Congress of the United States

WASHINGTON, DC 20510

October 5, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dr. Anthony S. Fauci
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane
Bethesda, MD 20892

Rochelle P. Walensky, M.D., MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Becerra, Dr. Fauci, Dr. Walensky, and Dr. Woodcock:

Throughout the COVID-19 pandemic, public health officials have not only ignored potential early treatments, but at times seem to have participated in an aggressive campaign against the use of specific early treatment options. Even though a basic tenet of medicine is: early detection allows for early treatment which produces better results; your agencies have overtly discouraged the use of cheap and widely-available early treatments like ivermectin in favor of expensive new drugs like Remdesivir (which costs more than $3,000 per treatment).[1] Despite the National Institutes of Health (NIH) funding a study examining the effectiveness of ivermectin as an early treatment for COVID-19, your agencies have already demonstrated your strong bias

[1] *See e.g.* Tweet, @US_FDA, Aug. 21, 2021, available at https://twitter.com/us_fda/status/1429050070243192839 ("You are not a horse. You are not a cow. Seriously, y'all. Stop it."). Consumer Update, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, U.S. Food and Drug Administration, Sept. 03, 2021, available at https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19. Sydney Lupkin, Remdesivir priced at more than $3,100 for a course of treatment, NPR, Jun. 29, 2020, available at https://www.npr.org/sections/health-shots/2020/06/29/884648842/remdesivir-priced-at-more-than-3-100-for-a-course-of-treatment.

against this and other potential early treatment drugs.[2] The Food and Drug Administration's (FDA) mocking of ivermectin, conflating a widely-available human drug that was the basis for Nobel prize winning research, with its veterinary version, has cast doubt over the integrity of this study's eventual results.[3] We strongly believe you should explain to the American people why your agencies have failed to sufficiently examine and ensure access to a growing list of drugs being used by doctors who have had the courage to ignore NIH's ongoing compassionless guideline of doing virtually nothing until COVID-19 patients are so sick they require hospitalization.[4]

Physicians have utilized a variety of repurposed drugs and vitamins to treat COVID-19 since the early days of the pandemic. As the list of potential drugs grows, we are concerned by your lack of urgency to explore, research, and recommend use of those drugs. In November and December 2020, Senator Ron Johnson, then-Chairman of the Senate Homeland Security and Governmental Affairs Committee, held two hearings with physicians discussing potential early treatments.[5] At the November 19, 2020 hearing, Drs. Peter McCullough, Harvey Risch, and George Fareed testified about real world experience and metadata analysis of multi-drug treatment protocols for early treatment of COVID-19.[6] Dr. McCullough also described the four pillars of pandemic response: 1) Contagion Control; 2) Early Home Treatment; 3) Hospital Treatment; 4) Vaccines.[7] At the December 8, 2020 hearing, Dr. Pierre Kory testified that "emerging publications provide conclusive data on the profound efficacy of the anti-parasite, anti-viral drug, anti-inflammatory agent called ivermectin in all stages of [COVID-19]."[8]

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[2] Large clinical trial to study repurposed drugs to treat COVID-19 symptoms, National Institutes of Health, Apr. 19, 2021, https://www.nih.gov/news-events/news-releases/large-clinical-trial-study-repurposed-drugs-treat-covid-19-symptoms. *See e.g.* National Institute of Allergy and Infectious Disease (NIAID) Director Dr. Anthony Fauci recently stated "[d]on't do it; there's no evidence that [ivermectin] works." 'Don't do it': Dr. Fauci warns against using ivermectin to treat or prevent COVID-19, Boston.com, Aug. 29, 2021, https://www.boston.com/news/coronavirus/2021/08/29/ivermectin-warnings-anthony-fauci-megan-ranney-fda/, CDC Health Advisory, Rapid Increase in Ivermecting Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19, CDC, Aug. 26, 2021, available at https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf.

[3] *See* Press Release, The Nobel Prize in Physiology or Medicine, Oct. 5, 2015, available at https://www.nobelprize.org/prizes/medicine/2015/press-release/, Ewen Callaway and David Cyranoski, *Anti-parasite drugs sweep Nobel prize in medicine 2015,* Nature, Oct. 5, 2021, https://www.nature.com/articles/nature.2015.18507; *See e.g.* Tweet, @US_FDA, Aug. 21, 2021, available at https://twitter.com/us_fda/status/1429050070243192839 ("You are not a horse. You are not a cow. Seriously, y'all. Stop it."). Consumer Update, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, U.S. Food and Drug Administration, Sept. 03, 2021, available at https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

[4] COVID-19 Treatment Guidelines, National Institutes of Health, Sept. 29, 2021, available at https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf.

[5] *See Early Outpatient Treatment: An Essential Part of a COVID-19 Solution: Hearing Before the S. Comm. On Homeland Security and Governmental Affairs* 116th Cong. (2020); and *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II: Hearing Before the S. Comm. On Homeland Security and Governmental Affairs* 116th Cong. (2020).

[6] *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution: Hearing Before the S. Comm. On Homeland Security and Governmental Affairs* 116th Cong. (2020).

[7] *Id*.

[8] *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II: Hearing Before the S. Comm. On Homeland Security and Governmental Affairs* 116th Cong. (2020).

Since these hearings, evidence of the potential of ivermectin and other repurposed drugs to treat COVID-19 has continued to accumulate. For example, Mexico City and India's Uttar Pradesh have both reportedly experienced positive outcomes after using ivermectin to treat individuals with COVID-19.[9] Mexico City apparently saw reduced hospitalizations and Uttar Pradesh experienced lower positivity and fatality rates.[10] Unfortunately, there appears to be a complete lack of information or interest by U.S. public health agencies to examine what factors contributed to these apparent positive outcomes.

Your agencies have also taken steps to curtail the use of potential early treatments. Even though an estimated 12 to 38 percent of doctor-office prescriptions are off-label treatment drugs, your actions have created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19.[11]

To justify your actions restricting access to COVID-19 drugs, your agencies claim that these treatments require randomized controlled trials (RCTs) before they can be deployed against the virus.[12] As mentioned above, NIH is funding an RCT on ivermectin that you appear to have already prejudged.[13] However, even in cases where an expensive and time-consuming RCT has proven a treatment's safety and efficacy, health agencies have failed to take action. For example, in April, following an RCT, the U.K. government authorized budesonide, an inhaled steroid to treat COVID-19 patients.[14] Unfortunately, more than five months later, your agencies have not recommended budesonide to treat COVID-19 patients in the U.S.[15]

By de facto requiring potential COVID-19 treatments go through RCTs or else be subject to your campaign of misdirection, you have dramatically tipped the scales in favor of expensive new drugs. Manufacturers of generic drugs do not have the profit margins to afford expensive RCTs. In the case of COVID-19, this strong bias against generic drugs has prevented early treatments from being widely adopted and has cost an untold number of lives.

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[9] Presentation by Dr. Pierre Kory, President and Chief Medical Officer, Front Line COVID-19 Critical Care Alliance, Sept. 2021 on file with staff; Maulshree Seth, *Uttar Pradesh government says early use of Ivermectin helped to keep positivity, deaths low*, Indian Express, May 12, 2021, https://indianexpress.com/article/cities/lucknow/uttar-pradesh-government-says-ivermectin-helped-to-keep-deaths-low-7311786/.

[10] *Id.*

[11] Congressional Research Service, Off-Label Use of Prescription Drugs, Feb. 23, 2021, available at https://www.crs.gov/reports/pdf/R45792. *See e.g.* Consumer Updates, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, U.S. Food and Drug Administration Sept. 03, 2021, available at https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.

[12] Letter from Andrew Tantillo, Acting Associate Commissioner for Legislative Affairs, U.S. Food and Drug Administration, to Ron Johnson, U.S. Senator, Jan. 15, 2021, available at https://www.ronjohnson.senate.gov/2021/1/fda-response-letter-to-senator-johnson.

[13] Large clinical trial to study repurposed drugs to treat COVID-19 symptoms, National Institutes of Health, Apr. 19, 2021, https://www.nih.gov/news-events/news-releases/large-clinical-trial-study-repurposed-drugs-treat-covid-19-symptoms.

[14] Interim Position Statement, Inhaled budesonide for adults (50 years and over) with COVID-19, U.K. Department of Health and Social Care, Apr. 12, 2021, available at https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/04/C1253-interim-position-statement-inhaled-budesonide-for-adults.pdf.

[15] COVID-19 Treatment Guidelines, National Institutes of Health, Sept. 29, 2021, available at https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf.

It is beyond puzzling that the federal government continues to ignore foundational medical principles like early treatment or natural immunity, that federal agencies lack basic data regarding vaccine immunity and durability, and that agencies will highlight the relatively few adverse events for one treatment—ivermectin—but largely ignore hundreds of thousands of adverse events and over 15,000 deaths reported on VAERS for COVID-19 vaccines.[16] As the number of breakthrough COVID-19 cases increase in the U.S. it is urgent that Americans have access to early treatment options.

Rather than seriously consider evidence showing the potential of early treatments including ivermectin, your agencies prefer to mischaracterize, conflate and misconstrue anything that goes against the mainstream narrative and the financial interests of the pharmaceutical industry. The American people deserve transparency from federal agencies and the most up-to-date information regarding COVID-19 to inform their health decisions. To better understand your agency's positions regarding early treatments for COVID-19, we respectfully request the following information:

1. Since 1996, the combined number of reported deaths associated with ivermectin on both VAERS and FAERS totals 379, with 3,680 adverse events.[17] In contrast, since December, 2020, the worldwide total number of deaths associated with COVID-19 vaccines reported on VAERS is 15,386 and the worldwide total number of adverse events exceed 725,000. In light of these numbers, please explain why the Centers for Disease Control and Prevention (CDC) and FDA believe that ivermectin presents a greater potential health risk, despite evidence showing its success in treating COVID-19, than the COVID-19 vaccines that have been associated with vastly more adverse events and deaths.

2. Please explain why your agencies have prejudged ivermectin's potential effectiveness while the NIH's phase 3 clinical trial of ivermectin remains ongoing.[18]

3. When did CDC begin to draft the August 26, 2021 health advisory on ivermectin?[19] Who made the decision to issue this health advisory? What specific data prompted and was used to draft the advisory?

4. Please provide a complete list of all early treatments (broken down by outpatient and inpatient) for COVID-19 that the federal government has examined and the amount funded for each treatment.

5. Please explain why budesonide has not been approved for COVID-19 patients in the U.S.

Please provide this material as soon as possible but no later than 5:00 p.m. on October 19, 2021. Thank you for your attention to this urgent matter.

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[16] VAERS is the Vaccine Adverse Event Reporting System.
[17] FAERS is the FDA Adverse Event Reporting System.
[18] ACTIV-6: COVID-19 Study of Repurposed Medications, ongoing, estimated completion date Mar. 2023, available at https://clinicaltrials.gov/ct2/show/NCT04885530.
[19] CDC Health Advisory, Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19, CDC, Aug. 26, 2021, available at https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf.

Sincerely,

Ron Johnson
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Tommy Tuberville
United States Senator

Michael S. Lee
United States Senator

Ted Cruz
United States Senator

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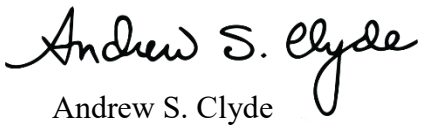

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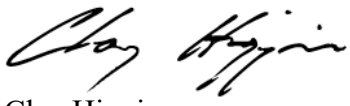

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