RAND PAUL
KENTUCKY

United States Senate

WASHINGTON, DC 20510

December 4, 2023

Dr. Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: Docket No. FDA–2023–N–2177 for "Medical Devices; Laboratory Developed Tests

Dear Dr. Califf:

I write to convey my grave concerns about the FDA's recent proposed rule on Laboratory Developed Tests (LDTs; Docket No. FDA–2023–N–2177), which would inappropriately impose the FDA's medical device regulatory framework on health care providers developing and performing LDTs as part of their professional practice.

The proposed rule clearly exceeds the FDA's statutory authority under the Federal Food, Drug, and Cosmetic Act (FDCA) and conflicts with implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which have successfully governed LDT regulation for decades. As observed in a white paper co-authored by Paul Clement, the former Solicitor General of the United States, and Professor Laurence Tribe of Harvard Law School, "FDA's novel effort to expand its jurisdiction is foreclosed by the plain text of the FDCA. Congress gave FDA the authority to regulate medical devices, and laboratory-developed testing services are not devices."[1] This legal interpretation was reaffirmed in a June 2020 memorandum by the General Counsel of the U.S. Department of Health and Human Services.[2]

Precisely because it has long been the mainstream view of legal experts that the FDA lacks authority to regulate LDTs in the absence of legislation to grant them such authority, both chambers of the 117th Congress twice considered—and twice rejected—a proposal to do exactly that. The *VALID Act of 2021* would have amended federal law to shift regulation of all *in vitro* clinical tests to the FDA, thus creating a statutory basis for a rule like the one recently published. This policy was extensively debated in the U.S. Senate Committee on Health, Education, Labor, and Pensions during the 2022 consideration of legislation to reauthorize FDA user fee programs related to drugs, medical devices, and biosimilar products. When Congress reauthorized these user fee programs later that year, it chose to omit the *VALID Act* policies from the

[1] Paul D. Clement & Laurence H. Tribe, *Laboratory Testing Services, As The Practice Of Medicine, Cannot Be Regulated As Medical Devices*, https://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf

[2] Robert Charrow, Gen. Couns., U.S. Department of Health and Hum. Servs. Mem. (June 22, 2020), https://www.thefdalawblog.com/wp-content/uploads/2021/11/HHS-Legal-Memo-on-LDTs-by-Charrow-00864663.pdf

reauthorization. At the end of 2022, the *VALID Act* was again considered by both chambers of Congress during negotiation of the Consolidated Appropriations Act, 2023. Again, Congress chose to omit the *VALID Act* policies when it passed that legislation to fund the government. Yet congressional debate about how to modernize the federal government's approach to regulating laboratory testing services remains ongoing. Coming as it does in the midst of those discussions, the proposed rule threatens to usurp the lawmaking role assigned to Congress by the U.S. Constitution.

The proposed rule also risks repeating the disruptions to patient care we saw during the crucial first months of the COVID-19 pandemic, when the FDA was empowered to enforce emergency use authorizations (EUAs) for all LDTs for SARS-CoV-2 due to the public health emergency. The FDA initially restricted clinical laboratories from testing and only issued an EUA for the CDC's test kit, which was later recalled, leaving the U.S. without any authorized tests as COVID-19 spread undetected through our communities. As the Deputy Director of the newly formed White House Office of Pandemic Preparedness and Response Policy recently acknowledged, "During the pandemic, diagnostics were clearly the elephant in the room of what went wrong…we will never actually know how much it delayed us, or how much mortality it caused."[3]

Remarkably, the consequences of the FDA having authority over LDTs during the pandemic are not even mentioned in the proposed rule. Likewise, the agency's legally mandated impact analysis does not address the policy's potential societal costs, economic costs, or the new burden it would place on the agency to regulate a vast portion of the health care sector it does not regulate currently. Under current law, CLIA governs some 320,000 certified laboratory entities, many of which are housed at our nation's most prestigious academic institutions and staffed by the leading researchers in the world. The proposed rule would effectively transfer the LDT market from these world-class, federally certified labs to large medical device manufacturers and other large companies whose business model equips them to navigate the FDA's medical device pathway. These unexamined impacts would likely have dire and far-reaching consequences by consolidating our nation's clinical laboratory market and preventing providers from offering testing services. The fact that these potential effects on our nation's health care sector were overlooked in the proposed rule suggest that the impact analysis is incomplete at best.

Perhaps most troubling, the proposed rule could have adverse consequences for patients. In 2011, the melanoma drug vemurafenib was FDA-approved along with a companion test. The drug sold well but physicians noticed that the FDA-approved companion test was failing to identify patients with melanoma who would respond to the drug. That experience should remind the agency that its expertise, though valuable in assessing drugs and devices, may not be readily transferred to LDTs. Subjecting all LDTs to FDA approval will inevitably lead them to become outdated and begin missing more patients as time goes on, because unlike LDTs in CLIA certified labs today, they will have to undergo lengthy product reviews for each new update or improvement. Many patients will not have the time to wait.

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[3] Riley Griffin, "Meet the White House's New Pandemic Office," *Bloomberg*, 30 Nov. 2023, https://www.bloomberg.com/news/newsletters/2023-11-30/preparing-for-the-next-pandemic-inside-the-white-house-s-new-response-office

For all the reasons above, I strongly urge the FDA to rescind its proposed rule so that Congress can continue its work to establish a modern oversight framework for laboratory testing services.

Sincerely,

Rand Paul, M.D.
United States Senator