THE REMDESIVIR PAPERS

By J.M. Phelps

and

Whistleblower Daniel LeMay (a pseudonym)

Are U.S. military treatment facilities and others hiding, or manipulating, the deadly results of clinical trials and more surrounding the controversial drug purported to be a treatment for COVID-19?

1.0 Overview

Writing for *American Thinker*, author Stella Paul once said, "Remdesivir may be the most despised drug in American history, earning the nickname 'Run Death Is Near' for its lethal record during COVID." The Remdesivir Papers captures the essence of her statement for service members and veterans across the country.

Data derived from the Department of Defense Joint Trauma System (JTS) by a military whistleblower offers a stark contrast to results of multiple clinical trials involving the liberal usage of remdesivir in military treatment facilities and other civilian facilities, as well as its potential contribution to, at minimum, hundreds of untimely deaths.

Interviews with that whistleblower indicate the trials surrounding the use of remdesivir and respective protocols for the treatment of COVID-19 either (1) provided half-truths or (2) kept their secrets close. Big Pharma played their part, and the Department of Defense bought it. Either the U.S. government blindly fell for all of it, considering remdesivir an acceptable treatment for COVID-19 despite a lack of evidence ... or it opened itself to investigation.

2.0 Remdesivir, Gilead Sciences, DOD, and the FDA

On January 31, 2020, Dr. Merdad Parsey, Chief Medical Officer at Gilead Sciences stated:

"Gilead is working closely with global health authorities to respond to the novel coronavirus (2019-nCoV) outbreak through the appropriate experimental use of our investigational compound remdesivir. Together with the U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (DHHS), the U.S. Department of Defense (DOD) - CBRN Medical, the China CDC and National Medical Product Administration (NMPA), the World Health Organization (WHO), and the U.S. National Institute of Allergies and Infectious Diseases (NIAID), and along with individual

¹ Paul, S. (2023, July 28). 'It's Murder': Remdesivir Victims Decry FDA's Shocking New Move. American Thinker. https://www.americanthinker.com/articles/2023/07/its murder remdesivir victims decry fdas shocking new move.html

researchers and clinicians, Gilead is focused on contributing our antiviral expertise and resources to help patients and communities fighting 2019-nCoV."²

With a patent valid for up to 20 years, Gilead had already created a monopoly on the drug in 2017.³ Interestingly, in the same year, two researchers⁴ from the University of North Carolina Gillings School of Global Public Health were awarded more than \$6 million⁵ to "accelerate the development of a promising new drug (remdesivir) in the fight against deadly coronaviruses." The researchers had discovered that the development of severe acute respiratory syndrome coronavirus (SARS-CoV) in mice could be prevented by remdesivir (GS-5734TM).

Although the investigational drug was developed by Gilead Sciences as a treatment for the Ebola virus in 2017, it was subsequently proven to be lethal in human patients with the virus in 2018.⁶ Curiously, in February 2020, remdesivir – despite its deadly history – was approved for use in clinical trials to evaluate its efficacy in the treatment of COVID-19.⁷

Published by *The New England Journal of Medicine* in November 2019, the use of remdesivir resulted in the highest mortality rate among participants in a trial of four investigational therapies for Ebola in the Democratic Republic of Congo.⁸

² Gilead Sciences, Inc. (2020, January 31). *Gilead Sciences Statement on the Company's Ongoing Response to the 2019 Novel Coronavirus (2019-nCoV)*. https://www.gilead.com/company/company-statements/2020/gilead-sciences-statement-on-the-company-ongoing-response-to-the-2019-novel-coronavirus-2019-ncov

³ United States Patent and Trademark Office. (2017, August 8). *Methods for treating Filoviridae virus infections*. <a href="https://web.archive.org/web/20200324191627/http:/patft.uspto.gov/netacgi/nph-parser?d=PALL&p=1&u=/netahtml/PTO/srchnum.htm&r=1&f=G&l=50&s1=9724360.PN.&OS=PN/9724360&RS=PN/9724360

⁴ UNC Gillings School of Global Public Health. (2017, August 31). *Gillings School researchers receive \$6M+ grant to fight infectious diseases*. https://sph.unc.edu/sph-news/gillings-researchers-receive-6m-grant-to-fight-infectious-disease/

⁵ U.S. Department of Health & Human Services. (2017). *NIH Research Portfolio Online Reporting Tools*. https://report.nih.gov/award/index.cfm?ot=&fy=2017&state=NC,46&ic=&fm=&orgid=578206&distr=&rfa=&pid=1885536&om=n#tab5

⁶ Mulangu, S. et. al. (2019, November 27). *A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics*. The New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

⁷ Gilead Sciences, Inc. (2020, February 26). *Gilead Sciences Initiates Two Phase 3 Studies of Investigational Antiviral Remdesivir for the Treatment of COVID-19*. https://www.gilead.com/news/news-details/2020/gilead-sciences-initiates-two-phase-3-studies-of-investigational-antiviral-remdesivir-for-the-treatment-of-covid-19

⁸ Mulangu, S. et. al. (2019). https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

Despite the deaths of 93 out of 175 (53.1 percent) of patients, 9 the broad-spectrum antiviral was eagerly considered for a possible COVID-19 treatment.

Population	ZMapp	Remdesivir	Difference, Remdesivir vs. ZMapp	МАЬ114
	no. of deaths/ total no.(%)	no. of deaths/ total no. (%)	percentage points (95% CI)	no. of deaths/ total no. (%)
Overall	84/169 (49.7)	93/175 (53.1)	3.4 (-7.2 to 14.0)	61/174 (35.1)

Source: Table 2 screenshot¹⁰

Shortly thereafter, at a Defense Department press briefing on March 5, 2020, Army Brig. Gen. Michael J. Talley, commanding general of U.S. Army Medical Research and Development Command (USAMRDC) and Fort Detrick, revealed "a cooperative research and development agreement with an industry partner is under review for the DOD to gain access to an antiviral drug for treatment use in our medical centers, our military treatment facilities." ¹¹

Five days later, it was announced that Fort Detrick's U.S. Army Medical Materiel Development Activity (USAMMDA), a subordinate command of USAMRDC, had entered into a Cooperative Research and Development Agreement (CRADA) with the American biopharmaceutical company Gilead Sciences. ¹² Headquartered in Foster City, California, Gilead agreed to provide remdesivir for the treatment of DOD personnel exposed to severe acute respiratory syndrome coronavirus (SARS-CoV-2), the causative viral pathogen of COVID-19. ¹³

⁹ Mulangu, S. et. al. (2019). https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

¹⁰ Mulangu, S. et. al. (2019). https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

¹¹ U.S. Department of Defense. (2020, March 5). *Defense Department Press Briefing Investigating and Developing Vaccine Candidates Against COVID-*

^{19. &}lt;a href="https://www.defense.gov/News/Transcripts/Transcript/Article/2104736/defense-department-press-briefing-investigating-and-developing-vaccine-candidat/">https://www.defense.gov/News/Transcripts/Transcript/Article/2104736/defense-department-press-briefing-investigating-and-developing-vaccine-candidat/

¹² U.S. Army Medical Materiel Development Activity. (2020, March 10). *USAMMDA Announces Agreement with Gilead Sciences to Provide Investigational New Drug for Warfighters Exposed to Coronavirus Disease*. https://usammda.health.mil/index.cfm/public affairs/news releases/2020/USAMMDA announces agreement with gilead sciences

¹³ Kime, P. (2020, March 10). *Army signs agreement with drug giant Gilead on experimental COVID-19 treatment*. Military Times. https://www.militarytimes.com/news/your-military/2020/03/10/army-signs-agreement-with-drug-giant-gilead-on-experimental-covid-19-treatment/

"The trust and hope placed in our team by the Department of Defense, the Department of the Army and the American public have already enabled us to make great strides in this fight, and we are eager to pursue this effort to the end," said Fort Detrick's Brig. Gen. Talley.¹⁴

A March 11, 2020 press release by USAMMDA shared that "in the CRADA, the USAMMDA Force Health Protection program will allow for the investigational use of remdesivir provided by Gilead, at no cost to the government, in the absence of any approved treatment options." In an April 2020 news report, *Quartz* stated very effectively: "News of the military's deal with Gilead was surprising, shining a light on the military's unique ability to acquire medications before the FDA has signed off on the same drug for average Americans, if it ever does." ¹⁶

According to a statement provided to *Quartz* by the USAMMDA, "Remdesivir was chosen because it was the most mature, broad spectrum antiviral drug in development and showed activity in vitro and in animal models in decreasing the viral replication against coronaviruses."

2.1 Full speed ahead

Alongside heightened interest by the military and its purported promise, remdesivir moved quickly through government scrutiny. The FDA issued an Emergency Use Authorization (EUA) for remdesivir on May 1, 2020^{17} – less than two months after the CRADA with Gilead was announced. In August, a press release by Gilead Sciences announced the submission of a New Drug Application (NDA) to the FDA for remdesivir under the name Veklury®. An NDA is "the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S."

¹⁴ Defense Visual Information Distribution Service. (2020, April 21). *Fort Detrick Installation Utilizes Whole of Government Approach to Tackle COVID-19*. https://www.dvidshub.net/news/368009/fort-detrick-installation-utilizes-whole-government-approach-tackle-covid-19

¹⁵ U.S. Army Medical Materiel Development Activity. (2020). https://usammda.health.mil/index.cfm/public affairs/news releases/2020/USAMMDA announces agreement with gilead sciences

¹⁶ MacLellan, L. (2020, April 9). *How the military secured a coronavirus drug that has yet to win FDA approval*. Quartz. https://gz.com/1834939/how-the-military-secured-experimental-covid-19-drug-remdesivir

¹⁷ U.S. Food & Drug Administration. (2020, May 1). *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment

¹⁸ Gilead Sciences, Inc. (2020, August 28). *Gilead's Investigational Antiviral Veklury® (Remdesivir) Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of Patients With Moderate COVID-19*. moderate-covid-19

¹⁹ U.S. Food & Drug Administration. *New Drug Application (NDA)*. https://www.fda.gov/drugs/types-applications/new-drug-application-nda

Near the end of May, *The Lancet* – one of the world's leading peer-reviewed journals – published the results of "a randomised, double-blind, placebo-controlled, multicentre trial" that occurred in China between February 6, 2020, and March 12, 2020. ²⁰ In summary, that trial brought concerns about the efficacy of remdesivir. While it has been suggested that the trial was stopped because "the epidemic of COVID-19 has been controlled well in China [and] no eligible patients can be enrolled at present," the authors of the study said, "remdesivir was stopped early because of adverse events in 18 (12%) patients versus four (5%) patients who stopped placebo early." ²¹

This begs a question with regard to the use of remdesivir: Did those conducting the study conclude that adverse events would have continued to more than double if the trial had continued?

2.2 FDA approval

With an inability to demonstrate efficacy²² accompanied by stock sliding in Gilead between 2015 and 2020,²³ it's interesting to note that "the U.S. has bought up virtually all the stocks [of remdesivir] ... leaving none for the U.K., Europe or most of the rest of the world," according to an April 2020 report by The Guardian.²⁴

Six months later, in October 2020, remdesivir (Veklury®) was approved by the FDA as the "first treatment for COVID-19" for certain populations of adult and pediatric patients. ²⁵ For remdesivir to be approved, the Federal Food, Drug, and Cosmetic Act required "substantial evidence of effectiveness and a demonstration of safety for the drug's intended use(s)." ²⁶

²⁰ Wang, Yeming et. al. (2020, May 16). *Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial.* The Lancet. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext

²¹ Wang, Yeming et. al. (2020). https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext

²² Yan, V. et. al. (2021, September 17). Why Remdesivir Failed: Preclinical Assumptions Overestimate the Clinical Efficacy of Remdesivir for COVID-19 and Ebola. ASM Journals, American Society for Microbiology. https://journals.asm.org/doi/10.1128/aac.01117-21

²³ Nasdag, Gilead Sciences, Inc. Common Stock (GILD). https://www.nasdag.com/market-activity/stocks/gild

²⁴ Boseley, S. (2020, June 30). *US secures world stock of key Covid-19 drug remdesivir*. The Guardian. https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug

²⁵ U.S. Food & Drug Administration. (2020, October 22). *FDA Approves First Treatment for COVID-* 19. https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

²⁶ U.S. Food & Drug Administration. (2020). https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

In considering a drug's approval, the FDA "conducts a benefit-risk assessment based on rigorous scientific standards to ensure that the product's benefits outweigh its risks for the intended population." For this reason, FDA Commissioner Stephen M. Hahn, M.D. affirmed, "[the] approval [of remdesivir] is supported by data from multiple clinical trials that the agency has rigorously assessed and represents an important scientific milestone in the COVID-19 pandemic." ²⁸

2.3 Approval questioned

For some observers, the FDA's rapid approval of remdesivir didn't pass muster. For example, *Vox*'s Umair Irfan wrote, "the FDA is once again promoting a Covid-19 therapy based on shaky evidence, [expressing that] researchers are concerned the FDA's first full approval of a Covid-19 drug doesn't have enough research behind it."²⁹

In 2021, Robert F. Kennedy Jr., explained in his book *The Real Anthony Fauci* that Dr. [Anthony] Fauci "[moved] the goal posts" and created new endpoints to "[allow] the drug to demonstrate a benefit."³⁰ Failing to provide the data necessary to prove the efficacy of the drug, the former chief medical advisor to then-president Donald Trump had asserted remdesivir showed "quite good news" and set a new standard of care for COVID-19 patients.³¹

And initially the World Health Organization (WHO) took issue with the FDA's decision, issuing "a conditional recommendation [in November 2020] against the use of remdesivir in hospitalized patients, regardless of disease severity, as there is currently no evidence that remdesivir improves survival and other outcomes in these patients." In the same month, a WHO trial determined that "the big story is the finding that remdesivir produces no meaningful impact on survival." But roughly a year and a half later, the United Nations intergovernmental agency reversed course to

²⁷ U.S. Food & Drug Administration. (2020). https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

²⁸ U.S. Food & Drug Administration. (2020). https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

²⁹ Irfan, U. (2020, October 24). *The FDA approved remdesivir to treat Covid-19. Scientists are questioning the evidence*. Vox. https://www.vox.com/21530401/remdesivir-approved-by-fda-covid-19-fda-gilead-veklury

³⁰ Kenndy Jr., R. (2021). *The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health*. Children's Health Defense, p. 65.

³¹ Park, A. (2020, May 1). Remdesivir Receives FDA Emergency Use Authorization After Promising Results as a Coronavirus Treatment. Time. https://time.com/5829170/remdesivir-study-results/

³² World Health Organization. (2020, November 20). *WHO recommends against the use of remdesivir in COVID-19 patients*. https://web.archive.org/web/20201130140431/https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients

"[suggest] the use of remdesivir in mild or moderate COVID-19 patients who are at high risk of hospitalization."³³

In a cohort study of over 2,300 veterans hospitalized with COVID-19, JAMA Network Open – a medical journal published by the American Medical Association – determined "remdesivir treatment was not associated with survival," 34 determining that there more deaths among those veterans who received remdesivir than those who did not (*see table below*). The length of hospital stay was also doubled among those who received remdesivir.

Characteristic	Received remdesivir	Did not receive remdesivir
Outcomes		
Death within 30 d	377 (15.9)	338 (9.6)
Length of stay, median (IQR), d	8.0 (5-15)	4.0 (2-9)

Source: Figure 1 screenshot³⁵

Further eroding the efficacy of remdesivir, in December 2021 – and again on September 23, 2024 – Gilead confirmed the presence of glass particles in lots of remdesivir³⁶ ... demonstrating that not only was the drug poorly formulated, it was poorly manufactured as well.

³³ World Health Organization. (2020). https://web.archive.org/web/20201130140431/https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients

³⁴ Ohl, M. et. al. (2021, July 15). Association of Remdesivir Treatment With Survival and Length of Hospital Stay Among US Veterans Hospitalized With COVID-19. JAMA Network. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781959

³⁵ Ohl, M. et. al. (2021). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781959

³⁶ Baletti, B. (2024, September 26). *Glass Particles Prompt Another Recall of Remdesivir, the Controversial Drug Hospitals Used to Treat COVID Patients*. The Defender, Children's Health Defense. https://childrenshealthdefense.org/defender/remdesivir-recall-glass-particles-covid-hospital-protocol/

3.0 Clinical trial observations

Corroborated at ClinicalTrials.gov, a searchable registry and results database hosted by the National Library of Medicine, service members and veterans participated in at least four Phase 3 Adaptive COVID19 Treatment Trials (ACTT) between February 2020 and June 2021, to include NCT04280705 [ACTT-1],³⁷ NCT04401579 [ACTT-2],³⁸ NCT04492475 [ACTT-3],³⁹ and NCT04640168 [ACTT-4].⁴⁰ Each of these trials was sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

According to the FDA, Phase 3 trials "demonstrate whether or not a product offers a treatment benefit to a specific population...[and] the results are more likely to show long-term or rare side effects."

Another trial, NCT04302766, was sponsored by U.S. Army Medical Research and Development Command (USAMRDC).⁴² While the actual study start and study completion dates are not available at ClinicalTrials.gov, information was first submitted to the registry and database in March 2020.

Sections 3.1 to 3.5 summarize the details of these five clinical trials.

³⁷ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial (ACTT)*. https://clinicaltrials.gov/study/NCT04280705

³⁸ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 2 (ACTT-2)*. https://clinicaltrials.gov/study/NCT04401579

³⁹ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 3 (ACTT-3)*. https://clinicaltrials.gov/study/NCT04492475

⁴⁰ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 4 (ACTT-4)*. https://clinicaltrials.gov/study/NCT04640168

⁴¹ U.S. Food & Drug Administration. (assessed October 3, 2024). *Step 3: Clinical Research*. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

⁴² National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://clinicaltrials.gov/study/NCT04302766

3.1 NCT04280705

NCT04280705 [ACTT-1] was conducted at 60 locations, involving 1,062 participants. 43

Military locations

Naval Medical Center San Diego, Naval Hospital Jacksonville, Benning Martin Army Community Hospital, Eisenhower Army Medical Center, Tripler Army Medical Center, Blanchfield Army Hospital, Community Walter Reed National Military Medical Center, Naval Medical Center Camp Lejeune, Womack Army Medical Center, William Beaumont Army Medical Center, Carl R. Darnall Army Medical Center, Brooke Army Medical Center, Naval Medical Center Portsmouth, and Madigan Army Medical Center.

Participants

Each participant met the criteria of being "admitted to a hospital with symptoms suggestive of COVID-19 infection ... [with] laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR) or other commercial or public health assay in any specimen."

- The placebo comparator group received "200 mg of remdesivir placebo administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir placebo while hospitalized for up to a 10 days total course."
- The experimental group received "200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10 days total course."

	Placebo	Remdesivir
All-Cause Mortality	77/521	59/541
	(14.8%)	(10.9%)
Serious Adverse Events	163/516	131/532
	(31.6%)	(24.6%)

^{*} Table derived from the adverse events tab at ClinicalTrials.gov. 44

This study had wide inclusion criteria and minimal exclusion criteria. A true placebo, like saline, wasn't used other than in circumstances where there were limitations on matching placebo supplies. The study makes no distinction as to who received which placebo. Furthermore, the original enrollment count was used in all result calculations which ignored those who didn't finish the trial for various reasons, including adverse events. Adjusted for those who didn't finish the trials (13 placebo and 24 Remdesivir), All-Cause Mortality for the placebo group would have fallen between 12.2 and 17.2 percent. For the remdesivir group, the percentage would have fallen between 6.4 and 15.3 percent.

Analysis: Overall, this study is problematic due to multiple confounding variables that appear to exist intentionally to present a positive outcome for the remdesivir group. As an example, if

⁴³ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial (ACTT)*. https://clinicaltrials.gov/study/NCT04280705

⁴⁴ National Library of Medicine. (accessed October 3, 2024). Adaptive COVID-19 Treatment Trial (ACTT). https://clinicaltrials.gov/study/NCT04280705?tab=results#adverse-events

every "All-Cause Mortality" in the placebo group was due, in part, to mechanical ventilation it could still be made to appear that the placebo was to blame. This study ended up being the only comparison between remdesivir and a type of placebo. A true safety profile couldn't be established by design and only enabled follow-on studies pairing remdesivir with other investigational drugs.

NCT04401579 [ACTT-2] was conducted at 71 locations, involving 1,033 participants.⁴⁵

Military locations

VA Palo Alto Health Care System, Naval Medical Center San Diego, Atlanta VA Medical Center, Southeast Louisiana Veterans Health Care System, Walter Reed National Military Medical Center, Womack Army Medical Center, Brooke Army Medical Center, Naval Medical Center Portsmouth, and Madigan Army Medical Center.

Participants

Each participant met the criteria of being "admitted to a hospital with symptoms suggestive of COVID-19 infection ... [with] laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR) or other commercial or public health assay in any specimen."

- The placebo comparator group received "200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10-day total course and 4 mg (2 tablets of 2 mg) of Baricitinib Placebo administered orally daily for the duration of the hospitalization up to a 14-day total course."
- The experimental group received "200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10-day total course and 4 mg (2 tablets of 2 mg) of Baricitinib administered orally daily for the duration of the hospitalization up to a 14-day total course."

	Remdesivir and Placebo	Remdesivir and Baricitinib**
All-Cause Mortality	37/518	24/515
	(7.1%)	(4.7%)
Serious Adverse Events	109/509 (21.4%)	88/507 (24.6%)

^{*} Table derived from the adverse events tab at ClinicalTrials.gov. 46

Analysis: This is representative of a "Remdesivir and" study with no true placebo group which confounds results. Interestingly, 59 participants didn't finish the trial due to death, which isn't characterized as being caused by the investigative treatments. Additionally, no data is presented specific to pre-existing conditions or comorbidities apart from those present in the exclusion criteria (if followed). It's worth noting that the exclusion criteria expanded to include individuals with liver and kidney conditions.

^{**} Baricitinib is an immunomodulator

⁴⁵ National Library of Medicine. (accessed October 3, 2024). Adaptive COVID-19 Treatment Trial 2 (ACTT-2). https://clinicaltrials.gov/study/NCT04401579

⁴⁶ National Library of Medicine. (accessed October 3, 2024). Adaptive COVID-19 Treatment Trial 2 (ACTT-2). https://clinicaltrials.gov/study/NCT04401579?tab=results#adverse-events

NCT04492475 [ACTT-3] was conducted at 64 locations, involving 969 participants.⁴⁷

Military locations

VA Palo Alto Health Care System, Naval Medical Center San Diego, Atlanta VA Medical Center, Tripler Army Medical Center, Southeast Louisiana Veterans Health Care System, Walter Reed National Military Medical Center, Womack Army Medical Center, Brooke Army Medical Center, Naval Medical Center Portsmouth, and Madigan Army Medical Center.

Participants

Each participant met the criteria of being "admitted to a hospital with symptoms suggestive of COVID-19 infection ... [with] laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR) or other commercial or public health assay in any respiratory specimen or saliva."

- The placebo comparator group received "200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10-day total course and a 0.5 mL placebo injection administered subcutaneously on Days 1, 3, 5, and 7 while hospitalized for a total of 4 doses."
- The experimental group received "200 mg of Remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of Remdesivir while hospitalized for up to a 10-day total course and 44 mcg of interferon beta-1a administered by a 0.5 mL subcutaneous injection on Days 1, 3, 5, and 7 while hospitalized for a total of 4 doses."

	Remdesivir and Placebo	Remdesivir and Interferon Beta-1a**
All-Cause Mortality	17/482	21/487
	(3.5%)	(4.3%)
Serious Adverse Events	66/466	86/474
	(14.2%)	(18.1%)

^{*} Table derived from the adverse events tab at ClinicalTrials.gov. 48

** Interferon Beta-1a is an immunomodulator

Analysis: Again, this is representative of a "Remdesivir and" study with no true placebo group which confounds results. Additionally, no data is presented specific to pre-existing conditions or comorbidities apart from those present in the exclusion criteria (if followed).

⁴⁷ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 3 (ACTT-3)*. https://clinicaltrials.gov/study/NCT04492475

⁴⁸ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 3 (ACTT-3)*. https://clinicaltrials.gov/study/NCT04401579?tab=results#adverse-events

NCT04640168 [ACTT-4] was conducted at 72 locations, involving 1,010 participants.⁴⁹

Military locations

Palo Alto Health Care System, Naval Medical Center San Diego, VA Eastern Colorado Health Care System, Atlanta VA Medical Center, Tripler Army Medical Center, Walter Reed National Military Medical Center, Womack Army Medical Center, Brooke Army Medical Center, Naval Medical Center Portsmouth, and Madigan Army Medical Center.

Participants

Each participant met the criteria of being "hospitalized with symptoms suggestive of COVID-19 infection ... [with] laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR) or other commercial or public health assay."

- One experimental group received "200 mg of remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of remdesivir while hospitalized for up to a 10-day total course; 4 mg of baricitinib administered as 2 tablets taken orally daily while hospitalized for up to a 14-day total course; and dexamethasone placebo administered as an intravenous injection daily while hospitalized for up to a 10-day total course."
- Another experimental group received "200 mg of remdesivir administered intravenously on Day 1, followed by a 100 mg once-daily maintenance dose of remdesivir while hospitalized for up to a 10-day total course; baricitinib placebo administered as 2 tablets taken orally daily while hospitalized for up to a 14-day total course; and 6 mg of dexamethasone administered as an intravenous injection daily while hospitalized for up to a 10-day total course."

	Remdesivir and Baricitinib	Remdesivir and Dexamethasone**
All-Cause Mortality	28/516	34/494
	(5.4%%)	(6.9%)
Serious Adverse Events	95/503	94/482
	(18.9%)	(19.5%)

^{*} Table derived from the adverse events tab at ClinicalTrials.gov. 50

** Dexamethasone is a corticosteroid.

Analysis: This is also representative of a "Remdesivir and" study with no true placebo group which confounds results. Additionally, no data is presented specific to pre-existing conditions or comorbidities apart from those present in the exclusion criteria (if followed).

⁴⁹ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 4 (ACTT-4)*. https://clinicaltrials.gov/study/NCT04640168

⁵⁰ National Library of Medicine. (accessed October 3, 2024). *Adaptive COVID-19 Treatment Trial 4 (ACTT-4)*. https://clinicaltrials.gov/study/NCT04640168?tab=results#adverse-events

3.5 NCT04302766

Sponsored by USMARDC, NCT04302766 was conducted at 22 locations (all military facilities), involving an undisclosed number of participants.⁵¹

Military locations

Naval Medical Center San Diego, Naval Hospital Jacksonville, Benning Martin Army Community Hospital, Eisenhower Army Medical Center, Tripler Army Medical Center, Blanchfield Army Community Hospital, Walter Reed National Military Medical Center, Naval Medical Center Camp Lejeune, Womack Army Medical Center, William Beaumont Army Medical Center, Carl R. Darnall Army Medical Center, Brooke Army Medical Center, Naval Medical Center Portsmouth, Madigan Army Medical Center, and others abroad.

Participants

Each participant met the criteria of being "DoDaffiliated personnel as defined in DoDI 6200.02, which includes emergency-essential civilian employees and/or contractor personnel accompnying the Armed Forces who are subject to the same health risk as military personnel" ... and "[having] a laboratory-confirmed COVID-19 diagnosis with moderate to severe disease presentation as determined by the principal investigator." This study used the broadest inclusion criteria and minimal exclusion criteria in comparison to other investigational studies.

Analysis: While the trial examined the effects of remdesivir on the treatment of COVID-19, there are no details available at ClinicalTrials.gov to determine the amount of remdesivir administered to participants. There are no results posted to determine all-cause mortality or serious adverse events.⁵²

⁵¹ National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://clinicaltrials.gov/study/NCT04302766

⁵² National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://clinicaltrials.gov/study/NCT04302766?tab=results

4.0 Run Death Is Near

The table below compares the placebo-only trial, the collective use of remdesivir in NIAID trials, and remdesivir use in the USAMRDC trial. For the NIAID trial column, figures were derived by adding each instance of all-cause mortality, as well as serious adverse events, from each of the four trials summarized in Sections 3.1-3.4.

	Placebo Only (ACTT-1)	Collective Use of Remdesivir in NIAID Trials (ACTT-1, ACTT-2, ACTT-3, and ACTT-4)	Use of Remdesivir in USAMRDC Trial (NCT04302766)
All-Cause Mortality	77/521	220/3253	Not reported
	(14.8%)	(6.8%)	
Serious Adverse	163/516	669/3473	Not reported
Events	(31.6%)	(19.3%)	

In four of five trials, the use of remdesivir resulted in a minimal positive effect on instances of all-cause mortality and serious adverse side events when compared to the administration of a placebo.

But what about the USAMRDC trial? Did the use of remdesivir in this trial result in a similar positive effect as it was reported in the other trials? Several questions need to be answered:

- How many participants were there in the trial?
- How many participants died in the trial?
- For those who died, what did the participants die from?
- How much remdesivir did participants receive? Was it 200 mg of remdesivir administered intravenously on day 1, followed by a 100 mg once-daily maintenance for 10 days? Or was there another treatment protocol offered?
- What were the results of the trial?
- Were some of the deaths attributed to COVID-19 then they could/should have been attributed to remdesivir or treatment protocol?

It's important that these questions be answered because data derived from the DOD's Joint Trauma System (JTS) by a military whistleblower offers a stark contrast to results of the other trials. That JTS data (*shown in the following table*) clearly depicts the liberal usage of remdesivir in military treatment facilities (MTFs) and other civilian facilities, as well as its potential contribution to, at minimum, hundreds of untimely deaths.

Date Range	Total Patients	Patients Treated with
	(Died)	Remdesivir (Died)
March 2020 thru April 2020	35	1
May 2020 thru October 2020	173	108
November 2020 thru July 2021	360	256
August 2021 thru December 2021	231	152
January 2022 thru March 2024	142	84
Total	941	601 (63.9%)

Source: Data provided by whistleblower through the DOD's Joint Trauma System

Shockingly, 64 percent of patients who died between March 2020 and March 2024 were treated with remdesivir. Interestingly, the World Health Organization reported in 2020 that only "about 3.4% of reported COVID-19 cases have died." Two years later, research has determined the infection fatality rate (IFR) had a median of "0.002% at 20-29 years, 0.011% at 30–39 years, 0.035% at 40-49 years, 0.123% at 50-59 years, and 0.506% at 60-69 years." ⁵⁴

Another study, published by *BMC Infectious Diseases*, determined that "the risk of severe and critical disease increases exponentially with age, but much less steeply than the risk of fatal illness."⁵⁵

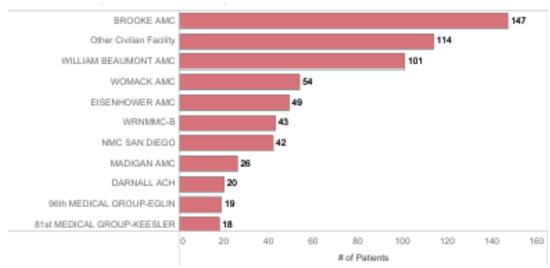
While the military is only a subset of the larger population, it's clear that service members and veterans who contracted severe COVID and were subsequently treated with remdesivir had a much higher chance of dying. Until results are shared publicly, there is no evidence of a positive effect to found in the USAMRDC trial.

According to data provided by the whistleblower, the number of remdesivir-related deaths depicted below occurred between March 2020 and January 2023 at a variety of MTFs across the country. Eight of 11 of these locations took part in the USAMRDC trial described in Section 3.5.

⁵³ World Health Organization. (2020, March 3). WHO Director-General's opening remarks at the media briefing on COVID-19 - 3 March 2020. <a href="https://www.who.int/director-general/speeches/detail/who-director-general-speeches/det

⁵⁴ Pezzullo, A. et. al. (2023, January 1). *Age-stratified infection fatality rate of COVID-19 in the non-elderly population*. Science Direct. https://www.sciencedirect.com/science/article/pii/S001393512201982X?via%3Dihub

⁵⁵ Herrera-Esposito, D. et. al. (2022, March 29). *Age-specific rate of severe and critical SARS-CoV-2 infections estimated with multi-country seroprevalence studies*. BMC Infectious Diseases. https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07262-0



Source: Graph provided by whistleblower through the DOD's Joint Trauma System

Is there a causal link between the use of remdesivir and the number of deaths at these facilities or any of the others around the country? That's a difficult question to answer because the data depicts the usage of remdesivir primarily on patients who were determined to have a severe or critical COVID-19 infection.

However, in some cases, these patients also had comorbidities (e.g., renal and liver disease) that could have been exacerbated by remdesivir and resulted in some of the reported complications such as acute renal injury and failure, as well as liver dysfunction and hepatic failure.

Obviously, not everyone who died was treated with remdesivir, but according to the whistleblower – and contrary to the results of clinical trials – "over 50 percent of those who died while hospitalized received remdesivir, [and] this was increasingly true between March 2020 and July 2021." Coincidently, the trials listed in this report were conducted at dozens of MTFs during this same period.

This begs the following questions:

- Why has the USAMRDC not published data on the number of deaths from participants in NCT04302766 nor the number of deaths of those who may not have been part of the trial itself but were treated with remdesivir in dozens of MTFs around the country?
- Furthermore, is remdesivir truly effective in preserving lives or are there alternatives with a better safety profile that should be explored? It is the "firm belief" of the whistleblower that the question presented about an alternative "was either never asked or never officially received."

Officials from neither USAMRDC Headquarters at Fort Detrick nor any of the U.S. locations involved in NCT04302766 responded to multiple inquiries made by the author of this report. A Freedom of Information Act (FOIA) request was submitted to the USAMRDC on September 24, 2024 (*see appendix 1*).

Coincidentally, according to the whistleblower, the DOD's Joint Trauma System became inaccessible on the same day the inquiries and requests were made. A week later, the site became operational.

In an effort to "retrieve insight into the clinical trial undertaken by USAMRDC," Rep. Clay Higgins (R-LA) sent a letter on September 27 to Secretary of Defense Lloyd Austin, copying the U.S. Health and Human Services Secretary, the U.S. Food and Drug Administration Commissioner, USAMRDC Commanding General Major General Paula C. Lodi, and others (*see appendix 2*).

5.0 Mis-Informed Consent

Section 6 of the Informed Consent Form for clinical trial NCT04302766 lists several common and less-common side effects attributed to remdesivir. At the time, participants were told "there have not been kidney problems seen in humans who have been given remdesivir." This is somewhat true, considering that in the previous Ebola virus treatment setting, there were no adverse events – to the kidneys or other organs – reported for the use of the drug. However, "the only adverse events reported in [the Ebola] trial were deaths." ⁵⁷

Regarding the treatment of people in Africa with the Ebola virus, the consent form simply read: "Some of these people had side effects." There was no mention that the use of remdesivir resulted in the highest mortality rate among participants in a trial of four investigational therapies for Ebola in the Democratic Republic of Congo.⁵⁸

For this reason, it's interesting to note that neither the Department of the Army Surgeon General nor the USAMRDC makes mention of the possibility of death in the informed consent provided to participants in the trial. Why? Were deaths during the trial inaccurately attributed to COVID-19 when they could/should have been attributed to the use of remdesivir?

It's also interesting to note that as early as May 2020, *MedPage Today* was encouraging health professionals to be on the lookout for adverse event risks involving the liver and kidneys. ⁵⁹ Only the mention of a common side effect – an increase in liver function test results – was included. Nothing was shared of the possibility of poor liver function.

⁵⁶ National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://cdn.clinicaltrials.gov/large-docs/66/NCT04302766/ICF 000.pdf

⁵⁷ Phend, C. (2020, May 19). *Remdesivir Safety Forecast: Watch the Liver, Kidneys*. MedPage Today. https://www.medpagetoday.com/infectiousdisease/covid19/86582

⁵⁸ Mulangu, S. et. al. (2019, November 27). *A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics*. The New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

⁵⁹ Phend, C. (2020). https://www.medpagetoday.com/infectiousdisease/covid19/86582

Four years later, it has been clearly determined that the use of remdesivir can result in many potential organ-based adverse effects.⁶⁰ These include:

- Cardiovascular: Hypotension, arrhythmias, and cardiac arrest
- Pulmonary: Dyspnea, acute respiratory failure, acute respiratory distress, pneumothorax, pulmonary embolism
- Hematological: Anemia, lymphopenia, coagulopathy
- Endocrine: Hyperglycemia
- Infectious: Pneumonia, septic shock
- **Gastrointestinal:** Nausea is the most commonly reported side effect in patients receiving remdesivir. Other side effects, such as elevated lipase vomiting, diarrhea, constipation, poor appetite, gastroparesis, and lower GI bleeding, have also been reported
- **Hepatic:** Hepatic manifestations characterized by Grade 1 to 4 increase in serum transaminases (ALT and AST) are the other most common adverse effects in patients treated with remdesivir. Other abnormalities include hyperbilirubinemia.
- Renal and Metabolic: Acute kidney injury or worsening of underlying chronic kidney disease, hypernatremia, hypokalemia
- **Neurological**: Headache, lightheadedness
- Skin: Rash, contact dermatitis, pruritus
- Psychiatric: Delirium
- Other adverse effects: Pyrexia, insomnia, multi-organ dysfunction, DVT, and hypersensitivity/anaphylactic reactions related to the infusion

Source: Screenshot⁶¹

Again, were deaths during remdesivir treatment trials wrongly attributed to COVID-19 when they could/should have been attributed to the use of the controversial drug? How many participants died? Some have independently concluded that COVID-19 was not responsible for kidney issues, for example⁶² – so what did they die from?

Section 7 of the Informed Consent Form stated: "A description of this treatment protocol will be available on http://www.ClinicalTrials.gov, as required by U.S law." It was also conveyed that a summary of results would be made available. To the contrary, neither has been provided.

⁶⁰ Aleem, A. et. al. (2024, February 28). *Remdesivir*. National Center for Biotechnology Information, National Library of Medicine. https://www.ncbi.nlm.nih.gov/books/NBK563261/

⁶¹ Aleem, A. et. al. (2024). https://www.ncbi.nlm.nih.gov/books/NBK563261/

⁶² De Chien, C. (2024, July 18). *Prevalence-of-Cause (POC)*. The Real CdC's Newsletter. https://therealcdc.substack.com/p/prevalence-of-cause-poc

⁶³ National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://cdn.clinicaltrials.gov/large-docs/66/NCT04302766/ICF_000.pdf

7. BENEFITS

You may not benefit from receiving this treatment. If remdesivir works, you may get better sooner and/or get a less severe disease.

A description of this treatment protocol will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Source: Screenshot Informed Consent Version 6.0 (23JUN2020) Section 7 64

While the other trials provided the dosage given to participants, the USAMRDC trial did not. Is this not required by U.S. law as stated in the informed consent?

Section 16 of the Informed Consent Form provided that "remdesivir treatment may be stopped, with or without your consent, if: 2) Your safety or health may be negatively affected."⁶⁵

How many participants were removed from the trial due to any one of the potential organ-based adverse effects listed above?

6.0 Path to Tens of Millions of Dollars

In November 2019, the administration of then-president Donald Trump sued Gilead Sciences for "profiting billions of dollars off taxpayer research without paying royalties" and charging patients up to \$20,000 a year for HIV-prevention drugs, according to *The New York Times*. 66

By spring 2020, *Public Citizen* estimated that taxpayers contributed at least \$70.5 million for the development of remdesivir.⁶⁷ According to *The Washington Post*, "Three federal health agencies were deeply involved in remdesivir's development every step of the way, providing tens of millions of dollars of government research support."⁶⁸ These agencies are likely the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and DOD.

⁶⁴ National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://cdn.clinicaltrials.gov/large-docs/66/NCT04302766/ICF 000.pdf

⁶⁵ National Library of Medicine. (accessed October 3, 2024). *Expanded Access Remdesivir (RDV; GS-5734™)*. https://cdn.clinicaltrials.gov/large-docs/66/NCT04302766/ICF 000.pdf

⁶⁶ Victor, D. (2019, November 7). *Trump Administration Sues Gilead, Maker of H.I.V.-Prevention Drugs*. The New York Times. https://www.nytimes.com/2019/11/07/business/gilead-truvada-hiv-lawsuit.html

⁶⁷ Public Citizen. (2020, May 7). *The Public Already Has Paid for Remdesivir*. https://www.citizen.org/news/the-public-already-has-paid-for-remdesivir/

⁶⁸ Rowland, C. (2020, May 26). *Taxpayers paid to develop remdesivir but will have no say when Gilead sets the price*. The Washington Post. https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/

According to *The Intercept*, the FDA granted an "orphan" drug status for remdesivir, allowing Gilead to profit exclusively for seven years.⁶⁹ Fact-checked by *USA Today*, "The claim that pharmaceutical company Gilead Sciences requested and received approval for a special status for a potential COVID-19 treatment is TRUE."⁷⁰

The Wall Street Journal reported in June 2020 that "the government price [for remdesivir] will be \$390 a dose, or \$2,340 a patient for the shortest treatment course and \$4,290 for a longer treatment course." An analysis shared by Public Citizen revealed that remdesivir could have been priced at less than \$1 per dose, or \$10 per full treatment, and still earn a reasonable profit for Gilead.⁷²

By July 2020, Sen. Elizabeth Warren (D-MA) and a group of lawmakers began calling attention to the high price, saying, "It is profoundly unfair to the American taxpayers that furnished over \$70 million in research costs for the drug to now be stuck paying the highest prices in the world." Despite its high cost, which resulted in an enormous financial benefit to Gilead, it's important to note that the drug's lethality continued to be ignored.

7.0 Transparency Matters

In June 2015, Gilead stock peaked at \$115.46 per share. As remdesivir was being offered as a treatment for Ebola, Gilead stock was approximately \$64-\$65 per share in mid-2017, climbing to over \$80 per share by fall. After failing to tackle Ebola, by the start of 2020 Gilead stock was closing at about \$63-\$65 per share. And by April 2020, as the U.S. announced its purchase of

⁶⁹ Fang, L. et. al. (2020, March 23). *Coronavirus Treatment Developed by Gilead Sciences Granted "Rare Disease" Status, Potentially.* The Intercept. https://theintercept.com/2020/03/23/gilead-sciences-coronavirus-treatment-orphan-drug-status/

⁷⁰ Brown, M. (2020, March 27). Fact check: Drugmaker Gilead Sciences claimed rights to a possible COVID-19 treatment. USA Today. https://www.usatoday.com/story/news/factcheck/2020/03/27/fact-check-coronavirus-gilead-sciences-received-withdrew-fda-orphan-status-remdesivir/2922115001/

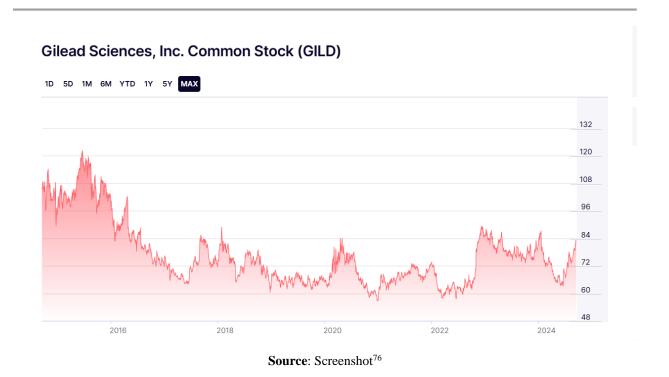
⁷¹ Walker, J. (2020, June 29). *Covid-19 Drug Remdesivir to Cost \$3,120 for Typical Patient*. The Wall Street Journal. https://www.wsi.com/articles/covid-19-drug-remdesivir-to-cost-3-120-for-typical-patient-11593428402

⁷² Public Citizen. (2020, May 4). *Gilead Should Price Remdesivir at \$1 Per Day*. https://www.citizen.org/news/gilead-should-price-remdesivir-at-1-per-day/

⁷³ Sen. Elizabeth Warren. (2020, July 16). *Lawmakers Criticize Trump Administration Deal That Allowed Manufacturer of COVID-19 Antiviral Drug Remdesivir to Charge U.S. Purchasers the Highest Prices in the World*. https://www.warren.senate.gov/oversight/letters/lawmakers-criticize-trump-administration-deal-that-allowed-manufacturer-of-covid-19-antiviral-drug-remdesivir-to-charge-us-purchasers-the-highest-prices-in-the-world

⁷⁴ Nasdaq. Gilead Sciences, Inc. Common Stock (GILD). https://www.nasdaq.com/market-activity/stocks/gild

"virtually all" the remdesivir around the world, 75 Gilead stock began to trend upward, closing at over \$83 per share by the end of the month.



Did investors take notice of an opportunity prior to the FDA's February 2020 approval of remdesivir to be used in clinical trials? Curiously, in February, the wife of Sen. Rand Paul (R-KY) purchased between \$1,000 and \$15,000 of Gilead stock. While trade disclosures are typically reported within 45 days, Paul's reporting did not occur until 16 months later. According to Paul spokesperson Kelsey Cooper, the initial filing was improperly transmitted, and the investment was made with the earnings of Paul's wife. While Paul, a medical doctor and respected senator, remains a strong voice against COVID-19 public health guidances and more, the timely investment remains suspicious. Considering the known lethality of remdesivir, it

further heightens concern.

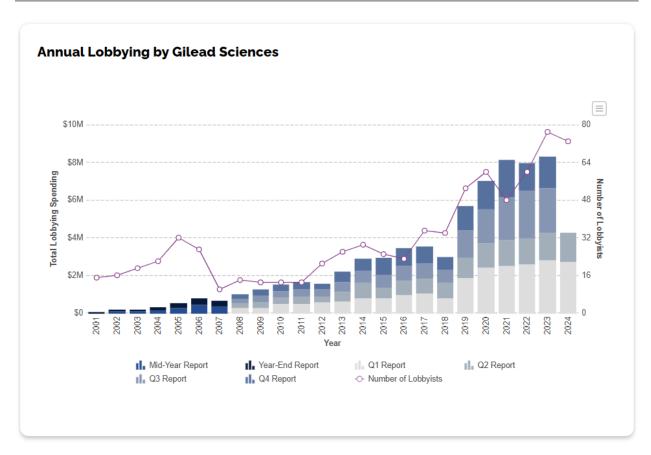
⁷⁵ Boseley, S. (2020, June 30). *US secures world stock of key Covid-19 drug remdesivir*. The Guardian. https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug

⁷⁶ Nasdag, Gilead Sciences, Inc. Common Stock (GILD). https://www.nasdag.com/market-activity/stocks/gild

⁷⁷ Fox, L. et. al. (2021, August 12). *Rand Paul reveals in late financial disclosure that his wife bought stock in company behind remdesivir in February 2020*. CNN. https://www.cnn.com/2021/08/11/politics/rand-paul-wife-stock-gilead-sciences/index.html

⁷⁸ Fox, L. et. al. (2021). https://www.cnn.com/2021/08/11/politics/rand-paul-wife-stock-gilead-sciences/index.html

However, considering the sharp rise of millions of dollars spent by Gilead's lobbying efforts in 2019, it's not surprising that members of Congress and others might be more familiar with the drug manufacturer's name in recent years.⁷⁹



Source: Screenshot⁸⁰

Between 2018 and 2021, total lobbying spending increased from about \$3 million dollars to \$8.1 million dollars – a 170-percent increase. OpenSecrets.org reveal's the organization's top recipients.⁸¹

⁷⁹ Open Secrets. (accessed 2024). *Client Profile: Gilead Sciences*. https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2024&id=D000026221

⁸⁰ Open Secrets. (accessed 2024). https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2024&id=D000026221

⁸¹ Open Secrets. (accessed 2024). *Gilead Sciences*. https://www.opensecrets.org/orgs/gilead-sciences/summary?topnumcycle=2020&contribcycle=2024&lobcycle=2024&outspendcycle=2022&id=D000026221&toprecipcycle=2024

Specific to the military, the government transparency site also reveals the Department of Defense⁸² and Department of Veterans Affairs⁸³ obligation of nearly \$12 million between 2019 and 2023 to Gilead Sciences, as well as authorized Veklury (remdesivir) distributors ASD Specialty Healthcare and AmerisourceBergen.⁸⁴ An awarding subagency of the DOD included the Defense Logistics Agency (DLA).⁸⁵

8.0 Recommendations

Deaths from remdesivir and the entire standard-of-care procedure were not limited to the five clinical trials, nor were they limited solely to military treatment facilities. The data provided in this report should warrant an investigation.

What a whistleblower has revealed should challenge military leaders and government officials to provide the truth of what happened in 2020 and beyond. Families deserve to know whether their loved ones were killed by COVID-19 or the liberal usage of remdesivir in military treatment facilities across the country and abroad.

⁸² USA Spending. (accessed 2024). *Advanced Search, Department of Defense*. https://www.usaspending.gov/search/?hash=e7b4dbc4d0bc3567eccc02d97d5ed40b

⁸³ USA Spending. (accessed 2024). *Advanced Search, Department of Veterans Affairs*. https://www.usaspending.gov/search/?hash=c729709f98c9e9ff8179717bf0d8f94b

⁸⁴ Gilead Sciences, Inc. (accessed 2024). *Gilead's Authorized Distributors*. https://www.gilead.com/medicines/authorized-distributors

⁸⁵ USA Spending. (accessed 2024). *Advanced Search, Department of Defense*. https://www.usaspending.gov/search/?hash=e7b4dbc4d0bc3567eccc02d97d5ed40b

Appendix 1

FOIA Request

From Jmphelps

To USArmy.Detrick.MEDCOM-USAMRMC.mbx.FOIA@health.mil

Date Tuesday, September 24th, 2024 at 10:16 AM

Dear FOIA Officer,

I am J.M. Phelps, a journalist writing for The Gateway Pundit, WorldNetDaily, and American Family News. I am submitting a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, for documents related to the Adaptive COVID-19 Treatment Trial (NCT04302766), specifically those involving remdesivir or other treatments tested in the trial.

I am requesting the following information:

- All study protocols related to the NCT04302766 trial, including the original protocol and any amendments made throughout the course of the study.
- Study findings and results, including all available data on the safety and efficacy of remdesivir (and any other treatments used in the trial), any adverse event data, final analyses, interim reports, or internal reviews.
- 3. Any internal reports or analyses regarding the study's findings and their implications, as well as correspondence between the U.S. Army Medical Research and Development Command (USAMRDC), Department of Defense, and other agencies or institutions, regarding the trial's results.

Clarification:

To avoid the need for clarification, please note that this request covers all relevant documents, including internal and external communications, reports, and study protocols, both in digital and physical formats.

Fee Waiver Request:

As a journalist, I am requesting a waiver of all associated fees as this information is being sought in the public interest and is intended for dissemination through published articles. The release of this information will contribute to the public's understanding of the government's role in the research and development of COVID-19 treatments, and I have no commercial interest in the data.

Please inform me if any portion of the request cannot be fulfilled or if fees exceed \$25 before processing.

Thank you for your time and attention to this matter. I look forward to receiving the requested information within the statutory time frame.

Sincerely,

J.M. Phelps

Freelance Journalist, American Family News, The Gateway Pundit, WND, and The Epoch Times (2021-2024)

CONFIDENTIALITY NOTICE: This communication with its contents and any attachments may contain confidential and/or legally privileged information. It is solely for the use of the intended recipient(s). Unauthorized interception, review, use, or disclosure is prohibited and may violate applicable laws including the Electronic Communications Privacy Act and subject you to liability. If you are not the intended recipient, please contact the sender and destroy all copies of the communication.

Appendix 2

CLAY HIGGINS 3no District, Louisiana Menaga, House Egerpoia Caucus



COMMITTEE ON HOMELAND SECURITY
CHARBMAN, BORDER SECURITY AND ENFORCEMENT
TRANSPORTATION AND MARTIME SECURITY
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
GOVERNMENT OPERATIONS AND
THE FEDERAL WORKFORD
NOTONAL SECURITY THE
BORDER, AND FORESTA AFFAIRS
COMMITTEE ON ARMED SERVICES
SEAPOWER AND PROJECTION FOREPS.

September 27, 2024

The Honorable Lloyd J. Austin III Secretary United States Department of Defense 1000 Defense Pentagon Washington, D.C. 20301

Secretary Austin,

As you may recall, in March 2020 the U.S. Army Medical Research and Development Command sponsored the clinical trial "Intermediate-Size Patient Population Expanded Access Treatment Protocol for Coronavirus Disease 2019 (COVID-19) Remdesivir (RDV; GS-5734TM)." According to its description, the trial involved DOD-affiliated personnel and the treatment of COVID-19 with Remdesivir.¹

Given the significance of this research and ongoing efforts to fully understand the government response to COVID-19, I respectfully request your insight into the clinical trial undertaken by USAMRDC. Specifically, I am requesting:

- Please provide participant data, including the number of participants, participant mortality rate, and cause of death for participants.
- 2. If there were mortalities during the trial, was the death caused by COVID-19 complications or from the Remdesivir administered during the trial?
- 3. What was the dosage of Remdesivir administered to participants throughout the course of the trial?
- All protocols related to this trial, including amendments and further clarifications that were issued throughout the trial.
- Was there a final study published? If so, please provide the study findings and results, including all available data as it relates to the safety and efficacy of Remdesivir, internal reviews, adverse event data, and final analysis.
- Please provide internal reports or analysis regarding the findings of the study and its implications. This includes correspondence between USAMRDC, DOD, FDA, HHS, and other agencies or institutions regarding the trial's results.

¹ "Expanded Access Remdesivir (RSV; GS-5734)" NIH National Library of Medicine, https://clinicaltrials.gov/study/NCT04302766

Providing this information will guide me as Congress continues to ensure that there is proper oversight of the trials undertaken by the federal government in response to the COVID-19 pandemic. As a member of the House Armed Services Committee, House Oversight and Accountability Committee, and House Homeland Security Committee, I believe it is crucial that the DOD and federal government be transparent in how they are using American taxpayer's treasure.

Thank you for your full and fair consideration of this request. Please do not hesitate to reach out to my office.

Respectfully,

Clay Higgins Member of Congress

CC:

The Honorable Xavier Becerra, Secretary, U.S. Health and Human Services

The Honorable Robert Califf, Commissioner, U.S. Food and Drug Administration

Major General Paula C. Lodi, Commanding General, USAMRDC

Mr. Darryl J. Colvin, Joint Program Executive Officer for Chemical, Biological, Radiological, and Nuclear Defense, Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, U.S. Department of Defense