December 4, 2023

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Medical Devices; Laboratory Developed Tests (Docket No. FDA–2023–N–2177)

Dear Commissioner Califf,

On behalf of The US Oncology Network (The Network), which represents over 15,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to comment on the Food and Drug Administration (FDA) proposed rule "Medical Devices; Laboratory Developed Tests (Docket No. FDA–2023–N–2177)."

The Network is one of the nation's largest and most innovative networks of independent, community-based oncology physicians, treating more than 1.4 million cancer patients annually in more than 600 locations across 30 states. The Network unites over 2,400 independent providers around a common vision of expanding patient access to the highest quality, state-of-the-art care close to home and at lower costs for patients and the health care system. We are committed to working with the FDA to enhance the delivery of cancer care and protect patient access to high-quality, affordable care in the most efficient manner.

Under the proposed rule, laboratory developed tests (LDTs) would be considered medical devices under the Food, Drug, and Cosmetic Act and subject to regulation by the FDA. With the growth of precision medicine in oncology, patient access to affordable, timely, laboratory testing is more important than ever. While we share the FDA's goal of ensuring the validity and reliability of LDTs, The Network has significant concerns that this proposal as drafted would reduce patient access to critical diagnostic testing and lead to consolidation of physician-owned labs.

The Network is concerned that this proposed rule would effectively require all laboratories to redevelop and revalidate many existing tests and then resubmit them for FDA review. This would require significant time and resources with the potential for severe consequences. For example, patients and providers may lose access to critical diagnostic testing as some products may be pulled off the market and some labs may go out of business due to insufficient resources to repeat the prior development and validation work. The revalidation process can be prohibitively difficult for certain rare diseases or rare indications. It could also delay introduction of new, innovative products. The increased costs resulting from this process are likely to be passed onto the patient and across the healthcare system. Additionally, smaller labs, including physician-owned labs—which are an integral component of the oncology ecosystem—may not be able to survive, leading to industry consolidation and reduced competition. As a result, our patients may be forced to travel further to have key labs drawn. Consolidation could also impact turnaround time for critical lab results.

Rather than subjecting all LDTs to FDA regulation, The Network supports more stringent validation requirements for LDTs through the existing regulatory framework from the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA). However, should FDA finalize this proposed rule, The Network strongly supports the grandfathering of existing tests, subject to evidence of

analytical and clinical validity and clinical utility. We also support flexibility for tests considered as standard of care and recommended in society guidelines where continuity of patient access is critical. Last, we believe peer-reviewed evidence of clinical validity and clinical utility (when published in respected scientific journals) should be taken into account, as should prior reviews by other regulatory bodies.

On behalf of The US Oncology Network, thank you for the opportunity to provide comments on this proposed rule. We welcome the opportunity to discuss the issues outlined above and any other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy at Ben.Jones@usoncology.com.

Sincerely,

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