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Cytology Proficiency Testing Regulations

Presented at CLIAC

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Chairman Turner, distinguished members of the Clinical Laboratory Improvement Advisory Committee, my name is Mark Stoler and I am here today to present a statement on behalf of the American Society for Clinical Pathology (ASCP). At ASCP, I am the Secretary of the Board of Directors and I am also a practicing cytopathologist at the University of Virginia Health Science Center in Charlottesville, Virginia.

ASCP appreciates the opportunity to provide this public statement regarding the need to fast track a modernized regulation governing cytology proficiency testing in this calendar year.

At the February 2005 CLIAC meeting, ASCP outlined the Society's decade long dialogue with the federal government regarding the need for CMS and CDC to update the cytology proficiency testing regulations to reflect the current science and everyday operations of the nation's laboratories providing cytology services.

Over the past year, the cytopathology community has presented a united front asking the federal government to resolve a number of technical and scientific issues with the current regulation. ASCP is encouraged by recent communications from the Centers for Medicare and Medicaid Services (CMS) indicating a willingness to address our community's concerns.

The formation of a CLIAC work group dedicated to a quick resolution of the cytology community's concerns around the regulation is a good first step and we urge this group to begin work immediately.

ASCP is a founding member the Cytopathology Education and Technology Consortium (CETC) and earlier this month the CETC released a document entitled "Scientific Issues Related to the Cytology Proficiency Testing Regulations."

This document outlines a number of elements ASCP believes are important for the CLIAC work group to address including:

Testing Intervals

New Technologies, and

the Grading System.

Once these three elements are addressed the community will feel more comfortable that the regulation is both fair and scientifically valid. Test results from the first year of nationwide proficiency testing are an important reminder to everyone in the laboratory community why we need to ensure that the regulation is grounded in modern scientific principles. A modernized regulation will allow us to accurately gauge the quality of today's cytology services -- the current test does not give us that opportunity.

Unfortunately, the December 02 *Los Angeles Times* article that reported failure rates among our colleagues threaten our field's integrity. Our community is dedicated to protecting women's health and we are prepared to address the education needs that exist within our own ranks. To determine the extent of these needs the regulation must reflect both laboratory practice and scientific principles.

ASCP is pleased that CMS and CDC are willing to work with the cytopathology community to address problems within the regulation. The formation of a workgroup

dedicated to community consensus and modernization of the regulation is an important development. ASCP stands ready to work with the federal government to address the complex issues regarding the promulgation of a new regulation that fulfils the requirements of CLIA.

Thank you for the opportunity to provide this statement to the distinguished committee.