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ACLA Comments to FDA on IVDMIA Guidance

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) submitted extensive comments to the Food and Drug Administration (FDA) on the draft In Vitro Diagnostic Multivariate Index Assay (IVDMIA) Guidance Document. ACLA stressed that this guidance represents a major shift in FDA policy toward the approval and oversight of clinical laboratory services and will impose many new mandates carrying the force of law on clinical laboratories, without the benefit of rulemaking. ACLA communicated a number of continuing concerns and major ambiguities with the FDA approach which will be very disruptive to laboratories, physicians, and most importantly negatively impact on patient care.

Alan Mertz, President of ACLA, said “Although ACLA shares the goal of ensuring continued access to innovative, safe, and effective laboratory services, FDA must first engage in a robust, interactive and comprehensive dialogue with the laboratory community and use a more formal process to meet the shared goal.” ACLA specifically asked to meet with FDA, and other agencies with regulatory jurisdiction over laboratories, prior to further action on this guidance.

ACLA comments raise fundamental problems with the guidance including the continued difficult issues related to the definition of an IVDMIA – an area that could have particularly troubling implications for the development of these innovative new services. The revised definition of IVDMIA remains subjective and as such is open to agency interpretation – resulting in an unacceptable patchwork of imprecise standards. Other key concerns include the redundancy and possible incompatibility between FDA’s Quality System and the Clinical Laboratory Improvement Amendment approach to quality assurance, the importance of a well thought out transition period, the problems that could arise with an “investigational device” label, adverse event reporting issues, and uncertainty regarding how test modifications will be regulated.

ACLA’s comments are posted on the web site at <http://www.clinical-labs.org> ACLA represents local, regional and national clinical laboratories throughout the United States.

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