

November 30, 2023

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Patient Advocacy Groups Support Proposed Rule re: Medical Devices; Laboratory Developed Tests (Docket No. FDA-2023-N-2177)

Dear Dr. Califf,

The undersigned patient advocacy groups write in support of FDA's proposed rule titled *Medical Devices; Laboratory Developed Tests*. In this proposed rule, FDA makes explicit that it has the authority to regulate all in vitro diagnostic tests, including those marketed as laboratory-developed tests (LDTs), under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, it proposes a policy whereby it will phase out its current enforcement discretion approach for LDTs, resulting in a situation where LDTs would generally fall under the same risk-based enforcement approach FDA currently uses for other diagnostic tests.

Our groups represent patients with a variety of diseases, ranging from common conditions like cancer to those that are rare, such as some eosinophilic disorders. Because some of these diseases impact small numbers of patients, it is often difficult to get companies to focus on diagnostics or therapeutics for them. But clinical care, regardless of the disease or its prevalence, requires quality diagnostics. For this reason, we support FDA's risk-based approach to regulating LDTs.

LDTs have become increasingly important in clinical practice but put patients at risk when they are unreliable. A 2015 report from FDA presented 20 case studies of problematic LDTs.¹ In the years since this report, many more LDTs have been developed and used on large numbers of patients without FDA oversight, many of which have been found to produce dangerously inaccurate results. Some of these tests include COVID-19 diagnostic tests,² genetic non-invasive prenatal screening tests,³ and Theranos blood tests.⁴

To date, FDA has chosen not to regulate LDTs despite its clear authority to do so under the 1976 Medical Device Amendments to the FD&C Act^{5,6} because early tests were fairly simple and used on a small number of patients.⁷ As a result, FDA does not even know how many tests are currently on the market,⁸ but they have clearly increased in number dramatically since 1976.

It has been over a decade since FDA first proposed regulating LDTs,⁹ which led to a 2014 draft guidance that was never finalized due to pressure from industry and Congress.^{10,11} Yet

Congress has repeatedly failed to pass legislation that would establish a regulatory framework for these tests.^{12,13} In the absence of legislative action in this critical area, FDA has proceeded with this regulation.

Accurate clinical tests are an essential component of patient care and FDA regulation of LDTs will ensure that patients and doctors are getting results that are reliable and clinically meaningful. We applaud the agency's work on this proposed rule.

Sincerely,

Asthma and Allergy Foundation of America
Breast Cancer Action
Breast Implant Safety Alliance (BISA)
CURED NFP (Campaign Urging Research for Eosinophilic Diseases)
Doctors for America
International FPIES Association (IFPIES)
MRSA Survivors Network
Ovarian Cancer Research Alliance
Patient Safety Action Network
Stupid Cancer, Inc
Washington Advocates for Patient Safety
Woodymatters

CC:

Jeffrey Shuren, Director of FDA's Center for Devices and Radiological Health (CDRH)
Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs, CDRH

¹ U.S. Food and Drug Administration. *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies*. 2015. [https://www.nila-usa.org/images/nila/The%20Public%20Health%20Case%20for%20FDA%20Oversight%20of%20LDTs%20110915\(2\)_508ed%20\(1\).pdf](https://www.nila-usa.org/images/nila/The%20Public%20Health%20Case%20for%20FDA%20Oversight%20of%20LDTs%20110915(2)_508ed%20(1).pdf).

² Shuren J, Stenzel T. Covid-19 Molecular Diagnostic Testing – Lessons Learned. *N Engl J Med*. 2020;383(17):e97(1)-e97(3).

³ U.S. Food and Drug Administration. *Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication*. 2022. <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication>. Accessed November 8, 2023.

⁴ Richardson L. *The Theranos Problem Congress Must Still Solve – Patients Need Protection*. The PEW Charitable Trusts. 2022. <https://www.pewtrusts.org/en/about/news-room/opinion/2022/01/12/the-theranos-problem-congress-must-still-solve-patients-need-protection>. Accessed November 8, 2023.

⁵ U.S. Food and Drug Administration. *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*. 2014. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/framework-regulatory-oversight-laboratory-developed-tests-ldts>.

⁶ Medical Device Amendments of 1976. P.L. 94-295.

⁷ The PEW Charitable Trusts. *What are In Vitro Diagnostic Tests, and How are They Regulated? Oversight May Not be Keeping Pace with Changes in the Diagnostics Market*. 2019. <https://www.pewtrusts.org/-/media/assets/2019/05/what-are-in-vitro-diagnostic-tests-and-how-are-they-regulated.pdf>. Accessed November 8, 2023.

⁸ The PEW Charitable Trusts. *What are In Vitro Diagnostic Tests, and How are They Regulated? Oversight May Not be Keeping Pace with Changes in the Diagnostics Market*. 2019. <https://www.pewtrusts.org/-/media/assets/2019/05/what-are-in-vitro-diagnostic-tests-and-how-are-they-regulated.pdf>. Accessed November 9, 2023.

⁹ U.S. Food and Drug Administration. FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests (LDTs), Date July 19-20, 2010.

¹⁰ Genzen JR, Mohlman JS, Lynch JL, et al. Laboratory-Developed Tests: A Legislative and Regulatory Review. *Clin Chem*. 2017;63(10):1575-1584.

¹¹ U.S. Food and Drug Administration. *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*. 2014. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/framework-regulatory-oversight-laboratory-developed-tests-ldts>.

¹² Congressional Research Service. *FDA Regulation of Laboratory-Developed Tests (LDTs)*. 2022. <https://crsreports.congress.gov/product/pdf/IF/IF11389>. Accessed November 15, 2023.

¹³ Okun, E. *Politico Playbook PM: What You Missed in the Omnibus*. Politico. 2022. <https://www.politico.com/newsletters/playbook-pm/2022/12/20/what-you-missed-in-the-omnibus-00074796>. Accessed November 15, 2023.