Volume XIV, Number 2 Monday, January 29, 2007

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Of Radiology, Pathology, GE, Siemens, and Philips

WHY THE SUDDEN INTEREST IN *IN VITRO* DIAGNOSTICS (IVD) by companies serving radiology? Over the past 12 months, what motivated **General Electric** to spend $8.13 billion and **Siemens AG** to spend $7.1 billion to acquire their own large IVD manufacturers?

I suspect the answer is: information. In healthcare, radiology and laboratory medicine have two things in common. First, each specialty is essential in helping physicians diagnose disease. Second, each specialty produces large amounts of information, most of which is useful to retain in the patient's permanent medical record.

In recent years, digitization of radiology images and software systems to capture, to study, to store, and to share this information has become a big business. Most large hospitals are spending heavily to digitize the output of the radiology services and GE, Siemens, and **Philips** are major providers of these imaging systems.

What other medical service generates large amounts of information that makes up a major part of every patient's medical record? It is laboratory medicine: clinical laboratory and anatomic pathology testing. Furthermore, as a growing number of genetic and molecular assays gain clinical acceptance, the amount of lab test data that must be captured, analyzed, and stored increases exponentially. The increased volume of such data already stresses the storage capacity of laboratory test data bases.

It is my belief that the world's largest suppliers of radiology systems and software share a strategy of providing information systems which combine the data from radiology and laboratory medicine. As this happens, they control the huge majority of information that make up the individual patient's electronic medical record (EMR).

As a business strategy, this has two complementary strengths. First, it positions these imaging companies to integrate imaging and *in vitro* diagnostics as technology and research reveals new clinical relationships between imaging and laboratory testing. Second, as the producer of informatics systems that collect, analyze, store, and share diagnostic data from imaging and lab testing, these companies position themselves to be major suppliers of informatics solutions to healthcare—at a time when integration of medical software systems is a major goal of health systems worldwide. TDR

IVD Stunner: GE to Acquire Abbott's Diagnostics Unit

Everything is sold but Abbott's Diabetes Care and its Molecular Diagnostics Business Units

CEO SUMMARY: General Electric Corporation made a dramatic entrance into* in vitro *diagnostics (IVD) by acquiring almost all of Abbott Laboratories' IVD business division. Once the sale is closed later this spring, GE will be the second major imaging vendor to buy its way into the IVD business. With its deep pockets, celebrated management skills, and vast reach into hospitals across the nation and the globe, GE could prove to be a tough competitor.

EVER SINCE **SIEMENS AG** ACQUIRED **Bayer Diagnostics** and **Diagnostic Products Corporation** (DPC) last summer, everyone in the *in vitro* diagnostics (IVD) industry wondered when **General Electric** would make its move into the IVD industry and which diagnostics company it would buy.

Those two questions were answered on January 18, when General Electric announced an agreement to acquire most of the diagnostics business of **Abbott Laboratories, Inc.,** of Abbott Park, Illinois. GE will pay $8.13 billion and the sale is expected to close by June, subject to "customary closing conditions" and regulatory approvals.

GE will acquire the bulk of Abbott's diagnostics business and Abbott's Point-of-Care diagnostics. During 2006, these businesses generated sales of approximately $2.7 billion.

Abbott Laboratories will keep two of its fastest-growing diagnostic business lines. It retains Abbott Diabetes Care (which involves glucose monitoring meters and test strips), and Molecular Diagnostics. Both business lines enjoyed double-digit rates of growth in recent years and expectations are that rapid growth will continue in these markets. In 2006, diabetes care generated revenue of about $1.15 billion while molecular diagnostics sales totaled about $140 million.

What General Electric gets for its $8.13 billion investment is one of the world's major IVD companies. Abbott's diagnostic business produces instruments, reagents, and other products in chemistry, hematology, immunoassay, and other

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 $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

areas of lab testing. GE will also get Abbott's point-of-care testing (POCT) business, which has experienced double-digit growth since Abbot acquired **I-Stat** in 2003. *(See TDR, March 15, 2004.)*

Abbott's Worldwide Sales

The change of ownership of Abbott's diagnostics division will affect many laboratories in the United States and around the world. One of the world's largest IVD firms, Abbott makes products that thousands of laboratories use worldwide. For this reason, many lab managers and pathologists will watch closely how GE operates its new IVD business division.

In the short term, not much is expected to change. Word is leaking out from inside Abbott that the existing IVD manufacturing facilities in Abbott Park will be unaffected for now. Administration, sales, marketing, and other operations will relocate to offices not far from the Abbott Park complex.

In fact, many lab directors have told THE DARK REPORT that they see the acquisition as a positive step. One reason is that General Electric is widely recognized for its efficient management culture. Therefore, some pathologists are confident the transition will go smoothly. Another reason is that these laboratorians believe GE has big plans for IVD. They say GE wouldn't have paid $8 billion to get into *in vitro* diagnostics unless it had a well crafted business strategy.

GE Healthcare CEO

General Electric discussed some facets of its strategy. Joe Hogan, President and CEO of GE Healthcare, said, "Through this acquisition, we create the opportunity to integrate our broad-based competencies in diagnostics, life sciences, and healthcare information technology. *In vitro* diagnostics and *in vivo* imaging continue to become more important in providing comprehensive diagnostic solutions.

"Our capabilities combined with Abbott's *in vitro* diagnostics and point-of-care diagnostic businesses," he continued, "will allow GE to provide customers with better tools for the full care continuum, enhancing their decision-making capabilities in key disease areas such as oncology and cardiology, and enabling early disease detection, diagnosis, and treatment."

There are several interesting aspects to this acquisition. For example, Abbott's CEO, Miles White, has told employees that GE CEO Jeffrey Immelt approached him several years ago to express an interest in buying Abbott's IVD business. If true, such interest indicates that GE has had a long-standing desire to enter the IVD market that predates imaging rival Siemens' acquisition of Bayer Diagnostics and DPC last year.

IVD's Growth Potential

Second, independent of GE's ability to integrate imaging, informatics, and molecular diagnostics into an array of clinically useful services, GE considers *in vitro* diagnostics to have better growth and profit potential than several of its other main business units. For example, it is selling its plastics division.

Third, by contrast, Abbott considers the high-volume, routine diagnostics business to be low growth, low profit when compared with its pharmaceutical division. In 2004, Abbott sold **Hospira**, a hospital products company that it considered to have limited growth potential. So its sale of the diagnostics business unit is part of an ongoing corporate program to shed slower-growing businesses and invest in higher-growth opportunities.

Relative to each companies' existing mix of businesses, that is why General Electric and Abbott Laboratories each considers this sale to be a win-win transaction. Further, both companies may recognize that GE's core competencies can contribute more to the future success of Abbott diagnostics than if the business unit stayed at Abbott Laboratories.

This factor is the fourth interesting aspect to the transaction. General Electric has world class skills in several relevant areas. It possesses advanced engineering capabilities in automation design and operation. Most of the instrument systems Abbott Diagnostics sold are highly automated and complex.

GE's Service Presence

Next, GE maintains one of the world's largest service organizations. Because of its imaging products, it has a sizeable service presence in healthcare, particularly in hospitals. That means it is likely that, across the United States, each day GE already has a service rep on site in larger hospitals. When the Abbott service team is added to its existing service team, GE is well positioned to offer improved service to laboratory customers at a lower cost.

On the financial front, GE has another benefit for laboratory customers. It is one of the world's largest sources of business capital. When a lab is ready to buy large analyzers and automated systems, GE can put together competitive financing packages. Plus, since GE may already be financing the hospital's imaging equipment, it has knowledge and existing relationships with hospital administration.

GE Bought Triple-G

Another point should not be overlooked. GE has a strong base in healthcare informatics. It sells imaging information systems. In recent years, it acquired **Triple-G Systems Group, Inc.,** and actively sells this laboratory information system product to laboratories. This aspect gives it experience and skills to integrate healthcare informatics effectively with new generations of analyzers and lab instruments.

Collectively, GE's core competencies explain why it believes it can develop further value from the existing Abbott Diagnostics client base. It already operates in the same hospitals where Abbott has laboratory customers. It knows the healthcare business. It sees opportunities to combine imaging and laboratory testing technologies to improve the early detection of disease. For these reasons, General Electric sees its entry IVD business as fully complementary to its healthcare business strategy. Finally, with both General Electric and Siemens AG now in the IVD business, it may only be a matter of time before Philips makes its own IVD acquisition. TDR

Imaging, Informatics, IVD: The Dream of Integration

WILL IT BE POSSIBLE TO INTEGRATE imaging, informatics, and molecular diagnostics? General Electric's public comments on this point strike the same chords as the public comments Siemens AG struck after its acquisition of Bayer Diagnostics and DPC. Clearly, both companies believe that new research and technology will make it possible to feed medical images and molecular markers to sophisticated software programs.

These software programs will sort through the imaging and molecular test data to identify relevant patterns. By combining imaging, informatics, and molecular diagnostics into an integrated diagnostic process, the output can provide clinicians with tools that support a more accurate and earlier diagnosis. It will be equally true that this blend of three inputs can identify relevant therapies and support close monitoring of the patient's progress.

Recent research shows that new imaging technologies can detect ever-smaller details, including tumors and other malignancies. However, the sensitivity and specificity of these new technologies have been insufficient to justify the use of these new imaging technologies in clinical procedures.

JVHL Signs A Contract With UnitedHealth Group

➤Hospital laboratory network seizes opportunity to help fill coverage gaps throughout Michigan

➤➤CEO SUMMARY: When UnitedHealth Group announced its exclusive national contract with Laboratory Corporation of America, Joint Venture Hospital Laboratories (JVHL) saw opportunity. That's because LabCorp does not have a significant presence in Michigan. JVHL parlayed its statewide network of 120 hospital laboratories into a five-year contract with UnitedHealth, positioning it to capture more market share.

BEHIND THE SCENES, there is an unfolding story linked to the new, "exclusive" national lab services contract between **UnitedHealth Group** and **Laboratory Corporation of America**. It's a story that runs counter to the public relations blitzes of both companies.

With little fanfare, UnitedHealth has quietly been negotiating with regional laboratories in selected cities to make them contract providers for laboratory testing. It's a tacit recognition by UnitedHealth that no single national laboratory company can serve its beneficiaries in every region.

This is true in Michigan, where LabCorp has never held a substantial share of the market in either Detroit or other areas of the state. That created an opportunity for **Joint Venture Hospital Laboratories** (JVHL), the network owned by nine Michigan health systems, to forge a closer and expanded relationship as contract provider for UnitedHealth.

Last month, JVHL signed a five-year contract to provide laboratory testing services for physician-office-originated testing in Michigan, effective on January 1, 2007. JVHL's success provides important lessons on how other regional laboratories can negotiate with UnitedHealth to become a regional contract provider. The cornerstones of JVHL's contract strategy were competitive pricing for lab services and the ability to provide data that UnitedHealth can use to improve healthcare outcomes.

➤Seizing The Opportunity

"In Michigan, hospitals have been successful with laboratory outreach programs," Jack Shaw, JVHL's Executive Director, said in an interview with THE DARK REPORT. "As a starting point, this meant that the laboratory members of JVHL have good market share, an established reputation, and the loyalty of many physicians. In fact, it would be tough for any commercial lab company to wrest physicians away from these successful hospital laboratories outreach programs.

"In discussions with us, UnitedHealth indicated that it wanted to ensure that lab testing referred by office-based physicians was performed according to their national objective of lab cost reductions," he

explained. "UnitedHealth saw that by contracting with JVHL it could achieve this goal without relying solely on their national contractor."

Smaller Book Of Business

Another factor may have been the relatively small number of UnitedHealth beneficiaries in the state. "In Michigan, UnitedHealth insures about 180,000 lives. These are primarily in the urban centers," said Shaw. "That's about 10% of JVHL's current book of business. It's also likely to be under 5% of the total book of private payer business done by all labs in Michigan.

"Several of our member hospitals had contracts with UnitedHealth for inpatient and outpatient testing," Shaw added. "When UnitedHealth announced its contract with LabCorp, we saw an opportunity to bring the UnitedHealth lab work originating in doctors' offices under contract.

"At the time, we had two reasons for contracting with UnitedHealth," he continued. "First, when Quest Diagnostics was dropped from the UHC contract, we felt there was a chance for JVHL hospitals to gain some of that business. As well, we didn't want that business to default to LabCorp," noted Shaw.

Already Serving Physicians

"Second, our hospital labs already do a significant share of physician office testing," he added. "Thus, we had an existing vehicle that could allow us to extend this line of business. We recognized that, if UnitedHealth followed through on its plan to have physicians direct much of their lab testing to contracted laboratories, this further opened a window of opportunity for JVHL. It was important to ensure that we were a participating laboratory provider on behalf of our hospitals. That was our contracting strategy, and UnitedHealth agreed."

With headquarters in Allen Park, Michigan, JVHL is an umbrella contracting entity for 120 hospital laboratory outreach programs in the state. "Whenever JVHL negotiates a managed care contract, it becomes a single point of contact for the payer, despite the fact that as many as 120 hospital laboratories may provide testing under that contract," Shaw said.

"In the case of UnitedHealth, several of our hospitals already had provider status for lab testing with UnitedHealth for lab specimens collected in hospitals," he added. "The new contract between JVHL and UnitedHealth covers only laboratory testing that originates in physicians' offices. It doesn't affect the hospital work, which they can continue to perform under their hospital contracts. And, all 120 of our participating hospitals can access the physician office work.

Discounted Fee-For-Service

"Pricing is competitive with UnitedHealth's standard fee-for-service schedule, which represents a discount from the Medicare fee schedule," Shaw said. "We didn't take a deeper discount than we have seen with other national contracts.

"To ensure compliance, UnitedHealth has two strategies," he continued. "One strategy involved paying the enrollee directly and letting the out-of-network laboratory contact the enrollee for payment. The second one is to have some kind of financial sanction against the physician if the physician repeatedly sends a specimen to an out-of-network laboratory.

"During our negotiations, it was clear that UnitedHealth was interested in the laboratory data that JVHL could provide," observed Shaw. "Further, UnitedHealth recognized that adding JVHL to their laboratory network would result in a smooth transition. That's because most Michigan physicians currently use a JVHL laboratory for some part of their work that gets done in hospitals. Physicians are already familiar with our laboratories.

JVHL Uses Lab Data As Contract Leverage

JACK SHAW, EXECUTIVE DIRECTOR of Joint Venture Hospital Laboratories (JVHL), said his company won a five-year contract to provide laboratory services to UnitedHealth Group (UHC) in part because the 120 hospitals in the JVHL network have the data that UHC wants.

"If a commercial lab does a test for a physician's office, there is no way the result of that test can populate the hospital's electronic medical record," said Shaw. "That creates a hole in the data.

"In the meantime, the hospital lab is collecting all the data on inpatients, outpatients, those in the emergency room, and anywhere else," he explained. "When a managed care plan has an area of testing excluded from the electronic record, it costs them later.

"If a patient has a test done by a commercial lab and then presents in the emergency room, that same laboratories test has to be redone, simply because the previous test result was unavailable to the ER physician," Shaw explained.

"In contracting, price continues to be a primary issue," he added. "But data is second because having a complete set of data helps managed care plans to control costs."

Continuum Of Care

"We believe that hospital labs have a legitimate place in the outreach market," Shaw explained. "They provide value in the continuum of care, especially in these days of electronic medical records. If hospitals do the lab work, then they can provide continuity of data that's absent when commercial labs do the work. The fact that UnitedHealth was willing to contract with us supports that idea.

"There were two key ingredients to JVHL's new contract with UnitedHealth," he said. "First, we were willing to be competitive on price. That was attractive to UnitedHealth, which wants to reduce the cost of laboratory services wherever possible.

"Second, lab data reporting was also a key ingredient," Shaw added. "The growing emphasis on electronic patient information is consistent with the services that hospital laboratories provide. JVHL's hospital labs have the electronic data that payers want.

"This UHC contract with JVHL shows that there's an opportunity for hospital labs to gain market share if they want to compete in this market," Shaw said. "When UHC signed a single-source contract with LabCorp, many in the lab industry believed this contract would hurt local laboratories. That's not our view. We see this as an opportunity for JVHL member labs to expand their market share."

THE DARK REPORT observes that JVHL's contracting success with United Health shows that professionally managed hospital laboratory outreach programs can be attractive network providers to major payers. Also, it shows that hospital labs can provide a full set of lab test data that payers value. **TDR**

Contact Jack Shaw at 313-271-3692 x211 or jshaw@jvhl.org

Mayo Rolls Out RFID After Only 5-Month Test

41 operating suites will get RFID tags and scanners to improve patient safety, productivity.

CEO SUMMARY: After running a test project for less than six months, The Mayo Clinic is preparing to expand its use of RFID tags and scanners, focusing on endoscopy specimens. By expanding the use of RFID, Mayo will implement the technology in 41 operating rooms, providing care to more than 20,000 surgical patients this year. Once a surgical nurse enters the patient and specimen data in the OR, the lab is able to use that same data to populate the LIS, thus reducing errors.

FOLLOWING A SUCCESSFUL PILOT PROJECT THAT USED RFID (radio frequency identification) tags to track biopsy specimens from operating rooms to the pathology laboratory, **The Mayo Clinic** will expand its use of RFID to track laboratory specimens.

On January 3, 2007, The Mayo Clinic of Rochester, Minnesota, announced that it was preparing to deploy RFID tracking tags and scanners into 41 operating rooms (ORs) this year. As many as 20,000 endoscopy and colon procedures are done annually in these operating rooms.

Technology Breakthrough

Mayo's use of RFID to track lab specimens is an important technology breakthrough for the laboratory industry. RFID has the potential to improve laboratory operations and work processes in many ways. Mayo's success using RFID is likely to inspire other hospitals, healthcare systems, and laboratories to follow suit.

The Mayo project is also significant because Mayo conducted a five-month pilot program in 2006, using RFID tags and scanners manufactured by **3M Company**. During the pilot program, which involved five operating rooms and one laboratory, Mayo tracked 1,800 tissue samples from the surgery suites to the lab. The benefits identified by Mayo during this pilot program were increased productivity, reduced errors, and improved patient safety.

"The results of the pilot were compelling enough to both of us that we saw an interest to expand it and to continue to quantify those results," said Bob Anderson, Director of Track and Trace Solutions for 3M, in St. Paul, Minnesota. "We believe Mayo is interested to expand beyond the endoscopy practice, but it will depend on the specific results from a broader deployment of RFID in endoscopy."

"I definitely am carrying the banner to have this technology pushed through other areas of the clinic," commented Schuyler Sanderson, M.D., Assistant Professor of Laboratory Medicine and Pathology, who oversaw 3M's pilot program and spoke to the Minneapolis *Star-Tribune*. "For breast, prostate, and skin biopsies, this would be a very good system to track those samples as well.

During the pilot project, nurses at Mayo would place patient's tissue samples in a container with an RFID label. They would then enter the RFID tag number, patient data, and specimen information into Mayo's surgical database.

Minimizing Data Entry Errors

The RFID system saves staff time, because staff can confirm quickly that the lab has the proper number of samples for each patient, Sanderson explained. In this way, RFID tracking reduces paperwork, thus freeing nurses to provide more patient care. What's more, RFID can minimize data entry errors because lab personnel do not need to re-enter patient data when the samples arrive at the lab. A swipe across the RFID scanner instantly captures the data, Sanderson said.

"Clearly, RFID has significant benefits in tracking specimens collected in endoscopy and surgical suites," Mike Hansberry, 3M's Senior Business Development Manager, told THE DARK REPORT. "Since nurses are very busy taking care of the patient, specimens that are collected may not be labeled until the end of the procedure, after the patient is wheeled out.

Pneumatic Tube System

"Many times, the laboratory is in another building from the endoscopy suite," Hansberry said. "Pneumatic tubes transport endoscopy specimens to the tube room where are they are logged before they are sent to the lab. At each step, the database has the information on the number of specimens coming to the laboratory from each patient. At the lab, the specimens are logged in and validated against the information in the database.

"When the pneumatic tube arrives at the laboratory, the lab can bring up all the information on that patient and associated specimens in the database simply by using the RFID reader in the lab," continued Hansberry. "Then, lab personnel can use the patient and specimen information to populate the laboratory information system. These steps eliminate potential transcription errors.

"The most significant benefit from RFID for healthcare organizations is in the area of patient care and patient safety," Hansberry commented. "This factor is paramount to healthcare providers.

"Operational efficiencies are another source of benefits," added Hansberry. "RFID allows the laboratory to see the number and type of specimens that are coming their way, thus allowing them to manage workload more efficiently. Further, the need to manually input information is reduced, which further improves data integrity."

Wider Use of RFID Expected

THE DARK REPORT notes that Mayo Clinic's decision to expand use of RFID was based on actual experience in using this technology. Its willingness to expand use of RFID tags and scanners in a stepwise fashion is a sign that it was impressed with the ability of RFID to improve patient safety, increase productivity, and reduce data entry errors.

In recent years, the cost of RFID technology has been a major barrier that's inhibited use of RFID in many healthcare settings, including clinical laboratories. When used in healthcare, RFID tags must often be engineered to handle a significant amount of data, and that can increase the price of the individual RFID tags. However, advances in design and manufacturing allow companies to more cheaply produce RFID tags. TDR

Contact Colleen Harris at 3M, 651-733-1566; Schuyler Sanderson, M.D., Mayo Clinic at sanderson.schuyler@mayo.edu.

Sanderson To Speak on RFID

Schuyler Sanderson, M.D., will speak about how Mayo Clinic's pathology department is using RFID at the upcoming* Executive War College *in Miami on May 10-11, 2007. Details at www.darkreport.com

Pathologist Says Labs Need Read-Write RFID

Developing read-write RFID chips would help labs reduce error rates and boost productivity

CEO SUMMARY: The current state of the art for radio frequency identification (RFID) tags employs read-only chips. Labs can use these RFID chips today to track specimens at intake. But pathologist William Neeley, M.D., is most enthusiastic about the potential of read-write RFID chips, which could help cut errors, improve patient safety, and boost staff productivity across all areas of laboratory operations.

RADIO FREQUENCY IDENTIFICATION (RFID) holds the promise of simultaneously boosting productivity and eliminating errors in clinical and pathology laboratories.

Along with **Mayo Clinic's** RFID project *(see pages 9-10)*, **Detroit Medical Center (DMC) University Laboratories** in Detroit, Michigan, and **ProPath** of Dallas, Texas, are taking active steps to introduce RFID into their lab operations. All three laboratories will be at the *Executive War College* in Miami, Florida, on May 10-11 and will discuss RFID in their presentations.

First-Mover Laboratory

One pathologist who is enthusiastic about the short-term potential of RFID in clinical laboratories is William Neeley, M.D., Medical Director at the Detroit Medical Center, University Laboratories. While many technologies offer such promise, Neeley believes there's no doubt about the significant potential for radio frequency identification. But there's one big hitch, he said. Currently, RFID uses read-only chips. When appropriate read-write chips are available for RFID, the benefits for laboratories will be obvious and dramatic, he said.

"A read-write RFID chip means that information can be added to the chip at different stations and at different times," noted Neeley. "By using read-write RFID chips, doctors' offices, hospitals, laboratories, and other providers could track specimens from collection to pathology reports. Not only would these chips help eliminate common data-entry errors, but they would allow providers and labs to locate lost specimens easily and quickly.

"Read-write RFID is a real solution for real problems," Neeley explained. "It will produce exceptional results. For labs, RFID's significant potential resides in read-write chips. Current technology has not yet delivered RFID chips that are small, inexpensive, highly reliable, and with adequate read-write memory. RFID is still in its infancy. As the technology advances, RFID will help clinical laboratories solve many problems they tolerate now, but want to eliminate.

"The laboratories here at Detroit Medical Center process 10 million billable tests annually for seven different hospitals," observed Neeley. "Our outreach program represents 50% of that volume. Because of our extensive in-house

capabilities, we send out only 0.8% of our work to outside laboratories. In any hospital with a broad test menu and high volumes of specimens, RFID has great potential. Our plan for RFID is different from what most laboratory administrators envision. We want to introduce RFID into the pre-pre-analytical step—at the point where the specimen is drawn.

Solving Problems

"So, for example, when a courier returns from a doctor's office, our staff wants to know exactly what tubes the courier has collected," he explained. "We sort through the tubes and match them to the doctors' orders. What if the courier is supposed to have 200 tubes and yet has only 199? What if our processing staff goes through those tubes and finds an order for a complete blood count but there's no lavender-top tube? What if we find a lavender-top tube but no order?

"If the doctor had the proper system, his staff could print and affix a bar coded label with an embedded RFID chip to the specimen," Neeley said. "The bar coded RFID chip would contain all the patient information, the stopper color, and the test order. It also would safeguard the patient's privacy.

"With one pass of the RFID scanner, the courier could collect and read a complete record of all the information from all the tubes in seconds, without having to handle each tube for a visual laser scan," he added. "The software would know that a CBC was ordered and match the required CBC test to the appropriate lavender tube.

"If something is missing, the system will tell the courier immediately," Neeley added. "While at the doctor's office, the courier could use a portable printer and print a message to the office staff to inform the doctor that a CBC test was ordered, but the tube for that patient's test was missing. In this way, RFID would allow the lab to identify and solve this problem while the courier was still in the doctor's office. And it wouldn't require the courier to have additional training.

"Contrast that with the current system, where the bag comes to the lab in the evening and our people match the tubes to each requisition," he said. "If a tube is missing or an order is missing, they fill out a problem card. The next morning, someone on our staff calls the doctor's office. The current process needlessly wastes manpower and frustrates the lab's clients.

"RFID can also make it easier and faster to store and retrieve specimens," continued Neeley. "When storing samples in a refrigerator, it's easy to accidentally put a sample in the wrong bin. By using an RFID antenna, it is possible to find one or more missing samples among 30,000 tubes in just seconds!"

THE DARK REPORT was the first to alert the laboratory industry about the potential of RFID technology to solve long-standing problems in laboratory operations. In 2004, we predicted that labs would need both bar code and RFID systems. *(See TDR, December 13, 2004).* In 2005, we were first to describe the use of RFID by the blood bank at **Georgetown University Medical Center in Washington, DC.** *(See TDR, February 14, 2005.)*

Almost Ready For Lab Use

THE DARK REPORT believes Neeley's enthusiasm for RFID is justified. Simply adopting RFID to the uses Neeley foresees will have a significant effect on productivity and on patient safety. RFID has unquestioned potential to help cut errors sharply in the collection, labeling, transport, and processing of specimens when they arrive in the lab. It is the same for tracking specimens through the laboratory and into storage. As Neeley points, out, however, further technology advances are needed before RFID will be ready for prime time in laboratory operations. TDR

Contact William Neeley, M.D., 313-966-0005 or wneeley@dmc.org.

Paperless at Bayou Path Generates Big Dividends

Implementing a document management system unlocks major gains in client service, cost savings

CEO SUMMARY: Over the past year, Bayou Pathology began eliminating its paper document records. Not only did efficiency improve dramatically, but the staff was able to deliver more professional service. Bayou's document management system started paying for itself immediately and both pathologists and staff love how the paperless system contributes to greater accuracy and increased productivity.

AS HEALTHCARE ADOPTS ELECTRONIC MEDICAL RECORD (EMR) systems, anatomic pathology groups are pursuing strategies that reduce or eliminate paper.

At **Bayou Pathology**, in West Monroe, Louisiana, going paperless meant implementing a document management system last year. Since that time, the five-physician pathology practice stopped wasting time looking for patients' records. "In less than a year, we have already seen a significant return on our investment," said Rubette Hebert, Business Office Manager for Bayou Pathology. "Now we can consider other uses for our records room.

"We can pull whatever document we need in just a matter of seconds," Hebert said. "We get all the information without ever leaving the desk. That's true whether we're talking to a patient, an insurance company, or another doctor's office. It's true if there's a question about a charge or a requisition, or about what the doctor actually ordered, or what the insurance actually paid or denied. We can answer any of these questions quickly and easily.

"Before we installed the DocFinity system from **Optical Image Technology**, we had to take a message, go look for the record or explanation of benefits, and then return the phone call," she explained. "If a paper record was lost, it would require significant effort to find the record needed to answer the question."

Increasing Efficiency

DocFinity is a document management system specifically designed to allow hospitals and physicians to make all aspects of their business paperless. Providers use it to create, store, manage, and retrieve patient information electronically. It will handle claims forms, business documents, and other paperwork in this way. The document manager links to the practice management system, so that all documents are associated with claims and other billing information. **Companion Technologies** of Columbia, South Carolina, offered the DocFinity product to Bayou Pathology.

"We don't have an electronic medical record system here at Bayou Pathology," said Hebert. "As a pathology practice, we don't keep individual patient charts, but this system has allowed us to manage the documents we are required to keep more

efficiently. This system has made us more productive even as it makes us appear more professional to hospital and physician clients."

Bayou's five pathologists and staff of 20 serve 15 mostly rural hospitals in northeast Louisiana and southern Arkansas. "A couple of these hospitals are fairly large," observed Hebert. "Most are outlying rural hospitals, where our pathologists serve as the medical directors for these facilities. We also serve about 300 physicians' offices in the same region.

Fast And Accurate Answers

"Each day, our office handles many phone calls, questions, and requests," she explained. "This system enables us to research these questions and provide accurate and quick answers. In that way, this system has helped to improve our relationships with our clients.

"One major benefit with this system is that it is rapidly paying for itself in the amount of time we save, not to mention the frustration we avoid by never losing documents," added Hebert. "With our old paper records, no matter how carefully they were filed, things got lost or were taken from the files and not returned.

"The electronic document management system gives us a uniform way to file all documents and information," she added. "To find an EOB (explanation of benefits), for example, all that's needed is the claim number. The time savings and increase in productivity over the past year have been remarkable. Our pathologists' philosophy is, no matter the cost, it is crucial to provide our staff with the necessary tools to do the job best. Document imaging certainly falls into this category.

"As configured, our new system cost about $25,000," she noted. "Ongoing maintenance runs about $5,000 per year. We have yet to do precise costing of the total overall return on investment that the system has generated. But the system more than pays for itself in time and labor savings.

"When we got this system, we scanned records beginning in 2005," she stated "If a record before 2005 is needed, someone will have go look through the files in the store room. In fact, our next step is likely to move the old paper records off site, since we need to keep some records for seven years. That will free up our 500 square foot storage room.

"In daily use, we decided to keep the previous two months of records here in the office," Hebert added. "We maintain just one filing cabinet and rotate two months of data before we destroy it. When I balance the accounts receivables (AR) each morning, I pull up all the batches in DocFinity to make sure every batch has been scanned and indexed," she said. "Then, I file the paper copies and shred the paper that we no longer need.

"The medical secretaries use DocFinity to file and track reports that come back from reference laboratories," Hebert said. "Doing so makes that process paperless as well."

THE DARK REPORT observes that, as pathology groups find ways to eliminate paper records, they become more efficient and responsive to hospital and physician clients. They also become more sophisticated in their use of technology, supporting further integration of healthcare informatics in the community.

Pathologists' Use of EMRs

Bayou Pathology's success at going paperless also illustrates a major difference between anatomic pathology group practices and physicians who regularly see patients in their offices. The electronic record needs of pathologists are much less complex than those of other physicians. For that reason, the document management system that Bayou Pathology adopted costs less than a full EMR system, but supports substantial improvements in productivity while also triggering significant cost savings. TDR

Contact Rubette Hebert at 318-323-1834 or rubette@bayoupathology.com.

Pay for Performance Update

CMS Gets Positive Results from Hospital P4P Demo

Findings from CMS' demonstration project mean pay for performance programs likely to spread

HOSPITALS IN THE FEDERAL PAY FOR performance demonstration project showed significant improvement in delivering quality in five clinical areas, according to a new report from the **Centers for Medicare & Medicaid Services** (CMS).

CMS said the second-year results from its Premier Hospital Quality Improvement Demonstration project means that 115 top-performing hospitals will earn $8.7 million in quality payments this year.

"The Premier hospital demonstration is showing that even limited additional payments, focused on supporting evidence-based quality measures, can drive across-the-board improvements in quality, fewer complications, and reduced costs," said CMS Acting Administrator Leslie V. Norwalk, Esq.

The Premier project involves more than 250 hospitals. Participating hospitals report process and outcome measures based on 30 quality indicators in five clinical areas. Those areas are acute myocardial infarction (AMI), heart failure, coronary artery bypass graft (CABG), pneumonia, and hip and knee replacement. Premier analyzes and validates the data for CMS.

CMS pays financial incentives for the top 20% of high scoring hospitals in each clinical area. The top 10% of hospitals get a 2% incentive payment for patients in each clinical area. Hospitals in the second decile receive a 1% incentive payment. For the second straight year, **Hackensack University Medical Center** in Hackensack, New Jersey, was a top performer in all five areas, CMS said. The hospital earned $744,000 for its efforts.

Charleston Area Medical Center (CAMC) in Charleston, West Virginia, got the second highest incentive award, $701,000, for achieving top performance in four clinical areas. CAMC also got the highest single award, $432,901, in one clinical area for providing high quality care to 883 Medicare patients who had a CABG. The second largest single award of $250,775 went to the **Bone and Joint Hospital** in Oklahoma City, Oklahoma.

Launched in October 2003, the project is part of an overall shift in how Medicare pays for care. Payments are based on value, not volume. Premier and Medicare are discussing extending the experiment, but Congress has asked Medicare to consider developing a new payment system that would emphasize rewarding the best care, *The New York Times* reported.

A payment system based on delivering quality would be a fundamental change in how healthcare is delivered. For laboratories and anatomic pathology groups, pay for performance will mean a shift in emphasis to support improved patient outcomes, both in hospitals and physicians' offices. TDR

CDC Seeks To Identify Best Laboratory Practices

➤Two workgroups to formulate recommendations that could affect P4P and proficiency testing

➤➤CEO SUMMARY: To advance the goal of enhancing the practice of laboratory medicine, the CDC has organized two teams of laboratory experts. They will study best practices and proficiency testing in medical labs nationwide. Such approaches as lab standards, voluntary reporting of adverse events, and adaptations of Six Sigma and Lean could help improve the quality of clinical laboratory testing. CDC aims to issue reports by September.

Over the next nine months, the federal **Centers for Disease Control and Prevention** (CDC) in Atlanta will undertake a project to define and identify best practices in laboratory medicine. The goal of the project is to enhance the practice of laboratory medicine by identifying ways to improve testing and services.

THE DARK REPORT believes that the CDC's effort bears watching because it could result in the development of new approaches to quality for laboratories. Also, the program could be a step toward introducing pay for performance programs in laboratory medicine.

➤A Three-Step Process

The first steps in the project involve having a team of lab experts from across the country develop a process to define, identify, categorize, and evaluate best practices and policies in laboratory medicine. The second step is to evaluate the effectiveness of proficiency testing (PT) programs in the United States to meet quality improvement, educational, and regulatory goals for clinical laboratories. In the third step, the CDC will produce a report describing the current state of the field of laboratory medicine.

"Laboratory professionals and other stakeholders have expended considerable effort to provide safe and effective laboratory medicine services, but clinical laboratories share many of the same vulnerabilities that affect the overall health care system," said Joe Boone, Ph.D, Associate Director for Science in CDC's Division of Laboratory Systems.

"Medical labs already meet minimum quality requirements for laboratory testing and for the manufacture of safe and efficacious reagents and medical equipment in clinical laboratories," observed Boone. "But nonregulatory approaches such as lab standards, participation in quality improvement programs, voluntary reporting of adverse events, and adaptation of methods such as Six Sigma and Lean have been used successfully in other fields and have improved the quality of clinical laboratory testing."

The CDC created two teams to pursue this project. One team is the Workgroup on Process for Evaluating Best Practices in Laboratory Medicine. The other team is the Workgroup on Proficiency Testing.

Pay for Performance

Lee H. Hilborne, M.D., MPH, is a member of the workgroup that is developing a process to identify and evaluate best practices in lab medicine. A Professor of Pathology and Laboratory Medicine at the **David Geffen School of Medicine at UCLA**, Hilborne is President-Elect of the **American Society for Clinical Pathology** and he also is Deputy Director for Global Health at the **RAND Corporation**.

"The CDC's efforts do not focus on increased regulation," Hilborne said in an interview with THE DARK REPORT. "CDC is a public health entity, not a regulatory body. As evidence continues to emerge regarding strategies to optimize patient safety and quality, responsible organizations will incorporate these strategies into their operations as internal process improvement projects.

"There is a growing national movement to expand pay for performance (P4P) programs. CDC, like other leaders in the field, recognizes that these P4P efforts must be based on best practices," Hilborne added. "Most best practices are process of care measures. Research is beginning to demonstrate practices where there is a clear and strong link between following the right processes and achieving good outcomes (which is ultimately what patients and providers want).

"If one wants to establish P4P initiatives, then they should demonstrate value," Hilborne explained. "There's no question that P4P will happen. The **Centers for Medicare & Medicaid Services has** already called for P4P for all disciplines. Defining appropriate P4P for laboratory medicine is more challenging than for many other specialties, but it is going to happen. The workgroup's efforts should make a significant contribution toward defining the best evidence-based practices that the entire laboratory medicine community can accept.

"There are all kinds of processes that laboratories nationwide are using and once they're reported widely, hopefully organizations would use them as internal process improvement projects," Hilborne said.

"What's more, the CDC understands that all P4P efforts will need to be based on best practices," Hilborne added. "My guess is that if you have a P4P effort and if you follow the right processes, you will produce good outcomes. That's what research shows.

"If, in fact, you wanted to put in a P4P initiative, you will want it to be of value," Hilborne explained.

Findings Reported

The CDC has contracted with the **Battelle Memorial Institute** in Columbus, Ohio, to manage the project. Battelle officials will disseminate the workgroups' findings to organizations and individual lab practitioners. It also will gather suggestions and comments from lab practitioners. One challenge the workgroups face is developing a way to analyze best practices.

"Everyone involved with the endeavor recognizes that identifying and analyzing best practices are challenging tasks," said Robert Black, a Senior Health Research Scientist with Battelle who is working with the CDC on the project. "But the objective is to begin nudging the field in the direction of evidence-based practice. Eventually that may mean using techniques that are analogous to clinical or community trials of

laboratory practices to identify definitive evidence of the most effective practices. The ultimate goal of healthcare is to provide quality outcomes for patients and improve the efficiency of the whole system while also avoiding errors.

Goals For Lab Medicine

"Currently, the field of laboratory medicine appears to be quite a ways from being able to do that," Black added. "The goal is start with the possible and work toward the desirable.

"This project is the continuation of the CDC's efforts at promoting quality and encouraging collaboration among the various stakeholders in laboratory medicine," Black explained. "The CDC has said it is interested in an approach that involves collaboration among the many stakeholders.

"We are keenly aware of the need to provide an opportunity for laboratory professionals to comment on the work as the workgroups proceed," Black added. "We encourage communication among the workgroups and the various stakeholders. We will seek comments and ask stakeholders to review early work products and make suggestions."

THE DARK REPORT observes that this new CDC initiative in laboratory medicine is designed to support "raising the bar" in the quality of laboratory testing and services delivered by laboratories in the United States. There is recognition by the workgroups that their findings are likely to influence laboratory pay for performance initiatives and proficiency testing programs in this country. Since the project involves identifying best practices, it is likely to have significant value for laboratorians. TDR

Contact Julie Taylor at CDC at 404-718-1013 or jtaylor1@cdc.gov or Robert Black 770-451-0882 x. 14 or blackr@battelle.org.

CDC Plans September Report on Results

BY SEPTEMBER, THE FEDERAL CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) will issue a report on the key factors affecting quality in laboratory medicine.

The report will discuss current standards for laboratory testing and services; regulatory oversight (including the Clinical Laboratory Improvement Amendments (CLIA); the effect of accreditation; reimbursement policies; performance measurement; quality improvement; and evidence-based decision making.

The report is one of three phases of the project. Another phase involves identifying best practices. CDC has recruited a workgroup that includes experts in health services research, performance measurement, clinical practice, and lab management. The workgroups will develop a process to identify, categorize, and evaluate best practices, but will not formulate best practices.

The third phase involves the evaluation of proficiency testing (PT). A workgroup representing providers of PT, PT material suppliers, users of PT, and accrediting organizations will develop recommendations for assessing PT. The workgroup will want to know if PT helps improve the quality of laboratory testing, educates laboratory medicine practitioners, and meets CLIA's regulatory goals.

CDC envisions the workgroup's deliberations as the beginning of a process that will enhance the effectiveness of proficiency testing programs for medical labs in the United States.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

To make its laboratory test results available to physicians via cellular telepones and wireless PDAs, **Spectrum Laboratory Network** of Greensboro, North Carolina, will use the MercuryMD service of **Thompson Healthcare**. Spectrum sales reps will install MercuryMD on the smartphones and/or PDAs of client physicians. This service allows physicians in Spectrum's affiliated network of hospitals in North Carolina and Tennessee to access "test results and all laboratory data relevant to a given patient via smartphone or PDA, regardless of location."

MORE ON: Wireless Access

Spectrum's office-based client physicians in a five-state area will also be able to use the MercuryMD service to access their lab test data. In recent years, Spectrum Laboratory Network has aggressively deployed sophisticated informatics technology to both harvest operational gains and differentiate itself in the marketplace from competing laboratories.

SONIC HEALTHCARE PURCHASES MINORITY INTEREST IN CPL

In recent weeks, **Sonic Healthcare Ltd**, of Sydney, Australia, announced it was purchasing the minority interest—approximately 18%—that it did not own in **Clinical Pathology Labor-atories, Inc.** (CPL) of Austin, Texas. The primary minority shareholders are CPL Chairman Robert Connor, M.D., and COO David Schultz. Sonic disclosed that it will pay $82.7 million for the 18% of CPL held by minority shareholders. Payment will be 50% in cash and 50% in the form of Sonic Healthcare stock, with the stock valued at a 17% discount to current share prices.

ADD TO: Sonic Healthcare

Sonic Healthcare is rapidly developing its laboratory testing business in the United States. Since acquiring CPL in 2005, it has purchased **Cognescenti Health Insitute, Inc.** in Orlando, Florida, and Nashville, Tennessee-based **American Esoteric Laboratories, Inc.** *(See TDRs, September 12, 2005, September 4, 2006, and December 18, 2006).* It is known that Sonic Healthcare is in active acquisition negotiations with several regional laboratory companies. By purchasing the remaining minority interest in CPL, Sonic may be establishing a new financial foundation for its business holdings in the United States.

TRANSITIONS

- Rick D. Ferguson is launching a new laboratory company in Southern California. **Women's Diagnostics, Inc.**, will operate a laboratory facility in Brea, California, and will focus on serving the needs of women's health clinics and ob-gyns. Ferguson was the founder and CEO of **FNA Clinics of America, Inc.**, which was purchased by Unilab, Inc., in January 2002. (*See TDR, January 28, 2002.*)
- At **Fairview Health** in Minneapolis, Minnesota, the new President of Laboratory Services will be Priscilla R. Cherry. She was formerly Director of Laboratory Consulting at **Premier, Inc.**, in Charlotte, North Carolina.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 19, 2007.

Preview #2

Executive War College

May 10-11, 2007 • Intercontinental Hotel • Miami

Effective Ways for Pathology Groups to Counter TC/PC Arrangements

Urology, gastroenterology, and dermatology groups are taking active steps to build their own anatomic pathology laboratories. In other cases, smaller specialty groups are negotiating arrangements that involve splitting the technical component (TC) and professional component (PC) with local pathologists. Get the inside scoop on what has been called the most financially-destructive trend to hit the anatomic pathology profession in two decades. Joe Plandowski is actively involved in working with both pathologists and specialist physicians in these "TC/PC" arrangements. Gain practical knowledge on how to effectively counter the worst of these proposals while maximizing your groups' ability to retain access to specimens referred by specialist physicians.

For program details, visit darkreport.com

UPCOMING...

- ***Just-In-Time Anatomic Pathology: How a Major Academic Hospital Delivers Same-Day Pathology Reports to Referring Clinicians.***
- ***Employer-Owned and Operated Medical Clinics: New Opportunity for Laboratories.***
- ***Frontiers in Laboratory Medicine Meeting in England Uncovers Powerful New Innovations.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE New Service!

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

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends