The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

December 4, 2023

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket No. FDA-2023-N-2177; Medical Devices; Laboratory Developed Tests Proposed Rule

Dear Commissioner Califf:

On behalf of 235 member hospitals, health systems, and other health care organizations, The Hospital and Healthsystem Association of Pennsylvania (HAP), is grateful for the opportunity to offer comments on the Food and Drug Administration's (FDA) proposed rule regarding laboratory developed tests. HAP appreciates the agency's commitment to ensuring the safety and effectiveness of medical devices used in health care settings. However, the unintended consequences of classifying laboratory developed tests (LDT) as medical devices and subjecting these diagnostic tools to the proposed regulatory framework will far outweigh the benefits of an additional layer of oversight, especially in the case of low and moderate risk tests.

The proposed regulatory framework would severely limit innovation. Several of our member institutions are considered pioneers in diagnostic testing and personalized care. Hospitals develop tests that are tailor-made for patients, allowing them to fill gaps in commercial test offerings and deliver cutting-edge care, particularly in their immune health and cancer care programs. Opportunities to explore diagnostic pathways that address the unique needs of patients are central to hospitals' capability to remain leaders in these treatment areas.

The same institutions lay the groundwork for new FDA-approved technologies by identifying unique clinical needs and offering solutions to address them in testing. Commercial manufacturers rely on this work to inform their business decisions. In one example, a laboratory in Pennsylvania pioneered the development of clinically available assays to diagnose heparin-induced thrombocytopenia (HIT) at a time when commercial diagnostic testing was not available. This advancement has since given way to the FDA-approved Enzyme-Linked Immunosorbent Assays (ELISA) of today. Continued flexibility around LDTs allows those closest to clinical care to move the field forward.

Enforcement discretion is critical to the local public health response and management of emerging pathogens. Laboratory developed tests from Clinical Laboratory Improvement Amendments (CLIA) high-complexity laboratories often lead the testing response and inform the medical community's understanding of new pathogens until commercial test offerings can be developed, approved, and manufactured at scale. The 2022 Mpox outbreak highlighted this process in action. The provisions of the proposed rule would effectively eliminate a CLIA high-

complexity laboratory's ability to contribute to the public health response in such a rapid and meaningful way.

Enforcement discretion for LDTs also allows hospitals the flexibility to meet the needs of vulnerable populations. Our members report that specialized LDT offerings are often the key to the medical management of patients with complex medical and social needs. For example, the modification of FDA-approved assays allows for more rapid assessment of tuberculosis. This helps practitioners initiate therapy more quickly and avoid harmful delays in diagnosis. The development of these alternate diagnostic pathways is not motivated by profit in the way that test development is prioritized by in vitro device manufacturers. It is motivated by a commitment to high-quality patient care. Our academic medical centers serve a high volume of patients that are uninsured or insured by public payors that pay under cost. Hospital laboratories often don't see a financial return on the investments made in specialized LDTs and will be unable to explore these pathways if they come with new administrative and financial burden.

Compliance costs will limit innovation at large institutions and limit access to testing at community hospitals. Compliance with these requirements would force hospitals to redirect financial and operational resources away from the development of new and innovative tests so that they can be used for application processing and program compliance. Under the FDA's medical device regulations, hospitals would have to submit a PMA, 501(k), or other application to the FDA and get approval to use tests that have already been validated and in use for years. In some cases, these requirements will result in more than a thousand applications in the first year and could mean, for some larger institutions, more than 50 applications per year even after the initial surge is complete.

Initial implementation of these regulations will limit hospitals' ability to offer routine tests as well as the personalized testing options they have come to rely on to provide high-quality care. In the first five years of implementation, the FDA will be flooded with applications that will undoubtedly result in significant delays in approvals. Our members point out that for many of the tests they offer, there is no replacement that exists from in vitro diagnostic manufacturers. This is true for both routine tests (i.e., electrolyte tests on non-blood body fluids) and more complicated tests such as non-invasive pre-natal screening. In cases where no replacement exists, the tests will have to be eliminated from the hospital's offering until approval can be secured. Additionally, doctoral staff will no longer be able to make test or testing procedure changes to adjust in real-time to improve the accuracy of certain tests based on the latest clinical research or to adjust to meet the unique needs of a patient or patient population.

The cost of FDA user fees and application fees will limit the types and number of LDTs offered by institutions and reduce patient access to innovative tests and streamlined care. The hospital industry is already in a tenuous financial position as the cost of labor, supplies, and pharmaceuticals continue to increase but are met with only marginal increases in reimbursement. In 2023, median operating margins are hovering around 1 percent. FDA

application fees can run from $20,000 to $441,000 for one test. For hospitals with thousands of tests that require approval, millions will be spent to maintain the status quo. For most hospitals, but especially community hospitals, it will become cost prohibitive to secure approval for current tests and to offer more specified testing going forward.

Current mechanisms provide adequate oversight of LDTs. LDTs are designed, manufactured, and used within a single laboratory. They are not distributed for commercial use and as such should not be subject to the FDA's regulatory framework for medical devices. Oversight of LDTs is already provided by CMS under CLIA, the College of American Pathologists, and other accrediting bodies. Hospitals must meet strict standards to be certified to offer high-complexity tests and the tests themselves must undergo an extensive validation process prior to use in patient care. The added layer of FDA oversight of these tests introduces barriers and unnecessary costs while adding limited benefit to this equation.

HAP joins others from the hospital community and its allied associations in advocating that the FDA not apply its device regulations to laboratory developed tests.

Sincerely,

John Myers
Vice President, Federal Advocacy