NANCY MACE
1ST DISTRICT, SOUTH CAROLINA

COMMITTEE ON TRANSPORTATION
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COMMITTEE ON OVERSIGHT
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Hon. Xavier Becerra
Secretary
Department of Health & Human Services
200 Independence Ave SW
Washington, DC 20201

February 15, 2022

Dear Mr. Secretary,

I write to ask why the Department of Health and Human Services (HHS) has not pursued additional prophylaxis and therapeutics that could have: helped save American lives; helped keep the American economy and educational system; and helped maintain the fabric of the nation and our way of life?

Specifically, it has come to my attention that even prior to the initial vaccines, HHS, and its components; the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), were aware of data and expert determinations that simple nasal hygiene could serve as an effective additional layer of protection against the SARS-CoV-2 virus. This information was published around the same time that the CDC issued guidance, unsupported by any clinical data, that Americans should wear face masks.

Then, more than a year ago, a random clinical trial (RCT) done at Vanderbilt University, which was funded by NIH and republished by NIH on its website, clearly found that the use of simple saline nasal cleansing significantly reduced the severity of COVID-19 cases among already infected, symptomatic outpatients. None of these patients required hospitalization and none received additional supportive care.

At about the same time, a smaller clinical case study done at Larkin Hospital in Florida found that the use of one specific nasal cleansing product by outpatients infected and symptomatic with COVID-19 reduced the time to negation in half (the period from when a person tests positive to tests negative for the virus was cut by 50 percent or more) and reduced the average symptomatic period to just four days. The patients studied at Larkin all had moderate co-morbidities. No other supportive care was given. None required hospitalization or developed a more severe case. This research is also republished on the NIH's website.

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1st District, South Carolina

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More recently, a RCT done at Augusta University (GA) found that the use of simple saline nasal hygiene in treating COVID-19-infected people over the age of 50 reduced the risk of hospitalization 8-fold—this could be interpreted that nasal hygiene also had a significant effect in reducing morbidity.

I am also aware that a number of other nations, including Israel and New Zealand, are using and encouraging nasal hygiene to counter this virus. (Both of these nations, for example, have significantly lower COVID-19 death rates than ours.)

At the same time, I have been made aware that there is new *in vitro* data out of the Institute for Antiviral Research at Utah State that finds the FDA Emergency Use Approval (EUA) approved antiviral Remdesivir is ineffective against the Delta strain.

Beyond treatment, I am aware of additional *in vitro* research showing that some of these nasal cleansing countermeasures are highly effective antivirals (they block adhesion (infection) in the nose where the overwhelming majority of COVID-19 cases originate); and/or virucidals (they kill or deactivate the virus). While this is lab data, in large measure because your agency has thwarted efforts to study these countermeasures, it is more data than HHS has had to back a range of decisions on COVID-19.

To the extent that these countermeasures can/may provide similar benefits outside the lab in the real world, they could greatly reduce our rates of infection and transmission. They literally, could help turn the tide of this pandemic. Yet HHS seems to refuse to even consider these other approaches.

The efficacy data with respect to nasal hygiene is vastly greater than the efficacy data your agencies have used to justify a host of mandates and grant multiple EUA for other countermeasures. Which raises a host of questions about HHS actions and motivations.

Many of these nasal cleansing products have been sold in the United States for decades with no significant adverse effect reports—a safety record that is vastly more robust and unblemished than the EUA-approved vaccines. They are low cost and readily available—literally available online and in your corner drugstore today.

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New data shows that Omicron is capable of reinfecting people up to two times in a single month. Other new data suggest that 30-days post-injection the EUA vaccines are ineffective in preventing Omicron. Which is to say our vaccine-focused strategy faces serious challenges.

Further, with literally millions of new cases around the world each day, the vast majority from an already breakthrough variant, we face the serious and ongoing threat of a new, even more problematic variant.

At the same time, CDC's own data indicates that just 40 percent of those who are vaccinated are boosted. When you add that number to the number of people who aren't vaccinated in the first place, a large majority of Americans are completely unprotected from the virus (including millions that your data implies are protected).

Moreover, every one of our current vaccines are focused on the virus' spike protein, which is the area of the virus that is most rapidly mutating. Moreover, we also know that even to the extent the current vaccines can help you from getting "more sick," they don't prevent you from carrying, shedding and infecting others.

These RCT's and other data compel me to ask:

- Why hasn't HHS and its component agencies informed the American people about the potential benefits of nasal hygiene in protecting against COVID-19?
- Why hasn't HHS and its component agencies informed American healthcare professionals about the potential benefits of nasal hygiene in treating those already infected with COVID-19?
- If for some reason HHS doubts the already available data—including data HHS paid for and has republished—why hasn't your agency worked with the manufacturers of these countermeasures to facilitate and fast-track testing (and if warranted EUA approvals) for these products? (In the same way you have gone to great lengths to fund and otherwise support the major pharmaceutical companies making the vaccines.) Isn't that the very essence of the scientific method?
- Has HHS, and/or its component agencies, turned down requests from researchers to run clinical trials with nasal hygiene products to determine clinical efficacy as COVID-19 countermeasures (treatment and prevention)? If so, why?
- What funding does HHS have available to facilitate trials and/or other research into the use of nasal hygiene as a countermeasure to COVID-19? Congress previously

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appropriated hundreds of millions of dollars to the agency for precisely this sort of research. If no money is presently available for research on nasal hygiene, why is that the case? Where/how did HHS and its component agencies spend the hundreds of millions of already appropriated COVID-19 early intervention funds?

- To the extent that HHS and its component agencies spent these already appropriate funds on truly experimental countermeasures—ones with no supporting data, no existing safety—why didn't HHS invest in already available, already proven safe, already data-backed, possible countermeasures? With a raging pandemic, why did HHS and its component agencies not race to identify and grab commercially off-the shelf low-hanging fruit?

Given the urgency of the threat our nation faces from the rapidly evolving COVID-19 pandemic, I would appreciate your most prompt attention to these issues. If you should have any questions about these requests, please do not hesitate to contact Jackson.puckey@mail.house.gov at any time.

I look forward to receiving your reply. Thank you in advance.

Sincerely,

Nancy Mace

Congresswoman Nancy Mace
SC-01 | Cannon HOB 212