



Association for Molecular Pathology

Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology

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September 27, 2012

The Honorable Michael Grimm
United States House of Representatives
512 Cannon House Office Building
Washington, DC 20515

The Honorable Amy Klobuchar
United States Senate
302 Hart Senate Office Building
Washington, DC 20515

Dear Congressman Grimm and Senator Klobuchar:

The Association for Molecular Pathology (AMP) is pleased to offer its strong support for H.R. 6118/S.3391, the *Taking Essential Steps for Testing Act*. AMP is an international medical and professional association representing approximately 2,000 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the *in vitro* diagnostics industry.

As you are aware, proficiency testing programs are formal quality assurance activities in which common specimens of known properties are distributed to and tested by participating medical laboratories. Results are submitted to the program sponsor, who informs the participating laboratory of its performance relative to the expected results and that of other participating laboratories. Laboratories enroll in proficiency testing to ensure the accuracy and quality of the diagnostic tests they perform.

It is routine practice for laboratories to refer specimens to other laboratories for tests or parts of tests that they do not perform in house. In addition, it is common for laboratories to refer specimens to other laboratories to confirm results or to compare results obtained by another method. Currently these routine, common and generally accepted practices could result in a laboratory having its CLIA certificate revoked for inadvertently sending a proficiency testing sample to another laboratory, even for specimens for which a laboratory's day-to-day procedure is to refer that testing to other labs. The *Taking Essential Steps for Testing Act* will prevent laboratories from unjustly losing their CLIA certificates in such situations. Moreover, this legislation will help ensure patient access to high quality testing services, by eliminating inappropriate disruptions or delays.

Thank you for introducing legislation that enables regulatory policy to keep pace with advances in laboratory medicine. AMP is very pleased that the House of Representatives has passed the bill under suspension of its rules, and we are optimistic that the full Senate will have the opportunity to vote on the legislation before the end of the session. We offer our support for the passage of this legislation and stand ready to assist you and your colleagues if needed.

Sincerely,

Iris Schrijver, MD
AMP President