

ACMG NEWS

For Immediate Release

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ACMG Makes Strong Recommendations on Regulatory Framework for Laboratory-Developed Tests (LDTs)

Bethesda, MD – October 27, 2015 | This week, as part of a coalition working with the American Medical Association, the American College of Medical Genetics and Genomics (ACMG), the nation's most experienced body in genetic testing and interpretation, sent a detailed recommendation addressing oversight and regulation of genetic testing as Congress, the U.S. Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services' (CMS) Clinical Laboratory Improvement Amendments (CLIA) Program determine how to move forward on laboratory regulation. ACMG has also been working directly with government and industry stakeholders on these issues.

The AMA Coalition Letter states that, "Imposing an entirely new regulatory regime on health care providers, the health care system and patients will deplete limited resources needed to strengthen existing requirements and inevitably constrict access to essential testing services as many public health, community and academic laboratories would find switching to a new regime cost-prohibitive." It later adds, "Equally concerning, a new regime would unnecessarily constrict the number of new tests providers are able to develop and offer patients, directly impacting access to breakthrough treatments and medical innovation."

Background and ACMG's Position: The FDA is currently working on a final regulatory framework for LDTs and policymakers are considering how best to clarify the rules for LDTs. In doing so, both the FDA and Congress must recognize that LDTs are used in a wide variety of settings, and that LDTs used for genetic testing and counseling need to be differently treated than other more routine diagnostic tests due to the rarity and genetic variability of genetic diseases. The ACMG believes that any oversight framework must ensure high quality genetic testing remains available to physicians and patients and that it keeps pace with the rapid innovation that currently characterizes this field.

ACMG's position elaborates on the importance of expert test interpretation, "Genetic and genomic tests are highly complex tests based on recently acquired and rapidly evolving knowledge; they are not tests that produce individualized results on their own but require expert interpretation informed by medical and family histories to ensure their safe and effective use by providers." ACMG also asks policymakers to evaluate ways to strengthen the CLIA program in balance with determining the appropriate role for FDA oversight.

“ACMG believes that a critical step in the continued improvement of genetic and genomic testing is to better balance the roles of the regulatory bodies involved in the oversight of test kit and device manufacturers (FDA) and of the practices of clinical laboratories (CLIA).”

Further, the AMA coalition letter parallels the ACMG recommendations by stating, “The undersigned organizations represent a diverse and broad community of medical centers, laboratories, physicians, and other professional health care providers involved in delivering medical care to millions of patients daily. We stand united in support of modernizing the oversight framework for high complexity clinical laboratory developed testing services and procedures primarily through reform of the Clinical Laboratory Improvement Amendments (CLIA). We agree that congressional action is needed to ensure that high complexity laboratory developed testing services and procedures are accurate, precise, clinically relevant, and monitored for continued quality performance largely through CLIA enhancements. The foregoing proposed modernization of the CLIA oversight structure is premised upon use of the clinical commons (readily available clinical validity information) to perform oversight functions. To the extent tests fall outside of the clinical commons, there should be a limited, well-defined role for the Food and Drug Administration.”

The ACMG has posted the following documents regarding Laboratory-Developed Tests on its website at www.acmg.net:

1. [AMA Coalition Letter](#)
2. [ACMG's Statement on Laboratory-Developed Tests](#)
3. [ACMG's Statement that Genetic Tests Are Different than Laboratory Developed Tests \(LDTs\)](#)
4. [The American College of Medical Genetics and Genomics: *Who We Are and What We Do*](#)
5. [Video of a Patient's Perspective on the Importance of LDTs](#)

About the American College of Medical Genetics and Genomics

The American College of Medical Genetics and Genomics (www.acmg.net) is the specialty society representing U.S. clinical and laboratory Medical Geneticists who are board certified by the American Board of Medical Genetics and Genomics, one of the 24 primary member specialty boards of the American Board of Medical Specialties. Fellows of ACMG are from four specialties: MD/DO Clinical Genetics and three MD or PhD laboratory specialties (Clinical Biochemical Genetics, Clinical Cytogenetics, and Clinical Molecular Genetics). ACMG's 1800 members also include genetic counselors, genetics nurses, and public health geneticists. It is the only nationally recognized medical organization dedicated to improving health through the practice of medical genetics and genomics.

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