

March 5, 2007

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Andrew C. von Eschenbach, M.D.  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857-0001

Reference: Docket No. 2006-0347 – Draft Guidance for Industry,  
Clinical Laboratories, and FDA Staff on *In Vitro* Diagnostic Multivariate  
Index Assays

Dear Commissioner von Eschenbach:

The undersigned organizations, which represent a broad spectrum of interest in the opportunities that ensue from personalized molecular medicine, are concerned that the Food and Drug Administration's (FDA) Draft Guidance on *In Vitro* Diagnostic Multivariate Index Assays (IVDMIA)<sup>1</sup> will impose new requirements on certain molecular and genetic tests without affording stakeholders the full procedural protections of notice and comment rulemaking. If FDA continues to believe that new requirements are necessary, we ask that the FDA engage in a formal rulemaking process rather than use the guidance document approach. Because of the importance of this issue and the impact it will have on healthcare innovation and business development, we also encourage the Agency convene an interactive public workshop to better inform the issuance of a Notice of Proposed Rulemaking.

FDA released the draft guidance document on IVDMIA in September 2006. The release of this draft guidance document was the first time stakeholders were informed of FDA's new thinking on this complex issue. Guidance, as consistently stated by FDA, is intended to represent the agency's current thinking on a particular topic without creating or conferring any new policy directives. However, this draft guidance will require, among other things, clearance or premarket approval from FDA – a significant and major change in the agency's historical policy regarding laboratory-developed tests.

FDA's draft IVDMIA guidance is a substantial departure from long-established FDA policy not to apply the medical device law to clinical laboratories offering laboratory-developed tests. Thus, the draft guidance constitutes a substantive

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<sup>1</sup> Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on *In Vitro* Diagnostic Multivariate Index Assays

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rule issued without the full procedural protections afforded by notice and comment rulemaking procedures; such as justification and analysis of impact, OMB review, availability of judicial review, and explanation of decisions made through publication in the Federal Register. These additional protections are critical when an agency plans to adopt new binding requirements, as FDA is planning through its IVDMA initiative.

The need for formal rulemaking goes beyond the legal and administrative considerations. As confirmed by a February 8, 2007 public meeting on the subject, the FDA guidance, as proposed, raises many technical concerns and questions that need further clarification and stakeholder input.

We thank you in advance for your consideration to convene an interactive public workshop and proceed – if necessary – to impose new requirements on IVDMA through formal notice and comment rulemaking.

Sincerely,

American Clinical Laboratory Association  
American College of Medical Genetics  
American Medical Technologists  
American Society for Clinical Laboratory Science  
American Society for Clinical Pathology  
ARUP Laboratories  
Association for Molecular Pathology  
CardioDx  
Clariant, Inc.  
College of American Pathologists  
Expression Analysis, Inc.  
Genetic Alliance  
Genetics and Public Policy Center, Johns Hopkins University  
InterGenetics Incorporated  
Mayo Clinic  
Oncotech Inc.  
RedPath Integrated Pathology, Inc.  
The Coalition for 21<sup>st</sup> Century Medicine