ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on March 21, 2024

The Subcommittee on Health will hold a hearing on Thursday, March 21, 2024, at 10:00 a.m. (ET) in 2123 Rayburn House Office Building. The hearing is entitled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule."

I. Witnesses

- **Susan Van Meter**, President, American Clinical Laboratory Association (ACLA)
- **Zach Rothstein**, **JD,** Executive Director, AdvaMedDx
- **Donald S. Karcher, MD, FCAP,** President of the College of American Pathologists (CAP)
- **Jeff Allen**, **PhD**, President and CEO, Friends of Cancer Research
- **Dara L. Aisner**, **MD**, **PhD**, Medical Director, Colorado Molecular Correlates Laboratory, Professor of Pathology, University of Colorado, Representative of the Academic Coalition for Effective Laboratory Developed Tests

II. Background

An estimated 70 percent of medical decisions are based on laboratory test results, with over 14 billion lab tests ordered annually.[1] Diagnostic science and precision medicine play an increasingly critical role in today's clinical care. Regulators and stakeholders must balance access, innovation, and appropriate oversight to ensure patients receive high-quality, accurate tests.

Over time, laboratory developed tests (LDTs) have become increasingly complex and produced in higher volumes for larger and more diverse populations.

Administrative Action

In implementing the "Medical Device Amendments of 1976", which established a risk-based regulatory framework for medical devices, the Food and Drug Administration (FDA) did not assert authority over LDTs. Without a formal definition, the FDA has traditionally considered LDTs to be in vitro diagnostic devices that are designed, manufactured, and used within a single laboratory that meets the regulatory requirements under the Clinical Laboratory Improvement

[1] U.S. Centers for Disease Control and Prevention. "Strengthening Clinical Laboratories." https://www.cdc.gov/csels/dls/strengthening-clinical-labs html.

Amendments of 1988 (CLIA) to perform high complexity testing.[2] The Centers for Medicare and Medicaid Services (CMS) regulate the quality of clinical laboratories and the clinical testing process pursuant to CLIA.

Starting in 2006, the FDA indicated its intent to regulate LDTs through a piecemeal approach by publishing draft guidance for a specific subset of LDTs called In Vitro Diagnostic Multivariate Index Assays (IVDMIA). The FDA never finalized this guidance. Instead, the agency held a public meeting in July 2010 to discuss more comprehensive oversight.[3]

Four years later, the FDA issued the draft guidance, "Framework for Regulatory Oversight of Laboratory Developed Tests," officially notifying Congress of its intent to begin regulating LDTs. In response to this notification, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on "Laboratory Testing in the Era of Precision Medicine," in 2016.[4] The FDA decided to delay finalizing the guidance in the interest of further public discussion.[5]

In January 2017, the FDA released the white paper, "Discussion Paper on Laboratory Developed Tests (LDTs)," to summarize the comments received in response to the 2014 draft guidance. In it, the FDA stated that it would not be issuing final guidance on the oversight of LDTs to give Congress the opportunity to develop a legislative solution.

In August 2020, the Department of Health and Human Services (HHS) announced the recission of materials related to the FDA's premarket review of LDTs, determining that the FDA may not require pre-market review of LDTs absent a formal notice and comment process.[6] The legal basis for the determination was detailed in a memorandum from the HHS Office of General Counsel.[7] In November 2021, HHS Secretary Becerra publicly withdrew the policy.[8]

On September 29, 2023, the FDA announced a proposed rule to amend the definition of "in vitro diagnostic products" in its regulations to make explicit that IVDs are devices under the Food, Drug, and Cosmetics Act (FDCA), including when the

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[2] U.S. Food and Drug Administration. "Laboratory Developed Tests." https://www fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests.
[3] Federal Register. "Oversight of Laboratory Developed Tests; Public Meeting; Request for Comments." https://www federalregister.gov/documents/2010/06/17/2010-14654/oversight-of-laboratory-developed-tests-public-meeting-request-for-comments.
[4] U.S. Senate Committee on Health, Education Labor and Pensions. "Full Committee Hearing: Laboratory Testing in the Era of Precision Medicine." https://www help.senate.gov/hearings/laboratory-testing-in-the-era-of-precision-medicine.
[5] Congressional Research Service. "FDA Regulation of Laboratory-Developed Tests (LDTs). https://crsreports.congress.gov/product/pdf/IF/IF11389
[6] "HHS Announcement on FDA Premarket Review of Laboratory-Developed Tests (LDTs)," https://crsreports.congress.gov/product/pdf/IN/IN11548.
[7] "Federal Authority to Regulate Laboratory Developed Tests," https://www.politico.com/f/?id=00000174-e9b2-d951-a77f-f9fe04fa0000.
[8] "Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory-Developed Tests," https://www regulations.gov/document/FDA-2023-N-2177-0103.

manufacturer of the IVD is a laboratory. As a result, the FDA's proposed policy would subject LDTs to oversight under the medical device authorities.

The preamble of the proposed rule describes a phase out of its general enforcement discretion approach for LDTs. The proposed phaseout would occur in five stages over a four-year period following the publication of the final phaseout policy. One year after the publication of the final phaseout policy, labs would be expected to adhere to adverse event reporting, correction, and removal reporting requirements. After two years, the FDA would enforce requirements other than adverse event reporting, quality systems, and premarket review requirements. Quality system requirements would be applicable three years after the publication of the final phase-out policy, while premarket review requirements for high-risk tests would be enforced after 3.5 years, but not before October 1, 2027. Finally, after four years, but not before April 1, 2028, the agency would enforce premarket requirements for moderate and low risk tests that require premarket submissions. The proposed rule limits categories of tests not affected by the phaseout policy to 1976-era LDTs, Human Leukocyte Antigen (HLA) tests, forensic tests, and public health surveillance tests.

Though certain stakeholders requested an extension of the public comment period,[9] the FDA maintained the 60-day comment period and received over 6,700 comments.[10] The final rule is under review with the Office of Management and Budget (OMB) as of March 1, 2024.[11] As indicated in the "2023 Fall Unified Regulatory Agenda", the final rule is expected to be published in April 2024.[12]

Legislative Approaches

In 2017, Reps. Larry Bucshon (R-IN) and Diana DeGette (D-CO) circulated a discussion draft of the "Diagnostic Accuracy and Innovation Act", which outlined a regulatory approach specifically for in vitro diagnostics, and included mechanisms for stakeholder feedback. The FDA released technical assistance on this discussion draft, proposing several novel regulatory approaches and pathways.[13] This feedback was incorporated into a new bill, known as the Verifying Accurate, Leading-edge, IVCT Development (VALID) Act, which was first introduced in the 116th Congress, and then reintroduced in the 117th and 118th Congress.

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[9] October 31, 2023. Letter from 89 organizations. "Request for an extension to the comment deadline to the Rulemaking Docket No. FDA-2023-N-2177, Medical De3vices: Laboratory Developed Tests. https://www myadlm.org/-/media/Files/Health-and-Science-Policy/Regulatory-Issues/2023/Sign-on-letter-comment-extension-LDT-rulemaking-October-31-2023.pdf?la=en&hash=ABF5F2FC779986A601FA246082B8D0006817C9DE.

[10] "Proposed Rule: Medical Devices; Laboratory Developed Tests, Posed by the Food and Drug Administration on Oct 3, 2023." https://www.regulations.gov/document/FDA-2023-N-2177-0001.

[11] "Pending EO 12866 Regulatory Review," https://www.reginfo.gov/public/do/eoDetails?rrid=431763.

[12] Office of Information and Regulatory Affairs. "Agency Rule List – Fall 2023." https://www federalregister.gov/documents/2023/10/03/2023-21662/medical-devices-laboratory-developed-testshttps://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=0910-AI85.

[13] "FDA's views on the Diagnostic Accuracy and Innovation Act (DAIA)." https://thefdalawblog.com/wp-content/uploads/2018/08/FDA-LDT-Draft-Leg.pdf.

The current version of the VALID Act, introduced by Reps. Bucshon and DeGette, would create a comprehensive framework for oversight of a new category of in vitro clinical tests (IVCTs), which include laboratory developed tests. This framework is intended to be better tailored to diagnostic tests than existing medical device authorities. Specifically, the VALID Act would establish a risk-based mechanism for the FDA to prioritize applicable regulatory requirements based on level of risk and benefit to patients, with exemptions for certain lower-risk and low volume tests. Additionally, the bill establishes a novel technology certification pathway under which IVCT developers can receive a laboratory or company-based certification for certain tests. The bill also includes provisions to provide public information on the types of tests available, test labeling, post-market monitoring and reporting, and quality and design requirements.

Other stakeholders have advocated for updating the Public Health Service Act (PHS) and modernizing the existing CLIA regulations and framework.[14] Legislative approaches such as the "Modernizing Laboratory Test Standards for Patients Act of 2011", introduced by Dr. Michael Burgess (R-TX) in the 112th Congress, and the *"*Verified Innovative Testing in American Laboratories (VITAL) Act of 2021", introduced by Senator Rand Paul (R-KY) in the 117th Congress, would expand CMS's regulatory authorities as applicable to LDTs. CMS has generally expressed concerns with such proposed regulatory schemes,[15] most recently in a January 2024 joint statement with the FDA.

III. Staff Contacts

If you have questions regarding this hearing, please contact Jolie Brochin, Abigail Carroll, or Emma Schultheis of the Committee staff at 202-225-3641.

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[14] *See, e.g.,* "Draft Legislation to Modernize the Clinical Laboratory Improvement Amendments (CLIA)," https://www.amp.org/AMP/assets/File/advocacy/Amendments%20to%20CLIA%20modernization%20legislative%20text%2011_7_23%20FINAL.pdf?pass=36; "Ensuring remote diagnostics for pathologists: an open letter to the US Congress," https://www.nature.com/articles/s41591-022-02040-6.

[15] "CLIA Overview… What is CMS' authority regarding Laboratory Developed Tests (LDTs) and how does it differ from FDA's authority? https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf ; Congressional Testimony before the Committee on Energy and Commerce, Subcommittee on Health U.S. House of Representatives. "Examining the regulation of diagnostic tests and laboratory operations." Nov. 17, 2015. https://www.govinfo.gov/content/pkg/CHRG-114hhrg99657/pdf/CHRG-114hhrg99657.pdf.