AMP releases statement on diagnostics in drug labels

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Today, the Association for Molecular Pathology (AMP) released its new position statement on the appropriate manner to reference diagnostic tests in drug labels. The association also met with officials from the United States Food and Drug Administration that participate in the effort to draft guidance documents for co-developed products and companion diagnostics to inform them of its new position statement.

With advances in genomic medicine, providers can use targeted therapy to tailor dosing, improve drug response, and to avoid adverse events. Pharmaceutical manufacturers control the label's content and can choose to describe a laboratory test by its molecular description or by its brand name. The latter limits pathologists from choosing the test that best suits the needs of their patients, physicians and laboratory environment. And 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.

"When the FDA approves a label that includes a brand name of a diagnostic kit, the medical community often views this as a tacit endorsement of that one company's test," explained AMP Professional Relations Committee Chair Dr. Elaine Lyon, "Indeed, diagnostic companies' marketing strategies might exploit this view."

Because healthcare providers 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. 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. Dr. Lyon expressed AMP's concern, "this would drastically increase healthcare costs and over-complicate the laboratory environment. And our greatest concern is that it 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 hopes that this new position statement will encourage pharmaceutical companies to reference diagnostic tests based on its molecular description and the FDA to work with industry to reinforce the appropriate labeling of its products.

AMP's specific recommendations include:

- 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.

More information: www.amp.org/

Provided by Association for Molecular Pathology