ETHICS AND PUBLIC POLICY CENTER

May 2, 2022

Via Federal eRulemaking Portal

Vice Admiral Vivek H. Murthy
Office of the Surgeon General
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: EPPC Scholars Comment for "Impact of Health Misinformation in the Digital Information Environment in the United States Throughout the COVID-19 Pandemic Request for Information (RFI)"

Dear Vice Admiral Vivek H. Murthy:

We are scholars at the Ethics & Public Policy Center (EPPC) and write in response to the request for comment on "Impact of Health Misinformation in the Digital Information Environment in the United States Throughout the COVID-19 Pandemic."[1] EPPC Fellow Dr. David Gortler is a former FDA medical officer who was appointed as senior advisor on drug safety to the FDA Commissioner, and EPPC Fellow Rachel Morrison is a civil rights attorney.

The request for information (RFI) seeks to understand the impact and prevalence of health misinformation during the COVID-19 pandemic. The RFI defines "health misinformation" as "health information that is false, inaccurate, or misleading according to the best available evidence at the time."

As highlighted below, we submit that the federal government was a purveyor of COVID-19 misinformation, leading to distrust in the government and health care systems and providers, and curtailing the ability of medical professionals to provide quality and lifesaving care to their patients.

Risk of Death from COVID-19

The federal government pushed universal lockdowns, masking, and social distancing, including for children, despite the fact that it was known early on that COVID was most often fatal for elderly people in poor health. Federal agencies all told us COVID-19 is fatal, even to children, despite knowing full well that it is 98% survivable overall, and dangerous only in proportion to age and comorbidities.[2]

[1] 87 Fed. Reg. 12,712.
[2] https://www.bmj.com/content/369/bmj.m1327

It was later elucidated that 2.1 million Americans, representing 0.62% of the U.S. population, reside in nursing homes and assisted living facilities. Yet according to an analysis in the 43 states that currently report such figures, an astounding 42% of all COVID-19 deaths have taken place in nursing homes and assisted living facilities.[3] A locus of fatalities in March 2020 was a single nursing home in Washington State.[4] In July 2020, the 0.7% of Pennsylvania's population who were nursing-home residents accounted for 69% of COVID deaths there.[5] Yet, several governors ordered chronically ill senior citizens with COVID discharged to nursing homes, leading to unnecessary exposures, illnesses, and deaths.

Downplaying Hydroxychloroquine and Ivermectin

When President Trump spoke of the promise of Hydroxychloroquine **(**HCQ) for treating COVID-19, the FDA scoffed even dedicating a government webpage to speak out against it use.[6] When physicians who had prescribed hydroxychloroquine safely to prevent and treat malaria and chronic diseases for six decades championed its off-label use to treat a potentially fatal malady for which no other known treatment existed, they were ostracized, and their medical licenses threatened. Pharmacies in several states had Pharmacy boards restrict pharmacies' dispensing of HCQ and Ivermectin **(**IVM) under the threat of discipline.

Today, conclusive clinical evidence of effectiveness in clinical trials has illustrated the benefit of hydroxychloroquine or ivermectin as detailed in *hundreds of thousands of patients* for both prophylaxis and early treatment.[7]

- Thirty-three of the 35 early treatment studies report a positive effect for hydroxychloroquine (64% improvement Relative Risk 0.36 [0.29-0.46]).[8]
- Late treatment is less successful, with only 68% of the 207 studies reporting a positive effect. Late-stage treatment is ineffective with hydroxychloroquine and all other antiviral medications as well.
- Eighty percent of randomized controlled trials (RCTs) for early, pre-exposure prophylaxis treatment report positive effects.[9] The probability of results as good or better for an ineffective treatment is 0.0059, (with $p<0.05$ being considered statistically significant).
- Meta-analysis using the most serious outcome reported shows 64% [54-71%] improvement for hydroxychloroquine's 35 early-treatment studies.[10] Results are similar after exclusion-based sensitivity analysis and after restriction to peer-reviewed studies.

[3] https://www.forbes.com/sites/theapothecary/2020/05/26/nursing-homes-assisted-living-facilities-0-6-of-the-u-s-population-43-of-u-s-covid-19-deaths/
[4] https://hub.jhu.edu/2020/04/01/alice-bonner-coronavirus-nursing-homes/
[5] https://www.forbes.com/sites/theapothecary/2020/05/26/nursing-homes-assisted-living-facilities-0-6-of-the-u-s-population-43-of-u-s-covid-19-deaths/
[6] https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.
[7] https://hcqmeta.com; https://ivmmeta.com.
[8] https://hcqmeta.com/#fig_fpearly.
[9] https://hcqmeta.com/#fig_fpre
[10] https://hcqmeta.com/#fig_fpearly

Restricting to the nine randomized controlled trials shows 45% [14-64%] improvement,[11] and restricting to the 14 mortality results shows 74% [61-83%] lower mortality.[12]

- Curiously, there is noteworthy evidence of bias toward publishing negative results in North America.[13] Worldwide, 80.7% of hydroxychloroquine studies show positive outcomes compared to only 46.6% of studies in North America. Consequently, studies from North America are 2.8 times more likely to report negative results than studies from the rest of the world combined, $p = 0.0000000153$, (with $p<0.05$ being considered statistically significant).[14]

In addition to the abundance of proof of their effectiveness, these drugs have a combined *nine decades'* worth of safety data, yet they are *still* somehow perceived to be inferior to Merck's molnupiravir (Lagevrio) and Pfizer's nirmatrelvir/ritonavir (Paxlovid). Both of these drugs were quietly given an EUA in late December of 2021, while data on ivermectin and hydroxychloroquine are at best completely ignored and at worst excoriated by Biden's FDA.

Lower cost and long-term safety notwithstanding, in contradiction to the decades and *hundreds of thousands* of participants treated with ivermectin or hydroxychloroquine, molnupiravir was granted an EUA based on a *single Merck-run* study involving a mere *716* participants receiving treatment. Pfizer's Paxlovid approval was based on a *single, Pfizer-operated* study involving a mere *607* participants receiving treatment. The FDA and the White House are promoting and funding two drugs that have been on the market for about one month, based on about one month's worth of safety data, versus two other drugs that have decades worth of safety data behind them, tested in a diverse, worldwide population. Despite that, the Biden administration has committed $5 billion of taxpayer funding for Pfizer's Paxlovid and $2.2 billion for Merck's molnupiravir, making them both instantaneous "blockbuster" drugs, since the criteria for a "blockbuster" drug is $1 billion in sales per year.[15]

The FDA's willful disinterest in anything hydroxychloroquine- and Ivermectin-related is unscientific and harmful to those who would have otherwise received benefit of those treatments.

Ignoring Natural Immunity and Waning Vaccine Efficacy

In September 2021, the Biden administration ordered approximately 100 million Americans to be vaccinated for COVID-19.[16] This included federal workers and contractors who work for the federal government and employees of businesses with more than 100 workers who must be vaccinated or tested on a weekly basis. When Biden announced the mandate, he warned, "If you break the rules, be prepared to pay . . . And by the way, show some respect." Businesses that did not comply were subject to fines of $14,000 per violation before the supreme court rejected the Biden mandate.[17]

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[11] https://hcqmeta.com/#fig_fpre
[12] https://hcqmeta.com/#fig_fpd
[13] https://hcqmeta.com/#bias
[14] https://hcqmeta.com/#fig_regionplot
[15] https://www.investopedia.com/terms/b/blockbuster-drug.asp
[16] https://www.whitehouse.gov/covidplan/
[17] https://www.nbcnews.com/politics/white-house/biden-announce-additional-vaccine-mandates-he-unveils-new-covid-strategy-n1278735

Irrationally, these orders *did not* exempt people who already have adequate Covid-19 antibodies due to a previous infection or vaccination.

We have learned that COVID mutates in the same way as cold or flu viruses. For that reason, the flu vaccine is reformulated annually; the COVID vaccine hasn't been. It's therefore only moderately effective against the original strain, much less so against newer variants. A long-term Israeli study and the well -stablished, decades-old concept of the Hoskin's Effect shows that natural immunity provides far more protection, even from variants of the disease, than the highly-touted vaccine.[18] That's consistent with everything we know about immunity.

The FDA has said nothing regarding the crumbling efficacy of mRNA vaccine administration.[19] In fact, the FDA is still promoting vaccination and boosters on its website's homepage.[20]

President Biden stated on December 14 that "This is a pandemic of the unvaccinated," and asked "How about making sure that you're vaccinated, so you do not spread the disease to anyone else?"[21] He added on December 21 that fully vaccinated people can safely celebrate the holidays.[22] Yet he conspicuously neglected to mention that the CDC has stated that anyone with an Omicron variant infection, including the vaccinated, can spread the virus to the vaccinated or the unvaccinated.[23]

Failure to Release Vaccine Safety Data

American physicians and pharmacists should not be forced into blindly recommending and administering COVID vaccines to their patients without first personally reviewing and being comfortable with available efficacy and safety information — not simply because the White House threatens them.

And here lies the problem: Americans and their medical providers *can't obtain* the full review on the Pfizer and Moderna vaccines because the FDA hadn't released its Pfizer Vaccine clinical efficacy and safety reviews to the public at that time. Americans are entitled to make informed decisions, and the FDA should disclose its safety and efficacy reviews for all to see. Having the White House mandate the administration of any vaccine without full transparency while Members of Congress are exempt is un-American and insulting.

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[18] https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1; https://pubmed.ncbi.nlm.nih.gov/9796045/
[19] https://rumble.com/vnouq3-twitter-user-video-showing-the-shifting-narrative-in-vaccine-efficacy.html; https://www.americanthinker.com/blog/2022/01/covid_boosters_for_omicron_are_not_highly_effective_and_americans_are_not_highly_protected.html
[20] https://www.americanthinker.com/articles/2022/03/fda_cdc_guilty_of_clinical_malpractice_and_scientific_fraud_by_inaction_and_omission_on_mrna_vaccine_safety_warnings.html
[21] https://www.washingtonpost.com/politics/2022/01/11/overwrought-pushback-pandemic-unvaccinated/
[22] https://www.cnbc.com/2021/12/22/5-things-to-know-before-the-stock-market-opens-wednesday-dec-22.html
[23] https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html

The FDA was secretive and non-transparent about public health data, and that only served to further harden all anti-vaccine, and vaccine-hesitant movements in America and abroad.[24]

Uncertain Risk of COVID-19 Vaccines

One of the undersigned, Dr. David Gortler, a former FDA medical officer and a drug safety expert, was the senior advisor to the FDA Commissioner on vaccine safety.[25] When President Biden took office, Dr. Gortler was dismissed along with all other scientific public health officials. Their non-partisan public health initiatives scrapped, including Dr. Gortler's duties monitoring COVID-19 mRNA vaccine safety.

The federal government has consistent stated the COVID-19 vaccines are "safe and effective." Yet VAERS has been flooded with more than a million reports of various health problems and more than 21,000 death reports since the introduction of the vaccines in late 2020.[26] The American people would like to know how safe, how effective, and for whom.

Studies acknowledged by FDA officials show that the FDA's various safety databases only collect an estimated 1 to 13 percent of all adverse events that occur.[27] If approximately 1 to 13 percent of adverse events are reported, extrapolating those numbers means the actual number of adverse health events could easily be in the hundreds of thousands in the United States, not to mention many millions worldwide. FDA and other public officials have repeatedly downplayed the significance of the VAERS reports, noting that just because a health problem occurs after getting the shot, it does not mean it was caused by it, repeatedly stating "correlation is not causation." But correlation does not mean no causation either.

Historically, the FDA has used "correlation" to make sweeping labeling changes on entire classes of drugs. For instance, in 2008, after fewer than 200 spontaneous VAERS reports of tendon rupture following administration of the class of antibiotics known as fluoroquinolones, FDA added a "black box warning" plus REMS prescribing restrictions.[28] Yet the same standard isn't being applied to mRNA vaccines despite the significantly more compelling death and serious adverse event findings.[29] The number of adverse evets have been so overwhelming that as of June 2021 Pfizer had to hire 2,400 additional employees to its staff taking on adverse event reports from its mRNA Comirnaty COVID-19 vaccine.[30]

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[24] https://www.forbes.com/sites/davidgortler/2021/08/24/how-the-fdas-lack-of-transparency-undermines-public-trust/

[25] https://www.forbes.com/sites/davidgortler/?sh=240a47311951; https://www.foxnews.com/opinion/fda-problems-biden-drug-public-health-compromised-dr-david-gortler

[26] https://openvaers.com/covid-data

[27] https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system

[28] https://www.fda.gov/news-events/press-announcements/fda-updates-warnings-fluoroquinolone-antibiotics

[29] https://thefederalist.com/2022/02/10/former-senior-fda-official-manufacturers-fda-negligent-in-not-investigating-covid-19-vaccine-risks-to-heart-health/

[30] https://freedomfirstnetwork.com/2022/04/latest-pfizer-document-dump-shows-the-company-had-to-hire-2400-new-employees-to-handle-wave-of-covid-vaccine-adverse-events

Nearly a year and a half later, following 11.6 billion vaccine doses having been administered worldwide, with 576 million of those in the United States alone, neither manufacturers nor the FDA have not made a single safety update nor a single warning addressing the hundreds of thousands of safety reports, in the FDA's VAERS database.[31]

Ignoring AED / VAED

Antibody Dependent Enhancement (or ADE) also known as Vaccine Associate Enhanced Disease (VAED) is a phenomenon in which binding of a virus to suboptimal antibodies (such as the case as when an older vaccine is given for new variants as is the case for Delta, Omicron, XE and/or its various subvariants) paradoxically *enhances* viral entry into host cells, followed by its replication.[32] ADE may cause enhanced respiratory disease and acute lung injury after respiratory virus infection.

New evidence has also shown that there were warnings within the original Pfizer application to the FDA regarding enhancement the FDA failed to properly research and address. Specifically, AED / VAED is a phenomenon observed in animals during vaccine development against the coronaviruses and measles, respiratory, and dengue viruses previously. In the past, when this phenomenon was found in other vaccine candidates including: measles, RSV virus and Dengue virus, and were terminated from further development.

In other words, instead of being protected by the vaccine, patients actually developed more severe infections and disease and subsequently had worse outcomes. From the data dump of the original Pfizer application of its Comirnaty vaccine,[33] we now know that this effect has been born out in the original Pfizer clinical trials, but the American public was NOT warned about this effect in the official Pfizer or Moderna review documents released to the American public by the FDA.[34] The 11,000+ pages of documents, released on April 1, 2022 reveal that the CDC, FDA and manufacturers knew that vaccine-induced ADE was occurring and worked to obfuscate it by claiming "no new safety issues have been raised."[35]

Child Vaccine Approval

The FDA approved COVID-19 vaccines in children under and advisory committee's questionable logic from unskilled advisory committee members who didn't understand regulatory affairs and who were apparently unaware that they could request additional safety studies.[36]

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[31] https://thefederalist.com/2022/03/25/why-arent-the-fda-and-cdc-informing-the-public-about-documented-adverse-events-after-mrna-injections/
[32] https://www.thegatewaypundit.com/2022/04/go-says-new-covid-variant-xe-found-uk-transmissible-variants-yet/
[33] https://www.infowars.com/posts/internal-documents-prove-pfizer-fda-knew-antibody-dependent-enhancement-occurring-in-vaccinated/
[34] https://web.archive.org/web/20210918205409/https:/www.fda.gov/media/152256/download; https://archive.org/details/httpswww.fda.govmedia155931download/mode/2up
[35] http://phmpt.org/pfizers-documents/
[36] https://www.nationalreview.com/2021/10/the-fda-shouldnt-cut-corners-on-child-vax-safety/

In a shocking on-video admission**,** in October 2021, Dr. Eric Rubin, an advisory-committee member to the FDA, said this during an official FDA hearing about the COVID vaccine in children five to eleven: "We're never going to learn about how safe the vaccine is until we start giving it. That's just the way it goes."[37] Dr. Rubin's comment the official FDA panel makes it clear that despite his Harvard and *New England Journal of Medicine* chief-editor pedigree and acumen, he does not understand the FDA's fundamental safety mission. Neither does the rest of the advisory committee.

Despite the admitted lack of safety data, the FDA "expert" advisory committee went on to vote 17–0 to approve it in five to eleven year old kids and the FDA granted emergency-use authorization of the vaccine, promoted as part of the White House narrative on vaccines.[38]

The fact remains that America's young children are not drug-safety research volunteers, and the panel's failure to comprehensively address safety concerns will only undermine its goal of mass vaccination of kids and their anti-vaccine or vaccine-hesitant parents. Because the Biden administration is fond of using the FDA as cover for its medical mandates, it is all the more important that the FDA produce comprehensive and conclusive safety data for public review *before* approving the vaccines — even if it's for emergency-use authorization (EUA).

A central question that seems to have been ignored by the FDA is whether emergency vaccination of children five to eleven years old was needed *at all*, given the well-established low risk of serious COVID complications in children, especially with the dominant variant and the availability of therapeutics with known safety records, mask-wearing, and social distancing as alternate protective measures.

In March of 2022, the *New York Times* informed Americans that kids as well as young adults did not benefit from the vaccine, and that the CDC intentionally hid those data showing the same.[39] The approval of vaccines for five to eleven year old kids illustrate the FDA leadership's profound lack of ability to follow its own ethical, clinical and scientific standards, and the agency's disregard for science in favor of pharmaceutical industry-friendly approvals.[40]

Pushing Boosters

On the issue of COVID-19 vaccine boosters, the Biden White House and various public health agencies offered confusing, shifting or outright contradictory guidance, weakening their own claims to authority and sowing distrust that undermines attempts to end this pandemic.

On August 18, 2021, Biden declared to all Americans, "Get a booster shot…. It will make you safer, and for longer. And it will help us end the pandemic faster."[41] Biden made this

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[37] https://twitter.com/GrabienMedia/status/1453362914312835073
[38] https://www.nationalreview.com/news/key-fda-panel-backs-pfizer-covid-vaccine-for-children-ages-5-11/
[39] https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html
[40] https://www.forbes.com/sites/davidgortler/2021/07/19/unforgivable-hypocrisy-from-fdas-career-cder-leadership/; https://www.forbes.com/sites/davidgortler/2021/06/11/fdas-new-cder-director-allows-approval-of-yet-another-expensive-scientifically-worthless-drug--expect-many-more/
[41] https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/18/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-2/

declaration while the CDC's Advisory Committee on Immunization Practices was *still* studying the issue and had not made any recommendations[42] The CDC advisory panel advised against approving boosters for people under 65, contradicting the president in turn.

The president's announcement, however, aligned with a September 17, 2021 recommendation by experts at the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC).[43] (At that time, the FDA still had not released its review of the Pfizer or Moderna mRNA vaccines to the public.)

Dr. Anthony Fauci recommended boosters before hearing from experts at the FDA's VRBPAC.[44] In response, there were several resignations of our nation's top government scientists working on the COVID response—including FDA senior vaccine science directors Marion Gruber and Phil Krause, and top CDC respiratory scientist Nancy Messonnier.[45]

Although the COVID vaccine appeared effective in combatting the original virus and prior variants, taking COVID-19 boosters for the Omicron variant might be akin to taking *last year's* influenza vaccine to prevent *this year's* influenza.

A study out of Columbia University examined the original mRNA vaccine's effectiveness against Omicron.[46] It warned that Omicron's "extensive" spike protein mutations "raise the specter that current vaccines and therapeutic antibodies would be greatly compromised." The study goes on to state: "We found [Omicron] to be markedly resistant to neutralization by serum not only from convalescent patients, but also from individuals vaccinated with one of the four widely used COVID-19 vaccines." Yet, the White House and federal government continue to push boosters.

Conclusion

While rightly concerned about health misinformation during a pandemic, we urge the federal government to look first inward to its shifting, contradictory, and unscientific response to the pandemic that has led to massive public distrust in the government and public health systems.

Sincerely,

David Gortler, Pharm.D. FCCP
Fellow, HHS Accountability Project

Rachel N. Morrison, J.D.
Fellow, HHS Accountability Project

[42] https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/18/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-2/
[43] https://www.nytimes.com/2021/09/24/world/covid-boosters-vaccine-cdc-director.html; https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations
[44] https://www.politico.com/news/2021/08/29/fauci-covid-19-booster-shot-recommendations-507210.
[45] https://www.nytimes.com/2021/08/31/us/politics/fda-vaccine-regulators-booster-shots.html; https://www.washingtonpost.com/health/2021/05/07/cdc-official-resigns/
[46] https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1.full.pdf