ASCT Hears Positions on Proficiency Testing

At the recent Annual Conference in San Antonio, the ASCT invited representatives of the College of American Pathologists (CAP), American Society for Cytopathology (ASC), American Society for Clinical Pathology (ASCP), and Centers for Medicare and Medicaid Services (CMS) to meet with the ASCT Executive Council to discuss their positions regarding cytology proficiency testing (PT) and proposed PT legislation. The discussion was an effort to build consensus and a better understanding among organizations in the ongoing proficiency testing debate.

All major professional organizations agree that the existing PT system is flawed. ASCT has provided organizational support and frequent testimony to the Clinical Laboratory Improvement Advisory Committee (CLIAC) based on actively solicited membership opinions. ASCT has also participated as a member of the Cytopathology Education and Technology Consortium (CETC) to recommend similar changes. All of these documents are published on the ASCT website. We have encouraged the CMS to expedite the rule making process for these regulatory changes. Most agree that reduced frequency of testing and restructured scoring and validation would significantly improve the current process.

As an organization, the ASCT has not stated a position regarding the recently introduced legislation HR1237. We struggle to balance our members' long-term best interest and the public interest both in real test quality and in perception, specifically maintaining public confidence in the testing we provide, given that cytology testing was one of the primary reasons for the passage of CLIA '88. We want women in America to have confidence that their Pap tests are being accurately evaluated.

The CURRENT statute in CLIA Section 393(f)(4)(B)(iv) includes a provision for periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing to take place to the extent practicable, under normal working conditions.

The PROPOSED CAP AMENDMENT TO CLIA Section 393(f) (4)(B)(iv) reads as follows: "Requirements that each clinical laboratory -- (I) ensure that all individuals involved in screening and interpreting cytological preparations at the laboratory participate annually in a continuing medical education program in gynecologic cytology that …"

HR 1237 essentially removes the current PT requirement and replaces it with required individual Continuing Education Programs, thus eliminating the current requirements to retest individuals that fail to achieve a minimum score of 90 and suspend primary screening for multiple failures. While not explicitly stated in the amendment, it seeks to parallel the Mammography Quality Standards Act (MQSA) in implementation.

The ASCT strives to be the collective *Voice* of the Cytotechnology profession; however we recognize the difficulty in speaking with one voice on such a divisive issue. We continue to endorse the changes to existing regulation based on direct membership input.

At the present time, the ASCT as an organization cannot give unconditional support to HR1237. Our concerns center primarily on the uncertainty of the rule making process *should* this legislation pass and also about the relevance of the MQSA to GYN cytology testing, knowing that the MQSA statute does not require proficiency testing while the CLIA statute explicitly requires PT of every laboratory. We concurrently ask that CMS expedite the proposed rule allowing organizations and individuals to make better informed decisions regarding options for change.

Information is summarized here in an effort to educate and encourage individuals to become informed and take the initiative to comment both on the regulatory and legislative agendas. We encourage members to communicate concerns to the Executive Council of ASCT, other professional organizations, CMS, and their legislators. Both collective and individual voices are vital if we are to improve this process.

Organization	Regulatory/CLIAC Change	Legislative Bill 1237
ASCT	Supports change and expedited rule making	Cannot give unconditional support as an organization, encourages individual member response as they deem appropriate
ASC	Does not oppose	Supports
ASCP	Supports change	Supports "intent" but not this bill
CAP	Unknown	Supports
CMS	Informational only, encourages comments on proposed rule	No position

	Pros	Cons
HR1237	Could eliminate requirements associated with current cytology proficiency testing regulations Educational program would replace current proficiency testing program.	Potential for "Unintended consequences", following the federal government's rule making process. New regulations could be burdensome and more onerous than the current cytology proficiency testing program. No national standards established against which to evaluate proficiency; No provisions to mandate suspension of cytology testing should significant question of proficiency of individuals be raised. Public and government (GAO report) are unlikely to allow cytotechnologists to be unaccountable.
Regulatory/CLIAC	Demonstrates a willingness to regulate ourselves, if the current proficiency testing program can be improved through rule making process. There have been participant failures in the existing program, particularly in laboratories without cytotechnologists. The required corrective actions for PT failure are punitive; failure may prohibit participants from practicing.	Costly. Existing proficiency testing program has not yet demonstrated improvement in quality of testing provided to patients. No other laboratory professionals are mandated to participate in **individual** PT. The required corrective actions for PT failure are punitive; failure may prohibit participants from practicing.