Volume X, Number 8 Monday, June 16, 2003

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

Transition Issues Breed Turmoil in Many AP Groups

PATHOLOGY GROUP PRACTICES ACROSS THE COUNTRY have yet to solve a major problem: in private practice settings, what is the right mix of compensation and equity for individual pathologists?

The question strikes to the nub of retirement expectations. During their professional careers, can pathologists build the value of their group practice so that, at retirement time, shareholder-pathologists have an equity share substantial enough to provide a comfortable retirement? To accomplish this, the business structure of the group practice must be managed so that it has value as an established business—value that potential buyers recognize and for which they will pay.

The lack of effective strategic business planning on this point was made painfully clear during the past five or six years. As the handful of pioneering pathology physician practice management companies (PPM) criss-crossed the country offering to buy pathology group practices, a rancorous debate emerged. In groups with both younger pathologists and pathologists nearing retirement, the older pathologists were motivated to accept a rich offer from a PPM, bank the sales proceeds, then work the few years remaining before retirement. At the same time, younger pathologists, with many career years remaining, felt sold down the river if they were outvoted by the near-retirement set.

In my opinion, pathologists have done themselves a disservice by failing to spend more time on two strategic issues. First, gaining agreement among partners as to whether the pathology group practice exists either: 1) to provide a vehicle to earn income; or 2) as a business which, even as it pays income to its pathologists, is building value as a business—value which a buyer will recognize by paying a fair price if the practice were to be sold. Second, once the first strategic decision is made, the second issue is how to recognize the contributions of shareholder-pathologists. How do new shareholders buy in? How does the group practice provide a mechanism for departing shareholders to cash out?

To help pathologists and their group practice administrators better understand these questions and their solutions, THE DARK REPORT, in conjunction with **Haverford Health Advisors**, is scheduling a two-day program on pathology transition topics. It will be held October 24-25, 2003 at the Hyatt Regency Hotel in Atlanta, Georgia. We'd welcome your suggestions, in advance, for topics that would interest you. TDR

Med Tech Training Via Long-Distance Programs

More lab managers consider distance training to be one viable response to the MT shortage

CEO SUMMARY: Students from as far away as Oregon and Hawaii are using the online distance training program at the Medical College of Georgia, located in Augusta, to get their Bachelor of Science degree and medical technologist certification. Because many regions do not have a local MT training program, labs are demonstrating growing interest and support for online long distance learning.

By June G. Smart, Ph.D.

ONLINE DISTANCE LEARNING (ODL) of medical technologists (MT) is still a whisper, but it could soon become the roaring voice to help resolve the growing shortage of medical technologists.

Because of the recognized national shortage of trained medical technologists (MT) and medical laboratory technicians (MLT), laboratories across the United States are taking steps to recruit people into the field and train them. However, one roadblock is the fact that few cities have active medical technologist training programs close enough to support their laboratories. One solution to this quandary is for local laboratories to affiliate with a med tech training program that incorporates long distance education.

Long distance training does work. For ten years, a med tech distance learning program at the **Medical College of Georgia** (MCG), in Augusta, has attracted students from throughout Georgia and as far away as Oregon and Hawaii. Whether students attend classes on-campus or via the Internet, they follow the same curriculum and share the goal of earning a bachelor's degree in medical technology.

MCG started a distance learning program in 1993 that allowed Medical Laboratory Technicians (MLT) to complete the Bachelor of Science in Medical Technology via multipoint videoconferencing. In 1999, the then-new Chairman of the Medical

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 778669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

Technology Department, Elizabeth Kenimer-Leibach, Ed.D., recognized that the Internet was mature enough to allow the program to teach a broader audience, one that had no previous clinical laboratory background. "We expanded to serve individuals with bachelor degrees in life sciences or those otherwise meeting core and science prerequisite requirements," she said. "A grant from the Intellectual Capital Partnership Program (ICAPP) of the Office of Economic Development at the **University System of Georgia** provided the funds for this expansion.

"This grants program is intended to foster partnerships between business and academia," commented Kenimer-Leibach. "The grant application was structured to include medical technology as a part of biotechnology. It's opened up a new field of academic partnerships in healthcare.

"ICAPP grant money allowed us to substantially improve our distance learning resources," she added. "We acquired the Tegrity System. This will allow us to digitally tape lecturers, zoom in on PowerPoint slides or demonstrations, and create multiple windows on the computer screen.

24/7 Access To Lectures

"This system allows the Internet student to be part of the on-campus class," continued Kenimer-Leibach. "They hear the questions and see other students. It can be real-time for them. However, if their schedule does not permit real-time, they can download the lecture from our server or watch streaming video on a 24/7 basis."

The online distance learning succeeds in med tech training because of close cooperation between participating hospital laboratories and the University. Since the inception of distance learning at MCG, some 50 students have completed degrees facilitated by either the GSAMS (Georgia Scientific and Academic Medical Systems, a statewide multipoint videoconferencing network) or, beginning in 1999, the Internet. For the fall term, 20 Internet students are expected to begin studies, with graduation scheduled for August 2005.

"Enrollment for the MT online distance learning program shows the power of the Internet," observed Kenimer-Leibach. "Students projected to begin in Fall 2003 are from Oregon, Hawaii, and Georgia. Students from Arkansas, Illinois, North Carolina, South Carolina, and Washington are in various stages of completing core and prerequisite requirements."

All Types Of Laboratories

"They represent small hospitals, military hospitals, and national reference labs such as **Quest Diagnostics Incorporated**," said Kenimer-Leibach. "When a student is accepted, they must be associated with a laboratory that will abide by the standards for MT certification set by NAACLS (**National Accrediting Agency for Clinical Laboratory Sciences**, the body that accredits programs of medical technology). To insure that the student will be successful, we visit the laboratory to verify that required standards are in place and mentoring support is available."

Time zones and location are not a problem. Students can download class materials at any time and communicate with their professors via e-mail. "Several students have family or other job commitments that prevent them from real-time participation in the lectures," explained Kenimer-Leibach. "They develop excellent time management skills and their dedication is obvious. Our distance learning students send us e-mails late in the evening and into the early hours of the morning."

Until recently, all students accepted into the distance learning program had an MLT background. "We've expanded that now to accept students with B.S. degrees in life science—such as chemistry, biology, microbiology," she noted. "We also accept 'traditional' students who have finished core and science prerequisites and want the BSMT degree.

"Unlike MLTs, these students need basic clinical lab skills," she added. "Prior to the traditional internship experience, they need additional training in basic laboratory techniques to experience the psychomotor side of medical technology. To facilitate this training in the clinical sites, we have developed extensive 'train-the-trainer' materials, complete with detailed instructor's manuals.

"We have large numbers of these 'non-MLT' students in the Atlanta area," Kenimer-Leibach explained, "They can go to the nearby **Gwinnette University Center**, a University System of Georgia facility. Here they learn basic skills prior to the traditional internship experience.

Hands-On Lab Training

"MCG faculty travel to Gwinnette to teach this cohort group," she noted. "Then students return to their clinical partners in the Atlanta area for their traditional internship experience. Their didactic training continues on the Internet concurrent with their laboratory training. Since most Internet students don't have a local cohort group, their basic laboratory skills training is handled at the affiliated clinical site."

Some regional divisions of the national laboratories want to use online distance learning to ease their shortage of MTs. Kenimer-Leibach recently started working with the **Quest Diagnostics Incorporated** lab

How Lab ODL Training Started in Georgia

"OUR LONG DISTANCE LEARNING PROGRAM sprang from an effort to support education in rural areas," stated Elizabeth Kenimer-Leibach, Ed.D., Chairman and Associate Professor at the Department of Medical Technology at MCG. "Back in 1993, Julia Crowley, Ph.D., then Chairman of the Department of Medical Technology at MCG, was awarded a federal grant to develop long distance education for rural areas.

"This grant allowed us to begin the first distance learning program delivered via the Georgia Scientific and Academic Medical System (GSAMS), a multipoint videoconferencing system," she continued. "GSAMS sites are located in academic institutions, libraries and hospitals across Georgia. We delivered live lectures, transmitted via a T-1 phone line, to two of these locations.

"Our GSAMS program was structured to allow medical laboratory technicians (MLTs) to reach the medical technologist (MT) level in two years as part-time students, without ever coming to campus," noted Kenimer-Leibach. "As new students, MLTs were given junior-level university experiential credit. Along with the two-year core requirements, they were able to graduate with a Bachelor of Science degree in Medical Technology while maintaining full-time employment.

"Obviously, because of the distance, our faculty could not teach psychomotor skills through Internet didactic training. This was accomplished by forming clinical partnerships with hospitals," she explained. "Lab managers were eager to become part of the program, because even in 1993 there was an MT shortage in Georgia. They were willing to accept a student if the student worked at the hospital.

"It was a win-win solution for all parties," she said. "That's because 90% of the students stayed at the hospital where they trained for at least two years. During the next six years, we graduated three classes of students who never studied on the MCG campus."

oratory in Atlanta. "Quest hires lab assistants with a B.S. science background, and plans to pay their tuition as they go through our ODL MT program," she commented. "Quest will 'grow their own MTs' through online distance learning."

Kenimer-Leibach also works with hospital human resource (HR) departments. "HR departments contact me when they have science graduates seeking lab employment and the applicant is willing to pursue certification," she stated. "We send the graduate our MT program materials and help them find a clinical partner so they can become either a 'campus' or an 'Internet' student."

Reduction In Tuition

Although education is an investment in the future, Kenimer-Leibach recognizes that the Internet program must be cost effective for Internet students. "We hope to have an out-of-state waiver for Internet students outside Georgia by the fall. Tuition costs will be somewhere between out-of-state and in-state costs," she said. "For Fall 2003 tuition, in-state and out-of-state students, are charged $1 and $535 per semester hour, respectively. However, ODL is cost-effective for us because we can train more students with the same number of faculty."

How did students from as far away as Oregon and Hawaii get involved in a Georgia MT training program? "People find us through our Web site," answered Kenimer- Leibach. "Because of the MT shortage, lab managers are looking for ways to help fill open positions. At the same time, MLTs and science graduates are looking to advance their education. We are 'education brokers' for future MTs and the Internet allows people to find us.

"For example, recently a student in Hawaii located us on the Web," she continued. "She suggested **Tripler Hospital**, a military hospital in Honolulu, as her clinical partner. We accepted her into the ODL program and will document the NAACL requirements at Tripler Hospital for the fall."

Kenimer-Leibach has advice for lab managers looking to place staff members in the MT ODL program. "It is important for lab managers to recognize how important it is for their students to get professional support within the lab," she observed. "On-site support by participating lab managers is fundamental to students' success. Students need mentors and professional role models to provide guidance and motivation.

"That leads me to another point. Participating lab managers should be sensitive to a student's exposure to those MTs in the local lab who grumble about their profession, but don't take positive steps to improve the situation," she noted. "These co-workers can have a negative influence on new students, who are generally enthusiastic about their new career choice. That is why it is important for lab managers to involve the laboratory staff in helping the student succeed. Since most students accept jobs where they train, lab managers should view students as new employees, since after training, there will be no need for orientation or recruitment costs."

Rich Source Of Knowledge

Kenimer-Leibach also remarked on another aspect of human nature that sometimes affects the online distance learning process. "At first, some lab managers were apprehensive about our program. They thought students might put them on the spot with their newfound knowledge," she noted. "However, we've found it to be just the opposite. Students view lab managers as a rich source of knowledge which complements class learning.

"We've also seen another benefit. Often the student's enthusiasm and natural curiosity turns infectious in the laboratory. Other staff members become motivated to undertake their own continuing education," observed Kenimer-Leibach.

"As a result of this interest in continuing education, we plan to request P.A.C.E. credits for those involved in the clinical education of our students," she explained. "Along with other new programs in the laboratory field, we are actively developing a Master of Sciences program in Biomedical Technology. It focuses on molecular techniques with clinical applications. Like our undergraduate programs, it is Internet-based for 'portability'."

More MT Students

There might be national contracts with hospital chains and clinical reference labs on the horizon. Kenimer- Leibach is committed to bringing ODL to more students and clinical partners to aid in solving the MT shortage.

Because of family commitments and other reasons, some laboratory assistants, phlebotomists and others cannot go to a college campus to get their degree. ODL offers them a way to accomplish that. THE DARK REPORT sees ODL as a viable way to assist in reducing the MT shortage and expand the knowledge of the laboratory workforce. It is also another solution for the post-graduate training sorely needed in molecular diagnostics, genomics and other developing fields.

To find out more about the program go to: *www.mcg.edu/MedTech/-MLT-Homepage.htm*. Should your staff want to rate themselves as long distance learners, go to: *www.mcg.edu/-MedTech/rating.htm.* TDR

Contact Elizabeth Kenimer-Leibach, Ed.D. at: 706-721-3046 or ekenimer@mail.mcg.edu.

Internet Opportunities For Lab Learning

Here are examples of other schools that offer online distance learning programs in various aspects of clinical laboratory activities.

MLT Associate Degree

- **St. Petersburg College**
  St. Petersburg, Florida
  www.spcollege.edu/hec/medlab
- **Barton County Community College**
  Grand Bend, Kansas
  www.bartonccc.edu/mlt/default.htm

MT BS Degree

- **George Washington University**
  Washington, DC
  www.gwumc.edu/healthsci
- **University of Texas Medical Branch**
  Galveston, Texas
  http://sahs.utmb.edu/cls/
- **University of Kentucky**
  Lexington, Kentucky
  www.mc.uky.edu/cls/CLS_Undergraduate_Program/CLS_Undergrad_Prog.htm

Clinical Management & Leadership

- **George Washington University**
  Washington, DC
  www.gwumc.edu/healthsci

Graduate Specialty Areas

- **University of Texas Medical Branch**
  Galveston, Texas; Blood Bank Technology (SBB)
  www.utmb.edu/sbb
- **Michigan State University**
  East Lansing, MI; Molecular Laboratory Diagnostics Certificate Program
  http://online-contined.msu.edu/program.asp?program=9
- **Partnership: CLMA and University of Medicine and Dentistry of New Jersey**
  Certificate in Clinical Systems Management
  www.umdnj.edu

Master of Science

- **Partnership: CLMA and University of Medicine and Dentistry of New Jersey**
  Master of Science in Health Systems
  www.umdnj.edu

Doc "Bill-Back" Policy Rewritten at LabCorp

Implementation of revised policy is noticed by laboratory competitors

CEO SUMMARY: Laboratory compliance continues to evolve. In response to changes it sees in the lab marketplace, Laboratory Corporation of America instituted a fundamental change in its policy toward billing back physicians who fail to provide documentation necessary for the lab to successfully bill Medicare. It no longer "bills-back" client-physicians for "unbillable" tests.

DURING THE PAST YEAR, executives at **Laboratory Corporation of America** reviewed the company's national policy on physician bill-backs and instituted revisions.

LabCorp's long-standing policy was established in 1997, after Medicare implemented medical necessity documentation requirements for laboratory tests. If Medicare rejected payment in cases where the referring physician failed to provide either appropriate documentation, diagnosis codes to support the medical necessity of the ordered laboratory tests, or valid ABNs, LabCorp's policy has been to "bill-back" physician-clients with a penalty charge.

Revamped Policy In Place

Based on its evaluation of the current situation, LabCorp revamped this policy. Starting last fall, LabCorp began distributing a letter to physician clients that includes the following language: "I am pleased to inform you that LabCorp is revising its policy with respect to Medicare medical necessity denials. We have listened to your concerns regarding the bill-back policy and, effective November 1, 2002, we have decided to stop billing our clients for claims denied by Medicare due to inadequate documentation of medical necessity."

Changing Marketplace

"Essentially, LabCorp changed its bill-back policies to reflect the changed nature of today's clinical marketplace," said Bradford T. Smith, Executive Vice President at LabCorp. "As we analyzed all the factors, we realized there was no longer the need for a universal policy of billing back physicians. We believe this mirrors a growing laboratory industry consensus on bill-backs.

"First, overall physician compliance with Medicare medical necessity requirements is much better today than seven years ago," noted Smith. "Within our client base, there is a high rate of overall compliance in providing us the information needed to appropriately bill Medicare.

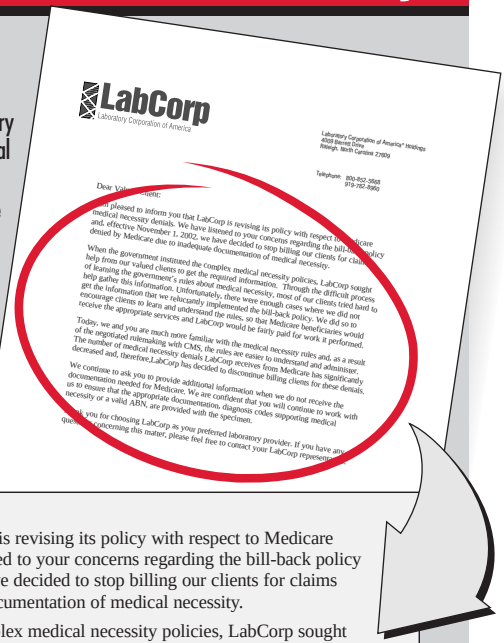
LabCorp Provides Notice to Physicians Of the Change in Its "Back Bill" Policy

LabCorp's Letter Informs Physicians about New Policy

At right is the letter to physician-clients from Laboratory Corporation of America which has surfaced in several regions of the United States in recent months.

The return address on these letters is usually the location of the LabCorp laboratory which provides direct support services to the physician receiving the letter. The letter at left originated in LabCorp's Raleigh, North Carolina lab facility.

Another interesting fact about this letter is that is lacks the signature of any LabCorp executive or manager. It is unusual for a laboratory company to announce this type of policy change using an unsigned letter on corporate stationary.


LabCorp
Laboratory Corporation of America

Laboratory Corporation of America® Holdings
4909 Barrett Drive
Raleigh, North Carolina 27609

Telephone: 800-762-5908
919-782-8989

Dear Valued Client:

I am pleased to inform you that LabCorp is revising its policy with respect to Medicare medical necessity denials. We have listened to your concerns regarding the bill-back policy and, effective November 1, 2002, we have decided to stop billing our clients for claims denied by Medicare due to inadequate documentation of medical necessity.

When the government instituted the complex medical necessity policies, LabCorp sought help from our valued clients to get the required information. Through the difficult process of learning the government's rules about medical necessity, most of our clients tried hard to help gather this information. Unfortunately, there were enough cases where we did not get the information that we reluctantly implemented the bill-back policy. We did so to encourage clients to learn and understand the rules, so that Medicare beneficiaries would receive the appropriate services and LabCorp would be fairly paid for work it performed.

Today, we and you are much more familiar with the medical necessity rules and, as a result of the negotiated rulemaking with CMS, the rules are easier to understand and administer. The number of medical necessity denials LabCorp receives from Medicare has significantly decreased and, therefore,LabCorp has decided to discontinue billing clients for these denials.

We continue to ask you to provide additional information when we do not receive the documentation needed for Medicare. We are confident that you will continue to work with us to ensure that the appropriate documentation, diagnosis codes supporting medical necessity or a valid ABN, are provided with the specimen.

Thank you for choosing LabCorp as your preferred laboratory provider. If you have any questions concerning this matter, please feel free to contact your LabCorp representative.

Dear Valued Client:

I am pleased to inform you that LabCorp is revising its policy with respect to Medicare medical necessity denials. We have listened to your concerns regarding the bill-back policy and, effective November 1, 2002, we have decided to stop billing our clients for claims denied by Medicare due to inadequate documentation of medical necessity.

When the government instituted the complex medical necessity policies, LabCorp sought help from our valued clients to get the required information. Through the difficult process of learning the government's rules about medical necessity, most of our clients tried hard to help gather this information. Unfortunately, there were enough cases where we did not get the information that we reluctantly implemented the bill-back policy. We did so to encourage clients to learn and understand the rules, so that Medicare beneficiaries would receive the appropriate services and LabCorp would be fairly paid for work it performed.

Today, we and you are much more familiar with the medical necessity rules and, as a result of the negotiated rulemaking with CMS, the rules are easier to understand and administer. The number of medical necessity denials LabCorp receives from Medicare has significantly decreased and, therefore,LabCorp has decided to discontinue billing clients for these denials.

We continue to ask you to provide additional information when we do not receive the documentation needed for Medicare. We are confident that you will continue to work with us to ensure that the appropriate documentation, diagnosis codes supporting medical necessity or a valid ABN, are provided with the specimen.

Thank you for choosing LabCorp as your preferred laboratory provider. If you have any questions concerning this matter, please feel free to contact your LabCorp representative.

"Second, in recent years, local medical associations in several states adopted positions opposing the practice of a laboratory billing back a physician if Medicare denied the lab's claim for payment based on lack of medical necessity documentation. Some medical associations have claimed this practice is illegal. In particular, medical associations in Texas, Florida, and Delaware have been vocal on this issue," he noted.

Medical Associations

"In some cases, the positions taken by these medical associations were not in compliance with Medicare requirements. As appropriate, LabCorp responded with accurate information. But the action of these medical associations reflects an important fact: their

physician-members consider bill-backs by laboratories to be an issue which needs attention.

"Third, we became aware that many laboratories had already recognized these realities," he added. "They had already adopted a bill-back policy which is similar to our revised policy.

"We learned about this first-hand during our acquisition discussions with laboratories," stated Smith. "As LabCorp bought clinical laboratory companies in recent years, we've had to review their compliance policies and implement our standards. Another source of knowledge is our review of laboratories offered to us for sale. Having looked at so many laboratories, we could see that our bill-back policy was out of step with the marketplace."

"...the action of these medical associations reflects an important fact: their physician-members consider billing back by laboratories to be an issue which needs attention."

Smith emphasized that LabCorp's switch in policy was carefully reviewed to insure that it is in compliance with applicable Medicare laws and regulations. "For those physicians who maintain high compliance, the revised policy allows LabCorp to reflect that experience," Smith added.

"Overall, about 8% of the Medicare patient test requisitions submitted to LabCorp lack at least some of the documentation required by medical necessity regulations," he said. "This is a very low rate of initial non-compliance, particularly when compared to the years immediately following the implementation of Medicare medical necessity requirements."

The revisions to LabCorp's national policy on billing back physician-clients did not go unnoticed by competing laboratories. In some instances, competing laboratories see LabCorp's change in policy as a more liberal interpretation of Medicare compliance requirements.

"Compliance Conundrum"

These concerns trigger a dynamic which THE DARK REPORT calls the "compliance conundrum." Simply put, labs with conservative, strict compliance policies believe they are at a disadvantage at retaining physician-clients and winning new accounts when compared to other laboratories in their city which may be operating with more liberal, looser compliance policies. *(See TDR, March 24, 2003.)*

Because many Medicare laws and regulations lack clarity and precision, providers, including clinical laboratories, are left to make their own decisions about what actions are compliant. Moreover, labs still struggle to achieve 100% physician cooperation in providing the information needed to properly bill Medicare for laboratory tests. Lacking unambiguous guidance from Medicare regulators, the spectrum of compliance approaches adopted by different laboratories does create competitive advantage in certain situations.

LabCorp's decision to revisit its original policy on billing back physician clients for Medicare tests which lack the necessary documentation is an example of how the marketplace changes. LabCorp's decision to change may be a sign that it is time for other laboratories to re-assess their own compliance policy on this issue. **TDR**

For further information, contact Brad Smith at 336-584-5171.

"Pay for Performance" Starts For Calif. Docs

Initiative links substantial incentives to clinical outcomes and other elements

CEO SUMMARY: California is a bellwether state for healthcare innovations. Six of its largest payers are collaborating on "Pay For Performance," a program which pays financial incentives to physician group practices which achieve measurable outcomes in clinical care, patient satisfaction, and implementation of information technology. It's expected to be a model for similar initiatives in other states.

By Kip Carpenter

FUNDED BY THE STATE'S largest health insurers, outcomes-based financial incentives are now a reality for physicians in California.

The program, called "Pay for Performance," is a statewide initiative designed to create a "business case for quality" at the physician group level. It is a collaborative initiative between six participating health plans—**Aetna**, **Blue Cross Blue Shield of California**, **CIGNA Healthcare**, **Health Net**, and **PacifiCare**. Payments from these payers will be made to physician groups based on each plan's individual bonus program.

Pathologists across the nation should pay close attention to "Pay For Performance." California is the nation's bellwether for bold initiatives in healthcare. If "Pay for Performance" leads to better healthcare outcomes and improves patient safety, then healthcare policymakers across the nation are likely to introduce similar bonus programs for physicians.

"This program was developed under the guidance of the **Integrated Healthcare Association** (IHA)," stated Beau Carter, IHA's Executive Director. "IHA is a statewide leadership group active in healthcare policy and managed care issues. In July 2002, it formed a task force of high-level executives from healthcare purchasers, health plan medical directors, and practice administrators and medical directors of physician group practices. The task force was chartered to develop a statewide incentive program under which physician groups could earn bonuses for documented performances.

2003 Is Program's First Year

"Based on the work of this task force, the 'Pay For Performance' incentive program was launched using calendar year 2003 as the first measurement year," commented Carter. " Financial incentives will not be paid to individual physicians, but to physician group practices which achieve performance levels in three areas of physician group activity: 1) clinical performance and quality; 2) patient satisfaction; and, 3)

California's Physicians React Warily To Concept of "Pay For Performance"

EARLY INDICATIONS ARE that physician group practices in California are taking one of three positions toward "Pay For Performance."

Position A: These are medical groups which demonstrate enthusiasm for the concept, stating "it's the right thing to do and we will strive to be 'best in class'."

Position B: Included are medical groups which remain wary of any promises made by payers, but are intrigued, observing, "Based on past experience, it's not wise to trust these health plans. But there might be real money here, so its best to tread carefully."

Position C: These are medical groups which simply don't accept the premises of "Pay for Performance" with the statement "This is a game our group does not want to play."

The Integrated Healthcare Association (IHA) believes that "Pay For Performance" will trigger significant changes in the way reimbursement flows from payers to providers. Some physician groups recognize that they can do a better job of improving the quality of care and patient services they provide. Over time, IHA's bet is the system will reinforce itself.

Each health plan will decide how much money it wants to put on the table for performance incentives, what thresholds will trigger payments, and whether it will write a check or increase capitation payments moving forward. The early impact of "Pay For Performance" will not be known until the first payments are made in 2004.

Questions involving laboratory testing have yet to be answered. The medical groups have access to laboratory test data, encounter data, and pharmacy data. Because medical groups are closest to the point of care, they have a motive to be data integrators. However, payers, claim they are the most efficient broker of information and want to position themselves to be the data integrator and provide measurement information to providers.

One interesting consequence of "Pay For Performance" is that it may stimulate competition for access to laboratory data and other clinical information in the short run, but encourage more collaboration in the long run.

the medical group's investment in information technology (IT).

"Clinical measures account for up to 50% of the total score," Carter continued. "For 2003, physician groups will be measured in treating the chronic conditions of asthma, diabetes, and coronary artery disease; and providing preventive services for breast cancer screening, cervical cancer screening, and childhood immunizations.

"The second domain is patient satisfaction, which accounts for 40% of the total score," noted Carter. "Individual patients' satisfaction will be evaluated in four ways: 1) communication with their doctor; 2) specialty care they received; 3) timely care and service, and, 4) an overall rating of care.

"The third domain involves information technology (IT) investment and will comprise about 10% of the total score. This measure evaluates a physician group's ability to integrate data at the group level and to provide physicians with data at the point of care," he explained.

"At least 300 medical groups are eligible to participate in 'Pay for Performance'," added Carter. "These groups represent about 35,000 physicians and provide medical services to

nearly 8 million enrollees in commercial HMOs and Point of Service (POS) health plans. Patients covered by Medicare+Choice or Medicare managed care plans will not be included in physician group measurements.

Group Gets The Money

Incentive payments under "Pay For Performance" will be made directly to the participating medical group practices. "We expect that some groups will pass this money on to individual physicians in the group," observed Carter. "However, IHA hopes that at least some of the money will be retained by the group and invested in information technology (IT) and care management items."

Based on measured performance during calendar 2003, plans are to issue first payments to physician groups by May/June 2004. During 2003, clinical measurements will be based on existing HEDIS specification, with modifications to reflect performance for the medical group.

"During year two, there are plans to tweak the measurement system as appropriate," Carter said. "Enhancements are expected. For example, hemoglobin A1c levels will be used in monitoring patients with diabetes. LDLC levels will be used to help measure treatment outcomes for patients who experience a cardiac event."

Initial Response Is Positive

Most California physicians practicing in medical groups which serve 50,000 or more patients are familiar with "Pay For Performance" and its objectives. " IHA did two direct mail campaigns to every physician group in California," stated Carter. "The general response was positive. That is encouraging, because so many aspects of California's managed healthcare system have been dysfunctional. As a result, physician groups have plenty of skepticism about payers and whether health plans will deliver on what they promise. So positive response to 'Pay For Performance' is an important sign that physicians are interested and supportive."

For laboratory managers and pathologists, the launch of "Pay For Performance" in California should be viewed as a milestone development. It is a pioneering effort to place real dollars in the hands of providers, based on documented measurement of outcomes in clinical and operational areas.

This trend will be particularly relevant to pathologists. As physicians, they can expect to participate in future versions of physician performance incentive programs. It is THE DARK REPORT'S expectation that such incentive programs will provide clinical outcome measurements that will eventually be used to rank physician performance. Such rankings will be used by employers, payers, and consumers to select top-performing physicians over those doctors whose outcomes are less effective.

Clear Message For Labs

"Pay For Performance" does send one clear message to clinical laboratories and pathology group practices. Efforts to measure provider performance and pay differential reimbursement based on performance are arriving in the healthcare marketplace. Even Medicare is discussing such initiatives. It is currently working on a way to evaluate and rank hospital performance. Its intent is to make this information available to the public to help them pick the "best" providers.

California may be first to implement a statewide provider incentive program. Stay tuned as similar initiatives appear in other parts of the United States. **TDR**

Contact Beau Carter at 925-746-5100.

Public Laboratory Rankings

Lab Acquisitions in 2002 Changed National Market

Four national competitors absorbed by Quest and LabCorp in their efforts to sustain growth

NEVER IN THE PAST THREE DECADES has there been so few laboratory companies—public and private—competing to offer lab testing services to office-based physicians.

At the end of 2002, THE DARK REPORT'S annual ranking of public laboratory companies showed just 11 firms. Of these, two (**Unilab Corporation** and **DIANON Systems, Inc.**) were under acquisition agreements at year-end and became part of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, respectively, since January.

The concentration of ownership and market share for laboratories servicing office-based physicians takes the lab industry into uncharted territory. In this testing segment, the two blood brothers share a national oligopoly. At the same time, each company holds a monopoly share of selected regional markets around the United States. It is a combination of national oligopoly built on regional monopolies, much like the airline industry. *(See TDR, May 13, 2002.)*

Unprecedented Advantage

Moving forward, it is unclear whether Quest Diagnostics and LabCorp will enjoy unprecedented competitive advantage because of their economies of scale, their ability to do exclusive contracts with diagnostic vendors for

General Reference Laboratories

Ranking By 2002 Annual Revenue ($s in millions)

Rank	Laboratory	2002 Revenue	% Change	2001 Revenue
1.	Quest Diagnostics Incorporated[1]	$4,108.0	+13.2%	$3,627.7
2.	Laboratory Corporation of America[2]	$2,508.0	+14.0%	$2,199.8
3.	Unilab Corp.[1]	$425.0	+9.0%	$390.2
4.	Lab*One*, Inc.[3]	$298.1	+27.5%	$233.9
5.	Bio-Reference Laboratories, Inc.[4]	$96.6	+19.8%	$80.6
	Total: General Reference Laboratories	**$7,435.7**	**+13.8%**	**$6,532.2**

[1] *Quest Diagnostics acquired Unilab in 2003.*
[2] *LabCorp acquired Dynacare in 2002.*
[3] *Significant portion of LabOne's revenues come from life insurance testing.*
[4] *BRLI's fiscal year ended 10/31/02.*

new assays, and their contracting clout with the nation's largest health insurers.

It could be the opposite. Classical economics is full of examples of how monopolist and oligopolist companies lost their pre-eminent position. It is common for such companies to lose touch with customers, to stifle innovation within the company, to maintain higher prices to support internal profits, and to fail to adopt new technologies and services. In such cases, nimble, lean competitors eventually capture significant chunks of market share.

Growth Is Tough Challenge

Sheer size has magnified the management challenges at the two blood brothers. For instance, to increase annual net revenues by 10%, Quest Diagnostics must grow revenues by $410 million, based on its 2002 base of $4.1 billion. At LabCorp, revenues must grow $250 million to support that same 10% growth rate. Even factoring in likely acquisition candidates, this is a daunting feat for either lab to achieve.

Within the anatomic pathology (AP) segment of the lab testing industry, there was equally interesting news. After enjoying spectacular growth in revenues and profits lasting almost a full decade, the public AP companies showed weakness in 2002. The boards at **DIANON Systems, Inc.** and **AmeriPath, Inc.** chose to sell their respective companies. At **IMPATH, Inc.**, management issues that surfaced during the year led to radical changes in its executive team during the first months of 2003.

Even as the list of public laboratory companies shrinks, there is another business trend in the lab testing industry which has gone unreported. Notwithstanding the paucity of new lab start-ups dedicated to providing office-based physicians with routine testing services, there is great vitality in the specialty testing segment.

Companies organized to provide laboratory testing to specific medical specialties, or to offer lab testing based on proprietary technology, are springing up in growing numbers. If the two blood brothers are to continue their growth-by-acquisition strategy, the lab industry may see some "specialty lab" deals in the coming years. Until now, that's one type of lab company which has generally not been an acquisition target. TDR

Niche & Pathology Lab Companies

Ranking By 2002 Annual Revenue ($s in millions)

Rank	Laboratory	2002 Revenue	% Change	2001 Revenue
1.	AmeriPath, Inc.[1] (pathology management)	$478.8	+14.4%	$418.7
2.	Impath Inc. (oncology).	$226.4	+19.4%	$189.6
3.	Specialty Labs (reference).	$140.1	-20.0%	$175.2
4.	DIANON Systems, Inc.[2] (anatomic pathology)	$190.0	60.3%	$125.7
5.	PharmChem, Inc.[3] (substance abuse)	$30.1	-31.4%	$43.9
6.	MedTox (substance abuse)	$52.0	+5.9	$49.1
Total: Niche & Path Lab Companies		***$1,117.4***	***+14.8%***	***$1,002.2***

[1] AmeriPath completed a sale to Welsh Carson Anderson & Stowe in 2003.
[2] LabCorp acquired DIANON during 2003.
[3] In 2002, PharmChem was delisted from NASDAQ and divested its operations in the United Kingdom..

Lab Industry Briefs

GENETIC ANALYSIS FROM TISSUE BLOCKS UNVEILED IN CHICAGO

IT WAS A SPECTACULAR DEBUT for a Northern California company now developing technology to allow genetic analysis of tissue blocks as a way to classify tumors.

The company is **Genomic Health, Inc.**, based in Redwood City, California. It is developing proprietary technology which uses "high-throughput analysis of fixed paraffin-embedded tissues to obtain and clinically validate genomic information in large-scale clinical trials."

At the **American Society of Clinical Oncology** (ASCO) meeting in Chicago earlier this month, several presentations were made about clinical studies which attempted to classify individual tumors based on analysis of tissue blocks using Genomic Health's technology. In one study reported at ASCO, Melody Cobleigh, M.D., Director of the Breast Center at **Rush-Presbyterian-St. Luke's Medical Center** in Chicago, looked at 79 breast cancer patients diagnosed between 1979 and 1999. Each patient had 10 or more cancerous lymph nodes, a sign of aggressive cancer.

Cobleigh searched for 185 genes related to cancer. She was able to identify that, in patients with three specific genes activated, the cancer was unlikely to metastasize. She also identified two genes that were associated with poor prognosis. Cobleigh and her team analyzed patients' tumor tissue that had been preserved in parrafin blocks and stored at the hospital.

Cobleigh did a similar study with two other sets of patients and got the same type of results. To validate the test, Cobleigh has already launched a larger study of breast cancer patients using tissue samples collected by international research cooperatives. "If our results are validated, we will have the test in a clinic in a year," predicted Cobleigh.

For the pathology profession, the technology under development at Genomic Health has two impacts. First, it can allow pathologists to make a more detailed diagnosis about specific types of cancer, to help physicians target care as appropriate. Second, it means the archives of tissue blocks stored by pathology groups throughout the nation will have greater value, both clinically and financially.

DIANON SALES STARS LEAVE LABCORP AMIDST RUMORS OF A START-UP

IN RECENT WEEKS, **Laboratory Corporation of America** has seen a small exodus of top-performing sales representatives from its recently-acquired **DIANON Systems** business unit.

These multiple resignations were apparently triggered by an ultimatum that the reps involved needed to sign the LabCorp sales contract and non-compete agreement. Also gone is Martin Stefanelli, who was DIANON's Vice President of Sales prior to the company's acquisition by LabCorp.

Because many sales reps who resigned recently were DIANON's leading producers, informed speculation is that a new company is under development. This start-up will offer anatomic pathology services and will hire a core group of ex-DIANON employees

THE DARK REPORT considered the DIANON sales team to be one of the company's "crown jewels." LabCorp has to be disappointed at how rapidly this asset is dispersing. TDR

"Companion Diagnostics" Enter Lab Marketplace

Expected to be good for diagnostic vendors, but mixed benefits for clin labs and drug firms

CEO SUMMARY: Although the field of pharmacogenomics is still in its infancy, it has begun to develop sub-specialty areas. "Companion diagnostics" describes the marriage of a therapeutic drug with a specific diagnostic assay that can identify which patients will benefit from a prescription and which will not. "Companion diagnostics" will generally have reasonable reimbursement for labs because of their high clinical utility.

WITH THE FIELD of pharmacogenomics, there is an emerging specialty called "companion diagnostics." This is the marriage of specific drugs with specific diagnostic tests that determine whether the drug is appropriate for individual patients.

The first examples of companion diagnostics demonstrate how certain diagnostic vendors gain economic benefit if their assay becomes linked to a specific drug. On the other hand, the economics of companion drugs work against the financial interest of pharmaceutical companies, illustrating the conflicts that pharmacogenomics will bring to healthcare.

A New Phenomenon

"Companion diagnostics got its start a few years ago," stated Joseph W. Plandowski, President of **Lakewood Consulting Group**, located in Lake Forest, Illinois. "Following its review of a new drug, for the first time ever, the FDA required that a specific molecular test be performed to assure the drug would only be prescribed for breast cancer patients who would benefit from this new drug.

"The FDA took this ground-breaking action because the clinical trial had revealed that about a third or less of the patients involved in the trial had demonstrated benefit from taking the drug," explained Plandowski. "There was no benefit to the rest of the clinical trial population. Upon further study, researchers conducting the trial determined that the cause of this variation in patient outcomes was tied to the over- or under-expression of the HER-2neu gene.

"Because a molecular assay could predict, with reasonable accuracy, which patients would benefit from the drug and which would not, the FDA decided to approve the drug subject to the use of the 'companion diagnostic' test," added Plandowski. "There were at least two factors in the FDA's decision. First, it did not make sense to give a drug to a patient who would not benefit from it. Second, it would save the annual cost of the drug, estimated to be at least $18,000, for patients who would receive little or no benefit."

The drug in question, Herceptin®, was developed by **Genentech**. **DAKO** worked with Genentech to develop the screening test, HercepTest®, which also received FDA approval. At this time, Dako was a small, privately-held Danish company specializing in cytology and histology stains, including a strong line of immuno-stains. However, once the FDA approved HercepTest, DAKO was positioned as the sole source for an exclusive and high demand test.

Good Times For DAKO

"Business has been good for DAKO since then," observed Plandowski. "In recent years, DAKO merged with another private company, **Cytomation**. Cytomation makes a line of flow cytometry equipment. Following that acquisition, Dako took the new name of **DakoCytomation**.

"The second drug to require a companion diagnostic was Gleevec®, developed by **Novartis**," he noted. "The FDA approved Gleevec for treating chronic myeloid leukemia (CML), but that indication did not require a companion diagnostic. However, Novartis did further work with the drug and obtained approval for the treatment of Gastro-Intestinal Stroma Tumors (GIST). The FDA required a companion diagnostic to select patients for this new application. **Ventana Medical Systems** worked with Novartis to develop the test, known as c-Kit.

FDA Approval Expected

"A third drug, Iressa®, is expected to follow the companion diagnostic route in a secondary application similar to the above scenario," added Plandowski. "Iressa was initially approved for the treatment of non-small cell cancers. Its secondary application for the treatment of head and neck cancers requires a companion diagnostic. DAKO was rumored to have the inside track on that test, known as Epidermal Growth Factor Receptor (EGFR).

"For clinical laboratories, the evolution of companion diagnostics will have mixed effects," he noted. "Because these tests have high clinical value, reimbursement is reasonable. However, since distribution of the tests or the test kits can be controlled by the diagnostic vendor, not all laboratories interested in performing the test may be able to buy kits.

"The mixed benefits scenario is also true for pharmaceutical companies. For them, an FDA approval linked to a companion diagnostic is a double-edged sword," he said. "One side of the blade cuts against them. Drug companies *do not* want an FDA-dictated companion diagnostic for their drugs. It limits the potential size of the market for that drug. Pharmaceutical companies prefer the traditional way—'one drug for all, whether it works on all or not.'

Blade Cuts Both Ways

"However, the other side of the blade cuts in their favor. Drug companies *do* want a diagnostic test they can use to sort patients for their clinical trials. Having only patients who respond favorably to their drug would make for spectacular clinical trial results with much smaller trial populations. It would also result in quicker FDA approvals and far less expense," stated Plandowski.

THE DARK REPORT observes that the early examples of companion diagnostics validate predictions that molecular diagnostics will have higher clinical utility. In the case of Herceptin and HercepTest, payers quickly recognized the value of this laboratory test because of its ability to determine whether or not a patient will benefit from a drug costing thousands of dollars per treatment cycle

Whether or not companion diagnostics prove to be profitable assays for individual labs depends on how diagnostic test developers choose to distribute such tests in the laboratory marketplace. TDR

Contact Joe Plandowski at 847-295-8805.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Not all segments of the laboratory testing industry are pushing intensely to oppose an expected attempt to reintroduce legislation restoring the 20% patient co-payment for Medicare Part B lab testing services. *(See TDR, May 27, 2003.)* Sources tell THE DARK REPORT that some of the more powerful lab organizations believe competitive advantage will accrue to them if the 20% copay returns. Thus, in contrast to past years, their efforts to lobby Congress are much less intense.

MORE ON: 20% Copay Lobbying

With the federal budget currently running a deficit, lab industry lobbyists are concerned that renewed efforts in Congress to re-establish the 20% patient co-payment for Medicare Part B lab testing services will be successful. For that reason, it is important for the lab industry to act in a unified manner, which some activists believe may not be happening at this time.

MICROSOFT HELPS PACLAB DEVELOP WEB-REPORTING

PACLAB, the regional laboratory network covering Washington State, is about to launch its Web-based lab test reporting portal for physicians, called PacNet. PacNet allows the physician to look at all his/her patient's lab test data, including hospital inpatient test results, by pooling relevant data from the eight participating hospital labs and **PAML**, the commercial lab partner. What makes PacNet unusual and noteworthy is that it was developed with the help of **Microsoft Corporation**.

ADD TO: PacNet

Both PACLAB and Microsoft expect that PacNet will demonstrate how new Web-based software tools can allow laboratories and other providers to extract clinical data from multiple repositories and present it to physicians through a single Web portal—without the delays and considerable expense of writing CPU-to-CPU interfaces between different LIS products. **Overlake Hospital Medical Center** in Bellevue, Washington will be the PacNet demonstration site for PACLAB. This hospital is near Microsoft's headquarters and provides healthcare services to many Microsoft employees and their families. After initial roll-out to all physician-clients of PACLAB, PacNet will be enhanced to add cumulative test data and possibly anatomic pathology reports.

CYTYC'S PAP IMAGER GETS FDA APPROVAL

Competition in the ongoing Pap smear war between **Cytyc Corporation** and **TriPath Imaging, Inc.** will heat up with the latest development. Last week Cytyc announced that it had received approval from the FDA to market its imaging System for commercial use. The company said the "cytotechnologist workload limit for the ThinPrep Imaging System has been established at 200 Imager-assisted slides in no less than an 8-hour workday, as described in the product labeling."

That's all the insider intelligence for this report.
Look for the next briefing on Monday, July 7, 2003

UPCOMING...

- ***Inside Look at How Labs Are Using Online Distance Learning to Develop MTs.***
- ***Nation's First Lab Facility Designed By an ISO-9000-Certified Lab: Surprising Innovations Trigger Big Gains.***
- ***Rethinking Pathology Group Practice Ownership: New Ways to Build Shareholder Value for Participating Pathologists.***

For more information, visit:
www.darkreport.com