August 2, 2007

The Honorable Nydia Velazquez Chairwoman Committee on Small Business U.S. House of Representatives Washington, D.C. 20515

Dear Chairwoman Velazquez:

As organizations committed to ensuring access to high quality laboratory testing for our nation's seniors, we are writing to express our strong support for the legislation you have prepared to repeal the Medicare competitive bidding demonstration project for clinical laboratory services authorized by section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The demonstration project mandated by MMA threatens the quality of laboratory services and access to those services by all residents of the demonstration area and beyond. Furthermore, it creates a substantial and cumbersome burden for laboratories, particularly small laboratories.

The undersigned organizations would also like to take this opportunity to thank you for calling the Small Business Committee hearing on July 25, 2007, which provided further details as to why the demonstration project must be repealed. As crafted by CMS, the proposed demonstration would require all laboratories receiving at least \$100,000 in Medicare payments to participate in the bidding process or automatically drop out of the Medicare program for three years. The Centers for Medicare and Medicaid Services (CMS) estimates that there could be 70 required bidders in the demo area. While no one knows how many winning bids will be accepted, it's probable that at least half of the required bidders will not be winners and will be forced to drop out of the Medicare program for three years. It's likely that many of the "losing" labs will be forced to close their doors because of the loss of the Medicare revenues and because ordering providers will have an incentive to send all their specimens to the winning bidders. Vulnerable patient populations will be at considerable risk of limited access to quality laboratory services if the testing capacity is reduced. Providers providing care to patients in nursing homes, Medicaid and other public programs could find themselves with compromised availability of time-sensitive laboratory test results.

Given CMS' lack of responsiveness to industry stakeholder concerns, the tremendous complexity of a competitive bidding demonstration for clinical laboratory services, and the likelihood that competitive bidding would curtail Medicare patients' access to such services, we strongly recommend that Congress take legislative action to stop this demonstration. Thank you for your leadership on this important issue.

Sincerely,

American Association of Bioanalysts American Association for Clinical Chemistry American Clinical Laboratory Association American Health Care Association American Medical Technologists American Society for Clinical Laboratory Science American Society for Clinical Pathology American Society for Microbiology **ARUP** Laboratories Bio-Reference Laboratories, Inc. Clarient Inc. Cleveland Clinic Clinical Laboratory Management Association College of American Pathologists Genzyme Corporation Laboratory Corporation of America Holdings

Marshfield Clinic Mayo Clinic National Cervical Cancer Coalition National Independent Laboratory Association Oncotech, Inc. PathNet Esoteric Laboratory Institute Precision Therapeutics Inc. Quest Diagnostics Inc. RedPath Integrated Pathology Roche Diagnostics Shiel Medical Laboratory Siemens Medical Solutions Diagnostics Spectrum Laboratories Sunrise Medical Laboratories Woodbury Clinical Laboratory Xdx Inc.