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Congress of the United States
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October 7, 2020

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

Dear Secretary Azar:

We write today with serious concerns about the nation's testing landscape and politics once again interfering with public health at the Department of Health and Human Services (HHS). For months, the Administration has failed to take responsibility for developing and implementing a national coronavirus disease of 2019 (COVID-19) testing strategy, which has resulted in uncontrolled spread of the virus and continuous supply chain problems. We now believe you have once again committed a grave error in overruling objections of career scientists at the Food and Drug Administration (FDA) by announcing that HHS would allow marketing of laboratory-developed tests (LDTs) without FDA review.[1, 2] This new policy, which was made without prior notice or warning, could lead to numerous faulty tests on the market, raising serious concerns about the reliability of tests used to detect COVID-19.

Since the beginning of the COVID-19 outbreak, public health experts have been calling on the Administration to improve access to reliable diagnostic testing to help slow the spread of the virus. While the initial development of diagnostic tests was far too slow and impaired our ability to gain control of the virus, on February 29, FDA issued guidance detailing how it would evaluate emergency use authorization (EUA) requests for molecular diagnostic tests, including LDTs.[3] Specifically, the guidance advised that laboratories should submit an EUA request for an

[1] U.S. Department of Health and Human Services, *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests*, (www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html) (August 19, 2020) (accessed Oct. 7, 2020).

[2] *HHS Chief Overrode FDA Officials to Ease Testing Rules*, Politico (Sept. 15, 2020).

[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*

LDT within 15 days of validating the test, which would then be evaluated by FDA.[4] This followed long-standing FDA policy and interpretation of the Federal Food, Drug, and Cosmetic Act (FFDCA). While the agency has typically exercised enforcement discretion for LDTs, allowing them to come to market without prior review, it has maintained that "clinical laboratories that develop [in-house] tests are acting as manufacturers subject to FDA jurisdiction under the [FFDCA]."[5]

During public health emergencies, such as the COVID-19 pandemic, FDA has enforced its jurisdiction over LDTs, requiring laboratories to seek authorization prior to marketing an LDT. This is warranted because, as former FDA Commissioner Scott Gottlieb recently wrote, in public health emergencies, diagnostic tests not only diagnose diseases that aren't completely understood, "but help guide analyses of disease progression and risks to public health. Precision matters. False negative results can have serious adverse consequences."[6]

Furthermore, Jeff Shuren, the Director of FDA's Center for Devices and Radiological Health, and Timothy Stenzel, the Director of the Office of In Vitro Diagnostics and Radiological Health, recently underscored this point in the New England Journal of Medicine. They wrote that many COVID-19 LDTs reviewed by FDA proved to have performance problems or be poorly validated. They also specifically noted that out of 125 EUA requests, FDA identified 82, or nearly 66 percent, with design or validation problems.[7] While several of these problematic tests were removed from the market, Drs. Shuren and Stenzel also discussed the constructive

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Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Admin. Staff (Feb. 29, 2020).

[4] *Id.*

[5] U.S. Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, *In Vitro Diagnostic Multivirate Index Assays – Draft Guidance for Industry, Clinical Laboratories, and FDA Staff* (July 26, 2007) (FDA-2006-D-0233); Letter from Leslie Kux, Assistant Commissioner for Policy, U.S. Food and Drug Administration, to Alan Mertz, American Clinical Laboratory Association (July 13, 2014) (responding to a citizen petition and concluding that "LDTs are 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); House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Jeffrey Shuren, Director, U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Hearing on Examining the Regulation of Diagnostic Tests and Laboratory Operations*, 114th Cong. (Nov. 15, 2015) (noting that "FDA regulates IVDs under the Medical Device Amendments of 1976, which applies to all devices" and "LDTs are IVDs").

[6] Scott Gottlieb, M.D., Twitter Thread – Feb. 24, 2020 (https://www.twitter.com/scottgottliebmd/status/1231944758261665795) (accessed Oct. 7, 2020).

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

nature of the EUA process, writing that in most cases where there were issues with an LDT, "FDA worked with laboratories to correct the issues and permit continued testing."[8]

We are disappointed that rather than follow this safer, more constructive approach, political leadership at HHS has chosen a reckless path, removing the requirement for LDTs to receive any review by FDA prior to their use during the worst pandemic of our lifetimes. This decision will increase the chances of false negative results, endangering countless lives, and weakening our understanding of COVID-19 as we head into fall and winter.

In addition to the potential for immediate danger related to the COVID-19 pandemic, the abrupt and cursory nature of the Administration's announcement has raised many questions about the reach of the new LDT policy and its ramifications for public health. According to press reports, at the time HHS decided to move forward, it did so before FDA regulators developed a plan for communicating the change in policy, and had not developed contingencies to deal with the consequences of the policy change.[9] In a highly unusual move, HHS posted the one-paragraph announcement online, and indicated the content of the announcement was created by Assistant Secretary for Public Affairs (ASPA) Michael Caputo, an official with no background in health care or diagnostic testing.[10]

In a public health emergency, clear communication matters. The poor rollout of this policy change already has caused confusion among care providers, test developers, and patients, and so far, HHS has failed to provide any clarity. Furthermore, although recent media reports have revealed the tenuous legal argument HHS has relied on to legitimize the policy change, questions about the policy's implications remain unanswered.[11] For example, although the Administration announcement indicated it was rescinding guidance, HHS has not yet specified which guidances, technical assistance documents, and other formal and informal documents and correspondence this announcement rescinds. Meanwhile, currently in-effect FDA guidance and, as recently as September 15, the agency's public website, continues to indicate that EUAs and premarket review are required for COVID-19 LDTs.[12] As recently as September 15, the agency's public website also included this same information.[13]

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[8] *Id.*

[9] *HHS Chief Overrode FDA Officials to Ease Testing Rules*, Politico (Sept. 15, 2020).

[10] *See* note 1.

[11] *Memo Details HHS Push to Upend FDA's Testing Oversight,* Politico (Oct. 2, 2020).

[12] *See* note 3.

[13] U.S. Food and Drug Administration, *Information for Laboratories Implementing IVD Tests Under EUA* (www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua) (accessed Sept. 15, 2020).

Additionally, while the announcement indicated that laboratories may voluntarily request and receive an EUA for an LDT, it is not clear what happens if a laboratory then fails to follow all requirements typically expected of a test manufacturer under an EUA, including requirements to submit adverse event reports.

Further adding to the confusion, the administration's frequently asked question (FAQ) document accompanying its announcement is misleading when it says premarket review for LDTs "was only being enforced during public health emergencies".[14] This is false. As recently as 2019, FDA has indicated it would pursue enforcement against unapproved LDTs that are used to test patients' responses to specific medications based on genetic variants.[15] The Administration's rash approach to changing this policy leaves open a question as to whether FDA still intends to exercise its enforcement over these tests.

Given the serious public health ramifications that could follow this change in policy, we ask that you provide responses to the following questions and document requests no later than October 21, 2020.

1. The June 22, 2020 memo authored by Robert Charrow, HHS General Counsel, indicates that he was "asked by departmental leadership to review the legal bases—both substantive and procedural—for FDA's regulation of laboratory developed tests."

    a. What was the impetus for the legal review by the HHS Office of General Counsel (OGC)?

    b. Who in departmental leadership requested this review?

    c. Please provide all legal memoranda developed by HHS OGC outlining its legal review and decisions regarding FDA's authority over LDTs.

    d. To what extent were FDA program staff, including the Director of the Center for Diagnostics and Radiological Health, consulted by your office on the policy and public health ramifications of HHS OGC's determination? Please detail the feedback HHS received from FDA program staff, including all policy memoranda and communications from FDA program staff to HHS related to this policy change.

2. The June 22 memo came shortly after FDA updated its guidance in May, outlining the agency's policy for COVID-19 tests during a public health emergency. This FDA

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[14] U.S. Department of Health and Human Services, *FAQs on Laboratory Developed Tests (LDT)* (Aug. 28., 2020) (www.hhs.gov/sites/default/files/laboratory-developed-tests-faqs.pdf).

[15] U.S. Food and Drug Administration, *FDA Issues Warning Letter to Genomics Lab for Illegally Marketing Genetic Test that Claims to Predict Patients' Responses to Specific Medications* (Apr. 4, 2019) (news release).

guidance still, as of October 6, notes that the two pathways for a LDT to come to market are via an EUA by FDA or through an authorization by a State or territory that has chosen to authorize laboratories within that State or territory for COVID-19 testing.

a. Was this guidance cleared by HHS prior to its issuance?

b. Did HHS OGC begin its legal review before or after this guidance was issued?

3. Please provide a list of all guidance documents, public technical assistance documents, warning letters, and other formal and informal issuances rescinded by the announcement "Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests".

4. Did the FDA Commissioner ever express disagreement with this policy to you or your staff? If so, please detail when this disagreement was shared with HHS, and provide copies of any communications detailing this disagreement.

5. The June 22 memo argued that FDA's determination that an LDT is a medical device is invalid unless the agency issues a "gap-filling" rule under notice-and-comment rule-making procedures. However, the HHS announcement maintains that sponsors may still voluntarily request, and FDA may still grant, EUAs for LDTs. The announcement further states that those with active EUAs to use an LDT to detect COVID-19 or its antibodies are not affected by the announcement. Under what authority may FDA grant EUAs for products that are not devices, drugs, or biologics?

6. Under the announced policy, if a laboratory voluntarily requests and receives an EUA prior to marketing a test, is that laboratory required to follow all FDA requirements of test manufacturers? For example, will these laboratories be required to report adverse events and performance data to FDA, and will they be required to provide FDA and CDC information sheets to patients? Is FDA prepared to receive adverse event reports for LDTs that have not received an EUA?

7. Is HHS maintaining a database of COVID-19 LDTs on the market that have not received an EUA? If so, please provide further details on when this database will be operational and whether or not it will be publicly accessible.

8. If an EUA for an LDT is withdrawn, may a lab continue to run the test previously covered by the EUA?

9. Will any Clinical Laboratory Improvement Amendments (CLIA) operations change as a result of this announcement? If so, please detail what changes will be made and the timeline for such changes.

10. The HHS announcement on its website indicates that the content of the announcement was created by the Assistant Secretary for Public Affairs (ASPA).

a. Was the accompanying FAQ document, discussed above, also created by ASPA?

b. Was ASPA consulted on any legal, policy, or political matters related to the announcement prior to its issuance?

c. Was FDA consulted on the announcement created by ASPA or the FAQ document prior to publication? If so, what feedback did the agency provide and was this feedback considered for inclusion?

Thank you for your prompt 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