



August 20, 2018

The Honorable Larry Bucshon
U.S. House of Representatives
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

RE: Request for Comment on U.S. Food and Drug Administration Technical Assistance on the “Diagnostics Accuracy and Innovation Act” Discussion Draft

Dear Representatives Bucshon and DeGette,

On behalf of LUNGEvity Foundation, the nation’s preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the 222,500 Americans diagnosed with lung cancer each year and the 527,228 Americans living with the disease, we appreciate the opportunity to submit our comments on the U.S. Food and Drug Administration (FDA) Technical Assistance (TA) on the “Diagnostic Accuracy and Innovation Act” (DAIA) discussion draft.

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community, LUNGEvity strongly believes there is a critical need to modernize the regulatory framework for clinical laboratory diagnostics, including laboratory developed tests (LDTs) and *in vitro* diagnostics (IVDs), in order to ensure patients and their health care professionals have access to high quality and innovative laboratory diagnostics. In this era of unprecedented scientific advancements in the diagnosis and treatment of lung cancer, it is essential that patients have access to tests that have been evaluated with stringent criteria for analytical and clinical validity.

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, diagnosed in about 85 percent of people with lung cancer.^{1,2} Since the discovery of the first epidermal growth factor receptor (EGFR) mutation in lung cancer in 2004, targeted therapies have become a major component of the treatment arsenal of NSCLC patients.³⁻⁵ Now at least 10 driver mutations in adenocarcinoma have been identified (EGFR, ALK, ROS, RET, ERB2/HER2 mutations, ERB2/HER2 amplifications, MET amplifications, MET mutations, TRK, BRAF, KRAS).^{6,7} In concert with the identification of an increasing number of targetable mutations is the development of novel, potent, and specifically targeted therapies. Currently, FDA-approved drugs for four mutations (EGFR, ALK, ROS1, and BRAF) are already in clinical practice, and several targeted therapies specific to other mutations are in clinical development.⁸



Below are three areas of our initial feedback of the FDA TA, focused on timeliness of review, grandfathering, and modifications. We are committed to working with you, the Congress, the Administration, and other stakeholders to ensure the voice of the patient is heard and carried out throughout the process of diagnostic regulatory reform.

- **Timeliness of Diagnostic Test Review** – It is crucial for patients with lung cancer to have timely access to the most up-to-date analytically and clinically validated diagnostics tests to aid them and their healthcare provider in decision making and to ensure access to life-saving and life-prolonging therapies. An efficient and modernized regulatory process for diagnostic test review is essential for patients to have access to the most innovative products. We appreciate FDA including principles that support overall timeliness in the review process and encourage further dialogue on efficient premarket review requirements and the important use of well-qualified entities as third-party reviewers.
- **Grandfathering** – We understand that grandfathering of LDTs is necessary and we encourage you to further review this section and the thoughts put forth by FDA, as well as to seek input from additional stakeholders. Specifically, we request that you ensure that the transition period is well defined, that there is consistency and transparency with risk classifications, and that there is a data submission requirement for all grandfathered tests within a certain period of enactment.
- **Diagnostic Test Updates/Modifications as New Assays are Approved** – As noted above 10 driver mutations in adenocarcinoma have been identified since 2004 and more are being discovered each year.^{6,7} It is crucial that the regulatory policy set forth is sufficiently flexible to allow for modifications to be made to diagnostic tests in a timely fashion to keep pace with science while ensuring high quality. Inclusion of FDA's use of change protocols in the TA is demonstrative of their commitment to supporting diagnostic innovation and we hope principles such as these will be further discussed to create an appropriate, efficient, and safe approach to diagnostic test modification.

We appreciate the FDA's TA on the DAIA discussion draft and understand that it is a necessary step in the process of moving forward legislative reform. However, the TA received from the FDA is new text and we urge you to give ample time for all stakeholders to fully weigh in and provide input. We also urge you to include the Centers of Medicare and Medicaid Services (CMS) in the review and input process of the authorities assigned in the act that would be carried forth and impact the Clinical Laboratory Improvement Amendments (CLIA) program.



Access to high-quality, timely diagnostic testing is crucial for patients with lung cancer. LUNGeivity is strongly supportive of efforts to modernize the regulatory framework for all laboratory diagnostics and we appreciate the opportunity to provide comments on the FDA TA on the DAIA discussion draft. We are committed to working with you, the Congress, the Administration, and other stakeholders to ensure diagnostic regulatory reform is enacted in a timely manner.

The comments outlined above can be discussed with my staff, myself, and LUNGeivity's Scientific Advisory Board, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care. I can be reached at 240-454-3100 or aferris@lungevity.org if you have any questions or would like to engage in further dialogue.

Thank you for your attention to this very important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Stern Ferris".

Andrea Stern Ferris
President and Chief Executive Officer
LUNGeivity Foundation

CC: Senator Orrin Hatch
Senator Michael Bennet

ABOUT LUNGEVITY:

LUNGeivity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the



organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

REFERENCES:

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8. Tan WL, Jain A, Takano A, et al. Novel therapeutic targets on the horizon for lung cancer. *Lancet Oncol*. Aug 2016;17(8):e347-362.