Volume XIII, Number 8 Monday, June 12, 2006

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

Turning Up the Heat in California

FOR THE PAST TWO DECADES, CALIFORNIA HAS BEEN A PACE SETTER in healthcare and the clinical laboratory industry. Events in recent weeks seem to indicate that California will continue to move ahead of other regions in developments that influence the clinical laboratory industry.

First, there is the impending birth of a new laboratory company in Southern California. A group of lab executives and professional investors have signed agreements to buy two Southern California commercial laboratory companies. Both sales are expected to close by the end of the month. What makes these two acquisitions interesting is that the buyers have the type of experience that makes it likely they will use these two laboratory acquisitions as a platform to build a national business in specialty, molecular, and esoteric testing.

The second development is the service of subpoenas to **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** by the California Attorney General. The subpoenas request documents and records involving Medicaid billing in the state for periods dating three to ten years ago. Whatever the motive behind these subpoenas, it raises the risk that healthcare regulators in California may establish some type of new legal precedent that has negative consequences for the entire laboratory industry. That's because state legislation and state court rulings in California tend to encourage other states to follow the same legal theories.

Remember, it was in California that the first laboratory whistleblower filed a *qui tam* suit against **National Health Laboratories** (NHL). That whistleblower was C. Jack Dowden. When the U.S. Attorney announced a settlement with NHL in December 1992, it included a $111 million fine and restitution, along with a guilty plea to two criminal counts and prison time for then-NHL CEO Robert E. Draper. The outcome of that legal action was the national enforcement effort which the federal **Department of Justice** (DOJ) dubbed "Lab Scam." By the time the worst was over in 1998, every major commercial laboratory company had paid fines and restitution totalling more than $1 billion.

Seen from that background, the subpoenas issued by California's Attorney General last month have the potential to trigger new legal theories about Medicaid billing that may prove harmful to the entire lab industry. TDR

New Lab Company to Buy Westcliff, Health Line

Ex-Specialty Labs' CEO leads executive team in acquisition of two Southern California labs

CEO SUMMARY: In Southern California, no one's talking for the record, but everyone's talking about the impending acquisition of Westcliff Medical Laboratories and Health Line Clinical Laboratories by a new laboratory company. The deals are expected to close by the end of this month. The new laboratory company is likely to be led by Douglas S. Harrington, M.D., formerly CEO of Specialty Laboratories, Inc.

IT HASN'T BEEN ANNOUNCED YET, and the two acquisitions are not expected to close until the end of this month, but details are leaking out about an impending sale of **Westcliff Medical Laboratories** and **Health Line Clinical Laboratories Inc.** Westcliff is located in Newport Beach and Healthline is based in Burbank, California.

Both labs are expected to be acquired by a new laboratory company. CEO of this new firm is likely to be Douglas S. Harrington, M.D., who was President and CEO of **Specialty Laboratories, Inc.** until March, 2005. Rumors also say the executive team will include Joe Barlow (currently at Health Line) and Dan Angress, who was formerly a Vice President at Specialty Laboratories until the spring of 2005.

This two-pronged deal was surprising, on several counts. First, Health Line Clinical Labs (HLCL) has a history of regulatory problems with Medicare and MediCal, the state's Medicaid program. In 2004, HLCL and its owners, Aramis Paronyan, M.D. and his wife, Netalee Lalabekyan, agreed to pay approximately $10 million to settle allegations of Medicare/Medicaid fraud and abuse involving the period 1996 through 2003.

Because of this history, and because of the terms of the Medicare/Medicaid settlement, potential buyers of Health Line Clinical Laboratories in recent years were especially careful in evaluating the lab's compliance. There was a perception in Southern California that a buyer of HLCL might find additional, unwelcome compliance problems after the sale.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

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In the case of Westcliff Medical Laboratories, the surprise was that Richard E. Nicholson, President, CEO and owner of the lab, was willing to sell at this time. Nicholson has been one of California's more successful laboratory owners over the past 15 years. Despite its relatively small size, Westcliff survived the intensely-competitive, HMO-dominated market in Southern California. In recent years, Westcliff has posted steady growth in specimens and revenue.

Combining Two Labs

Assuming that the acquisitions of Westcliff and Health Line close by month's end, the combination of the two labs would create one of the nation's larger labs with a primary business of providing routine testing to office-based physicians. It is estimated that each laboratory currently has annual revenue of between $40 million and $50 million. Combined, this would give the new lab enterprise a revenue base approaching $100 million.

Despite its relatively small size, Westcliff survived the intensely-competitive, HMO-dominated market in Southern California. In recent years, Westcliff has posted steady growth in specimens and revenue.

However, combining the two laboratories is likely to be a tough challenge. In recent weeks, the owners of both laboratories informed their employees about the impending sale of their labs. Employees have told others that, post-sale, the new owners intend to consolidate all the testing at the WestCliff laboratory facility in Orange Country. Historically, such laboratory consolidations have been disruptive to customers and created an opportunity for competing labs to pick up new accounts from dissatisfied clients.

However, the new lab owners may benefit from the fact that the major competitor in Southern California, **Quest Diagnostics Incorporated**, is already in the midst of its own consolidation. Quest Diagnostics is moving the operations from its two major laboratories into its new laboratory facility in West Hills, California. The fact that both laboratory organizations are undergoing consolidation at the same time is likely to make it tougher for these competitors to steal business from each other.

Once they take title to Westcliff and Health Line, the new owners will probably have a new primary business strategy. THE DARK REPORT considers it unlikely that Harrington and his executive team are buying these two laboratories simply to compete for the laboratory testing referrals of office-based physicians.

After all, Harrington has spent a large portion of his career at national esoteric laboratories, like **Nichols Institute** and Specialty Laboratories. He appreciates the profit potential of esoteric and molecular testing, compared to the reimbursement from chem panels and CBCs provided to primary care physicians.

Lab Talent Pool In So. Calif.

Thus, it is likely that the business plan of this new laboratory company will focus on specialty reference and esoteric tests, marketed nationally. What adds interest to this speculation is the fact that, around Southern California, this new laboratory company has the opportunity to recruit proven talent with experience in such companies as **US Labs**, **IMPATH**, Specialty Labs, **Clarient**, **Quest Nichols Institute**, **Focus Diagnostics**, and **Esoterix's** lab divisions in the region. **TDR**

Lab MUEs Reconsidered, CMS Changes Course

No clinical lab or anatomic pathology MUEs will be implemented until mid to late 2007

CEO SUMMARY: It may be a rare moment of common sense. Last month, Medicare officials stated their intent to exclude clinical laboratory and anatomic pathology CPT codes from the "Phase One" implementation of Medically Unbelievable Edits (MUEs). It is a positive step, and comes in response to educational efforts by a consortium which included 60 associations and organizations from the laboratory community.

MEDICARE OFFICIALS are indicating their intent to exclude anatomic pathology and clinical laboratory CPT codes from the current list of Medically Unbelievable Edits (MUEs) proposed for implementation in January 2007.

"In recent meetings with individuals from the **Centers for Medicare and Medicaid Services** (CMS), we've been told that CMS has recognized that a different approach is needed for the clinical lab and anatomic pathology codes," stated Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA) in Washington, D.C. "This recognition has triggered a number of decisions which could help ensure that any proposed MUEs for laboratory and pathology services are appropriate and do not negatively affect patient care."

As President of ACLA, Mertz was actively involved in a series of meetings with the CMS officials responsible for developing and implementing the MUE program. "During these meetings, the lab industry made a persuasive case that the existing MUE proposals, which involve 1,100 CPT codes, would be disruptive to both patient care and the healthcare system," he said.

"We pointed out that the criteria used to propose these MUEs are unclear," continued Mertz. "Also, there has never been a clear explanation or definition of either the overall process or the objective for implementing these edits."

New Developments

Mertz says that, during a May 25 meeting with CMS officials, several positive developments occurred. "During this meeting, CMS stated that its thinking on the appropriate ways to develop the MUE program was evolving," recalled Mertz. "CMS now indicates that implementation of MUEs will be much less widely-sweeping than what had been proposed. More specifically, the phase-in scheduled for January 2007 will focus primarily on anatomic anomalies and obvious typographical errors."

The big development was the exclusion of clinical laboratory and anatomic CPT codes from the scheduled January 2007 implementation. "Further, the laboratory community does not need to provide specific comments to the current MUE proposals by June 19," explained Metz. "CMS says it will establish a separate process and timeline for defining which clinical laboratory and pathology codes should be subject to MUEs. It will also involve the pathology and clinical laboratory community in defining the criteria to be used in developing such MUEs."

Need to Remain Cautious

Although these developments are welcome across the lab industry, Mertz is quick to caution that, as of this date, CMS has yet to issue written guidance that confirms these shifts in the existing timetable for the proposed MUEs. "Much of the reasoning and organization behind the original MUE proposals remains unknown," said Mertz. "The laboratory community must continue to work together. CMS needs input for it to evolve the MUE program in a fashion that accomplishes clear and objective goals while not compromising patient care."

Mertz's recommendation reflects the reality of working with the Medicare program. Not only does the bureaucracy work in ways unfathomable to the outside, but politics and Congressional mandates play a role in shaping how CMS develops and implements new policies.

During the next few months, it is expected that CMS will publish detailed guidance on how it intends to implement "Phase One" MUEs that are scheduled to take effect in January 2007. Once this guidance is published, the laboratory industry will need to maintain a common effort. The goal is to provide the input needed so that CMS can make fair, objective, and patient-friendly policies. TDR

Contact Alan Mertz at 202-637-9466.

First MUE Proposals Were Disruptive to Labs

WHEN THE FIRST LIST OF PROPOSED Medically Unbelievable Edits (MUEs) became known in December 2005, it was a most unpleasant surprise to the laboratory industry.

The list proposed service restrictions for about 80 anatomic pathology CPT codes and 1,100 clinical laboratory CPT codes. The most disruptive proposal was to limit CPT 88305 (Level IV–Surgical Pathology, Gross and Microscopic Exam) to two units of service per patient per day. If implemented, such a limitation would have severely compromised patient care and eroded the core finances of most community hospital-based pathology group practices. *(See TDR, January 16, 2006.)*

"In meetings between CMS (Centers for Medicare and Medicaid Services) and the laboratory community, we've pointed out several things," observed Alan Mertz, President of the American Clinical Laboratory Association (ACLA). "First, laboratory medicine CPT codes are far more numerous than those of other medical specialties, numbering more than 1,100. Second, these codes generally do not relate to a specific site in the body, making anatomic considerations mute.

"Third, while it is physically possible to perform only one appendectomy on a person," said Mertz, "for all practical purposes, it is difficult to define the number of surgical pathologies, molecular probes, and chemistry analytes for which, beyond that number, it would be considered 'unbelievable.'

"For these reasons, the process used to develop MUEs for clinical laboratory and anatomic pathology CPT codes must reflect the unique nature of laboratory medicine," noted Mertz. "That will require effective collaboration between CMS and the laboratory community."

Technology Update

Merck's HPV Vaccine Cleared For Use by FDA Last Week

It's the beginning of a new cycle of change in cervical cancer screening and treatment

IT'S BEEN A RACE between two pharma giants to get an HPV (*Human papillomavirus*) vaccine into the market. Last Thursday, **Merck & Co.**, Inc. jumped ahead of **GlaxoSmithKline**.

That was the day that the **Food and Drug Administration** (FDA) cleared Merck's Gardisil® for use in the United States. GlaxoSmithKline indicates that it expects to submit a pre-market application for Cervarix™, its HPV vaccine, before the end of the year.

Media coverage of the HPV vaccine race is extensive since these are the first vaccines specifically designed to prevent cancer. Because cancer is such a feared disease, the development of a vaccine that can prevent one type of cancer is considered newsworthy by the press.

FDA approval of an HPV vaccine is a significant event for clinical laboratories and anatomic pathology groups that offer Pap tests and HPV tests. Because an HPV vaccine is now available for clinical use, a new cycle of change in cervical cancer screening and treatment has commenced.

Lots of Promotion Expected

Merck is expected to heavily promote its HPV vaccine. It is approved for use in girls and women aged nine to 26. Merck states that "The FDA approved Gardisil for the prevention of cervical cancer; cervical pre-cancers (cervical intraepithelial neoplasia (CIN) 2/3 and adenocarcinoma in situ (AIS)); vulvar pre-cancers (vulvar intraepithelial neoplasia (VIN) 2/3); and vaginal pre-cancers (vaginal intraepithelial neoplasia (VaIN) 2/3)) caused by HPV types 16 and 18. Gardisil is also approved for the prevention of genital warts and low-grade cervical lesions (CIN 1) caused by HPV types 6, 11, 16 and 18."

New Technologies

The last comparable event in cervical cancer detection and treatment was the approval for new technologies for liquid preparation Pap tests and automated Pap test screening systems in the second half of the 1990s. That was followed by several published papers which linked HPV infections with cervical cancer.

Collectively, these developments led directly to a major overhaul of the recommended guidelines for cervical cancer screening. These were instituted by the **American Cancer Society** (ACS) and the **American College of Obstetricians and Gynecologists** (ACOG) about three years ago. The revised guidelines acknowledged the the emerging roles of liquid preparation Pap tests and HPV tests.

The HPV vaccines developed by Merck and GlaxoSmithKline are based upon new knowledge in two fields. First is the growing understanding of

the role HPV plays in causing cervical cancer, as well as other diseases. Second is the rapid advances in the technology of vaccine design and production. In particular, these new vaccines are recombinant vaccines.

Recombinant Vaccines

Until now, vaccine production has primarily involved growing viruses in eggs or other hosts. By contrast, recombinant vaccines are created using a process capable of producing only one viral protein (and not the whole virus) in a yeast or bacteria. The core science of recombinant vaccines is well established.

The leading companies in this field happen to be Merck and GlaxoSmithKline. In fact, Gardasil is the third new vaccine from Merck that has earned FDA approval during 2006. The other vaccines are RotateQ (to prevent gastroenteritis, a leading cause of severe infant diarrhea) and Zostavax (to prevent shingles in adults 60 and older).

The next step for clinical acceptance of Merck's Gardasil vaccine will come on June 29. On that date, the national Advisory Commitee on Imunization Practices from the **Centers for Disease Control and Prevention** (CDC) will meet to consider a recommendation that all girls between the ages of 11 and 12 be vaccinated with the HPV vaccine. For Merck, this is important because endorsement by this committee would encourage health insurers to establish coverage for the HPV vaccine.

Changes for Laboratories

For the laboratory industry, the approval of an HPV vaccine is a new factor that will alter established protocols for screening and treatment of cervical cancer. The HPV vaccines created by Merck and GlaxoSmithKline are engineered to provide protection against the HPV types, like 16 and 18, which cause the greatest numbers of cervical cancer. But since neither vaccine protects against all the HPV types, even vaccinated women will need to be screened for cervical cancer.

That means, in the near future, it is unlikely that there will be significant changes in established protocols for cervical cancer screening and treatment. That is likely to change in future years. First, greater numbers of women will have been vaccinated. Second, vaccine manufacturers will probably add more HPV types into their vaccines. Collectively, these factors will increase the complexity of cervical cancer screening—for both physicians and the laboratories which support them. TDR

GlaxoSmithKline Reports Benefits to Older Women

JUST FOUR DAYS before the FDA approved Merck & Co.'s HPV vaccine, GlaxoSmithKline reported that a clinical trial involving women aged 26-55 showed that its HPV vaccine, Cervarix, triggered an immune response that would provide these women with protection against HPV infection.

"For the first time, we see that a vaccine against cervical cancer is highly immunogenic in women over 25 years of age," stated the lead study investigator, Prof. Dr. Tino F. Schwarz of **Stiftung Juliusspital** in Würzburg, Germany. "The promising study results suggest that both younger and older women could be protected through vaccination from oncogenic HPV 16 and 18 infections and associated cervical lesions leading to cervical cancer."

The significance of this study is that the vaccine manufacturers are accumulating information to support the use of their HPV vaccines in women older than 25 years old. This would expand their market, since a larger number of women would be prospects to use the HPV vaccine.

Compliance News

California Attorney General Subpoenas Quest & LabCorp

Seeking documents related to MediCal billing for time periods reaching back three to 10 years

LITTLE IS KNOWN about the reasons why the Attorney General (AG) of California recently served subpoenas to **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**.

News of the subpoenas surfaced when both laboratory companies disclosed the news in regulatory filings with the **Securities and Exchange Commission** (SEC). Quest Diagnostics was first to disclose this fact in an SEC form filed on Friday May 19. Just four days later, on May 23, LabCorp filed a similar form with the same news.

Both companies, using almost identical wording, revealed that they had "recieved a subpoena from the California Attorney General seeking documents related to billing to the state's Medicaid program. The subpoena relates to various time frames ranging from three to ten years." Both Quest Diagnostics and LabCorp indicated that they would cooperate with the AG's office in this matter.

Many Are Still Unaware

Even three weeks after the public disclosure by the two blood brothers that each had received a subpoena relating to billings involving the MediCal program, few lab executives in the Golden State were aware of this development. Calls to the California Attorney's office have been met with the simple answer that it "cannot discuss any details about an ongoing investigation and it cannot confirm whether an investigation is taking place."

In a conversation with THE DARK REPORT, one lab executive who works in California observed that it has been a constant battle by clinical laboratories in the state to maintain adequate reimbursement for Medicaid testing. His concern was that these subpoenas had the potential to surface findings unfavorable to the lab industry—and that MediCal program administrators would use this negative development as a way to enact more onerous regulations for submitting claims.

THE DARK REPORT believes another explanation may be that a laboratory whistleblower has caught the attention of the California Attorney General's office. California has its own whistleblower law, similar to the federal *qui tam* statute.

Another possible link might be to research being conducted by the U.S. Attorney's office of Newark, New Jersey that involves the "business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999." Subpoenas in this matter were served to Quest Diagnostics and LabCorp in June 2005. *(See TDR, June 20, 2005.)* However, this remains speculation until government officials comment publicly on both matters. TDR

Affirmed by *Executive War College* Presentations

More Labs Opt to Use Middleware, Quality, and Lab Automation

CEO SUMMARY: Many of the nation's more innovative laboratory organizations are paying closer attention to laboratory productivity and operational performance. To achieve improved operations, these labs are putting three tools to greater use. They are using targeted automation solutions and giving middleware a greater role in the effort to squeeze ever more productivity from every aspect of lab operations. Lean and Six Sigma quality management methods are also growing in popularity.

By Robert L. Michel

NATIONALLY AND INTERNATIONALLY, clinical laboratories are becoming savvier about operational issues. That was a key theme which emerged from this year's *Executive War College on Laboratory and Pathology Management*, held in Miami, Florida on May 3-4.

In the pursuit of more efficient and effective operations, early-adopter laboratories are using a mix of automation, middleware, and quality management methods. It is this willingness to blend several solutions to achieve operational improvement which is a change from earlier years.

In fact, the growing interest in middleware across the lab industry is specifically rooted in the expanded use of laboratory automation and, to a lesser degree, use of quality management methods to improve work processes within the laboratory.

Triple Themes

The triple themes of targeted automation, middleware, and use of quality management methods could be heard within many of the 50 presentations delivered at this year's *Executive War College*. This is not a surprise, because it is a rational management response to such trends as declining reimbursement and growing shortage of medical technologists (MTs) and medical laboratory technologists (MLTs).

Moreover, when used together, these three tools of targeted automation, middleware, and quality management methods can produce greater benefits than when each is deployed individually. Lab directors and pathologists recognize this, which is why many first-mover laboratories have implemented all three approaches, often simultaneously.

Not only do these pioneering laboratories have lessons to teach, but they provide us with an early peek at how each of these three "mini-trends" contributes to operational efficiencies and work flow improvement. What follows is an analysis of each solution.

1 LAB SOLUTION ONE: Targeted or "Piece-by-Piece" Laboratory Automation

First is the use of automated solutions. Today's marketplace for laboratory automation looks very different, than, say, 10 years ago. In 1996, automation generally meant TLA (total laboratory automation). This was the concept of starting a specimen in pre-analytical and moving it through analytical and into storage without the need for humans to manually handle the tubes.

Ten years ago, there were only three primary vendors of TLA equipment and systems in the United States. As well, there were few laboratories buying the TLA solution. Even today, the number of sites in the United States where TLA has been installed remains a relatively small number.

What happened to laboratory automation over the past 10 years is a business school case study in customer demand. The demand for laboratory automation was strongest for task-targeted solutions that did not require a major overhaul of the entire laboratory's workflow.

This was first revealed in the demand for pre-analytical automation systems. From 2000 forward, sales of automated systems for pre-analytical functions grew steadily. Demand for such systems is directly related to an operational truth for almost all clinical laboratories.

It is widely-understood that labor is a major cost component of laboratory operations and that accessioning labor represents a significant proportion of total labor costs. Moreover, accessioners are relatively low-paid and turnover is high. Invariably, the need to actively recruit, train, and manage pre-analytic labor places great demands on management.

Thus, when looking at opportunities to use automation, it was logical for lab directors and pathologists to focus on pre-analytical systems. Starting in 2000, sales of pre-analytical automated systems began to grow. Typically, these systems had a stockyard for sorting specimens according to their destination. Among other functions, labs could include automated decapping, centerfuging, and aliquotting in their pre-analytical automation.

Sorted racks of tubes were delivered from this automated system to testing instruments by "sneaker power"—people walking from one station to the next. This avoided the expense—and inflexibility—of an automated transport line.

Over the past six years, demand also surged for another type of automated solution: the consolidated workstation. For example, putting chemistry and immunology testing into an integrated instrument suite has proved popular. This allows a laboratory to rearrange a high-volume work cell (without the need to reconfigure workflow throughout the entire laboratory) and significantly increase the productivity of technical staff in this work cell.

Within the United States, the demand for laboratory automation has centered around specific, targeted solutions. It also means that many laboratories in this country are buying and installing automation in a piecemeal fashion.

This is an important point, and provides some understanding about today's lab management mindset. Use of specific automation solutions to increase the productivity of labor is directly linked to laboratories' demand for middleware. It is also linked to the steadily increasing use of quality management methods in American laboratories.

After all, if a laboratory is installing automation in a piecemeal fashion, it runs up against that well-known imperative: "Don't automate bad work processes!" Task-targeted automation will speed up throughput in a specific work process within the laboratory. But, without work process redesign of the lab's entire work flow, this task-targeted automation solution can create interesting problems to work flow upstream and downstream from the automation.

As laboratory management recognizes this situation, it can choose two tools to help it resolve many problems related to automation. One solution is middleware. The other solution is the use of quality management principles to redesign work flow and improve or eliminate flaws in individual work proesses within the laboratory.

Automation Examples At the Exec. War College

LABORATORY AUTOMATION was a major theme in several presentations. For example, the newly-opened **Century City Doctor's Hospital** in Century City, California built a highly-automated laboratory specifically to take advantage of the latest technology. The objective was for the laboratory in this 190-bed hospital to operate 24/7 with just 15.5 FTEs, including phlebotomists.

At the laboratory of **Ingalls Memorial Hospital** in Harvey, Illinois, automated systems were installed in the core lab. Currently an automated, wireless system is being implemented in phlebotomy in order to achieve further productivity gains across the pre-analytical and analytical processes.

2 LAB SOLUTION TWO: Middleware Solutions To Unlock Productivity

This is a perfect segue into middleware and the reasons why laboratory use of this solution is exploding. Piecemeal introduction of laboratory automation

creates a demand for software solutions that can maximize the productivity of the automation, as well as help resolve some of the upstream and downstream workflow problems created by automation.

But there are two other factors which fuel the increased demand for middleware seen in the lab marketplace today. One factor involves how hospitals currently spend money on information technology. The second is linked to the increased number of hospital laboratory outreach programs which entered the marketplace during the past six to eight years.

Defining Middleware

In its simplest definition, middleware can be described as "software agents acting as an intermediary between different application components" (per *Wikipedia.com*). Laboratories have used middleware for years. Middleware is the software that connects different instruments to the LIS (laboratory information system). Middleware is the interface that allows different applications to interact with the LIS. Discrete software products to enable Web browser-based lab test ordering and lab test reporting are examples of middleware.

Historically, the laboratory's LIS vendor was a primary source of middleware. Whenever the lab wanted a new function, its LIS vendor would generally write the code necessary to support that function. Under this arrangement, few laboratories viewed these customized solutions as "middleware." They were generally considered to be enhancements to the LIS.

Another source of middleware has been *in vitro* diagnostic (IVD) manufacturers. As they introduced new instrument systems, these companies would provide the interface (middleware) that allowed the new instrument to communicate with the LIS.

MIddleware Examples at the Exec. War College

USE OF MIDDLEWARE in clinical laboratories is growing rapidly. That's because middleware is often a fast and surprisingly cheap way to solve a problem or boost productivity.

At this year's *Executive War College*, **Spectrum Laboratory Network** in Greenville, North Carolina shared how it was using information technology, including numerous middleware solutions, to support bringing in new sales while also streamlining work processes within the laboratory.

In Indianapolis, Indiana, **Mid America Clinical Laboratories** uses a number of middleware solutions to feed real-time data to both clients and internal customers and to automate work processes that eliminate manual steps and increase labor productivity.

This is why, during the 1990s, the primary vendors of middleware were the LIS and IVD companies. However, for a variety of reasons, most lab directors and pathologists did not view these products as "middleware."

In recent years, this long-standing status quo in LIS function has been altered. Multiple and fundamental changes in the healthcare marketplace are disrupting the long-standing relationships laboratories have maintained with their LIS vendors and IVD vendors.

Hospital IT Spending

One primary factor is how hospitals have redirected much of their spending on IT (information technology). In recent years, hospitals and health systems have devoted increasing amounts of money to integrate all their clinical data repositories, such as laboratory, radiology, and pharmacy. The hospital's goal is to present the physician with a single-screen view of patient data and to lay the groundwork necessary to implement a full EMR (electronic medical record) system.

This is the necessary step to enable the electronic medical record. In response to this shift in hospital IT spending, healthcare IT companies redirected their product development efforts to support this demand from their biggest-spending customers. But this shift in product emphasis within the IT vendors had consequences for laboratories.

Improving LIS Products

It means that fewer resources are devoted to enhancing and improving LIS products. It also means that hospitals are less inclined to invest in the newest generation of LIS products. First, they are putting most of their IT budget into IT integration. Second, hospital administrators recognize that there is relatively little incremental value in upgrading to a new LIS.

Because they are selling fewer LIS upgrades, IT vendors don't have an economic incentive to build new features into their products. Moreover, they are less inclined to agree to write custom code for their existing LIS customers.

This is the source of the squeeze which pushes laboratories to seek out a third-party source to write the specific middleware solutions the labs need to maximize the productivity of their automation.

It means that fewer resources are devoted to enhancing and improving LIS products. It also means that hospitals are less inclined to invest in the newest generation of LIS products.

When first approached by their lab customers about such solutions, many LIS vendors answer in one of three ways: 1) "We don't have the resources to create this code for you," or, 2) "It will take us many months or even one year to deliver the software solution you want," or, 3) "Here's the tens of thousands of dollars you'll need to pay us to program that software function."

Faced with any or all of these alternatives from their primary IT vendors, it was inevitable that lab managers and pathologists would look for third-party IT vendors who would say: "Yes! We can do this. We can do this in just a few weeks or months, and you will find the cost to be quite reasonable."

This phenomenon has been reinforced by steady improvements in computer hardware, software, new IT standards, and capabilities of the Internet. Collectively, these ongoing enhancements make it easier for a third-party vendor to create an effective software solution for a laboratory in an acceptable time period at a reasonable price.

IT Vendor Priorities

Thus, one reason laboratories have been encouraged to look past their traditional LIS vendors for middleware solutions is the fact that these same companies are busy serving the overriding IT priorities of hospitals and health systems. These IT firms have a motive to serve the larger needs and bigger IT budgets required to implement these hospital-wide IT projects.

But there is another major factor that encourages laboratories to purchase middleware from third-party sources. Each time a hospital decides to launch a laboratory outreach program, it creates the need for additional IT capabilities. These range from courier/logistics management, specimen tracking, and offering electronic lab test ordering/results reporting to office-based physicians, to coding, billing, collections, compliance, and customer service.

What makes these laboratories customers for middleware is the fact that

they have an LIS that was designed to serve an inpatient testing environment. In this role, their LIS may have performed quite satisfactorily. But, it was never designed to handle the needs and functions demanded by a hospital laboratory outreach program.

This makes middleware a perfect solution for the hospital laboratory that wants to ramp up an outreach program. Middleware gives the laboratory the outreach functions it needs—without having to upgrade or replace its LIS. Further, middleware is a way the laboratory can add specific outreach functions sequentially, whenever needed and as warranted by increased specimen volume. Best of all, profits from the outreach program can pay for each additional middleware solution.

3 LAB SOLUTION THREE: Lean/Six Sigma Quality To Drive Improvements

The third trend, use of quality management systems like Lean, Six Sigma, and ISO-9000, dovetails neatly with "piecemeal" automation and the increased use of middleware. Quality management systems give lab administrators and pathologists effective tools for improving productivity, reducing waste, and increasing the reliability of individual work processes.

Use of quality management methods has two consequences Each directly touches the lab's use of automation and middleware. One, it gives lab managers an effective tool to resolve the upstream and downstream work flow issues that can be created by automating a single part of the lab's work flow. Two, it creates an immediate and compelling need for accurate, detailed information in real time. That's because Lean/Six Sigma teams must gather accurate, immediate, and ongoing information about the work processes they are studying.

Lean/Six Sigma Examples At the Exec. War College

INVARIABLY, LABORATORIES WHICH ADOPT Lean and Six Sigma management methods achieve spectacular results.

This was certainly true at 1,500-bed **Jackson Memorial Hospital**, located in Miami, Florida. Not only did attendees at the *Executive War College* get to hear directly from the lab's Lean Team which implemented a redesign of the high-volume core laboratory, but many took advantage of the opportunity to do a site visit of the laboratory to learn how Lean projects helped the lab slash average turnaround time for inpatient testing, accompanied by a 50% improvement in productivity.

Another remarkable Lean project is happening at **Washington Hospital Center in Washington, D.C.**, where the laboratory team is using Lean to redesign workflow. The goal is to improve workflow to allow it to complettely remove an existing total laboratory automation (TLA) system in the high-volume, core lab.

Middleware is one way to meet that demand for detailed, real-time information, for all the reasons described above. It can be implemented quickly, it is reasonably-priced, and it can be customized to provide the precise data sets needed by management.

Work Flow Redesign

Further, once a laboratory decides to make a major commitment to implementing quality management methods, it begins to look at work flow in a holistic fashion. Rather than to view a problem as related to a specific work process, quality management systems teach laboratory staff how to identify upstream and downstream factors which contribute to or compound, the bad effects of a specific work process.

As published on THE DARK REPORT in recent years, effective use of quality management systems, such as Lean

and Six Sigma, has triggered substantial improvements in projects that require just 12 to 16 weeks to implement. It is common for the outcomes to include a 50% reduction in the average test turnaround time for inpatient testing, and 40% to 50% improvements in productivity and reductions of both errors and costs.

Strategic Perspective

Having explained each of these three trends—increased use of automation, increased use of middleware, and increased use of quality management systems—I would like to step up to a higher strategic perspective and answer two questions. Why have these three trends appeared almost simultaneously in the last six years, but not earlier than 2000? And why are these three trends interlocked and interrelated?

I answer the first question by pointing out that the decade of the 1990s was unkind, even brutal, to the laboratory industry. The disruptions caused by managed care and closed-panel HMOs were extremely destructive. Reimbursement fell precipitously. Access to patients was denied to laboratories that were not part of an HMO's provider network. Labs lacking contract access to patients lost major shares of their local market.

Provider Consolidation

Providers, including hospitals, physicians, and commercial laboratories, moved swiftly to create regional consolidated organizations and use the critical mass of these lab organizations to negotiate more favorable terms with managed care companies. Within the hospital laboratory sector, consolidation of hospital ownership into multi-hospital health systems thus triggered widespread consolidation and integration of the laboratories within the health system.

This consolidation and integration of laboratory services was generally accomplished by 2000. Thus, as hospital and health system administrators established operational and cost-control targets in subsequent years, pathologists and laboratory directors began looking at ways to streamline lab operations and boost productivity.

Not surprisingly, targeted automation solutions, useful software enhancements, and redesign of workflow and individual work processes were seen as effective methods to achieve the operational improvements needed to meet institutional goals. Moreover, all three solutions can be combined to further increase the benefits which accrue from their use in refining laboratory operations.

Publicity About Outcomes

It was the lab industry's first-movers and early adopters who were quick to see the potential gains from using these management tools. They were also willing to share their successes and lessons learned in public presentations and stories in the lab industry press. As other lab directors and pathologists saw the outcomes from these projects, it made it easier for them to convince hospital administration to provide the capital budget and other resources needed to introduce these tools into their own laboratories.

Thus, it is not surprising that so many presentations at this year's *Executive War College* included a discussion about the use of lab automation, middleware, and quality management systems. These three trends are proving to be highly-effective tools in the drive to improve the performance of laboratory operations while controlling or reducing costs. This is why it would be timely for labs to review their strategic priorities and look at ways to deploy these three management tools. TDR

Contact Robert L. Michel at 512-264-7103 and labletter@aol.com.

Dark Index

Good News for Regional Labs Competing Against Nationals

Each of the two blood brothers has growing, successful, "gadfly labs" in its own backyard

CAN REGIONAL LABORATORIES compete effectively against the two blood brothers? This question lies at the heart of the business strategy for most hospital laboratory outreach programs in the United States.

After all, in their community, the toughest competitors they face are likely to be **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. These lab behemoths hold most of the important managed care contracts, possess substantial economies of scale which can allow lower pricing, and have an extensive sales force to call on office-based physicians.

National Labs Lose Share

Yet, despite these impressive resources and other competitive advantages, the two blood brothers are losing market share in their own backyards—to two regional laboratories which are competing vigorously and successfully. These two thriving regional labs demonstrate that hospital lab outreach programs can compete effectively and produce worthwhile profits for their parent hospitals and health systems.

Not only does each of the two blood brothers have its own particular regional lab "thorn," but these smaller competitors have gained market share in their local areas for six or more years. For Laboratory Corporation of America, with headquarters in Burlington, North Carolina, it is **Spectrum Laboratory Network** which steadily grabs market share. Spectrum is located in Greenville, North Carolina, just 30 miles west of LabCorp's biggest laboratory facility.

Clients and regular readers of THE DARK REPORT are familiar with the Spectrum story. With an outreach revenue base of $25 million in 1999, this regional laboratory increased its revenue to $125 million by the end of 2005. Over the past five years, it has expanded its service network and now competes against LabCorp and Quest in the states of North Carolina, South Carolina, Virginia, Tennessee, and Georgia.

There are two linchpins to Spectrum's business strategy. One is to support a professional and aggressive sales force in the field. The second is to utilize sophisticated information technology to streamline lab operations, increase service levels, and offer enhanced electronic capabilities to physician-clients. *(See TDRs, October 7, 2002; March 7, 2005; and November 14, 2005.)*

In the case of **Quest Diagnostics Incorporated**, the regional laboratory competitor which continually eats away at its market share in the New York metropolitan area is **Bio-Reference Laboratories, Inc.** (BRLI). Quest Diagnostics has its headquarters and its largest laboratory facility in Teterboro, New Jersey. Just five miles away, in Elmwood Park, is BRLI's laboratory.

For its fiscal year ending October 31, 1999, BRLI posted revenues of $53.8 million. For fiscal 2005, its revenues totalled $163.8 million. Most of this growth has come from increasing its physician office clients in the New York metro area—a region where Quest Diagnostics is dominant and has a market share in the range of 70%.

Quarterly Earnings Report

In a quarterly earnings statement released just last Thursday, BRLI confirmed that this strong growth in specimen volume, revenue, and market share is continuing. Because its financial year ends October 31, Bio-Reference Laboratories, Inc. is always the first public laboratory company to report earnings from the latest quarter.

For its second quarter ending April 30, revenues increased by 18%, from $40.1 million Q2-05 to $47.2 million in Q2-06. Income before taxes was $4.1 million, an increase of 86.4% from Q2-05. This substantial growth is primarily from an increased number of physician office clients from the highly-competitive New York City metro area. Another component of growth is BRLI's niche testing business lines, some of which serve a national market. *(See sidebar at right.)*

Revenues Grew By $100 Mil

Both Spectrum Laboratory Network and Bio-Reference Laboratories have increased their revenue by $100 million during the past six years. That rate of growth is notable, particularly since both companies are profitable. What makes the accomplishment even more impressive is the each of these two labs are grabbing this market share from the home turf of the two blood brothers.

The business lesson from this success is instructive to lab administrators and pathologists involved in hospital lab outreach programs. It is possible to compete effectively—and profitably—against the national laboratories. But to achieve this success, it is necessary to invest capital and to apply the professional management talents necessary to build the lab and its sales program.

This is true of the most successful regional laboratory networks. **Joint Venture Hospital Laboratories** (JVHL) in Detroit and **PACLAB Network Laboratories** in Washington State demonstrate that properly-funded and well-managed outreach programs can be successful and profitable. TDR

Bio-Reference Builds Niche Test Markets

EVEN AS IT DEFINES ITSELF as a regional lab, Bio-Reference Laboratories, Inc. (BRLI) has a business strategy of developing testing niches at the regional level, then selling those lab testing services in the national market.

"Within our local marketplace, we are constantly looking for testing niches where we can add value, generate additional margin, and be viewed by physicians as having specialized clinical expertise," observed Marc Grodman, M.D., Chairman, President, and CEO of BRLI. "As we validate the delivery model and profitability of these testing niches, where appropriate, we will market them nationally."

One example is testing for jails and prisons. In past years, BRLI won contracts for prison testing in New York City and New York State. As it established enriched services specifically to serve the needs of healthcare practitioners in the corrections market, it has won lab testing contracts for prison systems in other states.

Another testing niche is molecular pathology. To serve clients in its core market around New York City, BRLI established specialized labs for FISH and similar tests. It now offers these services to clients throughout the United States.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Many changes are unfolding across the laboratory industry, so we begin with some of the more significant developments involving people:

TRANSITIONS

• One of clinical pathology's respected veterans is preparing to retire. Elkin Simson, M.D., Medical Director at the Center for Clinical Laboratories at **The Mt. Sinai Hospital** in New York City, will retire effective June 30, 2006. Dr. Simson plans to do some consulting as part of his retirement.

• Coming to The Mt. Sinai Hospital to assume some of Dr. Simson's responsibilities will be Melissa Pessin-Minsley, M.D. Currently she is Chief of Clinical Laboratory Services at **Cornell University–Weill Medical College** in New York City.

• Ran Whitehead will become the new CEO of **SED Laboratories, Inc.**, located in Albuquerque, New Mexico. Whitehead announced his resignation, effective at the end of June, as CEO of **Oregon Medical Laboratories** in Eugene, Oregon.

• **Spectrum Laboratory Network** of Greensboro, North Carolina, confirmed that it has hired Vicki DiFrancesco to be Executive Vice President, Sales and Marketing. She will leave her current position at **Specialty Laboratories, Inc.** and start at Spectrum on June 26, 2006.

• **Digene Corporation** of Gaithersburg, Maryland announced last week that Evan Jones, its Chairman and CEO, will retire at the end of the company's 2007 fiscal year, but not until a successor has been appointed. Jones has served as Digene's CEO for 16 years.

NEW LABORATORY ON AETNA CONTRACT

There's big news at **CBL Path, Inc.**, the fast-growing anatomic pathology company based in Ocala, Florida. CBL Path has signed a contract with **Aetna, Inc.** and will become an approved provider for the area around the New York metropolitan area, including Long Island, all of New Jersey and parts of Pennsylvania. The contract became effective after June 1, 2006. CBL Path's contract with Aetna is structured with the same basic terms as Aetna's contracts with the two national laboratory companies.

MORE ON: *CBL Path*

CBL Path is assembling a network of affiliated clinical laboratories to perform testing on Aetna-insured patients in the plans covered by the new contract. CBL Path will receive the capitated payments and will disburse funds to the local laboratories participating in its network. Aetna's interest in adding providers shows that opportunity still exists for smaller laboratories to gain provider status, if they can demonstrate innovative ways they can benefit the largest health insurance companies.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 3, 2006.

UPCOMING...

- ***Major Shifts in Managed Care Contracting Practices That Benefit Local Laboratories.***
- ***More Lab Acquisitions Ahead! Who Are the Buyers? Which Labs Are Targets?***
- ***IVD Executive Looks at Strengths, Weaknesses of Current Technology.***

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