Statement to the
Clinical Laboratory Improvement Advisory Committee

Presented by
George G. Birdsong, MD, FCAP

For the
Cytology Proficiency Improvement Coalition

September 5, 2007

1350 I St. N.W., Suite 590
Washington, D.C. 20005-3305
(202) 354-7100

Introduction

Good afternoon. My name is Dr. George G. Birdsong. I am the Director of Anatomic Pathology at Grady Health System in Atlanta, Georgia and Associate Professor Pathology & Laboratory Medicine at Emory University, School of Medicine. In addition, I currently serve as past President for the American Society of Cytopathology. However, today I come before you as a member of the Cytology Proficiency Improvement Coalition.

The coalition is currently composed of 60 State and national organizations representing physicians, laboratory medicine and cancer prevention advocates who are concerned with the current status and direction of Federal cytological public health compliance standards.

The coalition is here to advise CLIAC that while we appreciate the committee's effort to develop a regulatory model that addresses the profession's concerns with the current cytology PT regulation, we believe that enactment of the federal legislation H.R. 1237, the Cytology Proficiency Improvement Act of 2007, is a better approach.

This legislation would do the following:

- Suspends the current proficiency testing program effective upon enactment.

- Substitutes a requirement that laboratories ensure that all individuals involved in screening and interpreting Pap tests participate annually in a continuing medical education (CME) testing program in gynecologic cytology that test their locator, recognition and interpretive skills.

- Requires that the CME program be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.

- Requires the laboratory to maintain a record of the cytology continuing medical education results of each individual. Accrediting organizations will inspect CME results during regular laboratory inspections required by CLIA.

We believe that the current federal regulatory reform effort demonstrates the problems with embedding professional standards into federal regulations. The repeated delays and the absence of even a draft or proposed regulation, in our view, demonstrate how untimely and ineffective the regulatory process is for updating professional standards.

Based upon our projection; the process of revising the cytology PT regulations that began in 2006 will likely not be completed until 2009, meaning at least five years will have elapsed since the profession began requesting changes to the regulation in 2004.

From our vantage point, given the changing nature of medical science, it is highly probable that the revised regulation will suffer the same fate as the current regulation and that soon the profession will find itself again subjected to an out dated testing regime because CMS' regulatory scheme simply cannot keep pace with medicine.

The coalition also believes that the agency process for review of the regulation, which specifically prevented discussion of any alternative that would have required potential changes to the statute, demonstrates that the regulatory process is not only shackled by inordinate delays but also by a statute that hasn't been revisited in almost 20 years. By way of contrast, the Mammography Quality Standards Act, the only comparable statute establishing similar quality standards for a screening program, has been reauthorized by Congress twice and has been evaluated independently and extensively by the Institute of Medicine.

The coalition believes that the alternative approach reflected in HR 1237, is a responsible and viable alternative and that Congress, as the ultimate authority on this matter, should reexamine this program and adopt the approach outlined in HR 1237 in lieu of the pending CLIAC recommendations.

Conclusion

The national Cytology Proficiency Improvement Coalition remains steadfastly committed to insisting on and ensuring the highest quality laboratory testing for the women of this nation.

The Coalition is confident that by adopting this oversight model reflecting current industry and regulatory standards the Congress can assure the public of consistent performance by laboratories of valid and reliable cytological services.

In closing, for your additional information we are placing on the record a copy of the HR1237 and co-sponsor list, a brief summary of the Coalition endorsed legislation, and list of the current 60 state and national organizations that make up the Coalition.

Thank you.

H.R.1237 – The Cytology Proficiency Improvement Act of 2007
Title: To amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, and for other purposes.

Sponsor:	Representative Gordon, Bart [TN-6
Original Cosponsors:	Representative Nathan Deal (GA-9)
	Representative Tom Price (GA-6)

Cosponsors as of Tuesday, July 31st: 70

Abercrombie, Neil [HI-1]
Allen, Thomas [ME-1
Baldwin, Tammy [WI-2]
Blackburn, Marsha [TN-7]
Bonner, Jo [AL-1]
Bono, Mary [CA-45)
Boswell, Leonard L. [IA-3]
Boucher, Rick [VA-9]
Boustany, Charles W., Jr. [LA-7]
Burgess, Michael C. [TX-26]
Burton, Dan [IN-5]
Butterfield, G.K. [NC-1]
Buyer, Steve [IN-4]
Capps, Lois [CA-23]
Carnahan, Russ [MO-3]
Coble, Howard [NC-6]
Cohen, Steve [TN-9]
Cubin, Barbara [WY]
Davis, David [TN-1]
DeGette, Diana [CO-1]
Donnelly, Joe [IN-2]
Doyle, Michael F. [PA-14]
English, Phil [PA-3]
Eshoo, Anna [CA-14]
Foxx, Virginia [NC-5]
Gingrey, Phil [GA-11]
Gonzalez, Charles A. [TX-20]
Green, Gene [TX-29]
Hall, Ralph [TX-4]
Hare, Phil [IL-17]
Harman, Jane [CA-36]
Herseth, Stephanie [SD]
Hill, Baron [IN-9]
Hinojosa, Ruben [TX-15]
Hooley, Darlene [OR-5]
Holden, Tim [PA-17]
Jefferson, William J. [LA-2]
Kildee, Dale E. [MI-5]
Latham, Tom [IA-4]
Maloney, Carolyn [NY-14]
McGovern, James P. [MA-3]
McNulty, Michael R. [NY-21]
Moran, James P. [VA-8]
Murphy, Tim [PA-18]
Myrick, Sue Wilkins [NC-9]
Neal, Richard E. [MA-2]
Platts, Todd Russell [PA-19]
Pitts, Joe [PA-16]
Pickering, Charles "Chip" [MS-3]
Paul, Ron [TX-14]
Ramstad, Jim [MN-3]
Renzi, Rick [AZ-1]
Rogers, Mike J. [MI-8]
Ross, Mike [AR-4]
Rothman, Steve [NJ-9]
Roybal-Allard, Lucille [CA-34]
Ryan, Paul [WI-1]
Shimkus, John [IL-1]
Shuster, Bill [PA-9]
Sires, Albio [NJ-13]
Snyder, Vic [AR-2]
Sullivan, John [OK-1]
Weiner, Anthony D. [NY-9]
Weldon, Dave [FL-15]
Woosley, Lynn C. [CA-6]
Wynn, Albert [MD-4]
Young, Don [AK]

WHAT THE *CYTOLOGY PROFICIENCY IMPROVEMENT ACT* DOES

The *Cytology Proficiency Improvement Act* (H.R. 1237), introduced by Representatives Bart Gordon (D-TN) and Tom Price (R-GA) modifies and improves the *Clinical Laboratory Improvement Amendments of 1988* (CLIA) by replacing the current regulation that subjects pathologists and others who screen for cervical cancer to annual proficiency testing with an annual continuing medical education (CME) requirement that would provide laboratory professionals opportunities to improve their screening and interpretation skills in a constructive learning environment.

Pursuant to CLIA, CMS (then HCFA) proposed regulations in 1992 that would require a federal government proficiency test of individual pathologists and others who read Pap tests in the laboratory. The program, however, was not implemented until 2005, 13 years after the fact and its relevancy and effectiveness is now outmoded.

The bill's educational approach is consistent with the *Mammography Quality Standards Act*, for which the government rejected individual proficiency testing.

Specifically the bill would:

- require that laboratories ensure that all individuals involved in screening and interpreting Pap tests participate annually in a continuing medical education (CME) program in gynecologic cytology
- require that the CME program be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education
- require that the CME program provide each individual involved in screening or interpreting Pap tests with glass slides (or equivalent technologies) to test their skills
- include complex and ambiguous cases to promote learning and keep skills on the cutting edge of medicine
- require the laboratory to maintain a record of the cytology continuing medical education results of each individual
- suspend the current proficiency testing regulation effective upon enactment

The measure builds upon the existing federal quality control requirements of CLIA. It provides the laboratory director with an additional tool to evaluate the quality of cervical cancer screening by correlating continuing medical education results with actual day-to-day performance and taking corrective action if necessary.

Accrediting organizations will review the CME results, just as they review the other cytology quality assurance measures required under CLIA, during their inspection of the cytology section of the laboratory.

Cytology Proficiency Improvement Coalition

National Organizations

College of American Pathologists
American Society of Cytopathology
- Georgia Society of Cytology

American Society of Colposcopy and Cervical Pathology
Association of Directors of Anatomical and Surgical Pathology
Association of Pathology Chairs
US and Canadian Academy of Pathology
Arthur Purdy Stout Society of Surgical Pathologists
Papanicolaou Society of Cytopathology
American Pathology Foundation
National Association of Medical Examiners
American Clinical Laboratory Association
American Medical Association
American Medical Women's Association
American College of Obstetricians and Gynecologists
American College of Nurse Midwives
American Association of Bioanalysts
Cancer Research and Prevention Foundation

State Societies

Alabama Association of Pathologists
Arizona Society of Pathologists
Arkansas Society of Pathologists
California Society of Pathologists
Colorado Society of Clinical Pathologists
Connecticut Society of Pathologists
Delaware Pathology Society
Florida Society of Pathologists
Georgia Association of Pathologists
Hawaii Society of Pathologists
Idaho Society of Pathologists
Illinois Society of Pathologists
Indiana Association of Pathologists
Iowa Association of Pathologists
Kansas Society of Pathologists
Kentucky Society of Pathologists
Louisiana Pathology Society
Maryland Society of Pathologists
Massachusetts Society of Pathologists
Michigan Society of Pathologists
Minnesota Society of Pathologists
Mississippi Association of Pathologists
Missouri Society of Pathology
Montana State Pathology Society
Nebraska Association of Pathologists
Nevada Society of Pathologists
New Hampshire Society of Pathologists
New Jersey Society of Pathologists
New Mexico Society of Pathologists
New York State Society of Pathologists
North Carolina Society of Pathologists
North Dakota Society of Pathologists
Ohio Society of Pathologists
Oklahoma State Association of Pathologists
Oregon Pathologists Association
Pennsylvania Association of Pathologists
Rhode Island Society of Pathologists
South Carolina Society of Pathologists
South Dakota Society of Pathologists
Tennessee Society of Pathologists
Texas Society of Pathologists, Inc.
Utah Society of Pathologists
Vermont Society of Pathologists
Virginia Society of Pathologists
Washington State Society of Pathologists
West Virginia Association of Pathologists
Wisconsin Society of Pathologists, Inc.
Wyoming Society of Pathologists

Updated 8/27/07