United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

December 10, 2020

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

Dear Director Collins:

On December 8, the Senate Homeland Security and Governmental Affairs Committee held a hearing titled, "*Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II.*"[1] At the hearing, physicians discussed early outpatient treatments for COVID-19 — using widely available, low cost drugs that have been used safely for decades. The physicians testified that early outpatient treatments could possibly save hundreds of thousands of lives.

Physicians approach diseases by focusing on early detection and treatment, which generally allows for better outcomes. However, with COVID-19, physicians have expressed concerns that the treatment guidelines from public health authorities, such as the National Institutes of Health (NIH), do not recommend treatments until patients are sick enough to require hospitalization. The current NIH guidelines state, "there are insufficient data to recommend either for or against any specific antiviral or antibody therapy" for non-hospitalized patients.[2] The absence of more specific guidance for the early treatment of COVID-19 concerns these physicians because the symptoms of the virus often get worse, thereby making hospitalization more likely, as the virus progresses. We agree with these physicians that the goal should be to control contagion and provide early outpatient treatments that attack the disease in the before late-stage hospital treatment and possible death.

During our committee's hearing this week, the physicians discussed the importance of utilizing every possible treatment (FDA EUA indicated and approved US off-label drugs and those approved for COVID-19 in other countries) option to address the needs of individual patients, especially in times of emergency. One treatment highlighted at the hearing was ivermectin, a treatment that won its creator a Nobel Prize in medicine and that is included in the World Health Organization's "World's List of Essential Medicines."[3] Unfortunately, despite a number of new studies, the NIH has not updated its guidelines since August 27, 2020, and state that the "COVID-19 Treatment Guidelines Panel recommends against the use of ivermectin for the treatment of COVID-19, except in a clinical trial."[4] Separately, a physician and CEO of a pharmaceutical company discussed a widely distributed oral antiviral, favipiravir, which is available in 30 countries, but not the United States.[5]

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[1] U.S. Senate Committee on Homeland Security & Governmental Affairs, *Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II* (Dec. 8, 2020), https://www.hsgac.senate.gov/early-outpatient-treatment-an-essential-part-of-a-covid-19-solution-part-ii

[2] *Therapeutic Management of Patients with COVID-19*, National Institute of Health (Dec. 3, 2020), https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

[3] Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II: Hearing Before the Senate Committee on Homeland Security and Governmental Affairs, 116 Cong. (2020) (Statement of Dr. Pierre Kory).

[4] *Ivermectin*, National Institute of Health (Aug. 27, 2020), https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/ivermectin/

[5] *Why home treatment of COVID-19 with several drugs is crucial*, The Hill (Oct. 1, 2020), https://thehill.com/opinion/healthcare/518589-why-home-treatment-of-covid-19-with-several-drugs-is-crucial.

We believe that Congress and the federal government must respond to the urgency of the present situation. Many Americans are being severely impacted by the devastating consequences of this disease, and public health authorities and pharmaceutical companies have provided few solutions for early treatments. For these reasons, we believe it is urgent that the federal government expedite review of low cost, widely available, and potentially beneficial early combination treatments including anti-infectives (favipiravir, hydroxychloroquine, ivermection, azithromycin, doxycycline), corticosteroids (dexamethasone, hydrocortisone, prednisone, inhaled steroids), and antiplatelet/antithrombotic (aspirin, low-molecular weight heparin, novel anticoagulants) drugs. Because there are no conclusive randomized trials of any single product in any setting, we request the NIH to expand their review to all study designs, from all countries, in all treatment settings, and consider the evidence in terms of probability of therapeutic gain balanced with safety.

Therefore, we ask that you review each of the basic science [1-13], clinical [14-25], and epidemiologic [26-28] studies in the appendix and update the treatment guidelines accordingly. Please provide an update on the status of the review of all early outpatient treatments currently under NIH review, as soon as possible but no later than 5:00 p.m. on December 23, 2020.

If you have any questions about this request, please ask your staff to contact Shani Rosenstock and Josh McLeod of Chairman Johnson's staff at (202) 309-7189. Thank you for your attention to this urgent matter and your continued leadership.

Sincerely,

Ron Johnson
Chairman
Senate Committee on Homeland
Security & Governmental Affairs

Rand Paul
United States Senator
Senate Committee on Homeland
Security & Governmental Affairs

Appendix

1. Arevalo AP, Pagotto R, Porfido J et al. Ivermectin reduces coronavirus infection in vivo: a mouse experimental model. bioRxiv 2020.
2. Caly L, Druce JD, Catton MG et al. The FDA-approved drug Ivermectin inhibits the replication of SARS-CoV-2 in vitro. Antiviral Res 2020.
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