

From the Desk of R. Lewis Dark...

THE **RD**ARK REPORT

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

R. Lewis Dark:

Healthcare Accelerates Its Pace of Change.....Page 1

Sonic Healthcare Pays \$180 Million
In Acquisition of American Esoteric Labs..... Page 2

Technology Update: Product Cuts Claim Denials,
Boosts Payment from Insurers..... Page 5

2006's Top Lab Stories
Identify New Threats..... Page 6

Pathologist Is on Board
Of Central Florida RHIO.....Page 13

Global Lab Trends: There is Steady Convergence
In Laboratory Operations Worldwide.....Page 16

Intelligence: Late-Breaking Lab News..... Page 18

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



Healthcare Accelerates Its Pace of Change

DURING THE NEXT FEW YEARS, clinical laboratories and pathology group practices can expect to see the pace of change in healthcare and laboratory medicine accelerate. As that occurs, lab directors and pathologists will need to be faster at responding to evolving threats and opportunities.

Our selection of the “Top Ten Lab Industry Stories for 2006” makes my point. For example, take the bombshell announcement by **UnitedHealth Group, Inc.** in October that it was dropping **Quest Diagnostics Incorporated** as a provider on its national lab services contract. That left **Laboratory Corporation of America** as the sole national laboratory provider.

However, UnitedHealth’s decision also creates an opportunity for nimble regional laboratories. In a number of communities, UnitedHealth has reached out to establish a tighter relationship with selected regional laboratory providers. These newly-recast relationships open the door for those local laboratories to expand market share, particularly in cities where Quest Diagnostics has a significant presence, but will now no longer be a UnitedHealth contract provider.

Our second most important “Top Ten” lab industry story for 2006 is the literal explosion of interest by urologists and gastroenterologists to build laboratories and make anatomic pathology an in-house ancillary service for their group practices. This is having a devastating impact on national pathology lab companies as well as private practice pathologists based in community hospitals. Urologists and GIs typically refer a high volume of biopsies. Loss of those specimens and their associated revenues is proving disastrous to many pathology laboratories.

There’s another growing trend that has the potential to negatively affect the cash flow of clinical laboratories and pathology group practices. As more Americans enroll in high-deductible health plans and HSAs (health savings accounts), it means that laboratories will need to collect larger amounts of money directly from the patient. In fact, I predict that improved billing and collections will become a major business priority for most laboratories because of this fact. These are just three trends in our Top Ten list which illustrate how healthcare’s pace of change is accelerating.

Sonic Pays \$180 Million In Acquisition of AEL

Purchase of American Esoteric Laboratories puts Sonic Healthcare into new U.S markets

CEO SUMMARY: *In a transaction that was quietly negotiated, Sonic Healthcare Ltd. will purchase American Esoteric Laboratories, Inc. (AEL). News of the sale was released Friday and the sale may close in early January. Once it owns AEL, Sonic will have a major presence in Memphis, Tennessee. It will also gain regional laboratory operations in Tyler, Texas and Morristown, Tennessee.*

FOR ITS NEXT ACQUISITION in the United States, **Sonic Healthcare Ltd.** will purchase **American Esoteric Laboratories, Inc. (AEL)**. The sales agreement was announced last Friday.

Sonic Healthcare will pay US\$180 million for AEL. Currently, AEL has annual revenues of approximately \$US100 million. AEL is getting a good price for its lab business. Sonic indicates that it is paying a prospective multiple of 9.4 times EBITDA (earnings before interest, taxes, depreciation, and amortization). Subject to regulatory approvals, both companies hope to complete the sale early in January.

With the acquisition of AEL, Sonic Healthcare enters the Tennessee mar-

kets of Memphis and Morristown. It gains an expanded presence in Texas because of AEL's ownership of **DRL Labs, Inc.** in Tyler—a lab company AEL acquired just 12 weeks ago. (*See TDR, October 16, 2006.*)

Plans are to retain AEL's existing management team without major changes. Once the sale is completed, Robert Connor, M.D., currently Chairman and CEO of **Clinical Pathology Laboratories (CPL)**, Sonic's business unit in Austin, Texas, will become CEO of AEL. AEL's current Chairman and CEO is Brian C. Carr. Post-sale, he will provide consulting services to Sonic Healthcare.

Keeping the acquired lab's management team in place is consistent with Sonic Healthcare's business strat-

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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 \$11.90 per week in the US, \$12.50 per week in Canada, \$13.65 per week elsewhere (billed semi-annually).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • © The Dark Group, Inc. 2005 • All Rights Reserved

egy. The company likes to acquire regional laboratory companies and operate them without fundamental changes in personnel and operational structure. If Sonic follows this formula, AEL laboratories will continue to conduct business under the AEL name.

AEL is the third laboratory acquisition Sonic Healthcare has done in the United States. In August 2005, it purchased Clinical Pathology Laboratories. Earlier this fall, it purchased **Cognoscenti Health Institute** of Orlando, Florida. (See *TDRs, September 12, 2005 and September 4, 2006.*)

More Lab Acquisitions

THE DARK REPORT predicts that 2007 will see several more laboratory acquisitions by Sonic Healthcare. The company has approached a number of independent laboratory companies and has been able to initiate sales negotiations with several of them.

Owners of independent laboratories consider Sonic Healthcare to be an attractive buyer, particularly when compared to the two blood brothers. First, Sonic has a demonstrated history of purchasing regional laboratory operations, then allowing them to continue to serve their communities under the same business name and using the same employees. Last December, during a trip to Australia, THE DARK REPORT saw this first hand during site visits to Sonic laboratories in Brisbane, Sidney, and Melbourne.

Second, because Sonic needs laboratory facilities, infrastructure, and experienced people in almost any market it enters here in the United States, sellers of independent laboratories know that, post-sale, Sonic will not close existing facilities and lay off loyal employees to consolidate operations as is often done by the national labs. This is a major selling point for many lab owners because they want

their employees to have a continuing role after the acquisition.

Third, Sonic Healthcare is a company led by pathologists. It defines its core business mission to be advancing laboratory medicine in ways that support improved patient care. Leadership by pathologists is something many of the remaining regional laboratories here in the United States use to differentiate themselves from national lab providers within their local service areas.

In selling to Sonic Healthcare, American Esoteric Laboratories ends a relatively short business life. It was launched in April 2004 with \$70 million in venture funding. (See *TDR, April 26, 2004.*) Originally organized for the purpose of developing a national reference and esoteric testing business, AEL found itself acquiring regional lab companies that provided routine testing services to office-based physicians. Its biggest acquisition was **Memphis Pathology Laboratories** in Memphis, Tennessee. This was a laboratory joint venture between **MDS, Inc., Baptist Memorial Health Care, and Methodist Healthcare.**

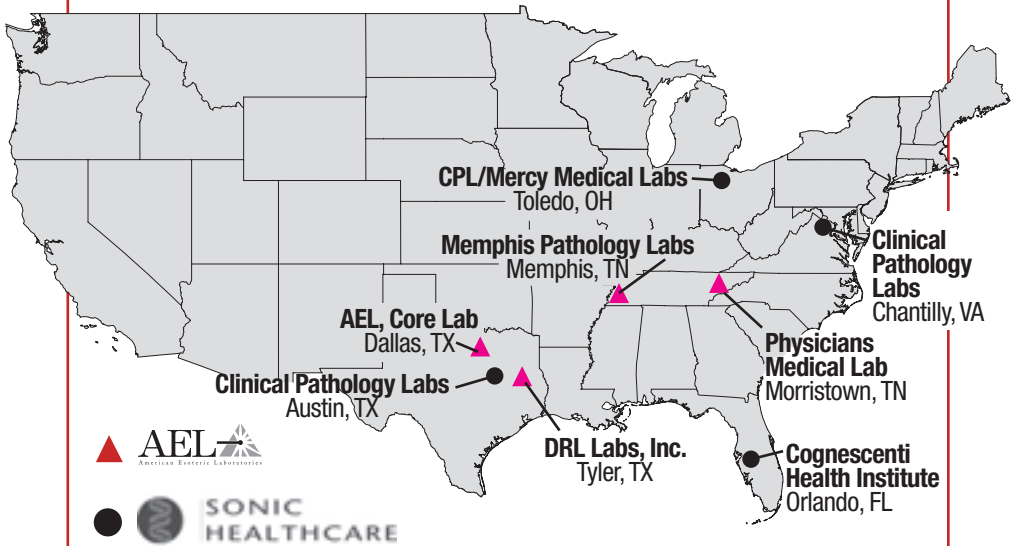
To date, AEL had only used \$60 million of its \$70 million capital base. Thus, an all-cash sales price of \$180 million, with a multiple of 9.4 times EBITDA, gives existing lab owners an insight into one buyer's valuation for an ongoing laboratory business.

Moving Fast In 2007

THE DARK REPORT believes that the acquisition of AEL will be the first of several significant regional lab company acquisitions by Sonic Healthcare during the next 12 months. As noted earlier, Sonic is known to be in discussions with a number of independent lab companies. Thus, Sonic's business strategy will likely be to establish a presence in multiple regions during the next year. **TDR**

Sonic Healthcare Ltd. on the Move: What American Esoteric Labs Brings to the Party

PROBABLY THE CROWN JEWEL INSIDE AMERICAN ESOTERIC LABORATORIES, INC. (AEL) is Memphis Pathology Laboratories (MPL). MPL has a large market share in Memphis, Tennessee and has posted strong growth rates in recent years. Within Sonic Healthcare's U.S. operations, Clinical Pathology Laboratories (CPL) is the anchor for its growing national business. Below is a map of the United States which shows the primary laboratory business divisions of Sonic Healthcare Ltd. and American Esoteric Laboratories.



AEL's Lab Acquisitions: 2004 to 2006

During its 32 months of operation, American Esoteric Labs acquired six laboratory business units. These are listed below. AEL also built a reference and esoteric core laboratory in Dallas, Texas.

<u>Lab Company Acquired</u>	<u>Date</u>	<u>Location</u>
ThromboCare Labs	04/04	Dallas, TX
Viral Diagnostics	04/04	Dallas, TX
Cenetrion Diagnostics	08/04	Austin, TX
Memphis Pathology Labs	09/04	Memphis, TN
Physicians Medical Lab	03/06	Morristown, TN
DRL Labs, Inc.	09/06	Tyler, TX

Technology Update

Product Cuts Claim Denials, Boosts Payment from Insurers

Electronic claims system may help laboratories collect more dollars from CDHP-insured patients

ONE CONSEQUENCE OF THE GROWTH of high-deductible health plans and health savings accounts (HSAs) is that clinical labs and pathology groups need to collect larger amounts directly from patients.

As predicted by THE DARK REPORT last year, bad debt levels are rising in communities where enrollment in high-deductible health plans has been significant. (See TDR, August 1, 2005.) In some cases, the laboratory must collect the full amount from the patient.

Now comes news of nationwide availability of an electronic system that facilitates real-time enrollment verification and delivery of claims. Such a system is a benefit to labs and pathology groups because it makes it feasible to verify eligibility and settle claims with the patient at the point of care.

Claims Management

The system is called EnterpriseEDI and is a health insurance claims and revenue cycle management program. The software is available as an application from **Companion Technologies**, in Columbia, South Carolina.

It is an ASP (application service provider) arrangement where the software resides remotely and customers access it via the Internet. The system offers pathologists, labs, and other physicians a way to forego a substantial investment in hardware and instead utilize software as a service (SaaS).

EnterpriseEDI allows physicians to process and transmit all payer claims directly from a desktop computer. The system performs compliance and eligibility checks to reduce denials. It also tracks claims status, highlights errors, allows for claims correction with minimal data entry, and automatically generates patient correspondence.

"It works with a billing system, so a lab or a pathologist would use a billing program to generate claims and our software would capture those claims and edit them to make sure they go to insurers expeditiously," said John Tempesco, Senior Vice President for Companion Technologies.

"The system helps to reduce billing cycle time by about a third," Tempesco said. "Medical labs generally have many relatively small claims compared with that of other typical practices. So, a program that allows practices to see claims status quickly provides significant benefits. With EnterpriseEDI, pathologists will not lose claims in the system and fewer claims will be rejected because the system identifies errors before they go out."

THE DARK REPORT observes that, as more patients are enrolled in high deductible health plans and HSAs (health savings accounts), labs and pathology group practices will benefit from more aggressive use of software tools such as EnterpriseEDI to improve billing and collections.

2006's Top Lab Stories Identify New Threats

Several disruptive events during the year promise to trigger widespread change

CEO SUMMARY: Presented here are *THE DARK REPORT'S* "Ten Biggest Lab Stories of 2006." Compared to earlier years, 2006 was not transformative for the laboratory industry. But it was an eventful year, particularly influenced by Siemens' decision to acquire DPC and Bayer Diagnostics, along with the decision by UnitedHealth Group to grant an exclusive national lab services contract to Laboratory Corporation of America.

OUR LIST OF THE "TOP TEN LAB STORIES FOR 2006" centers around two major themes. The primary theme can be described as the search for improved efficiency.

Of course, salted in the list are some standout stories with major relevance for the laboratory industry. For example, the decision by **UnitedHealth Group** to exclude **Quest Diagnostics Incorporated** from its national laboratory services contract is likely to trigger long-lasting consequences across a broad swath of the laboratory industry.

It can be argued that the UnitedHealth decision is also an example of the search for efficiency. After all, UnitedHealth is taking this step in pursuit of cost savings and other benefits.

Other Top Ten stories that involve the search for efficiency include specialty physicians bringing anatomic pathology in house, Medicare posting the fees it pays providers on its Web site, the growth of walk-in clinics in

pharmacies and retail stores, consolidation within the *in vitro* diagnostics (IVD) industry, and the achievement of **Sonora Quest Laboratories** in winning the Arizona Quality Program's highest honor.

Judging The "Buzz Factor"

If these 10 stories are weighted according to the "buzz factor"—that is, the amount of comment and speculation that followed the public news—then UnitedHealth's contract decision and **Siemens Corporation's** acquisition of **Diagnostic Products Corporation** and **Bayer Diagnostics** this spring would be number one and number two for 2006.

In the case of UnitedHealth, its decision is likely to trigger a cascade of consequences across the laboratory industry for several years to come. A list of basic questions illustrates why this will be true.

Can UnitedHealth exclude Quest Diagnostics as a contract provider and avoid experiencing widespread unhappiness among physicians and patients, not to mention troublesome disrupt-

tions in service? Will other large national health insurers decide to squeeze harder when it comes time to negotiate their laboratory services contracts? Does this shift in managed care contracting status quo between the two blood brothers mean that either or both will engage in aggressive price discounting to win future managed care contracts from the other?

Imaging Giants Enter IVD?

In the case of Siemens, its willingness to pay more than \$7 billion to acquire DPC and Bayer Diagnostics triggered much speculation. Would **GE** and **Philips**—competitors to Siemens in the imaging marketplace—also decide to acquire IVD companies? If they did, which IVD companies would they acquire? What will Siemens do with DPC and Bayer Diagnostics? Does Siemens have a plan to integrate imaging and *in vitro* diagnostics?

All of those questions will require time to answer correctly. It will take several more years to understand how the developments of 2006 will alter the laboratory industry.

Across the laboratory testing marketplace, probably the single most disruptive development of 2006 was the widespread and active interest by specialty physicians to convert anatomic pathology into an in-house ancillary service.

Across the laboratory testing marketplace, probably the single most disruptive development of 2006 was the widespread and active interest by specialty physicians to convert anatomic pathology into an in-house ancillary service. This is a trend which negative-

ly affects national pathology companies and community hospital-based anatomic pathology group practices.

Specialist physicians, particularly urologists, gastroenterologists, and dermatologists, are the source of large volumes of biopsies. When a pathology laboratory loses access to these cases, the revenue loss is significant. In many situations, revenue from specialty physician referrals is used by pathology groups to acquire new technology and expand the menu of test services they offer.

It is a reason why this trend is such a threat to private pathology group practices. Payers are actively trimming reimbursement for pathology professional services. Many payers are attempting to cease all payment for clinical pathology professional services. The result is an ongoing revenue crunch that hits smaller pathology groups particularly hard. The impact of these trends is compounded when urologists and GIs internalize anatomic pathology and cease referring specimens to national labs and local pathology group practices.

More Lab Acquisitions

Each year, THE DARK REPORT recommends that laboratories use these “Top Ten Lab Industry Stories for 2006” as the basis of a strategic review session with the lab’s executive team. It provides a helpful foundation to discuss the impact of specific trends and identify relevant responses to allow the laboratory to stay ahead of events.

Disruptive forces are loose within healthcare and the laboratory industry. As noted above, the managed care contracting status quo of several years received a significant jolt when UnitedHealth took its unexpected action. Similarly, Siemens’ huge bet in *in vitro* diagnostics may trigger a cascade of consequences in the months and years to come.

1

Upset to the Managed Care Status Quo: UnitedHealth's Unexpected Strategy

2 0 0 6

NEWS THAT UNITEDHEALTH GROUP would dump **Quest Diagnostics Incorporated** from its national contract on January 1, 2007 hit the laboratory industry with hurricane force. (See *TDR, October 16, 2006.*)

By selecting **Laboratory Corporation of America** to be its sole national laboratory provider, UnitedHealth has demonstrated the changing strategies and economics within the nation's largest payers. Because of consolidation and other factors, reducing the cost of spending on lab testing is a business goal that the nation's second largest health insurer is willing to pursue, despite considerable obstacles.

Experts predict that a significant number of physicians and patients will be unhappy about Quest Diagnostics' exclu-

sion from UnitedHealth's lab provider panel. Further, LabCorp will be scrambling to create the service infrastructure it needs to serve UnitedHealth physicians and patients in several regions around the country. So for both UnitedHealth and LabCorp, the exclusive national contract is a gamble with no certainty of major success.

What is true about this change in UnitedHealth's national contracting status quo is that regional laboratories and hospital outreach programs have been handed an opportunity to step in and win market share in their communities. Many independent laboratories tell THE DARK REPORT they are already picking up considerable amounts of new business. It would be ironic if UnitedHealth's decision proved a boon to community labs.

2

Anatomic Pathology Is Cannibalized by Its Most Important Customers

2 0 0 6

IT'S THE FASTEST-MOVING TREND to hit anatomic pathology (AP) in four decades. Ever-growing numbers of specialist-physicians are taking active steps to establish a pathology laboratory within their group practice. (See *TDR, July 3, 2006.*)

Across the specialties of urology and gastroenterology, there is keen interest in establishing anatomic pathology as an in-practice ancillary service. As it was with the emergence of anatomic pathology laboratory condominiums (pod labs) in 2004, THE DARK REPORT was first to identify and describe this trend for the pathology profession. (See *TDRs, July 19, 2004 and August 9, 2004.*)

In fact, within six months of THE DARK REPORT's exposé of AP lab condos,

the federal **Office of the Inspector General (OIG)** issued Advisory Opinion 04-17 and took a negative position on a proposed business model of AP laboratory condominiums.

In the 24 months since the OIG's advisory opinion, urologists and gastroenterologists did not lose interest in anatomic pathology. Instead, larger specialist groups took active steps to build their own histology laboratory and line up pathology professional services. Smaller specialist groups opted for TC/PC arrangements, where a willing pathology laboratory provides technical component (TC) services and the referring physicians make arrangements for the pathology professional component services, for which they bill directly.

3

Transparency in Health Pricing Arrives, Led By Medicare and Private Payers

2 0 0 6

MAKE NO MISTAKE ABOUT IT! Powerful players in the American healthcare system want consumers to choose their own providers and directly pay for more of the healthcare they receive.

Count the federal government (which currently pays for 40% of all healthcare in the United States) as one of those powerful players. This spring, the Medicare program began publishing the fees it pays for common procedures on its Web site (www.medicare.gov). The aim is to allow consumers to have more information about what hospitals and physicians are paid for certain services. (See *TDR*, March 20, 2006.)

But the feds are not alone. Allied with them on price transparency are the major private payers. By the end of

2006, **Aetna, Inc., Humana Inc., Cigna Corp., UnitedHealth Group Inc.,** and **Blue Cross Blue Shield** all made the prices they paid providers accessible to their beneficiaries. (See *TDR*, November 6, 2006.)

So far, THE DARK REPORT is the only laboratory industry resource which has explained this development and recommended that clinical laboratories and pathology group practices prepare to respond to this development. Already, several laboratories have reported an increase in the number of patients asking how much they will be charged for their laboratory tests. Labs with transparent pricing are likely to find it easier to collect directly from the patients they serve.

4

Anthem Raises Stakes in Fight Over Clinical Path Professional Fees

2 0 0 6

WHEN ANTHEM FILED lawsuits against three different pathology group practices over professional fees in Virginia this fall, it signaled an escalation in the ongoing battle between payers and pathologists over such payments. (See *TDR*, November 15, 2006.)

As a division of **Wellpoint, Inc.**, the nation's largest health insurer with 34 million beneficiaries, Anthem certainly has the deep pockets for a long court battle. The Anthem lawsuits seek a refund of clinical pathology professional fees it paid to pathologist-defendants during a three-year period, along with punitive damages.

Anthem's action comes despite the fact that the pathology profession has generally won favorable decisions in a

variety of state and federal courts over the past two decades. These courts have ruled that clinical pathology professional services are a direct benefit to patients and should be compensated.

What makes the Anthem lawsuits both notable and troubling is the point of law that might result from an Anthem victory. Anthem is seeking a refund of payments already made by them to the pathologists, under a valid contract that existed between Anthem and the pathologists at the time such payments were made. A court ruling in Anthem's favor would represent a new legal threat to all providers, not just pathologists. Further, these Anthem lawsuits do escalate the ongoing battle over clinical pathology professional fees.

5

Government Weighs Scales of Justice Against Execs of Impath and UroCor

2 0 0 6

IT WAS COINCIDENCE THAT, LAST JUNE, federal criminal cases were ended against former executives of both **Impath, Inc.** and **UroCor, Inc.** (See *TDR, July 24, 2006.*)

In the Impath case, all six defendants were found guilty in a scheme to manipulate the company's finances to produce as much as \$64 million in phantom revenue between 1999 and 2002. Four of these defendants were sentenced in June.

Impath ex-President and COO, Richard Adelson lost his jury trial and received a sentence of 42 months in prison, a \$1.2 million fine, and was ordered to pay restitution of \$50 million. Former Chair and CEO Anu Saad, Ph.D., had pled guilty earlier and was sentenced to three months in prison,

two years of supervised release, and given a \$6,900 fine.

In the UroCor case, all three defendants were acquitted in a jury trial. It was the first time federal prosecutors had indicted laboratory executives for violations of antikickback statutes. Prosecutors accused the defendants of inducing physicians through deeply discounted pricing and waiving charges for tests done as an out-of-network provider.

During the trial, defense attorneys argued that the federal government had failed to provide clear guidance on laboratory compliance. The jury evidently agreed, as it voted to acquit all three defendants. This trial's outcome complicates the issue of laboratory compliance, particularly in the area of inducement.

6

Big, Bigger, and Biggest: IVD Firms Use Acquisitions to Bolster Growth

2 0 0 6

DURING 2006, four significant consolidations in the *in vitro* diagnostic manufacturing industry demonstrated that acquisitions continue to be a favored way for companies gain market clout.

Siemens Medical Solutions paid \$1.86 billion for **Diagnostic Products Corporation** (DPC), followed weeks later by its \$5.21 billion acquisition of **Bayer Diagnostics**. Another blockbuster deal, at about the same time was the reverse merger between **Fisher Scientific International Inc.** and **Thermo Electron Corporation**. The combined revenues of these two companies top \$8 billion per year. (See *TDR, May 22, 2006.*)

Another significant transaction was the acquisition of Melbourne,

Australia-based **Vision Systems Limited** by **Danaher Corporation**. Losing bidders for Vision were **Ventana Medical Systems, Inc.** and **Cytec Corporation**. (See *TDR, November 6, 2006.*) The year ended with **TriPath Imaging, Inc.**, signing a definitive merger agreement with **Becton, Dickinson and Company** for a purchase price of about \$350 million.

In each case, these acquisitions will lead to a realignment of a specific segment of the diagnostic marketplace. Of these four acquisitions, the most closely-watched will be Siemens. As a major player in diagnostic imaging, its investment in DPC and Bayer Diagnostics has triggered plenty of speculation about its strategic plans for clinical diagnostics.

7

Pharmacy Chains Build Walk-In Clinics And Support On-Site Blood Draws

2 0 0 6

NATIONAL PHARMACY CHAINS are taking steps which could eventually make them competitors to clinical laboratories. The first step is the development of rapid, walk-in primary care clinics in pharmacies and other retail locations.

CVS Corporation raised the ante when it acquired MinuteClinic, which operates 83 retail clinics in 10 states, including 66 clinics in CVS pharmacies. At the time of this acquisition, one expert predicted that 10,000 retail walk in clinics would be operational by 2010. (See TDR, September 25, 2006.) Rapid, walk-in clinics are already operated by such major retail chains as Wal-Mart, Rite Aid, Osco, Sav-on Drugs, Kroger, Shoprite, and Piggly Wiggly.

Now, the need for Laboratory Corporation of America to add patient service center (PSC) sites to service UnitedHealth beneficiaries is causing LabCorp to court pharmacies as locations for patient drawing centers. It plans to have 250 draw sites open in MinuteClinic locations within CVS Pharmacies. LabCorp also signed a deal with Duane Reade to open 20 PSCs in Duane Reade pharmacies. These will be private rooms staffed by LabCorp employees.

As pharmacies gain experience in supporting blood draws, could they become interested in performing point of care testing on site that would support filling prescriptions? Recent events lend credence to such a prediction.

8

Number of Molecular Assays Grows And Shows Market-Moving Potential

2 0 0 6

MOLECULAR DIAGNOSTIC ASSAYS have increasing potential to transform the laboratory market nationwide, as two particular developments in 2006 showed.

During the year, more attention was focused on cytochrome P450 (CYP450). Tests based on CYP450 could help prevent adverse drug reactions (ADRs), a major source of deaths and healthcare expenses. (See TDR, April 10, 2006.) Testing individuals for genetic variations in CYP450 could help determine whether patients can metabolize drugs comprising 25% of the current formulary (representing 700 million prescriptions each year). The implication is that the volume of CYP450 testing is likely to grow steadily in coming years. It has the potential to be a revenue blockbuster.

Another development is the rapid clinical acceptance and revenue growth of RedPath Integrated Pathology, Inc., in Pittsburgh. RedPath is one of the first commercial laboratories to integrate genomic analysis with everyday pathology practice. (See TDR November 6, 2006.) Its technology allows pathologists to provide different tests that support both the diagnosis of cancer and the planning of treatment across multiple organ systems.

Clinicians are becoming quicker to utilize assays that incorporate new molecular technologies and are more sensitive tools for diagnosis and treatment. In turn, greater use of molecular-based assays should greatly benefit the pathology profession.

9

CAP Launches First-Ever Program Of Unannounced Lab Inspections

2 0 0 6

IN THE SPRING OF 2006, the **College of American Pathologists (CAP)** began a program of unannounced laboratory inspections. Also moving toward unannounced inspections was the **Joint Commission on Accreditation for Healthcare Organizations**. (See *TDR*, February 27, 2006.)

Unannounced inspections are one legacy of the startling mismanagement at **Maryland General Hospital's** laboratory in Baltimore in 2004. Investigators determined that, for more than 14 months, the laboratory had reported potentially inaccurate HIV and HCV results on at least 460 individuals. (See *TDR*, April 5, 2004.)

Discovery of this scandal led to an investigation by Maryland state health authorities and several congress-

sional hearings. During the hearings, CAP officials promised to tighten inspection and accreditation standards. Unannounced inspections are one result of those promises.

The unmistakable message to the laboratory industry from this development is that more transparency in the operation and performance of laboratories is on the way. Unannounced inspections are just one step in a national effort to make the entire healthcare system more accountable to patients and payers for quality and safety.

Clinical laboratories and pathology group practices can expect to see oversight of laboratory operations increase. Support for such reforms will come from both payers and regulators.

10

Sonora Quest Lab's Quality Program Highlights Direction for Lab Industry

2 0 0 6

IT WAS A LAB INDUSTRY MILESTONE when **Sonora Quest Laboratories (SQL)** earned the Arizona Quality Program's highest honor—the Governor's Award for Quality. (See *TDR*, February 6, 2006.)

It is the latest honor on Sonora Quest's quality journey. The laboratory organization adopted Six Sigma quality management methods several years ago and has used this initiative to boost customer and employee satisfaction, while increasing quality, improving profit margins, and developing closer relationships with managed care companies in the state.

THE DARK REPORT has regularly chronicled the experiences and successes of the first laboratory organizations to embrace quality management systems like Lean, Six Sigma, and ISO-9000.

When properly implemented, these management methods have helped laboratories to enjoy 50% gains in average turnaround time (for hospital labs), productivity, and error reduction.

Sonora Quest Laboratories may be the first lab organization to have won such a prestigious quality award, but it won't be the last. Growing numbers of laboratories, and hospitals are taking the first steps to introduce quality management systems into their organizations. This is a steadily-growing trend, and one with the potential to help all laboratories and pathology group practices meet the challenges of declining reimbursement and the need to spend heavily to acquire new diagnostic instruments and information technology.

Pathologist Is on Board Of Central Florida RHIO

Regional health information organization has several ambitious goals and objectives

CEO SUMMARY: *Participation in the development and implementation of Central Florida's nascent regional health information organization (RHIO) is helping Clinical Pathology Laboratories (CPL), of Austin, Texas, achieve four strategic goals. Philip Chen, M.D., Ph.D., CPL's Vice President and Chief Medical Informatics Officer, predicts that this RHIO will speed up the integration of healthcare informatics.*

REMEMBER CHINS? DURING THE 1990s, Community Health Information Networks were the first attempt to create a centralized regional health database that could be accessed by hospitals, physicians, other providers, and payers.

Now the acronym *de jour* is RHIO, which stands for Regional Health Information Network. RHIO describes the current generation of attempts to create a useful database of health information that can serve all healthcare stakeholders.

Seven Counties Involved

Because any healthcare data repository will hold a large amount of laboratory test data, it is important for regional laboratories to participate in the development and operation of their local RHIOs. In Florida, pathologist Philip Chen, M.D., Ph.D., was recently selected to be on the board of directors of the **Central Florida Regional Health Information Organization (CF-RHIO)** in Orlando. This RHIO serves seven counties in the Orlando metropolitan area.

Chen is Vice President and Chief Medical Informatics Officer for **Clinical Pathology Laboratories, Inc. (CPL)**, of Austin, Texas. He founded **Cognoscenti Health Institute** in Orlando, which CPL acquired earlier this year. (See *TDR*, September 4, 2006.)

"My involvement with the CF-RHIO serves four significant and strategic goals for our lab," observed Chen. "First, participating in this project helps us understand the specific ways that healthcare IT will evolve in our community. This gives us a leg up in our own strategic planning. It helps us align our lab's IT infrastructure to better meet the needs of the community we serve.

"Second, participating in the RHIO helps us stay in the forefront of medicine," he added. "Our physician clients trust us and look to us to guide their own IT strategy development. What's more, appropriate connectivity to clients improves service and leads to more secure and long-term client relationships.

"Third, participation gives our lab's executive team direct access to key

stakeholders in healthcare, such as other physicians, insurers, large employers, health system executives, community leaders, and government policymakers,” he explained. “We can use this access to share and educate our colleagues and partners in healthcare on the delivery of lab medicine and the importance of laboratory services.

Lab’s Place At The Table

“These days, attempts at healthcare reform and changes in reimbursement policy are being considered almost constantly,” said Chen. “That makes it important for laboratory executives to be heard in the decision making process. Being involved in the RHIO means we are included in discussions about exclusive lab arrangements, competitive bidding, preventive screening, reimbursement policy revisions, utilization management, and pay for performance, just to name a few strategic topics.

“The fourth benefit of participating may be the most important reason,” Chen said. “It helps us provide better care to our patients by weaving our laboratory more closely into the RHIO infrastructure. This ensures our ability to feed clinical data into the regional data repository. It also gives us access to relevant data about the patients and physicians we serve.

Risk Of Market Exclusion

“I am convinced that participation in the local RHIO is an absolute necessity in the current competitive environment in the marketplace,” declared Chen. “If we don’t participate in some way, eventually the role of laboratory medicine could be de-emphasized. That is why the participation of pathologists in these types of regional collaborations is essential.

“Laboratory test results affect 70% of medical decision making,” continued Chen. “All inpatient visits include

Still a Limited Number of RHIOs in the United States

REGIONAL HEALTH INFORMATION ORGANIZATIONS (RHIOs) require the collaboration of a wide variety of stakeholders to allow physicians, hospitals, laboratories, pharmacies, and other providers to share patients’ medical information at any time and in any setting.

Forrester Research, a technology research group in Cambridge, Massachusetts, states that RHIOs are expected to improve the quality of care, and avert medical errors. RHIOs should also help to lower healthcare costs by eliminating redundant diagnostic procedures, preventing complications, shortening delays waiting for paper charts, and reducing other inefficiencies.

In a report released earlier this year, Forrester said RHIOs are in their formative stages. It found seven small regional networks in operation and wide variability in architecture and governance models. “The rest of the country will follow, but more slowly than advocates expect, as stakeholders cast about to find the hundreds of millions of dollars needed to build a national network,” Forrester said.

laboratory testing, and greater than 70% of outpatient visits include lab testing. Laboratory data constitute the largest objective patient data set used in healthcare today. Clearly, all labs have a responsibility to support RHIO development.

“RHIOs are an important step in integration of the healthcare continuum,” he added. “It is logical for laboratories to play important roles in the development and operation of RHIOs.

“For CPL, participating in the development of Central Florida’s RHIO is not about positioning our lab for the future,” he said. “It’s about

positioning CPL for the state of the healthcare marketplace today.

“Florida is a hotbed for RHIO development,” noted Chen. “At this time, there are five major RHIOs under development, along with several smaller rural projects. Outside of Florida, a number of RHIOs are being developed.

RHIO Development

“Because the RHIO trend is still in its earliest phases, it is too early to predict what type of common organizational model will emerge,” said Chen. “However, the phrase, ‘No RHIOs are alike!’ seems to be generally accepted. Some are more advanced in technology development and implementation, particularly those in Cincinnati and Indiana. Other RHIO projects are more active in building infrastructure and developing governance.

“The Central Florida RHIO effort is likely to make a major impact on the laboratory industry when it comes to utilization,” predicted Chen. “One large insurance company here has reported that its claims data shows that the laboratory utilization rate in our state is 270% higher than the national average! For that reason, one of the first demonstration projects of the Central Florida RHIO is to analyze lab usage rates in Florida for appropriateness.”

Employers Took The Lead

But the Central Florida RHIO is significant for other reasons. “The **Florida Health Care Coalition** (FHCC) took the lead in developing this RHIO. Its employer-members in Central and Southeast Florida represent two million employees and spend several billion dollars per year on healthcare for their workers. As a result, FHCC was able to convince all stakeholders to participate in the RHIO. It’s unusual for employers to have so much clout in a market.”

Central Florida RHIO in Development

ORGANIZERS OF THE CENTRAL FLORIDA RHIO have one primary goal: to enable healthcare providers to access patients’ clinical information from a central portal.

“Other goals are to improve the quality of care, reduce medical errors, and boost efficiency,” stated Philip Chen, M.D., Vice President and Chief Medical Informatics Officer for Clinical Pathology Laboratories (CPL), of Austin, Texas. Chen is also a director of the Central Florida RHIO (CF-RHIO).

Currently, CF-RHIO includes representatives from 40 organizations, including area hospitals, physicians, medical laboratories, public health providers, insurers, higher education, and local businesses. The RHIO is part of the **National Health Information** (NHI) Infrastructure initiative to interconnect clinicians, so they can learn about a patient’s medical and medication history and make better treatment decisions. Over the next five years, CF-RHIO hopes to allow physicians and hospitals to access data created by clinicians anywhere in the country.

THE DARK REPORT observes that the development of RHIOs across the nation will be a significant development—not just for the laboratory industry, but for all types of healthcare providers. Therefore, as Chen points out, it is essential for pathologists and lab managers to be involved in their communities’ RHIO development and operation. Such participation will ensure that clinical laboratories have a place at the table and can maintain strong relationships with their client physicians.

TDR

Contact Phil Chen, M.D., at 407-882-0212 or pchen@labdoc.com.

Global Lab Trends

There is Steady Convergence In Lab Operations Worldwide

Common analyzers, common reagents support growing “international” standard for most labs

BY ROBERT L. MICHEL

IS THERE AN ACCELERATING CONVERGENCE OF LABORATORY OPERATIONS by major clinical laboratories throughout the world? In recent weeks, THE DARK REPORT has seen tantalizing evidence that the answer to this question should be “yes.”

This trend has strategic implications for independent commercial laboratories and hospital-based laboratories in the United States. It also has implications for *in vitro* diagnostics (IVD) manufacturers.

If laboratory operations are now following a path of global convergence, it could mean development of a universal standard for laboratory performance. However, this will not be a standard mandated by individual governments. It will be a *de facto* “best practices” standard—one that laboratories follow because it helps them deliver the highest quality laboratory services while at the same time maintaining or improving competitive position.

My thinking on this point crystallized during a week-long trip to Colombia earlier this month. THE DARK REPORT was hosted by two regional teams for **Roche Diagnostics** and **Sysmex Corporation**. In Cartagena, Colombia, the Roche region encompassing Central America and the Caribbean was conducting its second annual DIAMante program for laboratory lead-

ers within the Caribbean Basin. The Colombia Roche region was supporting that effort and arranged site visits of two large clinical laboratories in Bogota, Colombia for THE DARK REPORT.

The laboratory site visits came first during the trip and I shared some of the useful management insights that resulted from these visits in a DARK Daily e-briefing (which can be found at www.darkdaily.com). The DIAMante Conference took place on December 1. In attendance were approximately 40 senior-level lab directors and public health system administrators responsible for lab testing services in their countries.

Thirteen Nations Attended

Thirteen nations were represented, ranging from Guatemala and Panama in Central America to Cuba, Jamaica, and Barbados in the Caribbean. There is a significant point to make about this audience. The health systems in these countries have limited resources and national spending on health typically ranges from under 1% to 3% of gross domestic product (GDP). The scale of these labs is accordingly smaller, with 700 patients per day representing a large volume.

The one-day DIAMante conference was organized around the goal of helping attendees learn ways to more effectively sell the value that lab services can add to the health system. Four speakers were featured during the day. They were: Prof. Dr. José Louis Segú,

Prof. Dr. Jordi Ordóñez-Llanos (both from Spain), Robert Michel, and Dr. Alba Garzón of Colombia.

Thus, the faculty represented two speakers from Europe and one speaker each from North America and South America. The remarkable outcome was that all four speakers hit complementary points about how laboratory testing adds value to the entire health system. In other words, regardless of the regional differences in their respective health systems, all four speakers identified opportunities and institutional challenges in nearly identical ways.

Furthermore, throughout the day, questions and comments from attendees made it clear that these same opportunities and challenges were applicable in their own nations.

Four Universal Themes

I recognized four “universal themes” that translate into forces that would tend to cause laboratory operations in most countries to converge toward a common operational template. First, the most important laboratories in every nation, including the island nations of the Caribbean, are seeking accreditation that helps them relate their regional performance to that of other laboratories in other countries.

One path taken by these laboratories is to pursue compliance with ISO 15189—Medical Laboratory standards. Another path is to seek accreditation by an internationally-recognized provider. It is this market that the laboratory accreditation programs of the **College of American Pathologists (CAP)**, **Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)** and others would like to pursue.

Second, there is growing interest by laboratories to learn and implement Deming-based quality management systems. Dr. Garzón is an early Six Sigma practitioner at **Laboratorio Echevarra** in Bogota, where her laboratory is

achieving as high as 5.47 sigma in certain microbiology laboratory processes. Her presentation energized the attendees, many of whom expressed strong interest to immediately launch similar quality improvement initiatives in their own country’s laboratories, if they could access the expertise needed to do such programs successfully.

Third, another powerful factor feeding convergence of laboratory operations worldwide is the universal pursuit of improving patient safety and raising healthcare outcomes. In fact, the ability of a Lean or Six Sigma program to help a laboratory support these goals was widely recognized by attendees.

Fourth, for more than 15 years, the instrument systems and diagnostic assays sold by the leading *in vitro* diagnostics (IVD) manufacturers have been sold throughout the world, with relatively few significant modifications. During my site visits to laboratories in Colombia and to labs in Argentina last October, it was obvious to me that the IVD manufacturers have provided a common technology base. This technology base becomes a common bond among laboratories in almost any country and makes it possible for them to share operational successes and develop “world class” applications.

Collectively, I argue that these four factors are visible evidence that the operations and fundamental strategies of major laboratories in most countries worldwide are converging. This process will be ongoing and is unlikely to be stopped or derailed.

Thus, lab executives and pathologists in the United States would be well-served to pay closer attention to developments in international laboratory accreditation and the emergence of Web-based QA/QC programs. It will be these vehicles which form the foundation for an international set of laboratory management best practices. **TDR**

INTELLIGENCE

LATE & LATENT
Items too late to print,
too early to report



Last Friday, **Luminex Corporation** of Austin, Texas announced that it would acquire **Tm Bioscience Corp.** of Toronto, Ontario. Luminex will pay \$44 million, which represents a 41.5% premium for Tm shares based on the December 14 closing price. Tm Bioscience has tests for DNA-based diagnostics, including tests for infectious diseases and genetic mutations related to cystic fibrosis, sepsis, and other disorders. A number of these assays incorporate Luminex's patented technology.

CHOLESTEROL TESTS IN DOCS'S OFFICES

One area of testing which will be marketed to office-based physicians is quick cholesterol screenings. Promoters see it as a customer-friendly service that can generate additional revenue for physicians. However, experts note that not all instruments produce accurate results. Further, cholesterol testing from a finger stick sample is less preferred to a blood sample tested on a central lab's full chemistry analyzer.

MICRORNA MOLECULES EMERGING AS USEFUL LEUKEMIA MARKERS

In recent years, many research breakthroughs have used DNA and proteins to diagnose disease. Now useful discoveries involving RNA are poised to join the molecular diagnostic menu. Two microRNA (miRNA) molecules have been linked to a dangerous form of B-cell chronic lymphocytic leukemia (B-CLL), considered to be the most common human form of leukemia. Researchers at **Ohio State University (OSU)** in Columbus, Ohio published findings in *Cancer Research* that demonstrate a direct inverse association between expression of miR-29 and miR-181 and that of the TCL1 oncogene. "It works both directions," stated Yuri Pekarsky, Ph.D., Associate Professor in the Department of Molecular Virology, Immunology, and Medical Genetics at OSU's Comprehensive Cancer Center.

ADD TO: MicroRNA

"High expression of these miRNA's correlates with low expression of TCL1," continued Pekarsky, "an

indolent form of the cancer that is less likely to progress. A low level of miR-29 and miR-181 associates with a much more aggressive cancer." The research team must now determine if these MicroRNAs work at the transcriptional or translational level, so it will be some time before these markers can be used in a diagnostic assay.

BREAST CANCER TESTS

- **Quest Diagnostics Incorporated** has entered the market for predictive genetic breast cancer tests. Announced last Thursday, the Breast Cancer Gene Expression Ratio is designed to "to help physicians predict the risk of disease recurrence in women with estrogen receptor (ER)-positive, lymph node-negative breast cancer." Quest licensed technology from **AviaraDx Inc.** to use in this test.

- **Genomic Health Inc.** recently announced a contract with **Aetna, Inc.** for its Oncotype DX assay, which predicts the likelihood of disease recurrence for breast cancer patients.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, January 8, 2007.*

Save the Date!

EXECUTIVE WAR COLLEGE

May 10-11, 2007 • Intercontinental Hotel • Miami, Florida



UPCOMING...

- ***2007 Macro Trends for Clinical Laboratories.***
- ***CDC Sponsors New Workteams to Identify “Best Laboratory Practices.”***
- ***Inside Look at Regional Contracting Strategies of UnitedHealth.***



Check out our newest service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

Get started today!

For more information, visit:
www.darkreport.com