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Laboratory Testing Services Are Not the Practice of Medicine

St. Louis, Missouri – Clinical laboratory testing is **not** the practice of medicine says Mark S. Birenbaum, Ph.D., administrator of the American Association of Bioanalysts (AAB).

Contrary to a paper recently commissioned by the American Clinical Laboratory Association (ACLA) entitled "Laboratory Testing Services, As The Practice of Medicine, Cannot Be Regulated As Medical Devices," AAB's attorneys researched the legal issues and concluded that laboratory services are **not** the practice of medicine. AAB's General Counsel, Jeffrey J. Sherrin, from the Albany, NY, law firm of O'Connell & Aronowitz, commented, "Decades of federal and state law, as well as judicial decisions, have consistently confirmed the difference between how medicine and clinical laboratory testing are practiced, which directly contradicts the notion that laboratory testing constitutes the practice of medicine" (see attached article by Jeffrey J. Sherrin and Danielle Holley).

The federal CLIA statute, which applies to virtually all clinical laboratories, permits non-physicians to direct clinical laboratories, and CLIA specifies that the laboratory director is "responsible for the overall operation and administration of the laboratory, including the prompt, accurate and proficient reporting of test results" [Section 493.1359].

In addition, several attempts by organized medicine to establish that clinical laboratory testing is the practice of medicine have failed, with state courts in New York and Pennsylvania ruling that clinical laboratory testing is **not** the practice of medicine and is not subject to regulation by state Medical Practice Acts. In fact, virtually all existing state statutes/regulations governing clinical laboratories are separate and distinct from state Medical Practice Acts.

"The Clement/Tribe paper commissioned by ACLA outlines ACLA's strategy to challenge FDA's authority to regulate Laboratory Developed Tests (LDTs)," says AAB Administrator Mark S. Birenbaum, Ph.D. "While AAB strongly disagrees with ACLA's argument that clinical testing is the practice of medicine, AAB believes there are many other valid reasons why the FDA's current proposal to regulate Laboratory Developed Tests (LDTs) as medical devices is not appropriate and should be withdrawn. The 'practice of medicine' argument, however, is not a valid argument and is a red herring," says Birenbaum.

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In February, AAB filed written comments to the FDA stating that the FDA should work with the laboratory stakeholder community, Congress, and CMS-CLIA on a fair process for laboratory developed tests (LDTs) that recognizes the distinct differences between medical devices and LDTs, as well as the importance of CLIA's role in the oversight of laboratory testing. AAB wants to ensure that the quality, safety, and validity of LDTs is assessed, while allowing for innovations in laboratory testing that will benefit patients.

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*The American Association of Bioanalysts (AAB)**,** founded in 1956, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists, and medical laboratory technicians. AAB is committed to the pursuit of excellence in clinical laboratory testing by enhancing the professional skills of each of its members; promoting more efficient and productive operations; and representing the interests of its members. AAB's specialized membership sections include the AAB Associate Member Section (AMS), College of Reproductive Biology (CRB), Environmental Biology and Public Health (EBPH) Section, and the National Independent Laboratory Association (NILA). AAB provides a broad range of services, including representation before federal and state legislative and regulatory agencies, educational programs and publications. AAB's Proficiency Testing Service is approved under the federal CLIA regulations and is one of the largest PT providers in the United States.*