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Subj: ADLM Meeting with OMB OIRA regarding FDA Proposed Rule on LDTs

Dear Director Young, Administrator Revesz, & Associate Director for Health Spiro:

The Association for Diagnostics and Laboratory Medicine (ADLM) appreciates the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) taking the time to meet with us to discuss the Food and Drug Administration's (FDA's) proposed rule to regulate laboratory developed tests (LDTs). While this proposed rule has not yet been released, this issue has been discussed within the healthcare community for more than a decade. ADLM thinks it is premature for OMB to release this proposal, given:

- the lack of clarity regarding FDA's legal authority to regulate LDTs;
- concerns about whether the agency has the resources to implement the proposal;
- the significant administrative burden that would be placed on academic medical centers, commercial laboratories, and small community hospitals;
- its adverse effect on access to quality, timely care in medically underserved communities;
- the existing regulatory process already in place for overseeing LDTs; and
- the lack of a regulatory impact/cost-benefit analysis of the proposed rule.

FDA Authority to Regulate LDTs

The question of whether the FDA has the authority to regulate LDTs remains unanswered. In 2015, Paul D. Clement and Lawrence H. Tribe published a white paper on behalf of the

American Clinical Laboratory Association arguing that the agency was seeking to "*saddle a dynamic and innovative industry with sweeping new regulatory burdens without statutory basis*."[1]

Similarly, the Department of Health and Human Services (HHS) General Counsel echoed this concern in its 2020 analysis of the FDA's legal authority to regulate LDTs. The counsel stated:

- *"the Agency's jurisdiction to regulate these devices is not uniform and not as plenary as it is for a traditional device."*

- *"it appears likely that LDTs, even if they satisfy the constitutional and statutory "interstate commerce" requirements of the FDCA, would likely not satisfy the separate "commerce distribution" requirements of the premarket review provisions at sections 510(k) and 515."*

- *Section 301(k), the primary provision dealing with prohibited acts, turns on whether the device is "held for sale." While the courts in the past have given that term a broad reading to include devices that never leave a physician's office, a plain meaning assessment may not be as agency friendly."*

- *"many first-line sophisticated laboratories are operated by state public health departments or academic medical centers at large state universities. These laboratories, by definition, are not "persons," within the meaning of the Act, and not subject to many of the Act's requirements…"*[2]

ADLM suggests that OMB seek greater clarity on this issue before advancing the FDA proposal.

Congressional Perspective
It is important to note that the FDA has been aggressively backing the Verifying Accurate Leading-edge IVCT Development (VALID) Act, which would give the agency explicit regulatory authority over LDTs. To date, Congress has rejected efforts to include VALID in several legislative packages, thus denying FDA oversight of LDTs.

FDA does not have the resources to regulate LDTs
The FDA, by its own admission, is having problems hiring staff to meet its current responsibilities. To increase this burden would add to the agency's problems, while potentially

[1] January 2015 White paper, *Laboratory Testing Services, As the Practice of Medicine, Cannot Be Regulated As Medical Devices,* Paul D. Clement and Lawrence H. Tribe.
[2] June 2022 Department of Health and Human Services Memo to FDA on the agency's legal authority to regulate LDTs.

affecting patient care. The FDA's lack of resources to execute its existing mission was evident during the COVID pandemic when the agency had to limit review of COVID Emergency Use Authorization tests to those with a volume greater than 500,000 per week. The inability of the FDA to review new COVID-19 tests raised legitimate concerns about whether the agency has the bandwidth to oversee LDTs, which could conservatively involve the review of tens of thousands of submissions.

For comparison, at maximum capacity the FDA is averaging 2,825 510(k) clearances and 31.5 premarket approvals (PMAs) annually.[3] More specifically, the Office of In Vitro Diagnostics, which would have oversight of LDTs, received a total of 112 510(k) submissions for the most recent quarter of this fiscal year and 10 PMAs. It is clear the FDA does not have the staff nor resources to review many thousands of additional LDTs.

Adverse Impact on Healthcare Sector, Communities, and Patients

There appears to be a misconception that because the FDA is using its "enforcement discretion" that LDTs are unregulated. This belief is inaccurate. LDTs are subject to a variety of oversight mechanisms at the federal and state levels and by professional accreditation organizations. Expanding oversight to include another federal agency will, in many instances, add to the regulatory burden and costs of performing LDTs, possibly resulting in many clinical laboratories discontinuing these tests.

Currently, all clinical laboratories performing LDTs are regulated by the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the FDA under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. These testing facilities are categorized as high complexity laboratories, subject to stringent personnel (must be directed by an MD or board-certified PhD), quality control and proficiency testing requirements as well as regular inspections. In addition, clinical laboratories must conduct an extensive evaluation of the analytical and clinical performance of all tests performed by their staff. These robust quality practices and tools permit clinical laboratories to identify shortcomings, allowing them to take steps to avoid failure and errors – regardless of the source of a test (e.g., LDTs or FDA-approved/cleared).

ADLM is concerned that ongoing efforts to create a dual regulatory structure, which treats clinical laboratories as medical device manufacturers will force many academic medical centers and other healthcare providers to discontinue these LDTs, thereby delaying physician access to timely, often vital, life altering patient information. Further, there is no evidence that a problem exists with these tests. When asked to assess the quality of LDTs, the FDA took two years to find twenty examples of tests that might be problematic, many of which were disproven. It is

[3] March 3, 2021, JAMA Open Network Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017, Jonathan Dubin, MD, Stephen Simon, PhD, Kirsten Norrell, MD, Jacob Perera, BA, Jacob Gowen, BA, Akin Cil, MD.

important to note that FDA approval or clearance does not necessarily ensure high quality or error free test results; many FDA approved or cleared tests are recalled or considered less than optimal.

Existing Regulatory Process for Making Changes

ADLM supports modernizing the current CLIA standards that regulate clinical laboratory testing. We believe that changes to LDT oversight should be considered by the Clinical Laboratory Improvement Advisory Committee (CLIAC), which is the federal advisory body that guides CMS, FDA, and CDC on CLIA policy. This view is shared by the American Medical Association, the American Hospital Association, and many other medical and professional societies.[4] A new duplicative, costly regulatory process is not necessary and will hamper access to care.

Regulatory Impact Statement/Economic Analysis

Executive Order 12866 requires federal agencies to conduct an analysis of the benefits and costs of rules and, to the extent permitted by law, directs that regulatory action shall only proceed if it is determined that the benefits of a regulation justify the costs. If a proposed rule is determined to be a "significant regulatory action" the federal agency seeking action must provide a detailed rationale for those changes. Actions are deemed to be significant if implementation of a regulation is projected to exceed $200 million.

From a review of the OIRA website, it does not appear that the FDA has conducted such an assessment. ADLM believes that OMB should ascertain, in advance of releasing the FDA document, whether the proposal exceeds that threshold and, if yes, require the agency to perform the required assessment. Such a study would need to address the impact of FDA oversight on the economy, specific sectors of the economy, marketplace competition, and the public sector and local communities, among other factors.

Thus, the FDA would need to know:

- the number of LDTs performed;
- how many clinical laboratories will be affected;
- the impact on the communities serviced by those clinical laboratories, particularly medically underserved areas;
- the costs of adopting the regulatory changes (e.g., hiring staff, generating required evidence, developing submissions, etc.); and
- the healthcare impact (e.g., decline in innovation, less competition; patients unable to access tests; bad patient outcomes), among other information.

[4] November 5, 2021 joint letter from healthcare groups to the Clinical Laboratory Improvement Advisory Committee urging it to take up the LDT issue as part of CLIA modernization.

We believe when all the costs are calculated, it is likely that the FDA proposed rule would exceed the $200 million threshold and classified as a major rule subject to a cost-benefit analysis.

Therefore, ADLM reiterates its view that it is premature for the OMB to release the FDA proposed rule. If the OMB deems the FDA to have legal authority over LDTs, the FDA should first be required to issue a Request for Information (RFI) to gather the data needed to determine whether the proposal is a significant rule and, if it determines it is, conduct the required cost-benefit analysis.

ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

On behalf of ADLM, I would like to thank you for the opportunity to engage OMB on this proposal. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,

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President, ADLM