Congress of the United States
Washington, DC 20510

March 2, 2021

Mr. Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Cochran:

As the federal government works to combat the COVID-19 pandemic, we write to request that the U.S. Department of Health and Human Services promptly consider extensive new scientific data and use its statutory authorities to enhance and increase the current vaccine administration. Such action could save the lives of up to 40,000 American seniors.

Recent and re-examined data has demonstrated that both the Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines appear highly effective after only one dose to critical clinical endpoints, including transmission, hospitalization, severe disease, and mortality, relative to the two-dose regime currently authorized. Emerging evidence has been discussed in various peer-reviewed clinical journals including the New England Journal of Medicine and The Lancet.[1, 2, 3] Of note, a study evaluating patients in the United Kingdom found the first dose of the two vaccines was associated with an efficacy rate of 85 percent when compared to hospitalization rates.[4] In addition, the Center for Infectious Disease Research and Policy (CIDRAP) released a white paper calling for the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee and the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices to conduct an urgent review of all currently existing data and address the issue in emergency sessions.[5] As you may be aware, CIDRAP includes leading experts in public health, including a member of President Biden's COVID-19 Advisory Board. In response to this large and growing body of real-

[1] Sharon Amit, Gili Regev-Yochay, Arnon Afek, Yitshak Kreiss, and Eyal Leshem, "Early rate reductions of SARS-CoV-2 infection and COVID-19 in BNT162b2 vaccine recipients," *The Lancet* (2021), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)00448-7.pdf?fbclid=IwAR0Ht9QgW-oAR8NtkpWEIrTtH8rkjYDisAVy84jEyBr28H0jFCx8QWm3sp4.
[2] Noa Dagan, et al., "BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting," *New England Journal of Medicine* (2021), https://www.nejm.org/doi/full/10.1056/NEJMoa2101765.
[3] Fernando Polack, Stephen J. Thomas, Nicholas Kitchin, Judith Absalon, Alejandra Gurtman, Stephen Lockhart, John L. Perez et al., "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine." *New England Journal of Medicine* 383, no. 27 (2020), 2603-2615, https://www.nejm.org/doi/full/10.1056/NEJMc2036242?query=NC.
[4] Eleftheria Vasileiou, Colin R. Simpson, Chris Robertson, Ting Shi, Steven Kerr, Utkarsh Agrawal, Ashley Akbari et al., "Effectiveness of First Dose of COVID-19 Vaccines Against Hospital Admissions in Scotland: National Prospective Cohort Study of 5.4 Million People," *The Lancet* [Preprint] (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789264.
[5] University of Minnesota Center for Infectious Disease Research and Policy, Report 7: Reassessing COVID-19 Vaccine Deployment in Anticipation of a US B.1.1.7 Surge: Stay the Course or Pivot?, February 23, 2021, https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-report7.pdf.

world evidence, authors of these studies and others in the medical community are urging regulatory bodies to study real-world effects of these vaccines.[6]

As physicians and Members of Congress, we are committed to following the science and echo CIDRAP's urgent call to review all data to determine the best usage of our currently limited vaccine supply. Particularly considering the current scarcity of vaccines for our most vulnerable populations, we ask that you immediately consider using the authority granted to the Secretary under Section 564 of the Federal Food, Drug, and Cosmetic Act, specifically Section 564(g)(2),[7] to revise the Emergency Use Authorization (EUA) for the Pfizer-BioNTech and Moderna mRNA vaccines to allow for increased flexibilities in the timing of administering the second dose.[8, 9] Under Section 564(g)(2), the Secretary has the authority to revise an authorization if "other circumstances make such revision or revocation appropriate to protect the public health or safety."

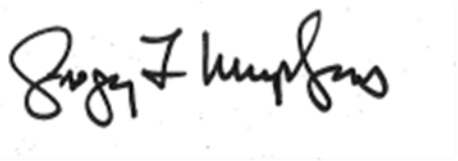
Last week, the U.S. passed a sobering milestone of over 500,000 deaths related to COVID-19. These are staggering statistics, and anything we can do to help prevent further tragedy – to further protect the public health and safety of the American people – should be fully employed. As CIDRAP noted, "there is a narrow and rapidly closing window of opportunity to more effectively use vaccines and potentially prevent thousands of severe cases, hospitalizations, and deaths in the next weeks and months." Inaction or delayed action may cause an unnecessary 40,000 American deaths for those over age 65. We must take advantage of this window.

We urge you to immediately use your regulatory authority – working in tandem with Pfizer-BioNTech and Moderna – to assist with continued data collection of real-world evidence and post-authorization vaccine safety monitoring. Based on all available clinical data, we ask you to consider issuing a revised EUA as soon as possible. As you know, vaccine distribution and administration has been met with challenges across the country. Evaluating all available clinical data now would allow states to more widely administer a single dose of both the Pfizer-BioNTech and Moderna mRNA vaccines until all vulnerable and essential populations are inoculated, and more vaccine doses become available.

We appreciate your efforts throughout this pandemic and thank you in advance for your prompt response and attention to this matter.

Sincerely,

Andy Harris, M.D.
Member of Congress



Gregory F. Murphy, M.D.
Member of Congress

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[6] Fox News, Opinion: Why first COVID vaccine dose is all I'll get for now, by Marty Makary, February 4, 2021, https://www.foxnews.com/opinion/first-covid-vaccine-dose-dr-marty-makary.
[7] 21 U.S.C. 360bbb-3
[8] U.S. Food and Drug Administration, Letter to Pfizer on COVID-19 vaccine, February 25, 2021, https://www.fda.gov/media/144412/download.
[9] U.S. Food and Drug Administration, Letter to Moderna on COVID-19 vaccine, February 25, 2021, https://www.fda.gov/media/144636/download.

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CC: Janet Woodcock, Acting Commissioner, U.S. Food and Drug Administration