College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

Direct Response To:
DIVISION OF GOVERNMENT AND PROFESSIONAL AFFAIRS
1350 I Street, NW, Suite 590
Washington, DC 20005-3305
202-354-7100 Fax: 202-354-7155
800-392-9994 • http://www.cap.org

Dr. Lou F. Turner, PhD
Centers for Disease Control
Clinical Laboratory Improvement Advisory Committee
1600 Clifton Road
Atlanta, GA 30333

June 13, 2006

Dear Chairman Turner:

On behalf of the College of American Pathologists, we respectfully request that CLIAC adopt the College's specific recommendations and modifications to the Cytology Proficiency Testing (PT) regulations implemented under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Importantly, while the College agrees with the intent of the legislation in terms of quality improvement, the CAP has never supported the underlying statutory requirement which unfairly singles out pathologists by establishing the only federal qualifying exam for board certified physicians. Towards that end, the College is continuing to urge suspension of the current regulations, and swift passage of legislation, if necessary, to replace the Cytology PT program with a more meaningful and cost-effective approach.

Fundamentally, the College believes that the Cytology PT regulations exceed the scope of the Act as mandated by Congress, and that there are serious flaws associated with the proficiency test and its implementation. Accordingly, the College believes that significant modifications must occur as soon as possible. Moreover, the regulations are seriously outdated. Scientific and technological advances, such as computer-assisted screening, location-guided screening, digital imaging and others, have made a significant and positive impact on the practice of gynecologic cytology since CLIA and the 1992 regulations were established. Yet, in the time these critically important developments have taken place within our profession, the regulation that would require federal proficiency testing for pathologists and cytotechnologists has stood still, resulting in a program rooted in outdated science and, even, obsolete procedures.

With respect to such scientific concerns, the College agrees with the conclusions drawn by the Cytopathology Education and Technology Consortium (CETC), which identified numerous problems with the regulations, including:

- Excessively frequent testing;
- Inadequate slide validation required (only 3 pathologists);
- Inappropriate/unfair scoring system and reporting terminology;
- Failure to incorporate modern techniques (such as computer assisted screening, or location-guided screening and HPV testing), and;
- Individual rather than laboratory proficiency as in all other PT.

Given these facts, as well as the knowledge that no other group of physicians or physician specialists is subject to similar federal qualifying examinations that supercede existing state medical licensing boards and medical specialty certification boards, the College is also recommending alternative approaches to Cytology PT. In addition, the College believes that a thorough regulatory analysis undertaken by the Agency must address the following additional issues:

- Is there evidence that PT improves individual performance?
- Does PT reduce false negatives or false positives?
- Does PT reduce mortality from cervical cancer?
- Should individual PT results be used punitively?

Below the College sets forth its specific concerns regarding the Agency's regulatory interpretation of CLIA, as well as recommendations on regulatory alternative approaches to Cytology PT.

Proposed Rulemaking

At the February 8, 2006 CLIAC meeting, the CMS and CDC stated that their focus was on developing regulations that would proceed through the rulemaking process. In addition, the agencies stated that, with input from organizations and PT programs, the proposed rule would address concerns and include an impact analysis with "accurate cost/benefit projections." As a new rulemaking, there is now not only the opportunity, but also the obligation on the Agencies to perform a thorough regulatory review that evaluates and addresses regulatory alternatives to the current PT standards.

The actual CLIA statute is straightforward and brief. In the Public Health Service Act, Congress directed the Secretary of HHS "to establish national standards for quality assurance in cytology services to assure consistent performance by laboratories of valid and reliable cytological services". With respect to PT, Congress directed the Secretary to establish national standards for the following quality assurance measures:

- Periodic confirmation and evaluation of the proficiency of individuals;
- Unannounced and announced on-site; and
- PT testing to take place, to the extent practicable, under normal working conditions.

Accordingly, the College believes fundamentally that enrollment of a cytology laboratory in a proficiency testing program, with proficiency testing administered by the laboratory for its

personnel, satisfies the stated concerns of Congress with respect to gynecologic cytology screening.

Regulatory Analysis

The Agency's role in the "checks and balances" of government is to perform an analysis of proposed regulatory actions.[1] The objective of the regulatory planning and review process is to establish a regulatory system that is "effective, consistent, sensible and understandable." [2]

In 2003, the Executive Administration, through the Office of Management and Budget (OMB), issued guidelines for federal agencies to follow for the performance of regulatory analysis. Importantly, as set forth in the OMB guidelines, regulatory analysis applies to any action by the agency, "regardless of the stage", and includes "rulemakings that rescind or modify existing rules." [3] The OMB guidelines make clear that a "good regulatory analysis" includes the following three elements:[4]

- Clear statement of need for regulations;
- Examination of alternative approaches; and
- Evaluation of costs and benefits of the proposed action and alternatives.

In this case, throughout the rulemaking process, the Agency has juxtaposed its uncertainty about the regulatory objectives with the legislative mandate under CLIA, implying that there is no alternative but to proceed with revised standards for cytology proficiency testing. However, the legislative intent of the Act and principles of rulemaking have been overlooked during this process. While Congress creates law to address a public need or interest, the Executive Administration, through the federal agencies, must assure that the regulatory system works for the public, not against them.[5] Accordingly, while the Agency should develop regulations to fulfill the legislative intent, it should also exercise oversight to identify regulated areas that are overly burdensome or are unjustified for the program costs.

Specifically, federal agencies are to ensure that the regulatory system protects the public, but "without imposing unacceptable or unreasonable costs on society."[6] So while it is correct that CLIA directs the Agency to implement a system for cytology proficiency testing, the Agency needs to consider the legislative intent behind this requirement in evaluating alternatives for the program standards. Moreover, the Agency must perform a thorough analysis of the costs and benefits of its proposed regulatory action to ensure that it is the most cost effective approach to achieve the intended objective. If the most cost effective approach is inconsistent with legislative mandate, or if there is no effective regulatory approach, either due to the lack of need or justification based upon a cost-benefit analysis, the Agency must advise the President,

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[1] *See* OMB Circular A-4, September 17, 2003
[2] 58 Fed. Reg. At 51735
[3] OMB Circular A-4, at page 1
[4] OMB Circular A-4, at page 2
[5] *See* Executive Order 12866, 58 Fed. Reg. 51735
[6] *Id.*

through the Office of Management and Budget (OMB), to recommend legislative reconsideration.[7]

Legislative Intent Behind Cytology Proficiency Testing (PT):

The College believes that the Agency has a large degree of discretion to revise the Cytology PT standards based on the legislative intent behind CLIA. CLIA requires that HHS establish "national standards for quality assurance in cytology services." [8] As noted, these standards must include "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals." [9] Significantly, CLIA does not specify whether these individuals must be enrolled individually in an approved proficiency testing program -- or whether a laboratory participating in such a program may administer the proficiency testing materials to its personnel on an "announced or unannounced" basis.

When evaluating proposed legislation for regulation of clinical laboratories, the House Committee on Energy and Commerce identified the lack of oversight of cytology screening as one of the key problems with laboratory quality. The report of the House Committee identified the following concerns with cytology services: [10]

(1) Improper collection of specimens;
(2) Cytologists screening excessive numbers of slides;
(3) Inspections of cytology laboratories by personnel unfamiliar with cytology;
(4) Lack of federal requirement for cytology proficiency testing; and
(5) Lack of quality control requirements on laboratories.

The Senate Committee on Labor and Human Resources[11] also addressed the need for national proficiency testing standards to improve laboratory performance. With respect to cytological testing, the Senate Committee concluded that "[t]he main problem stems from excessive technician workloads and the lack of continuing education programs for both technicians and physicians."[12] While the Senate Committee did believe that "proficiency testing should be the central element in determining a laboratory's competence,"[13] it was also of the opinion, like the House Committee, that the crux of the problem was overworked and under-trained technicians. The Senate Committee found that with respect to errors in reading pap smear results that fail to detect the presence of pre-cancerous or cancerous condition, "such errors are the result of overworked and undersupervised cytotechnologists."[14] To respond to this concern, the Senate

[7] *See* Executive Order 12866, 58 Fed. Reg. At 51739-51740
[8] 42 U.S.C. §263a (f) (4) (A).
[9] 42 U.S.C. §263a (f) (4) (B) (iv).
[10] House of Representatives Report 100-899
[11] Senate Report 100-561
[12] *Id.* at 5
[13] *Id.* at 25
[14] *Id.* at 27

Committee was of the view that the Secretary must develop "specific quality assurance standards for cytology services."[15]

From the reports of the House and Senate Committees, the legislative intent was clear to have federal standards for cytology testing. The final legislative mandate was the following provision in Section 353(f)(4)(B) of the Public Health Services Act:

> "The standards established under subparagraph (A) shall include-
> (i) the maximum number of cytology slides that any individual may screen in a 24-hour period,
> (ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,
> (iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,
> (iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions ..."

The focus of the reports and the subsequent legislative directive was to ensure cytology proficiency through prevention of excessive workloads and adequate education and training of cytotechnologists. Subparagraphs (i) and (ii) detail Congress' expectations for vigorous regulations by the Agency on workload. Assurance of adequate education and training in cytology screening is reflected under subparagraphs (iii) and (iv) rescreening protocols and PT. In both provisions there is an implied intent to assess performance. The use of rescreening protocols under subparagraph (iii) allows assessment of actual test performance over a period of time. The language for proficiency testing in subparagraph (iv), on the other hand, does not ask for actual performance measurements.

Despite the clear legislative intent to use rescreening protocols and PT in combination to assess performance, the Agency implemented a program that uses PT at a single point in time as the performance indicator that serves as the basis for penalties and remedial actions against individuals in the laboratory. In addition to disregarding the legislative intent, the Agency's decision was to create an overly burdensome PT program that ignores the collaborative nature of laboratory practice for cytology screening. "Normal working conditions" allow for the collaborative, team approach that is a fundamental aspect of the laboratory environment and most pathology practices. Testing of this collaborative process as an indicator of quality in laboratory medicine was built into the statutory scheme through the rescreening protocols.

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[15] *Id.*

Cytology PT as Quality Indicator:

In passing CLIA, Congress intended for studies to be conducted linking the regulatory approaches undertaken by the Agency with the impact on the reliability and accuracy of test results.[16] The original approach taken by the Agency imposed vigorous requirements for cytology proficiency testing based on assumptions of a link between PT and reduction in false negatives and positives. However, legislative intent clearly envisioned attention to the training and education aspect for cytology PT, and suggesting the excessive workload was more likely the cause of erroneous results. Neither the plain language of the statute nor the legislative intent suggested a need to design a PT program that would suspend the medical practice of pathologists based upon isolated test results.

As noted, the Agency is responsible for conducting "regulatory analysis" of the proposed action. In the final rule, the Agency identified the objective of CLIA to "improve the accuracy of clinical laboratory testing, thereby producing national public health benefits."[17] Importantly, however, the Agency recognized that it could not quantify these benefits, stating, "[t]here is no reliable means of quantifying these expectations, especially given the current lack of data on the clinical laboratory industry."[18] Yet, despite this acknowledgement of lack of empirical data, the Agency suggests in the preamble to the final rule that its proposed PT standards are based "on information and implementation experience from existing State PT programs for cytology."[19] Additionally, in the discussion of the regulatory analysis for the final rule, the Agency again acknowledges the lack of empirical data stating, "no data exist[s] for assessing current and future false negative and positive rates."[20]

Without supporting data, the Agency simply jumped to the conclusion that "IF" CLIA - through reductions in false positive rates - can reduce national expenditures for unnecessary testing and treatments" and "IF" CLIA - through reductions in false negative rates - can lead to earlier intervention" then savings "could result."[21] Such a conclusion is simply unacceptable in terms of a proper regulatory analysis.

While the Act clearly mandated the development of a cytology PT program, the Agency questioned from the beginning the link between PT and improvement in testing accuracy. Because it could not identify a known link between PT and quality improvement during the rulemaking process, the Agency noted the need for additional research, stating, "[t]he relationship between proficiency testing and the quality of laboratory testing will be examined as part of the CLIA studies."[22] While several commentators to the final rule proposed waiting to issue the final rule until studies could be completed, the Agency rejected the suggestion stating, "[t]he CLIA studies are extremely complex research projects and will require several years to complete[; t]herefore, while the results of these studies may impact future regulatory

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[16] *See* Senate Report 100-561 at 32
[17] Page 7106
[18] *Id.*
[19] *Id.* at 7040
[20] *Id.* at 7187
[21] *Id.*
[22] 57 Fed. Reg. at 7036

requirements, they should not delay implementation of basic good laboratory practice standards included in this regulation."[23]

The Senate Committee also held the same opinion regarding the need for additional research when adding a provision in the Act requiring studies on, "the link between various forms of regulations and the reliability and accuracy of test results; the extent and nature of problems in the diagnosis and treatment of patients caused by inaccurate test results, and the effect on test accuracy of various states of the testing process."[24] The report further stated that the research was necessitated "by the relative dearth of empirically based studies in this area."[25] The Agency responded in its rulemaking by stating:

> "Every effort will be made to develop information on proficiency testing as quickly as possible. **When the data is available, it will be used as a basis for making corrections and modifications, and to refine the proficiency testing standards** in the regulations."[26]

So, while Congress and the Agency were content with making assumptions on the link between PT and laboratory quality at the initiation of CLIA, it was both the legislative intent and agency mandate to perform studies to determine if there is an empirical link. Until such correlation is demonstrated, current rulemaking on PT should not continue based on these previously unproven assumptions. Any refinements or changes to the PT standards should be based on the conclusions in the studies. Moreover, the studies will assist in the development of the most cost-effective program going forward. To the extent the studies fail to prove a link between PT and test accuracy, the Agency can recommend changes to the regulations or legislative reconsideration to ensure that regulatory costs are redistributed to the most effective proven measures to reduce the mortality rate of cervical cancer, including increasing the frequency of screening through education of women and their primary care physicians.

Based on this uncertainty and knowing that there is no quantifiable benefit obtained from the current cytology PT standards, the Agency should focus its attention on creating a more cost effective approach to PT that focuses on the education and training objectives. This refinement to the PT program will not only fulfill the original legislative intent for cytology PT but will also allow the Agency to redirect the costs of this overly burdensome program to the obtainment of ascertainable benefits from the reduction of cervical cancer mortality rates through education of women and primary care physicians to increase rates of women receiving initial screening and re-screening tests, regardless of their ability to pay or location.

In the final rule, the Agency recognized the deficiencies in the process, noting both the lack of data and speculative nature of the regulatory analysis performed for the final rule.[27] Still, despite the acknowledged uncertainties of any correlation, the Agency concluded that: "Unlike

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[23] 57 Fed. Reg. at 7037
[24] Senate Report 100-561, at 32
[25] *Id.*
[26] 57 Fed. Reg. at 7036 (emphasis added)
[27] *See* 57 Fed. Reg. at 7187

most other laboratory subspecialties, the quality of cytology testing depends on the recognition and interpretative skills of the individual cytotechnologists and pathologists; therefore PT is focused on measuring these individual skills." Based on speculation and assumptions, the Agency designed a PT program that allows it to suspend the medical practice of a pathologist based upon isolated test results.

The Agency states as its motivation for the enforcement of the PT standards as the need "to identify individuals who need intensive remedial education to improve their performance."[28] However, neither empirical data or legislative intent support a PT program that restricts the ability of a pathologist to perform interpretative services under a valid medical license and with satisfaction of all necessary board certification, training and continuing education requirements. While the Agency responded to similar concerns raised during the original rulemaking process stating that "a measure of performance only in the area of gynecologic cytology ... does not threaten or supersede medical licensure of certification,"[29] that statement is untrue when the result of unsuccessful PT is to suspend an individual clinician's ability to perform a medical procedure for which is he/she is licensed and certified under applicable state law. This action against an individual clinician does supersede medical licensure or certification, as opposed to a suspension at the laboratory level under a broader program of quality assurance and quality control.

By its own admission in 1992, the Agency was not certain that CLIA was designed to achieve the agreed objectives to reduce false negatives and false positives in test results. The Agency questioned the design of CLIA stating, "more importantly, it cannot be assumed that improvement's in testing accuracy will directly translate into better treatment and outcomes. Laboratory testing is only one variable in the medical decision-making equation."[30] The Agency went further to state that, "CLIA has no bearing on the larger public health issue of whether the clinical questions are being asked are the appropriate questions-or, given the lack of access to care for many Americans, of whether the questions are being asked at all."[31]

As noted in its Regulatory Impact Analysis Statement in the final rule, the Agency stated:

> **"While the final rule is designed to protect all consumers from substandard quality laboratory work,** the CLIA program could in some instances thwart larger public health objectives by hindering the provision of screening services **to the poorest Americans. Ironically, this could be the case in cytological screening, which was the impetus for CLIA legislation."**[32]

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[28] *Id.* at 7040
[29] *Id.*
[30] *Id.*
[31] *Id.* at 7187
[32] 57 Fed. Reg. at 7187 (emphasis added)

Cost-Benefit Analysis

In addition to concerns regarding legislative intent, the Agency must complete its regulatory analysis by evaluating the costs and benefits of the planned regulation. This analysis should include a comparison of not only the benefits and costs of the planned regulation but also the potential benefits and costs of proposed alternative approaches.

At the time the final rule for Cytology PT was issued as part of the 1992 CLIA regulations, CMS's impact analysis concluded that the potential benefits exceeded the potential costs of the planned regulatory action. However, the analysis in the 1992 rule was not evidence-based and relied on assumptions, including that PT reduces false negatives and positives; and that reductions in false negatives and positives reduce unnecessary care by some arbitrary percentage. They then assigned a dollar value to this reduction in unnecessary care. They make this assumption without any empirical evidence to support it. In fact, in their analysis they clearly state that there is no established methodology to estimate the benefits of these regulations. Further, they readily admit they must rely on "ballpark estimates," and they recognize the value of earlier intervention brought about by comprehensive regulation is highly subjective.[33]

Since 1992, the data and methodologies used for cost-benefit analysis have advanced considerably. In fact, the 1999 Mammography Quality Standards Act (MQSA) regulations provided a very good example of how a more accurate cost- benefit analysis could be estimated. Given this information, a more appropriate cost-benefit analysis for the Cytology PT regulations should quantify to the extent possible the following:

1) To what extent does the current cytology proficiency testing framework reduce false negatives?
2) If false negatives are reduced due to proficiency testing, what would be the benefit of this reduction?
    a. Specifically, how many cancer cases a year would be affected?
    b. What would be the dollar savings in treatment costs associated with identifying and treating cervical cancer at early stages?
    c. How much would mortality be reduced if these programs were initiated and what would be the associated benefits per life saved from reductions in mortality?

The following provides a framework for answering these questions. We use some key findings in the literature to arrive at these estimates. We urge the Agency to conduct its own cost-benefit analysis to validate these findings.

[33] 42 CFR Part 493, CLIA of 1988

Effect of Cytology PT on Reductions in False Negatives

There are growing questions about whether the cytology proficiency test is a valid measure of the interpretative ability of the current cytology proficiency-testing program.[34]

"For many reasons, the testing conditions do not mirror the real world practice situation. In the interest of good patient care and quality assurance, most pathologists will show challenging cases or high-grade lesions to colleagues, in an effort to reach a consensus or "laboratory" interpretation. However, this type of collegial consultation is not permitted on a PT examination.

Even more worrisome is that reproducible and reliable material is extremely difficult to find. It is well documented that the Pap test is associated with considerable interobserver variability, even among so-called experts. Furthermore, increases in pass rates of tests may not necessarily be due to increased proficiency or improved knowledge or ability of the test-takers but may result from "gaming" of the system."

Thus, there is no conclusive evidence that the current cytology proficiency testing program will actually reduce false negatives.

Expected Benefits of Reducing False Negatives

The failures of adequately screening for cervical cancer go beyond the reductions of false negatives. Studies show that of the women that are found to have cervical cancer in a given year, 50 percent had never been previously screened. Another 10 percent had not been screened within the past 5 years. Only one third of these women would have a false negative test.[35] However, false negatives can be further divided into two categories. Two thirds of false negatives are due to sampling errors (cells from the abnormal area were not obtained and so could not be identified in the specimen). One third of false negatives are due to detection or screening errors (the abnormal cells are included in the specimen and are not identified as abnormal).[36]

When these probabilities are applied to the approximate 12,500 women who are diagnosed with cancer in a given year, false negatives associated with diagnostic and screening errors would affect approximately 1,240 women.

First of all, as stated earlier, it is doubtful that proficiency testing alone will eliminate all of these false negatives. If the optimistic assumption was made that proficiency testing may

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[34] Hughes, Jonathan H.; Young, Nancy A.; Wilbur; David C.; "2005 Regulatory PT Results: What Do They Really Mean?" CAP Today, May 2006, pp.48-50.
[35] Sawaya GE.; Washington, AE.; "Cervical Cancer Screening: Which Techniques Should be Used and Why? Clin. Obstet Gynecol. 1999, Dec; 42(4): 922-38.

[36] *Evaluation of Cervical Cytology*. Summary, Evidence Report/Technology Assessment: Number 5, January 1999. Agency for Health Care Policy and Research, Rockville, MD. http://www.ahrq.gov/clinic/epcsums/cervsumm.htm

reduce half of these false negatives, the question becomes, what would be the benefit of this reduction?

Any benefit derived from the reduction of false negatives should be based on two key measures. The first is that the earlier cervical cancer is detected, the lower the treatment costs. Cervical cancer is a slow growing cancer. Thus, many of the women with a false negative the first time, if screened within three years, will most likely be correctly identified and treated for cancer at an early enough stage. Given the above statistics, if we assume that only 10 percent of those women will have a repeated false negative associated with detection or screening errors when screened again in three to five years, that leaves only 123 women to be ultimately identified with advanced cervical cancer at later stages. A UK study found that the cost of treatment (adjusted for US$) would be approximately $10,594 dollars higher than if the cancer were identified at earlier stages.[37] Performing the math, the dollar benefit of identifying these false negatives at earlier stages would equal approximately $1.3 million.

A second benefit that some may assume is derived from correct identification of cervical cancer is reduction in mortality. However, again because cervical cancer is slow growing and can be captured ultimately by repeated screening, the mortality savings from proficiency testing is likely to be quite low. While the reduction in mortality rate from proficiency testing is difficult to ascertain, one can make a number of assumptions for illustrative purposes. Assume that at least 1 woman (or 0.8% of the 123 women) might have died due to false negatives. Using an estimate of $3 million as the value of life,[38] the above illustration would yield a total benefit $4.3 million and could be considered a top range estimate of benefits. Compared to the $20 million cost associated with proficiency testing program that was reported by the 1992 cost benefit analysis,[39] costs would significantly exceed benefits if the cost-benefit analysis were done more realistically and account for both increased treatment costs and expected reductions in mortality due to proficiency testing.

Alternative Regulatory Approach

Part of the regulatory analysis process is the identification and evaluation of alternative approaches to the regulatory objective. With the clear lack of empirical data demonstrating a link between individual proficiency testing and reductions in false negatives and positives, alternative approaches must be considered to achieve the stated objective. The College believes that the CLIAC should recommend modifications to the Cytology PT program to make it more consistent with the regulatory approach of the Mammography Quality Standards Act (MQSA).

The MQSA offers an alternative regulatory approach for a similar quality-of-care concern for diagnostic screening services that had the same regulatory objective to reduce false negative and positive rates. The MQSA also offers an analogous approach because the regulations

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[37] Wolstenholme, JL; Whynes, DK; "Stage-Specific Treatment Costs for Cervical Cancer in the United Kingdom," Eur J. Cancer, 1998 Nov; 34(12):pp. 1889-93.
[38] Value of life estimates vary widely and depend on age, occupation and industry of employment.
[39] 42 CFR Part 493, CLIA of 1988

under the MQSA were developed pursuant to the President's Executive Order 12866, and followed the requirements for "regulatory analysis." By comparing the requirements and sanctions under each regulatory scheme, the differing approaches become more apparent.

Although the CMS and CDC are responsible for implementation and enforcement of the cytology standards under CLIA, and the Food and Drug Administration (FDA) responsible for the mammography standards under MQSA, all are agencies under HHS and for both regulatory schemes, the agencies have defined the same regulatory objectives – to reduce false negatives and false positives. However, despite the identical regulatory objectives, the agencies have applied differing regulatory approaches to achieve the intended outcome.

With respect to CLIA, CMS and CDC take a punitive approach focusing on external enforcement. Conversely, the FDA program is outcomes-based and focuses on voluntary internal corrective action as a more effective mechanism for quality improvement. For cytology standards under CLIA, the agencies focus on PT to test and certify the competency of each individual. For mammography standards under MQSA, the agency is focused on assessing the competency of the facility by evaluating outcomes produced by the facility.

Based on hearings held in 1992, the Senate Committee on Labor and Human Resources raised concerns with the quality of mammography practice that were similar to the concerns raised previously for cytological services. Specifically, the Senate Committee found the following problems: (1) poor quality equipment, (2) lack of quality assurance procedures, (3) poorly trained radiologic technologists and interpreting physicians, and (4) a lack of facility inspections or consistent governmental oversight.[40]

In its undertaking, the FDA noted also its regulatory objective to "establish rigorous criteria ... to enhance the quality of mammography services in a manner that is reasonably achievable by mammography facilities."[41] Moreover, in accordance with the objectives of regulatory analysis, the FDA recognized the need to balance costs and benefits stating: "The agency recognizes the need to balance the benefits to be achieved from improved quality of mammography with the cost of those improvements and the impact such cost might have on access to mammography."[42]

In its assessment of quality standards, the FDA considered using proficiency testing as a personnel standard. The FDA concluded that it would be premature to establish performance standards based on PT because of the lack of consensus on testing standards and measurements.[43] Instead of proficiency testing, the FDA established a comprehensive mammography medical outcomes audit program, noting its potential to act as the basis for performance outcome standards.[44] The audit program is similar to the rescreening protocols required under the CLIA regulations by using actual test outcomes to assess performance.

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[40] *See* 62 Fed. Reg. at 55852
[41] *Id.* at 55854
[42] *Id.* at 55857
[43] *See id.* at 55863-55865
[44] *Id.* at 55856

The regulatory requirements of the final rule were adopted by the FDA only after an independent evaluation by the GAO confirming a link between the proposed regulatory action and the quality of mammography.[45] Moreover, in undertaking the implementation of the MQSA, the FDA recognized the need to balance the benefits to be achieved from improved quality of mammography with the cost of those improvements and the impact such cost might have on access to mammography. The result is that the MQSA Cost-Benefit Analysis is a more thorough and accurate estimation because the FDA:

- Used actual measures of test sensitivity and test specificity to represent average mammogram quality;
- Measured quality improvement as the percent decrease in the number of incorrect diagnoses; and
- Tied these rates to mortality and measure mortality avoidance in terms of dollars.

Using the regulatory approach under the MQSA as an alternative to CLIA, the Agency should consider the methodologies used by the FDA to perform regulatory analysis and evaluate the potential costs and benefits for the quality standards, and specifically, PT. The College firmly believes that if the Agency conducts a similar regulatory analysis, it will reach the inescapable conclusion that the more stringent rescreening protocols under CLIA are the most direct and accurate method of assessing laboratory performance. In addition, proficiency testing in its current form provides minimal measurable benefit, and is duplicative, costly, burdensome, and punitive to individuals.

CAP's Cytology PT Program

Previous to its approval as a recognized Cytology Proficiency Testing provider by CMS, the College had conducted an Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP) for more than fifteen years. This highly respected and scientifically proven field-validated gynecologic testing system consistently utilized interpretive categories and statistically validated grading to gauge proficiency of laboratories. A vast majority of affected laboratories, pathologists, and cytotechnologists have participated in this very effective program, where gynecological cytology slide examinations are generally reviewed by teams of individuals in the laboratory.

This educational approach is consistent with other provisions within CLIA. Thus, a rule requiring the enrollment of a cytology laboratory in a proficiency testing program, coupled with assurances by the laboratory that individuals have participated in proficiency testing on an announced and unannounced basis, would be consistent with the plain language of the statute. In this connection, it is noteworthy that 42 U.S.C. §263 (a) (b) and (c) refer to certification of laboratories by HHS whereas 42 U.S.C. §263a (f) refers only to the "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting gynecologic specimens." The textual analysis, involving the certification of laboratories by HHS with the "periodic confirmation and evaluation" of the skills of these individuals, supports the

[45] *See id.* at 55857

conclusion that the Cytology PT regulations would be within the discretion of the Agency. It suggests that the proficiency of individuals need only be periodically confirmed and evaluated and that formal enrollment of such individuals in a proficiency testing program is unnecessary.

Conclusion

Upon completion of its regulatory analysis, if the Agency cannot demonstrate a quantifiable link between cytology PT and the regulatory objective, the Agency should identify the deficiency to the President through the Office of Management and Budget. Pursuant to the President's Executive Order 12866, each federal agency is to identify for the Office of Information and Regulatory Affairs (OIRA) within the OMB any regulations that become "unjustified or unnecessary as the result of changed circumstances." The OIRA will, in coordination with the Executive Administration, consider asking Congress to reconsider the legislative mandate for the regulations.

The College is confident that by developing a method for the Agency to "assure consistent performance by laboratories of valid and reliable cytological services," required in the CLIA statute, focusing on a laboratory's team based practice will provide significant value due to the fact that the program will be able measure how well a laboratory is performing under present day practices and procedures. The regulations as currently implemented do not measure present day practice nor provide for an overall evaluation of laboratory performance in this area of laboratory testing.

The College of American Pathologists remains committed to ensuring the highest quality laboratory testing for our patients. However, the Cytology PT regulations as they stand are not necessary, will not improve quality and could result in the unintended consequence of discouraging well qualified pathologists from providing the service altogether.

Thank you for your full consideration of this important issue. We look forward to your response.

Sincerely,

Thomas M. Sodeman, MD, FCAP
President

cc: Honorable Mark B. McClellan;
Administrator, Centers for Medicare and Medicaid Services

Ms. Devery Howerton

Ms. Maribeth Gagnon