Summary Testimony of Susan Van Meter, President, American Clinical Laboratory Association before the Health Subcommittee of the House Energy & Commerce Committee, United States House of Representatives, March 21, 2024

Laboratory developed testing services—commonly known as LDTs or LDT services—are an indispensable pillar of our health care system. However, FDA's Proposed Rule—which would subject virtually all laboratory testing services to medical device regulation—would significantly undermine the ability of laboratories to develop and offer the innovative testing services relied on by millions of patients and their physicians.

Specifically, the Proposed Rule would limit or eliminate access to critical tests and increase healthcare costs, undermine diagnostic and medical innovation, and exceed FDA's statutory authority. If finalized, the rule would reduce patient access to laboratory testing services because some services would inevitably be removed from testing menus, not because they do not yield accurate and reliable results, but because seeking FDA approval can be prohibitively expensive. It would also markedly diminish innovation in the next generation of diagnostics because labs would be forced to redirect critical innovation efforts toward numerous backward-looking activities to justify tests that have been relied upon for decades. Moreover, FDA review will inevitably cause a bottleneck in access to innovative tests as the Agency has to work through an avalanche of applications for current and future tests. The Proposed Rule also exceeds FDA's jurisdiction: laboratory developed testing services are not devices, and FDA lacks authority to regulate them as such. Accordingly, the Proposed Rule represents a regulatory overreach, and it should be withdrawn for multiple policy and legal reasons.

ACLA maintains that legislation is the right—and only—approach for FDA to regulate professional testing services offered by laboratories. I commit, on behalf of ACLA, to continue working with this Committee to advance appropriate legislation that preserves the critical role of laboratory diagnostics and ensures that patients continue to have access to lifesaving tests.

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Susan Van Meter
President

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before the

Health Subcommittee of the House Energy & Commerce Committee

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Chairman Guthrie, Vice Chair Bucshon, Ranking Member Eshoo, and Members of the Committee, thank you for the opportunity to testify today. I am Susan Van Meter, President of the American Clinical Laboratory Association. ACLA is the trade association representing leading laboratories that develop and offer essential diagnostic tests to patients and providers. ACLA advocates for expanded access to the highest quality testing services, improved patient outcomes, and advancing the next generation of personalized care.

Laboratory developed testing services—commonly known as LDTs or LDT services—are an indispensable pillar of our health care system. They provide patients and physicians with diagnostic information to inform clinical care, power precision medicine, contribute to the discovery of novel therapeutics, and lead the fight against emerging pathogens. FDA's Proposed Rule—which would subject virtually all laboratory testing services to medical device regulation—would significantly undermine the ongoing ability of laboratories to develop and offer the innovative testing services relied on by millions of patients and their physicians.

Specifically, the Proposed Rule would limit or eliminate access to critical tests and increase healthcare costs, undermine diagnostic and medical innovation, and exceed FDA's statutory authority. If finalized, the rule would reduce patient access to laboratory testing services because some services would inevitably be removed from testing menus, not because they do not yield accurate and reliable results, but because seeking FDA approval can be prohibitively expensive. It would also markedly diminish innovation in the next generation of diagnostics because labs would be forced to redirect critical innovation efforts toward numerous backward-looking activities to justify tests that have been relied upon for decades. Moreover, FDA review will inevitably cause a bottleneck in access to innovative tests as the Agency has to work through an avalanche of applications for current and future tests. The Proposed Rule also exceeds FDA's jurisdiction: laboratory developed testing services are not devices, and FDA lacks authority to regulate them as such. Accordingly, the Proposed Rule represents a regulatory overreach, and it should be withdrawn for multiple policy and legal reasons.

ACLA maintains that legislation is the right—and only—approach for FDA to regulate the professional testing services provided by laboratories. I am grateful for the opportunity to discuss these critical issues and commit, on behalf of ACLA, to continue working with this Committee to advance appropriate legislation that preserves the critical role of laboratory diagnostics and ensures that patients continue to have access to lifesaving tests.

Introduction

Laboratories offering professional testing services have delivered groundbreaking innovations for decades. As one example, the first test to detect the BRCA gene mutation, which revolutionized breast cancer diagnosis and treatment, was a laboratory test developed by an ACLA

member. Laboratories are frequently the first to respond to emerging public health threats, such as COVID; play pivotal roles in the development of new drugs and biologics; and address unmet needs. We are proud of the extraordinary contributions that laboratories and laboratory developed testing services have made to advance the public health of this country.

Notwithstanding this history of advancing the public health, FDA is poised to reshape the regulation of laboratories by bypassing Congress and unilaterally imposing medical device regulation on the professional testing services that laboratories provide. But device regulation is inappropriate when applied to laboratories, and it does not strike the right balance between maintaining access and encouraging diagnostic innovation. Moreover, FDA justified its proposed regulatory action based on a profoundly inaccurate picture of the services that laboratories provide. The "evidence" used by FDA was flawed and, in many cases, unconfirmed. Further, FDA failed to consider the robust oversight that currently applies to laboratory testing services and the important public health contributions provided by laboratories. FDA's reliance on flawed data led directly to the Agency's failure to appropriately assess the costs and benefits of the Proposed Rule.

FDA's proposal raises profound concerns, both as a matter of public policy and as a matter of law. These concerns are detailed in our public comments submitted to the docket on FDA's rulemaking, which are also attached as supplemental materials. We outline here three primary areas of concern: access to testing, diagnostic innovation, and lack of legal authority.

FDA's Rule would Undermine Access to Testing

FDA's Proposed Rule would have significant adverse consequences for patients because it would limit or eliminate access to critical tests across the country. Device law imposes rigid and burdensome validation requirements that are not required of laboratories under existing regulatory

frameworks, and the costs of compliance with device regulation and pursuing premarket authorization is high—higher than FDA estimates. For example, the cost of samples needed to perform validation studies to FDA's expectations can itself be cost-prohibitive, even before considering the cost of running the studies themselves. Inevitably, laboratories would be forced to make difficult decisions about which tests can generate enough revenue to justify the high costs of pursuing FDA marketing authorization, such that many tests would have to be withdrawn from the market and would become unavailable to patients.

Indeed, most testing services offered by laboratories do not generate significant revenues, and we are acutely concerned about tests that serve small patient populations, such as for rare diseases. Those are the tests that would likely be the first to be dropped from testing menus, causing patients to lose access to important tests. Moreover, these added costs would be imposed at the very time when reimbursement for testing is being cut.

The Proposed Rule would also harm access to testing because laboratory testing capacity would suffer as laboratories shift their focus to backward-looking medical device compliance activities instead of performing tests for patients. Under the Proposed Rule, laboratories would have to devote significant resources to developing and implementing device policies and procedures to comply with the early stages of the rule and to the backward-looking exercise of re-validating existing tests and preparing device premarket submissions (to the extent they can afford to do so). Given the timelines proposed by FDA, this work would need to begin immediately. However, there is a dire workforce shortage in the laboratory industry, and there simply are not enough laboratory professionals to support compliance with the Proposed Rule while maintaining current testing levels. This is likely to have disparate impacts for already underserved populations.

And, let me be clear, an exemption for academic medical centers is not the answer to these problems. ACLA appreciates the important role of AMCs in the health care delivery system and the scientific and clinical expertise developed within AMCs, and we recognize their contributions to clinical and medical research. However, establishing an exemption for AMCs would create negative health disparities for populations without access to an AMC. A likely effect from such an exemption would be that patients in urban areas with better access to AMCs would have easier access to diagnostic services, while folks in more remote areas would not have access to potentially life-saving tests. Moreover, there is no reasoned basis for treating particular test developers, including AMCs, differently than commercial laboratories, and doing so would be arbitrary and capricious in violation of the Administrative Procedure Act.

Access to innovative tests would also be harmed because device regulation would cause an FDA-review bottleneck, which would be orders of magnitude greater than what the Agency experienced during the COVID pandemic. Because the Proposed Rule includes no grandfathering provision, FDA would receive an avalanche of applications—measured in the tens of thousands—for existing tests that would overwhelm the Agency's resources. Even if existing tests were grandfathered, the number of anticipated annual submissions would overwhelm the Agency. This would slow patient access to innovative tests as FDA deals with an overwhelming increase in workload, leading to extended review times and fewer FDA resources to engage with applicants and developers.

For example, FDA's estimates (which are almost certainly low) suggest that the initial number of premarket approval applications (PMAs) for laboratory developed testing services would be greater than the cumulative number of original PMAs processed by FDA in the entire history—going back to 1976—of medical device premarket review. Similarly, the anticipated annual number

of PMA submissions for laboratory developed testing services would increase FDA's annual workload for diagnostics by over 500%, and that does not take into account other application types or other regulatory responsibilities. Even if FDA down-classifies diagnostic tests, as it has announced it intends to do, that would simply shift the burden to review of de novo applications, but it would not significantly reduce the surge in workload.

As we saw during the COVID pandemic, despite dedicated staff who strove to meet the challenge of a global pandemic, FDA lacks the resources to deal effectively with such surges in regulatory responsibilities. During the pandemic, resources had to be diverted from other parts of the Agency, and applications and interactions with FDA related to non-COVID diagnostics were placed on hold. Moreover, even if FDA were authorized to hire more resources, there simply are not enough trained scientists and regulatory professionals to go around. FDA would be competing with laboratories that also would need to dramatically increase hiring of the same professionals (who already are in shortage) to deal with the new regulatory system. Additionally, recognizing approvals by New York State as approvals of LDT services for purposes of device regulation could lessen, but would not eliminate, this burden, and such recognition would not fix the fundamental legal and policy problems with imposing device law on testing services. The impact of this rule, if finalized, would reverberate throughout the health care system.

Impacts for patients would be real and serious. For example, last year, an ACLA member laboratory obtained marketing authorization of a groundbreaking genetic test that assesses a patient's predisposition to cancer and identifies the genetic origin for dozens of cancer types. This was the first FDA marketing authorization of its kind. However, it took the laboratory over a year and seven figures to prepare for the submission, and then took FDA over two and a half years to review and authorize it. During that time, the laboratory performed the same test for over 230,000

patients, of which more than 22,000 tested positive for an actionable result. Had FDA's rule been in place, the laboratory could not have offered the test until it was authorized by FDA, and those 22,000+ patients and their families would not have been able to learn about their risk of cancer or had their cancer care informed by their genetics. This is the cost of device regulation, which was not designed for regulating professional laboratory services.

FDA's Rule would Slow Innovation in Diagnostics

FDA's Proposed Rule would have significant adverse consequences for patients because it would undermine diagnostic and medical innovation. As noted above, labs would be forced to focus on backward-looking medical device compliance activities to justify the continued availability of tests that have been relied upon for decades. That also means diverting resources away from the development of the next generation of diagnostics for cancer, infectious disease, cardiovascular disease, neurological conditions, and numerous other diseases and conditions, including rare diseases and diagnostics for underserved communities, such as pediatric patients.

The drain on innovation would be driven not just by the direct costs of FDA regulation, which would be significant, but also because the medical device framework is wrong for regulating professional laboratory testing services. Currently, laboratories can identify the need for a new clinical test, develop and validate that test, and introduce it within a matter of months. Then trained laboratory professionals can fine-tune and adjust the performance of their testing services to meet patient and physician needs. However, the rigid requirements of device law directly conflict with the flexibility under existing law that supports laboratories' ability to ensure that patients and providers receive the important diagnostic information they need. In fact, numerous aspects of device law—from the basic approval standards of safety and effectiveness, to labeling and quality

system requirements—do not fit laboratory testing services. The device premarket review system cannot account for the rapid evolution in diagnostic services occurring in oncology, neurology, infectious disease, and numerous other areas.

For example, consider oncology tests. In the oncology space, treating physicians rely on the professional testing services provided by laboratories because they incorporate the latest scientific developments to inform the judgment of trained professionals, including diagnostic markers or combinations of markers. Often these developments are reflected in the clinical literature or in well-accepted guidelines from professional organizations. In fact, several ACLA member laboratories that have obtained FDA approval for oncology tests have found that physicians turn to laboratory developed tests (sometimes offered by the same laboratories) because FDA-approved testing kits often fail to reflect the latest advances in patient care. But device law would fundamentally change this paradigm by requiring lengthy premarket review for all or most such updates. Medical device authorities do not allow for the rapid innovation required to meet recognized scientific advancements and the standard of care. These barriers to innovation would add months or years to the development lifecycle for new laboratory developed testing services—months and years that can make a life-or-death difference to a patient.

All of this would result in less investment in research and development and slow the next generation of diagnostics for cancer, infectious disease, and numerous other diseases and conditions.

Legal Concerns

Regulating laboratory developed testing services as devices is beyond the Agency's jurisdiction. The statutory authority to regulate devices delegated to FDA in the Food, Drug, and Cosmetic Act (FDCA), originally in 1938 and amended many times since, extends to physical

products that are sold and distributed by manufacturers. Congress has always been clear—FDA regulates medical products, but health care services are beyond the agency's reach. Laboratory developed tests are professional services in which trained laboratory professionals use various tools to derive test results for patients. There is no physical product for FDA to regulate. FDA's assertion that a laboratory developed test is a device is no less misguided than calling a surgery—performed by a physician using various tools—a device.

The development and performance of laboratory testing services is also regulated under a separate statutory and regulatory framework—the Clinical Laboratory Improvement Amendments of 1988 (CLIA)—and complementary state laws that interact with CLIA. The text of the FDCA, together with the legislative history and broader statutory framework of the FDCA and CLIA, make clear that laboratory developed tests are not devices, and that Congress did not grant FDA authority to regulate those professional services. FDA's claim that it has authority to regulate laboratories in this way rests on an implausible assumption that the entire laboratory industry has been operating in violation of the FDCA for decades, and only now has FDA decided to act.

Conclusion

Over the past several years, ACLA worked collaboratively with this Committee, as well as FDA and other stakeholders, on legislation that could have established a role for FDA in an appropriate regulatory system for all diagnostics. ACLA's goal throughout that process was to strike the right balance between encouraging innovation, maintaining access, and establishing a regulatory approach that accounts for the unique features of laboratory diagnostics. ACLA steadfastly maintains that legislation is the right—and only—approach for FDA to regulate laboratory develop testing services. We would be pleased to again work with members of this

Committee to advance appropriate legislation that preserves the critical role of laboratory diagnostics and ensures that patients continue to have access to lifesaving tests.

Thank you for this opportunity to testify today, and I look forward to your questions.