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July 25, 2012

The Honorable Michael Grimm
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Grimm:

The College of American Pathologists (CAP) is pleased to support your legislation, the *Taking Essential Steps in Testing Act* (H.R. 6118). Your leadership on this issue is greatly appreciated. The legislation takes an important step toward bringing common sense reforms to sanctions for proficiency testing (PT) referral under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The CAP represents 18,000 pathologists who practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers and federal and state health facilities. With extensive experience as a quality standards-setting organization, the CAP accredits more than 7,000 laboratories and enrolls as many as 23,000 laboratories in its PT programs.

As pathologists, we're all too familiar with the severe sanctions imposed on laboratory directors, typically pathologists, for inadvertent PT referral violations. As an accreditation organization, we understand the dire and costly consequences of closing hospital laboratories when a PT sample is sent to another laboratory by accident. Sanctions under CLIA for referral of a PT sample to another laboratory are mandatory, including revocation of the laboratory's CLIA certificate for one year. In addition, the laboratory director and laboratory owner are banned from operating or owning a laboratory for two years.

The CAP believes that PT is an important measure of laboratory quality. Laboratories periodically receive PT samples to analyze. Tests results are reported to determine accuracy. However, by law, laboratories cannot refer all or part of a PT specimen to another laboratory, even if sending out the PT specimen follows laboratory protocol for patient samples, or even if the referral was generated by automated specimen processing.

While the prohibition on PT referral was intended to penalize laboratories that intentionally circumvent PT procedures, CLIA leaves little room for enforcement discretion. As a result, a growing number of laboratories across the country have been sanctioned for inadvertent PT referrals, facing potential shut down, disruption in patient care and substantial settlement costs.

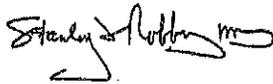
Your legislation would give the Centers for Medicare and Medicaid Services (CMS) much needed flexibility to match sanctions to the level of noncompliance. The TEST Act would still forbid the practice of PT referral. CMS would still be able to hold "bad actors" accountable to the fullest extent of the law. However, the agency could impose lesser sanctions, if at all, for inadvertent PT referrals. In the future, more modifications may be needed to make sure that PT

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keeps pace with evolving laboratory practice. In the meantime, this legislation will protect hospitals and laboratories from unwarranted sanctions that could impede patient care.

We urge prompt passage of this legislation and look forward to working with Congress and CMS to further define where the lines are drawn and provide more certainty to those who participate in the PT program.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley J. Robboy MD". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stanley J. Robboy, MD, FCAP
President