September 9, 2021

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

The Food and Drug Administration's failure to authorize sufficient rapid at-home antigen tests is leaving the United States without a key tool against the ongoing COVID-19 pandemic. Because of this failure, America faces high prices and shortages of these critical tools.

Until recently, the Director of the Food and Drug Administration's Office of In Vitro Diagnostics and Radiological Health (OIR), Dr. Timothy Stenzel, who oversees authorization of COVID-19 rapid tests, restricted authorization to two products. These tests were produced by Quidel Corporation and Abbott Laboratories, where Dr. Stenzel previously held significant positions, most recently as the Chief Scientific Officer of Quidel from 2009 to 14 and Senior Director of Medical, Regulatory, and Clinical Affairs for Abbott Molecular (a Division of Abbott Laboratories) from 2003 to 07.

We are concerned the FDA's failure to authorize additional rapid tests is the result of corruption related to Dr. Stenzel's previous affiliations with Quidel and Abbott.[1] Additionally, there is evidence that Dr. Stenzel or an affiliated FDA official specifically encouraged and promoted Quidel products during the pandemic.[2]

We write to request an immediate investigation into Dr. Stenzel and the FDA's failure to authorize additional rapid at-home antigen tests throughout the COVID-19 pandemic. As you conduct this investigation, we request that you place Dr. Stenzel on administrative leave or replace him as the officer over this critical product segment.

As of today, the FDA has granted Emergency Use Authorization (EUA) to the following at-home rapid antigen tests for COVID-19:[3]

Rapid, At-Home Covid Tests with EUA

Original EUA Issued	Entity	Diagnostic
March 31, 2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test
March 31, 2021	Abbott Diagnostics	BinaxNOW COVID-19 Antigen Self Test
June 4, 2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test
August 23, 2021	Access Bio, Inc.	*CareStart* COVID-19 Antigen Home Test
August 24, 2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test

As shown, Quidel and Abbott Diagnostics enjoyed a significant advantage by being the only two companies with authorized products from March 31 until June and then late August. Although several

[1] Duke Pathology, *Alum Headed for 'Once-in-a-Lifetime Job' at FDA*, https://pathology.duke.edu/alum-headed-to-fda.
[2] *See Quidel: Our Response to Covid-19,* (Nov. 27, 2020), https://www.youtube.com/watch?v=E5rbDvv326s (around 00:30 seconds).
[3] FDA.gov, *Antigen Diagnostic Tests for SARS-COV-2*, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.

additional tests received authorization late last month, they do not appear to be widely available because of the lag in authorization, while investment by other entrants is likely chilled by the FDA's regulatory bottleneck. Today, Quidel and Abbott still appear to be the most widely available rapid antigen test products.

The difference between the availability and cost of rapid antigen tests in the U.S. and Europe is stark. Germany, for example, has approved more than 50 rapid tests, including products made by American companies that have not received authorization in the United States.[4] This has created an enormous price difference between countries with competitive markets, where consumers can purchase such tests for the equivalent of several dollars, and the U.S., where retailers are currently charging $23.99 for Quidel and Abbott testing kits, and both companies are still failing to meet demand even at these exorbitant prices.[5]

COVID-19 testing has been a windfall for Quidel, which is the result of the company receiving early authorization of its rapid test and other testing products. In fact, Quidel and Abbott are the two companies with the most EUAs for all COVID antigen diagnostics, with each company currently having five (5) EUAs.[6] The FDA not only failed to authorize enough tests – it has actively discouraged the use of what appear to be high quality products, including the Innova Medical Group Rapid Antigen test, which has been used by the millions in the United Kingdom and is being sold for a fraction of Quidel and Abbott's price.[7]

Considering this situation, we ask that HHS immediately investigate Dr. Stenzel's involvement in the FDA's failure to authorize more rapid at-home antigen tests throughout the pandemic, including his relationship with Quidel and Abbott, and place Dr. Stenzel on administrative leave during the course of any such investigation.

Regards,
American Economic Liberties Project

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[4] Alex Tabarrok, Marginal Revolution, *Why Doesn't the United States Have Test Abundance* (Aug. 25, 2021), https://marginalrevolution.com/marginalrevolution/2021/08/testing-abundance.html.

[5] CVS.com, https://www.cvs.com/shop/abbott-binaxnow-covid-19-antigen-self-test-2-tests-for-serial-testing-prodid-550147 ("out of stock online" as of Sept. 7, 2021).

[6] FDA.gov, Antigen Diagnostic Tests for SARS-COV-2, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.

[7] FDA, *Stop Using Innova Medical Group SARS-COV-2 Antigen Rapid Qualitative Test: FDA Safety Communication* (June 20, 2021), https://www.fda.gov/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication. *See also*, Fierce Biotech, *U.K. Doubles Down on Innova's Rapid COVID-19 Test, After FDA Urged Users to Throw it Away* (June 18, 2011), https://www.fiercebiotech.com/medtech/u-k-doubles-down-use-rapid-covid-test-after-fda-urged-users-to-throw-it-away.