December 4, 2023

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

Re: Comments on Food and Drug Administration Draft Rule on Laboratory Developed Test Regulation (Docket No. FDA-2023-N-2177)

Dear Commissioner Califf,

On behalf of the American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, thank you for the opportunity to provide feedback on the Food and Drug Administration's (FDA's) draft rule on laboratory developed test regulation (Docket No. FDA-2023-N-2177).

Cancer patients rely on accurate and clinically valid diagnostic tests to optimize their treatment options, and ACS CAN has long called for harmonizing and modernizing the regulatory framework. ACS CAN's overarching goal for diagnostic reform legislation is to ensure that patients have confidence in the results of diagnostic tests, which have become increasingly critical in the management of cancer. Currently, diagnostic tests undergo widely different oversight depending on whether they are submitted to the FDA for review or are offered as laboratory developed tests (LDTs). This difference opens the door to the possibility that test results for the same analyte may vary depending on where the test is conducted, potentially leading to incorrect treatment decisions and patient harm if a test result is not valid. Cancer patients and their physicians should be able to trust the information produced by a diagnostic test regardless of where that test is conducted.

For the past several years ACS CAN has joined with a broad coalition of stakeholders in calling for legislative reform of the diagnostics space, specifically supporting the Verifying Accurate, Leading-edge IVCT Development (VALID) Act as way to achieve that reform. Our preference is still for Congress to pass legislation to modernize and harmonize diagnostics oversight; however, we also support the Administration's proposal to begin that harmonization via rulemaking. We have focused our comments below on areas of the draft rule that are of the most importance to our organization.

Risk Classification
We strongly support the concept of a risk-based oversight framework, which focuses oversight proportionally on tests based on risk to a patient if a test result is incorrect. A large number of cancer tests would be included in the highest risk tier, and we support the greater level of review proposed.

Implementation
ACS CAN supports the phased implementation of the proposed rule, beginning with registration, listing, and adverse event reporting. We further support the prioritization of high-risk tests as the first category to be brought in for review under the new rule.

As new tests become subject to regulatory requirements, especially pre-market review, FDA will be tasked with a significantly increased workload. The timing of implementation has been designed to align with the next Medical Device User Fee Amendment (MDUFA) reauthorization with an eye toward enabling increased resources for FDA. Securing these resources will be critical to ensuring that the new rule is carried out in an efficient manner that does not hinder test development or patient access.

Conclusion
We continue to support efforts to modernize and harmonize diagnostic test oversight and believe it will not only improve care delivery in the short-term but will also ensure patients continue to benefit from emerging personalized therapies. As you work to finalize and implement the rule, we encourage you to consider our comments and ensure that the final rule ensures patient safety and confidence in diagnostic tests. We look forward to continuing to work with you. If you have any questions regarding our comments, please contact Mark Fleury (mark.fleury@cancer.org).

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network