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January 26, 2023

The Honorable Kevin McCarthy
The Speaker of the House of Representatives
United States Capitol
Washington, DC 20515

House Committee on Energy & Commerce
ATTN: Chair Cathy McMorris Rodgers
2125 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Speaker and Chairwoman Rodgers:

As the chief legal officers of our respective States, the undersigned attorneys general write to urge the new Congress to modify, clarify, and rescind the emergency-use authorization authority under which the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA") approved novel COVID vaccines, override any such emergency-use authorizations that may still be in effect, prevent any future abuse of this provision, conduct rigorous oversight to establish what mistakes were made in this regard, consider revising the liability protections provided by a prior Congress, and confirm what President Biden has admitted and what the American people in their sound judgment know: any valid grounds for claiming a state of medical emergency due to COVID have ended; normalcy and the rule of law must be restored.

HHS and FDA continue to misuse the authority granted to the agencies for times of emergency. In particular, they continue to rely on emergency powers to justify numerous uses of novel vaccines that are not only failing to halt the transmission of COVID, but are also exposing young people (who are least likely to be harmed by COVID) to unnecessary risks. And while some vaccines have received full approval for some uses, shockingly, as recently as *last month*, FDA is still invoking its emergency use authorization authority to push vaccines out to *infants*.[1]

"The pandemic is over,"[2] according to President Biden. Yet, despite the President's proclamation[3], his Administration continues to operate under

[1] https://www.fda.gov/media/150386/download
[2] https://www.npr.org/2022/09/19/1123767437/joe-biden-covid-19-pandemic-over
[3] President Biden's declaration that the pandemic is over should also be understood as an admission against interest: his Administration's continued actions invoking emergency authority, including but not limited to any emergency use authorizations for vaccines, now lack any valid basis they may once have had.

emergency authorities. From student loan forgiveness to a moratorium on evictions, the President and his Administration continue to attempt to push through an authoritarian agenda based on an emergency that, according to the President, does not exist.

When emergency authorization was granted two years ago to get the first vaccines distributed, that authorization inherently considered the voluntary nature of the vaccine and the understanding that though the potential risks were not fully known, the benefits were believed to outweigh the risks for those most vulnerable to COVID. Of course, that was long before the federal government sought to mandate the vaccine nearly nationwide, and we have since learned far more about the vaccines, their efficacy, and their potential risks.

In short, things have changed. The American people, in their characteristic spirit of resilience, have learned to live with COVID. Even President Biden noted that people generally are no longer wearing masks, and mandates to do so have disappeared from all but the most sensitive areas. Schools, shops, restaurants, and businesses are open. City streets are bustling. The idea that we are still in the midst of a medical emergency flies in the face of the facts on the ground. Yet, HHS and FDA continue to perpetrate the myth that an emergency exists to aggrandize their power at the expense of people's freedom.

While many local abuses of authority have subsided, the Biden Administration continues to abuse and attempt to expand its authority even today. Therefore, the new Congress should act swiftly to clarify and amend the various statutory emergency authority provisions which FDA and HHS have abused in their unrealistic and impractical quest to operate under emergency authority indefinitely. Among other things, Congress should further narrow the unilateral authority that agencies and the President have during times of emergency, restoring the rightful balance between the branches of government. Given the lengths the Administration has gone to over the last two years to implement its agenda, it is without doubt that the Administration will use any emergency hook to clothe itself in powers previously unanticipated by Congress. These reforms will both bring an end to the ongoing attempt at medical tyranny, and ensure that the American people will never again be subjected to such an onslaught.

Additionally, the new Congress should reconsider the exceptionally broad liability protections which were enacted in 2005 in the form of the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d–6d. While some form of claims limitation may be appropriate to ensure America has a robust domestic supply of vaccines and other medical products, the PREP Act is particularly sweeping in scope. By its terms, it provides immunity to all state and federal claims for loss from vaccines and other "covered countermeasures" under emergency declarations by the HHS Secretary; purports to insulate the Secretary's actions under the Act from *all* federal and state judicial review, including mandamus; and separately preempts "any provision of [state] law or legal requirement" that might bring accountability for "covered persons" whose actions

in the area of vaccines and other measures may harm the states' citizens.[4] Particularly in light of this Administration's willingness to embrace a never-ending state of emergency, it is clear that the PREP Act deserves reconsideration and possible reform.

Currently, for an emergency authorization, the law requires the Secretary to conclude that the medical product in question may be effective in "diagnosing, treating, or preventing" a disease or condition.[5] While this may have been an acceptable position for the first approval in 2020, we now know much more about both the disease and the vaccines. In 2020, the vaccines were supposed to stop the spread by limiting who would get COVID.[6] In early 2021, reports were that the vaccines were in fact successful at preventing transmission.[7] However, we now know that people, such as Dr. Anthony Fauci, who are vaccinated, boosted, and boosted again, still can get COVID.[8] Repeatedly.[9] Nor do the vaccines assist in diagnosing or treating COVID. While those who are vaccinated may in some cases have less severe symptoms, that does not constitute treatment. The vaccines are not offered to people once they have COVID; they're offered to people prior to getting COVID. This is because COVID treatment and management for the overwhelming number of Americans is rest. According to the CDC, "[m]ost people with COVID-19 have mild illness and can recover at home. You can treat symptoms with over-the-counter medicines, such as acetaminophen (Tylenol) or ibuprofen (Motrin, Advil), to help you feel better."[10] Based on this knowledge, the vaccines, if considered today, likely would not pass the threshold question of whether the HHS Secretary could authorize them for emergency use.

Nevertheless, HHS and FDA persist. This is made worse by incidents of illness in younger people who are by and large not at high risk from COVID. In fact, the vaccine authorization panel concluded that the vaccines do not prevent passing the virus to other family members. This was after FDA's approval of the vaccines for the child immunization schedule. This Administration has increasingly become a global outlier in its insistence that *all* children should be vaccinated. More needs to be done—legislation, oversight, administrative reform, and public education—to stop this power and profit grab from continuing to steamroll our young people.

The emergency must have an expiration date. The Secretary of HHS has authority to approve the "emergency use" of certain products, but if the emergency never ends, then the Secretary has the authority to unilaterally issue final approval. Any declaration of emergency, for whatever purpose, can be an

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[4] Possible recourse is limited only to situations in which someone can prove "by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury." 42 U.S.C.A. § 247d-6d(c)(3), (d). Even proving "recklessness" is not enough. *Id.* § 247d-6d(c)(1)(B).

[5] See 21 U.S.C. Sec. 360bbb-3(c)(2)(A).

[6] https://www.cnbc.com/2020/11/09/covid-vaccine-pfizer-drug-is-more-than-90percent-effective-in-preventing-infection.html ("Pfizer and BioNTech announced Monday their coronavirus vaccine was more than 90% effective in preventing Covid-19 among those without evidence of prior infection . . .").

[7] https://fortune.com/2021/04/01/its-official-vaccinated-people-dont-transmit-covid-19/

[8] https://www.nih.gov/news-events/news-releases/niaid-director-fauci-tests-positive-covid-19

[9] https://www.cnn.com/2022/07/30/politics/joe-biden-covid-19-positive/index.html

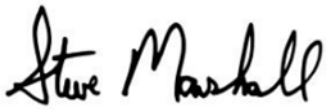
[10] https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html

end run to get around pesky and inconvenient statutes, regulations, public comments, etc. And if these emergencies never end, "the liberties our Constitution's separation of powers seeks to preserve would amount to little."[11]

Congress cannot allow bureaucrats buried deep within an agency to run roughshod over the President and Congress itself. The President has declared the pandemic over. Congress, too, is back to ordinary business. When we turn on the news at night, we rarely see masks worn by Administration officials, Congressional leaders, or even staff and media surrounding them. The White House Briefing Room appears as crowded as it was in 2019. Americans of all backgrounds and ages understand that the pandemic, and thus the emergency, are over. Federal agencies cannot be allowed to usurp Congress' authority and implement backdoor vaccine approvals (or other policies) by simply claiming an emergency.

We encourage the new Congress to move quickly to limit HHS' and FDA's ability to unilaterally declare an emergency and approve unproven drugs that could cause harm to Americans, override any remaining emergency use authorizations for COVID vaccines, consider reforms to the sweeping liability shield created in 2005, and ensure that our liberties and system of government are robustly protected against any such future attempts at medical tyranny.

Sincerely,



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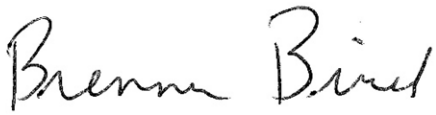
[11] *Nat'l Fed'n of Indep. Bus. v. DOL, OSHA*, 142 S. Ct. 661, 670 (2022) (Gorsuch, J., concurring).



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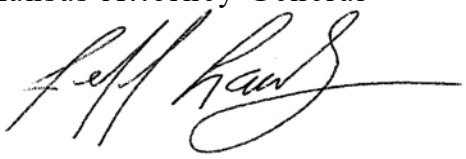

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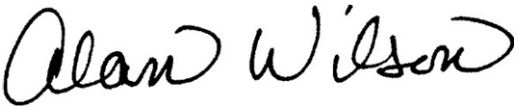

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