Clinical Laboratory Improvement Advisory Committee

Summary Report

May 12-13, 1999

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CENTERS FOR DISEASE CONTROL AND PREVENTION

Clinical Laboratory Improvement Advisory Committee (CLIAC)

May 12 - 13, 1999

Summary Report

Table of Contents

I. Record of Attendance

II. Welcome and Introductory Information

III. Orientation for New Members

- # Travel Guidelines
- # Federal Advisory Committees
- # Administrative Procedure Act / Conflict of Interest
- # History of Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- # CLIAC Process

IV. Call to Order - Full Committee Introductions

V. Presentations and Committee Discussion

- # CLIA Update
  - Centers for Disease Control and Prevention (CDC)
  - Health Care Financing Administration (HCFA)
  - Food and Drug Administration (FDA)
- # Transfer of Test Categorization / Waiver Review to the FDA
  - Test Categorization and the Complexity Model
  - Integration of Test Categorization / Waiver and the Review Process
  - Implementation and Inspection of Test Complexity

CLIAC Summary Report

May 12 - 13, 1999

Table of Contents (cont.)

Laboratory Test Results of Public Health Importance / CLIA Reporting Requirements

- Perspectives of the Council on State and Territorial Epidemiologists (CSTE), the College of American Pathologists (CAP), and the American Clinical Laboratory Association (ACLA)
- Overview of CDC Activities
- Committee Discussion

Remaining Gaps in Laboratory Y2K Preparedness

- HCFA Update on Y2K Activities
- FDA Update on Y2K Activities
- CDC Update on Y2K Activities
- Laboratory View

VI. Public Comments

VII. Concluding Remarks

VIII. The Addenda

Record of Attendance

Committee Members
Dr. Toby Merlin, Chair
Dr. David Baines
Dr. George Birdsong
Dr. Thomas Bonfiglio
Dr. Ronald Cada
Dr. Joseph Campos
Dr. Patricia Charache
Dr. Brenta Davis
Dr. Andrea Ferreira-Gonzalez
Dr. Jaime Frias
Dr. Susanne Gollin
Dr. Verlin Janzen
Ms. Diana Mass
Ms. Sharon Radford
Dr. Larry Silverman

Ex Officio Members
Dr. Joe Hackett (representing Dr. Steven Gutman), FDA
Dr. Robert Martin, CDC
Ms. Judith Yost, HCFA

Liaison Representatives
Ms. Kay Setzer (HIMA)

Centers for Disease Control and Prevention
Ms. Nancy Anderson
Dr. Rex Astles
Ms. Carol Bigelow
Ms. Billie Bird
Dr. Joe Boone
Ms. Gail Bosley
Ms. Diane Bosse
Ms. Genoria Bridgeman
Ms. Carol Cook
Ms. Maribeth Gagnon
Ms. Sharon Granade
Dr. Thomas Hearn
Dr. Ed Holmes
Dr. Devery Howerton
Dr. Kati Kelley
Dr. Ira Lubin
Ms. Gloria Kovach
Mr. Kevin Malone
Dr. Adam Manasterski
Dr. John Ridderhof
Dr. Eunice Rosner
Ms. Renee Ross
Mr. Jim Seligman
Ms. Marianne Simon
Mr. Darshan Singh
Ms. Elva Smith
Ms. Rhonda Whalen
Dr. Laurina Williams

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, Health Care Financing Administration; 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 will also include a non-voting liaison representative who is a member of the 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 law, the reader should not infer that all of the advisory committee's recommendations will be automatically accepted and acted upon by the Secretary.

WELCOME AND INTRODUCTORY INFORMATION **Addendum A**

Dr. Toby Merlin, CLIAC Chair, began the orientation session for new CLIAC members by introducing Dr. Robert Martin, Director, Division of Clinical Laboratory Systems (DLS), Public Health Practice Program Office (PHPPO). Dr. Martin welcomed the CLIAC, and stressed the value of the Committee's input to the Department of Health and Human Services and the agencies responsible for implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Dr. Martin also thanked DLS staff who support the CLIAC meetings, after which the CLIAC members and CDC staff present at the meeting made self-introductions.

As part of the orientation, Dr. Martin presented the organizational structures of CDC, PHPPO, and DLS. He described the major CDC initiatives for the year 2000, and DLS priorities, which are currently being identified through the development of a strategic plan for the Division. He then summarized the projects and activities conducted in DLS, and turned the meeting back to Dr. Merlin for further introductory comments.

Dr. Merlin outlined the framework for CLIAC operations, emphasizing that they are an advisory committee, and are not responsible for writing regulations. He added that the meetings provide an opportunity for open discussion by Committee members, and the CLIAC serves as a connection between CDC and the laboratory community. He urged CLIAC members to assist in making laboratorians aware of the opportunity for public input on the CLIA regulations by providing comments and attending the open public meetings. He also asked the members for input on agenda items for future meetings.

ORIENTATION FOR NEW MEMBERS

Travel Guidelines **Addendum B**

Ms. Renee Ross, Committee Management Specialist, DLS, reviewed the travel rules and guidelines that apply to CLIAC members. She briefly outlined policies and procedures for making airline reservations, and reimbursement of allowable expenses, including hotel, meals, ground transportation, and other miscellaneous expenditures.

Federal Advisory Committees **Addendum C**

Ms. Gloria Kovach, Committee Management Specialist, CDC, described the Federal Advisory Committee Act (FACA) passed on October 6, 1972, explaining the role and purpose of federal advisory committees. She said that more than 1000 federal advisory committees exist, and serve as a means of public participation in the government decision-making process. Members in the committees are appointed by relevant government agencies, with committee membership balanced to represent varying points of view, expertise, geographic distribution, gender, ethnic and minority groups. Committee members are special government employees when they serve on advisory committees, and are subject to the same rules as other government employees when in this capacity. Most federal advisory committee meetings are open to the public, except where there are issues of national security, industry trade secrets, or other proprietary information being

discussed. However, even closed meetings are announced to the public via the *Federal Register*.

Administrative Procedure Act / Conflict of Interest **Addendum D**

Mr. Kevin Malone, Senior Attorney, Office of General Counsel, Office of the Director, CDC, briefly explained how federal laws are enacted and regulations developed with input from the public at several points in the process. He noted the CLIAC was established in 1992 to provide a means for public input on the CLIA regulations, which will continue to evolve as laboratory testing and technology change over time. He then introduced a videotape on FACA and ethical issues that pertain to special government employees which was shown to the CLIAC.

Following the videotape, Mr. Malone gave a brief overview of conflict of interest rules that apply to CLIAC members. He stated when serving on the Committee as Federal employees, members should not have financial interests that would compromise their participation. However, he explained, in as much as financial conflicts of interest are inherent in certain instances of advisory committee membership, waivers are granted if the need for service outweighs the conflict.

CLIA History and Overview **Addendum E**

Dr. Devery Howerton, Chief, Laboratory Practice Standards Branch, DLS, presented a chronological overview of the CLIA law and its implementation, emphasizing key features of the law, and revisions to the regulations since publication of the final regulation in 1992. She explained that the regulations are based on the complexity of laboratory testing, and reviewed the CLIA technical standards, including proficiency testing (PT), patient test management, quality control, personnel, and quality assurance. Dr. Howerton also outlined the roles of the Health Care Financing Administration (HCFA), CDC, and Food and Drug Administration (FDA) in CLIA implementation, and showed how CLIAC fits into the organizational structure of the Department of Health and Human Services (HHS) and these three HHS agencies.

CLIAC Process **Addendum F**

Dr. Merlin concluded the orientation session by describing the process usually followed at CLIAC meetings. He explained that, in general, presentations are made to the CLIAC by HHS representatives or technical experts on a specific topic, and group discussions are held by the Committee. Since the meetings are public, there is also opportunity for public comment. Although there is often a group consensus at the end of a discussion, it is uncommon for the CLIAC to take an actual vote on an issue. Dr. Merlin then read section 493.2001 of the CLIA regulations describing the establishment and function of the CLIAC. He also explained there are instances where there is a need for CLIAC Subcommittees or Workgroups on certain issues relevant to clinical laboratory testing. Dr. Martin noted that although the CLIAC is an advisory committee, some meetings are primarily informative and not intended to solicit specific advice. Dr. Thomas Hearn, Acting Deputy Director, DLS commented that the CLIAC has been beneficial to HHS in identifying gaps in clinical laboratory quality and suggesting areas to be addressed.

CALL TO ORDER - FULL COMMITTEE INTRODUCTIONS

Dr. Merlin called the CLIAC meeting to order, and reviewed the role of this Advisory Committee. Dr. Martin welcomed CLIAC members who had not attended the orientation session and summarized the materials covered. All CLIAC members made self-introductions and disclosure statements of their relevant financial interests as they relate to the topics to be discussed during the CLIAC meeting.

PRESENTATIONS AND COMMITTEE DISCUSSION

CLIA Update

Centers for Disease Control and Prevention (CDC) **Addendum G**

Dr. Devery Howerton updated the Committee on CDC's recent activities relevant to CLIA, covering progress on regulatory revisions, the status of State applications for CLIA exemption, computer-based cytology PT, and genetic testing activities. In doing so, she discussed the final quality control rule and the proposed rule for cytology PT being drafted. She mentioned an upgrade to the computer-based cytology PT system under development, and the study conducted to evaluate the correlation between work performance and PT in cytology. This study has been completed and is being published in the *American Journal of Clinical Pathology*. In the area of genetic testing, she described several projects that DLS is participating in to identify and address needs pertaining to this emerging technology. Dr. Howerton provided the address for the DLS Internet website (http://www.phppo.cdc.gov/dls), a source of information about CLIA and relevant CDC activities.

Several CLIAC members asked for clarification of points made by Dr. Howerton regarding the publication of regulations being developed, and the status of the computer-based cytology PT system. One member expressed concern that there is an increasing shortage of quality personnel in the clinical laboratory community, and suggested this issue be addressed at a future CLIAC meeting.

Health Care Financing Administration (HCFA) **Addendum H**

Ms. Judy Yost, Director, Division of Outcomes and Improvements (DOI), Center for Medicaid and State Operations (CMSO), HCFA, summarized HCFA's CLIA implementation activities. She referred the Committee to HCFA's website for additional information on CLIA (http://www.hcfa.gov). In her presentation, Ms. Yost reviewed HCFA data on laboratory certification, CLIA-exempt States, accreditation organizations, survey deficiencies, and enforcement, and provided a copy of the new CLIA application form (highlighting changes). She stated that currently 51% of laboratories have certificates of waiver, and perform 3% of the total volume of tests. She added that when California and Florida obtain exempt status in the near future, approximately 22% of the laboratories in the United States will be exempt - leaving a significantly lower number of laboratories supporting the CLIA program. Ms. Yost next discussed the CLIA validation review findings and HCFA's evaluation of disparate cases to

determine whether the majority of these cases occurred in specific states. For 1996 - 1997, HCFA observed that there were 26 disparate cases which occurred in 14 different states, concluding that there is not a correlation between disparate cases and certain states. She also mentioned HCFA's contract for specialized surveys of cytology laboratories and the training for general surveyors in this specialized area of testing. She said that HCFA plans to increase specialized training for surveyors in other areas of the laboratory as well. Last, Ms. Yost discussed program integrity/fraud and abuse investigations being conducted by HCFA in coordination with other government agencies, including the Department of Justice. She described a pilot project underway in three states which would allow a surveyor conducting a CLIA inspection to recognize fraud and abuse and refer it to appropriate authorities, while still maintaining the educational focus of the CLIA inspection.

A CLIAC member asked why data was not included on validation review findings in exempt States. Ms. Yost answered that as of the last period for conducting validation reviews, there were no disparate cases in exempt States. Another member asked whether the role of surveyors to identify fraud and abuse would be expanded to accreditation organizations if the pilot project is successful. Ms. Yost said that under deemed status, the accreditation organizations are to have an educational focus to their survey processes. However, HCFA will provide them with liaison or contact information for other agencies (i.e., FDA, Occupational Safety and Health Administration) if a problem is identified. A CLIAC member disagreed that the disparate cases related to validation inspections are evenly distributed, noting that 13 of the 26 cases were found in three States.

Food and Drug Administration (FDA) **Addendum I**

Dr. Joseph Hackett, Deputy Director, Division of Clinical Laboratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA, reported on the FDA process for review and classification of clinical laboratory devices and reagents. He described the 510(k) and PMA review processes, and briefly noted the differences between the two. He mentioned the FDA's regulation on analyte specific reagents, which includes requirements for in-house (home brew) laboratory tests. He then stated this is a time of change for the FDA and much re-engineering and reform is taking place. Dr. Hackett discussed binding agreements, a part of the PMA process in which a manufacturer is given assurance as to all necessary data before submission, and modular reviews, in which reviews are completed one portion at a time.

A CLIAC member asked whether FDA and/or HCFA review naturopathic or homeopathic procedures as to their validity or CLIA applicability. Ms. Yost said that if these tests or procedures produce health assessment information, they meet the definition of laboratory testing under CLIA. Although CLIA does not directly assess the clinical utility of laboratory testing, it can prevent the use of invalid procedures if the laboratory can not show evidence of test or method validation. A few CLIAC members expressed concern that the CLIA test categorization and waiver review process is being turned over to the FDA at a time when the FDA is decreasing scrutiny of technology and testing procedures, due to limited resources. They stated it will be difficult for the FDA to take on additional responsibilities without significantly increasing resources. Dr. Hackett explained there is already a redirection of resources within FDA to

increase the scrutiny of new technology and tests, and added the FDA is requesting the same number of FTE's for doing test categorization and waiver reviews as currently allocated for CDC's activities.

Transfer of Test Categorization / Waiver Review to the FDA

Test Categorization and the Complexity Model **Addendum J**

Dr. Howerton presented an overview of the issues to be addressed pertaining to the current processes used at the CDC for test categorization and review for waiver, the transfer and integration that will take place at the FDA as they assume these responsibilities, and the implementation of CLIA with respect to test categorization and waiver. She gave the anticipated timeline for the transfer to occur, summarized the relevant parts of the CLIA statute and regulations, and gave a status report for these activities at the CDC.

Several CLIAC members had questions regarding the criteria for waiver, particularly the criterion that the test "poses no unreasonable risk of harm to the patient if performed incorrectly." They did not believe that any test could meet this requirement. Dr. Joe Boone, Associate Director for Science, DLS, noted that this criterion is included in the CLIA statute, and acknowledged it may appear difficult to meet. However, he explained that in the waiver review process, this criterion is addressed by including very stringent accuracy requirements to ensure that a waived test has a very low likelihood of obtaining an erroneus result. The Committee also discussed waiver of tests based on clearance by the FDA for home use. Some members raised the concern that there are significant differences between patients performing self-testing to monitor specific disease conditions and waived tests performed in a physician's office or other setting. They also pointed out that the criteria used by the FDA for home use clearance address safety and efficacy as compared to a similar test, and are different from the criteria used to evaluate a test for waiver, which include specific requirements for accuracy. Another issue mentioned pertaining to waiver is access to testing, and the balance that must be considered between access and the accuracy of tests that are available. It was suggested that these waived testing issues be revisited and addressed at a future CLIAC meeting.

The Committee also asked the CDC to provide additional data on waived tests, especially those waived based on FDA home use clearance. This information was presented later in the meeting by Ms. Rhonda Whalen, Senior Health Scientist, LPSB, DLS. She reported that 457/618 waived test systems are in three of the original eight categories specified in the 1992 final regulations, those being dipstick/tablet reagent urinalysis, urine pregnancy tests (visual comparison), and blood glucose devices (FDA cleared for home use). She added that 9 test systems to measure or detect 4 additional analytes have been waived based on FDA clearance for home use.

Integration of Test Categorization / Waiver and the Review Process

Dr. Hackett briefly reported on the FDA's plans to integrate the test categorization and waiver reviews into their current 510(k) and PMA review processes, and the training that is currently taking place to complete the transfer. He stressed that the FDA's evaluations will essentially be

the same as those conducted by the CDC, and noted the FDA has some concern there will be an overwhelming number of waiver applications submitted when they assume the responsibility for reviewing these requests.

Implementation and Inspection of Test Complexity

Ms. Yost addressed the impact the transfer of test categorization/waiver reviews will have on HCFA in implementing CLIA. She stated that, initially, HCFA had questions as to consistency, communications and whether information would continue to be reported to laboratories and surveyors in a timely manner. There were also questions about costs to the CLIA program and maintaining budget neutrality in light of the transfer. However, she reported the FDA and CDC have worked to make the transfer process transparent, and she emphasized these efforts must continue. She gave several examples as to the many ways HCFA uses test categorization and waiver information to illustrate the importance of a smooth, successful transfer of responsibilities.

Laboratory Test Results of Public Health Importance

Dr. Martin introduced this discussion topic, explaining there are a number of problems with reporting laboratory test results back to the State of origin. Issues pertaining to this have been described in several reports, including a February 1999 Government Accounting Office Report on Emerging Infectious Diseases, which addressed laboratory reporting and disease surveillance. There are a variety of possible solutions to the problems, such as States being more vigilant about managed care contracts, required reporting under Medicaid/Medicare or other regulations such as CLIA, or improved voluntary reporting. However, all of these solutions have potential drawbacks, including increased costs for laboratories to modify data systems and/or provide staffing, shipment of specimens back to the State of origin, and jurisdictional issues. Each State has its own reporting requirements, which vary substantially. Dr. Martin concluded by stating that, at this meeting, presentations would be made by individuals representing laboratories, epidemiologists, and the CDC. The main purpose for including the topic on the agenda was to surface relevant laboratory quality issues in order to begin considering whether CLIA is the appropriate mechanism to address reporting of public health laboratory test results.

Perspectives of the Council of State and Territorial Epidemiologists (CSTE), the College of American Pathologists (CAP), and the American Clinical Laboratory Association (ACLA)

Addendum K

Dr. Jane Koehler, Outbreak Investigations Section, Georgia Department of Public Health, presented the view of the State epidemiologists (CSTE) and responsibilities of a State Health Department in disease reporting. She explained the process for review and evaluation of notifiable diseases, and resulting followup. She also listed other ways in which reportable disease data is used and gave reasons for reporting.

Dr. Robert Baisden, Director of Clinical Laboratories at the Medical College of Georgia, spoke on behalf of hospital and other clinical laboratories (CAP) and their responsibility to report test

results to public health agencies. He acknowleged the vital role played by the laboratory as part of public health surveillance, but mentioned several issues to be considered when evaluating a system for reporting laboratory data. These include confidentiality issues, cost of meeting reporting requirements, and limitations on usefulness of reported laboratory data. Dr. Baisden encouraged uniformity in reporting requirements as one way to facilitate accurate laboratory reporting, including electronic reporting of public health data. He also supported public compensation to defray the costs of hospital and laboratory reporting and surveillance. He recommended the issues of public health reporting requirements be kept separate from laboratory quality issues addressed by CLIA.

Ms. JoAnne Glisson, representing the ACLA, an advocacy group for large clinical laboratories, described the unique challenges that face these facilities. She said they do not see patients, and in many cases do not receive diagnostic information or an original physician's signature on orders, necessary for reimbursement. With respect to public health reporting requirements, Ms. Glisson commented their laboratory requisitions contain only basic demographic information, and may not have everything needed for reporting. Although she stated an electronic reporting process could pose security problems, if possible for these to be addressed, she urged a standard list of notifiable diseases (with standard demographics) be developed nationally, reported in an electronic format.

Overview of CDC Activities **Addendum L**

Dr. Robert Pinner, Medical Epidemiologist, National Center for Infectious Diseases, CDC, discussed the uses of surveillance data gathered as a result of public health disease reporting, and explained there are different emphases at the Local, State, and Federal government levels. He gave examples in which laboratory-based surveillance data is used by the CDC to identify and follow trends, evaluate trends, monitor changes in infectious agents, measure the impact of changes in practice, and facilitate research and planning. He said the CDC is trying to find a better way to integrate the different ways in which data is reported to them, and briefly described the emerging public health electronic laboratory reporting standards being developed. The electronic standard includes the use of Health Level 7 as a Format Standard, and LOINC (test names) and SNOMED (results) as Coding Standards.

Committee Discussion

Dr. Merlin summarized the presentations and raised issues for Committee discussion. He stated there is currently no Federal regulation or standardized process for notifiable diseases. Reporting is done on a State by State basis, which leads to an irregular, error-prone process. The CDC's proposed template for electronic reporting is one potential mechanism for standardizing the process, but issues of patient confidentiality must be addressed. Dr. Pinner added that surveillance is conducted at the State level in the United States, and that the CDC's role is in collaboration with the States. Dr. Martin noted at this time, the CDC is asking CLIAC for input and suggestions on these issues, but not for a specific recommendation as to how to proceed.

In response to the presentations, Committee members expressed the need for a standard, national

list of reportable diseases, especially for laboratories that serve multiple states. Members also expressed support for the concept of electronic reporting, and suggested working with vendors of laboratory information systems to develop a standardized electronic system. Concerns were noted about potential costs to implement a national electronic reporting system, patient confidentiality issues, and development of a system that could easily be updated if changes are needed. Different viewpoints were shared about how a national reporting system should be implemented. Some CLIAC members said that Federal regulations should require reporting, and suggested this could be covered under CLIA as part of the laboratory director's responsibilities to ensure laboratory quality and ultimately, the quality of patient care. These individuals stated that required reporting may facilitate budgeting for this task. Other members supported use of a structure separate from CLIA to implement a reporting system, and mentioned compensation to laboratories for reporting.

The CLIAC also discussed the need for improved communication between the public health system and practicing physicians or other providers of medical care, and better integration of public health with patient care. One CLIAC member noted that a physician's education does not include public health issues, and there is a lack of awareness of public health in the medical community. In some cases, there is even competition between private physicians and State or County health departments (e.g., immunizations). Dr. Martin and others acknowledged that with better communication and increased awareness of public health issues, there is significant potential for improvement in laboratory reporting.

Remaining Gaps in Laboratory Y2K Preparedness

HCFA Update on Y2K Activities

Ms. Yost reported on several measures HCFA has taken to ensure their systems will be Y2K compliant, and to encourage laboratories and providers to test their systems and implement contingency plans. With regard to CLIA and laboratory preparedness, she said that surveyors are not directed to look at Y2K compliance unless there is a specific problem. However, she added that surveyors should review laboratory quality assurance plans to prevent or resolve problems. Laboratories should have contingency plans in place for critical tests. Ms. Yost also noted data has shown that physicians are not concerned with Y2K, and said that the Commission on Office Laboratory Accreditation (COLA) is working to address this. HCFA and COLA both have 800 numbers for Y2K related problems - HCFA's number is 1-800-958-HCFA. Other steps taken by HCFA for Y2K preparedness include certification of their CLIA billing and certificate systems, sending letters to 1.3 million providers asking them to assure Y2K compliance, and the identification and testing of mission critical systems for compliance. HCFA will not implement any new systems between October, 1999, and March, 2000, in another effort to minimize potential Y2K related problems.

A few CLIAC members questioned why surveyors are not checking for Y2K compliance as part of laboratory inspections. Ms. Yost responded that any problems should be identified through other aspects of the survey process.

FDA Update on Y2K Activities **Addendum M**

Dr. Hackett reviewed the actions of the FDA pertaining to Y2K compliance. He reported the agency has information available on the FDA website (http://www.fda.gov/cdrh/yr2000.html), including a database giving the Y2K status for manufacturers and instruments. However, the program is voluntary and does not provide a comprehensive list. He also reminded the CLIAC of the FDA's MedWATCH program for reporting device failures and malfunctions, which can be accessed via the FDA website or calling 1-800-FDA-1088. He said it is the responsibility of manufacturers to notify users of their instruments' Y2K status, and the FDA will take action if maufacturers do not take steps to ensure Y2K compliance.

CDC Update on Y2K Activities **Addendum N**

Dr. Rex Astles, Health Scientist, LPSB, DLS, began CDC's update by demonstrating a number of government, professional organization, and industry websites that provide helpful information on Y2K preparedness and compliance. He then introduced Mr. Jim Seligman, Director, Information Resources Management Office, CDC, who addressed Y2K plans for CDC and the Federal government in general. Mr. Seligman stated the CDC is very close to being ready for Y2K, and outlined the government's plan to ensure compliance for systems that are critical to the infrastructure of the nation. This plan would focus on high impact Federal programs (e.g., CDC's public health surveillance), contingency plans for the government and its partners, enhancing public confidence, day one planning for the early stages of the new millenium, and establishing communications and command centers. Mr. Seligman also mentioned an MMWR article published May 7, 1999 on assessment of public health computer readiness for 2000, and noted this survey will be repeated.

Laboratory View on Y2K Activities **Addendum O**

Mr. Kirk Lafler, a Y2K consultant, presented the results of a survey assessing the status of hospital laboratories. He conducted a phone survey of 250 laboratories over a three month period, which showed 97% of these laboratories expect to be Y2K compliant by December 31, 1999. He outlined potential sources of Y2K related problems in laboratory information systems, and made recommendations for how to detect and identify such problems, and establish action and contingency plans. Mr. Lafler is now in the process of conducting a similar survey of physician office laboratories.

PUBLIC COMMENTS

There were no public comments for the CLIAC on any issues.

CONCLUDING REMARKS

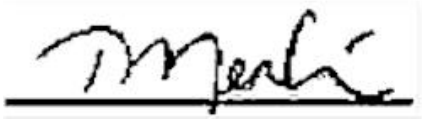
Dr. Martin concluded the CLIAC discussion by listing significant issues identified during the course of the meeting for future consideration by the CLIAC. These are as follows:

- Criteria and processes for waiver, home use testing
- Quality of workforce - training and competency
- Authority of the laboratory director to determine the appropriateness of testing
- Access to laboratory services
- Reporting laboratory tests of public health importance back to the State of origin

He asked the Committee for additional items of importance to be addressed, and it was suggested that qualifications and training needed to perform Mohs' surgery and tissue examination be discussed.

Future dates for CLIAC meetings were announced as: September 22-23, 1999; March 29-30, 2000; and September 27-28, 2000. Dr. Merlin thanked the CLIAC for their participation and adjourned the meeting.

I certify that this summary report of the May 12-13, 1999, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.



Toby L. Merlin, M.D.
Chair