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## United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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To Interested Parties:

Clinical diagnostics play a critical role in our health care system, influencing nearly 70% of all health care decisions. Diagnostic technologies are also the cornerstone of precision medicine and personalized therapies, and as such warrant oversight to ensure regulators are facilitating their continued progress, safety, and accuracy.

Stakeholders and policymakers broadly recognize the need for reform to the regulatory frameworks that oversee laboratory services and diagnostic products. In the nearly 50 years since the Medical Device Amendments (MDA) of 1976 established the Food and Drug Administration's (FDA) framework for medical devices, advancements in in vitro diagnostic (IVD) technologies have necessitated improvements to this framework to support timely patient access to safe and effective diagnostics, especially those intended for special or rare disease populations. At the same time, clinical laboratory medicine has evolved in the 35 years since the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were enacted, demanding standards that reflect advancements in molecular and genomic testing and ensure appropriate oversight over these tests.

In the past, Congress has considered proposals to bring needed reforms to diagnostics regulation. These efforts have been unsuccessful and have resulted in missed opportunities to implement substantive updates to both regulatory frameworks. To further guide ongoing discussion of these matters, I welcome your insights on the following topics, specifically addressing the actions Congress should pursue to meet the challenge of ensuring patient access to timely and advanced diagnostics. Please submit any responses to [diagnostics@help.senate.gov](mailto:diagnostics@help.senate.gov) by **April 3, 2024**.

### FDA Regulatory Framework for Diagnostics

1. How well is FDA's medical device framework working for the regulation of diagnostic products? Are there improvements that should be made?
  - a. Of these specific changes, which would require Congressional action, and which can be effectuated by FDA alone?
2. Does the current device regulatory framework support the review of diagnostics that are developed using AI or that incorporate AI?
3. What, if anything, makes diagnostics distinct among FDA-regulated medical products to warrant specific attention to how AI may be used in the review of product submissions?

4. Are the regulatory pathways intended to evaluate diagnostics for special populations (i.e. rare diseases or genetic disorders) working?
  - a. How could they be enhanced to accelerate and authorize products for special populations, for example, certain companion diagnostics for rare biomarkers?
5. Are there regulatory hurdles to expanding the settings in which diagnostics are performed, i.e. point-of-care (POC) tests performed in patients' homes?
  - a. In what ways could/should FDA leverage regulatory flexibilities to reduce testing barriers?
6. What are your views on FDA's implementation of predetermined change control plans; is FDA's approach in its recent guidance readily applicable to IVDs and other diagnostic products?
7. Does FDA's current risk classification framework properly measure risk versus regulatory controls for diagnostics products?
  - a. If not, how can FDA's risk-based regulatory approach to diagnostics be improved to better align the degree of regulatory oversight with patient risk and benefit?
8. In considering reforms to FDA's risk classification framework for diagnostics, what types of IVDs should be exempt from premarket review?
  - a. What factors related to risk management should be applied to risk classification of IVDs?
9. Is the "safety and effectiveness" standard against which diagnostics are reviewed the most appropriate review standard to assign risk management for clinical tests?
10. Do the proposed reforms to FDA's device framework warrant the establishment of a new regulatory pathway specific to diagnostics? If yes, what are the principles that should guide such a new framework, as it would be applied to diagnostics currently subject to FDA premarket review?

#### CLIA Regulatory Framework for LDTs

1. What updates to the clinical laboratory regulatory structure under CLIA should Congress consider to reflect the latest scientific practices and safety standards?
2. What are your views on the effectiveness and use of the Clinical Laboratory Improvement Advisory Committee (CLIAC) in providing scientific and technical guidance to inform potential updates to CLIA standards?
3. Do the proficiency testing programs currently approved by the Department of Health and Human Services (HHS) reflect the latest clinical standards of laboratory medicine? Are there specialties, subspecialties, or analytes that should receive greater consideration for HHS approval?
4. How well does the existing enforcement structure under CLIA work in ensuring compliance with regulatory requirements and taking action against noncompliance? What should be improved, if anything at all?
5. Should legislative reforms address CLIA's quality system requirements? If yes, which of those changes would require Congressional action, and which could be effectuated by CMS alone?

6. Where does redundancy exist, if at all, within the current CLIA regulatory structure with respect accreditation standards under federal and state licensure programs, as well as through CMS-approved accreditation organizations?
7. In considering legislative reforms to CLIA, should LDTs be defined in statute? What aspects of test development would characterize such a definition?
8. How should Congress consider issues relating to the practice of medicine and its relationship with labeling for LDTs? Should there be additional oversight of the information conveyed to patients serviced by LDTs?
9. Should certain CLIA regulations be updated, would it necessitate a reevaluation of the CLIA fee schedule?
10. What compliance challenges would legislative reforms to CLIA create? How should new regulatory requirements apply to tests currently available to patients?

Sincerely,

*Bill Cassidy, M.D.*

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Bill Cassidy, M.D.  
Ranking Member  
U.S. Senate Committee on Health,  
Education, Labor, and Pensions