



Association for Molecular Pathology
Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology

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March 1, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0059

Thank you for the opportunity to submit written comments on the implementation of the FDA's Prescription Drug Labeling Improvement and Enhancement Initiative. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,000 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the in vitro diagnostics industry.

In 2009, the Center for Drug Evaluation and Research (CDER) changed the labels for two anti-EGFR monoclonal antibodies, cetuximab and panitumumab. As you may know, patients with mutations in the KRAS gene respond to these drugs and hence, reflect a subpopulation of patients. In a letter to Center Director Dr. Janet Woodcock,¹ AMP commended CDER on these changes. At that time, numerous CLIA certified laboratories were conducting KRAS testing as laboratory developed tests (LDTs) under the guidance of qualified laboratory directors. AMP was very pleased to see that the new labeling for these drugs referenced the biological description of the gene and mutation analysis for KRAS, and that it did not refer to market brand names for the assay(s) used in the studies.

When FDA includes a brand name of a diagnostic kit on a drug label, the medical community often views this as a tacit endorsement of that one company's test. Diagnostic companies sometimes lead physicians to believe that one FDA approved/cleared test is preferred over another FDA approved/cleared test or other validated test simply because it is included by name on the drug label. This effectively ties the hands of the pathologist and clinical laboratories, who should be free to choose the test that best suits the needs of their patients, physicians and laboratory environment, and is a disincentive for the development of alternative and possibly improved versions of assays for the same analyte.

AMP commended the FDA and CDER for establishing this significant precedent of referencing the biological description of a diagnostic test in the labeling of a companion therapeutic. This ensured that laboratory directors are able to use their clinical judgment to select the most appropriate test method. We hope that as the Center implements new standards for facilitating optimal communication through drug

¹ http://www.amp.org/publications_resources/position_statements_letters/WoodcockLtr_DxonRxLabels_082709.pdf

labeling, that you also consider how best to incorporate molecular diagnostic information into a drug's label to ensure that patients receive high quality personalized healthcare. Thank you very much for considering these comments and please do not hesitate to call on AMP if we can provide assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer L. Hunt". The signature is fluid and cursive, with the first name "Jennifer" being more prominent than the last name "Hunt".

Jennifer L. Hunt, MD, MEd
President