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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Competing Against Regional Laboratories

SINCE THE 1980S, THERE HAS BEEN COMPETITIVE TENSION between publicly traded laboratory companies and their regional counterparts—both independent labs and hospital laboratory outreach programs. It's an understatement to say that both sectors of the laboratory community often wish the other was not around.

During the past 20 years, each class of laboratories has bedeviled the other—in ways too numerous to mention. Long-time readers of THE DARK REPORT are well-informed on these issues, as we have regularly analyzed how this competitive tension has triggered all sorts of consequences for the entire lab industry.

I believe regional laboratories will soon face another challenge, one that may threaten their access to managed care patients at reasonable reimbursement. In fact, it is a threat that THE DARK REPORT was first to identify several months ago. *(See TDR, February 19, 2007.)* At that time, we reported how **Laboratory Corporation of America** is developing a strategy to use regional "managed laboratory networks" as a managed care contracting vehicle to improve its competitive position with national health insurance companies.

LabCorp's inspiration for this strategy is the **Oxford Health Plan** laboratory network developed by **Quest Diagnostics Incorporated** several years ago. After **UnitedHealth** acquired Oxford, then granted LabCorp an exclusive national lab testing contract, LabCorp assumed management of this lab network from Quest Diagnostics. LabCorp and UnitedHealth are planning to replicate this "managed laboratory network" model in many communities across the United States. (*See pages 6-9.*) Serious work to actualize this plan will take place in 2008.

Inspired by the original Quest/Oxford regional "managed lab network," UnitedHealth and LabCorp intend to use these networks as a way to bring more regional labs under contract. Will it be a win-win business arrangement for the payer, the national lab managing the network, and the regional labs and hospital outreach programs in the network? Judging from the complaints that flowed from the Oxford and **Empire Blue Cross Blue Shield** networks developed by Quest Diagnostics, not likely. In those networks, local labs were offered reduced reimbursement, weren't able to provide selected tests, and were excluded from participating in all the health plans offered by that payer. However, time will tell in the case of UnitedHealth. LabCorp's new CEO has a different strategic prospective and he may have some surprises up his sleeve. TDR

Siemens Acquires Dade, Builds IVD Powerhouse

When deal closes, Siemens claims crown as the global colossus in *in vitro* & *in vivo* diagnostics

CEO SUMMARY: In just 15 months, Siemens AG has pulled out its checkbook three times to spend more than $14 billion to acquire major in vitro diagnostics (IVD) companies. When it closes the purchase of Dade Behring, Siemens will be in the first rank of global IVD manufacturers. It has also declared that it is now the world's largest diagnostics company because of its combined market share in imaging and clinical lab testing.

THIS YEAR'S HOTTEST STORY is consolidation in the *in vitro* diagnostics (IVD) industry, and the latest stunner is the pending acquisition of **Dade Behring, Inc.**, by **Siemens AG**. In a deal announced July 25, 2007, Siemens will pay approximately $7 billion to purchase Dade Behring, of Deerfield, Illinois.

The deal is expected to close within 90 to 180 days. When it does, this acquisition will trigger significant changes in the lab industry, for at least five reasons.

First, it removes another first-rank IVD manufacturer from the market as an independent company. That directly reduces the choices available to clinical laboratory buyers, since there will be one fewer independent competitor.

Second, upon closing the purchase of Dade Behring, Siemens vaults into the ranks of the largest IVD companies. In recent years, **Roche Holdings** and **Abbott Laboratories, Inc.**, have been the world's number one and number two largest IVD manufacturers.

Third, many financial experts believe that Siemens' acquisition of Dade Behring will trigger further consolidation in the IVD market. Other players in the IVD industry are likely to respond with additional acquisitions as a way to expand their product portfolios, to gain market share, and to prevent competing IVD companies from acquiring those assets.

Fourth, as Siemens continues to invest heavily to build its capabilities in *in vitro* diagnostics, it creates additional pressure on competitors **General Electric Corp.** and **Philips Electronics N.V.** to develop a strategy for *in vitro* diagnostic testing that

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supports these companies' existing *in vivo*/imaging businesses.

Fifth, the premium price that Siemens will pay to acquire Dade Behring reinforces the higher valuations paid for IVD companies and clinical lab firms during the past 24 months. Such prices are a market demonstration of investor conviction that advances in molecular diagnostics and genetic medicine will fuel substantial growth in diagnostic testing in the coming years.

High Value For Dade Behring

Siemens will pay $77 in cash for each share of Dade Behring. That's a 38% premium over Dade's prior day closing share price of $55.91. Some analysts in Europe were critical of the price Siemens will pay. "People obviously think that $7 billion for Dade Behring is far too much," declared Thomas Radinger of **Pioneer Investments** in Munich, Germany. His firm has a $96 billion investment portfolio and holds Siemens' stock.

On the other hand, Siemens was not the only bidder for Dade Behring, a company that has posted strong growth in revenue, operating profits, and earnings over the past several years. *(See TDRs, October 28, 2002, and June 25, 2007.)* Other firms were interested in buying Dade. Further, bidding for Dade Behring was unfolding during the same time that GE held an agreement to purchase the diagnostics business division of Abbott Laboratories, Inc., for a price of $8.13 billion.

Encouraged To Buy Again

Siemens' willingness to move aggressively to purchase Dade Behring is also a sign of another corporate strategy. Among other things, it means that, after paying $1.86 billion to buy **Diagnostics Products Corporation** (DPC) *(See TDR, May 22, 2006)* and $5.21 billion to buy **Bayer Diagnostics** *(See TDR, August 14, 2006)*, Siemens' executives found few negatives to change their views about the short-term and long-term growth potential of clinical diagnostics. Armed with the confidence gained from the DPC and Bayer acquisitions, Siemens forged ahead to do a single IVD deal that would place the company among the world's largest IVD firms.

Since announcing the acquisition agreement, executives from both companies have said little in public. At the time of the DPC and Bayer acquisitions, Siemens' executives had continually stressed that Siemens did not want to have a presence in an industry unless it holds a market share that is number one or number two. They noted that the combined immunoassay business lines of DPC and Bayer gave them a number one position globally in that segment of IVD.

Siemens was probably attracted to Dade Behring for several reasons. One, Dade Behring has a large international presence, particularly in smaller and mid-sized laboratories. It serves approximately 25,000 customers in 36 countries and has an installed base of 41,400 instruments. Dade Behring's diversified book of clients represents an opportunity for Siemens to cross sell product lines it acquired when it bought DPC and Bayer.

Marketplace Momentum

Two, and not to be underestimated, Dade Behring has momentum in the marketplace and is profitable. For the second quarter, it reported a 42% increase in earnings and an 8.2% increase in revenue. It is a dynamic organization positioned for additional growth.

Three, Dade Behring has a corporate culture and a customer focus that sets it apart from many of its IVD competitors. These attributes were likely to be a good fit with Siemens' existing IVD units. For example, DPC was a highly respected, family-led enterprise while Bayer Diagnostics was part of a German-owned corporation. It is probable that Dade Behring's successes in developing what its CEO, Jim Reid-Anderson, likes to describe as a "customer-facing organization"

More IVD Consolidation: Which Firm Is Next?

EXPECT MORE CONSOLIDATION in the *in vitro* diagnostics (IVD) industry. That's a safe prediction for a simple reason. In the past 15 months, five of the world's largest IVD manufacturers have signed agreements to be acquired!

That's a major acquisition, on average, every three months. Of course, General Electric's agreement to acquire the diagnostics business of Abbott Laboratories has been dissolved. But the other four major acquisitions are proceeding to a closing without anticipated difficulties.

The table below, which ranks the world's 15 largest IVD companies, provides compelling evidence of how rapidly consolidation is changing the face of the IVD industry. It is a trend that will continue. For example, in the day's following the announcement that Siemens would acquire Dade Behring, Reuters News Service published a story that identified likely IVD consolidation candidates by name, listing these firms: **Beckman Coulter**, Abbott Laboratories' diagnostics businesses, **Johnson & Johnson's Ortho-Clinical Diagnostics** division, **Gen-Probe**, **Cepheid**, **Quidel**, **Luminex Corp.**, and **Hologic** (itself in the process of acquiring Cytyc Corporation–see table below).

Concentration of ownership within the IVD industry is steadily reducing the number of independent companies competing for clinical laboratory business.

Leading In Vitro Diagnostic Companies (by 2005 revenues)

Company/Country of Origin	IVD Sales ($ Millions)	Total Co. Sales ($ Millions)	IVD as Business % of Total
1. Roche Diagnostics (Switzerland)	$6,300	$27,000	23%
2. Abbott Labs (U.S.–IL)[d]	$3,800	$22,300	17%
3. Bayer Diagnostics (Germany)[b]	$2,500	$32,000	8%
4. Becton Dickinson (U.S.–NJ)	$2,500	$5,400	46%
5. Beckman Coulter (U.S.–CA)	$1,900	$2,400	79%
6. Dade-Behring (U.S.–IL)[e]	$1,700	$1,700	100%
7. Ortho-Clinical Diagnostics (U.S.–NJ)	$1,400	$50,514	3%
8. bioMerieux (France)	$1,200	$1,200	100%
9. Sysmex (Japan)	$716	$716	100%
10. Bio-Rad Labs (U.S.–CA)	$618	$1,200	52%
11. Arkray (Japan)	$470	$470	100%
12. Diagnostic Products Corp. (U.S.–CA)[a]	$399	$399	100%
13. Olympus America (Japan)	$384	$8,300	5%
14. Cytyc Corp. (U.S.–MA)[c]	$362	$508	71%
15. Gen-Probe (U.S.–CA)	$306	$306	100%
TOTAL Top 15 IVD Companies for 2005	**$24,555**	**$154,413**	**16%**

Source: Public Filings, Medical Product Outsourcing, June 2006.

Acquisitions since 2005, by chronological order:

a *Diagnostic Products Corp. acquired by Siemens for $1.86 billion, 2006.*

b *Bayer Diagnostics acquired by Siemens for $5.2 billion, 2006.*

c *Cytyc Corp. to be acquired by Hologic, Inc. for $6.2 billion, deal pending, July, 2007*

d *Agreement for General Electric Corp. to acquire Abbott Laboratories' diagnostics business for $8.13 billion. Signed in January, 2007. Agreement dissolved in July, 2007.*

e *Dade Behring to be acquired by Siemens AG for $7.0 billion, deal pending, July, 2007.*

played a role in Siemens' decision to acquire Dade Behring.

Four, Dade Behring has a strong position in technology and a thriving research and development program. Its new Dimension Vista® instrument is in the early phases of launch and attracting positive attention. These resources would compliment Siemens' existing IVD assets.

More Consolidation Ahead

THE DARK REPORT observes that there is nothing extraordinary about Siemens' decision to invest $14 billion to literally buy itself a front row seat in clinical laboratory testing. As the table presented in the sidebar on the previous page demonstrates, investor interest in the IVD industry is at fever pitch. In the past 15 months, five of the world's 15 largest IVD companies have entered into agreements to be acquired!

That pace of transformation is remarkable. Moreover, the IVD industry is prepared for even more consolidation. General Electric is the one example that validates this point. Although the General Electric–Abbott Laboratories agreement collapsed last month, popular wisdom is that General Electric will definitely make a major move into *in vitro* diagnostics.

A Future Oligopoly?

Viewed against Siemens' willingness to spend $14 billion to become one of the world's largest IVD companies, one can assume that General Electric would be equally willing to make a comparable investment to buy any IVD firm or clinical laboratory that captures its interest and is deemed to be a strategic fit.

Further consolidation in the IVD industry would bring the clinical laboratory marketplace closer to the day when it becomes an oligopoly, both in the United States and worldwide. Having a limited number of suppliers would then change the way clinical laboratories select lab testing technology and vendors. TDR

Roche Continues to Pursue Ventana Medical Systems

THERE'S ANOTHER *IN VITRO* DIAGNOSTICS (IVD) CONSOLIDATION STORY PLAYING OUT as of press time. Roche Holdings is in the midst of a hostile tender offer for all the outstanding stock of Tucson, Arizona-based **Ventana Medical Systems, Inc.**

It was June 25 when Roche announced that it would pay $75 per share for Ventana shares. This was a 44% premium over the previous day's closing price of $51.95 and represented a total cash purchase price of about $3 billion for Ventana. In 2006, Ventana reported annual sales of $238.2 million.

By offering a price that was at a hefty premium to Ventana's current share price—and more than 12 times annual revenue—Roche must have felt confident Ventana shareholders would respond favorably by tendering their shares to Roche.

Meanwhile, Ventana's executive team criticized the hostile take-over offer. Its board issued a statement advising shareholders not to accept Roche's tender offer.

Then, on July 25, Roche announced that it would extend the tender offer for another four weeks. The offer will now expire at 5 p.m. EDT on August 23, 2007. As part of this announcement, Roche stated that owners of Ventana stock representing a total of 10,000 shares had signed commitments to sell under terms of the tender offer.

Because Ventana's outstanding number of shares exceeds 34 million, this does not appear to be an encouraging sign for Roche. It is unusual for smaller companies to resist acquisition, particularly when the buyer is a much larger company and offers a significant premium over the current market value for the outstanding shares of the takeover candidate.

Roche is interested in Ventana Medical Systems because it believes Ventana's anatomic pathology products and technology pipeline would complement its own products.

Quest, LabCorp Slug It Out In Battle for Market Share

Executives from both companies discuss strategies and tactics for winning more business

CEO SUMMARY: In reporting second quarter earnings, both Laboratory Corporation of America and Quest Diagnostics Incorporated discussed market developments. There were no surprises in the comments made by executives of both companies. Quest Diagnostics emphasized that it is hanging on to a significant amount of the pull-through testing associated with UnitedHealth business. LabCorp acknowledged that each managed care contract creates its own opportunities and challenges.

IT'S BEEN A HIGH-PROFILE FIGHT for **UnitedHealthcare** patients between **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. Now the companies' reports of second quarter earnings provide useful insights about the progress of this ongoing war for market share.

Quest Diagnostics Incorporated of Lyndhurst, New Jersey, said second quarter revenues were $1.6 billion, an increase of 3.7% compared with the prior-year level. Its second quarter income dropped 9%, to $142 million, compared with $156 million in the same quarter a year earlier. The second quarter this year includes the results of **AmeriPath, Inc.**, which Quest Diagnostics acquired in May. The acquisition of AmeriPath increased consolidated revenues by 4.4%.

Quest Diagnostics reported that clinical testing revenues increased by 2.1%, and clinical testing volume, measured by the number of requisitions, decreased 6.0%. Revenue per requisition increased 8.6% for Q2-07, compared with to Q2-06. The acquisition of AmeriPath increased clinical testing volume by 1.8% and revenue per requisition by 3.1%. Quest Diagnostics disclosed that the change in contract status with UnitedHealthcare reduced consolidated revenues by approximately 4.4% and testing volume by about 7%.

LabCorp Sales Up 15.4%

Laboratory Corporation of America, based in Burlington, North Carolina, said revenues for the quarter were $1,043.1 million, an increase of 15.4% compared with revenue for the same period in 2006. Net earnings increased 10.5% to $128.7 million, compared with $116.4 million in the year-earlier quarter. Excluding restructuring and other special charges recorded in 2007, net earnings increased 14.1% to $132.8 million. LabCorp further noted that testing volume, measured by accessions, increased 14.2%, and price increased 1.2% compared with those numbers from the second quarter of 2006.

Since Quest Diagnostics ceased to be a contract provider for UnitedHealth earlier this year, about 75% of the test volume related to that contract has been lost, according to company officials, who state that more of this business may switch over in the second half of the year. The UnitedHealth (UNH) contract had represented $400 million in revenue, said Robert A. Hagemann, Corporate Vice President and CFO for Quest Diagnostics.

Focus on Cutting Cost

"About 60% of our costs are variable and we have been adjusting those cost levels over the past six months," he said in a conference call with financial analysts on July 24. "We have cut the number of full-time equivalent employees by 2,000 since the beginning of the year. Most of that has been through normal attrition. We have been deliberate in cost cutting so that we do not affect service levels. We have looked at every process across the company and the cuts have been reasonably proportionate—both in the labs, outside the labs, and in administrative functions.

"Also, in the first quarter, we incurred some extra costs in trying to retain business," he said. "We avoided those costs in the second quarter and continued to make progress in pulling out variable costs.

"So far, we have taken out about $200 million in costs on an annualized basis," Hagemann explained. "On top of that, we expect to reduce costs by about another $500 million on an annual basis by 2009."

As a point of comparison, that $700 million in total cost cuts would equal about 11% of the $6.3 billion that Quest Diagnostics reported as revenue in 2006.

Target of 20% Margin

"This cost cutting is designed to get us to an operating margin of 20% of revenue—that is our aim," declared Hagemann. "The structural cost cutting is designed to offset the loss of the UnitedHealth business. Some of it is designed to offset the pricing pressure, and some of it is designed to allow us to invest in growth and service differentiation as we continue to grow the business."

Cost cuts and new managed care contracts helped the company deliver improved results, said Hagemann and Surya N. Mohapatra, Ph.D., Chairman and CEO. "Now that we have signed contracts with **Cigna** and **Aetna**, a number of uncertainties have been eliminated," commented Mohapatra. "Plus, we feel that each managed care organization is different. They are not all adopting only one strategy for a long term [lab testing] contract with low transaction fees. We have signed a number of contracts and believe that what happened in October is not a trend."

Quest Diagnostics believes it is succeeding in retaining pull-through specimens associated with its original UnitedHealth business. "In addition," added Hagemann, "we have seen no additional loss of discretionary work, meaning that when physicians have a choice, they continue to choose Quest Diagnostics."

More Tests Per Requisition

In answer to a question, Hagemann explained the company's improved results were not driven by price. "It's driven by a mix shift, meaning the mix of tests and the number of tests ordered per requisition," he replied. "We don't see any significant increases in price per test; rather, we see pricing pressure. And that's not necessarily going away, but we feel good that we have signed a number of managed care contracts and the market recognizes that we provide a difference in terms of the level of service we offer."

Despite improving results, Quest acknowledges it faces a number of challenges. "One thing that worries me a bit is whether the activities of last October [the UnitedHealth contract decision] have created a new water line for this industry," explained Mohapatra. "So, we are reducing our dependency on routine, low margin testing, diversifying our billing, and emphasizing higher margin segments, such as esoteric testing and anatomic pathology.

"Second, we are opposed to competitive bidding, but the government is doing this [Medicare] demonstration project,

LabCorp Discusses Unfolding Plan to Bring Regional Labs into "Managed Care Networks"

ONE OF THE THREE PRIMARY GOALS that Laboratory Corporation of America has for its exclusive national contract with UnitedHealth is to establish a series of regional "managed lab testing networks" in various communities. *(See TDR, February 19, 2007.)*

These would be organized in the same fashion as the **Oxford Health Plans** laboratory network, originally created by Quest Diagnostics Incorporated when Oxford was an independent health insurance firm. Oxford is currently owned by UnitedHealth and LabCorp has assumed management of the Oxford laboratory network arrangement under its exclusive national contract with UnitedHealth.

During the July 24 conference call, a research analyst asked LabCorp CEO David P. King if he expected further gains from LabCorp's contract with UnitedHealth to come from smaller regional labs or from Quest Diagnostics in the coming months. "We are working with UnitedHealth on the [regional laboratory] network management issue," responded King. "It will be 2008 when we get that off the ground. There are systems issues that make it a little less simple than it might seem. But we are committed to the network model and UnitedHealth is committed to the network model. We expect to see progress with the networks next year."

It is important for regional laboratories to monitor these developments and prepare a strategy to respond to them. LabCorp and UnitedHealth believe that the creation of regional "managed lab networks," based on the Oxford laboratory network model, will help them reduce UnitedHealth's overall laboratory spend while bringing more regional laboratories under a contract with prices that are closer to what has been negotiated with UnitedHealth's exclusive national contract laboratory. Another stated goal will be to standardize the flow of laboratory data provided to UnitedHealth.

and so that's a concern of ours," added Mohapatra. "A third issue is to have the right people doing the job for us. Execution in the marketplace is critical for us because we have been under price pressure and then the price pressure got worse."

Managed Care Contracts

Looking forward, Hagemann explained that Quest had been seeking to extend the length of contracts it holds with managed care companies. "There are a number of managed care contracts that we need to work on and generally our contracts are one to three years," he said. "That means almost 50% come up [for renewal] in any single year. Right now, we have 60% signed up and the majority are signed up into 2010. So we have stretched out the cycle going forward. In addition, the **Humana** contract is still out."

Both Quest Diagnostics and LabCorp discussed the Humana contract on their respective conference calls with analysts. LabCorp CEO David P. King stated on his call with analysts, "We believe Humana has just under eight million members; Cigna about 10 million; Aetna about 15 million; UnitedHealth about 28 million; and **Wellpoint** about 35 million," he said. "Beyond that, we will not comment on the book of business we have, except that we expect an announcement from Humana soon. They issued an RFP (request for proposal), we responded, and we are in discussions."

King also disclosed that LabCorp is interested in working more closely with **Wellpoint, Inc.** "Wellpoint has a new CEO and I thought it was important to meet her and introduce myself to other members of the executive team," King said. "In a competitive situation and given a fair opportunity to compete, we believe we will be successful."

Earlier this year, LabCorp lost out on a contract with Aetna, which Quest

Diagnostics won on an exclusive national basis. "We lost some Aetna business in the run up to the announcement," King explained. "Our competitor is very tough and they were out there pursuing the Aetna business. And we lost some business in the quarter and, as we got later into June, we tended to lose more, although not enough to move the needle much."

UnitedHealth Achievements

On the subject of the UnitedHealth contract, there was cautious optimism. "UnitedHealth business came aboard faster than we expected. LabCorp is doing a higher volume of testing for UnitedHealth than we predicted at this point," commented King. In discussing the transition payments that will be made to UnitedHealth based on controlling leakage, King noted, "we expect exposure to leakage will be 25% less than the contractual maximum defined in the contract.

"There is still an opportunity to increase the run rate we have with UnitedHealth and to increase the pull-through testing associated with the UnitedHealth contract," he added. "Also, there is still leakage and that is an opportunity to gain more business.

"As it is with any contract, generating pull-through associated with the UnitedHealth business is more art than science," observed King. "We're pleased with our pull-through rate. There are more potential pull-through opportunities as doctors begin to understand how good we are."

PSCs In Pharmacies

There is also satisfaction with the use of pharmacies as sites for patient service centers (PSCs). Responding to a question about LabCorp's PSC build-out program, King stated, "I think the in-store PSC model is a great model. We are continuing to look at opportunities to create more in-store PSCs with **Duane Reade** and with other pharmacy companies."

LabCorp continues to feel that the laboratory testing marketplace is dynamic and it is possible to build different segments of the business. For example, LabCorp Vice Chairman and Chief Legal Officer, Brad Smith, laid out some milestones recorded during the past quarter. "We've seen an increase in esoteric testing to 40% of our revenues," he noted. "Image-guided Pap screening is increasing. During the quarter, 56% of liquid preparation Pap test orders included a request for image-guided Pap screening. Similarly, this quarter saw a 60% increase in the number of reflex or primary screening tests for HPV, relative to the same quarter last year."

Higher Valuations For Labs

In a topic of interest to pathologists and lab directors, analysts asked about the higher prices paid for recent laboratory acquisitions and how that would affect LabCorp's lab acquisition strategy. "The acquisition environment is competitive and pricing is higher than it was in the past," responded King. "**Sonic Healthcare** has made four or five acquisitions and they have the appetite to continue to make acquisitions.

"So now there is a third competitor in the market that wasn't there before," he continued. "I view them as an aggressive competitor. We are aware that they will be interested in a number of the acquisitions that we also consider attractive."

Apparently cost cuts are actively under way at LabCorp, although this subject was not discussed during the conference call. Information is circulating across the lab industry in recent days that LabCorp is in the midst of quietly cutting middle management positions in each region. It is said that the objective is to pare back as many as 70 employees per region, but no positions will be eliminated that deal directly with clients or patients.

Should this prove to be true, it is a sign that, all public optimism aside, like Quest Diagnostics, LabCorp faces similar pressure to maintain margins by reducing costs as a response to lower pricing. TDR

PSA, MED3000 Merger Creates Opportunities

➤Rapid evolution in billing and collection is one factor in this consolidation action

➤➤CEO SUMMARY: Pathology Service Associates, LLC, has found a merger partner that will allow it to offer more products to its pathology clients and to expand into new service areas. By merging with MED3000 of Pittsburgh, Pennsylvania, PSA also gains access to enhanced informatics capabilities that it can roll out to its pathology group clients. This merger is a sign that the cost of sustaining an effective billing/collections program is skyrocketing.

RAPID AND CONTINUAL CHANGES in billing and collection for anatomic pathology services is a significant development that caused **Pathology Service Associates, LLC** (PSA), to merge with **MED3000, Inc.**, a healthcare management company based in Pittsburgh, Pennsylvania. The merger closed on July 31, 2007, and terms were not disclosed.

The merger is significant because PSA is the country's largest single-specialty provider of pathology revenue cycle management (billing and collections), as well as a provider of services in practice management and marketing. It serves more than 75 independent pathology practices, representing 400 pathologists, in 27 states.

"Both parties benefit in this marriage," stated Laura Chaney, PSA Vice President. "MED3OOO gains market presence for providing billing and business services to pathologists and a platform to do the same for other hospital-based specialty physicians. For its part, PSA now has access to the capital resources required: 1) to grow our core business; 2) to invest in state-of-the art technology; and, 3) to expand into new regional markets.

"One direct benefit for our pathology clients will be MED3OOO's data warehouse," she added. "We have long been interested in this capability. PSA has large amounts of pathology data and we continually use it to support political advocacy initiatives that benefit pathologists. PSA also uses this pathology data to provide information to payers as evidence in support of appropriate reimbursement for new and existing codes."

➤Independent Division

"Post-merger, PSA's management team and mission remain a constant," said Al Sirmon, PSA President. "PSA will continue to operate under its name and as an independent division of MED3000. We remain committed to pathology. All our service lines will continue. To this established tradition of service will be added new capabilities and more sophisticated information technology. We are moving forward specifically so we can help our pathology clients access and use new technologies to support their own pathology practice."

PSA's decision to merge with MED3000 is a strategic response to rapid evolution in revenue cycle management across the healthcare system, as well as ongoing advancements in technology. "Over the past five to seven years, there has been a staggering pace of change in the billing industry," noted Chaney. "There is continual change in the application and use of electronics and informatics in the process, both on the provider side and the payer side. This tends to create technology and capital barriers for pathology practices and small billing companies to be successful."

"Recent trends include new NPI (National Provider Identifier) and efforts to implement pay-for-performance systems," she continued. "These changes come on the heels of ANSI standards required by HIPAA and a number of other things, all of which proved time-consuming and costly to implement. Both the pace and scale of emerging trends make it extremely difficult, and capital-intensive, for pathology practices and billing companies to maintain the required infrastructure. While PSA handled these changes very well, we recognized the importance of our own access to capital and sophisticated expertise in information technology to maintain our service edge in the marketplace."

Requirements And Mandates

"We hear this same story from our clients and other pathology groups around the country," noted Sirmon. "Sustaining a high-performance billing and collection service is harder now than it has been at any time in the past. Each year brings more requirements and mandates. Each year, reimbursement for many clinical services declines.

"Just as pathologists are struggling with declining reimbursement, PSA and all billing companies experience a decline too—since our fees are directly related to what we collect for the physicians," explained Sirmon, "When our clients get a 10% cut in reimbursement, PSA also gets a 10% drop in reimbursement. That squeezes every billing company, as well as the pathology groups that do their own billing.

"In this environment, smaller billing companies are hard pressed to stay in business. Moreover, 30% of the 3,300 pathology practices in the United States continue to do their billing in-house. These 1,200 pathology groups have shrinking financial resources to maintain and upgrade their billing and collections capability—even as they face the need and the pressure to buy new electronic systems and add capabilities required to meet new mandates," explained Sirmon.

Looming EMR Deadline

"For example, there's a deadline looming in coming years for physician practices to implement electronic medical record systems (EMRs). Also looming is the implementation and use of the new ICD-10 system," he continued. "Each of these requirements means pathology practices will need new systems or major upgrades to sustain effective billing and collections."

"And that can be expensive," added Chaney. "Many groups have software systems that simply can't accommodate the extra digit that ICD-10 will require. For these practices, it could cost as much as $250,000 or more for a new system or system enhancements required to meet ICD-10 and other mandates. "

PSA views this situation as an opportunity. "We can tap that market and serve it well because many pathologists and other physicians will not want to invest the resources to meet these new requirements," noted Sirmon. "It will motivate them to consider outside billing solutions. The fact that PSA also offers practice management and marketing services differentiates us in the marketplace."

Sophisticated Partner

In MED3OOO, PSA gains a sophisticated partner that is already involved in several sectors of healthcare. "MED3OOO focuses on advancing the performance of medical practices, health systems, physician networks, and EMS departments," said Patrick Hampson, Chairman and CEO of MED3OOO. "We work with more than 9,000 physicians, hospitals, and health system clients to improve clinical outcomes, operational results, and financial returns through improving operations and technology resources. The addition of PSA will expand MED3OOO's service offerings and broaden our presence in the hospital-based physician market."

"In acquiring PSA, MED3OOO gains immediate access to pathologists and other hospital-based physicians," explained Sirmon. "Hospital-based physicians have specific billing and collections needs, and PSA brings that experience and expertise to MED3OOO."

Even as PSA helps MED3000 expand services to hospital-based physicians, PSA will gain capabilities that allow it to help its client pathologists interface with the EMRs of office-based physicians. "Their EMR product is called InteGreat Concepts, Inc., and we are ready to explore ways to link this system with PSA's pathology clients and their referring physician base," observed Sirmon.

Billing Industry Changes

THE DARK REPORT observes that this merger marks the second time in the past 12 months that one of the pathology profession's largest national providers of billing and collection services has been acquired by a larger company. It demonstrates that professionals in billing and collections recognize that their own resources are inadequate to maintain pace with new payer requirements and a steady stream of statutory mandates.

Independent of these factors, information technology is undergoing radical improvements in shorter product cycles. New hardware and software must be acquired to maintain a state-of-the art billing and collection service.

Informed by the strategic decisions of PSA and **Per Se Technologies** (which sold itself to **McKesson Corporation** earlier this year), it is likely that many of the 1,200 independent pathology groups still using in-house billing and collection services will soon face a business dilemma: the effectiveness of their billing and collection efforts is declining because they have not invested in the necessary upgrades to maintain high efficiency—but the cost of the upgrades or new information systems cannot be recovered by the increase in percent of billed dollars that are collected.

From that perspective, a logical prediction is that pathologists will soon migrate away from in-house billing and collections, in favor of larger agencies capable of upgrading and investing regularly to sustain a high ratio of collected dollars in a cost-effective manner. TDR

Contact Laura Chaney and Al Sirmon at 843-629-2979.

Founder Continues in New Role with PSA

FOR A FOUNDER OF Pathology Service Associates, LLC, of Florence, South Carolina, the merger with MED3000 will mean some changes.

It was 1995 when Louis D. Wright, Jr. M.D., and his pathologist-colleagues launched PSA as an organization to provide advanced business management services and expertise to private practice pathology groups. Now a leading voice for the profession, Wright is a member of the Board of Governors of the **College of American Pathologists** (CAP).

Wright will continue in a new capacity following PSA's merger with MED3000. He will be an advisor. His particular vision is to help PSA and MED3000 integrate various information systems so that PSA's 400 pathologists, the 30,000 physicians who refer them patients, and the 300 hospitals where they practice can pass data and information seamlessly in ways that enhance clinical service and operational efficiency.

Unprecedented Activity Across Lab Medicine

Wow! Here are six sectors of lab medicine, and each is undergoing major transformation

CEO SUMMARY: Laboratory medicine is now considered one of the best opportunities to profit as the demand for healthcare services skyrockets, both in the United States and throughout the world. This is why a flood of investment capital is washing into the laboratory industry. Loaded with capital and eager to profit in the diagnostic gold rush, investors are paying ever higher prices for laboratories and in vitro diagnostics firms.

By Robert L. Michel

DURING THE PAST 24 MONTHS, there has been unprecedented activity in every major sector of the laboratory medicine profession.

Below are examples that frame my point. They also provide a springboard to explore the causes and consequences of these events to clinical laboratories, pathology group practices, independent laboratory companies, and all the vendors who provide instruments, reagents, supplies, and information technology to laboratories.

MANAGED CARE CONTRACTING: The announcement in October 2007, that **UnitedHealth Group** had granted an exclusive national contract to **Laboratory Corporation of America** and excluded **Quest Diagnostics Incorporated** as a provider set off intense competition to grab business now at risk. In many communities, regional labs and hospital outreach programs negotiated regional contracts with UnitedHealth, some for the first time ever, and began to capture new accounts from physicians with UnitedHealth patients.

Now, each major managed care contract that comes up for renewal or goes to bid is closely watched. Competition has intensified in what was a quiet sector in laboratory medicine.

CLINICAL LAB ACQUISITIONS: During the past two years, a wave of new buyers has come into the market and bid up the price of clinical laboratory assets. In the last issue of THE DARK REPORT, we published data showing that **Sonic Healthcare Ltd.** of Sydney, Australia, has acquired seven labs over this period and invested about $820 million. **Apax Partners, L.P.**, a private equity company, paid top dollar to purchase **Spectrum Laboratory Network** of Greensboro, North Carolina, in November 2005. Recently **Laboratory Partners Inc.** of Palo Alto, California, has closed the purchase of two labs, including **Terre Haute Medical Laboratory** in Terre Haute, Indiana.

Of course, the two blood brothers have not stopped their acquisitions of clinical laboratories. A number of their lab purchases, however, are not disclosed publicly, since the size of the purchase is not considered a material fact. Yet these small acquisitions, done at regular intervals, play a role in helping both national laboratories report quarterly increases in specimen volume and revenue.

ANATOMIC PATHOLOGY SERVICES:

There's hot action in this sector, but much of it is below the radar screen. Of course, Quest Diagnostics Incorporated's willingness to pay $2 billion to acquire **AmeriPath** raised many eyebrows. Yet, that valuation is in keeping with other recent acquisitions and investments. **Pathology Partners** in Irving, Texas, was bought by equity investors and now operates as **Caris Diagnostics**. **Lakewood Pathology Associates** in Lakewood, New Jersey, was similarly acquired by equity investors last year.

Further, the list of independent anatomic pathology companies providing national services grows steadily. Despite the trend for specialist physicians to bring pathology in-house, many of these national pathology companies are growing, adding more pathologists, and expanding their services. For example, **Aurora Diagnostics** of West Beach Gardens, Florida, finished its first full year of operations and disclosed that it had done eight acquisitions and was posting about $60 million per year in revenue.

MOLECULAR DIAGNOSTICS:

With advances in genetic medicine and molecular technology, a flood of new assays is finding clinical acceptance. The business model here is to control proprietary or patent-protected assays and be the exclusive source of such testing.

On the laboratory side, new start-ups appear regularly. **RedPath Integrated Pathology** of Pittsburgh, Pennsylvania, has shown impressive growth in specimen volume and revenues. Similarly, **Signature Genomic Laboratories** of Spokane, Washington, and **Access Genetics** of Eden Prairie, Minnesota, have found ready acceptance in the marketplace.

On the supplier side in molecular pathology, the most spectacular example is **Ventana Medical Systems, Inc.**, of Tucson, Arizona. It has enjoyed healthy growth rates in revenue and income—healthy enough to attract the attention of **Roche Holdings.** Roche is in the midst of a hostile takeover offer and is willing to pay $3 billion to acquire Ventana and its $282 million in annual sales! Similarly, last fall, **Vision Systems Limited** of Melbourne, Australia, attracted acquisition offers from Ventana and then **Cytyc Corporation**, before selling, at a substantially higher price, to **Danaher Corporation** of Washington, DC.

IN VITRO DIAGNOSTIC FIRMS:

This same investment fever is white hot in the traditional *in vitro* diagnostics (IVD) industry. For example, the headline story in this issue is the $7 billion agreement that will make **Siemens AG** of Erlanger, Germany. the owner of **Dade Behring, Inc.**, based in Deerfield Park, Illinois.

On page five, you will see a table that lists the world's 15 largest IVD companies, ranked by their 2005 sales. In the past 15 months, five of these 15 IVD firms have entered into acquisition agreements! This is a pace of consolidation not seen, even during the 1990s. And that won't be the end of it. Wall Street analysts predict further consolidation in the IVD sector of laboratory medicine.

HEALTH IT COMPANIES:

Healthcare continues to move toward an integrated, paperless environment where data and information can flow seamlessly between patients, physicians, hospitals, labs, and payers. Investors and healthcare's major information technology (IT) players are positioning themselves, and laboratory medicine is part of the equation.

Today's news is the sale of **Misys Healthcare Systems'** business division with most of the former **Sunquest** products, including laboratory, radiology, and pharmacy systems, to a private investment group in California.

Also, in this issue is the news that **Pathology Service Associates, LLC**, of Florence, South Carolina, the largest company in the United States devoted to billing for pathology services, has sold itself to **MED3000**, based in Pittsburgh, Pennsylvania. And it was just last year that **McKesson Corporation** scooped up **Per Se Technologies, Inc.**, itself a major provider of billing and collection services to hospital-based physicians, including pathologists. In the laboratory middleware space, **Data Innovations, Inc.**, of South Burlington, Vermont, recently completed its purchase of **P.G.P. s.a.**, of Brussells, Belgium.

What Does It All Mean?

These six business and service sectors of laboratory medicine represent the full spectrum of activity across our profession. The list of noteworthy developments in each of these sectors provides incontrovertible evidence that the laboratory industry is in the midst of a remarkable period of change.

Sorting out what all these developments mean is the challenge. This intelligence briefing is designed to help you connect some dots and begin to see the larger picture unfolding in laboratory testing services today.

In my view, the laboratory industry in this country is poised for a transformational epoch unlike any seen in the past four decades. The *Mirriam-Webster Dictionary* defines epoch as "an extended period of time usually characterized by a distinctive development or by a memorable series of events."

Market-Shifting Activities

That definition aptly describes the past 24 months for the laboratory testing industry in the United States. In each key sector of economic activity (clinical lab and pathology lab providers, IVD manufacturers, IT vendors, payers, and bio-tech developers) you and I can identify market-shifting and memorable activities.

I believe the impact of these events will be magnified, for an overlooked reason. Our economy, our healthcare system, and our lab medicine profession is more integrated and interconnected that at any time in history. A simple example makes my point: what would happen in your laboratory or company if, even just for a single day: a) your IT network failed; or, 2) your Internet connection went down; or, 3) your wireless and cellphone services failed?

Note that I was only postulating a failure in communications or access to information. What would happen to many of your organizations if overnight delivery services ceased to operate? Or ceased to operate reliably? That's the source of daily specimens and primary work product for many labs and many vendors. Don't forget, overnight delivery services did shut down in the days following 9-11, causing widespread disruption in the ability of many labs to perform and deliver timely test results.

Help In Developing Strategies

Laboratory directors and pathologists can use these six lab medicine activity sectors to develop a timely and accurate strategic analysis. My point in this intelligence briefing is to provide evidence and examples that demonstrate how the pace of change is accelerating across the length and breadth of laboratory medicine.

The change can be dramatic. In just 15 months, four of the 15 largest IVD suppliers to laboratories have come under new ownership. That directly affects your laboratory organization if it changes the company currently supplying you. It also reduces your product and vendor choices next time you are ready to buy.

Rapid change always creates threats, as well as opportunities. My goal is to help you anticipate and prepare for the threats, while recognizing the opportunities in time to gain competitive advantage. TDR

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Misys Health Restructures By Selling Two Divisions

Misys divests its LIS products and other ancillary systems as it shifts strategy

CEO SUMMARY: Misys Healthcare Systems of London, England, has sold its diagnostic LIS systems to Vista Equity Partners of San Francisco, California, for $381.5 million. The deal raises several questions, particularly for those labs currently running Misys laboratory information systems (LIS). Will the new owner make the substantial investment required to upgrade the LIS and to add a molecular diagnostics module?

THERE'S ANOTHER SHAKEUP in the LIS (laboratory information system) marketplace. On July 24, **Misys Healthcare Systems** of London, England, announced the sale of its diagnostics information system business and its enterprise clinical records division. Divesting this unit raises a number of questions particularly for those labs that run the Misys LIS system and want to know what to expect from the new owner in terms of service and upgrades.

Among the products to be sold is Misys' LIS products, along with its pharmacy, radiology, and inpatient hospital management systems. **Vista Equity Partners** of San Francisco, a private equity firm, bought this unit for $381.5 million.

Misys' enterprise clinical records system is known as Misys CPR. That business division will be sold to **QuadraMed, Inc.,** of Reston, Virginia, for $33 million.

"It's interesting that an equity investment firm bought the diagnostic information system business," commented Bruce A. Friedman, M.D., "because this is a challenging area of clinical software in terms of development, sales, and service. Lab professionals use their LISs non-stop and are demanding customers." Friedman is an Active Emeritus Professor, Department of Pathology at the **University of Michigan** in Ann Arbor. He is an expert on lab information systems and writes the blog *www.labsoftnews.com.*

Was Investment Adequate?

For Friedman, the sale of the Misys Diagnostics Information Business raises a number of key points. "For example, did Misys invest adequately in R&D of their product such that the LIS software has kept pace with the competition?" he asked. "Its installed base of LIS users has great value for the new equity investor because the switching costs of installing another LIS is steep. So, those customers are likely to remain for a while to determine how the company will proceed. As a result, the new buyers can extract some continuing revenue from the annual system support fees.

"But the software has fallen behind, in terms of how it compares with other LIS products," observed Friedman. "It is likely that the installed base of LIS users has been hunkering down with the current system—hoping for an upgrade.

"From what I know about the Misys system, it appears to be missing a state-of-the-art molecular diagnostics module," Friedman said. "Given how quickly labs have adopted to molecular testing, every LIS needs the ability to manage complex molecular test data effectively.

Functionality Needed

"In fact, this issue raises another question: How much will the new owner invest to upgrade this LIS product?" asked Friedman. "To be fully competitive—and to retain the installed base of hospital and laboratory customers—the new owner needs to invest to bring their LIS up to the functionality of competing systems.

"The investment required to upgrade the LIS product is likely to be significant," he noted. "At the same time, the buyers will need to reassure their installed base that there is an appropriate and wise guiding hand for this software firm.

Focusing on Diagnostics

"I believe the LIS business and the clinical lab industry have a rosy future because the future of healthcare will be diagnostic-centric," Friedman explained. "Also, I believe the future of *in vitro* diagnostics (IVD) is bright, with two of the largest corporations in the world ready to invest a combined $23 billion in the IVD industry." That's the approximate total that **Siemens** and **General Electric** (with its now-defunct agreement to buy the diagnostics business of **Abbott Laboratories**) have done with the deals they've announced since the fall of 2003 when GE bought *Amersham* for $9.5 billion. The pace of IVD purchases has picked up considerably in recent months. *(See pages 3-6.)*

"So that raises yet another question: Can the Misys LIS capitalize on this rosy future of diagnostic-centric healthcare?" Friedman asked. "I'm not sure, because, for the new buyers, their challenge will be to move the installed base of laboratory customers, using upgraded LIS and other software products, to a new performance level that supports the ability of these labs to take advantage of the opportunities of a diagnostic-centric healthcare system. In my opinion, that would require, as a ballpark guess, an investment of at least $100 million."

Calls to Vista Equity Partners were not returned. In a statement issued when the deal was announced, Robert F. Smith, Vista's Managing Principal, said, "We are long-term investors in technology-enabled companies that provide leadership in their markets. We are committed to the healthcare market....We look forward to working with this leadership team to continue to grow our presence in the acute care space. Vista plans to operate the Diagnostic Systems organization as a cohesive, self-sustaining business that continues to provide market leading product development, marketing, sales, service. and support for current and future customers."

For fiscal year ending May 31, 2006, Misys reported revenues of $160 million and operating profit of $46.6 million.

The CPR business that Misys will sell to QuadraMed consists of products that collect and share hospital data. For the latest fiscal year ending on May 31, 2007, CPR generated revenue of $30.8 million and a before-tax loss of $8.5 million.

THE DARK REPORT observes that Smith's statements are likely reassuring to those lab directors running Misys systems. But as Friedman said, these customers are interested in functionality. If a laboratory information system does not keep pace with those systems its competitors offer, then soon the lab itself will be out of business. As molecular test volumes increase, labs need systems that manage the complex information generated by these tests. **TDR**

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

These days, it seems as if all sorts of physicians want to cut themselves a slice of the anatomic pathology pie. Now its podiatrists! Sources tell THE DARK REPORT that a large podiatric group in Atlanta has opened its own in-office pathology lab. Reportedly, this lab is generating more than $100,000 in revenue per month analyzing tissue specimens from toenails and feet.

2 OF 10 DOC GROUPS IN CMS P4P PROJECT EARN REWARDS

Last month, the **Centers for Medicare & Medicaid Services** (CMS) announced that, in the first year of its three-year Medicare Physician Group Practice (PGP) demonstration project, all participating physician groups improved the clinical management of diabetes patients. This pay-for-performance (P4P) project rewards physicians for coordinating and managing the overall health care needs of patients with chronic conditions. Ten participating groups achieved the target performance measure on seven of the ten diabetes clinical quality measures and two of the groups met all 10 targets CMS had set.

ADD TO: P4P

Only two groups—**Marshfield Clinic** and **University of Michigan Faculty Group Practice**—earned performance payments for quality and efficiency of $7.3 million as their share of the $9.5 million that Medicare saved through the program. CMS officials said the lack of rewards for the other groups could be due to greater than anticipated start-up costs. Participating physicians said the program resulted in increased use of information technology, such as patient registries, and use of nurses to coordinate care. Appropriate utilization of laboratory tests and proper follow-up on results by participating physicians was an important element in this Medicare physician P4P demonstration project.

TRANSITIONS

Laboratory Corporation of America named Don Hardison to be Executive Vice President and Chief Operating Officer, effective September 4. Hardison was most recently President and CEO for **EXACT Sciences Corporation** of Marlborough, Massachusetts. He also served in executive positions with **Siebel Systems, Inc.**, **Quest Diagnostics Incorporated**, and **SmithKline Beecham Clinical Laboratories, Inc.**

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 27, 2007.