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Remdesivir for Covid-19: $1.6 Billion for a "Modestly Beneficial" Drug?

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The U.S. Department of Health and Human Services has recently "bought" all of Gilead Science's Remdesivir for $1.6 billion. "500,000 doses at $3,200 per patient – to be available to American hospitals but not for other countries"[6]

That's $1.6 billion tax dollars for a virtually untested drug showing only marginal efficacy in the hospital setting.

How could such a thing happen?

Introduction

If you believe an urgent call from the Yale School of Public Health that was recently published in the *American Journal of Epidemiology*— the top epidemiology journal in America — hydroxychloroquine (HCQ) + azithromycin is the quickest and most effective way to halt the Covid-19 pandemic.[1]

According to this Yale statement, hydroxychloroquine – a cheap, natural anti-malarial tree-bark known as quinine for 400 years – is highly effective during Phase 1 of Covid-19, while the virus is loading into the body.

As the first line of defense, it should be immediately, freely, and widely available to symptomatic high-risk patients – through doctors' offices, outpatient clinics, and hospitals across the land.

Indeed, under the directorship of Dr. Anthony Fauci, a National Institute of Allergy and Infectious Diseases (NIAID) a clinical trial had been launched on May 14 to look into it.[2]

The HCQ + azithromycin protocol is being used successfully by France's top, award-winning microbiologist, Dr. Didier Raoult. He is director of the Infectious and Tropical Emergent Diseases Research Unit in Marseille (Institut Hospitalo-Universitaire) (IHU), with 200 staff. Raoult, now almost a celebrity in France, has recently published his protocol and results, showing an overall 1.1% case fatality rate.[3]

The same protocol has also been highly successful in China, India, Senegal, and Brazil.[4]

So why suddenly is the U.S. government and the media ignoring recommendations from these top specialists,[5] and waiting, instead, until people get very sick and hospitalized to treat them with the relatively untested drug, Remdesivir, which is administered

intravenously?

Why has the U.S. Department of Health and Human Services just bought up all the Remdesivir it could order – 500,000 doses at $3,200 per patient – to be available to American hospitals but not for other countries?[6]

To put Remdesivir's cost in perspective, the CDC reports that the flu vaccine costs from $12-$18 a dose.[7]

The government, in order to justify its mind-boggling price, would need to show exceptional efficacy in saving lives. Efficacy, that is, once the disease has been allowed, through failure to use the HCQ + azithromycinearly preventive approach, to advance to Phase 2 (the dangerous inflammatory period) and Phase 3 (ICU ventilator intubation, often leading to death).[8]

What do studies say about the efficacy of remdesivir?

There are three main studies that have examined remdesivir as a treatment for Covid-19:

1. The first, a study of seriously ill patients, was originally reported in the *New England Journal of Medicine* on April 10, 2020. Treated with "compassionate-use" remdesivir, clinical improvement was observed in 36 of 53 patients (68%).

The article was co-authored by 56 people, some of whom were on the staff of remdesivir's producer, Gilead Sciences.[9] The study was funded by Gilead, and writing assistance was provided by David McNeel, also of Gilead.[10]

The following day, April 11, the Science Media Centre published expert reactions to the compassionate study from five British university professors. These assessments were not encouraging: "the research doesn't prove anything at this point;" "the data is almost uninterpretable;" the research should be treated "with extreme caution."[11]

2. A Wuhan, China randomized, double-blind, placebo-controlled trial of 237 patients was accidentally leaked by the World Health Organization and published in *The Lancet.* It showed no statistically significant clinical benefits from remdesivir:

"The antiviral medicine remdesivir from Gilead Sciences failed to speed the improvement of patients with Covid-19 or prevent them from dying, according to results from a long-awaited clinical trial conducted in China." [12]

This *Lancet* study also found that some 14% of patients in the treatment group died after 28 days, compared to 13% in the group that did not receive the treatment.

And it further reported that "remdesivir was stopped early because of adverse events in 18 (12%) patients versus four (5%) patients who stopped placebo early."[13]

3. The preliminary results of a NIAID remdesivir trial of 1063 patients showed a "modest" benefit in a controlled clinical trial:

"The infected people who received remdesivir, an experimental drug made by Gilead

Sciences that cripples an enzyme several viruses use to copy their RNA, recovered in an average of 11 days versus 15 in patients who received a placebo. 'Although a 31% improvement doesn't seem like a knockout, 100% [success], it is a very important proof of concept,' said Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases (NIAID)."[14]

Health Policy Watch reported that "the death rate was 8% in the group that received remdesivir compared to 11.6% in the control group, although this result was not statistically significant." Dr. Fauci told reporters that "what [this trial] has proven is that a drug can block the virus."[15]

The excerpt below from a June 24 article in the *British Medical Journal* assesses the problems in the foregoing studies. (One of the four co-authors, Fiona Godlee, is the editor-in-chief of the *BMJ)*:

> "A serious imbalance in covid-19 research strongly favours the study of drug treatments over non-drug interventions, with many studies too small or too weak to produce reliable results. Equally concerning is the release of partial or preliminary findings before peer review—often through commercial press releases—that is distorting public perceptions, ongoing evaluations efforts, and political responses to the pandemic.
>
> Remdesivir is a key example. The antiviral drug, made by US company Gilead, was unapproved at the start of the pandemic, but in early April the New England Journal of Medicine published a small descriptive study of a compassionate use scheme for patients with covid-19. Gilead funded the study, a third of the authors were Gilead employees, and Gilead's press release reported "clinical improvement in 68% of patients in this limited dataset." Despite being a non-randomised, uncontrolled, company funded study of just 53 patients, media headlines described "hopeful" signs and reported "two thirds" of patients showing improvement.[16]
>
> Two weeks later, the Lancet published a randomised placebo controlled trial of remdesivir from China, finding no statistically significant clinical benefit in the primary outcome of time to clinical improvement. Twelve per cent of participants taking remdesivir stopped treatment early because of adverse events, compared with 5% taking placebo. The trial was stopped before meeting recruitment targets."[17]

To summarize, the only study demonstrating even marginal efficacy for remdesivir shows it to reduce hospital recovery times 31%, from 15 days to 11 days.

What is the justification for spending $3,200 tax dollars per Covid-19 patient to save four days in hospital, unless it is to shorten hospital stays, thereby saving the average U.S. bed cost of approximately $2000 per day, while delaying hospital saturation that could leave some people untreated to die?

Leaving people untreated to die could cause civil unrest, which may be the covert political reason for spending the $1.6 billion.

None of the studies mention side effects of the drug. In the China study, kidney injury led to discontinuation for one patient, and in its use for ebola, liver risks were identified.[18]

How much does it cost to produce remdesivir?

The Institute for Clinical and Economic Review (ICER) is a non-profit organization seeking to improve healthcare value through clinical and cost-effective analyses.[19]

In a May 1, 2020 study, the ICER calculated that the cost of producing the remdesivir "final finished product," including the pharmaceutical ingredients, formulation, packaging, and a small profit margin, was $9.32 US for a 10-day course of treatment. They rounded this up to $10.[20]

Dr. Fauci's NIAID Clinical Trial Evaluating Hydroxychloroquine and Azithromycin Closes Early

On June 20, 2020, nine days before the Department of Health and Human Services announced its $1.6 billion purchase of remdesivir on June 29, its NIAID branch closed a clinical trial that had been launched May 14 to investigate whether the inexpensive combination, hydroxychloroquine plus azithromycin, might be an effective treatment when given early in the course of the disease.[21]

The Department of Health and Human Services knew that hydroxychloroquine (aka chloroquine) was effective against coronavirus because chloroquine was tested against the SARS-1 virus during the outbreak in 2002. This work was written up in 2005, under the auspices of the U.S. Centers for Disease Control in Atlanta, which reports to the Department of Human Health and Services.[22]

Truth, as the saying goes, is stranger than fiction.

Who was responsible for this debacle?

Dr. Fauci has served in the National Institutes of Health under six presidents.

Were these bizarre decisions carried out under his authority? Or were they forced upon him from higher up? Or has he become a victim of regulatory capture[23] by the drug industry?

Whatever the answer, this unprecedented fleecing of the American public should have been shouted from the rooftops, had there been a functioning US media.

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Notes

[1] Harvey A. Risch, "Early Outpatient Treatment of Symptomatic, High-Risk Covid-19 Patients that Should be Ramped-Up Immediately as Key to the Pandemic Crisis," *Amer. J. Epid,* 27 May 2020 (https://academic.oup.com/aje/advance-article/doi/10.1093/aje/kwaa093/5847586). Risch is Professor at the Yale Schools of both Medicine and Public Health.

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[3] Jean-Christophe Lagier, et al, "Outcomes of 3,737 COVID-19 patients treated with

hydroxychloroquine/azithromycin and other regimens in Marseille, France: A retrospective analysis," *Travel Medicine and Infectious Disease*, 25 June 2020 (https://www.sciencedirect.com/science/article/pii/S1477893920302817). Rault has 2,300 indexed medical journals in print.

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[5] Elizabeth Woodworth, "The Media Sabotage of Hydroxychloroquine Use for COVID-19: Doctors Worldwide Protest the Disaster," *Global Research*, 30 June 2020 (https://www.globalresearch.ca/media-sabotage-hydroxychloroquine-covid-19-doctors-worldwide-protest-disaster/5717382).

[6] US Department of Health and Human Services, "Trump Administration Secures New Supplies of Remdesivir for the United States," June 29, 2010 (https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html).

[7] Centers for Disease Control and Prevention, Vaccines for Children Program, "CDC Vaccine Price List," updated 1 July 2020 (https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html#adflu).

[8] Dr. Raoult identified the three stages of Covid-19 while treating 3,737 patients with HCQ+azithromycin at his own clinic: "At the first viral stage, one must give medicines against the virus, in the second inflammatory phase, one needs to give medications against that [inflammatory] reaction, and then in the third phase, it's work to be done in intensive care units." Summarized from Didier Raoult, at: "The Marx Brothers are Doing Science: the Example of RECOVERY," 9 June 2020 (http://covexit.com/professor-raoult-compares-the-oxford-recovery-trial-academics-to-the-marx-brothers/).

[9] Jonathan Grein, and 55 other authors, "Compassionate Use of Remdesivir for Patients with Severe Covid-19," *New England Journal of Medicine*, 11 June 2020 (https://www.nejm.org/doi/full/10.1056/NEJMoa2007016), *"Editor's Note: This article was published on April 10, 2020, at NEJM.org."*

[10] Jason D. Goldman, et al., "Remdesivir for 5 or 10 days in Patients with Severe Covid," *New England Journal of Medicine*, no date in header (https://www.nejm.org/doi/pdf/10.1056/NEJMoa2015301?articleTools=true). *Sidebar:"This article was published on May 27, 2020, at NEJM.org."*

[11] Prof. Duncan Richards et al., "Expert reaction to a study about compassionate use of remdesivir for patients with severe COVID-19," *Science Media Centre*, 11 April 2020 (https://www.sciencemediacentre.org/expert-reaction-to-a-study-about-compassionate-use-of-remdesivir-for-patients-with-severe-covid-19/).

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[18] Crystal Phend, “Remdesivir Safety Forecast: Watch the Liver, Kidneys,” *Medpage Today*, 19 May 2020 (https://www.medpagetoday.com/infectiousdisease/covid19/86582).

[19] https://en.wikipedia.org/wiki/Institute_for_Clinical_and_Economic_Review

[20] Melanie D. Whittington and Jonathan B. Campbell, “Alternative Pricing Models for Remdesivir and Other Potential Treatments for COVID-19,” Institute for Clinical and Economic Review, 1 May 2020 (https://icer-review.org/wp-content/uploads/2020/05/ICER-COVID_Initial_Abstract_05012020-3.pdf).

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[22] Martin J. Vincent et al., “Chloroquine is a potent inhibitor of SARS coronavirus infection and spread,” *Journal of Virology*, 22 August 2005 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/).

[23] “Regulatory capture is a theory that regulatory agencies may be dominated by the interests they regulate and not by the public interest.” In: Will Kenton, “Regulatory Capture,” *Investopedia*, 23 October 2019 (https://www.investopedia.com/terms/r/regulatory-capture.asp).

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