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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Growth Conundrum Confronts Quest and LabCorp

AFTER MORE THAN TWO DECADES of buying up almost every attractive laboratory asset that came up for sale—and with few lab acquisition candidates left to buy—**Laboratory Corporation of America** and **Quest Diagnostics Incorporated** find themselves in an interesting conundrum. As public companies, any increase in the value of their shares is directly linked to growth rates in specimen volume, revenue, and net profit.

On the other hand, simply because of their huge size relative to the laboratory services marketplace, the ability of the two blood brothers to achieve sustained rates of growth of 10% and 15% per year is a major challenge. Let me explain why the numbers work against them.

By year's end, Quest Diagnostics will post revenue of around $7.7 billion. Revenue at LabCorp will be in the range of $4.5 billion. Thus, for each lab company to grow revenue by 10% during 2009, Quest will require $770 million in new business and LabCorp will require $450 million. That's the need for $1.2 billion in new business between them, and in just one year!

Thus, as you will read on pages 10-16 in this issue, each of the national lab companies have multiple strategies to generate new specimens, more revenue, and greater net profits. The days of rapid growth in revenue and net profits because of acquisitions and conversion of conventional Pap smear business to thin-layer Pap tests are long past. Both national labs must successfully execute a series of business growth initiatives to generate additional revenues and increased net profit in today's competitive lab marketplace.

This is why the laboratory services marketplace has seemed rather quiet over the past year. The two national laboratories are adjusting to a market where growth-by-acquisition is no longer the primary strategy to achieve increased revenue and net profit. Now each company must craft a long-term business plan to deliver sustained growth that satisfies investors.

That is why the conversation is shifting at both LabCorp and Quest Diagnostics to new opportunities in genetic and molecular testing. It is why there are plans to serve the developing wellness and prevention emphasis in healthcare. That brings employers onto the radar screen as potential customers. And, I predict that Quest Diagnostics and LabCorp will steadily increase their presence and activity in other countries. LabCorp's new agreement in Abu Dhabi is one example of this. *(See Page 18.)*

TDR

Medi-Cal Hits Pathologist For $6.4 Million Payment

Failing to find records at two closed labs, administrative judge pins penalty on pathologist

CEO SUMMARY: Once again, government health bureaucrats are overreaching in their efforts to reduce spending and collect money from any source. A California pathologist has been hit with a Medi-Cal demand for $6.4 million in repayments, simply because he served as laboratory director for two lab companies that Medi-Cal knew had closed before auditors requested records. Without a successful legal challenge to this Medi-Cal position, a dangerous precedent may be set.

FOLLOWING AN AUDIT OF MEDICAID CLAIMS submitted by two now-defunct independent lab companies, California Medi-Cal officials took the unprecedented step of making the pathologist who served as laboratory director for these two labs personally responsible to repay alleged overpayments of $6.4 million.

Medi-Cal auditors concede that the laboratories—not the pathologist—received the payments. But Medi-Cal contends that the pathologist should be responsible to repay millions simply because he served as the lab director during the audit period.

This case has several troubling ramifications for pathologists, both in California and nationally. First, if an administrative law judge's recent ruling is allowed to stand, California's Medi-Cal program has a legal precedent that defines a laboratory medical director as a "provider." Under Medi-Cal rules, a "provider" incurs a host of legal liabilities beyond the customary lab director role of testing oversight. Currently, laboratory directors are not required to enroll in Medi-Cal or sign any agreement to participate as a provider.

Second, because Medi-Cal is part of the federal Medicaid program, precedents established in this matter may inspire Medicaid officials in other states to similarly pursue pathologists serving only as laboratory medical directors. This would make them personally responsible for repayment of overpayments, penalties, and similar regulatory violations.

"Clearly, this ruling will affect other physicians who serve as pathologists for laboratories and potentially other physicians who serve in director roles for other licensed facilities," stated attorney Dawn A. Brewer, of Beverly Hills, California. Brewer represents

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

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the pathologist in this case. "Physicians will be less likely to serve in these capacities, or will serve under different arrangements, if they will be subject to personal liability for funds they do not personally receive."

The facts are straightforward. Two laboratories based in Los Angeles—**Clinical Technical Laboratory** (CTL) and **Goodwill Diagnostic Laboratory** (GDL) operated as corporations. During 1999, both laboratories were issued Laboratory Registration Certificates by CMS (then HCFA), along with Medi-Cal provider numbers and CLIA compliance certificates. These licenses and certifications listed pathologist Kazuo Yamazaki, M.D., as laboratory director. The certificates also listed the owners of the corporations.

Lab Firms Close in 2002

Between 1999 and January 2, 2002, both laboratories made claims to, and received payment from, the Medi-Cal program under their tax identification numbers. Yamazaki never billed the Medi-Cal program and never received payment from the Medi-Cal program. In early 2002, each lab received sanctions leading to revocation of the CLIA certificates. Each lab ultimately ceased testing.

Months after both lab companies ceased operations, the state Controller's Office (SCO) initiated an audit of each lab's payments from Medi-Cal. Auditors initiated a review of the laboratories even though the SCO knew that both lab companies had closed and gone out of business. The SCO findings for both laboratories reflect that "the telephone number listed was no longer in service" and "no business was in operation at the service address on file."

"In neither audit was the SCO able to obtain any records to substantiate the billings by Goodwill or Clinical for the respective audit periods," court records show. "On March 31, 2003, and April 3, 2003, the Department issued notices of alleged overpayments to the aforementioned laboratories seeking repayment of monies. Timely appeals were filed on April 29, 2003, for each facility."

"Ultimately, auditors concluded that they had no records to review so they had to conclude that all the monies paid to these corporations should be repaid," wrote Brewer in a letter to the **California Clinical Laboratory Association** (CCLA). "The auditors issued their findings, based upon a Medi-Cal *provider's* [TDR emphasis] regulatory obligation to keep and make available records to support claims."

Brewer next wrote, "Auditors testified that, after they had concluded their work, someone in the Department's Office of Legal Services informed them that Business & Professions Code Section 1265 would render Dr. Yamazaki jointly and severally responsible to repay Medi-Cal for the overpayments to the corporations. Despite this, auditors did not include any such authority in their demands and neither did the Department."

Here is the nub of this case. Without any attempt to find the owners of the closed laboratories, auditors contacted Yamazaki as the laboratories' director because his address is listed with the Medical Board of California. Although Yamazaki explained that he had long since resigned from the laboratories and had no records of the laboratories' Medi-Cal claims or payments, Medi-Cal officials applied an unusual and aggressive interpretation of a state statute to render Yamazaki personally responsible to keep and maintain the laboratories' Medi-Cal records, although he had no continuing relationship with the laboratories and the businesses had closed.

Lab Director As "Provider"

When challenged on why or how a lab director could possibly maintain records he did not own or control, much of which would be in the laboratories' electronic information systems, Medi-Cal officials testified that a "laboratory director" could be considered a "provider" under Medi-Cal. Thus, under the law, Medi-Cal providers are

required to keep and make such records available. Having made this attenuated leap of logic, auditors then decided that Yamazaki, as the Laboratory Director for both lab companies, was thus personally responsible for the $6,372,492 that Medi-Cal seeks to recover.

Trial Scheduled for February

Following Yamazaki's original appeals in 2003, the case slowly worked its way through the system. In October, 2006, Administrative Law Judge Michael A. D'Onofrio of the California Department of Health Services ordered Yamazaki to pay the $6.37 million. This summer, D'Onofrio denied Yamazaki's appeal of the October 2006 decision. Following this ruling, Yamazaki filed suit. His case is pending and is scheduled to be heard on February 27, 2009, in the Sacramento County Superior Court.

"This is an overpayment matter," said Brewer. "Medi-Cal wants to be repaid what it determined was overpaid to the laboratories. The State concedes that Yamazaki never received any payments. But the State insists that the laws that require Yamazaki's name to be on the labs' licenses also require him to repay overpayments made to the laboratories. No laboratory director who agrees to serve in this medical and scientific role has an understanding that he or she may be personally responsible for overpayments to the laboratory. We cannot imagine why a pathologist would agree to serve as a laboratory director in the future if this ruling stands."

Sweeping Definition

"The State's sweeping interpretation of a "provider" could include anyone who works for a provider," Brewer explained. "Under the finding of the administrative law judge, anyone serving as an officer or a director of a corporation can be considered as a provider. Of course, Yamazaki was neither an officer nor a director for these corporate laboratories. The Department's interpretation of who is a provider includes anyone who might have some responsibilities for day to day operations of the provider. This reach goes much further and could include everyone from the receptionists and billers to administrators, accountants and attorneys as 'managing employees and agents of the provider.' That's very far out there.

"It's one thing to say that Medi-Cal wants those involved in an operation to comply with Medi-Cal standards for eligibility to serve beneficiaries and Medi-Cal standards for the quality of services. It's quite another thing to say that the individuals who work for a provider are financially responsible for the provider's overpayment. This is especially true where the provider must enroll under a written agreement with Medi-Cal but most employees never see the agreement—much less sign such an agreement."

Friend Of The Court Briefs

This intelligence briefing in THE DARK REPORT is the first published news about Yamazaki's battles against California's Medi-Cal program. Dawn Brewer, his attorney, is seeking support for Yamazaki. She has asked the California Clinical Laboratory Association, the **California Association of Pathologists**, and the **California Medical Association** to consider filing *amicus curiae* (friend of the court) briefs in the case.

What makes this case worth watching is not just the novel legal theory by Medi-Cal auditors that a pathologist laboratory director is also a "provider," thereby opening the door to new legal claims that could have chilling effect on the willingness of pathologist to serve patients in the Medi-Cal program. But there is the unanswered question as to why auditors—and the State Attorney—did not more vigorously look for the owner of record for the two lab companies in question. That is the individual with unquestioned legal responsibility...and also the person who got the money! TDR

Contact Dawn A. Brewer at 310-442-9530 or Dawn@DBrewerlaw.com.

Cytology Lab Uses Lean to Simplify Processes

First Lean project improves staff productivity while cutting 132 work steps in histology to just 82

CEO SUMMARY: Like many labs today, the gynecologic cytology laboratory at the University of Iowa Hospitals and Clinics had a pre- and post-analytical work flow with many complex steps. This work flow—heavily influenced by a legacy of previous information systems—was inefficient, contained unnecessary redundancies, and lacked systematic measures for preventing errors. That all changed when the Department of Pathology did its first Lean project, greatly improving work flow and staff productivity.

IN RECENT YEARS, LAB MANAGEMENT at the **University of Iowa Hospitals and Clinics** in Iowa City, Iowa, became suspicious that work processes within the cytology laboratory were less than optimally efficient. Management had confidence in the competence and capabilities of the entire laboratory staff, but discussions about the pre-analytical and post-analytical phases of the workflow always seemed to lack a solid, consensus understanding.

Efforts to modify workflow proved frustrating because the myriad of steps were not well understood. Management wanted to understand why seemingly simple changes could not be implemented easily. Frontline staff wanted management to see and understand the full picture. The lack of a consensus understanding was creating tensions, and, despite the best intentions to improve processes, the same pre-analytical and post-analytical processes remained in place. However, that all changed this spring when, for the first time, staff in the Department of Pathology applied Lean methods to streamline, simplify, and improve each step from specimen receipt to billing.

"The results were remarkable!" noted Kent Becker, MT, CLS, Anatomic Pathology Coordinator, who led the Lean team on this process improvement project. "We were able to slash the number of decisions required in pre-accessioning and technical and professional billing by 37%, from 49 to 31. At the same time, we eliminated 41% of the work flow steps required in these areas. We reduced the total number of process steps from 138 down to 82."

Steps to Improvement

These achievements were so impressive that, when the University of Iowa Department of Pathology presented its Lean strategy as a poster at the *Lab Quality Confab* in Atlanta last month, judges awarded it First Place in the anatomic pathology category. Along with this recognition came an award check of $2,000.

"This was our first Lean project," recalled Becker. "We studied work processes involved in gynecologic specimen receipt and accessioning. We transformed the process from a batch-and-queue workflow to single piece flow. We also eliminated

process constraints and put in a systematic way to reduce labeling errors. Following implementation of the new work processes, staff has flexibility in managing the workflow—rather than having to wait almost two hours for the flow of specimens to reach their workstations."

The team also identified and eliminated inefficiencies in billing processes. Today, the previously complex processes are well understood and well documented, allowing the 18,000 cytopathology specimens the lab processes each year to move through smoothly and efficiently.

Needless Complexity

The story is particularly useful for any lab manager who may have inherited complex processes that have been resistant to improvement. These are legacy processes that commonly are rationalized by the phrase, "that's just the way we've always done it." In addition to Becker, the Lean team included Operations Manager Jeanne Myers, Financial Officer Rose Meyer, Cytotechnologist Chad Hoffman, Clerk Typist Cheryl Lown, and Laboratory Technician Tanika Moreland.

The problem for this team was that, prior to the Lean project, no one person in the cytopathology lab at the 680-bed UI Hospitals and Clinics, an academic medical center in Iowa City, could fully explain the rationale for the existing pre- and post-analytical processes.

"We didn't completely understand why we had all these steps from pre-accessioning through billing," Becker explained. "After so many years of doing these steps, staff accepted this situation as 'the way we've always done it.' There was no documentation from the people who created these work steps to explain their purpose. Over the years, people had moved on, but the work processes they established remained. Existing lab staff followed those same processes simply because they always had.

"It was needlessly cumbersome and frustrating," he said. "At times, even talking about it was frustrating because the staff that performed it everyday couldn't always explain it sufficiently. In the past, we had managers who tried to understand it but could never grasp the full scope of the process to make good decisions about how to fix it.

"When the Lean team was formed, we decided that the way to start was to do a full-blown process analysis," continued Becker. "So, the team developed detailed process maps to identify all the steps in the processes and to assess for deviations from Lean principles, sources of waste, and process steps that created defects.

"Using sticky notes and a dry-erase board, the team identified every step in the pre- and post-analytical processes," he said. "Then, we converted the notes from the dry-erase board to formalized electronic process maps. The process mapping proved to be a key analysis tool because it facilitated a consensus understanding and a thorough assessment of the 'as is' process. This analysis unraveled and documented a complicated workflow, allowing us to see why the situation created frustration.

The Need to Ask Why

"Once we had the process written out on paper, we used the 5-Whys tool to ask ourselves this question over and over: 'Why do we do it this way?' Everything about our processes revolved around batching our specimens," he explained. "We had to drill down into the reasoning. The 5-Whys tool requires that you keep asking 'why?' about every step until it becomes absurd to ask anymore. You can't ask why only once. If you do, you get only a surface reasoning. You have to keep asking 'why?' until you get into the real rationale behind what you're doing. It's almost annoying for some. But when used appropriately, it's helpful and revealing.

"You can't begin to change a workflow before you fully understand its 'why?'," he said. "Without that understanding, potential changes could actually worsen the existing situation. It is imperative to know which work flow steps add value and which do not.

Lean Project Dramatically Reduces Number Of Processing Steps in Cytology Laboratory

USE OF LEAN METHODS ALLOWED THE TEAM at the University of Iowa's Department of Pathology to dramatically reduce the number of discrete work steps required to process specimens in the cytology laboratory. They eliminated 41% of the original 138 work steps.

Gynecologic Cytology Laboratory Process Improvement

(This table identifies where the Lean project was able to reduce the number of individual work steps required in the pre-Lean cytology laboratory work flow.)

Process	Before		After		% Reduction		
	Decision	Action	Decision	Action	Decision	Action	Overall
Pre-accessioning	11	37	3	5	-73%	-86%	-83%
Accessioning	23	70	22	55	-4%	-21%	-17%
Technical Billing	4	6	1	3	-75%	-50%	-60%
Professional Billing	11	25	5	19	-55%	-24%	-33%
Totals	**49**	**138**	**31**	**82**	**-37%**	**-41%**	**-40%**

Source: Department of Pathology, University of Iowa Hospitals and Clinics, Iowa City, 2008.

Below are listed some of the important changes in work flow at the cytology laboratory at the University of Iowa's Department of Pathology that resulted from applying Lean methods.

Summary of Process Improvement Results

Before		After
Specimens accessioned in batches.	→	Single piece flow.
Push system creates excess supply of pre-produced labels enables labeling errors.	→	Pull system allows labels to be printed by LIS on demand when the accessioning number is assigned, meaning no excess supply of preprinted accessing numbers.
Work lists produced in excess and before they were needed.	→	Worklists are produced just before use.
Specimens were pre-labeled with accessioning number before accessioning, unconnected to accessioning number assignment.	→	Labeling occurs immediately after the LIS assigns the accessing number, reducing labeling errors.
No patient identifiers on accessioning number labels.	→	Labels include accessing number and patient identifiers.
Labeling was inconsistent among workstations.	→	Labeling is standardized among workstations.
Specimens accessioned at outreach workstation need to be re-labeled in Cytopathology.	→	No re-labeling or rework, removing the chance of labeling error.
Bottlenecks and delays because workstations could not accession concurrently.	→	Concurrent accessioning enabled, alleviating bottlenecks and delays.
Workflow management was inflexible, imposing limitations at the start and end of each day.	→	Removing constraints on workflow, makes production flexible and means accessioning can occur throughout the day, every day.

Source: Department of Pathology, University of Iowa Hospitals and Clinics, Iowa City, 2008.

"Once we had that information, we could identify each process step as either adding value or simply waste," he observed. "That meant we knew the value-added steps to keep while eliminating the ones that didn't add value.

"Each part of the process analysis allowed us to see the peaks and valleys in production," Becker continued. "We didn't want anything waiting in queue or have any specimens set aside in batches. In Lean, batching is inefficient because it prevents a continuous flow in the system. It introduces spikes in production processes and your work backs up. Then, the next process inherits that pent-up supply. For the sake of the downstream processes, we aimed for a continuous flow.

"To eliminate spikes, we investigated and measured the specimens held in waiting," he said. "We looked at time stamps on requisitions to know how long they were delayed from receipt until accessioning. We found that—even though we had staff ready to start work at 8 a.m.—each day staff had to wait for up to two hours before they were processing specimens.

"The process mapping showed that staff couldn't do certain parts of their work until 9:20 a.m or 9:56 a.m. each morning," stated Becker. "That meant that even though the area was staffed for eight hours of capacity each day, they were, in reality, constrained to about 5.5 hours of time they could devote to these processes. The staff was known to be productive in the meantime and the work was getting done, but the current process limited the lab's ability to 'flex' its production across that full eight hours or to adapt whenever unexpected increases in volume occurred.

Challenging But Rewarding

"Once our Lean team identified all the places where we could eliminate waste, we redesigned the process on paper and then did feasibility trials to see how it would work through trial and error," Becker continued. "The new processes came close to working right away. The diverse representation and talents of the team members were key because feasibility was essentially "baked-in". We did make minor adjustments here and there, such as how and when we applied labels. Even though we made minor tweaks, there was no option to revert to the old way.

Adding Value

"From all of this, we learned that a process-focused, employee-involved approach to operational management can effectively identify and address problems and inefficiencies in lab workflows," Becker concluded. "The application of Lean principles effectively reduced waste within the laboratory's processes. It is proof that manufacturing-based quality improvement methods can be used to improve operational efficiency and effectiveness in a clinical lab.

"In addition, these process changes have yielded opportunities for improvements in related processes," he said. "The team from this project has made recommendations for other process improvements in the laboratory, creating momentum for continuous improvements throughout the laboratory.

"Overall, this was a challenging but rewarding Lean project that showed the value of applying quality improvement methods from manufacturing to the lab," he said. "Also, it helped us to close the gap between the frontline personnel and the operational management people.

"What was more rewarding than actually tweaking processes was proving that these things work," added Becker. "Now we have a new management approach and a new set of operational tools that we can apply to other processes. As an institution, we are in our Lean infancy. But this project gave Lean credibility with our staff, and there is enthusiasm and interest for us to apply Lean in various other areas or our laboratory in the future." TDR

Contact Kent Becker, MT, CLS, at 319-356-4431 or kent-becker@uiowa.edu.

Similar Strategies—Achieved by Different Tactics

LabCorp And Quest Report 3rd Quarter Financial Performance

CEO Summary: In third quarter earnings reports, both national lab companies posted modest gains in specimen volume, revenue, and net profit. More telling is the relative quiet in the current market for lab testing services. With no obvious opportunities to fuel double-digit rates of growth, the two blood brothers are pushing forward with similar business strategies. However, each lab company is pursuing those strategies with uniquely different tactics and emphasis. Here's an in-depth comparison of events unfolding with Quest Diagnostics and LabCorp.

IT'S BEEN TWO YEARS SINCE ANYTHING as dramatic and disruptive as the 10-year exclusive national contract between **Laboratory Corporation of America** and **UnitedHealth** has shaken the laboratory testing marketplace. *(See TDR, October 16, 2006.)*

As the consequences of this development rippled across the lab testing industry, there were new threats and opportunities for independent labs and hospital laboratory outreach programs. That made 2007 a busy and interesting year. By contrast, 2008 has lacked that level of drama and disruption. With things relatively quiet, it seemed like a good time to check on the two blood brothers and see what business strategies each lab is pursuing. Because of sheer size, the actions taken by either company can have consequences to almost all laboratory testing providers in this country.

Last month, **Quest Diagnostics Incorporated** and LabCorp each announced financial performance for the third quarter. Confirming the rather quiet state of the current laboratory testing marketplace, neither earnings announcement contained news of dramatic improvement in specimen volume, revenue, or net profit.

At Quest Diagnostics, revenue was up 3.4%, to $1.8 billion. Net income for Quest grew by 13%, from $98 million in Q3-07 to $110.8 for Q3-08.

LabCorp experienced faster revenue growth. Its $1.1 billion in revenue represented an 11.2% gain. By contrast, net earnings were flat. Its $111.9 million in net earnings for Q3-08 was up just 0.6% from net earnings of $111.2 in Q3-07.

During conference calls with analysts, both companies discussed the state of their respective businesses. These comments provide useful information about the laboratory testing marketplace, along with insights into their different business strategies. Not only do the overall comments by executives of the two lab testing companies indicate a relatively quiet time in the laboratory marketplace, but each company is pursuing similar strategies—while using different tactics—to increase revenue and improve net profit.

➤ Fast-Growth Areas Of Testing

Quest Diagnostics stressed five specific strategies or growth opportunities during its earnings call. First was to call attention to its fastest growing areas of testing. "Gene-based and esoteric testing revenues grew by almost 10% during the quarter," noted Surya N. Mohapatra, Chairman, President, and Chief Executive Officer at Quest Diagnostics. "Testing volume for Vitamin D, testosterone, *chlamydia*, *gonorrhea*, and HPV all grew at double digit rates."

Mohapatra also mentioned that areas of routine testing with strong growth included food allergy testing and non-food allergy testing, up 25% and 20% respectively. Testing for celiac disease increased by 25%, and orders for the its branded colorectal screening test were up 15%.

The second strategy targets healthcare's shift from acute care to emphasizing wellness, prevention, and early detection. "As you have heard me say before, as we enter the decade of diagnostics, healthcare is moving from a focus solely on curative care to a recognition of the value of detection, prevention, and personalized care," he said. "Consider our collaborations to drive awareness of the value of early detection of colorectal cancer. To date, payers including **Aetna**, **Cigna**, **Independence Blue Cross**, and the State of Tennessee, have given hundreds of thousands of our convenient InSure tests to their members, employees, and residents."

That wellness theme continued in a discussion of Quest's initiatives in employer health and wellness programs. Mentioned by name were **Domino's Pizza**, **Jeld-Wen**, and the Houston Independent School District. It was noted that the **Google Health** relationship was being expanded by allowing Google Health users to order, on their own, a limited menu of laboratory tests.

"We think wellness is a great opportunity," explained Mohapatra. "We have built up a business line called Blueprint for Wellness... Going forward, you will see us focus on this area... I consider wellness testing as important as illness testing."

Overseas Lab Revenue

Next came the third business strategy. Quest Diagnostics has big expectations for revenue growth from its overseas laboratory operations, particularly in India. "In the next three to five years, we expect enormous growth from India, which has a middle class of 300 million people," observed Mohapatra. "We have built a state-of the art laboratory and expect to develop business, not just from physicians and hospitals, but also from pharma companies for clinical trials and from life insurers."

The fourth strategy centers around opportunities in hospital laboratory testing. Of particular interest to hospital laboratory directors were statements about Quest Diagnostics' hopes for increasing its presence in the hospital lab testing segment. "I have had discussions with many hospitals which would like to have somebody manage their laboratories with high quality tests," said Mohapatra. "Then they don't have to spend extra capital to update their laboratories. We see that, going forward, we will work with hospitals to manage their labs and also to update their labs."

Hospital Lab opportunities

In answering an analyst question on this point, Mohapatra noted that "I'm talking about doing high quality, innovative tests for hospitals—which we are very well positioned to do, either by managing their laboratories or providing them tests because we have the volume and the expertise... with our strength in the hospital business, I look forward to deeper market share...and gaining more presence in the hospital market."

Mohapatra also had some specific views about hospital laboratory outreach programs and their limitations as competitors. "As far as the outreach business is concerned, I think there will be 10 or 12 outreach businesses, but once you go above a certain region and above certain dollars [revenue], an outreach laboratory has the same costs as everyone else. It must have managed care contracts, logistics, billing. What we have seen over the past 18 months is a number of outreach laboratories for sale."

The fifth business theme discussed was improving operations and eliminating costs. "Our cost reduction program, announced last year, is on track to reduce our cost structure by $500 million," noted Mohapatra. "We expect to have delivered $300 million in annualized savings as we exit this year, with the balance in 2009.

"Mohapatra noted that "I'm talking about doing high quality, innovative tests for hospitals—which we are very well positioned to do, either by managing their laboratories or providing them tests..."

"Last quarter, I outlined the major elements for our program, which include using Lean Six Sigma to increase productivity in our labs," he continued. "Driving more of our purchasing through master contracts to take advantage of our scale. Better alignment of our service capacity with patient and sample flows. Optimizing logistics routes and using more fuel efficient vehicles. And deploying enhanced connectivity to our customers, patients, and service centers to reduce specimen data entry, improve billing, and lower our bad debt."

During the Quest conference call, two other aspects of the laboratory market were discussed. One involved managed care pricing and the other was bad debt trends from the patient-pay segment.

Quest Diagnostics has not seen strong downward pressure on pricing by managed care companies this year. However, it has felt the effects of contract pricing negotiated during the previous 24 months. "...At the beginning of the year, some of the price concessions that we made last year—when we renegotiated managed care contracts—kicked in," said Robert A. Hagemann, Quest's Chief Financial Officer. "And that's certainly been one of the things that put downward pressure on the margins this year, which are being offset by some of the cost reduction programs. Pricing is much more stable than it was a year ago because all of those contracts were negotiated for multi-year periods."

Patients Paying Lab Bills

When asked about bad debt related to patient self-pay, Quest's Chief Financial Officer, Robert A. Hagemann answered, "[Self-pay revenue is] between 5% and 6% of our total revenues. It has not changed dramatically... and that's mostly uninsured that we classify as self-pay. Embedded in our third party [segment] is the portion associated with [patient] deductibles and co-pays, which is about equal to that amount. So, in total, there is probably 10% of 12% of our revenues that we collect from patients and that has not changed dramatically."

At LabCorp, the strategic business priorities are similar in nature to the five elements discussed by Quest Diagnostics. But LabCorp has a different focus and market execution, as indicated in the assessment which follows.

During its third quarter earnings call, LabCorp executives stressed the company's drive to expand the volume of esoteric testing, currently at 35%, to 40% of the company's revenues. That strategy is part of a more comprehensive effort to position LabCorp as a player in healthcare's shift from acute care to early detection and wellness."

That strategy is centered around personalized medicine. "Many of you have heard me say I believe healthcare will always be physician-centric, but that increasingly patients will expect and require treatment based on their specific personal characteristics, including their genetic makeup," stated David P. King, LabCorp President and CEO. "...the three drivers that will move us forward for personalized medicine are esoteric testing, our outcome improvement programs, and companion diagnostics."

As the first primary growth driver, "our goal is to increase esoteric testing to 40% of our revenues in the next three to five years," he continued. "...We will continue to introduce new esoteric tests to respond to scientific discoveries, such as the importance of the K-ras gene for colorectal cancer drug selection, to improve patient care and outcomes, and to satisfy unmet medical needs."

LabCorp's second growth driver strategy is to expand its testing presence in outcome improvement programs. The current push is in the area of chronic kidney disease (CKD). Some 26 million Americans suffer from CKD and it is the ninth leading cause of death in the United States. Also, because these patients have a chronic condition, testing to support management of each patient's disease will be regularly performed for years.

Double-Digit Growth

In November 2006, LabCorp acquired **Litholink Corporation**, a laboratory specializing in kidney stone analysis. LabCorp has broadened Litholink's products and services for CKD. "The Litholink program for kidney stone management has been extremely well received, and we are seeing double-digit revenue growth, uniform acceptance from payers, and premium reimbursement," stated King.

"Litholink's CKD program focuses on identification of patients who have reduced or deteriorating kidney function," he continued. "Through collaboration with local nephrology groups, we focus on

educating primary care physicians about the importance of identifying CKD through laboratory testing of EGFR, albumin, parathyroid hormone, and other accepted measures of kidney function. Our sophisticated report, developed with input from an international panel of CKD experts, guides the physician on how to use appropriate medication, dietary modifications, and procedures to slow the process of the disease and prevent further damage to the kidneys."

Positive Physician Reaction

According to King, physician reaction to this specialized lab testing has been "enthusiastic." He stated that LabCorp now has several nephrology groups doing collaborative outreach with LabCorp to help primary care physicians identify patients with diminished kidney function and to launch appropriate care.

Some payers have also responded favorably. "One of our managed care partners has assigned internal resources to assist us in physician and patient recruitment," noted King, "Furthermore, the Medicare Improvements for Patients and Providers Act of 2008 instructed CMS to establish demonstration projects to improve the treatment of CKD in the Medicare population. We are working to have our CKD outcome improvement program qualified for this important CMS and Medicare demonstration project."

Companion Diagnostics

The third growth driver discussed was companion diagnostics. To position itself in this market, in December 2007, LabCorp acquired **Tandem Labs**, a contract research organization (CRO) headquartered in Salt Lake City, Utah. As King explained, "Our clinical trial division continues to help pharmaceutical companies develop diagnostic tests that provide guidance on administering the proper dose of the proper drug to the proper patient at the proper time. Our Tandem division is a leader in biomarker discovery, and is seeing strong growth year-over-year as pharmaceutical companies seek markers to assess drug safety and efficacy."

King then addressed a market development that has major positive implications for the entire clinical laboratory industry. "Drug repositioning has emerged as a corporate strategy with companies such as **ARCA Biopharma** and **Vanda Pharmaceuticals**," noted King, "[They are] focused on in-licensing existing compounds that have not performed well in broad trials, then developing tests to target patient populations in whom the drugs are effective. We have entered into relationships with both of these companies to develop companion diagnostics, and are excited about these and other opportunities in this rapidly-growing field."

Growing Acceptance

Another sign that the concept of companion diagnostics is gaining traction within the healthcare system is the relationship that LabCorp is developing with **Medco Health Solutions, Inc.**, a pharmacy benefit manager. LabCorp is collaborating with Medco on Tamoxifen and Warfarin. "A significant number of employers who secure their pharmacy benefit management from Medco have enrolled in this innovative program," declared King, "which provides specific lab testing to assess the safety and efficacy of these drugs prior to dispensing them to patients."

Like Quest Diagnostics, LabCorp does not see strong downward pressures on pricing with its managed care contracts at this time. In answer to an analyst's question, King noted that most price reductions realized in last year's contracts have had their effect. "Also positive, we are contractually going to receive escalators from a couple of the contracts that we renegotiated at the beginning of 2008," he commented. "....We are cautiously optimistic we are not going to see the kind of pricing reset that we saw in 2007. So generally I

Two Blood Brothers Share Similar Views Of Current Laboratory Testing Marketplace

DURING EACH LABORATORY COMPANY'S THIRD QUARTER EARNINGS CALL WITH ANALYSTS, executives at Quest Diagnostics Incorporated and Laboratory Corporation of America discussed their respective company's strategies to support growth in specimen volume, revenue, and net profit. This table demonstrates the similar strategies of the two firms, while highlighting the different tactics and programs each is pursuing to realize corporate goals and objectives.

COMPARING BUSINESS STRATEGIES AND TACTICS

STRATEGY: Expand Volume in Higher-Value Reference and Esoteric Testing

How at Quest: *Develop gene-based and esoteric testing and educate clinicians in their use. Revenues from these tests are up 10% for the quarter.*

How at LabCorp: *On-going program to grow esoteric testing to 40% of test volume (currently at 35%). Work with academic collaborators like **Yale** and **Duke** to identify, validate, and bring new assays to market.*

STRATEGY: Emphasis on Wellness, Early Detection, and Preventive Care

How at Quest: *Work with payers such as Aetna and Cigna, to encourage colon cancer screening and similar testing programs. Offer health and wellness programs to employers with "Blueprint for Wellness". Develop Google Health relationship.*

How at LabCorp: *Litholink acquisition anchors major market effort to expand testing for chronic kidney disease (CKD). Create programs to support personalized medicine. Program with MedCo on Tamoxifin and Warfarin to test and screen patients for safety and efficacy.*

STRATEGY: Opportunities to Expand Presence in Hospital Lab Testing

How at Quest: *By providing tests and/or managing hospital labs in ways that reduce the need for a hospital to invest capital in its laboratory.*

How at LabCorp: *Continue to identify opportunities for acquisition of hospital laboratory outreach testing programs.*

STRATEGY: Emphasis on Operational Improvement and Cost Reduction

How at Quest: *Reduce cost structure by $500 million by the end of 2009. Use Lean and Six Sigma to drive productivity and service improvement.*

How at LabCorp: *Pursue the LabCorp 2010 Initiative "to drive service quality and operational improvements." One step is to close Herndon, Virginia, lab facility by year's end.*

STRATEGY: Grow Revenue from Overseas Sources

How at Quest: *Expand existing laboratory businesses in Mexico, United Kingdom, and India. India is considered Quest's best revenue growth opportunity of the three.*

How at LabCorp: *Not discussed on the conference call. LabCorp's Dynacare lab business in Canada has limited revenue growth potential.*

would agree with the comment that [managed care contract] pricing seems to have stabilized, and we should see some real price improvement in 2009."

Along with pricing for managed care contracts came a discussion of how aggressive payers had become about controlling leakage. "I think there has been increased focus on it [reducing out-of-network lab testing] among our managed care partners," said King. "On the other hand, ...managed care has had a lot on its plate this year, so increased focus has not necessarily led to increased activity. But in general, we do see a strong desire from our managed care partners to move out-of-network business into a network. And even to move in-network business from higher-cost [lab] providers to lower-cost providers."

➤LabCorp 2010 Initiative

Cutting costs is a constant theme with the two national labs and LabCorp has told Wall Street about its LabCorp 2010 Initiative, which King described as "a comprehensive plan to drive service quality and operational improvements, and to optimize our growth platform." One cost control measure is to close the LabCorp laboratory in Herndon, Virginia, by year's end.

LabCorp is also watching bad debt from patients, because of enrollment growth in high-deductible health plans (HDHPs). During the conference call, LabCorp executives estimated that patient pay represented about 17% of revenue (including uninsured, self-pay, deductible, co-pay, and out-of-pocket sources).

This side-by-side look at the strategies and specific business initiatives under way at LabCorp and Quest Diagnostics demonstrates the similarities in how both companies view the current lab testing marketplace. With no obvious opportunities for a "big-hit" business strategy, each laboratory seems focused on improving its day-to-day performance and the services it offers to its customers. TDR

Sales Force Targeted To Support Objectives

WITH FEWER LAB ACQUISITION OPPORTUNITIES available to support revenue growth, the national labs are turning more attention to using their respective sales forces to achieve corporate growth targets.

During the recent call with analysts, LabCorp Chairman and CEO David King noted that his lab company was using its sales force to help offset the impact of any declines in patient visits to client physicians. "We have a sales force that we can direct to customers and specialties where we think they are going to see less impact from patients not coming to the doctor," he stated.

King also discussed how LabCorp could target its sales force. He noted that LabCorp can provide its sales team with information about which doctors are likely to see chronically ill patients (and thus likely to be a heavier user of laboratory testing), as well as what types of esoteric tests will be of highest interest in such specialties as oncology, endocrinology, and rheumatology.

This indicates that LabCorp is developing its capabilities in database marketing. Outside of healthcare, a number of Fortune 1000 corporations have been quite effective at using database marketing to improve the productivity and sales performance of their sales teams. When used effectively, database marketing can allow a company to significantly increase the revenue generated by its existing customers.

Lab Briefs

MASSACHUSETTS LAW MANDATES CPOE USE BY HOSPITALS IN 2012

EARLIER THIS YEAR, Massachusetts passed a law that requires all hospitals in the state to implement CPOE (computerized physician order entry) by 2012. The same law requires all hospitals in the state to adopt electronic medical record (EMR) systems by 2015.

There are 73 acute care hospitals in the state and only 13 currently have some form of CPOE in place. However, several of Massachusett's main academic centers have been national leaders in establishing CPOE within their institutions. Thus, the major attention will be on how community hospitals find the money and resources to comply with this mandate.

The law was passed with the help of a broad coalition of stakeholders. The coalition included the **Massachusetts Hospital Association** and the **Massachusetts Council of Community Hospitals**. A study by **MassTech** and the **New England Health Care Institute** projected that potential annual savings from use of CPOE should be in the range of $2.7 million per hospital. The study noted that CPOE systems cost a hospital about $2.1 million and the costs of operating such systems run about $435,000 per year. Based on these numbers, it is estimated that hospitals will recoup their investment in CPOEs in about 26 months.

Once most hospitals in Massachusetts comply with this mandate, experts will be watching to see how CPOE improves patient safety and whether CPOE contributes to improved patient outcomes. At a minimum, widespread use of CPOE in Massachusetts hospitals will require physicians to accept the need to use a computer to place orders. That may help laboratories in the state by encouraging more office-based physicians to personally utilize electronic ordering of laboratory tests.

More interesting will be the fact that widespread use of both CPOE and EMR systems in acute care hospitals in Massachusett is likely to generate a large volume of accurate data, collected in real time. This data will allow researchers to evaluate which treatment pathways are associated with better patient outcomes. In turn, that may lead to a large number of new evidence-based medicine guidelines.

HCA AND PAML EXPAND LAB OUTREACH VENTURE IN SALT LAKE CITY

AFTER JUST MONTHS IN OPERATION, the laboratory joint venture in Utah between **MountainStar Health** and **PAML** has already expanded. On October 31, 2008, it was announced that 239-bed **Ogden Regional Medical Center (ORMC)** had become part of **MountainStar Clinical Laboratories, LLC**.

That's a sign that the laboratory outreach joint venture between MountainStar (a health system owned by **Hospital Corporation of America [HCA]**) and Spokane, Washington-based PAML has enjoyed a solid start. Administrators at Ogden RMC must have recognized the financial, operational, and community benefits of the lab outreach JV.

MountainStar Clinical Laboratories formally launched operations earlier this year. Two of MountainStar's eight hospitals were first to participate in the joint venture. They are 297-bed **St. Mark's Hospital** of Salt Lake City, Utah, and 116-bed **Lakeview Hospital** of Bountiful, Utah. PAML contributed its laboratory operation in Salt Lake City to the joint venture. *(See TDRs, December 10, 2007 and March 3, 2008.)*

Because HCA is a for-profit hospital corporation, it is likely to be keeping a

watchful eye on the financial success of this lab joint venture. Thus, one consequence of the MountainStar/PAML pairing is that it may prove to be a business relationship that HCA finds useful to introduce into other cities where it operates multiple hospitals.

MOVE TO HIPAA 5010 PROPOSED FOR APRIL 2010

IT WAS AUGUST 22, 2008 when the federal Health and Human Services (HHS) Department published proposed rules to adopt updated HIPAA standards. Included were proposals to transition to HIPAA transactions version 5010 because the current version (4010) is incompatible with ICD-10.

In the proposed rules, HHS established April 2010 as the implementation date for use of version 5010. Implementation of ICD-10 is proposed for October 1, 2011. If the rule is published without amendment, that means laboratories and pathology groups will have just 16 months to prepare for implementation of HIPAA transactions version 5010.

For this implementation to succeed, lots of work must be done by payers and the Medicare program. The **Blue Cross Blue Shield Association** recently pointed out that "Version 5010 is a major re-write of the HIPAA transaction standards, with more than 850 individual changes."

LABCORP INKS DEAL TO ESTABLISH LABORATORY IN EMIRATE OF ABU DHABI

HERE'S A CLEAR SIGN of the internationalization of laboratory testing services. On November 4, 2008, **Laboratory Corporation of America** announced that it had agreed to participate with **Mubadala Healthcare** to establish the National Reference Laboratory in the Emirate of Abu Dhabi.

Mubadala Healthcare is a subsidiary of **Mubadala Development Company** and its sole shareholder is the Government of the Emirate of Abu Dhabi. Thus, LabCorp is partnering with the government to establish a state-of-the-art laboratory capability in the Emirate.

The objective is to establish a laboratory facility that will centralize lab testing services for the Emirate. It will provide routine, reference, and esoteric testing. Currently, Abu Dhabi sends some reference and esoteric tests to Europe and other countries.

Earlier this year, THE DARK REPORT traveled to Riyadh, Saudi Arabia, to participate in a pathology conference and visit several laboratories in the region. Flush with petrodollars, countries in the Gulf Region are spending heavily to improve healthcare services for their inhabitants and create the necessary infrastructure.

This is happening in the Emirates, like elsewhere in the region. However, Abu Dhabi and neighboring Dubai also have ambitions to become major players in global medical tourism. Expect to see Abu Dhabi announce more relationships and affiliations with leading healthcare providers and academic health centers as it works to achieve this goal.

KLAS TO ISSUE LIS "PERCEPTION" REPORT

HOSPITAL LABORATORIES CURRENTLY ASSESSING THE NEED to upgrade their laboratory information system (LIS) or purchase a new LIS might be interested in a new report expected to be published by **KLAS Research** of Orem, Utah, during November.

KLAS is preparing what it calls an "LIS perception report." The focus of the KLAS report will be on the question of whether a "best of breed" LIS can be interfaced and function as effectively in a hospital as an LIS which is fully integrated with other hospital data systems. KLAS recognizes that laboratory directors tend to select "best of breed" LIS solutions, while hospital CIOs generally prefer enterprise (integrated) LIS solutions. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In this country, medical tourism is generally understood to mean someone traveling to a foreign country to access less expensive healthcare. But a handful of U.S. hospitals are ready to make domestic medical tourism a paying proposition—and boost their occupancy rates at the same time. Earlier this year, Maine-based grocery company **Hannaford Brothers** announced that employees needing hip and knee replacements could have the surgery done at a Singapore hospital. With a knee replacement costing $43,000 in the U.S. versus $9,000 in Singapore, the savings would be significant. What happened next surprised executives at Hannaford.

MORE ON: Hannaford

Hannaford's Director of Associated Health and Wellness, Peter Hayes, explained, "After the announcement, I got calls from several [U.S.] hospitals offering to match Singapore on pricing." Hannaford, which is self-insured, responded by asking **Aetna**, which manages its health benefits, to evaluate these offers and negotiate a favorable agreement. Hannaford selected a hospital in Boston. Employees using this source for knee or hip surgery will pay no deductible or out-of-pocket. The employee and a companion will also get a travel allowance. Experts believe more U.S. hospitals will respond to the threat of medical tourism by negotiating special package pricing with selected employers.

MEDTOX REPORTS REVENUE GAIN FOR THIRD QUARTER

MEDTOX Scientific, Inc., of St. Paul, Minnesota, reported third quarter financial performance. Revenue was up almost 9%, from $15.7 million in Q3-07 to $17.4 million in Q3-08. Known as a drugs of abuse testing (DOA) lab, in recent years MEDTOX has diversified its lab testing services. Like other DOA labs, MEDTOX saw a decline in test referrals from existing industrial clients due to a slack economy. However, solid growth of its clinical laboratory business, combined with new DOA clients, were responsible for the company's overall revenue growth.

GENOMIC HEALTH GROWS RAPIDLY

Genomic Health, Inc., of Redwood City, California, reported that revenue grew 78% for third quarter. Sales of the company's Oncotype DX breast cancer assay reached $28.1 million for Q3-08, compared with $15.8 million in Q3-07. The company reports that more than 75,000 patients have been tested with the Oncotype DX assay.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 1, 2008.