February 3, 2015

Comments submitted electronically via [www.regulations.gov](http://www.regulations.gov) [Docket No. FDA-2011-D-0360]

Dear Ms. Serrano and Mr. Ripley,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA’s) Proposed Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) [Docket No. FDA-2011-D-0360]. FASEB comprises 27 scientific societies, collectively representing over 120,000 biological and biomedical researchers. Several FASEB societies represent investigators and clinicians actively engaged in the development and use of LDTs or who rely on them in their clinical work and for the conduct of their research. Some FASEB societies will also be providing comments based on the expertise and perspectives of their membership.

LDTs are the product of basic and clinical research and represent the power of translational research to advance modern medicine. Their regulation presents challenges because of the myriad types and uses of LDTs in clinical laboratories. A regulatory infrastructure should contain requirements sufficient to demonstrate the accuracy and precision of laboratory tests—thereby safeguarding the public—while facilitating the appropriate application of emerging technology to patient care in the least burdensome manner.

Discussions regarding the proper mechanism for regulating LDTs have been divisive across the healthcare and research communities and have spanned decades. We found diversity in the views of our members as well, and we were unable to achieve consensus regarding which federal agency or oversight framework would simultaneously best serve patients, clinicians, and researchers. FASEB societies were able to agree, however, on two key areas that we ask regulatory agencies to consider before proceeding with any new oversight framework.
More time must be taken to fully understand the LDT landscape and the implications of proposed oversight mechanisms on all stakeholders
FASEB believes that more time is necessary to evaluate the current healthcare ecosystem within which LDTs are developed and administered before changing the current regulatory paradigm. As noted during a recent FDA Workshop¹, there are several areas within the proposed oversight framework that are redundant with existing reporting mechanisms or require more detailed explanation. Therefore, we urge FDA to take additional time to engage all appropriate stakeholders—including researchers, clinicians, patients, payer organizations, the in vitro diagnostic laboratory community and industry, and representatives from other federal agencies, such as Centers for Medicare and Medicaid Services (CMS) and National Institutes of Health (NIH)—in transparent discussions to clarify both the Agency's definition of an LDT and risk-based classification system before finalizing any guidance or new regulations on LDTs.

FDA should work with organizations currently involved in the oversight of LDTs to determine data points already collected and prevent increased administrative and regulatory burden
Regulatory burdens are a significant and growing obstacle to progress in biomedical research. Responses to 2007 and 2012 surveys administered by the Federal Demonstration Project indicated that approximately 42 percent of a federally funded investigators’ research time was devoted to administrative reporting requirements.² Therefore, prior to proceeding with any changes to the oversight strategy for LDTs, FDA should work with investigators and laboratories actively engaged in the development and administration of these tests to minimize potentially duplicative reporting requirements. Such organizations include, but are not limited to, CMS, College of American Pathologists, Clinical Laboratory Improvement Advisory Committee of the Centers for Disease Control and Prevention, and test registries such as NIH Genetic Testing Registry. Furthermore, cost-benefit analyses of proposed new reporting requirements should be conducted prior to any changes of the enforcement structure. Such analyses should be transparent and take into consideration the perspectives of the full range of LDT stakeholders, including researchers, healthcare providers, payers, and patients.

In conclusion, FASEB appreciates that the oversight of LDTs is a complex topic that affects many different endeavors. The FDA should work to resolve all concerns highlighted above prior to finalizing a guidance document or other regulation on LDTs. We urge the Agency to take additional time to survey the existing LDT landscape and work with all stakeholders to identify and mitigate unintended consequences that could have negative effects on patient care and the conduct of innovative, life-saving research.

Sincerely,

Joseph R. Haywood, PhD
FASEB President