Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

March 12-13, 2003

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
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Summary Report

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Committee Members

Dr. Toby L. Merlin, Chair
Dr. George Birdsong
Dr. Joseph Campos
Dr. Patricia Charache
Dr. Brenta Davis
Dr. Kathryn Foucar
Dr. Ronald Gagné
Dr. Cyril (Kim) Hetsko
Ms. Cynthia Johns
Dr. Ronald Luff
Dr. Margaret McGovern
Dr. Valerie Ng
Dr. Timothy O'Leary
Mr. Stewart Lee Richardson
Dr. Lawrence Silverman
Mr. Albert Stahmer
Dr. Lawrence Sturman
Dr. David Sundwall
Dr. Roland Valdes
Dr. Alice Weissfeld

Ex Officio Members

Dr. Robert Martin, Centers for Disease Control and Prevention
Mr. Donald St. Pierre (for Dr. Steven Gutman), Food and Drug Administration
Ms. Judith Yost, Centers for Medicare & Medicaid Services

Liaison Representative - AdvaMed

Ms. Luann Ochs, Roche Diagnostics Corporation

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 Services (formerly, 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 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. Toby Merlin, CLIAC Chair, welcomed the Committee members and called the meeting to order. He reviewed the role of CLIAC and asked Committee members to make self-introductions and give financial disclosure statements relevant to the topics to be discussed during the meeting. Dr. Merlin recognized Committee members completing their term and thanked them for their contributions and service to CLIAC. In addition, he discussed his own transition, later in the month, from CLIAC Chair to CDC employee, and announced that Committee member, Dr. David Sundwall, will be assuming the role of acting CLIAC Chair at the next meeting. In addition, Dr. Edward Baker, Director, Public Health Practice Program Office (PHPPO), CDC, and Executive Secretary of CLIAC, informed the Committee that he is retiring from CDC, effective March 31, 2003, to accept a position at the University of North Carolina (Chapel Hill) School of Public Health.

AGENCY UPDATES

■ Centers for Medicare & Medicaid Services (CMS) Update

CLIA Final QC Regulation ***Addendum A***

Ms. Judith Yost, Director, Division of Laboratory Services, CMS, provided a summary of the Clinical Laboratory Improvement Amendments (CLIA) Final QC Regulation (68 FR 3640), which was published in the *Federal Register* on January 24, 2003. She began by briefly reviewing the February 28, 1992, CLIA Final rule with Comment and the quality control (QC) and high complexity laboratory director phase-in provisions contained in that rule. She informed CLIAC that the January 2003 CLIA Final QC rule ends these phase-in provisions as of February 28, 2003 (laboratory director), and April 24, 2003 (QC). Additionally, this rule updates the CLIA regulations to incorporate many of the Committee's recommendations, respond to public comments, and reflect new technologies and clinical laboratory research data gathered over the past 10 years. Ms. Yost described the re-formatting of the regulations to parallel the path of a specimen as it moves through the laboratory and to better integrate basic quality systems concepts throughout the laboratory and all testing phases. She then highlighted several of the QC Final rule's revisions and, in particular, the flexibility given to laboratories to determine their own QC mechanisms. Ms. Yost reemphasized CMS's focus on an educational approach to implementation, including allowing laboratories one survey cycle (2 years) to attain compliance with the new regulations. Ms. Yost provided the members handouts detailing the regulatory changes in the Final QC rule **(*Addendum B*)**, and noted that additional information is available on CMS's CLIA website (www.cms.hhs.gov/clia). She briefly discussed guidance documents that are currently under development and will be posted at a later date on CMS's website.

Committee Discussion

- One member inquired about the manufacturer's responsibility related to quality control requirements. Ms. Yost responded that test system manufacturers still need to include QC instructions in their labeling; however, FDA will not be reviewing these instructions for CLIA compliance. While the CLIA regulations continue to require laboratories to follow the manufacturer's QC instructions, each

laboratory performing nonwaived testing will also need to ensure that the test system performs adequately within its particular testing environment.

- Another member asked if a laboratory performing high complexity testing must ensure that each specialty and subspecialty departmental director meets the CLIA laboratory director board certification requirement for individuals with a doctoral degree. Ms Yost responded that the individual identified on the facility's CLIA certificate as Laboratory Director is the individual that must meet the laboratory director qualification requirements.

Ambulatory Safety Initiative ***Addendum* C**

Dr. Scott Young, Senior Clinical Advisor, Office of Clinical Standards and Quality, CMS, informed the Committee about the Ambulatory Safety Initiative to improve patient safety and quality of care in the ambulatory setting. The basis for this Initiative was the Institute of Medicine's report, *Crossing the Quality Chasm*, which noted that patients in ambulatory settings do not reliably receive care consistent with clinical guidelines; that there are significant risks to patient safety and quality of care in these settings; and that substantial gains in quality and safety depend on the incorporation of clinical information systems. The Leapfrog Group, the Agency for Healthcare Research and Quality, CMS, and other interested stakeholders are collaboratively working through a Quality Task Force to address these issues, adopting a strategy to promote information technology systems in physician offices, which have the capacity to provide clinical decision-making support and data exchange. He explained that the Leapfrog Group is a large coalition of public and private organizations and purchasers of healthcare that have united to generate new thinking on value purchasing and to use the leverage of large employers to propose "leaps" to the medical community and facilitate quality improvement in healthcare. The Quality Task Force's three areas of focus are electronic prescribing to increase legibility and decrease the occurrence of drug interaction and dosage errors; electronic test results management to alert the practitioner of test results not reviewed and to decrease unnecessary test ordering; and electronic care reminders (E-care) to prompt the practitioner to remind patients to schedule office visits, laboratory or other services, or to identify patients in need of monitoring. Dr. Young briefly described other HHS health-information technology initiatives and the Quality Task Force's next steps.

Committee Discussion

- The CLIAC members commended the work of the Ambulatory Safety Initiative to reduce medical errors, but suggested that the task force substitute the term "laboratory errors" with "errors in the use and management of laboratory data," to clarify they do not mean "bad" data.
- Committee members commented that several private sector organizations have similar information technology (IT) initiatives. Dr. Young responded the Task Force recognizes there is no single solution and is currently engaged in dialog with other government and nongovernmental organizations regarding cost efficient information systems for physicians.
- One member asked how the E-care reminder would benefit patients, since many people may not have computers in their home or office, and voiced concern about how this would impact patient privacy issues. Dr. Young clarified that this initiative is directed toward information systems in the practitioner's office, not the patient's home or office.
- Another member emphasized the need to develop closed-feedback systems to maintain linkage between physicians and patients and thus address problems presented by a migratory healthcare environment. As an example, the member noted that laboratory results are sometimes returned to

the laboratory because the patient has moved or the doctor has left the practice.

- Several members speculated how an IT system could be effectively implemented in all physician offices, how it would be financed, and what incentives would exist for physicians to use for purposes other than billing. One committee member postulated that CMS could consider IT use in the ambulatory setting as a best practice standard and tie reimbursement to physician offices that embrace IT systems.

■ Food and Drug Administration (FDA) Update

Office of In Vitro Diagnostic Device Evaluation and Safety ***Addendum D***

Mr. Donald St. Pierre, Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health, FDA, presented an overview of OIVD's structure, goals, and activities. He commented that the FDA Modernization Act of 1997 was the driving force behind the establishment of this new office, which will provide cradle-to-grave oversight of in vitro diagnostic devices (IVD) by consolidating all of FDA's IVD regulatory activities (premarket, postmarket, and enforcement) into one office. The office will shift from a premarket review to a quality systems approach and a patient safety team has already been created to look at new ways to identify and resolve problems. He then discussed OIVD's progress reconsidering the Analyte Specific Reagent (ASR) regulation and the development of a proposed rule to expand FDA's authority, and the drafting of a multiplex testing guidance.

Committee Discussion

- Several Committee members asked if the current FDA regulations governing laboratory information systems (LIS) for blood transfusion services would be expanded to include other LIS. Mr. St. Pierre responded that blood establishment computer software is under the purview of FDA's Center for Biologics Evaluation and Research (CBER)--which is now part of OIVD--is responsible for regulating the collection of blood and blood products and. LIS systems are currently classified as Class I exempt products and most of the reported problems relate to software revalidation. He added, at the present time, there are no plans to include non-blood establishment LIS under CBER's regulations.
- Several members commented that changes in science and technology often out-pace regulatory change, leading to conflicts with the regulatory process. They asked if FDA was assessing possible acceleration of the product review process. Mr. St. Pierre affirmed that FDA is initiating changes that should accelerate and improve the review process.
- One member inquired why FDA is interested in regulating Class I exempt ASR's, considering the agency's limited resources and the current political climate of decreased regulation. Mr. St. Pierre explained that the ASR rule was created in response to concerns related to genetic "home brew" testing and the need for oversight. He added that oversight of ASR's is clearly within FDA's authority.

Rapid HIV Test Approval/Waiver ***Addendum E***

Dr. Elliott Cowan, Senior Regulatory Scientist, CBER, Office of Blood Research and Review, FDA, presented an overview of the OraSure OraQuick® Rapid HIV-1 Antibody Test recently approved by

FDA. He explained the initial November 2002 premarket approval was as a CLIA moderate complexity test and included some restrictions on its sale, distribution, and use. He reviewed the test's intended use, restrictions, step-by-step instructions and its clinical trial data. In January, following OraSure's submission of additional data, FDA granted the test a CLIA waiver. Dr. Cowan emphasized that sales and intended use restrictions remain unchanged for the waived test, and quality assurance program recommendations are under development by CDC.

Committee Discussion follows CDC Update

■ Centers for Disease Control and Prevention (CDC) Update

Rapid HIV Testing ***Addendum F***

Dr. Thomas Hearn, Deputy Director, DLS, PHPPO, CDC, presented an update on CDC's Rapid HIV testing activities. He stressed the CDC activities are a collaborative effort with public and private health partners to respond to the changes in the HIV epidemic and testing technology. Activities include advising the confirmation of all reactive OraQuick® Rapid HIV-1 Antibody Test results using either a Western Blot (WB) or Indirect Immunoflourescence Assay (IFA); drafting quality assurance guidance; and developing training and educational materials.

Committee Discussion (CDC and FDA Updates)

- A few members asked if the OraQuick® Rapid HIV-1 Antibody Test is capable of withstanding environmental stresses, such as temperature extremes and improper storage conditions. Dr. Hearn indicated the test's use in Africa has demonstrated that the reagents are quite stable, and the use of external controls helps to detect any deterioration. Dr. Cowan added that temperature limitations are listed in the package insert and the user has the responsibility to follow the package insert instructions. Also, the procedural controls should indicate whether the device is functioning properly.
- One member asked about false positive results and how Western Blot indeterminate sera would perform with this test. Dr. Cowan responded it would be unrealistic to expect no false positives, but added, the sensitivity and specificity of the test is excellent.
- Members asked if fingerstick samples and specimens from different age groups, specifically neonatal specimens, were included in the validation studies; and if future studies would include assessment of test performance in the field. Dr. Cowan responded the validation studies did not include neonatal specimens and that the package insert's limitation section states that test performance has not been demonstrated in persons under 13 years of age. He explained that fingerstick samples were not included in the validation study and that the studies were similar to other waived test studies. He also remarked that FDA would closely monitor test performance in the field, taking action if it does not correlate with the test specifications established in the clinical trials.
- One member asked why the test may not be used for blood and tissue donor screening. Dr. Cowan responded that appropriate studies have not been done to support its use in donor testing.
- A number of Committee members sought further clarification on the waived product's use and sales restrictions and reassurance that the restrictions prevent self-testing. They also asked for a

clearer definition of who can purchase the product and who has the legal responsibility for misuse of the test. Dr. Cowan and Dr. Hearn emphasized this is the first waived test to have restrictions and the purchaser of the test kit must be aware of, and comply with, all of these restrictions. Dr. Cowan stressed the sales restriction limited its purchase to a clinical laboratory and/or an agent of a clinical laboratory. He further emphasized the purchaser assumes responsibility for proper use of the product and adherence to all test performance requirements. He indicated that legal responsibility for test misuse is an interpretation of law and would require review by legal counsel.

- Several CLIAC members commented on the importance of having a quality assurance protocol and wondered how compliance can be assured at non-traditional testing sites performing waived tests. They also questioned the lack of follow-up on the false negative test results in the clinical trials, voicing concern about the sensitivity and specificity in the clinical trail data given the prevalence of the disease in the U.S. population and the projected number of rapid HIV tests to be performed annually. Based on this projection, one member estimated the statistical probability of false negative test results and asked if this number was an acceptable "minimal" risk to the public. Dr. Hearn acknowledged that the CDC collaborative workgroup developing the quality assurance guidance has had similar concerns and is examining all options to identify laboratory practices to assure quality testing and minimize risk of harm. He encouraged CLIAC members to watch the CDC satellite broadcast April 24, 2003, 1:00 – 3:00 PM (EDT) addressing quality assurance issues in rapid HIV testing.
- Dr. Merlin reassured the Committee that its opinions and concerns about the waived rapid HIV test have been heard. In closing, Dr. Merlin stressed that HHS will continue to strive to ensure HIV testing is safe, effective, timely and responsive to the needs of patients and public health.

Quality Institute Conference 2003

Dr. Joe Boone, DLS, PHPPO, CDC reminded the Committee that the Quality Institute Conference will be held April 13-15, 2003, in Atlanta, Georgia. He provided an agenda, encouraged CLIAC members and visitors to attend, and reviewed plans for the conference He described the conference's focus of making the laboratory a key partner in patient safety and the plans to seek participation of healthcare partners in an interactive workgroup setting. The workgroups will help to identify the laboratory's "fit" in the healthcare delivery system, how errors can be reduced, and how the quality of patient care can be improved as a result.

CytoView II™ Demonstration ***Addendum G***

Ms. Maribeth Gagnon, DLS, PHPPO, CDC, updated CLIAC on CytoView II™, a DLS-developed computer-based cytology proficiency testing (PT) program. She reported the CDC and Maryland study comparing cytology computer-based proficiency testing with glass-slide proficiency testing has been completed, the data analyzed, and publication of the study results is forthcoming. She explained that improvements in the CytoView II™ version software have increased its similarity to a glass-slide format and provided additional flexibility and access through laptop delivery. She then demonstrated several test menus, pointing out such features as microscopic simulation and bookmarking. Ms. Gagnon encouraged the Committee to view the CytoView II™ demonstrations available to the general public on the DLS website at http://www.phppo.cdc.gov/cyto/CytoView_Demo.asp

Committee Discussion

- CLIAC members congratulated CDC on its 10-year perserverance and diligence in developing the concepts and improving the technology to make computer-based cytology PT possible. They encouraged expanding computer-based PT to all applicable areas of laboratory microscopy and developing it as a web-based tool.
- Ms Gagnon agreed that there is a myriad of potential applications for the technology. She discussed CDC's efforts to find partners interested in expanding its use and further developing the technology.
- One member voiced some concern about the differences between "video" cytology and "real" cytology fields of view, indicating that simulating the microscope itself would be very helpful. Another member asked if the hardware requirements would limit program use and availability.
- Ms. Gagnon described the hardware requirements as "off the shelf" technology and not a factor that would limit the use of the computer-based program. She agreed that having a virtual slide program to include microscope simulation would be ideal, but technology is not available to accomplish this.
- Several members asked about the study's results and how performance on the glass-slide PT compared with performance on the computer-based PT. Ms. Gagnon responded the data indicates some correlation between the two PT methods, and reminded the Committee that all of the study's results will be published in a peer-reviewed journal.

Bioterrorism Activities *Addendum H*

Laboratory Response Network - Response to a Bioterrorism Event

Dr. Mike Miller, Chief, Laboratory Response Branch, Bioterrorism Preparedness and Response Program, National Center for Infectious Diseases, CDC, described the Laboratory Response Network's (LRN) vision to establish an integrated multi-level laboratory network to provide rapid and critical laboratory capacity for response to bioterrorism (BT), emerging infectious diseases, and other public health threats and emergencies. He reviewed the LRN partners and collaborative efforts to build this capacity and outlined the Network's membership structure. The role of the Sentinel Laboratories (formerly Level A) is to recognize, rule-out, and refer suspected organisms; the role of the Reference Laboratories (formerly Level B and C) is to perform confirmatory testing; and the role of the National Laboratories (CDC and USAMRIID) is definitive characterization. He emphasized that one of CDC's roles in ensuring response capacity is to collaboratively work to improve the public health infrastructure. CDC provides each LRN laboratory agent-specific protocols; standardized reagents and controls; proficiency testing; a laboratory referral directory; secure communications systems; training and technology; and appropriate vaccinations for laboratory workers. He concluded with a summary of LRN future goals, emphasizing the ultimate goal of a fully integrated response network, both nationally and internationally.

Committee Discussion

- CLIAC was impressed with the evolving laboratory response network and the collaborative effort of the current LRN membership and partners in enhancing the capacity of the public health laboratories. One member asked about the capacity of Level B and C laboratories to screen for all possible BT agents. Dr. Miller answered that the development of reagents and BT agent panels by CDC will allow reference laboratories (formerly Level B and C laboratories) to have broad confirmatory capabilities. It is only the more exotic agents that require referral to CDC and USAMRID laboratories for confirmation.

PRESENTATIONS AND COMMITTEE DISCUSSIONS

■ Direct Access Testing - Overview *Addendum I*

Dr. Toby Merlin began his overview by defining direct access testing (DAT) as testing the consumer self-orders, pays for out-of-pocket, and is largely responsible for interpreting and, as necessary, following up. He noted, it is not patients requesting the testing for medical care, but consumers, who are self-ordering tests and their test purchases are made without physician consultation. Dr. Merlin continued, media reports on DAT focus on consumer/patient empowerment with no physician or insurance company intervention, and factors such as convenience, cost savings, and privacy are reasons for the popularity of these services. For example, DAT offers the advantage of anonymous HIV and drug testing. This is an important consideration for consumers who do not want an insurance company, employer, or the family physician to know they have been tested or to have access to their results.

Dr, Merlin pointed out that DAT represents a major paradigm shift in healthcare, moving from a physician focus to a consumer focus. Approximately 10-15% of hospital and commercial laboratories currently offer direct access testing and market their services primarily to the "worried well" and the "well-heeled." While some laboratories restrict this service to a limited testing menu, others have no restrictions and offer a wide range of tests to the consumer, including genetic tests. The majority of self-orders are for screening tests and wellness profiles.

Dr. Merlin concluded by asking CLIAC to defer its discussion on DAT until all of the invited speakers, representing various perspectives, have completed their presentations.

■ DAT- Impact of CLIA *Addendum J*

Ms. Rhonda Whalen, Chief, Laboratory Practice Standards Branch, DLS, PHPPO, CDC, reviewed relevant sections of the CLIA regulations and discussed their application to laboratories offering DAT. Simply, all CLIA requirements that apply to nonwaived testing also apply to nonwaived testing offered directly to consumers. She explained that CLIA defers to state law regarding who may order tests and/or receive test results. In other words, if a state allows DAT, so does CLIA. Currently, thirty-two states permit some form of direct-to-consumer testing. A few states have no DAT requirements, thereby permitting DAT. Eighteen states prohibit DAT, but enforcement can be challenging. As an example, Ms. Whalen noted that while Georgia prohibits DAT, some laboratories still advertise this service. They by-pass the state law by having a physician on-staff who will order any laboratory test the consumer selects. Ms. Whalen concluded her presentation by asking the Committee to consider in its discussion: the appropriateness of the CLIA requirements regarding DAT; alternatives to regulations, such as guidelines; and other potential options or approaches for assuring safe and appropriate DAT. In this regard, she directed the members to their notebooks for a copy of a Federal Trade Commission (FTC) presentation to the Secretary's Advisory Committee on Genetic Testing, which reviewed FTC's jurisdiction and oversight relative to advertising. **(Addendum K)**

■ DAT- A Physician's Perspective *Addendum L*

Dr. Verlin Janzen, a physician in private practice and laboratory director, presented a physician's perspective on direct access testing. He first noted that the professional physician organizations have yet to take an official stance on direct access testing; their attention has been focused on other issues, such as the Health Insurance Portability and Accountability Act (HIPAA). Dr. Janzen proceeded to summarize results of an informal on-line survey he conducted using the American Association of Family Practitioners' State Officer Listserv. Of the 18 physician respondents, approximately half, while aware of DAT, were neutral on the topic, commenting that it (DAT) was going to happen anyway. However, several of the physicians said they would repeat any test obtained through DAT before initiating treatment.

Although media reports describe today's consumers as more informed, capable, and responsible, Dr. Janzen questioned whether this is true with regard to laboratory test results. He expressed concern about a consumer's ability to reliably interpret test results and make decisions for self-treatment, citing examples of the complex treatment guidelines currently used by physicians for conditions such as hypercholesterolemia and diabetes. While he acknowledged that most consumers support DAT because of convenience, access, rapid turn-around times, and anonymity, he questioned whether DAT would result in unnecessary medical procedures and noted insurers typically do not pay for consumer-ordered testing. Other concerns include the ultimate cost of unnecessary testing and frequent re-testing by the worried well; delayed diagnosis due to false negative results or ordering the wrong test; and the consumer's ability to handle "bad news" results without the immediate consultation traditionally provided by a physician. Dr. Janzen mentioned the potential misuse of this service for drugs of abuse testing and asked the Committee to consider whether it is appropriate for people to manipulate the system by having these tests performed prior to pre-employment testing to make sure they will "pass." On the other hand, he also pointed out the benefits of DAT, such as its potential role in early disease detection; its convenience to travelers or "snow-birds" needing monitoring tests such as prothrombin levels; and the anonymity DAT offers. In closing, Dr. Janzen recommended the following: DAT should be restricted to a limited menu of tests, such as those available "over-the-counter"; DAT advertising should be restricted or limited because advertising can create a market for unnecessary testing and fad tests; reimbursement should be limited to those tests that are medically necessary; because of liability concerns, DAT results should not be sent to physicians; laboratories performing DAT should be responsible for providing pre- and post-test counseling; and anonymous vs. confidential test results need to be addressed.

■ DAT- A Laboratory's Perspective *Addendum M*

Mr. Hughes Bakewell, Vice President of Consumer Testing, Quest Diagnostics, informed the Committee that direct access testing is a misnomer when applied to Quest. DAT implies that the consumer always orders the test but, at Quest, a physician is the one who does the ordering. He noted that consumerism is the driving force for the growing trend in DAT; consumers want control, they are increasingly better educated, and they have access to health information through the Internet. Also, many consumers prefer DAT to self-testing because they don't like sticking their own fingers or they don't trust home-use testing

kits.
Mr. Bakewell reviewed the mandatory building blocks a business should consider when planning to offer DAT. He stressed the importance of legal counsel, consumer-friendly reports; customer service; health department reporting protocols; consumer-payment collection systems; and patience. The Quest philosophy is to offer only a limited DAT menu because some tests are inappropriate for self-ordering. In addition, Quest uses independent physicians to review test requests, authorize the release of results, and contact consumers/clients with critical values, encouraging them to seek a physician's care. Quest does not diagnose or treat disease.
Mr. Bakewell reviewed Quest's marketing strategy, industry reactions, and the typical purchaser profile. He noted physician reaction to this service has been minimal. Their main issues have been that consumers may want free telephone consults after receiving results; consumers may not be capable of interpreting results; the physician may be by-passed in the patient's healthcare; the consequences of false positive and false negative results; and that consumers won't proactively address health issues. Physicians also do not want to receive test results on an individual they have not seen because of potential liability.
Mr. Bakewell shared what is anticipated to be the future drivers for direct access testing. One of these factors relates to the significant penetration of consumer-driven healthcare plans. Consumers will undoubtedly be careful with the limited "bucket of money" their plans will allow and they will attempt to use it cost-effectively. These consumers will drive changes in healthcare as they look for quality, cost (value), and aspects of healthcare that are not needed. They will thoughtfully consider whether a physician office visit is warranted. Other factors will be the increased pharmaceutical marketing shift from patient/doctor relationships to the consumer and focused efforts by major retailers to develop screening/wellness services. In addition, the availability of actionable gene-based testing will increase the demand for anonymity, particularly if a consumer has a family history of certain diseases. Finally, consumers will insist on these services as their access to information and awareness of the benefits of screening tests increases.

- **DAT- A Consumer Group's Perspective** ***Addendum N***

Mr. Charles Inlander, President of the People's Medical Society, a medical consumer advocacy organization, noted that DAT is not a new phenomenon, but is becoming more commercial in response to consumer demand. He described today's healthcare consumer as empowered, educated, demanding, critical of the healthcare system and providers, and the driving force for changes in healthcare. He added, consumers view healthcare as a service and expect high clinical and ethical standards for this service. They expect clinical competence, fair pricing, sound business practices, and timely communication. They want greater access to services and higher quality care. They are angry at being treated as 'medical idiots' and are no longer willing to tolerate the parent/child provider-consumer relationship.
Mr. Inlander explained that 34 states currently allow DAT and primary care physicians tend to support it. He discussed the advantages, such as direct access to needed services; reduced costs as a result of eliminating the "middle man"; ability to monitor one's own health; and empowerment of consumers to take charge of their own health. He also discussed the disadvantages, such as potential loss of control by physicians over patient management; inability of consumers to interpret test results; potential for

unscrupulous laboratories to take advantage of consumers; the tendency of hypochondriacs to inappropriately use the service; and increase in test costs as the demand for DAT increases. However, he continued, the advantages outweigh the disadvantages, and the disadvantages can be addressed through education, oversight, regulation, and enforcement. Mr. Inlander concluded his presentation with a discussion of issues that will need to be addressed: insurance coverage; state variation on access and oversight; expansion of direct access testing; limitations on the number of tests that can be ordered in a given year; ownership of results; and resistance from other providers.

Committee Discussion

Dr. Merlin suggested the Committee frame its discussion around the following questions: What advice, if any, should CLIAC provide the Secretary relative to DAT; how intrusive should government be in this issue; and how or where should government intervene?

- One member iterated that consumers are proactively seeking information and paying out-of- pocket for this service, suggesting a systems failure in our healthcare delivery system if consumers feel this service is needed. This member pointed out CLIAC may not have enough breadth to address this issue, and recommended that CDC work collaboratively with other agencies that may have some oversight authority relative to DAT.
- One member asked Mr. Bakewell how physicians from his organization can address the appropriateness of test requests when consumers are ordering tests at a remote site. Mr. Bakewell replied that Quest's test menu is limited to tests Quest believes are appropriate to offer consumers, and noted that some consumer-ordered test requests are questioned and occasionally denied. He gave an example of a 25-year-old male requesting a prostate-specific antigen test. This was questioned by the Quest physician, who contacted the individual and found out there was a family history of prostate cancer. Based on this additional information, the test was performed.
- Relative to the issue of anonymity vs. confidentiality of test results as a driver for DAT, Dr. Janzen noted that CLIAC should also consider the ethical consequences of offering DAT for infectious diseases for which positive results must be reported to the state health department. For example, if an individual's HIV test result is positive, is there an ethical responsibility to notify a spouse? The Committee acknowledged that there may be many unintended consequences and ethical issues surrounding DAT and again questioned whether CLIAC was an appropriate forum for addressing them.
- The public health impact of offering certain tests through DAT, such as genetic testing, was discussed. One member, noting that results for these tests require complex interpretation, expressed concern about offering these tests directly to the public with insufficient interpretation and bypassing physicians and genetic counselors. He warned that laboratories offering these tests might be liable for the consequences.
- Members noted that a common advertising practice is to use fear, and in this case, fear of adverse health conditions. This tactic often stimulates inappropriate test requests by consumers.
- A brief discussion centered on how to design a safety net to protect the majority of people using DAT, and whether some of the concerns could be resolved by requiring laboratories to provide mandatory disclosure at the time of service purchase. Members surmised that disclosures may only offer a partial solution because most people don't read them. One member noted that laws exist for advertising and truth in labeling, but many laboratories planning to offer DAT may not know about them. He questioned whether laws should be enacted that only allow evidence- or science-based

tests to be offered through DAT. Dr. Janzen commented that a worthless test done well is no better than a good test done poorly.

- Some members questioned whether laboratories would provide, when necessary, pre-test and post-test counseling, since there may not be a physician to do it. Many members stated that laboratories offering these tests through DAT should also provide the counseling.
- Members also discussed how DAT laboratories should handle abnormal results. One member disagreed with a suggestion that abnormal results be sent to a primary care physician. He noted that our country has a shortage of primary care physicians and they should not be burdened with receiving abnormal results on individuals they have not seen. Another member proposed there may be other contingencies to consider, such as having the laboratory's pathologist talk to the consumer. Ms. Whalen reminded the Committee that CLIA does require the laboratory to ensure that consultation is available to its clients on matters related to the quality of the test results and their interpretation concerning specific patient conditions.
- One member suggested that the role of CLIAC is to discern whether DAT is a laboratory quality issue. There are many questions to be answered, such as who can order a test for an individual; whether positive results for notifiable diseases should be reported to public health departments; whether a parent has the right to order a test on a child; whether a child can order a test; and at what age one can order a test. Another Committee member replied that state laws regarding children vary, and gave an example of one state that limits DAT testing on children to those tests in which the specimen source does not require "the breaking of skin." Mr. Bakewell stated that Quest does report positive results for notifiable diseases to the state public health department.
- Dr. Sturman, CLIAC member and Director, Wadsworth Center, New York State Department of Health, informed the Committee that New York (NY) introduced new legislation pertaining to DAT. This legislation allows the clinical laboratory to provide a service (testing) for which it is licensed to perform at the request of the person on whom the service will be performed. The test results must be reported in writing and only to the person requesting the testing. While regulations that will govern DAT are still to be promulgated, guidance has been drafted that specifies that the DAT testing menu must be limited to those analytes for which a FDA-approved test kit or collection device is available over-the-counter without a prescription. However, laboratories are not required to accept test requests from consumers; they may refuse a request from an individual they judge not competent to order the test. Dr. Sturman explained that the testing in NY is not anonymous; the consumer must provide identification. In addition, there are special requirements for HIV testing regarding confirmation, confidentiality, and reporting.
- Some members expressed that they did not agree with developing additional regulations to address the DAT, but rather efforts should focus on enforcing the applicable regulations already in place; one example being CLIA, which requires all facilities that perform testing on human specimens to be certified.
- The Committee acknowledged that the DAT market will grow and several members feel it must be legitimized. Consumers must be able to obtain a test result, know that it is legitimate, and be able to share it with their healthcare provider. Giving legitimacy to DAT could potentially aid in filling the gap of healthcare access and cost to the uninsured.
- Mr. Inlander commented that DAT issues will ultimately end up in the political arena and CLIAC should be prepared to give advice. He suggested CLIAC bring all interested parties together to collaborate and resolve DAT issues.

- Dr. Martin suggested that mechanisms are needed to gather data and obtain input from other agencies and groups. He asked the Committee to consider the role of industry and consumers in collecting information, adding industry could be a major contributor by providing tracking studies.
- One member urged that this topic remain a priority for CLIAC and noted the importance for developing guidelines for the changes that are taking place in healthcare. Members agreed that an important role for CLIAC in this issue will be in public education.

PUBLIC COMMENTS

Dr. Jared N. Schwartz, College of American Pathologists (CAP) ***Addendum O***

Ms. Robin Strombler, Vice President, Government Affairs, American Society of Clinical Pathology (ASCP) ***Addendum P***

Ms. Elissa Passiment, Executive Vice President, American Society for Clinical Laboratory Science (ASCLS) ***Addendum Q***

Dr. George B. Vaughan, President and Chief Executive Officer, HealthcheckUSA ***Addendum R***

SPECIAL PRESENTATIONS

- Dr. Toby Merlin and Dr. Tom Hearn presented certificates and plaques to departing CLIAC members, Dr. George Birdsong, Dr. Brenta Davis, Dr. Joe Campos, Dr. Timothy O'Leary, and Dr. Larry Silverman, in appreciation of their contributions to the Committee.
- Dr. Edward Baker presented a plaque to Dr. Toby Merlin in gratitude for his contribution to public health and leadership as CLIAC chair.
- Dr. Toby Merlin presented a plaque to Dr. Edward Baker acknowledging his leadership as Executive Secretary of CLIAC.
- Dr. Robert Martin presented a plaque to Ms. Rhonda Whalen in recognition of her 30 years of government service, indicating that a majority of her service has been with the CLIA program.

ADJOURN

Dr. Merlin adjourned the Committee. The next CLIAC meeting is scheduled for September 17-18, 2003.

I certify that this summary report of the March 12-13, 2003, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

/s/ Toby Merlin, M.D., CLIAC Chair Date: June 16, 2003