group wasn't enough, the adult clinical trial forming the basis of the initial FDA approval was heavily flawed.

As The Vault Project reported on April 18, internal emails obtained by the Epoch Times through a Freedom of Information Act Request showed Dr. Anthony Fauci, chief medical advisor to the President, and top officials at the National Institute of Allergy and Infectious Diseases (NIAID) changed the endpoint for remdesivir during the middle of its clinical trial to make the drug look effective.

According to the emails, the endpoint measuring the effectiveness of the drug was changed from measuring the effectiveness against death and various forms of hospitalization on day 15 to time to recovery through day 29.

Instead of counting how many people taking the drug were kept alive on ventilators or died, among other measures, the NIAID said it would instead judge the drug primarily on a different outcome – how long it took surviving patients to recover.

Death and other negative outcomes were moved to secondary measure status and were no longer the key measure of remdesivir's performance.

In other words, a federal agency, directed by Fauci, used U.S. tax dollars to fund a study for a drug that was going to be the sole recommended treatment for COVID patients and when results showed it didn't work, the agency conspired with the drug company to change the endpoint during the trial to make

it look like it did.

Gilead Sciences on April 29, 2020, announced the results of remdesivir and within hours, Fauci, the director of the NIAID told White House reporters results of the trial proved the drug “can block the virus” that causes COVID.

What Fauci failed to mention is the endpoint was changed to facilitate that statement and remdesivir actually does no such thing.