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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

California Is Lab Industry's Bellwether Again

IT'S NO COINCIDENCE THAT two recent lab industry developments are centered around lab companies in California. Repeatedly that state has proven to be a valuable bellwether of lab industry trends for the nation.

On the lab regulatory front, state officials from the **California Department of Health Services** (CDHS) have sanctioned **Specialty Laboratories, Inc.**, based upon regulatory deficiencies observed during visits to its laboratory facility in Santa Monica in June and October, 2001. Based on their findings, and subsequent negotiations with Specialty Labs to develop an acceptable Plan of Correction, the Centers for Medicare and Medicaid (CMS) is sanctioning Specialty Labs and revoking its CLIA-88 license because of deficiencies under CLIA regulations. *(See pages 2-5.)*

As of press time, neither state nor federal lab regulators have issued public statements concerning the Specialty Labs matter. This makes it hard to determine whether there is a broader message to the lab industry behind the sanctions leveled against Specialty. But action to revoke a public lab company's CLIA-88 license, particularly one as well known as Specialty Labs, is a sign that laboratory regulators are assuming a tougher stance toward identified violations of public laws and regulations. Since California regulates clinical laboratory operations more tightly than most other states, actions taken by CDHS and CMS against Specialty Labs may be an early market signal of a change in enforcement policy by regulators.

The other development is the acquisition of **Unilab Corporation** by **Quest Diagnostics Incorporated**. *(See pages 6-14.)* By purchasing Unilab, Quest Diagnostics is buying dominant market share of the "physicians' office segment" of lab testing in California. Pooled with its existing lab operations in California and its clout with managed care plans, Quest Diagnostics is poised to dominate the Golden State. With antitrust regulators likely to approve the deal, since they judge market share by the total lab testing pie (adding hospital inpatient testing, physicians' office laboratory [POL] testing, and physicians' office referral testing together), it is a sentinel event in the evolution of the nation's competitive marketplace.

On both counts, the two events in California reveal that government regulators—one group monitoring lab operations, one group monitoring anti-trust behavior—are signaling the type of directions they will tolerate for the nation's clinical laboratories. TDR

State, Federal Regulators Target Specialty Labs

Specialty Laboratories' CLIA-88 license "yanked" by CMS laboratory enforcers

CEO SUMMARY: Specialty Laboratories, Inc. has earned the dubious honor of being the first-ever publicly-traded laboratory to have its CLIA-88 license revoked by federal regulators, terminating its right to payment for services covered by Medicare and Medicaid. The revocation is slated to take effect on April 26, but is subject to a court appeal that suspends the revocation until a decision is rendered.

NEWS THAT STATE AND FEDERAL laboratory regulators had **Specialty Laboratories, Inc.** targeted in their crosshairs captured the full attention of the nation's clinical laboratory industry.

On April 15, Specialty Labs publicly acknowledged that it faced a revocation of its CLIA-88 license due to "action taken by the federal **Centers for Medicare and Medicaid Services** (CMS) as the result of alleged noncompliance by Specialty with requirements of the federal Clinical Laboratory Improvements Act of 1988 (CLIA-88), including, subject to appeal, revocation of Specialty's CLIA-88 certificate and termination of its right to payment under the Medicare and Medicaid programs."

The sanctions issued by federal lab regulators were triggered by deficiencies noted during inspections of Specialty Laboratories conducted by the **California Department of Health Services** (CDHS). CDHS represented the State of California and acted as agent for CMS.

A CDHS agent identified deficiencies during a CLIA complaint survey of Specialty Labs that was conducted on June 25-26, 2001. These deficiencies were confirmed at a follow-up visit on October 9-10, 2001.

Based on its findings, the state generated written notifications to Specialty Laboratory "citing the fact that supervisors and testing personnel failed to possess current California clinical laboratory personnel licenses." It requested cor-

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rective action for these and other deficiencies that were noted during the surveys and inspections.

Sanctions And Revocation

On April 18, 2002, Specialty Labs filed a Form 8-K report with the **Securities and Exchange Commission**. Included in this filing is a copy of the April 12, 2002 letter sent to Specialty Labs by the CMS Regional Office in San Francisco. This letter imposed the sanctions noted above and detailed many of the deficiencies. Readers of THE DARK REPORT can access this public filing by going to Specialty's Web site at *www.specialtylabs.com*.

In response to the revocation of its CLIA-88 license, Specialty Labs is filing an appeal. By so doing, the implementation of CMS's license revocation and other sanctions is suspended until an administrative law judge issues a ruling. Effectively, this allows Specialty Labs to continue performing testing as a CLIA-88-licensed laboratory. However, the stakes are huge. If Specialty loses this appeal, it will have to stop performing lab tests.

Medicare Billing Affected

As part of this situation, Specialty Labs terminated billing for Medicare and Medicaid services as of February 22, 2001. The lab company believes it can be paid retroactively for such services if its appeal is upheld. It also believes that its hospital clients can legally bill Medicare and Medicaid, because Specialty's CLIA-88 license remains valid during the appeals period. The company is requesting a confirmatory opinion from CMS on this point.

"The State of California issued sanctions against Specialty Laboratories involving three separate points," stated Ken August, Public Affairs Officer for CDHS. "First, we gave them a directed plan of correction. Second, civil money penalties totalling $224,000 were assessed, based on a fine of $1,000 per day from a date last fall through March first.

"Third, once Specialty Laboratories corrects the identified deficiencies and is again in compliance, the State of California will maintain a program of random, on-site monitoring for a period of three years," noted August.

Feds Levy Four Sanctions

As detailed in the April 12 letter, following months of discussion, CMS (and CDHS) did not consider Specialty Lab's latest Plan of Correction (POC) to be acceptable. Its patience exhausted, CMS issued sanctions involving four elements. One, it revoked Specialty Lab's CLIA-88 certificate, subject to appeal. Two, it cancelled the lab company's approval to receive Medicare and Medicaid payments. Three, it imposed a civil money penalty of $3,000 for each day of non-compliance. Four, it imposed a directed plan of correction by which "CMS may notify Specialty's customers of its non-compliance and the nature and effective date of any sanctions imposed."

THE DARK REPORT discussed this situation with Paul Beyer, President of Specialty Laboratories. "We erroneously interpreted California regulations," he said. "How we built our staffing models was deemed to be out of compliance. In California, technical staff has a designation as CLS—clinical laboratory scientist. Regulations call for clear and constant supervision of testing. We are working to revise our Plan of Correction and will submit it to the authorities shortly."

Beyer was quick to point out one overlooked aspect of this matter. "There are no patient care issues," he stated. "That is why we continue to perform testing. Anytime there are

Specialty Labs' Management Now Must Deal With a Passel of Unique Problems

FACED WITH REVOCATION of its CLIA-88 license, executives at Specialty Laboratories must now deal with a host of consequences.

First and most importantly, Specialty Labs faces potential loss of its license to perform lab tests. If that happens, it can no longer perform lab testing. Development of a Plan of Correction (POC) to restore regulatory compliance is now high priority.

Second, the value of its stock has fallen dramatically. This may draw lawsuits from disgruntled shareholders who believe the company did not fully disclose the material facts of its troubles with CDHS and CMS in a timely fashion.

Third, Specialty Labs has a big damage control job ahead with its customers. Its problems with CMS undoubtedly make many hospitals nervous about continuing to refer testing to the lab. Because Specialty Labs' customers are themselves familiar with CLIA regulations, they have legitimate questions about the management integrity behind the testing performed at Specialty Labs, as well as the integrity of the lab test results. Allegations by state and federal regulators that unlicensed or improperly licensed personnel have been performing tests and supervising testing will certainly draw intense scrutiny by skeptical pathologists and lab administrators.

Taken collectively, these challenges place Specialty Laboratories at a crossroads. Its ability to successfully overcome all these problems will require adroit management skills. The irony of this situation is not lost on most lab executives and pathologists, because Specialty Laboratories has long prided itself on the quality of testing it performs, its innovations in esoteric testing, and the service it provides its customers.

concerns about patient safety, regulators will close a laboratory."

Beyer demurred when asked more detailed questions about this situation and the reasons why such an intense dispute developed between Specialty and government regulators since the "complaint survey" visits by CDHS on June 25-26, 2001 and October 9-10, 2001.

What Started This Mess?

Lab regulators identified a range of deficiencies during their visits to Specialty Laboratories. However, many deficiencies seem to center around unlicensed personnel performing lab tests and unlicensed personnel supervising lab testing.

California has regulations that define the educational requirements and experience required for the designation of "clinical laboratory scientist" (CLS). For that reason, the terms "medical technologist" and "medical technician" often used in other states, are not part of California's regulatory scheme.

THE DARK REPORT has learned that, in some cases, Specialty hired individuals who were board-certified in their area of laboratory medicine. But, for whatever reason, after arriving in California, neither Specialty nor the individuals had satisfied the full requirements for state licensure.

From a variety of sources, THE DARK REPORT has pieced together an early assessment of the situation. The April 12 letter from CMS to Specialty contains details about some of the most important non-compliance issues. On page 3 of the letter, paragraph four states "Persons unlicensed in California were observed in all sections performing clinical laboratory activities not permitted under BPC

§1269. While performing these clinical laboratory activities, the unlicensed personnel were not subject to the required direct and constant supervision under BPC §1206(a)(8)."

Similarly, on page 4 there is a statement that characterizes staffing practices this way "...Based on the large number of unlicensed personnel supervising and performing clinical laboratory testing in multiple specialty testing areas of the laboratory and [the] deficiencies previously cited in prior surveys..." Thus, concern about unlicensed staff performing and supervising testing represents a key element.

"Tech"/"Non-Tech" Ratios

In fact, the letter does identify some staffing ratios. On page five, it states that Specialty provided a "current list of personnel" showing 349 total staff, identified as "two directors and 142 other persons licensed under BPC Division 2, Chapter 3." There were "205 unlicensed persons, two listed as Technical Consultants, four Lead Technicians, nine Technicians III," and so forth. It also noted that "two unlicensed persons in the Cytogentics and Genotyping sections are listed as Technical Director on Attachment 58."

Of the 349 individuals, regulators identified only 144, or 41.2%, as licensed. Such statements indicate that regulators were specific in identifying what they considered to be deficiencies in the staffing model used at Specialty. Assuming, for the moment, this is true, there may be several factors that influenced how and why Specialty Laboratories organized its testing operations the way it did.

One contributing factor would be the shortage of trained medical technologists in the Santa Monica area of Los Angeles. It's no secret that Specialty Labs' unique test mix is labor-intensive; many of the assays are complicated, time-consuming and require more hands-on effort by the technical staff. Another factor is Specialty's rapid growth in specimen volume. Executives at the troubled lab have long acknowledged that hiring and retaining adequate technical staff has been a challenge.

Working Environment

The second factor probably involves management practices. It can be speculated that temporary surges in specimen volumes would bump up against the inadequate supply of technically-trained labor. It would not be surprising to find that, whenever there was a lack of sufficient licensed "clinical laboratory scientists" to handle large volumes of specimens, temporary "work-arounds" were implemented. Some of these, whether intentional or not, seemed to have become part of the daily routine.

In at least one area of the lab, the deficiencies identified by CDHS were serious enough to cause Specialty Labs to cease testing in that department. Sometime in February, Specialty ceased testing in its cytogenetics department and laid off most of the staff. Since that date, it refers cytogenetics specimens to other labs.

Unprecedented Sanctions

Because the action of CDHS and CMS to place serious sanctions and revoke the operating license of a publicly-traded lab company is unprecedented, it must be assumed that allegations of non-compliance involve more serious deficiencies than "sloppy recordkeeping" or "poorly-maintained procedure manuals."

It may well be that the reasons for this situation have to do with how pressures of a fast-growing laboratory business led to inappropriate decision-making. There is certainly much more to this story and the details will eventually become public knowledge. TDR

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Quest Pays $1.1 Billion To Acquire Unilab Corp.

Its second lab purchase in 2002 positions Quest Diagnostics to dominate California

CEO SUMMARY: Quest Diagnostics Incorporated is showing its muscle. The dust had hardly settled on its $500 million acquisition of American Medical Laboratories when the lab industry's behemoth announced that it would pay $1.1 billion to buy Unilab, by far the largest lab testing company in California. Integration of the two laboratory operations is planned to occur over the next two years.

YANKEE BASEBALL GREAT Yogi Berra's classic malaprop "it's *deja vu* all over again" aptly characterizes **Quest Diagnostics Incorporated's** acquisition of **Unilab Corporation**, based in Tarzana, California.

After all, Unilab itself was once part of **MetPath**. It was created back in 1988 when MetPath spun-off several laboratories it owned in the Western United States into a company called **MetWest** (renamed Unilab in the 1990s).

MetPath was then owned by **Corning Corporation** and was itself spun-off by Corning in 1997 to become Quest Diagnostics. Viewed from this perspective, the merger of Quest Diagnostics and Unilab is a simply the reunion of two separated branches of the same family tree.

Merger Announcement

Quest Diagnostics and Unilab announced the merger on April 2. Quest Diagnostics will pay for Unilab shares using a combination of stock and cash. It will also assume $200 million of Unilab's debt. The total value of the transaction will be about $1.1 billion.

Unilab generated revenues of $390 million during 2001. It operates three sizeable laboratories in Tarzana, San Jose, and Sacramento and has 39 rapid response laboratories and 396 patient service centers. It also holds managed care contracts with most of the state's largest HMOs and IPAs (independent physician associations).

Quest's California operations include the two laboratory facilities it picked up when it bought **SmithKline Beecham Clinical Laboratories** (SBCL) in 1999. These are located in Dublin and Van Nuys. It also performs reference and esoteric testing at the **Nichols Institute** laboratory, located in San Juan Capistrano.

Quest Diagnostics expects to eliminate as much as $30 million per year of costs following integration of Unilab with its California operations. Savings will come from moving Unilab's reference test to Nichols Institute, consolidating laboratory opera-

Value of Clin Labs Rises With Quest's Purchases

Not surprisingly, even as the number of independent commercial laboratory companies dwindles in the United States, their market value as an ongoing business is increasing.

In purchasing **American Medical Laboratories** and Unilab Corporation this year, Quest Diagnostics was willing to pay a multiple of up to 12.5 times EBIDTA (earnings before interest, depreciation, taxes, and amortization). Net earnings at both acquired labs were negligible because each had considerable levels of debt which had to be serviced from cash flow.

Quest Diagnostics was willing to pay a strong price for both labs because each had a strong cash flow and customer base. After retiring the debt from both companies, and following cost reduction measures, Quest Diagnostics believes it can squeeze an additional $45 million per year in cash flow from both acquired labs, whose combined revenues in 2001 totaled $690 million.

tions, bringing Unilab's bad debt ratio and DSO down to Quest Diagnostics' current ratio, and eliminating redundant infrastructure, such as courier routes, patient service centers, and rapid response labs in the state.

Measured Pace of Integration

As it did with the SBCL acquisition, Quest Diagnostics will integrate and consolidate Unilab's business with its own in a measured fashion. In an analyst call, Quest Diagnostics Chairman and CEO Ken Freeman stated "our strategy anticipates closing certain facilities to rationalize capacity in California. Some positions will be eliminated over time, which we expect to address primarily through normal, voluntary attrition, as we've done in past integrations."

Unilab's President and CEO, Bob Whalen, will remain with Quest Diagnostics after the acquisition is finalized. "Bob Whalen will lead the integration of our California operations," noted Freeman. "He will be responsible for our local California business."

Supported By Lab Industry

One immediate consequence of the Unilab transaction is that Quest Diagnostics will become the dominant commercial laboratory competing for physicians' office business in California.

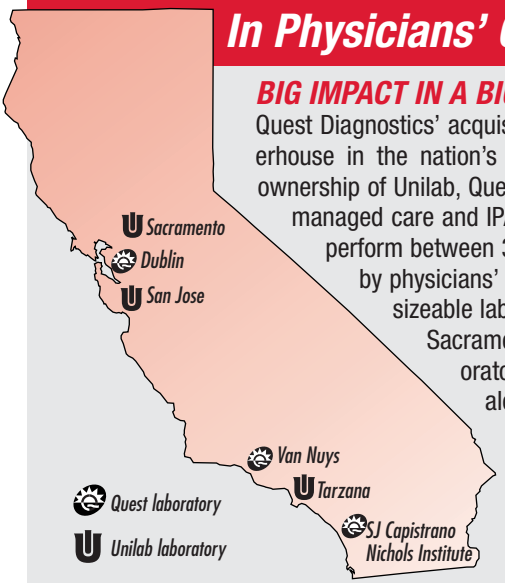
In public filings, Unilab has acknowledged that "we believe that our revenues in 2000 represented approximately 25% of the California independent clinical laboratory testing market and approximately twice the annual sales of the next largest independent clinical laboratory in California." The second largest lab in California has been Quest Diagnostics (estimated by Unilab to hold a 12.5% market share).

Based on Unilab's estimates, post-acquisition, Quest Diagnostics will hold at least 37.5% of the lab testing referred by physician's offices in the State. Its market share will be higher in Northern California, where, outside of **Laboratory Corporation of America's** lab facility in Reno, there are no independent commercial labs doing $5 million or more per year in revenue.

In Southern California, excepting LabCorp, there are about six viable independent labs with revenues of at least $5 million per year. But none have annual sales exceeding more than about $30-35 million annually.

It is another characteristic of the California marketplace that hospital laboratory outreach testing programs are not a major factor in serving the testing

Quest Becomes California's Big Dog In Physicians' Office Testing Market



BIG IMPACT IN A BIG STATE!

Quest Diagnostics' acquisition of Unilab creates a new powerhouse in the nation's most populous state. After taking ownership of Unilab, Quest Diagnostics will hold most major managed care and IPA contracts In California. It will also perform between 35% and 50% of all testing referred by physicians' offices in the state. Unilab operates sizeable lab facilities in Tarzana, San Jose, and Sacramento. Quest Diagnostics' major laboratories are in Dublin and Van Nuys, along with its esoteric lab facility at Nichols Institute. Full integration and consolidation of the two lab systems are planned to take place over a two-year period.

	Quest Diagnostics	Unilab
Lab sites:	30 full service labs nationally, 100+ rapid response labs	3 full service labs, 39 rapid response labs; all in California
Patient Service Centers:	1,300	396
Employees:	29,000	3,600
2001 Revenue:	$3.63 billion	$390.2 million
Requisitions:	105 million	15 million
CEO:	Ken Freeman	Robert Whalen

needs of physicians' offices. Observers attribute the relative lack of hospital lab outreach programs in California to poor hospital finances in the 1990s and exclusionary managed care contracts in favor of Unilab, Quest Diagnostics, and LabCorp. Such contracts meant hospital lab outreach programs could not get paid for lab testing referred to them by physicians' offices.

From this perspective, the acquisition of Unilab by Quest Diagnostics represents a significant development for California. Most of the state's testing referred by physicians' offices will be performed by Quest Diagnostics. This situation can be expected to skew the competitive dynamics within the state.

Once again, California becomes a bellwether for the lab industry. Quest Diagnostics' newly-enlarged market clout will surely impact managed care contracting patterns and access by smaller independent labs to patients in the physicians' office testing segment. TDR

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NEWSMAKER INTERVIEW

"We are striving to create a full array of products and services that meet the needs of physicians and hospitals."
—Kenneth Freeman

NEWSMAKER INTERVIEW

Ken Freeman Discusses Plans to Integrate AML and Unilab

After its $1.7 billion buying spree, Quest Diagnostics Incorporated now must tackle integration of two lab firms.

CEO SUMMARY: Once again, Ken Freeman and Quest Diagnostics Incorporated is altering the national market for clinical laboratory testing. By acquiring American Medical Laboratories and Unilab, the nation's largest lab company is expanding its presence in California, Nevada, and Washington, DC. In this exclusive interview with THE DARK REPORT, Chairman and CEO Ken Freeman explains the strategic business reasons why Quest Diagnostics pursued these two acquisitions. He also talks about important trends in the marketplace for clinical laboratory testing. The interview was conducted by Robert Michel, Editor-In-Chief of THE DARK REPORT.

EDITOR: Taken together, the acquisitions of **American Medical Laboratories, Inc.** (AML) of Chantilly, Virginia and **Unilab Corp.** of Tarzana, California represent an investment by **Quest Diagnostics Incorporated** of about $1.7 billion dollars. That's a huge investment. What does Quest hope to accomplish with these transactions?

FREEMAN: Robert, we see four primary benefits. One, it helps us broaden access and distribution for patients and physicians. Two, it's an opportunity to further accelerate growth in two segments of testing—esoteric and gene-based assays. Three, it expands our access to some highly-desirable geography. Four, both companies bring talented people into our company.

EDITOR: Could you elaborate on the geographical aspects of these two acquisitions?

FREEMAN: The Las Vegas lab facility of AML gives us a sizable laboratory presence in Nevada. Las Vegas is a very attractive market for lab testing because it has been the nation's fastest-growing metropolitan area since the early 1970s. AML also has extensive lab business in Washington, DC and Northern Virginia.

EDITOR: What about California, where Quest already has a presence?

FREEMAN: According to census data, California has the largest year-to-year increase in population of all 50 states, so it is also a fast-growing market for laboratory testing. Unilab brings us an extensive infrastructure of patient service centers and rapid response laboratories in that state.

EDITOR: Turning to the AML acquisition, you've commented publicly that you intend to maintain the company's reference and esoteric testing activities at the Chantilly laboratory.

FREEMAN: Yes.

EDITOR: You're on record as stating that gene-based testing at Quest Diagnostics is a fast-growing segment of the business, and AML's reference testing division is expected to contribute to this growth. Could you provide some details?

FREEMAN: Let me approach it this way. Esoteric testing, including gene-based and non-gene-based, comprises 13% of our revenues, which were $3.6 billion in 2001. Gene-based testing at Quest Diagnostics is growing by 20% per year and totaled about $275 million in 2001. Non-gene-based esoteric testing is growing about 10% per year and totaled $200 million during 2001.

EDITOR: And you expect these growth rates to continue?

FREEMAN: Yes. As individual esoteric assays gain widespread clinical acceptance, they tend to become "routine" lab tests. That is one of the evolutionary drivers to the laboratory business. We believe this same phenomenon will happen to gene-based testing in coming years.

EDITOR: That nicely frames the reasons why Quest was interested in AML's esoteric testing business. You see it as a fast-growing part of diagnostic testing. But I suspect there are other strategic business reasons for the interest in AML's esoteric division.

FREEMAN: True on both counts. The events of September 11 certainly showed how dependent the lab industry is on the air transport system. For example, about 95% of our highly-esoteric testing is sent cross country to **Nichols Institute** in Southern California. AML's esoteric laboratory in Chantilly gives us the ability to perform a full menu of esoteric testing on both coasts. We consider this to be an important strategic growth opportunity for Quest Diagnostics.

EDITOR: That would certainly give you a unique feature in the marketplace. No other national esoteric testing lab currently performs testing on both coasts.

FREEMAN: We expect to use AML's Chantilly lab facilities to improve the turnaround time for highly-esoteric testing. That will be good for hospital clients, physicians, and patients.

EDITOR: If Quest Diagnostics is to realize the full potential of AML's reference and esoteric testing assets, it must become more successful in developing send-out business from the nation's hospitals. Is this true?

FREEMAN: That's correct. Your readers know that hospitals send out about 3% of their test volume—those tests which are highly-esoteric and are not time-dependent. As Quest Diagnostics moves forward, it has the paradox of being a competitor with hospitals that perform outreach testing as well as a provider of testing. This kind of paradox is not unique to healthcare. It exists in many industries. We understand that we must distinguish ourselves to succeed in this market segment.

EDITOR: When marketing to hospitals for their send-out testing, how will Quest set itself apart from competing reference labs?

FREEMAN: First, we have the opportunity to provide unsurpassed quality. As you know, we are implementing Six Sigma methods to boost the level of per-

formance in all aspects of our company's services. Second, we offer the broadest menu of testing available in the lab industry. Third, we have over 300 M.D.s and Ph.D.s who are available for physician-to-physician consultation on the most complex cases. Fourth, we have a comprehensive array of connectivity options. For hospitals, our MedPlus division offers an electronic medical record (EMR), called ChartMaxx™. An Internet-based EMR, called *e*Maxx™, will be available later this year. Fifth, we are consistently among the first labs to offer the most innovative new tests. Access to such testing is particularly valuable to hospitals seeking to maintain close relationships with physician-specialists.

EDITOR: Certainly that is a full menu of service options. From my perspective, the two key differentiators will probably turn out to be service—once the full impact of Six Sigma takes effect on Quest's work flow processes—and early access to new lab test technologies. If Quest Diagnostics uses Six Sigma principles to noticeably reduce error rates in logistics, specimen handling, lab accidents, billing mistakes and the like (which are common to most laboratory operations today), that would certainly encourage hospitals to overcome their reticence to send specimens to a lab competing in their outreach market. Equally important, I think, will be the early, sometimes exclusive, access that you and **Laboratory Corporation of America**, as national lab providers, will have to new diagnostic technology.

FREEMAN: I fully agree. My commitment to improving our basic lab services is such that I personally certified as a Six Sigma Black Belt. This requires four full weeks of training and personally leading improvement projects. Our company goal is to constantly eliminate the sources of errors that are common to all laboratory operations. At the same time, access to new technology is important to differentiate Quest Diagnostics. We've seen big changes in this area.

EDITOR: In what way?

FREEMAN: When I first joined the lab business six years ago, our phone in Teterboro was certainly not ringing off the hook with phone calls from innovators wanting to offer us new tests and new concepts for the lab marketplace. What a change in five years! Every week we now get at least one call from a start-up company or institution wanting to explore how Quest might help introduce their product or service into the national marketplace.

EDITOR: Quest's ability to gain "first access" to new diagnostic technology on favorable terms is certainly demonstrated by any number of agreements already on the books. For example, the 1998 agreement between **Cytyc Corporation** and Quest which made ThinPrep® the exclusive enhanced Pap test at Quest certainly illustrates this competitive benefit. HIV typing and viral load testing is another area of early-mover advantage.

FREEMAN: Yes. Similarly, we recently signed agreements with **Roche Diagnostics** to develop and commercialize gene-based tests and with **diaDexus, Inc.** to license its proprietary technology to detect and monitor osteoporosis.

EDITOR: Clearly one message that Quest is sending to the lab marketplace with its AML acquisition is that it intends to become a more forceful competitor in the hospital send-out segment of lab testing. Can we shift gears now and talk about the Unilab acquisition and its impact on your strategic business plans? Certainly California has proven to be a financially-challenging state for clinical laboratories.

FREEMAN: That's true. We have no misconceptions about the difficulties which lie ahead. But we believe that Unilab is a great fit with our organiza-

tion. It has an unmatched service infrastructure throughout the state and strong relationships with the major insurance companies and IPAs (independent physician associations).

EDITOR: However, Quest Diagnostics has its own considerable service infrastructure in California. The need to rationalize and integrate the two lab organizations triggers a different set of management challenges.

FREEMAN: We have two strong cards to play. One, I consider Quest Diagnostics to be battle-tested in this management area, as evidenced by our smooth integration of **SmithKline Beecham Clinical Laboratories** (SBCL). Two, many members of Unilab's management team, led by its current President and CEO Bob Whalen, will stay on. They've already demonstrated their ability to handle California's rough-and-tumble lab marketplace.

"My commitment to improving our basic lab services is such that I personally certified as a Six Sigma Black Belt."

EDITOR: In fact, it should be recognized here that Quest Diagnostics' acquisition of SBCL and its subsequent integration was, without question, the best job of post-acquisition management seen in the public lab company sector since the mid-1980s. Compared to the go-go lab acquisition wave of 1985-1995, there were relatively few significant problems and very little of the acquired SBCL business was lost in the post-acquisition period. That is certainly good evidence that Quest is capable of smoothly integrating its California laboratory operations with those of Unilab.

FREEMAN: We expect that to be true. Plus, the leadership of both Unilab and AML will remain to help with these transitions. Robert Whalen, President and CEO of Unilab and Tim Brodnick, President and CEO of Unilab, are each strong and capable leaders. Both individuals have demonstrated their ability to create a customer-focused laboratory organization. We are pleased that, going forward, they will continue to contribute as part of the team at Quest Diagnostics.

EDITOR: You've mentioned electronic connectivity options between Quest and its hospital customers. Since Unilab had its own connectivity strategy with physicians, what type of strategy will Quest Diagnostics deploy in California?

FREEMAN: We believe that electronic connectivity between our labs and our lab customers, whether hospitals or physicians, is one way we can differentiate ourselves from other lab competitors in the marketplace. We are creating a suite of connectivity products to meet the needs of our customers. Along with our traditional in-house solutions, Internet-enabled and non-Internet-enabled, we've acquired a new product. **LabPortal.com** was part of the AML acquisition. This complements the offerings of MedPlus—ChartMaxx and *e*Maxx—which I mentioned earlier.

EDITOR: Could you comment on the importance of the electronic medical record and how it relates to laboratory test data?

FREEMAN: Medical records are a traditional problem for the healthcare system. Often they are difficult to retrieve and just as often they are incomplete. Laboratory test data is a major component of a patient's long-term medical record. We believe there is an opportunity for laboratories to add value by supporting the migration to an electronic medical record (EMR).

EDITOR: Is that why Quest Diagnostics considered the MedPlus acquisition to be strategically relevant?

FREEMAN: Yes. We must be capable of feeding lab test data into EMR systems. As you know, growing numbers of hospitals and health systems are working to implement EMR solutions. Quest Diagnostics wants to be in a position to support this effort.

EDITOR: Does HIPAA play a role in this as well?

FREEMAN: Certainly. Our MedPlus division is developing highly-confidential, HIPAA-compliant electronic medical records designed for use by physicians, physician groups, and hospitals.

EDITOR: Since Quest Diagnostics has taken early steps to introduce Internet-based lab test ordering and results reporting, could you talk a little about how physicians are responding to these features?

FREEMAN: Our experience to date mirrors what most of the lab marketplace has seen. Physicians are much more willing to access lab test results via the Web than to place lab test orders over the Web. However, Web-based lab test ordering is taking hold, albeit at a slower rate than results reporting.

EDITOR: From your experience, then, the steady migration toward browser-based lab test ordering and results reporting is underway?

FREEMAN: That's true and it is a trend which will help labs add value to their hospital and physician customers.

EDITOR: What about direct patient access to lab test results? With your early implementation of *mydailyapple.com*, have you seen a steady increase in the number of patients actively retrieving their lab test results from the Web site?

FREEMAN: Based on our experience to date, this is an area of lab services which remains in its infancy. However, enthusiasm expressed by those consumers using the Web to access their lab test results confirms for us that this feature will become very, very important over time.

EDITOR: In other words, although the volume of patients seeking to access their lab test results to date has been limited, there is a growing number of consumers who are quite motivated to have access to their laboratory test data. Could you elaborate?

FREEMAN: You and I both know that the consumerism movement in health care is still in its early days. But I can foresee the day when, with the permission of the referring physician, patients will access their lab test results. I believe that consumer demand for access to this type of information will stimulate changes to state laws that currently restrict such access.

"...we think it is imperative that the lab industry embrace Six Sigma principles and use them to improve the quality of lab testing services provided to all customers."

EDITOR: What I hear you saying must mean that early-adopter patients, those who were first to access *mydailyapple.com* to see their lab test results, have been enthusiastic and ardent supporters of this feature. Is that true?

FREEMAN: Yes, that's right. In fact, I am continually amazed at this phenomenon. Frequently when I speak in public, I ask for a show of hands by anyone who has seen their lab test results. The number who respond is often astonishingly small. This would surprise those physicians who consider lab test data to be "their" information. Our experience with such initiatives as *mydailyapple.com* indicates that the consumerism movement in healthcare is going to change that situation rather rapidly.

EDITOR: Those are fascinating insights. Could you discuss the role of anatomic pathology in the strategic plans for Quest Diagnostics?

FREEMAN: We consider anatomic pathology to be a very important area of high growth. That is why we are excited about the additional pathologists who are joining us as a result of these two acquisitions. There are a number of subspecialists among them, particularly in dermatopathology and histopathology.

EDITOR: Ken, you've been very specific in addressing the various strategic business plans that led Quest Diagnostics to acquire AML and Unilab. Now I'd like to explore, in more detail, the impact that ISO-9000 and Six Sigma management methods are having within Quest Diagnostics. That's because a handful of laboratories are just starting to learn the power of these techniques to deliver better operational execution in lab testing, accompanied by higher quality and lower costs. This is an important trend in the laboratory industry. It is also one business strategy where Quest Diagnostics has definitely made a major commitment that is far ahead of the lab industry as a whole.

FREEMAN: I'd be glad to, because I am passionate about this subject.

EDITOR: What types of Six Sigma projects are underway and what types of measurable results have been obtained?

FREEMAN: First, over the past two years, all our employees have been through Six Sigma foundation training, which involves a minimum of three hours. So we all know the basic principles. Second, we have trained 130 Black Belts and that number is increasing monthly. They are trained and supervised by 12 Master Black Belts, most of with experience outside healthcare, from major corporations such as **General Electric** and **Allied Signal**. Third, we have 200 active projects underway

EDITOR: And what about measurable results from such projects?

FREEMAN: In Arizona, one project was: 1) to reduce the average wait time required for patients at our service centers to get a blood draw; and 2) to reduce variability in wait time. Following the project, wait times were reduced by 50%. In fact, patients noticed that wait times had improved measurably and told their physicians about this positive improvement.

EDITOR: Other examples?

FREEMAN: We are making a big push to improve billing. Of our 180 Black Belt projects, as many as 30 involve billing. As part of this, we have engaged the payers. After all, when we submit a clean claim, it saves the payer time and money in processing and reimbursing. There are similar projects underway in logistics, accessioning, testing, reporting, and so forth. We believe that Six Sigma is an incredibly powerful tool and, although we view it as a source of competitive advantage, we think it is imperative that the lab industry embrace Six Sigma principles and use them to improve the quality of lab testing services provided to all customers.

EDITOR: That's a powerful statement. As some of these Black Belt projects at Quest are completed, would you share the results with readers of THE DARK REPORT? It would be a great way to demonstrate to other laboratory executives and pathologists that these techniques have great value for all types of laboratories.

FREEMAN: I'd be happy to do that.

EDITOR: With our time drawing short, I'd like to thank for your candid comments about the two acquisitions, as well as your thoughts on several other aspects of the lab industry.

FREEMAN: Thanks! It was a great opportunity to share perspectives. TDR

Contact Gary Samuels at 201-393-5597.

Managed Care Update

HMO Enrollment In Decline; PPOs Capture 48% of Market

ENROLLMENT IN THE NATION'S HMOs has declined in each of the last two years. Experts now believe the heyday of the classic closed-panel, gatekeeper model of the HMO has ended.

"HMOs are in full retreat," observed Bryant Armstrong, a healthcare consultant in the Dallas office of **Hewitt Associates**. "They are not dead by any means. But their day as the prominent provider is over."

As HMOs have fallen out of favor, PPOs (preferred provider plans) have become increasingly popular with consumers. As HMO enrollment dropped from 31% of the population to 23% in 2001, PPO enrollment jumped from 28% to 48% during the same period.

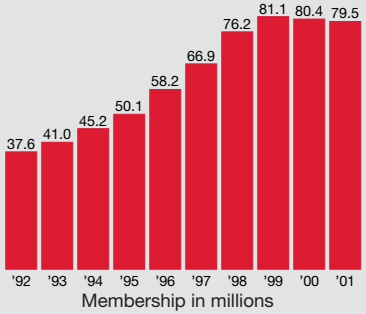
Moreover, the cost gap between HMOs and PPOs has narrowed. Hewitt Associates says that, through most of the 1990s, HMOs were about $1,000 per year cheaper than PPOs. But cost increases have cut this difference down to only $300 in recent years. "Since HMOs offer no competitive advantage in pricing, consumers are opting for other types of plans," stated Armstrong.

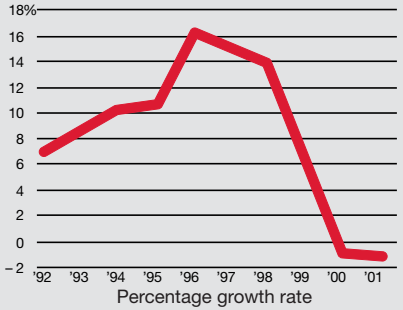
The consumer switch into health plans offering discounted fee-for-service reimbursement is good news for most clinical laboratories and pathology group practices. Once many HMOs signed exclusive lab provider contracts with national lab companies, local lab providers found themselves locked out.

However, the consumer shift back toward PPO-types of health plans should make it easier for local labs and path groups to negotiate contract access with insurers. Physicians and consumers want choice and this should help local laboratory providers. TDR

Numbers Tell the Story: Consumers Opting Out of HMOs

As the two graphs below demonstrate, consumers flocked to HMOs through most of the 1990s. But that love affair ended. Beginning in 1998, growth rates for HMO enrollment began to fall precipitiously as consumers shifted toward PPO-types of plans.





Source: Kaiser Family Foundation

Lab Industry Briefs

ACTIVITY AT DYNACARE HINTS AT POSSIBLE SALE, LABCORP MAY BE BUYER

With **Quest Diagnostics Incorporated** snapping up independent lab companies right and left in recent months, the question asked by many is "Where's **Laboratory Corporation of America**?"

On the sell side, **American Medical Laboratories** and **Unilab** have been acquired by Quest Diagnostics. The largest remaining independent commercial laboratory serving the physicians' office segment is **Dynacare, Inc.**, based in Dallas.

It's not surprising, then, that rumors about a possible sale of Dynacare to LabCorp have been circulating. THE DARK REPORT believes there is some substance to these rumors, for a number of reasons. One, Dynacare's revenue base may be at a high-water point. Some of its lab ventures have unraveled, the most recent involving the termination of its lab testing relationship with the **Kelsey-Siebold Clinic** in Houston. This was a major client for Dynacare's Houston laboratory division.

Two, in the Northwest, Dynacare's very successful lab operation has a restless partner in **Swedish Hospital**. As affiliations between hospitals change in Seattle, the original business reasons for the Swedish-Dynacare business relationship, launched in 1994, may cause Swedish to pursue other laboratory testing options at some future point.

Three, THE DARK REPORT has heard from multiple sources that corporate records have been shipped out of several Dynacare sites around the country. These are the types of documents that a buyer would need to review in performing due diligence prior to a final agreement to purchase. No one has said the buyer is LabCorp. However, there are reports of LabCorp employees in the field telling physicians that LabCorp is a likely buyer of Dynacare.

This combination of facts and rumors doesn't confirm that Dynacare is actually for sale or that LabCorp is the likely buyer. However, such rumors often have some factual basis that gets distorted as the rumors circulate. So it will not be a total surprise if, in the coming months, such an announcement was made by the two companies.

IMPATH SUSTAINS GROWTH, BUT ATTRACTS GREATER INVESTOR SCRUTINY

SUSTAINED GROWTH IN CASE VOLUME was reported by **IMPATH Inc.** in its first quarter financial earnings report.

The anatomic pathology company has carved out a growing piece of the market in cancer diagnostics. IMPATH reported that its case volume increased by 13% over same quarter last year. Lymphoma/leukemia and diagnostic tumor cases were the fastest growing segments, increasing 24% and 21%, respectively over the same quarter last year.

Its revenues were up 25% for the quarter, to $52.8 million. However, net income declined due to one-time charges related to the **Tamtron** acquisition *(see TDR, January 28, 2002)* and the discontinuance of certain acquired technologies. Besides IMPATH's continued double-digit growth in caseload, it also posted a 3% increase in revenue per case, which was $840 for the quarter.

In recent months, IMPATH's billing practices and financial reporting of accounts receivables have generated

much debate among professional investors. Not surprisingly, IMPATH devoted considerable attention in its earnings release to these matters. Its DSO was reported at 113 days. The company also predicted that DSO would fall to around 100 days by the end of 2002.

Of interest to pathologists is IMPATH's efforts to develop revenues from its cancer data base and tissue banking initiatives. IMPATH Predictive Oncology generated $6.8 million in revenues for the quarter, which was a 98% increase over same quarter last year. IMPATH announced that its data base now has "915,000 patient profiles and outcomes data on 2 million individuals."

Local pathology groups should note the extent of IMPATH's national client base. It now claims that 2,000 hospitals refer it cases, along with 570 oncology practices.

VISIBLE GENETICS SEES GROWTH IN SALES OF HIV GENOTYPING KITS

IT'S THE FIRST ROUND in the battle between FDA-approved test kits for HIV genotyping versus "home brew" tests offered by national labs.

Following FDA approval of its TRUEGENE HIV-1 Genetyping Test last fall, **Visible Genetics Inc.** reports steadily increasing demand. This is the first FDA-approved kit for HIV-1 genotyping to hit the diagnostic marketplace. Visible Genetics has signed agreements with selected laboratories it feels have the right resources to market the test to clinicians.

Visible Genetics reports that revenues climbed about 35% from fourth quarter to first quarter and expects sales to total about $3.7 million. It also said that March sales of the TRUEGENE test kits will total about 7,000 units.

In past issues, THE DARK REPORT has discussed the growing trend to "brand" diagnostic tests. One element of a branding strategy is to restrict the number of labs which can offer the test. This might cut smaller, local labs out of the distribution channel.

But another facet of the branding phenomenon is when national labs "brand" their home brew version and continue to offer it to clinicians, even after an FDA-approved test kit becomes available.

In the case of Visible Genetics' FDA-approved TRUGENE HIV-1 test, it is competing against home brew HIV genotyping tests offered by certain national labs. It will be an early opportunity to see what types of diagnostic test branding strategies work best in the clinical marketplace.

ABBOTT LABS CLOSER TO FDA COMPLIANCE IN DIAGNOSTICS DIVISION

IT WAS BIG NEWS when the FDA declared certain diagnostic manufacturing facilities at **Abbott Laboratories** to be out of compliance with Quality System Regulations in the fall of 1999.

The FDA required Abbott to cease selling more than 120 diagnostic tests, an action which took effect in early 2000. *(See TDR, November 22, 1999.)* Many lab customers were highly displeased over the situation, because of the disruption and expense caused by having to either convert to other test methodologies or bear the higher costs of sending those tests out.

In the past two years, Abbott has worked with the FDA to demonstrate compliance. In December, the most recent inspections were conducted by an FDA inspection team and the **Center for Biologics Evaluation and Research** (CBER). Abbott expects an answer sometime in April or May that it is in manufacturing and regulatory compliance. TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

Careside, Inc.'s point-of-care instruments for routine chemistry and hematology are moving into the clinical marketplace. *(See TDR, November 22, 1999.)* Through January, the company, based in Culver City, California, had placed 73 units, with another 17 on order. Careside's marketing strategy is to emphasize sales of these instruments to physician office settings rather than hospitals. It offers three products, the CARESIDE Analyzer, the H-2000 Hematogy Analyzer, and the CARESIDE Connect record management system which creates the electronic bridge to feed test results into the LIS or patient information system.

FDA CLEARS ORASURE'S UPLINK TEST SYSTEM

OraSure Technologies, Inc.'s UPlink™ test system for opiates was recently cleared by the FDA. This makes it the only point-of-care, oral fluid-based test for opiates to have FDA clearance. OraSure is developing a multiplex test system using UPlink technology.

STREP BACTERIA ACQUIRE RESISTANCE TO ANTIBIOTICS

First proof that Group A streptococcus is gaining resistance to common antibiotics was announced by researchers in a report published by the *New England Journal of Medicine* last week. In a study conducted at **Children's Hospital of Pittsburgh**, researchers discovered that lab tests were uncovering a strain of Group A streptococcus that was not killed by erythromycin. Pediatric patients with strep were successfully treated with penicillin or amoxicillin. According to Judith Martin, M.D., one of the researchers, in January 2001, about 15% of patients with strep had the resistant strain. This had increased to 18% by school years' end, in June 2001.

ADD TO: *Strep resistance*

Dr. Martin and her colleagues believe the erythromycin-resistant strep bacteria are not unique to Pittsburgh. She said it's likely that this strain will be found elsewhere in the United States. The discovery that certain strains of Group A streptococcus are resistant to erythromycin is considered important evidence that antibiotics are being overprescribed. One recommendation is that physicians begin testing for antibiotic-resistant strains by using throat swabs.

BREAKING NEWS!

James Peter, M.D., Ph.D. Steps Down at Specialty

As this issue of THE DARK REPORT went to press, **Specialty Laboratories, Inc.** announced on April 22nd that James B. Peter, M.D., Ph.D. was stepping down as Chairman and Chief Executive Officer. Existing Board Members Thomas R. Testman will become Chairman and Douglas S. Harrington, M.D. will become interim CEO. In a telephone conversation with THE DARK REPORT, Dr. Peter paraphrased Harry Truman by saying that "the buck stopped with him." He also noted that Specialty Laboratories was moving expeditiously to resolve its issues with lab regulators and was devoting major resources to maintain the integrity and quality of its lab testing.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 13, 2002.

PREVIEW #8

EXECUTIVE WAR COLLEGE

May 7-8, 2002 • Astor Crowne Plaza Hotel • New Orleans

Topic: Why The Digital Health Record Is Changing How Docs Use Clinical Labs

As vendors develop systems to help physicians practice medicine in a "paperless" environment, they implement their own solutions for electronic test ordering and results reporting. Here's an inside look at how MedicaLogic's clinical management systems are changing physician's practice habits, including how they order tests and view results.

Full program details available—call 800.560.6363
or visit darkreport.com

UPCOMING...

- ***Linking Labs with LOINC: Real World Stories What Works—and What Doesn't.***
- ***Malpractice Insurance Premiums Soaring for Pathology and Clin Labs.***
- ***An Inside Look at New Business Models For Anatomic Pathology Services.***

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