November 18, 2014

Margaret Hamburg, MD
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

On behalf of the undersigned organizations, which represent a broad and diverse array of stakeholders including, but not limited to, hospitals, clinical laboratories, physicians, other health care providers and industry involved in delivering medical care to millions of patients daily, we are writing to request that the Food and Drug Administration (FDA) withdraw the proposed draft guidance, "Framework for Regulatory Oversight of Laboratory Developed Tests" and associated guidance. The draft guidance documents conflict with existing regulations and would impose substantial new requirements on clinical laboratories, hospitals, physicians, and other health care providers without complying with notice and comment rulemaking as required under the Administrative Procedures Act (APA).

On October 3, 2014, the FDA issued draft guidance proposing to establish new and significant regulatory requirements on hospitals, clinical laboratories, physicians, other health care providers and industry offering laboratory developed testing services. The FDA's statutory authority to regulate laboratory developed testing services and the scope of the proposed guidance remains a matter of significant legal controversy, and while a number of the undersigned organizations do not waive their legal claim that the FDA lacks the statutory authority to regulate laboratory developed testing services, to the extent that it is established that the FDA does have such authority, all of the undersigned are unanimous that the overwhelming weight of legal authority dictates that the proposed new requirements outlined in the draft guidance must be issued through notice and comment rulemaking.

Laboratory developed testing services are a vital area of medical practice impacting the majority of patients across the country, and any wholesale change in oversight and regulation must be done with full consideration of the clinical realities of health care delivery. The APA establishes a simple procedure for rulemaking so that interested parties are given an opportunity to participate in the rulemaking through submission of written data, views, or arguments. Notice and comment will increase the likelihood that the agency will be able to achieve regulatory goals without jeopardizing the current delivery of testing services to patients and the continued advancement in testing and patient care.

Aside from the FDA's legal obligation to proceed through notice and comment rulemaking, the FDA's compliance with the APA would provide essential protections for the regulated to ensure that subsequent

changes are promulgated with notice and in a deliberate, informed manner consistent with law. Protections afforded by the notice and comment rulemaking process include the requirement that the Agency respond to all stakeholder comments and undertake an economic impact analysis of the new regulatory oversight to assess the estimated burden on the regulated. The foregoing are critical exercises to address widely-held concerns with the lack of specificity and clarity in the proposed guidance that undermine the ability of impacted stakeholders to provide constructive and informed feedback on the proposed changes. Finally, guidance documents do not carry the legal certainty and weight of regulations that provide the regulated reasonable assurances and ability to comply with the FDA's requirements.

We look forward to working with the FDA, other federal agencies, and other stakeholders to ensure that any change in the current policy regulating laboratory developed testing services does not jeopardize the delivery of health care in the country or the practice of medicine, and that patients continue to have access to medically necessary clinical care.

Sincerely,

Organizations & Other Stakeholders

American Clinical Laboratory Association
American Hospital Association
American Medical Association
Medical Group Management Association
American Academy of Facial Plastic and Reconstructive Surgery
American Association for Clinical Chemistry
American Association for the Study of Liver Diseases
American Association of Bioanalysts
American Association of Clinical Endocrinologists
American College of Cardiology
American College of Medical Genetics and Genomics
American College of Osteopathic Surgeons
American College of Rheumatology
American Gastroenterological Association
American Osteopathic Association
American Society of Hematology
ARUP Laboratories
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Avalon Healthcare Solutions
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Coalition for 21st Century Medicine
Crescendo Bioscience, Inc.
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National Independent Laboratory Association
National Society of Genetic Counselors
NeoGenomics Laboratories Inc.
North American Spine Society
Quest Diagnostics
Seattle Children's Hospital
XIFIN

Laboratory Directors

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