ACMG
American College of Medical Genetics and Genomics
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October 23, 2023

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

Re: Request for extension of the public comment period for the FDA proposed rule on Medical Devices: Laboratory Developed Tests (0910-AI85); Docket No. FDA-2023-N-2177

Dear Commissioner Califf,

The recently released proposed rule for Medical Devices: Laboratory Developed Tests (0910-AI85) has the potential to significantly change clinical testing throughout the United States. Due to the complexity and impact of the rule, the American College of Medical Genetics and Genomics (ACMG)[1] requests that the US Food and Drug Administration (FDA) extend the public comment period to at least 120 days.

If finalized, this proposed rule would affect clinical laboratory test offerings, the ability to quickly modify tests in response to clinician requests, and patient access to clinical testing. The proposed rule includes a request for additional information for several topics to better understand the impact of the rule and scenarios in which exceptions/enforcement discretion may be needed to minimize disruptions to clinical care. Through this, the FDA acknowledges that

[1] Founded in 1991, the American College of Medical Genetics and Genomics (ACMG) is a prominent authority in the field of medical genetics and genomics and the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics. The only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization, the ACMG provides education, resources and a voice for more than 2,600 clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

7101 Wisconsin Avenue, #Suite 1101
Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-381-9379
www.acmg.net

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the proposed rule could significantly change clinical testing, especially at smaller laboratories. The guidance specifically states that "*sudden change could negatively affect the public, including patients and industry*". It is vital to patient care that the impact of this rule be carefully and thoroughly assessed before the FDA considers finalization.

We request that the December 4th public comment deadline be extended by at least 60 days to allow stakeholders time to assess the impact of the proposed rule. We ask that FDA announce this extension promptly so stakeholders can develop plans for gathering the necessary information to respond to the proposed rule, including the specific areas in which FDA has requested additional information.

Sincerely,

Susan D. Klugman, MD, FACMG
President
American College of Medical Genetics and Genomics

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Bethesda, MD 20814
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Fax: 301-381-9379

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