



FOR IMMEDIATE RELEASE
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ACLA RESPONDS to SACGHS REPORT RELEASE
“U.S. System of Genetic Testing: A Response to the Charge of the Secretary of HHS”

The American Clinical Laboratory Association (ACLA) shares the Secretary’s Advisory Committee on Genetics Health and Society (Committee) overarching goal to ensure that genetic technologies and test methodologies continue to keep pace with innovation and remain accessible to enhance and benefit individual personal healthcare. However, ACLA is concerned that the recommendation for regulatory oversight could have unintended consequences if interpreted to mean that FDA’s Food Drug and Cosmetic Act requirements should be applied to all laboratory diagnostic tests without full stakeholder input and involvement.

Alan Mertz, President of ACLA said “Any change in the regulatory oversight of these critically important tests has to be fully informed by the laboratory community to ensure interagency coordination, elimination of regulatory redundancies and duplications. Although there are many similarities between FDA’s and CLIA’s regulatory requirements there are clear redundancies and duplications that if not coordinated, harmonized and streamlined will stifle innovation in this area.”

ACLA has proposed a regulatory model that builds on interagency coordination, is consistent with principles of least burdensome, fills all the identified “regulatory “gaps”, avoids overlapping and potentially conflicting requirements and allows for a participatory approach that draws on the expertise of industry stakeholders, CMS, and FDA. The model also invokes public-private partnerships thus avoiding significant new costs for the agencies.

ACLA represents local, regional and national clinical laboratories throughout the United States.

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