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ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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May 11, 2020

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

Dear Secretary Becerra:

On October 7, 2020, we wrote to former Secretary of Health and Human Services (HHS) Alex Azar with serious concerns about his decision to remove the authority of the Food and Drug Administration (FDA) to require premarket review of coronavirus disease of 2019 (COVID-19) laboratory developed tests (LDTs).[1] As we wrote then, this policy change raised questions about the reliability of tests on the market and threatened to alter our understanding of COVID-19 outbreaks and the progression of the pandemic.

Unfortunately, despite objections from career scientists at FDA and other public health experts, the Trump Administration policy revoking FDA's authority remains in place. Access to accurate diagnostic tests is a vital piece to our ongoing effort to stop the spread of COVID-19 and eventually ending the pandemic. We therefore request that you immediately reverse the Trump Administration's shortsighted policy and restore FDA's premarket review authority and oversight over COVID-19 LDTs.

While FDA has typically exercised enforcement discretion for LDTs, allowing them to come to market without prior review, the agency has maintained that "clinical laboratories that develop [in-house] tests are acting as manufacturers subject to FDA jurisdiction under the [Federal Food Drug and Cosmetic Act]."[2] During public health emergencies, including the

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[1] Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Anna Eshoo, and Rep. Diana DeGette, House Committee on Energy and Commerce, to Alex M. Azar II, Secretary, U.S. Department of Health and Human Services (Oct. 7, 2020).

[2] U.S. Food and Drug Administration, *In Vitro Diagnostic Multivirate Index Assays – Draft Guidance for Industry, Clinical Laboratories, and FDA Staff* (July 26, 2007). *See also* Leslie Kux, FDA Assistant Commissioner for Policy, Letter in Response to American Clinical Laboratory Assn. Citizen Petition of June 4, 2013 (July 13, 2014) (concluding that "LDTs are

COVID-19 pandemic, FDA has enforced its regulatory authority over LDTs, requiring laboratories to seek authorization prior to marketing the test. On February 29, 2020, FDA issued guidance detailing how it would evaluate emergency use authorization (EUA) requests for COVID-19 LDTs and other molecular diagnostic tests.[3] Specifically, the guidance advised that laboratories should submit an EUA request for an LDT within 15 days of validating the test, which would then be evaluated by FDA.[4]

The Trump Administration upended LDT regulation on August 19, 2020, when HHS hastily posted a one-paragraph announcement stating that FDA would no longer require premarket review of COVID-19 LDTs, absent notice-and-comment rulemaking.[5] Although HHS said in its announcement that LDT developers could continue to voluntarily seek EUAs for their tests, FDA then announced on October 9 that it would decline to review EUA requests for LDTs.[6]

Following this announcement, concerns were raised that new LDTs would no longer be eligible to receive an EUA, and thus would not be eligible for liability protections under the Public Readiness and Emergency Preparedness (PREP) Act. As a result, HHS attempted to shoehorn a fix to the problem of its own creation by instructing the National Cancer Institute (NCI) to review LDTs in FDA's stead.[7] In the last days of the Trump Administration, HHS also entered into an uncompetitive, sole source contract to farm out these important responsibilities to NDA Partners, a private consulting firm.[8]

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devices within the plain language of the FDCA," and that "FDA has consistently maintained its authority to regulate LDTs under the FDCA for many years but has chosen to exercise enforcement discretion); Jeffrey Shuren, Director, FDA Center for Devices and Radiological Health, *Examining the Regulation of Diagnostic Tests and Laboratory Operations*, Statement before the Subcommittee On Health, Committee on Energy & Commerce (Nov. 15, 2015) (noting that "FDA regulates IVDs under the Medical Device Amendments of 1976, which applies to all devices" and "LDTs are IVDs").

[3] U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Policy for Coronavirus-2019 Tests During the Public Health Emergency: Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Admin. Staff* (Feb. 29, 2020).

[4] *Id.*

[5] Congressional Research Service, *HHS Announcement on FDA Premarket Review of Laboratory-Developed Tests (LDTs)*, (Dec. 3, 2020) (CRS Rept. IN11548).

[6] *FDA to stop reviewing COVID-19 lab tests, raising concerns in Congress*, Biocentury (Oct. 7, 2020).

[7] *Another U-turn for COVID-19 testing regulation as HHS requires FDA to re-prioritize LDT review*, Biocentury (Nov. 17, 2020).

[8] *Trump admin enlists private firm to review some COVID-19 tests*, Politico (Jan. 17, 2021).

This long winding path of regulatory uncertainty has been misguided from the start. The former FDA Commissioner and career scientists at FDA reportedly opposed the move, telling HHS officials that the decision could lead to inaccurate tests flooding the market.[9] In a New England Journal of Medicine article published weeks after the HHS announcement, Jeff Shuren, the Director of FDA's Center for Devices and Radiological Health, and Timothy Stenzel, the Director of FDA's Office of In Vitro Diagnostics and Radiological Health, illustrated the importance of FDA's premarket reviews. In that article, written prior to the August 19 HHS policy change, FDA found many problems related to performance or poor validation in COVID-19 LDTs.[10] According to Drs. Shuren and Stenzel, FDA found design or validation problems in nearly 66 percent of LDT EUA requests, and noted that in most cases, FDA worked with laboratories to correct any issues to allow for continued testing.[11]

The steps the Trump Administration took to address the problems created in the policy decision's wake—namely asking NCI to review tests, and later contracting with NDA Partners to provide review—were woefully inappropriate. Only FDA has the legal responsibility, as well as the experience and expertise, to evaluate the accuracy and reliability of diagnostic tests. In the midst of a viral pandemic, this responsibility should not be handed off to an obscure federal contractor or a different enterprise within the federal government. While NCI is home to world renowned researchers, the institution does not have experience in regulating diagnostic tests or evaluating the risk-benefit profile of products to determine whether LDTs should receive an EUA.

As our nation continues to confront the COVID-19 pandemic with a hope of soon returning to normal patterns of life, access to accurate and reliable tests will remain critical. We ask that you take steps to ensure the quality of these tests by reversing the Trump Administration's misguided policy on LDTs and restoring FDA's premarket review authority.

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[9] *HHS chief overrode FDA officials to ease testing rules*, Politico (Sept. 15, 2020).

[10] Jeffrey Shuren and Timothy Stenzel, *COVID-19 Molecular Testing — Lessons Learned*, New England Journal of Medicine (Sept. 9, 2020).

[11] *Id.*

Thank you for your attention to this matter. Should you have questions about these requests, please contact Stephen Holland of the Majority staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Anna G. Eshoo
Chairwoman
Subcommittee on Health

Diana DeGette
Chair
Subcommittee on Oversight
and Investigations