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March 5, 2007

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President

BY ELECTRONIC SUBMISSION: <http://www.fda.gov/dockets/ecomments>

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers lane, Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays (IVDMIA)s; Availability [Docket No. 2006D-0347]

Division of Dockets Management:

The Association of American Medical Colleges (AAMC) is a nonprofit association that seeks to improve the nation's health by enhancing the effectiveness of academic medicine. It represents all 125 U.S. and 17 Canadian accredited allopathic medical schools, nearly 400 major teaching hospitals and health systems, and 96 academic societies, encompassing 105,000 faculty, 67,000 medical students, and 104,000 residents. The AAMC is pleased to comment on this important issue, and is strongly supportive of the overall goal of the proposed guidance, namely to ensure that IVDMIA)s commercially available to physicians and the public are safe, technically accurate, and clinically valid. However, AAMC is concerned that regulation of these tests not result in a burdensome and inefficient process that would hinder research and development and discourage investment.

Literally hundreds of tests that would be classified as IVDMIA)s have become commercially available in recent years. Many of these tests are genetically based, purport to predict the future course of a particular disease or responsiveness to therapeutics, and are used in making critical clinical decisions about interventions such as surgery and chemotherapy. Yet, there is currently no government agency providing oversight to ensure that test results are safe and both technically accurate and clinically valid. AAMC believes that providing such assurance is critically important and that the FDA is capable of providing such oversight, but that FDA must do so in the most expeditious and efficient manner possible.

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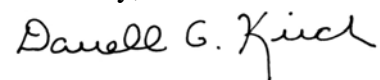
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First, it should be made explicit that this guidance only applies to tests that are intended for commercial use as opposed to tests that will only be used for research. Second, a possible approach might be to provide “preliminary” or “conditional” approval based on data that can be obtained by reasonable and less expensive methods, followed by post-marketing follow-up analysis to confirm validity. For example, one could test samples from patients whose clinical courses are already known rather than doing a more expensive and time consuming prospective trial. We suggest that the FDA might consider convening an expert panel to consider the advisability of such a two-step process and to provide recommendations on the data that would be required for tentative approval.

Because this is the first time that the FDA has undertaken oversight of IVDMIAAs, it has the opportunity to develop a new paradigm for regulatory approval that could then be applied to other substances and procedures that the agency regulates.

We thank you for the opportunity to comment. If you require further information from us, please contact Howard B. Dickler, M.D., Director for Clinical Research, at 202-828-0567 or hdickler@aamc.org.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive style with a large, prominent 'K'.

Darrell G. Kirch, M.D.