

United States Senate

WASHINGTON, DC 20510-1304

October 21, 2021

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

The Honorable Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Secretary Becerra and Acting Commissioner Woodcock:

The Biden Administration's dramatic efforts to scale up vaccinations for 77 percent of eligible Americans has been an impressive and successful initiative. But more than a year and a half into the COVID-19 pandemic, our nation's testing infrastructure remains an important and under-developed aspect of our public health emergency response. This is especially true following President Biden's laudable vaccination requirements through the Occupational Safety and Health Administration (OSHA)—which rely on rapid, dependable testing options to keep workplaces safe. I write to urge the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) to explore additional flexibilities in its regulatory framework for at-home rapid testing, in order to reflect the public health benefit of accessible, reliable, affordable testing capacity.

Since the outset of the pandemic, the FDA has utilized an array of tools to swiftly and impressively respond to the nation's testing needs, issuing emergency use authorizations (EUAs) to more than 400 COVID-19 tests and sample collection devices. In September 2021, the United States averaged approximately 1.5 million COVID-19 tests per day, largely a reflection of the robust capabilities of our public health and commercial laboratories. But as the pandemic shifts to a new stage where vaccinations have reopened large segments of society but infections—either breakthrough cases or among the unvaccinated—remain a potent concern, the ability to have immediate, dependable testing is imperative.

Accessing rapid antigen tests as a way to promote safety in return-to-work, travel, education, or other gatherings will be necessary at this new phase of the pandemic. These at-home tests can complement the gold standard of polymerase chain reaction (PCR) testing, which typically has a turnaround of several days for results. I am pleased to see the Biden Administration support this premise by investing \$1 billion in at-home tests earlier this month to help quadruple the market to 200 million tests per month by the end of the year.

In order to maximize the public health benefit and utility of this rapid testing capacity, FDA and HHS should explore appropriate flexibilities in its regulatory standards to better enable additional accurate, at-home rapid tests to come to market and be accessible in an over-the-counter (OTC) manner for the general public.

Alongside the clinical value of PCR diagnostics to confirm an individual's infection, the ability to have quicker notification times and at-home access is not just a matter of convenience, but of public health interest to specifically detect when someone is infectious and provide accurate, actionable information about transmission risk. Yet despite the different functions between clinical diagnosis and mitigating transmission, the FDA establishes the same validation standards for these rapid antigen tests as for the more thorough PCR diagnostic tests, which can remain positive even beyond an individual's isolation window. Presently, a rapid antigen test seeking an EUA to be available OTC for at home use must demonstrate 80 percent sensitivity including among asymptomatic individuals to a PCR test. Yet the Centers for Disease Control and Prevention (CDC) recognizes that individuals who have already recovered from COVID-19 can still have detectable virus specimens for three months, suggesting that this reality could be weighed when assessing testing sensitivity standards. Given the public health benefit of the immediate and actionable information that a rapid at-home can provide, it may be possible to maintain accuracy without applying a commensurate sensitivity threshold of the longer positivity result window that a PCR test can detect.

While I strongly support the FDA's work to ensure the highest quality and confidence in tests on the market, especially PCR diagnostics to confirm an infection, there may be value and a credible way to safeguard accuracy while exploring a flexible public health approach for rapid tests to demonstrate an alternate threshold of sensitivity given the distinct role they can play. There currently are a few rapid antigen testing products on the market which may be appropriate as predicates for sensitivity in such a public health standard.

Attention to the promise of rapid at-home tests is just one aspect that of the nation's broader testing infrastructure, and it should not come at the expense of further support for the capacity of PCR tests, which remain the most common and accurate form of testing. In exploring a framework that reflects the reality of this public health testing capability, it remains important that the administration of at-home tests be properly authenticated and relevant data results shared with public health authorities to ensure an accurate and complete picture of the level of transmission in a community. To the extent that FDA and HHS work with manufacturers of rapid at-home tests, visibility into results will remain an important function.

I also urge HHS to continue its efforts of using funds appropriated by Congress from the American Rescue Plan, and prior COVID-19 relief legislation, to ensure FDA-authorized tests are widely disseminated, accessible in high-risk communities, and affordable so that cost does not pose a barrier to this public health tool—as many peer countries have done. Thank you for your consideration of this request to help promote our shared public health and testing goals.

Sincerely,



Richard J. Durbin
United States Senator