December 4, 2023

Commissioner Robert Califf, MD
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

***SUBJECT: [Docket No. FDA-2023-N-2177], Medical Devices; Laboratory-Developed Tests, Proposed Rule, Federal Register (Vol 88, No 190), October 3, 2023***

Dear Commissioner Califf:

On behalf of our more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed rule that would clarify in vitro diagnostic products (IVDs) as devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory, and in conjunction, phase out the current general enforcement discretion approach for laboratory-developed tests (LDTs) so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

LDTs are diagnostic tests that are not commercially distributed to other laboratories, but rather are developed, validated, and performed in-house by individual laboratories. These tests are not devices; they are diagnostic tools developed and used in the context of patient care. Hospitals and health systems rely on LDTs to provide patients with timely access to accurate and high-quality tests for conditions for which no commercial test exists, or where an existing test does not meet current clinical needs. LDTs range from routine tests to more complex molecular and genetic tests in cancer, heart disease, and rare and infectious diseases, and are typically developed in close collaboration with clinical caregivers to support early and precise diagnosis or monitoring and guidance of patient care.

The FDA plays an essential role in safeguarding public health, but this rule — if finalized as proposed — would have significant unintended consequences for the delivery of medical laboratory services, raising costs to the overall health care system and introducing diagnostic delays that could harm patient care. **The FDA must revise its proposed rule and consider alternative approaches that take into account the unique role of hospital and health system laboratories, which rely on LDTs to support direct patient care. Specifically, we urge the FDA to continue enforcement discretion for hospital and health system LDTs.**

**Hospital-based laboratories are already subject to significant oversight from several entities, including the Centers for Medicare & Medicaid Services (CMS), state agencies, and accreditation**

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**bodies such as the Joint Commission or College of American Pathologists, in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).** High-complexity hospital and health system-based laboratories that offer LDTs do so following strict quality standards and validation requirements as specified by CLIA. Introducing an additional, resource-intensive layer of regulation under the FDA will threaten hospital-based laboratories' ability to offer LDTs.

Hospitals continue to face significant financial challenges in the wake of the COVID-19 pandemic and would be unable to bear the significant costs associated with complying with FDA's unfamiliar device regulatory framework and exorbitant user fees, as proposed in the rule. One California health system alone reports performing 309 different LDTs. With the FDA annual registration fee for each test alone at $7,653 in federal fiscal year 2024 and typical organizational costs for premarket approval around $10,000-$20,000 per test, it would be untenable for any hospital or health system to dedicate the significant financial and staff resources required to pursue FDA submissions for each of these tests. Further, we are concerned with the FDA's capacity to complete the necessary reviews of the volume of LDTs that would be required under the rule in a timely manner.

As a result, many LDTs currently offered by hospitals would likely cease to exist, dramatically slowing innovation in laboratory medicine and leading to patients' loss of access to critical tests. For example, many hospitals and health systems offer LDTs that would not be profitable for private laboratories to develop, such as tests for rare diseases or small subsets of populations like many pediatric tests, for which FDA-approved tests often do not exist. If hospital and health system laboratories are unable to offer these LDTs, they will likely not be offered elsewhere.

The proposed rule would also force hospitals to rely on sending tests to outside laboratories, resulting in diagnostic and treatment delays for patients. In our members' experience, results for urgent tests for acutely ill patients can take more than five days to receive, at which point the result may no longer be useful to informing the patient's care plan, resulting in poorer outcomes. More broadly, the lack of timely test results from an in-house laboratory will increase patients' length-of-stay and increase costs to the overall health care system. These delays will be even more likely if the vast majority of LDTs shift from in-house hospital-based laboratories to private commercial laboratories.

**The FDA must consider alternative policies that will continue enforcement discretion for LDTs to ensure the availability of timely, high-quality, and cost-effective diagnostics in the hospital setting.** In addition to blanket enforcement discretion for hospital and health system-based laboratories, CHA would support the grandfathering of existing LDTs or other mitigating policies such as continued enforcement discretion for certain types of LDTs. This includes low- and moderate-risk LDTs, such as modifications to FDA-approved IVDs. We also stand ready to work with Congress, the FDA, and CMS to modernize CLIA regulations while ensuring that patients do not lose access to innovative, life-saving diagnostic tests. CHA appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Megan Howard
Vice President, Federal Policy