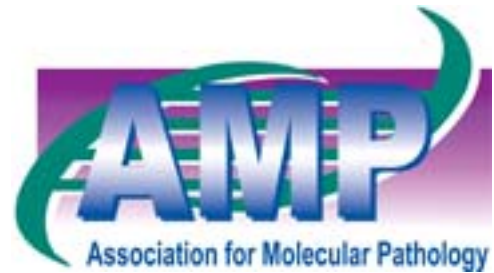


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FOR IMMEDIATE RELEASE

FDA Draft Guidance Should Focus on “Companion Biomarkers” and Provide for Use of LDTs

WASHINGTON, DC, October 12, 2011—The Association for Molecular Pathology (AMP) submitted comments to the Food and Drug Administration (FDA) regarding the FDA’s “Draft Guidance for Industry and Food and Drug Administration Staff – In Vitro Companion Diagnostic Devices”.

In AMP’s remarks, the organization applauded FDA for discouraging the inclusion of test brand names or manufacturers in therapeutic product labeling. However, AMP also expressed concerns that FDA’s proposed approach to Companion Diagnostics could compromise the quality of patient care, and restrict the availability of certain laboratory-developed testing services that have become the standard of care for many diseases or conditions.

According to the FDA, the draft guidance is intended to provide a policy for reviewing test kits which are used to guide the administration of concomitantly approved or previously approved therapeutic products. The form FDA’s final guidance takes could have a significant effect on how AMP members provide care for patients

“AMP applauds FDA for its recognition of the unfavorable effects of therapeutic product labeling that specifies a particular manufacturer’s diagnostic test, said Mary Steele Williams, AMP’s Executive Director. “We have been discussing this issue with FDA for over two years. By emphasizing testing rather than specific vendors, FDA will encourage the development and advancement of diagnostics.”

However, AMP strongly cautioned the FDA that several key aspects of the current draft guidance threaten to impede patient access to testing and may slow the effective implementation of new diagnostic tests. AMP underscored its concerns by citing the problematic nature of the document’s title – specifically its predominant focus on diagnostic devices instead of the companion biomarkers.

“FDA’s primary focus should first and foremost be the companion biomarker, not the associated diagnostic tests,” said Dr. Elaine Lyon, Chair of AMP’s Professional Relations Committee. “From a medical standpoint, the relevant parameter is the biological relationship between a biomarker and its associated therapeutic product, not the individual test or tests by which the biomarker is detected. It is important that FDA not inadvertently impede diagnostic advancement by locking in platforms through its promotion of ‘companion devices.’”

AMP also noted the restrictive nature of a number of FDA’s proposed policies. For example, AMP questioned FDA’s proposed policy of limiting the approval of drugs and biologics to those for which an FDA approved assay is available, which appears to exclude the possibility of approving drugs based on studies conducted using laboratory developed tests.

“Approving drugs for use with laboratory developed tests should be decided on a case-by-case basis, weighing the harms and benefits,” said Dr. Roger Klein, Chair-Elect of AMP’s Professional Relations Committee. “In many instances CLIA-certified laboratories may offer laboratory developed assays for a biomarker that utilize standard molecular diagnostic techniques with which there is significant clinical experience. Under some circumstances, FDA approval of a therapeutic product for use with a

biomarker measured by a laboratory developed test would likely shorten the timeline for bringing the benefits of the drug to patients, without a significant increase in medical risk.”

In summary, AMP’s comments are:

- AMP applauds FDA discouraging the inclusion of test brand names or manufacturers in therapeutic product labeling
- FDA’s primary focus should be the companion biomarker rather than specific tests to measure it
- FDA’s policy of limiting approval of novel therapeutic products linked to biomarkers to those for which an FDA cleared or approved assay is available is too restrictive
- Reflexive classification of tests for companion biomarkers as high risk may impede the commercial development of new assay and the advancement of new test methods
- Final determination of significant risk for the purposes of compliance with IDE regulations should primarily be made by the institutional review board overseeing the study
- Pharmaceutical and diagnostic sponsors should be required to provide data on the negative predictive value of a test used to predict drug or biologic responsiveness
- Pharmaceutical and diagnostic sponsors should be required to submit studies of all assays for companion biomarkers for peer reviewed publication

For a full text of the comment document, visit

http://www.amp.org/publications_resources/position_statements_letters/documents/AMPResponseCompanionDx_Final.pdf

About AMP

The Association for Molecular Pathology (AMP) is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics, and genomics. For more information, please visit www.amp.org.

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