



AMP Position Statement: Reference to Diagnostic Tests in Drug Labels - May 2011

Background: Concern that drug labels may tacitly endorse one diagnostic over another

With advances in genomic medicine, providers can use targeted therapy to tailor dosing, improve drug response and avoid adverse events. Many drugs, especially in the field of oncology, now include information about molecular diagnostics in their labeling. Pharmaceutical manufacturers control the label's content and can choose to describe a laboratory test by its molecular description or by its brand name.

When the FDA approves drug labeling that includes the brand name of a diagnostic test, the medical community often views this as a tacit endorsement of that one company's test; indeed, diagnostic companies' marketing strategies may exploit this view. This limits pathologists from choosing the test that best suits the needs of their patients, physicians and laboratory environment. Rather than consulting with the molecular pathologist to consider all relevant information from the patient's medical history, together with the most effective laboratory testing strategy at the least cost, treating physicians such as oncologists may reflexively order the test listed in the labeling. Therefore, referencing diagnostic tests by their brand names in drug labeling may create a situation where patients are not receiving optimal care. Further, AMP believes this will restrict patient access to subsequently approved/cleared and increasingly innovative tests.

The various pharmaceutical companies with different therapies for the same indication, *e.g.*, monoclonal antibody versus small molecule, may partner with different diagnostic companies to develop a test that will select patients for that therapy. Because oncologists may request testing using the test identified in the drug labeling, and payers may only reimburse if that specific test is used, laboratories will be put in the challenging position of having to purchase and verify multiple test kits for the same analyte. Moreover, if the oncologist chooses to switch therapies, *e.g.*, intravenous to oral, testing by the brand diagnostic on the new drug's labeling could be requested or required by payers, which would be duplicative. This would drastically increase healthcare costs, over-complicate the laboratory environment, and limit the laboratory professional's ability to practice in the best interest of the patient population to be served, hence potentially reducing the quality of care.

In addition, if a diagnostic company was to sell its test exclusively to one laboratory, all specimens would have to be shipped to that laboratory for testing even if the source laboratory has access to a different FDA approved or cleared test for the same analyte. This could result in restricting the patient's access to one specific test, which may create additional burdens to the patient including the collection of subsequent samples, increased out-of-pocket costs, and delayed treatment.

AMP Position:

- To promote patient safety and high quality care, AMP recommends that FDA specify that diagnostics be described by the biological description of the gene or mutation in drug labeling and that identification of recommended diagnostic testing not be by brand name. Essential performance characteristics (*e.g.* limit of detection) can be specified. Standardized HUGO nomenclature should be used.
 - AMP notes that The Clinical Laboratory Standards Institute (CLSI) avoids identifying products by brand name in their Guidelines.
- Identification of diagnostic tests by brand name in drug labeling is only appropriate in the description of relevant clinical studies; AMP recommends that in the remainder of the label, pharmaceutical manufacturers reference the biological description.