Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
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August 27, 2009

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

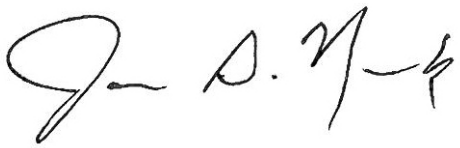
Dear Dr. Woodcock,

I write to you today regarding the recent class labeling changes to anti-EGFR monoclonal antibodies, cetuximab and panitumumab. AMP is an international medical professional association representing approximately 1,700 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics.

Currently, numerous CLIA certified laboratories are 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 discincentive for the development of alternative and possibly improved versions of assays for the same analyte.

AMP commends the FDA and the Center for Drug Evaluation and Research for establishing this significant precedent of referencing the biological description of a diagnostic test in the labeling of a companion therapeutic. This ensures that laboratory directors are able to use their clinical judgment to select the most appropriate test method. On behalf of AMP, I thank you very much for your leadership on this issue and for working to ensure that patients receive high quality personalized healthcare. Please do not hesitate to call on AMP if we can provide assistance.

Sincerely,



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