

March 1, 2021

The Honorable Francis S. Collins, M.D., Ph.D.  
Director  
U.S. National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Director Collins:

Thank you for your January 29, 2021 response to my December 10, 2020 letter. I appreciate the information provided; however, I remain frustrated by the lack of transparency from public health agencies, and the general federal response to the COVID-19 pandemic. Specifically, it is unclear how the government utilizes available data to make policy decisions regarding certain COVID-19 treatments and vaccines. I write to request information regarding this issue, as I believe the federal government should ensure that physicians and COVID-19 patients have access to every tool in the toolbox to combat this crisis.

In November and December 2020, physicians testified about their experience and available research that demonstrates that certain early treatments for COVID-19 are safe and effective.<sup>1</sup> These physicians also stressed that early detection and treatment are key factors in fighting diseases and providing better patient outcomes.<sup>2</sup> Despite the support for the development and usage of early treatments for other diseases and decades of safety data, early treatments for COVID-19 have been largely ignored or subjected to undue criticism. Public health agencies like the Food and Drug Administration (FDA) continue to make assertions that the known and potential risks of certain early treatments do not outweigh the known and potential benefits.<sup>3</sup> For example, although ivermectin is a widely-available, FDA-approved drug, the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel stated there are insufficient data to recommend either for or against the use of ivermectin for the treatment of COVID-19.<sup>4</sup> Notwithstanding this

---

<sup>1</sup> *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution: Hearing Before the S. Comm. on Homeland Sec. & Governmental Affairs*, 116th Cong. (2020), *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II: Hearing Before the S. Comm. on Homeland Sec. & Governmental Affairs*, 116th Cong. (2020).

<sup>2</sup> *Id.*

<sup>3</sup> *Frequently Asked Questions on the Emergency Use Authorization (EUA) for Chloroquine and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients*, U.S. Food and Drug Administration (Jun. 15, 2020), <https://www.fda.gov/media/136784/download>.

<sup>4</sup> *Ivermectin*, National Institute of Health (Feb. 11, 2021), <https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/ivermectin/>.

The Honorable Francis Collins, M.D., Ph.D.

March 1, 2021

Page 2

official guidance, physicians are successfully treating patients with these FDA-approved, off-label treatments.<sup>5</sup>

In contrast, the amount of available data on the safety of the COVID-19 vaccines, at this time, is limited. This, of course, is due to the fact that these vaccines were only recently developed and have been granted Emergency Use Authorization (EUA) as experimental vaccines by the FDA.<sup>6</sup> According to the FDA, these vaccines have not completed clinical trials and do not appear to have adequate follow-up for either safety or efficacy.<sup>7</sup> Despite limitations on generalizability and adverse event data on vaccines for emergency-use, the federal government is urging individuals to get vaccinated beyond the range of inclusion criteria for the randomized trials. For example, the Centers for Disease Control and Prevention (CDC) acknowledged that, “[N]o data are available yet on the safety of COVID-19 vaccines in lactating women” or breastfed infants.<sup>8</sup> Yet the CDC still advises that pregnant and breastfeeding women and people that have recovered from COVID-19 may be vaccinated.<sup>9</sup>

To better understand the federal government’s continued efforts to ensure physicians and patients have treatments for COVID-19, I respectfully request the following information:

1. According to the FDA, the 21st Century Cures Act required the federal government to take into account real-world evidence generated “by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies.”<sup>10</sup> Please describe how NIH has considered real-world evidence in its COVID-19 treatment decisions, recommendations and guidelines, including the specific discussions on all available relevant studies, published and preprint.
2. My December 10, 2020 letter listed a number of treatments (favipiravir, azithromycin, doxycycline, etc.) that were not discussed in the January 29, 2021 NIH response. Please provide an update on the status of the review for these early treatments, as well as other potential treatments (intracellular anti-infectives, corticosteroids, anticoagulants).
3. For all treatments listed in the January 29, 2021 NIH response, how many have undergone a large-scale conclusive (placebo-controlled, endpoint driven, adequately powered, positive unbiased primary endpoint) randomized controlled trial?

---

<sup>5</sup> *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II: Hearing Before the S. Comm. on Homeland Sec. & Governmental Affairs*, 116 Cong. (2020) (Statement of Dr. Pierre Kory).

<sup>6</sup> *COVID-19 Vaccines*, U.S. Food and Drug Administration (Feb. 23, 2021), <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.

<sup>7</sup> *Emergency Use Authorization for Vaccines Explained*, U.S. Food and Drug Administration (Nov. 20, 2020), <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.

<sup>8</sup> *Pregnancy or Breastfeeding*, Centers for Disease Control and Prevention (Feb. 12, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>.

<sup>9</sup> *Frequently Asked Questions about Vaccination*, Centers for Disease Control and Prevention (Feb. 19, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>.

<sup>10</sup> *Real-World Evidence*, U.S. Food and Drug Administration (Nov. 30, 2020), <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>.

4. The January 29, 2021 NIH response stated “other trials also demonstrated that hydroxychloroquine (HCQ) is not effective in treating COVID-19.” For each of these “other trials,” please provide the findings of those trials, the specific numbers of days that HCQ was given as a treatment in those trials, whether the trials were examining outpatient or inpatient, low-risk patients or high-risk patients, and whether zinc or other treatments were provided along with HCQ.
5. Please provide every study that informed the Treatment Guidelines to recommend against HCQ use in hospitalized patients, and in non-hospitalized patients outside of clinical trials. Please confirm that this collection of studies was comprehensive for all available studies, published or preprint at the time of publication.
6. Please provide the data and information that informed the federal government’s decision that individuals that are pregnant, breastfeeding, are of childbearing potential, or have had COVID-19 and recovered should be vaccinated. Additionally, please provide the number of individuals over age 55, and the number of pregnant or breastfeeding subjects that were included in each vaccine trial.
7. Please explain the NIH’s estimates for how long natural immunity (circulating antibody immunity, T-cell immunity and B-cell memory) from COVID-19 lasts. Please provide the number of confirmed COVID-19 re-infections with fully sequenced SARS-CoV-2 requiring hospitalization and mechanical intubation.
8. I have heard from physicians that have concerns about the extent to which public health agencies have reviewed and analyzed the severe adverse event and mortality data available in the Vaccine Adverse Event Reporting System (VAERS). For each death or serious adverse reaction listed on VAERS, please state whether the COVID-19 vaccine was administered to a COVID-19 recovered patient who would have been strictly excluded from the mRNA vaccine trials or to pregnant women, children, and others who may have been vaccinated without antecedent safety data from the FDA submissions of these products; and whether the individual had preexisting conditions.
9. Please explain when public health agencies will have sufficient data for final vaccine approval.
10. The December 3, 2020 CDC guidance stated “[C]urrently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP [health care personnel] will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.”<sup>11</sup> Has this data been provided to federal agencies? If yes, please explain why the February 12, 2021 CDC guidance continues to say data do not exist.<sup>12</sup>

---

<sup>11</sup> *Vaccine Recommendations and Guidelines of the ACIP*, Centers for Disease Control and Prevention (Dec. 3, 2020), <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html>.

<sup>12</sup> *Pregnancy or Breastfeeding*, Centers for Disease Control and Prevention (Feb. 12, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>.

The Honorable Francis Collins, M.D., Ph.D.

March 1, 2021

Page 4

Thank you for your attention to this urgent matter.

Sincerely,

Ron Johnson  
United States Senator