Congress of the United States
Washington, DC 20515

September 2, 2020

Stephen Hahn, M.D.
Commissioner
United States Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Hahn:
We are writing to request the United States Food and Drug Administration (FDA) consider an expedited authorization and lower sensitivity standards for low-cost, rapid, in-home coronavirus tests. In the absence of an authorized vaccine or cure for COVID-19, returning to a normal way of life will require affordable, frequent testing for almost all Americans.

The medical research community is working to develop technology[1] that would allow a user to test their own saliva on a paper strip indicating if the individual may be infectious with COVID-19 within as little as 15 minutes. At a price point as low as one dollar per strip, these screenings can easily be mass-produced and distributed usage daily or every other day.

While the current sensitivity-standard is appropriate for polymerase chain reaction (PCR) testing for those who are showing symptoms or have recently been in contact with a COVID-19-positive individual, reopening our economy will require a scalable solution. A recent Duke University paper[2] co-authored by Mark McLellan, the former FDA Commissioner under President George W. Bush, argues for, "broad availability of more rapid but sometimes less accurate screening tests...to detect outbreaks sooner and give people more confidence in their workplaces and schools." These faster tests can catch people when they have the highest levels of virus -- that is, when they are most contagious -- and often before symptoms begin to show. We need a broad public health strategy that allows for consistent monitoring of institutions and communities.

We appreciate the FDA's recently released application template[3] for at-home testing, which signals the importance of these types of screening tools, but we have heard from experts who believe the standard remains too strict. Based on the work of scientists from Harvard University and the University of Colorado, Boulder, we are concerned that FDA's current testing authorization pathway does not provide a means by which FDA could authorize these low-cost, rapid, in-home screening devices in a timely manner for our current need. We urge the FDA to recognize frequent screenings serve a different role than diagnostic tests and give favorable consideration under current rules or create a separate pathway for this additional public health tool.

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[1] https://news.harvard.edu/gazette/story/2020/08/cheap-daily-covid-tests-could-be-akin-to-vaccine/
[2] https://healthpolicy.duke.edu/sites/default/files/2020-08/COVID%20testing%20legislative%20recs%20FINAL_WITH%20COVER%208-6-2020.pdf
[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-posts-new-template-home-and-over-counter-diagnostic-tests-use-non

CDC analyses[4] suggest that we are identifying only about one in ten[5] cases of COVID-19, mostly because we are testing so few people with highly sensitive but resource-intensive PCR tests. A high-frequency test would easily make up the gap in sensitivity. Ashish Jah, Director of the Harvard Global Health Institute wrote in a recent *TIME*[6] op-ed, "if everyone took an antigen test today—even identifying only 50 percent of the positives—we would still identify 50 percent of all current infections in the country – five times more than the ten percent of cases we are likely currently identifying because we are testing so few people."

Until we have a widely administered vaccine or highly effective treatment for COVID-19, re-opening schools and returning our lives to normal will require an accessible testing strategy that is far broader than currently possible. The United States still tests fewer than one million people per day. Recent reports of backlogged results due to overstrained labs and shortages of personal protective equipment and testing reagents suggest that our current system is near daily capacity. A recent study from the *Journal of the American Medical Association Network Open*[7] finds that safely reopening college campuses this fall will require screening the nation's nearly 20 million postsecondary students every two days. This is impossible under our current testing strategy.

We value the FDA's work to validate and authorize Emergency Use Authorizations allowing for pooled PCR tests and diagnostic saliva-based testing, but we must have every tool available. We urge the FDA to utilize its existing authority and consider options such as providing an expedited pathway for authorization of low-cost, rapid, at-home COVID-19 screenings during this global pandemic, including paper-strip testing. Knowing with greater likelihood whether a person is transmitting the virus can influence behavior and will be key to curbing infections and reopening our economy.

We also urge you to coordinate across federal agencies, including the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA), to engage in a public information campaign to explain the difference between diagnostic and screening tests.

We appreciate the FDA's hard work throughout this crisis and recognize the need for a flexible approach to taking on the current pandemic. We appreciate your attention to this critical and timely matter.
Sincerely,

Ro Khanna
Member of Congress

Rodney Davis
Member of Congress

[4] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768834
[5] https://www.washingtonpost.com/health/2020/06/25/coronavirus-cases-10-times-larger/
[6] https://time.com/5873444/radically-rethink-covid-19-testing-approach/
[7] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768923?resultClick=3

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Bill Foster
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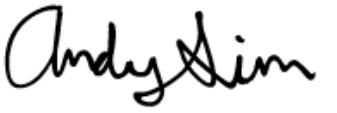

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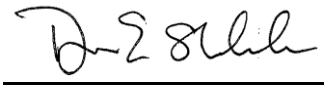

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