Regulation of laboratory-developed tests (LDTs) remains a controversial issue for both regulators and industry.

The Food and Drug Administration (FDA) views LDTs as medical devices and regulates them as such, said Don St. Pierre, deputy director of the FDA Office of In Vitro Diagnostic Device Evaluation and Safety. St. Pierre spoke at the Lab Institute 2009 conference, presented by Washington G-2 Reports in September in Washington, D.C.

In contrast, David Mongillo, vice president for policy and medical affairs at the American Clinical Laboratory Association, asserted at the conference that LDTs are not medical devices and therefore should be regulated under the Clinical Laboratory Improvement Amendments (CLIA), rather than by the FDA.

“We need two regulatory separate pathways: one for medical devices and one for laboratory-developed tests,” he said.

St. Pierre said the agency is concerned that molecular-diagnostic tests are reliable, and that their value and limitations are understood. The developers must establish the validity of the tests, he added.

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-- Don St. Pierre, Food and Drug Administration
“Test kits distributed outside the lab should undergo FDA review, but some LDTs enter the market without review,” St. Pierre said. “The problem is that people are going outside the original intent of the regulation.”

St. Pierre indicated that a change in FDA policy is a possibility, but added, “This is not going to be solved tomorrow. I guarantee it.”

In September, ASCP weighed in with comments on the definition of LDTs to the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. ASCP’s comments were a response to the July 24, 2009, draft technology assessment, “Quality, Regulation and Clinical Utility of Laboratory-developed Tests,” conducted by the ECRI Institute Evidence-based Practice Center and issued by AHRQ at the request of the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS).

ASCP commended CMS and AHRQ for their efforts to establish a measure of quality for LDTs. “ASCP is pleased that the document attempts to clearly define the term ‘molecular genetic test’ through descriptions of the assays, specific examples and their intended diagnostic purpose,” said then-ASCP President Barbara J. McKenna, MD, FASCP. ASCP further agreed that evaluation of laboratory-developed molecular tests should include the test’s analytic and clinical validity, but cautioned that clinical utility remains a subjective standard that depends on how clinicians use assay results to manage patient treatment, not on an objective quality inherent in the test method.

“Requiring complete proof of clinical utility as a prerequisite for marketing of these assays might impede or even prevent patient access to them,” ASCP asserted. “A lengthy approval process that requires definitive evidence of clinical utility might hinder the development of these assays, preventing American researchers from implementing translational findings into clinical practice.”

ASCP President Mark H. Stoler, MD, FASCP, added that evidence of clinical validity is the key to offering patients tests that are truly useful and not wasteful of valuable health care resources. “Striking the proper balance is one of the major conundrums of our rapidly evolving times,” he said.

Also in September, the College of American Pathologists announced its recommendations for strengthening oversight of LDTs. The recommendation calls for “a three-tier, risk-based system that would protect patients by ensuring every LDT is reported to one or another oversight bodies depending on where a test is placed in a graduated system of review based on the test’s potential risk to patients.”

Reference