United States Senate
WASHINGTON, DC 20510

August 26, 2020

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

Dear Secretary Azar:

I write to express my concerns regarding the Department of Health and Human Services' decision to allow the marketing of all laboratory-developed tests (LDTs) without Food and Drug Administration (FDA) review. This unprecedented action exacerbates the Administration's failures to develop and implement a testing system during the COVID-19 pandemic,[1] severely undermines FDA's ability to ensure that critical tests deliver accurate, reliable results, and could seriously damage public confidence in testing accuracy at a moment when sustaining that trust is essential. It's unconscionably reckless for the Trump Administration to allow low quality COVID-19 tests to flood the market as people across the country are relying on the tests to make life and death decisions.

Last week, in a one-paragraph announcement on its website, the Department imposed severe restrictions on FDA's ability to oversee LDTs and reversed FDA's longstanding regulatory scheme for certain LDTs, including during an emergency.[2] Absent from the Department's cursory statement is any public health basis or legal support for its change in policy regarding these tests.

The middle of a devastating pandemic is the wrong time for the Administration to choose not to use all of its available authorities to ensure COVID-19 tests deliver accurate, reliable results. By weakening FDA testing surveillance and review efforts, the policy change will encourage the proliferation of inaccurate, if not fraudulent, tests. At a time when schools, employers, and health care systems are seeking to use testing to protect health and safety, eliminating regulation of products integral to the COVID-19 response puts the health of people across the country at greater risk during the COVID-19 pandemic and erodes public trust in FDA's oversight of medical products. This type of "bureaucratic fight" over the review of medical products — described by one public health expert as "threatening FDA's science and independence" [3] — raises new questions about FDA's autonomy to review and approve COVID-19 vaccines according to established legal and regulatory standards.

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[1] https://www.help.senate.gov/imo/media/doc/HELP%20Committee%20Democratic%20Staff%20Testing%20Report%20FINAL.pdf
[2] https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html
[3] https://www.cnn.com/2020/08/21/health/covid-lab-developed-tests-fda-hhs-bn/index.html

The Department's policy shift may have other far-reaching public health consequences, including potentially hindering FDA's ability to enforce compliance with new or existing emergency use authorizations for COVID-19 LDTs,[4] as well as clearances and approvals for non-COVID-19 LDTs, such as cleared or approved companion diagnostics.[5] These effects on FDA's enforcement authorities further increase the danger that people will rely on unreliable tests to make decisions about their lives and the lives of their families. Without oversight over these tests, FDA cannot ensure they continue to meet standards for safety and effectiveness.

This move to work around FDA's authority is even more alarming in light of President Trump's recent decision to baselessly and falsely accuse FDA of being part of a conspiracy to slow progress on COVID-19 vaccines and treatments. These efforts to undermine the work of FDA scientists, with statements that chip away at public trust and actions that strip away the agency's regulatory authority, are incredibly dangerous. The American public must have absolute confidence that experts at FDA are being empowered not sidelined, and that the agency is basing its decisions on science, not political pressure or conspiracy theories.

I request that you provide a briefing within 15 days that includes officials from all relevant agencies involved in this matter to obtain further information. To further discuss compliance with this request, please contact Kathleen Borschow and Katlin McKelvie Backfield with my Health, Education, Labor, and Pensions Committee Staff at (202) 224-0767.

Sincerely,

PATTY MURRAY
United States Senator
Ranking Member, Senate Health, Education,
Labor, and Pensions Committee

[4] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#LDTs
[5] https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools