

Clinical Laboratory Improvement Advisory Committee

Summary Report

September 22-23, 2004

**Doubletree Atlanta/Buckhead Hotel
Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES



**Clinical Laboratory Improvement Advisory Committee
September 22-23, 2004, Summary Report
Table of Contents**

- I. Record of Attendance**
- II. Clinical Laboratory Improvement Advisory Committee – Background**
- III. Call to Order and Committee Introductions**
- IV. Agency Updates**
 - **Food and Drug Administration (FDA)**
 - ◆ **Status of FDA Waiver Guidance Document**
 - ◆ **Update on Rapid HIV Test Waivers**
 - **Centers for Medicare & Medicaid Services (CMS)**
 - ◆ **CLIA Statistics; QC for the Future**
 - ◆ **CMS COW Project Update**
 - ◆ **CMS COW Project – Fiscal Year 2002**
 - **Centers for Disease Control and Prevention (CDC)**
 - ◆ **Waived Testing**
 - ◆ **Genetic Testing**
 - ◆ **Cytology Proficiency Testing**
 - ◆ **Futures Initiative**
- V. Presentations and Committee Discussion**
 - **Non-regulatory Approaches to Laboratory Improvement – Introduction**
 - **International Perspective: Non-Regulatory Quality Measures for Medical Laboratories**
 - **Quest Diagnostics’ Experience: Non-Regulatory Quality Standards**
 - **Overview of National Voluntary Standards for Laboratory Improvement**
 - **NCCLS: Global Consensus Standardization for Health Technology**
 - **CDC: Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus**
 - **American Society for Microbiology (ASM) Practice Guidelines**
 - **College of American Pathologists (CAP): Non-Regulatory Approaches to Laboratory Improvement**
 - **COLA: Voluntary Standards and Non-Regulatory Approaches to Laboratory Improvement**
 - **Joint Commission on Accreditation of Healthcare Organizations (JCAHO): Raising the Bar for Patient Safety**
 - **Implementation of NCCLS Antimicrobial Susceptibility Testing Standards**
 - **Institute for Quality in Laboratory Medicine**
- VI. Public Comment**
- VII. Adjourn**

Record of Attendance

Committee Members Present

Dr. David Sundwall, Chair

Ms. Joeline Davidson

Dr. Kathryn Foucar

Ms. Paula Garrott

Dr. Peter Gomas

Dr. Cyril M. (Kim) Hetsko

Dr. Anthony Hui

Dr. Patrick Keenan

Dr. Michael Laposata

Dr. Margaret McGovern

Dr. Dina Mody

Dr. Valerie Ng

Dr. Barbara Robinson-Dunn

Dr. Jared Schwartz

Mr. Albert Stahmer

Dr. Lou Turner

Dr. Thomas Williams

Dr. Jean Amos Wilson

Committee Member(s) Absent

Dr. Kimberle Chapin

Mr. Kevin Kandalft

Acting Executive Secretary

Dr. Robert Martin

Ex Officio Members

Dr. Toby Merlin, CDC

Ms. Daralyn Hassan and Ms. Raelene Perfetto (for Ms. Judith Yost), CMS

Dr. Jean Cooper (for Dr. Steven Gutman), FDA

Liaison Representative - AdvaMed

Ms. Luann Ochs, Roche Diagnostics Corporation

Record of Attendance, continued

Centers for Disease Control and Prevention

Ms. Miriam Alter	Ms. Wendi Kuhnert
Ms. Nancy Anderson	Dr. Harvey Lipman
Dr. Rex Astles	Dr. Adam Manasterski
Ms. Pam Ayers	Ms. Leslie McDonald
Ms. Carol Bigelow	Ms. Diane Ricotta
Dr. Joe Boone	Dr. John Ridderhof
Ms. Diane Bosse	Dr. Darshan Singh
Dr. Bin Chen	Dr. Suzanne Smith
Ms. Joanne Eissler	Dr. Susan Snyder
Ms. Maribeth Gagnon	Dr. Julie Taylor
Ms. Sharon Granade	Ms. Patricia Thomas
Ms. Lauren Green	Mr. Howard Thompson
Dr. Jim Handsfield	Ms. Pam Thompson
Dr. Tom Hearn	Ms. Glennis Westbrook
Ms. Jerri Holmes	Ms. Rhonda Whalen
Dr. Devery Howerton	Ms. Darlyne Wright

Department of Health and Human Services (Agencies other than CDC)

Ms. Carol Benson (FDA)	Ms. Daralyn Hassan (CMS)
Dr. Elliott Cowan (FDA)	Ms. Raelene Perfetto (CMS)

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 25 public citizens attended one or both days of the meeting.

Clinical Laboratory Improvement Advisory Committee

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

The Committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed (formerly, Health Industry Manufacturers Association) and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

Due to the diversity of its membership, CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may eventually result in changes to the regulations, the reader should not infer that all of the advisory committee's recommendations will be automatically accepted and acted upon by the Secretary.

CALL TO ORDER – INTRODUCTIONS/FINANCIAL DISCLOSURES

Dr. David Sundwall, CLIAC Chair, welcomed the Committee members and called the meeting to order. He introduced himself as a practicing physician with many years of experience representing the private sector on issues of public health policy. He then acknowledged the vast diversity of experience and talent represented by the CLIAC membership and introduced five new members: Ms. Joeline D. Davidson, Dr. Patrick A. Keenan, Dr. Dina R. Mody, Dr. Lou F. Turner and Dr. Thomas L. Williams.

Dr. Robert Martin, Executive Secretary of CLIAC and Director, Division of Laboratory Systems (DLS), Public Health Practice Program Office (PHPPPO), CDC, also welcomed the members and expressed his appreciation of the Committee. He acknowledged the Committee's work is critical in providing assistance to establish the framework of laboratory practice in the United States.

To set the tone for the meeting, Dr. Sundwall shared that there is a growing interest among federal and state policy makers to address public concern about the quality of laboratory testing, based on recent incidents reported by the press, by adding additional regulation through legislation. He noted the responsibility of CLIAC is to consider the evidence and be well prepared to counter arguments for additional legislation and regulatory burdens unless stronger regulations are needed and to advise the Secretary of HHS. For that reason, Dr. Sundwall announced the focus of the meeting would be non-regulatory approaches to laboratory improvement. He then distinguished between minimal requirements included in regulations and best practices/consensus voluntary standards. He also addressed the importance of collecting data related to the implementation and utility of voluntary standards.

Dr. Sundwall explained the requirements and process for public disclosures, including those for conflict of interest. All members made self-introductions and financial disclosure statements relevant to the meeting topics.

AGENCY UPDATES

■ Food and Drug Administration (FDA)

Status of FDA Waiver Guidance Document

Addendum A

Dr. Jean Cooper, Division Director, Chemistry and Toxicology Devices, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA, briefed the Committee on OIVD's involvement in recent events relative to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). She informed the members that the waiver guidance document is a high priority for FDA and input from CLIAC, CDC, CMS and AdvaMed has made the document more flexible and scientifically grounded. She briefly highlighted the types of modifications made to the previous waiver guidance issued by FDA, OIVD's process for developing the current draft waiver guidance, and the plan to release the draft guidance for external comments by year's end.

Committee Discussion

- A member asked when a final rule would be published. Dr. Cooper stated FDA hopes to have the draft waiver guidance available before the end of the year for comments, with another year to finalize the guidance. Subsequently, development of the waiver regulation will require rulemaking and additional time. In answer to a question of whether FDA intends to use the final waiver guidance while the regulation is being developed, Dr. Cooper replied the waiver guidance would be used as soon as it is finalized.
- Members requested information about FDA's acceptable total allowable error rate for the proposed studies to support a waiver request. Dr. Cooper replied there is no specific range or number applicable to all assays. FDA is striving for a statistical approach and is encouraging suggestions from CLIAC and others on how to proceed.
- Ms. Luann Ochs, AdvaMed Liaison to CLIAC, thanked the Committee members and FDA for incorporating many of AdvaMed's recommendations in the waiver guidance document, especially the principles of risk analysis and risk assessment. She asked about FDA's intentions for post-market surveillance. Dr. Cooper explained post-market surveillance would differ from traditional surveillance; there will be more of a working relationship between manufacturers and end-users. Manufacturers will need to communicate their use of flex studies, risk analysis, and quality control (QC) information to the end-user. Dr. Sundwall noted that distributors have expressed an interest in sharing educational information with their customers and asked Ms. Ochs if distributors could play a role in this communication process. She replied that distributors are not part of AdvaMed; each manufacturer should work with their distributors on ways to improve communication with and education of the end-user.

Update on Rapid HIV Test Waivers

Addendum B

Dr. Elliot Cowan, Associate Director, Division of Emerging and Transfusion Transmitted Disease, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA, provided an update on CLIA-waived rapid HIV tests. He informed the Committee the OraQuick® Rapid HIV-1 Antibody Test name has changed to OraQuick® ADVANCE Rapid HIV-1/HIV-2 Antibody Test, reflecting the extension of waived status to include HIV-2 antibody detection. Additionally, this test has recently received waiver approval for use with oral fluid specimens. He also noted the Uni-Gold™ Recombigen® HIV test has received waiver approval for capillary and venous whole blood specimens. Dr. Cowan compared the sensitivity and specificity of the OraQuick® and Uni-Gold™ test systems and mentioned the sale restrictions FDA has placed on rapid HIV tests. He concluded by notifying the Committee of the statistical validation studies being performed and the possibility of developing an algorithm using multiple rapid HIV tests for confirmation.

Committee Discussion

- A member requested clarification of "invalid" rapid HIV test results and asked how frequently invalid results occur. Dr. Cowan explained that invalid test results occur infrequently and the test system instructions recommend that invalid tests be repeated. If problems continue, the customer service representative should be contacted.

- Dr. Robert Martin mentioned the importance of understanding how to interpret rapid HIV test results in populations with varying prevalence of disease. He added that DLS is still heavily involved in CDC's rapid HIV training efforts and asked Dr. Devery Howerton to elaborate. Dr. Howerton, Chief, Laboratory Practice Evaluation and Genomics Branch, DLS, briefed the Committee on CDC's role in training those who provide rapid HIV testing and counseling primarily in outreach settings, community-based organizations, and public health centers. Dr. Cowan then expressed appreciation for CDC's training efforts and support of rapid HIV testing and applauded the quality assurance (QA) program CDC developed for their publicly funded sites performing rapid HIV testing.
- Several members expressed concern about whether processes are in place to monitor waived HIV test sales restrictions, to include assuring each testing site is CLIA-certified and provides a quality assurance program. Dr. Cowan stated FDA is not involved in these aspects; manufacturers provide a "customer agreement" in each kit to explain the rapid HIV test requirements and sales restrictions to the purchaser. Currently, the agreement relies on the "honor" system for purchaser compliance; however, states often impose additional requirements for rapid HIV testing. Referring to CDC's rapid HIV training efforts, Dr. Martin explained when a federal agency collaborates with public health clinics or community-based organizations, it has a responsibility to convey information about the test system, its intended use, important procedural criteria, and limitations.
- A member inquired whether public health disease reporting has been impacted by the use of waived rapid HIV tests in public health clinics/community-based organizations and whether states have data pertaining to the number of tests performed versus the number of HIV cases reported. Dr. Tom Hearn, Deputy Director, DLS, PHPPO, CDC, commented CDC has cooperative agreements to collect data during the rollout of waived rapid HIV testing at CDC-funded organizations and suggested a future report on those data.
- A member commended FDA and CDC on the successful implementation of the waived rapid HIV tests and the increased percentage of individuals tested who receive their test results. One study showed 99% of individuals received rapid test results versus 60% of individuals with standard tests. The member also pointed out that during the next decade, as data are collected, it will be of interest to determine the impact on patients receiving care and disease management following detection via rapid HIV testing.

■ Centers for Medicare & Medicaid Services (CMS)

CLIA Statistics, QC for the Future Meeting

Addenda C, D

In the absence of Ms. Judy Yost, Director, Division of Laboratory Services (DLS), CMS, Ms. Rhonda Whalen, Chief, Laboratory Practice Standards Branch, DLS, PHPPO, CDC, gave her presentation. Ms. Whalen reviewed the CLIA statistics as of August 2004 and provided an update on CMS's CLIA activities. This included information about the revised surveyor guidelines, published January 12, 2004, and posted on the CMS CLIA website (www.cms.hhs.gov/clia/). She also mentioned the CMS surveyor training in November 2004, and the availability of four CLIA brochures explaining the quality system regulation published January 24, 2003.

Ms. Whalen cited concerns raised about the accreditation process and noted CMS will be meeting November 16, 2004, with state, federal, and private accrediting officials and state regulators to discuss improvements to the CLIA accreditation and inspection process.

Ms. Whalen then reviewed the status of the notice of proposed rule making (NPRM) for genetic testing. She noted CMS and CDC are clarifying some issues before the rule begins the clearance process and reminded the Committee of the extensive process of rulemaking. Ms. Whalen summarized current and future QC issues faced by testing facilities and announced CMS is planning a workshop entitled “QC for the Future – Equivalent Quality Control Workshop” on March 18, 2005, in conjunction with the NCCLS Leadership Conference (*Addendum E*).

CMS Certificate of Waiver (COW) Project Update

Addendum F

Ms. Raelene Perfetto, Medical Technologist, DLS, CMS, updated the Committee on the COW project. She emphasized data presented at the February 2004 CLIAC meeting were *preliminary* data from CMS visits to COW facilities during 2002 and 2003. CMS has since validated the 2002 data and is in the process of evaluating the 2003 data. Some of the validated data differ from the preliminary data but most remains the same. In particular, preliminary, unvalidated data showed 2% of the surveyed COW laboratories operated under immediate jeopardy (IJ) conditions, posing imminent and serious risk to human health, but revised data showed only two cases of IJ. She reported there were several reasons why some preliminary data had to be revised during the validation process. These included the use of a new data entry system unfamiliar to some of the surveyors, data entry errors, and lag time from survey date until the time of data compilation. In addition, some surveyors initially interpreted testing beyond the scope of the laboratory’s certificate as an IJ situation without contacting CMS to determine the validity of the IJ citation. Ms. Perfetto informed the Committee of CMS corrective actions, e.g., additional surveyor training, clarification of the definition of IJ, and the requirement to report and confirm with the regional and central offices before entering IJ information into the database. Databases have also been redesigned to prevent data entry for some survey questions until confirmation of the information is obtained from CMS.

Ms. Perfetto said CMS is currently completing validation of the 2003 COW data and evaluating data from the 2004 surveys. She mentioned that a proposal to continue COW surveys indefinitely has been submitted to CMS management and emphasized data continue to reflect quality problems in COW facilities.

CMS COW Project, Fiscal Year (FY) 2002

Addendum G

Ms. Daralyn Hassan, Medical Technologist, DLS, CMS, presented an overview of the results and compliance issues from the CMS 2002 COW Project. She noted there were persistent regulatory issues with facilities either not having or not following manufacturer instructions, and there is an ongoing need for education/training on CLIA and laboratory procedures for waived testing personnel. She reiterated a significant number of COW facilities fail to follow manufacturer’s instructions, and there are no data available to determine whether tests perform as intended when instructions are not followed. However, Ms. Hassan reported 96% of COW facilities revisited by surveyors demonstrated improvement by implementing one or more of the recommendations given during the COW survey process. Ms. Hassan shared some of the positive feedback CMS has received regarding the survey process and summarized CMS recommendations regarding the

COW project.

Committee Discussion

- A member requested information on the clarified definition of IJ provided to surveyors. Ms. Perfetto responded that the clarification dealt with the issue of testing beyond the scope of the CLIA certificate. Another member expressed that testing beyond the scope of the certificate does not correspond with the definition of IJ the Committee received at the February 2004 meeting, which was “imminent and serious risk to human health.” Ms. Perfetto reiterated that the problem was with some of the surveyors interpreting “testing beyond the scope of the certificate” as not having appropriate quality assurance systems or personnel qualifications in place for the level of testing (moderate or high complexity), which could present a risk. Some of the surveyors had been interpreting these as IJ situations without obtaining CMS confirmation. During validation of the data, these erroneous entries were identified and corrected.
- Another member suggested CMS consider forming a category other than IJ for deficiencies involving COW laboratories performing non-waived tests.
- CLIAC members noted that the February 2004 CLIAC Summary Report and addendum did not accurately reflect the corresponding presentation and discussion regarding IJ data (the preliminary data presented to CLIAC showed 2% of surveyed COW laboratories operated under IJ conditions, whereas the February 2004 CLIAC Summary Report and addendum reported the verified and revised data showing 2 cases of IJ). Some members mentioned they presented the preliminary data at subsequent organizational and professional meetings and stated they should have been notified at the time of data correction. Dr. Sundwall agreed and apologized for the oversight. He explained that some Committee members were informed, but this information should have been shared with the entire Committee. He also commented that the current (September 2004) CLIAC Summary Report should acknowledge the discrepancy between what was actually presented at the February 2004 meeting and what was posted in the meeting’s CLIAC Summary Report on CDC’s website. Ms. Whalen explained the Committee’s discussions prompted by the high number of IJ cases in the preliminary data were not reported in detail in the February 2004 CLIAC Summary Report since those discussions were based on data subsequently determined to be incorrect. She further explained that the IJ data listed in the addendum of the February 2004 CLIAC Summary Report were corrected before release with an accompanying note that the data were corrected.
- A member stated the IJ data presented by Ms. Hassan seemed to be in conflict with the revised data from the February 2004 CLIAC meeting; e.g., CMS is currently stating one case of IJ and the revised data mentions two cases of IJ. Ms. Hassan explained there was one case of IJ associated with the CMS COW survey visits, while the second case was reported from a nursing home investigation. CMS included the information regarding the second case in the revised data to illustrate proactive steps were taken toward preventing similar incidents in nursing homes.
- A member inquired whether the CMS data could be extrapolated beyond the inspected laboratories. Ms. Hassan responded the sample size was small, representing only 2% of COW laboratories, and the sample selection was not completely random. She noted, however, the data are consistent from year to year and correlate well with similar studies of waived testing practices.

■ Centers for Disease Control and Prevention (CDC) Update

Waived Testing

Addendum H

Dr. Devery Howerton updated the Committee on plans to publish CMS COW data in conjunction with other waived testing data collected by CDC in the *Morbidity and Mortality Weekly Report (MMWR)*, as discussed at the February 2004 CLIAC meeting. She noted, since corrected data from the COW surveys did not indicate a significant number of IJ cases, a more appropriate route would be to publish a comprehensive report incorporating CMS survey data, CDC's Laboratory Medicine Sentinel Monitoring Network data, and a "good laboratory practices" guideline for waived testing in *MMWR's Recommendations and Reports*. Dr. Howerton then gave an overview of waived testing statistics, outlined a proposal to create a workgroup to develop the guideline, and provided a proposed timeline to develop and publish the *MMWR Recommendations and Reports* article.

Committee Discussion

- A member noted the Joint Commission on Accreditation of Healthcare Organization's 2004 Laboratory Accreditation Standards includes a section on waived testing and suggested there may be other organizations with material that could be used as a framework for developing a good laboratory practices guideline for waived testing.
- Dr. Sundwall requested and received volunteers from the CLIAC to participate in the Good Laboratory Practices for Waived Testing Workgroup. The Committee also supported CDC's proposal to include additional individuals on the workgroup who are stakeholders with regard to waived testing, e.g., clinicians, nurses, and manufacturers.
- Dr. Sundwall suggested a letter be sent to CMS emphasizing the importance of continued funding for the CMS COW surveys and monitoring of waived testing facilities. Members agreed and Dr. Sundwall and Dr. Martin agreed to formulate the letter.

NOTE: Shortly after the September 2004 Meeting, Ms. Yost notified Dr. Sundwall that CMS had received funding to continue the COW surveys in 2005 and a letter from CLIAC to CMS was not needed. Ms. Yost thanked CLIAC for its continued support of CMS's waived laboratory surveillance.

Genetic Testing Update

Addendum I

Dr. Joe Boone, Associate Director for Science, DLS, PHPPPO, CDC, presented an overview of CDC's efforts to establish a sustainable process to make quality control (QC) materials available to the genetic testing community in order to promote and facilitate QC, test validation, proficiency testing/external quality assessment (PT/EQA), and the development of new genetic tests. He summarized projects related to these efforts from 1998 to the present and reviewed three QC Materials for Genetic Testing Conferences, organized by CDC in collaboration with the National Institutes of Health (NIH), and the National Institute of Standards and Technology (NIST) in 2003-2004. Participants of the conferences, including experts in genetic and genomic testing from professional organizations, government agencies, industry, laboratories, and academic institutions, developed recommendations for assessing areas needing improvement, prioritizing, and sustaining the process to collect, store, validate, and distribute QC materials at a

reasonable cost.

In addition, Dr. Boone reported on the activities and outcomes from the May 2004 Rare Disease Testing Conference, a collaborative effort of CDC, NIH, the Health Resources and Services Administration, the American Society of Human Genetics, the American College of Medical Genetics, the Genetic Alliance, and Emory University. He provided the CLIAC members two articles from the Journal of Molecular Diagnostics referencing quality assurance issues in molecular genetic testing. (*Addenda J, K*)

Committee Discussion

- A member asked for an estimate of the top five genetic tests currently performed. Committee members with genetics expertise responded that only the test for cystic fibrosis carrier status is considered a standard of care, but other frequently performed tests include fragile X, factor V Leiden, factor II (prothrombin) mutation, and HFE-related hereditary hemochromatosis.
- Another member asked if these efforts were in collaboration with those doing newborn screening using tandem mass spectrometry. Dr. Boone replied some of the participants who attended the Rare Disease Testing Conference are involved with newborn screening. He discussed the issue of nonuniformity of newborn screening test menus among states and past debates regarding whether these tests are actually genetic tests. Currently, he said, the consensus is they are genetic tests.
- One member commented on the use of controls by making a comparison between hemoglobinopathy testing, where a laboratory does not include a positive control for every possible variant found with isoelectric focusing; and multiplex cystic fibrosis testing, where a laboratory may be expected to have a positive control for every mutation to be detected. The commenter speculated the difference in control requirements might be due to variation among professional group recommendations. The commenter further expressed an expectation of guidance from CLIA, since genetic testing regulations are being formulated for publication as a proposed rule. Dr. Sundwall asked Dr. Boone and Ms. Whalen if the unpublished CLIA proposed rule for genetics testing would address proficiency testing, QC, or personnel-related requirements. Ms. Whalen responded that the current CLIA regulations contain general quality control requirements that are applicable to genetic testing as well as specific requirements for cytogenetics. The genetic testing regulation under development would include proposed requirements for personnel and quality control procedures specific to genetic testing.
- Dr. Boone raised the issue of “genetic exceptionalism” confronting the entire advisory community, including CLIAC. He noted there is no clear decision whether genetic testing should be treated differently than other laboratory testing.

Cytology Proficiency Testing

Addendum L

Ms. Rhonda Whalen updated the Committee on CDC’s progress in developing its computer-based alternative (Cytoview™ II) to glass slide-based proficiency testing (PT) for cytology. She reported the findings of a recent CDC study, undertaken with the Maryland Department of Health and Mental Hygiene, to compare gynecologic cytology PT performance using glass slides and virtual slides. This study demonstrated that, with field validation of virtual slide test challenges by both pathologists and cytotechnologists, computer-based PT can be effectively equivalent to

glass slide-based PT. Ms. Whalen noted the journal *Acta Cytologica* has approved for publication an article detailing the study.

Committee Discussion

A Committee member raised the question of possible selection bias, asking what fraction of Maryland cytologists the study volunteers represented. Ms. Whalen said there were originally 122 volunteers out of about 600 Maryland examinees, but participants were limited to in-state volunteers to achieve more control for biases resulting from excess time between testing events and from the order of testing events. The same member requested a numerical breakdown of test volunteer age/experience levels, as they might relate to variable experience with and acceptance of computer formats. Ms. Whalen responded a post-test interview queried examinees about their comfort level with the virtual format. The data indicated those less comfortable with virtual format and those taking longer to complete the test achieved lower scores on the virtual test.

Futures Initiative

Dr. Martin acknowledged Dr. Suzanne Smith, Acting Director, Public Health Practice Program Office (PHPPO), CDC, for her contributions to CLIAC. Dr. Sundwall also complimented her for her enthusiasm and advocacy for the field of laboratory medicine. Dr. Smith thanked CLIAC and DLS for the recognition, noting that in presenting this update on CDC's Futures Initiative, it would be the last time she would address CLIAC from her role as PHPPO Acting Director, as she would be moving to a position in CDC's Office of the Director. Referring to CDC's new organizational chart (*Addendum M*), she stated most CDC Centers, Institutes, and Offices would remain the same. She summarized the process for change, saying there was much discussion following an outside-in approach to an agency evaluation initiated by CDC Director, Dr. Julie Gerberding. This approach was designed to inform CDC leadership of necessary organizational changes to increase CDC's effectiveness. From a variety of proposals, CDC leadership chose a blended model that would maintain the strengths of several important units, yet accomplish necessary changes to CDC's organizational structure. Although many organizational units will remain unchanged, PHPPO and the Epidemiology Program Office will not remain as separate entities. Dr. Smith described the transition as an opportunity for PHPPO and DLS to grow their missions, ideas, and talents to further benefit CDC. Most of DLS will be part of the Coordinating Center for Health Information and Service (CoCHIS). Centers within this unit will interact directly with consumers and other important sectors external to CDC. Dr. Smith commended DLS's strength in establishing and maintaining external partnerships, citing examples of its work with the Institute for Quality in Laboratory Medicine (IQLM) and long-term relations with CMS and FDA. She stated the Futures Initiative provides an opportunity for the laboratory sector to lead the way toward CDC's new iteration.

NON-REGULATORY APPROACHES TO LABORATORY IMPROVEMENT

■ Introduction

Dr. Robert Martin introduced the meeting's main topic: Non-Regulatory Approaches to Laboratory Improvement. He discussed the responsibility of government to assure protection of the public's health and the challenge this represents in an era of rapidly emerging and evolving laboratory testing technologies. He suggested more timely and responsive alternatives to regulatory processes are needed to keep pace with scientific discoveries and new technologies while assuring quality care. Dr. Martin noted the healthcare industry has lagged behind other industries in the trend towards non-regulatory approaches to quality issues. However, the healthcare industry is striving to improve. In conclusion, Dr. Martin said the meeting's presentations on non-regulatory approaches to laboratory improvement would provide a foundation for discussing possible alternatives to regulation as a means to assure quality.

■ International Perspective: Non-Regulatory Quality Measures for Medical Laboratories

*Addendum N**

Dr. Michael Noble, Department of Pathology and Laboratory Medicine, University of British Columbia, director of an ISO-certified (International Organization for Standardization) microbiology PT program for Canadian clinical and water laboratories, provided an overview of the global approach to laboratory standards. He began by stating the move towards uniform laboratory standards worldwide is seen in two different lights. One group views it as global harmonization and a means to improve trade and healthcare and another group views it as international globalization leading to a loss of jobs. He detailed the evolution of quality management relative to ISO standards, describing it as a 45-year linear progression from quality management in general (ISO 9000-continuous improvement and client satisfaction) to quality management for laboratories (ISO 17025-technical competence) to quality management for medical laboratories (ISO 15189-laboratory cycle and principles of clinical management). He also discussed the benefits derived from the ISO standards documents, noting that each builds upon the other while retaining their unique strengths. Dr. Noble stated together, the three documents provide a solid basis for management to self-direct toward improving the quality of medical laboratory performance, with ISO 15189 rapidly becoming an international standard. The mutual recognition arrangement (MRA), detailed in ISO 17025, provides laboratory accreditation reciprocity between nations.

Dr. Noble discussed challenges faced when forming consensus documents. He suggested these relate mostly to difficulties inherent in the consensus process wherein numerous organizations want to ensure the final documents are useful in their individual settings. Additionally, there is a linguistic challenge (e.g., accreditation versus certification versus registration) with different groups assigning different meanings to each of these terms. Dr. Noble concluded by reiterating ISO 15189 is becoming the standard for quality systems in medical laboratories worldwide.

***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

Committee Discussion

- A Committee member asked if the ISO organization began in the United States. Dr. Noble replied Bell Laboratories developed a quality process that evolved into a military standard, then a NATO standard, then a British Standards Institute standard. ISO evolved at each step until it became what it is today, a 72-country organization of equal voices to create voluntary consensus documents. The first ISO conference was held in Geneva, Switzerland in 1974.
- Another member inquired where the ISO is headquartered, who staffs it, and how it is funded. Dr. Noble replied that the Secretariat is located in Geneva and member dues and the sale of standards fund ISO activities.
- A member inquired about the ISO certification process. Dr. Noble explained ISO certification is a voluntary process. An organization seeking certification must be approved by an association recognized by ISO to perform certifications and must undergo annual inspections. Certification fees are dependent on the organization's size and complexity.
- Some members requested clarification about the ISO standards development process. Dr. Noble described five voting steps: working document, committee draft, international draft, final international draft, and standard. If there are not enough consensus votes to proceed during one of these steps, the committee has the option of placing the idea/recommendation as a technical report/guidance document, which does not carry as much weight as a standard. Dr. Noble emphasized ISO standards are reviewed every five years and either re-adopted or revised.
- Dr. Sundwall asked if NCCLS and ISO standards are competitive or complementary. Dr. Hearn replied NCCLS considers ISO standards complementary to NCCLS standards.

■ Quest Diagnostics' Experience: Non-regulatory Quality Standards

Addendum O

Mr. George Pounds, Manager, Clinical Immunology at Nichols Institute, Quest Diagnostics, began his presentation with an explanation of the reasons why Quest sought ISO certification and adopted the Six Sigma methodology. He suggested thinking of ISO as a systems or infrastructure approach and Six Sigma as a more focused method for effecting process improvements. Quest's business goals – increase the quality of laboratory service, increase productivity and efficiency, and attract and retain the most qualified employees – were not met by compliance with regulatory standards alone. Mr. Pounds described the stepwise approach to ISO and Six Sigma implementation throughout Quest and detailed the lessons learned and benefits derived from these undertakings.

In terms of cost savings, Mr. Pounds provided examples illustrating Quest's perspective that quality will always be the lowest cost option to the overall system. He explained costs may increase in a given area or step in a process, but in terms of the overall system, the best quality system will also be the lowest cost system. Mr. Pounds detailed the evolution of quality in manufacturing from the 1920s to the present, and in the clinical laboratory industry from the 1950s to the present, noting clinical laboratories have only recently begun to employ the highly evolved system of strategic quality management. He provided an illustration of the stages of quality defined in NCCLS GP26 and the extent to which they are addressed by the some of the

various regulatory and non-regulatory programs (CLIA, CAP, ISO 15189, and ISO 9001), as well as Six Sigma. Mr. Pounds concluded his presentation with a discussion of the 2000 revision of ISO 9001.

Committee Discussion

- Dr. Sundwall inquired whether the cost savings demonstrated by Quest are replicable to other laboratories that have attained ISO certification. Mr. Pounds explained Quest's cost savings resulted from the combination of ISO certification and Six Sigma. He is aware of two other ISO-certified facilities that have also realized dollar savings.
- A Committee member stressed one of the critical components of both ISO and Six Sigma is the total commitment of the senior executive team over the long term. The member further noted the average tenure of a CEO today in a major healthcare system is less than three years, creating a major healthcare crisis resulting in not having the management and decision-making environment needed for these quality programs.
- In response to a query on the role of strategic planning, Mr. Pounds explained the Quest CEO leadership team distributes a strategic plan "roadmap" annually to all business units addressing quality and financial information and employee satisfaction issues. The business units design their individual strategic plans to align with this high-level plan.
- A member inquired about the use of information technology (IT) in this project. Mr. Pounds replied IT was critical in the first 1-2 years of implementation, which were spent creating a system of reliable measures to gauge improvements.
- A member observed that laboratories successful at implementing high-level quality programs tend to be reference laboratories with strong, creative IT support and a more predictable work pace, neither of which is typically found in hospital laboratories. Mr. Pounds commented Quest's success with the IT aspect relied on pairing a laboratorian with an IT representative.
- Another member reported chronic staff shortages prevent dedicating personnel for work on ISO implementation, stating data supported this situation as similar elsewhere. Mr. Pounds acknowledged that in a hospital environment, administration support and funding is vital, whether provided through internal staffing or obtaining outside consultation.
- Members asked whether Quest relied on the expertise of its own employees to address quality issues or employed consultants and whether employee involvement resulted in improved organizational buy-in. Mr. Pounds replied Quest relied on employee expertise to address quality, as they are most familiar with the business. Results of Quest's employee satisfaction surveys affirm that involving employees creates a team atmosphere.

■ Overview of National Voluntary Standards for Laboratory Improvement

Addendum P

Dr. Thomas Hearn, Deputy Director, DLS, PHPPPO, CDC, and President of NCCLS, introduced the topic of voluntary standards and summarized how they differ from regulations in their purpose, process, impact, and oversight. He noted regulations serve a useful function, providing a safety net for patient care, but represent the low bar for quality. In contrast, voluntary standards often represent higher standards of quality and address additional aspects such as technical

dimensions, management direction, and basic customer service elements. Dr. Hearn stated the presenters represent organizations known for their voluntary standards development and they will share their experiences in setting voluntary standards and the impact of those standards. He then provided a framework to guide Committee discussion following the presentations.

■ **NCCLS: Global Consensus Standardization for Health Technology**

Addendum Q

Dr. Robert Habig, President Elect, NCCLS, and Vice President, Regulatory Affairs and Compliance, Abbott Laboratories, defined NCCLS as a consensus standards organization accredited by the American National Standards Institute (ANSI) and a volunteer, not-for-profit, global, and educational organization with multi-constituency. Dr. Habig reviewed NCCLS's principles, responsibilities, and activities and explained its project selection, document development, and evaluation processes. He pointed out that NCCLS standards, guidelines, and documents are distributed and used worldwide, recognized by FDA, used in professional practice guidelines, and referenced in government regulations and international standards. He discussed new technical and process developments for the organization and noted an upcoming Equivalent Quality Control Workshop sponsored collaboratively by the American Association for Clinical Chemistry (AACC), the American Society for Clinical Laboratory Science (ASCLS), AdvaMed, CDC, CMS, FDA, and NCCLS on March 18, 2005, in Baltimore, Maryland. Dr. Habig announced NCCLS's name will change, effective January 1, 2005, to the Clinical and Laboratory Standards Institute (CLSI).

■ **CDC: Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus (HCV)**

*Addendum R**

Dr. Frederick Nolte, Professor of Pathology and Laboratory Medicine, Emory University School of Medicine, and Director, Clinical Microbiology and Molecular Diagnostic Sections, Emory Medical Laboratories, shared his experience participating in a CDC workgroup to develop guidelines for hepatitis C virus (HCV) antibody testing, confirmation, and result reporting. He acknowledged there was a lack of established guidelines for this testing before this workgroup was formed and there is still a lack of understanding by healthcare professionals regarding screening and confirmatory test performance characteristics and interpretation of test results. The workgroup consisted of representatives from FDA, the public health community, hospital and independent laboratory sectors, and medical laboratory professional organizations such as the American Society for Clinical Pathology (ASCP), the College of American Pathologists (CAP), and AACC. The workgroup developed testing guidelines and an algorithm for confirmatory testing, which were published February 7, 2003, in CDC's *MMWR*.

In discussing the impact of the guidelines, Dr. Nolte noted that adoption of the guidelines' algorithm saved his institution \$31,000 annually but acknowledged it may result in added costs to facilities that have not routinely confirmed positive screening test results. He identified other positive impacts of following the guidelines as improvement in the accuracy of test results, better

utilization of medical resources, and better public health surveillance.

***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

Committee Discussion

- One member asked Dr. Nolte who bears the extra cost for the recommended reflexive confirmatory testing. He responded the costs are passed along to the patient.
- Another member asked Dr. Nolte whether the signal to cutoff ratios are reported to physicians, and if so, whether physicians know how to interpret them. He replied the signal to cutoff ratio values are not reported; these values are for the laboratory's use. A positive screening test result is reported as a low positive or a high positive result and the test report informs the physician of the reflexive confirmatory testing to follow. Laboratories that do not routinely perform reflexive testing should advise physicians when additional testing is recommended.
- When asked how to garner physician acceptance of recommended reflexive testing, Dr. Nolte responded his organization has a committee of physicians that annually reviews all reflex testing protocols in the laboratory. The committee consists of "opinion leaders" that convey the need for reflexive testing to the medical staff.
- A member inquired whether different hepatitis C strains exhibit different antibody responses using the antibody screening tests. Dr. Nolte responded there were some concerns with earlier generations of screening and nucleic acid tests, but the problems have largely been eliminated in subsequent test generations.
- Dr. Nolte was asked whether recombinant immunoblot assay (RIBA) is the gold standard for HCV testing and for recommendations regarding indeterminate RIBA results. He responded that RIBA is the gold standard for antibody testing and when RIBA results are indeterminate, the options are to retest the patient after a waiting period or to proceed to nucleic acid testing.
- Ms Louann Ochs informed the Committee the reimbursement rate (\$27) quoted in the presentation for HCV nucleic acid testing has been challenged by industry. She stated CMS has agreed this rate is too low and needs to be raised; however, the change has not yet been implemented.

■ The American Society for Microbiology (ASM) Practice Guidelines: Development and Publication

Addendum S

Dr. Alice Weissfeld, President and CEO of Microbiology Specialists Incorporated, and former CLIAC member, presented ASM's process for writing its practice guidelines, *Cumulative Techniques and Procedures in Clinical Microbiology*, better known as the Cumitech series. She explained ASM's collaborative approach in identifying topics and writing guidelines.

Dr. Weissfeld also reviewed the purpose of the Cumitech series and gave examples of current Cumitechs and those under development. She explained ASM's "fast-track approach" to write and post urgent guidelines on ASM's website, with a turnaround time of six to eight months, and provided some examples, such as the Clinical Laboratory Bioterrorism Readiness Plan Template and guidelines specific to bioterrorism agents.

Committee Discussion

One member commented Cumitechs are excellent guidelines and pointed out the importance of circulating the information, particularly in the infectious disease community.

■ College of American Pathology (CAP): Non-Regulatory Approaches to Laboratory Improvement

Addendum T

Dr. Richard Friedberg, Chairman, Department of Pathology, Medical Director, Baystate Reference Laboratories, and active on numerous CAP committees, presented an overview of CAP's non-regulatory approaches to improvement in clinical and anatomic pathology laboratory medicine. CAP's Quality Improvement Programs focus on developing and implementing quality improvement activities, establishing realistic benchmarks, accreditation, research, and professional education. Dr. Friedberg described these programs, which include Q-PROBES, Q-TRACKS, Surveys Interlaboratory Comparison Programs, EXCEL, scientific literature and consensus statements, and continuing education programs. He discussed some of the quality issues studied by Q-PROBES and Q-TRACKS and gave examples of interventions and positive outcomes resulting from a Q-TRACKS study of wristband errors. He identified the new 2005 Q-PROBES and Q-TRACK offerings and acknowledged the challenges laboratories face in providing outcomes data. Dr. Friedberg announced CAP was recently awarded a CDC cooperative agreement, "Assessment of Quality Assurance Best Practices Using Clinical Outcomes Evidence," which should yield needed real-time data.

Committee Discussion

- A member inquired whether the EXCEL PT Program would be burdensome for waived laboratories and if the EXCEL program has data showing participation by COW laboratories that were also inspected by CMS. Ms. Whalen responded CMS has a database to track laboratory participation in PT programs and it may be possible to link this database with CMS data of laboratories inspected through the COW project. Discussion among members followed regarding CMS data showing approximately 7% of COW laboratories participate in PT programs. Several members commented that economics is a barrier to getting PT programs into waived testing facilities. One member suggested lawyers and risk managers may be more likely to offer support for funding PT programs as a mechanism for quality improvement because they see it as a way to decrease liability. Hospital and finance administrators are less likely to subscribe to anything other than what is required, unless there is a financial incentive to do so.
- A member pointed out the need for communication and increased sharing of data among organizations, e.g., JCAHO and CAP, so hospital administrators and CEOs nationwide would be aware of current quality issues in laboratory medicine. Examples were shared among members of instances where issues addressed by CAP's Q-PROBES were adopted by another organization and resulted in the development of a standard.

■ **COLA: Voluntary Standards and Non-Regulatory Approaches to Laboratory Improvement**

Addendum U

Mr. Max Williams, Director, Policy and External Affairs, COLA, described COLA as a physician-directed organization of 6,700 laboratories, originally founded for physician office laboratories, with deemed authority from CMS as a CLIA-approved accrediting organization. Mr. Williams explained COLA's guiding principles for standard development, the use of its constituency expertise in developing standards, and its evaluation/benchmarking processes. He announced COLA is currently adding the specialties of cytology and histopathology to its program. Mr. Williams concluded his presentation by describing COLA's current and future considerations for performance improvement, e.g., quality management systems, ISO 15189, on-line education, risk mitigation, improving waived test performance, and drivers for performance improvement.

■ **Joint Commission on Accreditation of Healthcare Organizations (JCAHO): Raising the Bar for Patient Safety**

Addendum V

Ms. Joanne Born, Executive Director, Laboratory Accreditation Program, JCAHO, described JCAHO as a non-profit healthcare accrediting body for hospitals, laboratories, ambulatory and long-term care facilities, and home health agencies. The organization sets standards and develops National Patient Safety Goals (NPSGs) to improve healthcare quality. Ms. Born explained JCAHO's Sentinel Event Advisory Group develops NPSGs to address gaps identified in healthcare quality and she detailed the NPSG development process. To evaluate an organization's compliance with standards and NPSGs, JCAHO uses "tracer methodology," in which surveyors select a patient, resident, or client and use that individual's record as a roadmap to move through the organization's systems of providing care and services. Ms. Born concluded by discussing JCAHO's 2005 National Patient Safety Goals for laboratories – improve accuracy of patient identification, improve effectiveness of communication among caregivers, and reduce the risk of healthcare-associated infections.

■ **Implementation of NCCLS Antimicrobial Susceptibility Testing Standards**

*Addendum W**

Dr. Fred Tenover, Associate Director for Laboratory Science, Division of Healthcare Quality Promotion, National Center for Infectious Diseases, CDC, detailed the role and implementation of NCCLS Antimicrobial Susceptibility Testing (AST) standards in clinical microbiology (specifically, bacteriology). He began by stressing the importance of AST data collected by clinical microbiology laboratories throughout the country and their usefulness individually and aggregately. These data are used to manage therapy for infections in individual patients, guide empiric therapy, and serve as the basis for infection control activities. He noted the data have considerable value for use in local, regional, and national databases for evaluating trends in emerging resistance.

Dr. Tenover explained that in developing AST standards and guidelines, NCCLS considers data from the pharmaceutical industry, government and public health agencies, academia, and

individual microbiologists. The current NCCLS AST standards for bacteriology are addressed in six documents and provide methods for antimicrobial susceptibility testing, quality control and assessment, interpretive criteria, and recommendations for reporting results. Dr. Tenover added that a future document will address AST for “orphan” organisms and guide laboratories in testing and reporting organisms when no interpretive criteria are available. NCCLS responds to customers by annually distributing updated M100 Supplements, which provide new and revised breakpoints, new screening tests, and clarifications of testing methods. The supplements also address major changes in standards, answer questions raised by users regarding test methods or breakpoints, and encourage continuous feedback to NCCLS headquarters.

Dr. Tenover described the methods for establishing sensitive, resistant, and intermediate breakpoints for organisms using either disk diffusion or MIC methods and noted there are some problems related to AST methods, breakpoints, and QC testing. In response to some of these problems, NCCLS plans to publish updated breakpoints for *Enterococcus faecium* and daptomycin, a new table devoted to *Neisseria meningitidis*, and a new document addressing testing of fastidious and infrequently isolated organisms. Dr. Tenover emphasized the goal of the AST standards is to generate accurate and meaningful results.

***Note:** The addendum was revised from material provided in the Committee’s notebooks to reflect last minute updates by the presenter.

Committee Discussion

- One Committee member inquired whether cautionary instructions for working safely with *Neisseria meningitidis* would be included in the new M100 table. Dr. Tenover affirmed that the new document has safety warnings for these organisms. In addition, there is now a table on safely testing organisms used as agents of bioterrorism.
- Another member asked about the cost effectiveness of the new vancomycin screening guideline. Dr. Tenover responded the new guideline is viewed as interim until automated susceptibility systems are capable of detecting vancomycin-resistant *Staphylococcus aureus* (VRSA).

■ Institute for Quality in Laboratory Medicine (IQLM)

*Addendum X**

Dr. Toby Merlin, Associate Director for Laboratory Medicine, DLS, PHPPPO, CDC, updated the Committee on activities related to IQLM. He stated there are opportunities for improvements in quality and safety in U.S. healthcare and cited reasons why the laboratory is a focal point for improvement. Noting attention should be paid to quality in all phases of laboratory testing, he said the IQLM seeks to address these issues by promoting improvements in laboratory testing and services to benefit public health. Dr. Merlin reviewed the nine-part IQLM agenda and projects underway: creation of an awards and grants program, development of laboratory and partner networks, development of indicators and progress monitors, and creation of a national report to identify issues and best practices. He pointed out that the IQLM is designed to accomplish these goals through the cooperation of laboratory professionals, clinicians, accrediting organizations, consumers, administrators, policy makers, the diagnostics industry,

and payers. After listing IQLM's partner organizations and a brief review of the Awards, Indicators, and Networks Workgroups and their leaders, Dr. Merlin concluded with a schedule of upcoming IQLM events: the October 2004 Partners and Workgroups Meetings and the April 2005 IQLM Conference.

***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

Committee Discussion

- A Committee member suggested the IQLM is the best forum for bringing groups together to inspire greater participation in voluntary activities to improve quality. Another member expressed appreciation for the IQLM's initiatives and stressed laboratorians must be proactive in raising hospital administrators' awareness of the laboratory's impact on patient outcomes.
- One member proposed the IQLM should concentrate on identifying incentives to change behavior that will result in improved quality, outcomes, and healthcare. Some insurers are considering setting reimbursement levels contingent on various quality measures. The member further commented some laboratories are willing to participate in the voluntary efforts of organizations such as CAP and COLA. Members agreed financial incentives trigger actions and emphasized performance measures should be tied to the reimbursement process.
- A member asked whether any risk management organization was involved in the IQLM. Dr. Merlin responded that the Association of Risk Managers is a partner organization.
- Another member suggested IQLM focus on obtaining better data and commented that data demonstrating impact on patients, determining outcomes, and illustrating the inverse relationship between quality improvement and cost would gain the attention of administrators. Dr. Sundwall responded that the Laboratory Health Care Coalition has funded a study conducted by economist Dr. Frank Lichtenberg of Columbia University, to quantify the economic benefit of clinical laboratory testing.
- Ms. Luann Ochs stated the importance of using marketing strategies to publicize laboratory success stories. She commented that emphasizing the financial impact of quality and efficiency and stressing small investments would provide great returns. Dr. Merlin responded that the April 2005 IQLM Conference will focus on the business case for quality. Additionally, bestowing the first IQLM awards will enhance efforts to draw public attention to accomplishments in laboratory medicine.
- A member observed the extensive coverage given to health information and standards in the popular media and suggested the need for a media award specifically for reporting the importance of laboratory quality as it relates to care for a given disease.
- Other comments made by Committee members include the following:
 - There is a need to communicate to the public and to payers the importance of demonstrating in measurable ways that quality is important. To effect quality improvement, the laboratory should communicate directly with both physician and patient clients, helping them to use the information generated by the laboratory so the client perception of the laboratory is as a source of high-quality information that will improve healthcare.

- A shift in public policy toward the pay-for-performance approach currently under consideration by CMS and other insurers could result in the untoward consequence of a two- or three-tiered healthcare system.
- In order to inform the policy-making process, congressional delegate members or their legislative aides on health issues should be invited to the laboratory to observe the quality processes in place and to witness first-hand the laboratory's critical role in patient care.
- As hospitals bring new information systems online, a laboratory interface with the IT committee to build algorithms into the system to enforce practice guidelines will encourage best practices.
- Quality improvement pilot programs in underserved hospitals that may be more open to making policy and procedural changes known to result in cost savings could perhaps be conducted under the auspices of CDC.

■ PUBLIC COMMENT

Computer-Based Proficiency Testing for Cytology

Addendum Y

Dr. George Birdsong, American Society of Cytopathology submitted a written comment

■ ADJOURN

Dr. Sundwall acknowledged the Committee's concerns as to the extent non-regulatory approaches can result in quality improvement due to the limited resources available to adopt and participate in these voluntary programs. He concluded the meeting with a review of the following action items:

- The Good Laboratory Practices for Waived Testing Workgroup, chaired by Dr. Jared Schwartz and Dr. Kathy Foucar, will meet and report its findings to CLIAC in February 2005.
- The Chair will write a letter to CMS on behalf of the Committee, supporting continuing the CMS COW surveys beyond 2004. (NOTE: Shortly after the September 2004 Meeting, Ms. Yost notified Dr. Sundwall that CMS had received funding to continue the COW surveys in 2005 and a letter from CLIAC to CMS was not needed.)

Dr. Sundwall announced the 2005 CLIAC meetings are scheduled for February 16-17, and September 7-8, and adjourned the CLIAC meeting.

I certify this summary report of the September 22-23, 2004 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

/s/

Dated: 1/5/2005

David Sundwall, M.D., CLIAC Chair