Volume XIV, Number 9 Monday, June 25, 2007

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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Recognizing Laboratory Leadership

WHEN **LABORATORY CORPORATION OF AMERICA** CLOSES ON THE SALE and becomes the owner of **DSI Laboratories, Inc.**, of Fort Meyers, Florida, it will mark the end of one of the nation's oldest hospital laboratory outreach programs.

I consider this to be a good news/bad news story. The good news is that DSI's owner, **NCH Healthcare System**, is selling its lab outreach program for between $40 million and $89 million and will use that cash to further its mission in patient care. The bad news is that an energetic, independent laboratory organization, founded in 1984, becomes the latest casualty in the ongoing consolidation of the American laboratory industry.

Before DSI Laboratories disappears as an independent, regional laboratory, I would like to recognize its CEO, Paul Gotcher, for his achievements. During his tenure at the helm of DSI Labs, Gotcher has demonstrated a knack for developing a vision, then guiding his laboratory team toward achieving that vision.

Of particular importance to the entire laboratory industry was Gotcher's guts to be one of the very first in the United States to introduce Lean and Six Sigma techniques into the heart of the hospital laboratory: its high volume core laboratory. During 2002 and into 2003, a DSI team at 400-bed **Naples Community Hospital** applied Lean and Six Sigma techniques to reengineer work flow in specimen collection, specimen transport, and specimen processing. A Lean work cell was created in automated chemistry and hematology. This nine-instrument cell, staffed with nine med techs at peak periods, post-Lean could be operated by one med tech—although two med techs were typically scheduled. Of equal importance, average test turnaround time from receipt in lab dropped 51%, to just 35 minutes. *(See TDR, September 8, 2003.)*

Gotcher has long experience with hospital laboratories and outreach programs. In the 1990s, he was CEO of **Sonora Laboratory Sciences** in Phoenix, Arizona. Later, as an executive at **ARUP Laboratories, Inc.**, in Salt Lake City, Utah, he worked with client hospitals throughout the United States to help them develop inpatient and outreach laboratory services.

In fact, were LabCorp to be serious about developing effective joint ventures and collaborations with hospital laboratories, it couldn't do better than to bring Gotcher into its executive ranks, give him a boost in pay, and listen to his recommendations on how to develop win-win business relationships with hospital-based laboratories. TDR

LabCorp Buys Hospital Outreach Lab in Florida

National lab company acquires an improved market presence along Florida's West Coast

CEO SUMMARY: Once again, a national laboratory has seized the opportunity to acquire a strong regional laboratory. This time it's the sale of DSI Laboratories, Inc., of Naples, Florida, to Laboratory Corporation of America. DSI's owner is NCH Healthcare System, which owns two hospitals in Naples. Terms of the deal were not revealed. LabCorp will buy the outreach testing assets of DSI, and NCH will retain the inpatient laboratories.

PATHOLOGISTS AND LAB DIRECTORS operating hospital laboratory outreach programs expressed surprise at the news, announced last week, that **Laboratory Corporation of America** would acquire **DSI Laboratories, Inc.**, of Fort Meyers, Florida.

LabCorp will purchase DSI from **NCH Healthcare System**, which operates two hospitals in Naples, Florida. DSI Laboratories is a successful laboratory outreach program. According to the *Naples Daily News*, in 2006, DSI had revenues of $39.3 million and expenses of $38.5 million, which produced income totalling $794,000.

Founded in 1984 as a stand-alone enterprise operated by NCH, DSI Laboratories manages the consolidated laboratory services for the hospital system. It also is a major provider of laboratory outreach testing services to office-based physicians and has enjoyed steady growth in specimen volume and in revenue in recent years. It currently operates 20 patient service centers in Collier, Lee, and Sarasota counties.

The terms of the deal were not disclosed and LabCorp declined to comment beyond statements in a press release. A spokesperson told THE DARK REPORT that LabCorp's strategy in Florida was "competitively sensitive."

NCH and LabCorp announced the agreement to DSI employees on Monday, June 18. LabCorp is buying everything but the two inpatient laboratories at **NCH Downtown Naples Hospital** and **NCH North Naples Hospital**. DSI said its employees would remain after the sale and

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.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

that LabCorp intends to retain the DSI name. NCH plans to keep 120 of the current employees to run the clinical laboratories at its Downtown Naples and North Naples hospitals.

NCH Needed Cash

THE DARK REPORT observes that a major motivation for NCH to sell its laboratory outreach business is the need to realize the capital value of this business asset. Because of increased competition from another hospital in Naples, NCH is expected to post operating losses in 2007. *(See sidebar at right.)*

Using recent sales of laboratory companies as a guide, it is likely that NCH was paid a handsome price for DSI Laboratories. For example, if LabCorp was willing to pay either 1.5 times annual revenue or 2 times annual revenue, that would generate a sales price to NCH Healthcare System of $60 million or $80 million, respectively. The sale of DSI Laboratories to LabCorp is subject to review by the federal government. Neither party disclosed an expected closing date for the transaction.

Reallocating an Asset

The NCH sale of DSI is one of several in recent years in which a hospital has sold its laboratory outreach program to generate cash. In 2005, the health system owners of **Spectrum Laboratory Network**, in Greensboro, North Carolina, sold a majority interest in this laboratory company and its outreach testing business, to **Apax Partners, LP**. It is estimated that the health system owners realized more than $100 million cash as a result of the sale. *(See TDR, November 14, 2005.)*

Another similar transaction was the sale by **Health Alliance** in Cincinnati, Ohio, of its laboratory outreach business to **Lab*One*, Inc.** (now part of **Quest Diagnostics Incorporated**). That sale in 2004 brought the selling hospital organization $43.9 million in cash. *(See TDR, February 23, 2004.)* TDR

NCH Is Using DSI Sale To Raise Needed Capital

FACING OPERATING LOSSES DUE TO NEW COMPETITION IN NAPLES, FLORIDA, NCH Healthcare System is raising needed cash by selling DSI Laboratories, Inc., to Laboratory Corporation of America.

The new competitor is **Hospital Management Associates** (HMA), a national for-profit hospital company with headquarters in Naples. It operates 61 hospitals in 12 states. In May 2006, HMA paid $125.5 million to buy the 83-bed hospital and outpatient medical center known as **Cleveland Clinic Naples**. It renamed the facility **Physicians Regional Medical Center**.

It is estimated that NCH Healthcare System will lose as much as $20 million during 2007. NCH acknowledged the need for capital, stating that the sale of DSI represents a reallocation of hospital assets. "Those assets are better used in our core function," said Chairman Carl Westman of NCH Healthcare System.

Allen Weiss, M.D., President and CEO of NCH, agreed. "NCH will benefit by enabling us to reallocate resources and maximize our efforts in enhancing the core service for which we are most respected throughout the region and the state: inpatient care," he said. "In addition, the transaction will help fortify our balance sheet and help support our ability to offer competitive wages and benefits to continue to retain and attract quality employees."

NCH is an integrated healthcare system with 681 licensed beds. In the two hospitals, 535 independent physicians care for more than 31,000 patients each year. NCH does about 500 open heart surgeries and delivers 4,500 babies each year.

DSI Sale Shows Value Of Lab Outreach Program

LabCorp's acquisition of DSI Laboratories confirms a number of laboratory industry trends

CEO SUMMARY: For other hospital laboratory outreach programs, the pending sale of DSI Laboratories, Inc., of Fort Meyers, Florida, to Laboratory Corporation of America provides useful insights about the market value of these programs. Applying general formulas for determining a sales price, DSI Labs' $40 million in yearly revenue may have fetched between $40 and $89 million for its owner, NCH Health System.

THERE ARE SEVERAL SIGNIFICANT ASPECTS to the pending sale of **DSI Laboratories. Inc.**, of Fort Meyers, Florida, to **Laboratory Corporation of America** of Burlington, North Carolina.

First, it is the latest example of a health system choosing to sell its laboratory outreach program in order to raise capital that can be reinvested in other areas of the health system's primary business: acute and critical care.

Second, the sale demonstrates that LabCorp and **Quest Diagnostics Incorporated** continue to the primary drivers in the ongoing consolidation of laboratory testing services in the United States. They stand ready and willing to bid aggressively for any attractive laboratory business that comes to market.

Third, the sale demonstrates that outreach labs have substantial capital value for the specimen volume and cash flow they produce. A conservative estimate is that LabCorp will pay between $40 million and $80 million for DSI Laboratories.

Fourth, DSI Laboratories provides an example of how a professionally-managed laboratory outreach program can create a service infrastructure that can equal or exceed that of the national laboratories within that same community.

Fifth, LabCorp's statement that it will continue to operate its new acquisition under the name DSI Laboratories, Inc., confirms that the national laboratories have finally learned an important lesson. Retaining the name of the acquired regional laboratory helps in retaining clients.

Insights For Lab Directors

For laboratory directors and pathologists currently managing a hospital laboratory outreach program, a study of the DSI–LabCorp deal can be useful in several ways. Probably the most useful insight is that a well-run, professionally managed laboratory outreach program can be a surprisingly valuable asset.

Although neither party to the sale has yet revealed the purchase price, an estimate of value can be developed, using two methods. One method is to take annual sales and multiple that by a factor that reflects recent, comparable sales in the

marketplace. Under that approach, DSI's 2006 revenue of $39.3 million could be multiplied by a factor of no less than one, and as much as two, generating an estimated sales price of as little as $40 million and as much as $80 million.

Determining Market Price

Another method is to calculate cash flow—the amount of income that remains after subtracting the direct cost of testing. EBIDTA (Earnings before Interest, Depreciation, Taxes, and Amortization) is often used as a valuation benchmark. In the case of DSI Laboratories, if cash flow is assumed to be 15% of $39.3 million, that would equal $5.9 million per year.

It is known that, when Quest Diagnostics acquired **AmeriPath, Inc.** last month, it was willing to pay $2 billion, or 15 times cash flow, for AmeriPath. Use that same multiple for DSI, and 15 times $5.9 million would generate a valuation of $88.5 million for DSI's outreach business.

These are impressive numbers to a hospital CEO, particularly if the hospital is operating in the red. The ability to convert a laboratory outreach program into cash, ranging from $40 to almost $90 million, certainly can get the attention of the hospital CEO. As noted on pages 3-4, in recent years the hospital owners of both **Spectrum Laboratory Network** in Greensboro, North Carolina, and **Health Alliance** in Cincinnati, Ohio, decided to sell their laboratory outreach programs for amounts ranging from $44 million to more than $100 million.

Educating CEOs About Value

THE DARK REPORT recommends that laboratory administrators and pathologists managing laboratory outreach programs should discuss these three sales and valuations with their CEO and CFO. It will help them understand that their laboratory outreach program, besides generating cash flow each year, is building value as a capital asset. This makes it easier to obtain investment funds when the outreach program needs additional equipment or infrastructure in order to grow further.

It should also be noted that representatives from the two blood brothers regularly call on hospitals and health systems with laboratory outreach programs specifically to discuss a potential sale. This was true at DSI Laboratories.

"They [LabCorp] were attracted to DSI," said Carl Westman, Chairman of the Board of Trustees at **NCH Health System**, the owner of DSI Labs. "They were very aggressive, I think (that) is a good way to describe their desire to talk with us."

In fact, over the years, LabCorp made regular visits to NCH and DSI Laboratories to express their willingness to buy DSI Labs. As the timing of this deal shows, NCH wasn't interested—until the health system began losing money this year. Reports are that NCH could lose between $11 million and $20 million this year.

Operating Under Pressure

Peripherally, LabCorp's exclusive contract with **UnitedHealth** was a factor. UnitedHealth has a significant concentration of beneficiaries on the west coast of Florida. LabCorp will add DSI's 20 patient service centers (PSCs) to the 23 it already operates. That will give LabCorp a total of 43 PSCs in the region.

A final observation about the DSI–LabCorp sale is that NCH Health System will continue to own and manage its two hospital laboratories. In fact, about 120 of DSI Labs' 400 employees will remain with NCH to staff these laboratories.

The unwillingness of NCH to allow a national laboratory to own or manage, under contract, its hospital laboratories is a reminder that hospital administrators like to maintain control of their laboratory. The insistence by hospital CEOs to control their laboratories is a major hurdle that prevents national labs from developing contracts that allow them to manage hospital laboratories. TDR

$18 Million Judgment For Errors by Laboratory

Unclear test requisition led to confusion between laboratory and ordering doctor

CEO SUMMARY: In a wrongful birth lawsuit, a high-risk pregnancy physician in New Jersey requested a cytogenetics test on a pregnant mother, but LabCorp's cytogenetics lab never did the test. After the baby was born with myotubular myopathy—the same deformity the mother had sought to prevent—she sued and won a jury verdict in her favor against her high-risk pregnancy doctor, LabCorp, and LabCorp's cytogenetics lab director.

In New Jersey, a $28 million jury award against a physician, a national laboratory, and a cytogeneticist-laboratory director hinged on a cytogenetics test that was never performed.

The circumstances of the case have important legal implications for pathologists and laboratory directors. The case also demonstrates how the growing use of genetic testing has the potential to establish new legal precedents.

Following a February trial, a jury decided against defendants Aldo Khoury, M.D., the patient's doctor; **Laboratory Corporation of America**; and James Tepperberg, M.D., who is director of LabCorp's cytogenetics laboratory. The jury award was $28 million, with liability assigned as follows: 50% to Khoury ($14 million); 40% to LabCorp ($11.2 million); and, 10% to Tepperberg ($2.8 million).

Following the jury verdict, the defendents agreed to a settlement which totaled $18 million, of which Khoury and LabCorp will each pay $9 million.

The case of *Wanda Tineo, as the guardian for son Justin Tineo v. St. Joseph's Regional Medical Center, et al,* offers important lessons for pathologists and lab directors. The issues turned on which party was negligent, LabCorp's cytogenetics lab or the ordering physician. The ordering physician was Aldo Khoury, M.D., a specialist in high-risk pregnancies who is affiliated with **St. Joseph's Regional Medical Center** in Paterson, New Jersey. Early in her pregnancy, Khoury's patient, Wanda Tineo, had asked about her risk of transmitting myotubular myopathy to her unborn infant.

Mistakes Made

"In filling out the lab requisition, Khoury was not clear in requesting which tests LabCorp should perform," said Gerald O'Connor of **O'Connor & Dumas** in Chatham, New Jersey. O'Connor was Tineo's attorney. The baby, Justin, was born in 2003 and was diagnosed with myotubular myopathy.

"A number of mistakes were made," stated O'Connor. "First, the doctor who wanted the test for myotubular myopathy called LabCorp on the phone and said he

Tineo's Court Verdict Has Lessons for Labs

THERE IS AT LEAST ONE SIGNIFICANT LEGAL ISSUE for pathologists and lab directors as a result of the Tineo case, said attorney Jane Pine Wood. Wood is a lawyer with **McDonald Hopkins**, a law firm in Cleveland, Ohio.

Wood said the lessons for other labs in this case are clear. "Looking at the facts in this case, it is appropriate that the two parties would be liable—at least partially," she said. "The issue that is important for laboratories and medical directors is this: every day, doctors write what they want in all different ways on requisition forms. In this case, if the laboratory has a history of periodically performing tests that are written in odd places on the test requisition and then arbitrarily ignores a request for a test and didn't do it, it could have some responsibility.

"In light of this case, laboratories should review their existing policies on this point," continued Wood. "Labs should be careful with any policies that say, 'We don't do tests unless they are specifically ordered in the proper section of the test requisition.' The lesson from this case is your staff should be informed that, whenever they see anything in writing on the test requisition that is not in the appropriate box to request a test, they need to follow up with the doctor to confirm what he wants.

"Also, I could see a different outcome in this court case if LabCorp had a policy in which it doesn't perform any testing unless such tests are requested in the requisition check boxes and clearly printed on the requisition," added Wood. "When a sales rep or anyone from the lab is in the physician's office, he or she should explain clearly that the laboratory has a policy that specifies it won't do any test unless it is requested in the proper box and that, per this policy, the laboratory would not do any follow up with the doctor to see if he or she wanted a test not requested in the proper way.

"If this policy was crystal clear and there was no deviation from this policy, then possibly LabCorp might not have been held responsible in the Tineo case," Wood explained. "But once the plaintiff had established that LabCorp had a practice of following up with doctors to clarify things written out of place on a test requisition, then the court ruled LabCorp had the obligation to continue to do so."

was testing for myotubular myopathy. He asked how much fluid he needed to submit for the test. On that phone call, LabCorp allegedly never told him they did not have the capability to perform the test and would need to refer the test to another laboratory.

"Second, the defendant, James Tepperberg, M.D., was LabCorp's director of its cytogenetics lab. He testified at his deposition that the box that LabCorp uses on its requisition (which says 'diagnosis, sign, or symptom'), means for what condition the doctor wants the lab to test. Written on the form was 'myotubular myopathy.' So the logical inference was that the laboratory knew the doctor wanted the test done for myotubular myopathy. But the doctor only checked off amniocentesis.

"However, before you can test for myotubular myopathy, you have to know whether the embryo is a male or a female," O'Connor continued. "So they did a chromosomal amniocentesis. Nobody at LabCorp even knew what myotubular myopathy meant. Nor did they attempt to find out—even though they testified at the

deposition that they rely on what the doctor writes on the form."

An expert witness at the trial who is a pathologist and geneticist, and who asked not to be identified, told THE DARK REPORT that Khoury erred when he completed the requisition form. "Khoury requested standard tests and left blank the large box that ordering physicians use to order a test not listed in the check boxes," the expert witness explained. "Then, at the top, in the billing section in the ICD-9 box, someone in the ordering doctor's office wrote 'hx [history] mytuberal [sic] myopathy.'"

Rare Genetic Defect

Myotubular myopathy is a rare gene defect that affects muscle development. When Justin was born with the defect, his mother sued for wrongful birth. Under New Jersey law, a family can seek compensation for emotional distress and medical expenses when health professionals fail to warn parents about possible birth defects.

O'Connor said, "The doctor has some liability and LabCorp has some liability. In the form LabCorp sent back to the doctor under the diagnosis section at the very top, they wrote 'history of myotubular myopathy.' So the doctor—who had never seen a test result for myotubular myopathy—thought that, since they wrote 'history of myotubular myopathy' on the top of the report, that this chromosomal report indicated there was no myotubular myopathy."

The expert witness told THE DARK REPORT that only a few laboratories in the United States do molecular testing for myotubular myopathy. "Because myotubular myopathy was combined with history, that could mean anything," observed the expert witness. "And that is the crux of the case. The plaintiffs claimed that someone at the cytogenetics lab should have realized that Khoury wanted the myotubular myopathy test, which LabCorp doesn't do. LabCorp should should have sent it out to a lab that does this test or called Khoury to learn more about it.

"Instead LabCorp simply did what was checked off in the checkboxes, which is what a lab should do," the expert witness said. "A laboratory can't go against the doctor's orders. The laboratory reported out normal chromosomes and normal results. At that point, Khoury should have noticed that there was nothing in the report about mytubular myopathy, and he should have known that the test for myotubular myopathy is a molecular (DNA) test, not a cytogenetic (chromosome) test. Instead, he simply informed the patient that the tests came back normal and told the patient she didn't have to worry anymore."

Rare Genetic Defect

THE DARK REPORT observes that this case turned on two issues that labs face almost daily. First, ordering physicians often fill out requisitions in unusual ways. Second, when they do, some labs will tell ordering physicians: "Test not done." Some experts said laboratories should have a consistent policy about calling ordering physicians to clarify requests on the test requisition that are unclear.

THE DARK REPORT also learned that LabCorp made another error in this case. During testimony, there was discussion about whether Tepperberg had sometimes called ordering physicians in some cases when there were questions about which tests were being ordered. In this case, Tepperberg allegedly didn't call Khoury to explain that LabCorp did not do the test for myotubular myopathy and that Khoury should submit a request for this test to another laboratory.

As noted in the sidebar on the previous page, attorney Jane Pine Wood of McDonald Hopkins advises that all labs should implement specific policies to prevent miscommunication on lab requisition forms. Clearly, the failure to implement such procedures can expose a laboratory to large malpractice claims. TDR

Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.

NEWSMAKER INTERVIEW

Global Laboratory Trends Dominated By Rising Costs and Labor Shortage

"The Web has transformed many industries and it's clearly affected our industry. This trend will help raise the bar in quality and overall performance among laboratories and manufacturers."

—Jim Reid-Anderson
Chairman, President, and CEO of Dade Behring

➤➤ ***CEO Summary: Recently, THE DARK REPORT conducted a roundtable interview with executives of Dade Behring. Present were Jim Reid-Anderson, Chairman, President and CEO; Donal Quinn, Chief Operating Officer; and Mark Wolsey-Paige, Chief Strategy and Technology Officer. Topics discussed ranged from domestic and global trends in the clinical laboratory industry to evolving business strategies in the* in vitro *diagnostics (IVD) industry—and Dade Behring's responses to these developments. The interview was conducted by Editor Robert L. Michel.***

EDITOR: There's high interest in the new products introduced by **Dade Behring Inc.** in recent months. It is expected to shift the competitive market because your company is ready to compete for the business of high volume laboratories, here and across the globe. That makes it timely to discuss Dade Behring's views on current issues now confronting laboratory administrators and pathologists. After all, it has been almost five years since your last interview with THE DARK REPORT. *(See TDR, October 28, 2002.)*

REID-ANDERSON: Oddly enough, in terms of our overall view, it hasn't changed with regard to what I said to you five years ago. Dade Behring continues to be the largest company in the world that's solely dedicated to clinical diagnostics. We serve about 25,000 customers around the world, and have about $1.7 billion in annual revenue.

EDITOR: Why is this distinction important?

REID-ANDERSON: Since we don't have business lines to serve the research market or other biotech industries, our focus is solely on clinical diagnostics. That gives us a unique and intimate understanding of the needs and opportunities in clinical laboratory services.

EDITOR: Because you believe that, over the past five years, the same basic forces continue to shape the evolution of the clinical lab marketplace, let's review the key points.

REID-ANDERSON: We believe there is a broad trend in the industry that involves the role of clinical diagnostics in the life cycle of patient care. It is recognized that fast, accurate diagnosis helps save lives and promotes wellness. Further, if used appropriately, laboratory testing has the potential to help contain healthcare costs overall. That area is a strong trend and one on which we are focused.

EDITOR: I suspect that you see a problem, along with an opportunity.

REID-ANDERSON: Yes. The problem is that the relative amount of funding for diagnostic testing has declined in recent years.

EDITOR: Could you explain that?

REID-ANDERSON: Numerous reviews of healthcare spending show that diagnostics represents just 2% of total healthcare costs. When you and I spoke last, diagnostics was about 3% in these same spending tallies. So, diagnostic's proportion of the total healthcare spend has declined significantly in a short time. Despite the fact that diagnostics continues to be the basis for 70% of healthcare decision making, the profile of laboratory medicine is not high enough. Policymakers do not fully understand the benefits that can come from diagnostics.

EDITOR: What other issues confront laboratories today?

REID-ANDERSON: A primary issue is the continuing increase in cost, both in operating the laboratory and providing healthcare services. Another primary issue is laboratory labor—both the availability of labor and its cost.

EDITOR: Those were tops on your list of issues five years ago.

REID-ANDERSON: Nothing has changed on these points. Of course, there are many other areas of focus, such as informatics and reimbursement pressures. These are issues that affect the United States and many European countries. On the demand side, in all of the developed countries, you have aging populations. This generates increased demand for diagnostic testing and other healthcare services.

QUINN: We have operations in 35 countries and this trend is common across the globe. Many countries are introducing DRG-style approaches to control the rising cost of care.

EDITOR: Does the introduction of DRGs (Diagnosis-Related Groups) trigger certain consequences to the healthcare system?

QUINN: DRGs have been used in the United States since the 1980s with some success. But this type of focus on costs leads to market consolidation. Outside the United States, Australia provides probably the best example. Australia has experienced strong market consolidation on the one hand, followed by privatization on the other hand. Because of consolidation, Australia's lab market is now controlled by about seven large lab companies. We see a similar trend in France and Germany.

EDITOR: So, you see a clear trend of a concentration of lab services into fewer and larger laboratory companies.

QUINN: Yes, and this creates a dilemma for labs undergoing consolidation. They must reduce costs while at the same time maintaining or improving turn-around times and the quality of care.

EDITOR: Let's shift gears and talk about how Dade Behring is positioning itself to respond to these trends and the evolving needs of clinical laboratories.

REID-ANDERSON: At the time of our last conversation five years ago, Dade Behring was just beginning to see the results of a change in corporate strategy. During our early years in the 1990s, the primary focus was placing instruments. It was the traditional, sales-driven culture that was common to many corporations. About the time of our reorganization and corporate refinancing, we changed our strategy to adopt a customer-first culture. We think you will see this culture shift reflected in our people.

EDITOR: That's an interesting strategy for differentiation. Can you explain how you are creating that difference?

REID-ANDERSON: Of our worldwide staff of 6,300 employees, more than half are what we describe as "customer facing." One of our priority goals is customer retention. We are able to retain customers because we consistently help them acquire the right solution for their needs, and then we provide consistent service day in and day out. We recognize that business goals can only be met by having people within our company who are focused on meeting the needs of our customers.

EDITOR: Let me be a skeptic, for a moment. All companies say they want to use customer service to deliver competitive advantage. What is different at your company?

Donal Quinn

➤"Because of consolidation, Australia's lab market is now controlled by about seven large lab companies. We see a similar trend in France and Germany."

REID-ANDERSON: Of course we aim to deliver products and middleware solutions. But we recognize that it is equally important to service those products very well for five or more years—throughout the length of the contract. Our goal is to provide the same intense level of service at the end of the contract as we did at the beginning. We believe lab customers recognize this level of service commitment.

EDITOR: You are talking about a business strategy that, at its heart, is unrelated to healthcare and lab industry trends.

REID-ANDERSON: Even though it's important to respond to market trends, you also have to focus on the customer. That's because every lab has its own unique set of requirements—regardless of market trends. We have identified 14 points of contact that we have with our customers. We relentlessly measure how we meet our customers' expectations on each of these 14 points of contact.

WOLSEY-PAIGE: Robert, one point might help you better understand this corporate strategy. If you recall, during the 1990s, Dade Behring was a company put together by Wall Street investors. They acquired products and business divisions from several different IVD industry players. Our challenge was to mesh what were five different company cultures into a single Dade Behring culture. Emphasizing customer satisfaction was an effective way to align and unify the thinking of all our employees.

EDITOR: That is an excellent point. Most lab directors and pathologists tend to overlook the fact that today's Dade Behring is a consolidation of several earlier—and well-established—diagnostic vendors. I would like to switch topics again and discuss technologies. In particular, what are Dade Behring's views about progress in proteomics and informatics, as they relate to clinical laboratory testing?

WOLSEY-PAIGE: Since our reorganization in 2002, we have steadily increased our annual investment in research and development. We intend to use technology as the strategic complement to the customer-facing organization. This will play out in two ways. First, we will use technology to advance the clinical mission of the laboratory. Second, we will use technology to improve both the clinical efficiency and the work flow efficiency of the laboratory. Both of these objectives are met with our Dimension Vista® platform.

REID-ANDERSON: Five years ago, Robert, we discussed the Dimension Vista® platform. At the time, it was called Project Epsilon. We are now shipping that product to customers and what I described in our conversation is now in use in laboratories.

WOLSEY-PAIGE: Let me connect our perspectives on technology to the lab industry macro trends we discussed earlier. The laboratory industry is poised for great times. Demand for laboratory testing increases even as labs have new assays that offer increased sensitivity and specificity. Most physicians and the people making clinical decisions value the capabilities of technology. But the pressures of increasing costs and declining reimbursement mean that laboratories have little margin for error. We hope to provide our customers with technology and solutions that help them succeed, despite these negative economic trends.

EDITOR: Essentially, you aim to support the effort of laboratories to reduce the margin for error in how clinicians utilize lab tests. Do you see progressive laboratories executing a strategy to participate in the pre-pre analytical activity of the clinician and the post-post analytical activity of the clinician? That's where clinicians decide what test to order and then, after getting the test results, how to treat the patient.

QUINN: Among the leading laboratories, we see this trend. To support this trend with technology, we are building expert systems into our instrument platforms and middleware. These are designed to manage work flow and aid in evaluating results and interpretation.

EDITOR: Are labs in other countries deploying expert systems on a wider scale than we see in the United States?

QUINN: That varies widely. For example, there is a great deployment of expert systems in Germany. However, in some areas of medicine, there's an aversion to anything that's perceived as cookbook medicine. That issue must be overcome for expert systems to gain wider acceptance. Across our product line, the strongest demand for this capability is in protein testing, as well as segments of the microbiology market. Those are areas where we've seen great demands for that capability.

REID-ANDERSON: I'd like to get back to the question you asked a few minutes ago about trends and technology. I'd like to add a few others. The first one involves

the prevalence of integrated analyzer systems. Market data collected by independent companies indicates that the number of integrated analyzer systems is growing rapidly. In the United States, about 46% of labs have integrated systems and most of these simply combine chemistry and immunoassay testing on the same platform.

EDITOR: Will this trend continue?

REID-ANDERSON: Definitely. The United States is ahead of the rest of the world in terms of using integrated instrument systems. In 2001, independent data showed that integrated instrument systems represented about 19% of the U.S. lab market. And the most recent survey, completed during 2006, shows that integrated instrument systems now hold about 46% of the market in the United States. This is a big area for Dade Behring, since we have a market share of approximately 81% of those integrated systems with our Dimension family.

EDITOR: Are laboratories moving toward this type of solution as a way to automate work processes and streamline work flow?

REID-ANDERSON: That is a major motivation. This is a trend now extending into all of the international markets. Now, I don't believe 100% of U.S. labs will have integrated systems 10 years from now. But, by 2017, it could be 80% to 90%. Globally, probably fewer than 20% of labs now use integrated instrument systems. The trend toward instruments that can do more will be huge.

EDITOR: Is it true that another significant trend in laboratory instrumentation since 2000 is the growth in demand for pre-analytical systems? After all, pre-analytical automation can positively affect workflow through the rest of the laboratory, as well as help address the labor shortage facing most laboratories.

REID-ANDERSON: That was going to be my next point and you just hit on it: automation. We totally agree with your points about automation. We predict that a broader and more capable variety of solutions will be available in the future. At one time, experts believed that only high volume labs would have these solutions. But advances in technology now make it possible for mid- and high-volume labs to incorporate these solutions.

EDITOR: Is that why we're seeing automation as an important labor substitution strategy? In other words, the technology is enabling a lot more solutions than what was called automation in 1995 or 1996?

REID-ANDERSON: Yes, absolutely. Another trend we've seen in the *in vitro* diagnostics (IVD) marketplace is that laboratory customers expect their vendors to deliver enhanced services. This goes beyond higher expectations for the performance and reliability of instruments and reagents. They want their suppliers to provide superior support services, along with help in developing solutions that advance the clinical and operational performance of their laboratory.

EDITOR: This trend could be described as the interest of laboratory customers to work with suppliers who provide added value, such as the operational consulting teams we now see at many IVD manufacturers.

REID-ANDERSON: You describe the change in the expectations of laboratory customers. This is one reason why we adopted a "customer focused" business strategy. Donal, I know you have strong opinions about this trend, right?

QUINN: Yes. That's correct. Given the pressures that we've talked about where consolidation is happening in a particular market, how does a laboratory truly differentiate what they do from competing labs? If they can provide a differentiated service to their customers, then they are almost guaranteed to be able to continue to grow and develop.

EDITOR: Thus, in your view, an IVD manufacturer such as Dade Behring can differentiate itself with its laboratory customers if it can provide these labs with the help, knowledge, and service package they need to achieve a similar differentiation with their own customers?

QUINN: Our goal is to ensure that we support them in that effort, and therefore be in a position where we truly deliver on a consistent basis day in and day out. We aim to delight our customers at every point of contact. That is our fundamental approach in the marketplace.

Jim Reid-Anderson

➤"The United States is ahead of the rest of the world in terms of using integrated instrument systems."

EDITOR: If you were to articulate some of the specific steps that Dade Behring takes in terms of service and performance 'on the street' for customers that would differentiate Dade from the other major IVD companies, what are they?

QUINN: We measure our performance against the 14 different points of contact. We look at each of those points in terms of their importance to our customers. It's no surprise that the number one need, in every country across the globe, is the performance of the field service organization. Another priority is to look at each laboratory as being unique. Every laboratory has unique needs and that provides us an opportunity to develop a solution to meet that lab's specific needs. In some cases, it may be how a large, multi-hospital health system wants to integrate lab testing services across multiple sites. In another situation, it may be how we help the laboratory exploit e-commerce.

REID-ANDERSON: In addition, we try to find supplementary support for our customers as well. I'll give you an example. This is something new since we talked earlier. About five years ago, we developed a scholarship program because we understood that our customers had problems recruiting staff to work in labs. We are investing over $1.25 million in nine countries to fund scholarships for students who are pursuing degrees as clinical laboratory professionals. That program has become extremely successful. It's grown every year, and that differentiates us as well. The scholarships are one area in which we have increased our investment.

EDITOR: On the topic of investment, this may be a good time to talk about the type of new technologies you expect to see in the marketplace in coming years.

REID-ANDERSON: With so many laboratories looking for integrated solutions, help in refining work flow, and the in-house capability to offer a broad menu of tests, we've aligned our technology efforts to support these objectives. One approach is ultra-integration. That involves the combination of chemistry and immunochemistry and enhancing it by adding much more capability. We have built the ability to perform nephelometric protein testing into our new Dimension Vista® platform so we can offer the same quality of measurement on our chemistry/immunochemistry analyzer that has been the hallmark of stand-alone nephelometers in the past. Improving ease of use is a priority too.

EDITOR: Could you comment more on that point?

REID-ANDERSON: Our goal is to develop and deliver solutions which take labor contact out of the laboratory. For example, our new analyzer has highly automated calibration and QC procedures. Customers recognize the value of that benefit. In addition, our customers want to monitor the instrument and discern differences in performance and intervene

proactively to deal with any variation. We responded to this need by designing our Dimension Vista® instrument very differently from early Dimension platforms, adding the ability to monitor the instrument remotely. We have wanted this for a number of years. We designed the instrument with hundreds of sensors, all of which can be tracked over the Internet. That allows us to continuously monitor the performance of the instrument remotely. Over time, as we get more experience with this data, we will be able to proactively intervene before a problem develops by sending a service rep to the site or calling the customer if we see a potential issue. Also over time, we will mine the data, allowing us to make design changes to make our instruments even more reliable.

EDITOR: The value of LOCI™ technology is that it increases the sensitivity of the next generation tests, right?

REID-ANDERSON: Yes. We talked about LOCI™ a few years ago and it has unique advantages. Mark can provide more detail on that topic.

WOLSEY-PAIGE: Yes, the actual performance will speak for itself as labs gain more experience working with individual assays on the Dimension Vista® menu. An important factor is the homogeneous nature of the technology. For example, there's literally no difference in the way you process a chemistry test or a immunochemistry test other than the measurement station that it stops at and the light wave length you are flashing. This greatly simplifies the mechanical processing requirements for the system and means there is no time penalty on the instrument with this format.

REID-ANDERSON: We are also seeing another dividend from our research budget, which has been 9% of revenue in recent years. Our current technology pipeline has more than 100 products approaching introduction. Last year, Dade Behring had more tests approved by the FDA than all the other top five competitors put together. When you combine new instrumentation and new assays with our focus on service, we believe that lab customers will be very interested in the solutions we are bringing to market.

EDITOR: One area that I am curious about is the migration of QA/QC functions onto Web-based systems that allow real-time collection of data from laboratories worldwide. Will this development force IVD manufacturers that have been inconsistent in the quality of the reagents they ship from one batch to the next to have more consistent outcomes?

Mark Wolsey-Paige

➤"Let me address the informatics part of this equation. The integration of *in vitro* diagnostics and healthcare informatics is already underway."

REID-ANDERSON: Absolutely. The Web has transformed many industries and it's clearly affected our industry. This trend will help raise the bar in quality and overall performance among labs and manufacturers. We focus on this area intensely. To the best of my knowledge, we are the only company that has no outstanding issues with the FDA. We work to ensure that we are not in a position to have such an issue. As laboratories access real time peer data, information flows more effectively and laboratory directors are able to measure how they're performing versus other laboratories. At the same time, they will be able to assess the consistency and quality of their vendors' reagents.

EDITOR: Do you think that, as laboratories adopt Lean and Six Sigma methods, that these quality management tools will make it easier to make relevant comparisons of

their operational performance against other laboratories across the globe? For example, it becomes possible to look at analytical performance in terms of a Six Sigma rate—errors per million events—and compare it with the Six Sigma rate of other labs?

QUINN: These tools are effective in many ways and indeed Six Sigma is one metric that absolutely could be applied across the globe. Even though we talk about our strategic market, there are numerous laboratories in other countries that could match the standards that we see in some developed markets. That is true in the 35 countries in which we operate. As an organization, we welcome all kinds of transparency that can show how our products match up with the competitive offerings of other companies.

EDITOR: I am curious as to whether you believe that market and regulatory forces are raising the quality bar in diagnostic manufacturing—the supplier segment in laboratory testing.

REID-ANDERSON: That is certainly true. We have a strong focus on this area and that's due in part to what happened about a decade ago when most of us joined the company. We had an issue with the FDA that was a defining moment for us as a management team. At the time, we said we would never allow ourselves to be in that position again. Now we listen with great care and attention when we interact with the FDA. We take immediate action on any problems that are identified.

WOLSEY-PAIGE: This is a rigorous effort. Along with FDA visits to our instrument and reagent manufacturing sites, we have an internal team that conducts surprise audits of our sites. If anything pops up as a result of those inspections, we fix it before it becomes an issue. In addition, we pay independent auditors to do surprise audits. In that way, we know exactly where we stand on QA and QC issues.

REID-ANDERSON: As you can see, not only does our manufacturing team get detailed information from customers on how we're performing, but we're independently checking quality. We know we must work to maintain the customer's trust in our quality.

EDITOR: One topic I'd like to pursue involves the potential to combine imaging, IVD, and informatics as **Siemens** and **General Electric** are attempting to do.

REID-ANDERSON: As you recall from our conversation five years ago, ongoing consolidation of the IVD industry is something we predicted. At that time, we pointed out that consolidation would come from two areas. One source would be mergers and acquisitions among IVD manufacturers. The second source would involve major conglomerates buying into this industry. That has happened during the past 18 months, as Siemens and GE each acquired IVD manufacturers.

EDITOR: These two companies directly raised the profile of *in vitro* diagnostics with Wall Street. However, with your knowledge of technology and the market, can either or both of these companies integrate *in vivo* and *in vitro* diagnostics with informatics in ways that add value to clinicians?

REID-ANDERSON: There will be plenty of debate about that question. It may take as long as 10 or 15 years to fully realize the anticipated benefits in linking these technologies.

WOLSEY-PAIGE: Let me address the informatics part of this equation. The integration of *in vitro* diagnostics and healthcare informatics is already underway. So, as long as we adhere to standards and our systems provide information in a format that flows seamlessly into laboratory information systems and other clinical repositories, the desired benefits will accrue to the healthcare system.

EDITOR: Going back to the intersection and integration of *in vivo* and *in vitro*, we

see announcements that technology allows an imaging procedure to see smaller and smaller structures of the human body. So, one could speculate that radiologists can now find structures inside organs that indicate possible early stage cancers. It's not actionable information because the clinician doesn't know if the cells are benign or malignant. Is it reasonable to assume that advanced imaging technologies could find that structure at an early stage. Then, the clinician could use fine needle aspiration to collect those cells and let molecular pathology confirm if they're malignant. Would this be an example of how a Siemens or a GE could marry imaging procedures with clinical lab testing, thus enabling that imaging procedure to become a clinically appropriate procedure?

Jim Reid-Anderson

➤"...the vision of integrating imaging and *in vitro* diagnostics tends to downplay how advances in molecular diagnostics will arm clinicians with increasingly sensitive, highly accurate assays."

WOLSEY-PAIGE: It's certainly reasonable. As the scenario plays out, the challenge will be managing the cost to the healthcare system. Obviously, it has a lot of appeal, but it is apt to be expensive if the number of interventions increase. The key to making the sale is building the value add—it's a similar issue with PSA testing.

REID-ANDERSON: Also, the vision of integrating imaging and *in vitro* diagnostics tends to downplay how advances in molecular diagnostics will arm clinicians with increasingly sensitive, highly accurate assays. Look forward by five to 10 years. In that time, we will increase the number of onboard specialty tests that target disease for which there currently are no tests. Those disease states would include cancer. Furthermore, new assays that are more specific, more accurate, and more sensitive will be capable of early diagnosis in the way you describe. This is the specific direction of our research and development efforts. New assays will give physicians and patients greater knowledge and will be much more affordable for our customers.

EDITOR: That's an interesting prediction. Let's look next at the informatics goals discussed by Siemens and GE. They are discussing the benefits of combining laboratory information systems (LIS) with data such as radiology images. Eventually, that could mean the ability to fabricate a workable electronic medical record (EMR) that could be used with clinical database systems. What are the strategic merits to this vision?

WOLSEY-PAIGE: This endeavor would certainly provide advantages. The main challenge is how you evolve from today's information technology (IT) market position to this future state. To achieve the data integration you described, companies would need to migrate from a relatively small share position in the information systems market to a position where a sizeable number of laboratories adopt their LIS products. Building a commanding market presence will take time—along with a significant investment.

EDITOR: Time is growing short. We've covered a wide range of topics about trends and developments in the laboratory industry. Many thanks to all of you for participating in this discussion.

REID-ANDERSON: You are welcome. Donal Quinn, Mark Wolsey-Paige, and I enjoyed the opportunity to update our views on these subjects. As you have learned, everyone here at Dade Behring is optimistic about the future of clinical laboratory services. TDR

Contact Connie DuBois at 847-236-7038 or connie_dubois@dadebehring.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It should be boom time for companies selling Clinical Information Systems (CIS). A research report from **Millennium Research Group** (MRG) of Waltham, Massachusetts, predicts that patient safety programs will fuel a demand by health systems for CIS products. The report, "U.S. Markets for Acute Care Clinical Information Systems," says hospitals are adopting CIS to help them provide adequate, timely care, and prevent errors.

ADD TO: CIS Demand

In the report, Millennium Research Group (*www.mrg.net*) defines the CIS market to include radiology information systems, pharmacy and medication management information systems, cardiovascular and cardiology information systems, laboratory information systems, emergency department information systems, and critical care information systems. MRG notes that this market was valued at over $900 million in 2005. By 2010, MRG predicts revenues in the CIS market will exceed $1.5 billion.

NEW BLOOD TEST FOR DEPRESSION EARNS AWARD

A new blood test for mental illness won a prestigious award earlier this month in London, England. **Medical Futures** is an organization in London that promotes developments in healthcare. On June 14, Medical Futures (*www.medicalfutures. co.uk*) gave its Overall Mental Health & Neurosciences Innovation Award to Sabine Bahn, M.D., a consultant psychiatrist at **Cambridge University**, for development of a blood test that can be used to diagnose mental health diseases such as depression or schizophrenia using novel bio-markers. Bahn has reported that her test is based on distinctive chemical "signatures" that are associated with four different mental health disorders. Bahn noted that "We have found markers which are changing in the brain, spinal fluid, and in the blood, so we have focused on identifying a signature of several markers in the blood." The test can identify patients predisposed to mental illness long before they present with symptoms. Should clinical studies validate the effectiveness of this assay, it will open up a new channel of lab testing with psychiatrists and other clinicians in the mental health field. The World Health Organization predicts that depression will be the second biggest healthcare burden by 2020, ahead of cancer and HIV, and behind only heart disease.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

…how **PACLAB Network Laboratories** of Seattle, Washington, now holds a 30% market share, about equal to the market shares held by each of the two national labs in the Seattle metro.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 16, 2007.