Congress of the United States

House of Representatives
Washington, DC 20515

February 16, 2021

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

Dear Acting Commissioner Woodcock,

As vaccines roll out across the country, our nation will still need a robust COVID-19 testing strategy to monitor and contain the virus. Different types of tests serve different purposes. The PCR testing broadly used now is an excellent diagnostic test, ideal for people with symptoms. By comparison, an easily accessible antigen test with a fast result that can be taken at home or in the workplace, without a prescription, could serve an entirely different purpose. It could help identify asymptomatic people before they spread the disease to others, and allow our communities and Main Street businesses to operate much more safely. Used on a regular basis, this sort of at-home antigen testing is a critical tool in the public health toolbox.

Since the beginning of this crisis, the New Democrat Coalition has been laser-focused[1] on enacting a national recovery strategy[2] through widespread, coordinated testing, tracing, and containment. **As members of the New Democrat Coalition, we write today to urge you to use your authority to conduct an independent comparative evaluation of rapid, lateral flow antigen tests.**

Regularly performed, at-home testing helps individuals make informed decisions and is a critical strategy for controlling the spread of COVID-19, yet the U.S. is still not using it effectively. Of course, no single testing regimen or prevention technique is entirely effective on its own, but frequent home testing will catch infectious asymptomatic people who might not otherwise get tested, or who become infectious following a negative PCR test.

A full year into the pandemic, FDA has still only authorized a single at-home test available without a prescription. The price point of that test effectively puts it out of reach for that vast majority of Americans to use with any regularity, and limits the purchasing power of the government, which could procure and distribute tests. And the manufacturing capacity falls far

[1] https://newdemocratcoalition.house.gov/media-center/press-releases/new-democrat-coalition-urges-house-and-committee-leadership-to-act
[2] https://newdemocratcoalition.house.gov/media-center/press-releases/new-democrat-coalition-urges-house-leadership-to-implement-a-national-recovery-strategy

short of what is needed in this moment. Realistically, to use this as a public health tool to stop the spread, we'd need to have widespread testing multiple times per week.

The barrier to getting rapid tests into the hands of Americans is two-fold: one, we need to know which test gives the best result and two, we need to manufacture and distribute these tests at scale so that every person has access to inexpensive, rapid tests.

We share your commitment to quality and understand the enormous volume of Emergency Use Authorization (EUA) applications. That is why we believe undertaking a similar approach for rapid, lateral flow antigen tests as was taken to independently evaluate the performance of certain serology tests is a necessary step to meet current testing needs.

As part of a collaboration between the FDA and National Cancer Institute, last year Frederick National Laboratory for Cancer Research completed comparison testing to validate antibody tests[3] to ensure effectiveness and standardization—essentially comparing apples to apples. If lateral flow antigen tests could get this treatment, we would be able to identify and confidently select the best tests to scale.

In order to best inform our ongoing work to effectively implement a national testing strategy, we ask the following questions:

1. Does the FDA currently have the authority to conduct an independent evaluation of rapid antigen tests as described? Is additional Congressional Authorization needed?
2. Would the FDA be able to conduct such an evaluation of already authorized tests, in addition to tests submitted to the FDA awaiting authorization?
3. Does the FDA currently have plans to undertake a standardized evaluation of rapid antigen tests?
4. Under the current process could the validation testing results be used in the determination of granting an EUA?
5. What additional resources would be needed to conduct this evaluation and update it as needed?
6. Based on previous efforts, how long would you estimate such an evaluation may take?
7. Could evaluating comparative effectiveness of all submitted tests at the same time help reduce the backlog of EUA submissions?

This pandemic has been long and hard on all of us. Even as the vaccine gives us a light at the end of the tunnel, we know this virus continues to circulate and mutate. We are going to have to live with COVID-19 for a long time. Having accessible, inexpensive rapid antigen testing is key to allowing our economies to open and our families to stay safe.

We encourage you to take action today that will help pave the way for widespread, inexpensive home tests and stand ready to support these efforts. We look forward to working with you as you navigate and implement a powerful and effective national testing strategy.

Sincerely,

[3] https://federallabs.org/news/nci-and-fnl-lead-federal-effort-to-evaluate-antibody-tests-for-covid-19-virus

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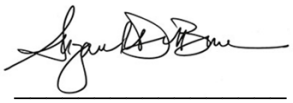

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cc: Francis Collins, Director, National Institutes of Health
Rochelle Walensky, Director, Centers for Disease Control and Prevention