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For Immediate Release
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ACLA Urges Health Subcommittee to Adopt Provisions on User-Fees and Laboratory-Developed Tests

Washington DC – The American Clinical Laboratory Association today urged the House Energy and Commerce Health Subcommittee to approve provisions in its device user-fee legislation that would allow HHS to waive user fees for clinical laboratories and lab-developed tests (LDTs), and that would further require FDA to notify Congress 60 days prior to issuing a guidance on the regulation of LDTs. ACLA conveyed its recommendations in a letter sent today to the chairman and ranking member of the subcommittee.

“We think both provisions are important steps in enabling continued innovation in the field of personalized medicine and creation of well-paying jobs for highly skilled American workers,” said ACLA President Alan Mertz.

The user-fee provision would give the HHS Secretary authority to waive medical device user fees in the interest of public health. FDA has indicated that, if the authority is granted, the agency intends to exercise that authority with respect to LDTs.

“ACLA members participated in many months of negotiations with FDA and other stakeholders to reach agreement on device user-fee reauthorization legislation (MDUFA), and this waiver provision was an important part of the agreement for ACLA,” said Mertz.

Mertz also applauded a provision in the legislation that would require FDA to notify the House Energy and Commerce Committee and the Senate Labor and Health Committee at least 60 days prior to issuing guidance on FDA regulation of LDTs. FDA would also be required to include the anticipated details of the draft or final guidance.

“We support this provision because any FDA guidance in this area would be a major change in policy, one that ACLA has serious concerns about,” said Mertz. “This provision provides greater transparency about what FDA intends to do and is, therefore, something ACLA supports.”

Mertz said that ACLA especially appreciates the efforts of Rep. Michael Burgess (R-TX) in offering the provision, as well as his legislation, HR 3207, the Modernizing Laboratory Test Standards for Patients Act, that would enhance oversight of LDTs under the Clinical Laboratory Improvement Amendments. ACLA strongly supports HR 3207.

ACLA is a national association representing the leading national, regional, esoteric, and pathology clinical labs. For more information, visit the ACLA website: www.acla.com