

# Ivermectin Could Have Saved Millions of Lives, Why Was It Suppressed

By Richard Gale and Dr. Gary Null

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Theme: <u>Law and Justice</u>, <u>Science and</u>
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In 2004, the US Congress passed an amendment to the Federal Food, Drug and Cosmetic Act known as Emergency Use Authorization (EUA). This piece of legislature legalized an antiregulatory pathway to allow experimental medical interventions to be expedited without proper safety evaluation in the event of bioterrorist threats and national health emergencies such as pandemics. At the time, passage of the EUA amendment made sense because it was partially in response to the 2001 anthrax attacks and the US's entry into an age of international terrorism. However, the amendment raises some serious considerations. Before the Covid-19 pandemic, EUAs had only been authorized on four occasions: the 2005 avian H5N1 and 2009 H1N1 swine flu, the 2014 Ebola and the 2016 Zikra viruses.

Each of these pathogen scares proved to be false alarms that posed no threat of any pandemic proportions to Americans. The fifth time EUAs were invoked was in 2020 during the Covid-19 pandemic, which seemed far more plausible than previous EUAs.

Before the government can authorize an EUA to deploy an experimental diagnostic product, drug or vaccine, certain requirements must be fulfilled.

**First,** the Secretary of the Department of Health and Human Services (HHS) must have sufficient proof that the nation is being confronted with a serious life-threatening health emergency.

**Second,** the drug(s) and/or vaccine(s) under consideration must have sufficient scientific evidence to suggest they will likely be effective against the medical threat. Despite being insufficient, the evidence must at least include preclinical and observational data showing the product—diagnostic test, drug and vaccine—targets the organism, disease or condition.

**Third,** although the drug or vaccine does not undergo a rigorous evaluation by the FDA, it must at least show that its potential and known benefits outweigh its potential and known risks. In addition, the product must be manufactured in complete accordance with standard

quality control and safety assurances.

However, when we look back at the government's debacles during the Covid-19 pandemic, two other EUA requirements should be spotlighted. On the one hand, an EUA cannot be authorized for any product or intervention if there is an FDA approved alternative product already available, unless the experimental product clearly shows to have a significant advantage. Moreover, and perhaps more important, EUAs demand informed consent. Every individual who receives the drug or vaccine must be thoroughly informed about its experimental status and its potential risks and benefits. Recipients must also be properly informed about the alternatives to the experimental product and nobody should be forced to take it.

One final EUA requirement is that there must be robust safety monitoring and reporting of adverse events, injuries and deaths potentially due to the drug or vaccine. This is the responsibility not only of the private pharmaceutical manufacturers but also the FDA, physicians, hospitals, clinics and other healthcare professionals.

Obviously there are important cautions to be considered after reviewing the EUA requirements and the dangerous implications if they are not properly followed or at worse abused. Foremost are the inherent heath risks of any rapid response of experimental medical interventions, especially novel drugs and vaccines.

As we observed during the FDA approval process and roll out of Pfizer's and Moderna's mRNA Covid-19 jabs and J&J's adenovirus vaccine, no long-term human trials were conducted to even estimate a reliable baseline of their relative efficacy and safety.

But perhaps equally important, the public should only place their trust in these EUA-approved experimental drugs and vaccines if their evaluation by federal health authorities is conducted in a manner that is completely transparent and takes every potential ethical challenge into consideration. However these cautions were categorically ignored and transgressed in every conceivable way. Moreover, conflicts of interests plagued the entire EUA review process.

Most egregious was that **Anthony Fauci** at the NIAID and other federal officials had full knowledge that other FDA-approved drugs existed that could effectively treat Covid-19 infections. The antiparasitic and antiviral drug Ivermectin best stands out.

**Ivermectin** was first introduced to the market in the early 1980s as an anti-parasitic drug for veterinary infections. However, its effectiveness was observed to be so remarkable and multifaceted that researchers started to investigate its potential for treating human diseases. In 1987, the FDA approved ivermectin for treating two parasitic diseases, river blindness and stronglyoidiasis, in humans.

Since then an enormous body of medical research has grown showing ivermectin's effectiveness for treating other diseases. Its broad range <u>antiviral properties</u> has shown efficacy against many RNA viruses such avian influenza, zika, dengue, HIV, West Nile, yellow fever, chikungunya and earlier severe respiratory coronaviruses. It has also been found effective against DNA viruses such as herpes, polyomavirus, circovirus-2 and others. The drug is capable of modulating a host immune response during viral infections and reduces pro-inflammatory cytokines that contribute to viral tissue damage.

Unsurprisingly, its discovers Drs. William Campbell and Satoshi Omura were awarded the 2015 Nobel Prize in Physiology and Medicine. Ivermectin was not a drug simply hidden away in a back closet; rather it has been prescribed to hundreds of millions of people worldwide. Given its decades' long record of in vitro efficacy, it should have been self-evident for Fauci, the CDC and the WHO to rapidly conduct in vivo trials to bring ivermectin into becoming a first line of defense for early stage Covid-19 infections and for use as a safe prophylaxis. For example, if funding were devoted for the rapid development of a micro-based pulmonary delivery system, mortality rates would have been miniscule and the pandemic would have been greatly lessened. Repurposing ivermectin could have been achieved very quickly at a minor expense.

However, despite all the medical evidence confirming ivermectin's strong antiviral properties and its impeccable safety record when administered properly, we instead witnessed a sophisticated government-orchestrated campaign to declare war against ivermectin and another antiviral drug, hydroxychloroquine (HCQ), in favor of far more expensive and unproven experimental drugs, such as Remdesivir. Unlike the US, other nations were eager to find older drugs to repurpose against Covid-19 to protect their populations.

A Johns Hopkins University analysis offered the theory that a reason why many African countries had very few to near zero Covid-19 fatalities was because of widespread deployment of ivermectin. In February 2020, the National Health Commission of China, for example, was the first to include hydroxychloroquine in its guidelines for treating mild, moderate and severe SARS-2 cases. Why did the US and most European countries under the spell of the US and the WHO fail to follow suit?



Schematic showing IMPα's role in nuclear transport of host and viral proteins, and mechanism of inhibition by ivermectin. (a) Host proteins, such as members of the STAT or NF-κB transcription factor families, localize in the nucleus through the action of the IMPα/β1 heterodimer, where the "IBB" (IMPβbinding) region of IMPα (green curved line) is bound by IMPβ1 to enable cargo recognition by IMPα within the heterodimer; IMP\$1 subsequently mediates transport of the trimeric complex through the nuclear pore (NPC, nuclear pore complex) embedded within the nuclear envelope (NE) into the nucleus. This is followed by release within the nucleus to enable the transcription factors to carry out normal function in transcriptional regulation, including in the antiviral response. IMPα can only mediate nuclear import within the heterodimer with IMP $\beta$ 1. (b) In viral infection, specific viral proteins (e.g., NS5 in the case of DENV, ZIKV, WNV) able to interact with IMP $\alpha$  utilize the IMP $\alpha/\beta 1$  heterodimer to access the nucleus and antagonize the antiviral response [14,27,28]. This is critical to enable optimal virus production as shown by mutagenic and inhibitor studies. Which SARS-CoV-2 proteins may access the nucleus in infected cells has not been examined (see Section 3). (c) The IMP $\alpha$  targeting compound ivermectin binds to IMP $\alpha$  (binding site shown as red lozenge) both within the IMP $\alpha$ / $\beta$  heterodimer to dissociate it, and to free IMPα to prevent it binding to IMPβ1, thereby blocking NS5 nuclear import [11]. GW5074 (see <u>Table 1</u>) has been shown to exhibit a similar mechanism [29].

Early in the pandemic, physicians in other nations where treatment was less restricted, such as Spain and Italy, were sharing data with American physicians about treatments they found were effective against the SARS-2 virus.

In addition, there was a large corpus of medical research indicating that older drugs with antiviral properties could be repurposed. Doctors who started to prescribe drugs such as

ivermectin and HCQ, along with Vitamin D and zinc supplementation, observed remarkable results. Unlike the dismal recovery and high mortality rates reported in hospitals and large clinics that relied upon strict isolation, quarantine, and ventilator interventions, this small fringe group of physicians reported very few deaths among their patient loads. Even those deaths reported were more often than not compounded by patients' comorbidities, poor medical facilities and other anomalies.

Very early into the pandemic, **medical papers were showing that ivermectin was a highly effective drug to treat SARS-2 infections.** In April 2020, less than a month after the WHO declared Covid-19 as a global pandemic, Australian researchers at the Peter Doherty Institute of Infection and Immunity had <u>published their paper</u> "The FDA- approved drug ivermectin inhibits the replication of SARS-CoV-2 virus in vitro." Monash University's Biomedicine Discovery Institute in Australia had also published an early study that ivermectin destroyed SARS-2 infected cell cultures by 99.8 percent within 48 hours. But no government health official paid any attention.

## The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro

Leon Caly, a Julian D. Druce, Mike G. Catton, David A. Jans, and Kylie M. Wagstaff<sup>b,\*</sup>

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Abstract Go to: >

Although several clinical trials are now underway to test possible therapies, the worldwide response to the COVID-19 outbreak has been largely limited to monitoring/containment. We report here that Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity *in vitro*, is an inhibitor of the causative virus (SARS-CoV-2), with a single addition to Vero-hSLAM cells 2 h post infection with SARS-CoV-2 able to effect ~5000-fold reduction in viral RNA at 48 h. Ivermectin therefore warrants further investigation for possible benefits in humans.

#### <u>Source</u>

As of June 2023, a database for all reports investigating ivermectin against Covid-19 infections records a total of 209 studies, 161 peer-reviewed, and 98 involving controlled groups reporting an average 67 percent improvement for early infections and an 85 percent average success rate for use as a prophylaxis to prevent Covid-19 symptoms.

Moreover, prescribing ivermectin reduced mortality by 50 percent, compared to Remdesivir's 12 percent. An <u>Italian study</u> observed a 416 percent increase in hepatocellular injuries among hospitalized Covid-19 patients treated with Remdesivir. Even the WHO released a "conditional recommendation 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."

Although the science shows that HCQ should not be prescribed for late stage Covid-19 infections, it is highly effective as a very early stage treatment, with a 62 percent improvement rate and 72% reduction in mortality. These rates are far superior to those shown for Remdesivir and other FDA-approved EUA drugs. One study of 585 patients treated with HCQ along with azithromycin and zinc were relieved in under 3 days and none were hospitalized, required ventilation or died. Another study published in the journal *Clinical and* 

*Translational Science* reported 73% reduction in hospitalization with no serious adverse events.

Regarding Pfizer's novel Covid-19 drug Paxlovid, the verdict remains open; the company does not permit independent random-controlled trials to investigate its drug. Therefore, we only have Pfizer's own data to rely upon. Nevertheless, *The Lancet* published <u>a study</u> by a team of Chinese scientists at Shanghai Jiao Tong School of Medicine that managed to look at Paxlovid's use among critically ill patients hospitalized with Covid-19. The study reported a 27 percent higher risk of the infection progressing, a 67 percent increased risk in requiring ventilation, and 10 percent longer stays in ICU facilities.

Although the EUA amendment provides some protections to authorized drug and vaccine manufacturers, it was the Public Readiness and Emergency Preparedness Act (PREP) in 2005 that expanded liability protections. In addition to protecting private corporations, PREP also shields company executives and employees from claims of personal injury or death resulting from the administration of authorized countermeasures. The only exceptions for liability are if the company or its executive offices are proven to have engaged in intentional and/or criminal misconduct with conscious disregard for the rights and safety of those taking their drugs and vaccines.

During the pandemic, the FDA issued widespread EUAs with liability immunity for the PCR diagnostic kits for SARS-2, the mRNA vaccines and anti-Covid-19 drugs such as Remdesivir, molnupiravir and Paxlovid. Even the PCR test failed to go through a robust evaluation to determine whether it could accurately predict a SARS-2 infection. Curiously, the Secretary of the Department of Health and Human Services invoked the PREP Act on February 4, 2020 giving liability protections; this was over a month before the pandemic was officially announced, which raises serious questions about prior-planning before the viral outbreak in Wuhan, China.

From the pandemic's outset, Fauci embarked on the media circuit to promise Americans that federal health agencies were doing everything within their means to get a vaccine on the market because there was no available drug to clear SARS-2 virus infections. As we have seen with respect to ivermectin alone, this was patently false. Rather the government placed an overriding emphasis on vaccination with a near total disregard for implementing very simple preventative measures to inhibit infections from progressing. Once mass vaccinations were underway, we were promised that the SARS-2 virus would be defeated and life would return to normal. In retrospect, we can look back and state with a degree of certainty that American health authorities and these products' corporate manufacturers may have violated almost every EUA requirement. Everything that went wrong with the PCR kits, the experimental mRNA vaccines and novel drugs could have been avoided if the government had diligently repurposed effective and safe measures as pandemic countermeasures. Very likely, hundreds of thousands of lives would have been saved.

Shortly after the pandemic was formally announced, and with no promising treatment in sight, the FDA recommended HCQ but then quickly reversed its decision in June after Fauci publicly announced the future arrival of Gilead's novel drug Remdesivir. The FDA's approval of Remdesivir baffled many scientists, according to the journal *Science*, who were keeping a close watch on the drug's clinical reports about a "disproportionally high number of reports of liver and kidney problems"

Similarly the FDA issued a warning statement against the use of ivermectin. Although Merck

was ivermectin's manufacturer, the company discredited its own product. Shortly after ridiculing its drug, the Alliance for Natural Health <a href="reported">reported</a>, "Merck announced positive results from a clinical trial on a new drug called molnupiravir in eliminating the virus in infected patients." Molnupiravir has a poor efficacy rate across the board including viral clearance, recovery, and <a href="hospitalizations/death">hospitalizations/death</a> (68 percent). One trial, funded by Merck, concluded the drug had no clinical benefit. More worrisome, molnupiravir was found to potentially contribute to <a href="lethal mutations">lethal mutations</a> in RNA viruses. The drug also has life-threatening <a href="adverse effects">adverse effects</a> including mutagenic risks to human DNA and mitochondria, carcinogenic activity and embryonic death.

And still the FDA considers these novel patented drugs to be superior to ivermectin. Favoring a vaccine regime and government-controlled surveillance measures to track every American's movements, American health officials blatantly neglected their own pandemic policies' severe health consequences. Ineffective lockdowns, masks, social isolation, unsound critical care interventions such as relying upon ventilators, and the sole EUA approvals of the costly and insufficiently effective drugs brought about nightmares for tens of millions of adults and children. Again, the FDA worked in concert with the pharmaceutical industry to increase profit and revenues rather than improve human health and assure patient safety. This was all undertaken under Fauci's watch and the heads of the US health agencies in direct violation of the EUA requirements to only authorize drugs and medical interventions when no other safe and effective alternative is available. As we have seen, alternatives were available and these were well known throughout the government health agencies. Instead of acting upon them and awarding EUAs to HCQ, ivermectin and other potential off-patent drugs, the government preferred to submit to their pharmaceutical masters' demands and the financial mills that feed the CDC's and FDA's coffers.

The 3-year history of the pandemic highlights a sharp distinction between dependable medical research and pseudoscientific fraud.

We witnessed the CDC adopting a common Soviet era practice to redefine the very definition of a vaccine and the parameters of vaccine efficacy in order to fit their economic and ideological agendas.

This explains Washington's frequent uninformed decisions and its aggressive public relations endeavors to silence medical opponents. According to cardiologist Dr. Michael Goodkin's private investigations, several of the most cited studies discrediting ivermectin's antiviral benefits were funded by the NIH and Bill Gates and intentionally manipulated in order to produce "fake" results. These studies were widely distributed to the AMA, American College of Physicians and across mainstream media to author "hit pieces" to demonize ivermectin. The government's belligerent and reactive diatribes, brazenly or casually advocating for censorship, were direct violations of scientific and medical integrity and contributed nothing towards developing constructive policies for handling a pandemic with a minimal cost to life. The consequence has been a less informed and grossly naïve public, which was gaslighted into believing lies.

Now that ivermectin, and to a lesser extent HCQ, have been recognized by more and more physicians as part of a first line defense to prevent and treat SARS-2 infections, we can realize that the FDA's EUAs for the Covid-19 vaccines and novel experimental drugs were in fact an attack on the amendments and PREP directives.

Neither the vaccines nor drugs warranted emergency authorization because effective and

safe alternatives were readily available. No doubt a Congressional investigation would uncover criminal misconduct, and this misconduct and conscious fraud have contributed to numerous unnecessary medically-induced injuries and deaths. Moreover, these violations of the PREP Act may have the potential to lead directly into medical crimes against humanity as outlined in the Nuremberg Code.



Nuremberg Trials. 1st row: Hermann Göring, Rudolf Heß, Joachim von Ribbentrop, Wilhelm Keitel. 2nd row: Karl Dönitz, Erich Raeder, Baldur von Schirach, Fritz Sauckel. (Office of the U.S. Chief of Counsel for the Prosecution of Axis Criminality/Still Picture Records LICON, Special Media Archives Services Division (NWCS-S)

Between 1946 and 1947, Nazi medical doctors were tried in Nuremberg, Germany. Known as the "Doctors' Trial", the court found 16 of 23 doctors guilty of human experimentation that involved conducting experiments with lethal drugs and substances, sterilization, forced euthanasia and other heinous acts. These medical atrocities were conducted on some of the most vulnerable populations.

Seven Nazi doctors were executed by hanging. What became known as the Nuremberg Code after the tribunal is not a legally binding document, however it has held significant ethical and historical importance for medical research and human experimentation. The Code is regarded as a milestone in the development of international criminal law. It has informed international and domestic guidelines and regulations on human subjects, and many countries have implemented legal and ethical frameworks inspired by the Code to regulate their medical research and protect their citizens from medical abuse.

Despite serving as the baseline for modern medical ethics, it is unfortunate that no binding

international treaty or declaration has been specifically initiated that directly abides by all of Nuremberg's obligations. Nor has the Nuremberg Code been officially adopted in its entirety as law by any nation or major medical association.

On the other hand, other international treaties, such as the Universal Declaration of Human Rights, the World Medical Association Declaration of Helsinki (which is not legally binding), the International Covenant on Civil and Political Rights (ICCPR) and the International Ethical Guidelines for Biomedical Research on Human Subjects incorporate some of Nuremberg's main principles that aim to protect people from unethical and forced medical research.

Although the US signed the ICCPR as an intentional party, the US Senate never ratified it. The ICCPR's Article 7 clearly states, "No one shall be subject to torture or cruel, inhuman or degrading treatment or punishment," which can legally be interpreted to include forced medical experimentation implied as cruel, inhuman treatment. Other ICCPR articles, 6 and 17, are also applicable to medical experimentation to ensure ethical conduct, obtaining proper informed consent and the right to life and privacy. For a moment, consider the numerous senior citizens in nursing homes and hospitals who were simply administered experimental Covid-19 vaccines without full knowledge about what they were receiving. And now how many children are being coerced by the pseudoscience of health officials' lies to be vaccinated without any knowledge of these mRNA products' risk-benefit ratio?

International organizations, such as the United Nations, have the moral obligation to investigate violations to human rights outlined in the Nuremberg Code. Now that it has been convincingly ascertained that Pfizer and Moderna intentionally concealed their mRNA vaccine trials' safety and efficacy data and the government repeatedly lied to the American public, it is time to hold these parties to account. Forced and mandated Covid-19 vaccination violates the Code's demand for "voluntary consent of the human subject is absolutely essential" and the ICCPR's prohibition that "no one shall be subjected without his free consent to medical or scientific experimentation." Mandates to take dangerous experimental vaccines have ruined families, and livelihoods.

The US is also a signatory to the Helsinki Declaration, which, although not directly aligned with Nuremberg, shares much in common. The Declaration also shares some common features with the EUA amendment and PREP Act. These include voluntary informed consent—which is universally accepted, adequate risk and benefit information about medical interventions, and an emphasis on the principle of medical beneficence (promoting well-being and the Hippocratic rule of doing no harm). It also guarantees protections for vulnerable groups, especially pregnant women and children, which the US government and vaccine makers directly violated by conducting trials on these groups with full knowledge about these vaccines' adverse events in adults. In addition, weighing the scientific evidence to assess the risk-benefit ratios between prescribing ivermectin and HCQ over Pfizer's, Merck's and Gilead's novel experimental drugs conclusively favors the former. This alone directly violates the ethical medical principles noted above.

However, the failure to repurpose life-saving drugs is less criminal than the motivation behind it to make room for a new generation of genetically engineered vaccines that have never before been adequately researched in human trials for long term safety. This mass experimentation, which continues to threaten the health and well-being of millions of people, is global and can legally be interpreted under the Nuremberg Code as a genocidal attack on humanity. If the emerging data for increasing injuries and deaths due to the Covid-19 vaccines is reliable—and we believe it is—the handling of the pandemic can be

regarded as the largest medical crime in human history. In time, and with shifting political allegiances and public demands to hold our leaders in government and private industry accountable, the architects of this medical war against civilization will be brought to justice.

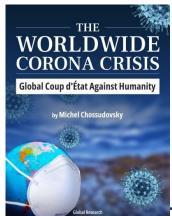
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**Richard Gale** is the Executive Producer of the Progressive Radio Network and a former Senior Research Analyst in the biotechnology and genomic industries.

**Dr. Gary Null** is host of the nation's longest running public radio program on alternative and nutritional health and a multi-award-winning documentary film director, including his recent Last Call to Tomorrow

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