Fauci and Top Officials Changed Endpoint of Remdesivir During Clinical Trial to Make Drug Look Effective, Emails Show



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, <u>internal emails</u> show.

Just hours after Fauci announced the results of the remdesivir trial, internal <u>emails show</u> researchers involved in the trial and the NIAID – who funded the study – were not prepared to answer questions about why remdesivir's endpoint was changed while the trial was in progress.

According to emails obtained by the <u>Epoch Times</u> through a Freedom of Information Act (FOIA) Request, the endpoint

measuring 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 <u>said</u> 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 would no longer be 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-19 patients and when results showed it was a dangerous flop, the agency worked with the drug company to change the endpoint during the trial to make it look like it worked – all while suppressing drugs like ivermectin and hydroxychloroquine, which are heavily substantiated by studies showing they actually are effective at reducing COVID mortality by as much as 50% and preventing the disease from the outset.

Remdesivir is a highly toxic "FDA approved" drug indicated for adults and children for the treatment of COVID requiring hospitalization. Remdesivir increases a patient's <u>risk of</u> <u>death</u> and renal failure, but hospitals are monetarily incentivized by the government to prescribe it and Fauci would only allow this drug to be used for COVID treatment despite more effective and safer alternatives. Thousands of Americans have died of COVID because they were <u>deprived access</u> to effective treatments in an effort to prioritize remdesivir.

According to the <u>National Institutes of Health</u>, an endpoint is a "targeted outcome of a clinical trial that is statistically analyzed to help determine the safety and efficacy of the therapy being studied." Gilead Sciences on April 29, 2020, <u>announced the results</u> of its drug, remdesivir. 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 that the endpoint was changed to facilitate that statement and remdesivir does no such thing.

Endpoints must be validated prior to beginning the clinical trial and are the basis for determining whether the study met its objective or, in the case of interventional clinical trials, will be the data taken into account for regulatory approval.

Allowing an endpoint to be manipulated during a trial is like playing a game with a clearly defined set of rules, and then changing the rules halfway through when it's clear you're losing so that you can declare yourself the winner. It's called, "cheating." Applying this analogy to remdesivir, it's called "bad science."

According to <u>The Epoch Times</u>, Dr. Andre Kalil, an infectious disease expert who helped run one of the remdesivir trial sites, told Fauci, Dr. Clifford Lane, and John Beigel, NIAID officials, at 3:19 a.m. on April 30, 2020, he received multiple requests from colleagues and reporters who wanted to know why the primary outcome was changed while the trial was in progress.

## Kalil wrote:

"Believe or not, but I even heard nonsense things such as a conspiracy theory that Gilead opened the database and changed the primary outcome to favor the trial results. In order to prevent more conspiracies, I thought about a transparent and objective way to respond to these questions, so we can all be on the same page."

The proposed statement was redacted. Lori Dodd, an NIAID

statistician, responded by saying she liked what Kalil wrote. Shortly after, Beigel, the trial's principal investigator, said he was "merging the two" in an email that was also redacted.

A draft statement was sent to the U.S. Food and Drug Administration (FDA), which "cleared with Gilead" a paragraph about the regulator's "commitment to expediting" COVID treatments and how the agency had been in touch with Gilead about making remdesivir available to patients "as quickly as possible, as appropriate."

In other words, the NIAID, FDA and pharmaceutical company who stood to profit from the approval of remdesivir worked together to come up with a statement to explain why the endpoint was manipulated to make an ineffective drug look effective. It's the equivalent of a group of co-conspirators getting together after a bank robbery to "get their stories straight," to lessen their chances of being arrested.

The statement was still being adjusted at 3:20 p.m., according to a communication Jennifer Routh, an NIAID spokeswoman, sent to Beigel, Lane and others.

"We now have 10 media inquiries asking about why the primary endpoint in the remdesivir study changed," Routh said, adding: "We need a statement to respond as soon as possible. Is this OK to send or is this still under review?"

The draft statement was redacted.

Multiple media outlets inquired about the changing endpoint, including the Wall Street Journal, CNN and the Washington Post. Dr. Steven Nissen, a cardiologist at the Cleveland Clinic, told <u>The Washington Post</u> that government scientists shifted the endpoint because they "thought they weren't going to win, and they wanted to change it to something they could win on." Henry Drysdale of the University of Oxford chastised the NIAID for not being open about reporting their results. "Whenever I see an explanation like this when an outcome-switching has happened, that's fine, but you were not open about this when you reported your quote-unquote exciting results."

## Here is the NIAID's official statement:

"Little was known regarding the natural course of COVID-19 when the trial was initially designed, and the initial endpoint chosen specified a single timepoint for evaluation, namely day 14. However, with the growing knowledge during the epidemic, we learned that COVID-19 had a more protracted course than previously known. Further concerns were raised about the reliance on a single time point for evaluating treatment effects.

"While still blinded to treatment assignment, NIAID statisticians performed modeling of what happens if the right day is not picked for assessment, which revealed that meaningful treatment effects could be missed with that primary endpoint. Time to recovery avoids this issue, and the change in primary endpoint seemed appropriate given the evolving clinical data. This change in primary endpoint was made without any knowledge of data from ACTT [the name of the clinical trial], before any interim data was available."

The endpoint change was finalized on April 2, 2020, and the primary measure became one of many secondary outcomes, but on the trial's official page, the change was not reported until April 16, 2020.

On April 24, 2022, a teleconference that included Dr. Francis Collins, Director of the National Institutes of Health still listed the original primary endpoint, with data current as of April 6, 2020. After the trial results were released, remdesivir was immediately declared the new standard of care for COVID patients and the government began to promote this one drug at the expense of all other drugs.

What's also clear from the emails, is that Gilead, before results were announced, sent a press release to Beigel that the company planned to issue "just before the market opens tomorrow AM."

"There will be a lot of interest after that statement," Beigel wrote, sharing the release with Routh, Lane, and others with NIAID. Fauci reviewed the release and signed off.

After the Gilead and NIAID announcements on April 29, 2020, Tomas Cihlar, a senior vice president at Gilead, wrote to Lane – who helped come up with the justification for changing the clinical trial endpoint – thanking him for the ACTT trial "and the amazing work your clinical team did."

"Congratulations," Cihlar responded.

Part of Lane's response was redacted.

"I am glad for Gilead as well," Lane also wrote.

According to <u>Becker's Hospital Review</u>, Gilead saw \$5.6 billion last year in sales from remdesivir.

## Emails show Fauci used erroneous COVID mortality numbers

According to the batch of <u>emails</u> obtained by The Epoch Times, Fauci also used erroneous COVID numbers during a press conference with President Trump. Fauci "used the old mortality numbers," Routh wrote shortly after Fauci spoke.

"Just spoke with Dr. Fauci on phone. He confirmed he has the new numbers," Kimberly Barasch, NIAID employee, said. "To be clear though, he USED the old numbers," Courtney Billet, an NIAID spokeswoman, responded. "And I talked to him just now on the phone and he confirmed we should stick with those in written statement."

"Fauci was great. Good job to all who prepped him, and thanks for trying to squeeze in the updated numbers," Dodd later wrote.

"Thanks to all for the help-the process wasn't pretty but it worked out in the end!" Billet said.

Fauci never corrected his error, nor did the "fact-checkers."