



**Statement for the Record of John Auerbach, MBA
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**“Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II”
Senate Homeland Security & Governmental Affairs Committee
Full Committee Hearing
December 8, 2020**

Chairman Johnson, Ranking Member Peters and Members of the Committee: Thank you for the opportunity to submit this statement for the record on behalf of Trust for America's Health (TFAH). Our organization is a nonprofit, nonpartisan public health policy, research and advocacy organization. At TFAH, we envision a nation that values the health and well-being of all and where prevention and health equity are foundational to policymaking at all levels of society. We recommend policies to advance an evidence-based public health system that is ready to meet the challenges of the 21st century, and the Coronavirus Disease 2019 (COVID-19) pandemic is one of these great challenges.

We have been invited to submit this statement on the public health implications of early access to outpatient treatment and to offer considerations for ensuring these treatments meet reach the people most in need as part of a larger public health strategy for responding to the pandemic.

This hearing is timely, as the nation is experiencing a post-Thanksgiving surge of over 200,000 new cases per day, and sadly over 2,000 deaths per day over the past week.¹ These numbers are truly staggering and extremely disheartening to the work of public health officials, healthcare providers, advocacy and community-based organizations, and researchers who have been working tirelessly over the past year to try to bring this deadly virus under control. Investments made by Congress have brought vaccines and therapeutics closer to a reality, but more needs to be done. While this hearing is on access to outpatient treatments, we believe this discussion has implications for other medical countermeasures, such as vaccines. We offer the following recommendations for the Committee and Congress:

Let Science Drive the Policies and Operations of Federal Agencies: It is critical that the nation's public health and scientific agencies that are involved in the research and development, evaluation, and allocation of outpatient treatments be free to work without risk of political interference. Even perceptions of political interference in the evaluation of drugs, devices and vaccines have enormous implications for trust in government and in medical research. We must remain vigilant that the urgency of finding treatments and other products does not come at the cost of guaranteeing the safety and effectiveness of these countermeasures. Faith in our institutions, as well as faith in the scientific breakthroughs that could help us out of this

¹ “US All Key Metrics.” The COVID Tracking Project at the Atlantic. As of Dec 5, 2020.
<https://covidtracking.com/data/charts/us-all-key-metrics>

pandemic, are at stake. In September 2020, a bipartisan group of seven former Food and Drug Administration (FDA) Commissioners published an opinion outlining examples of concerning actions that could impact the FDA's scientific standards and warned that the "perception of political influence matters."² If the American people feel they can no longer trust the FDA to protect them from harmful products and advance effective products, we may see people refusing to access a COVID-19 vaccine in the future.

Improve Communications and Transparency: FDA and other federal agencies must be transparent throughout the pandemic on evidence behind emergency use authorization (EUA) and other decisions. The Government Accountability recently found that evidence to support FDA's therapeutic authorization decisions has not always been transparent, and recommended ways to uniformly disclose information from its scientific reviews for EUAs.³ This transparency is important to rebuild public trust.

In October 2020, TFAH partnered with UnidosUS and the National Medical Association to host a convening on ways to earn and improve trust in and access to a safe and effective COVID-19 vaccine in communities of color and Indigenous communities. The overwhelming takeaway from this meeting was that trust must be earned. As we have seen, trust in medical research is especially low among African Americans, due to centuries of exploitation by American scientists and physicians.⁴ Many medical groups at our meeting stated they would not feel comfortable recommending a vaccine without access to data. These same lessons must apply to therapeutics being discussed at this hearing. Communications and engagement must be frequent as evidence changes, be culturally and linguistically appropriate, clearly communicate the risks and benefits, and be accessible to a range of medical providers and populations.

Equity in Access: Newly advanced treatments have the potential to reduce severe illness in some patients. However, there are major challenges in allocating treatments. First, demand for outpatient treatments far outstrips supply, as most states are only receiving hundreds of doses per week.⁵ Second, some of these treatments require access to an infusion center, which can be a challenge for people in rural or underserved areas. Allocation decisions for scarce products must be made based on risk, population, and equity. Within states, allocations should take into account social vulnerability. Some people of color and Indigenous communities have suffered disproportionately from COVID-19 and have also had a harder time accessing prevention and response resources, such as testing.⁶ We know that people who are uninsured are less likely to

²7 former FDA commissioners: The Trump administration is undermining the credibility of the FDA. *Washington Post Opinion*, Sept 29, 2020. <https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/>

³ COVID-19: Urgent Actions Needed to Better Ensure and Effective Federal Response. Government Accountability Office. Nov 30, 2020. <https://www.gao.gov/reports/GAO-21-191/>

⁴ RC Warren et al. Trustworthiness before Trust – Covid-19 Vaccine Trials and the Black Community. *New England Journal of Medicine Perspective*, Nov 26, 2020. <https://www.nejm.org/doi/full/10.1056/NEJMp2030033>

⁵ Allocation of Bamlanivimab by Jurisdiction, in PHE.gov. Dec 5, 2020.

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/allocation.aspx>

⁶ L Rubin-Miller, et al. COVID-19 Racial Disparities in Testing, Infection, Hospitalization, and Death: Analysis of Epic Patient Data. Kaiser Family Foundation, Sept 16, 2020. <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/>

have healthcare access, meaning people without insurance could have higher barriers to receiving outpatient treatments or could be too sick to benefit from them by the time they gain access to care.^{7 8} Federal and state policymakers must therefore address barriers to access within communities, such as engaging, training, and resourcing facilities that serve populations at disproportionate risk and guaranteeing access regardless of ability to pay.

Expand Public Health and Prevention Measures: As a public health organization, we would be remiss if we did not emphasize that outpatient treatments must be only one tool in a multifaceted approach to bringing the pandemic under control. Early outpatient treatment will only be effective if we can identify COVID-19 infections among target populations within the appropriate time. We are almost a year into the pandemic, yet there are shortages of testing supplies, personal protective equipment and other medical supplies.⁹ We still have major data gaps, including lack of disaggregated data reporting by health systems and laboratories, with health departments attempting to track the disease with archaic methods such as telephone and fax.¹⁰ We urge Congress to quickly pass COVID-19 legislation with robust funding for public health response activities such as vaccination, testing, contact tracing, and surveillance. We also ask Congress to look ahead to rebuilding and modernizing public health infrastructure, so that we can prevent the next pandemic before it reaches this level of devastation. For more information, see TFAH's [Blueprint for the 2021 Congress and Administration](#), which outlines why a sustained investment in state, local, tribal and territorial public health as well as the Centers for Disease Control and Prevention (CDC) is absolutely critical to saving lives in pandemics and public health emergencies.

We thank you for the opportunity to offer our statement today. This Committee has a long-standing interest in health security issues, and we appreciate your continued interest in ways to address the COVID-19 pandemic.

⁷ J Tolbert et al. Key Facts about the Uninsured Population. Kaiser Family Foundation. Nov 6, 2020.

<https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>

⁸ L Rubin-Miller, et al. COVID-19 Racial Disparities in Testing, Infection, Hospitalization, and Death: Analysis of Epic Patient Data. Kaiser Family Foundation, Sept 16, 2020. <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/>

⁹ COVID-19: Urgent Actions Needed to Better Ensure and Effective Federal Response. Government Accountability Office. Nov 30, 2020. <https://www.gao.gov/reports/GAO-21-191/>

¹⁰ A Greenblatt. Faulty Data Systems Are Still Hampering Pandemic Response. Governing, Dec 1, 2020. <https://www.governing.com/now/Faulty-Data-Systems-Are-Still-Hampering-Pandemic-Response.html>