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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Boost for Consumer Choice in Healthcare

OVERLOOKED BY MOST LAB EXECUTIVES AND PATHOLOGISTS was a ruling made last month by the Internal Revenue Service (IRS). It was a significant ruling, but neither the media nor many people in the United States understood its significance. As a result, this ruling got little news coverage.

But for the laboratory industry and the entire healthcare system, this IRS ruling is a profound development. On June 26, the IRS ruled that money provided by employers for employees' out-of-pocket medical expenses will *not* be subject to tax. Moreover, it also ruled that the employee can roll over unspent funds from year-to-year and retain these monies if he/she switches jobs or retires. The IRS term for these programs is "Health Reimbursement Arrangements" (HRA). In making these decisions, the IRS is giving HRAs equal treatment with existing employer-sponsored health benefit plans.

For lab directors and pathologists concerned about the corrosive effects that irrational Medicare and Medicaid policies are having on the private healthcare sector as well as the ever-looming threat of a nationalized health system, this IRS ruling is a major and positive development. It allows employers and insurers to develop health benefit plans which emphasize consumer choice in healthcare decisions. One such type of health plan is called "defined contributions." It gives the employee, say, $2,000 to pay for 100% of the first care provided in a year. The employee would then pay, out of pocket, the next $1,000 of health expenses, after which the company-provided health policy would pay all health expenses for the year exceeding $3,000. *(See TDR, January 28, 2002.)*

Defined contribution-types of health plans encourage better consumer choices when spending healthcare dollars. After all, any of that first $2,000 unspent during the year can be rolled into the next year. Some HRAs, such as Medical Savings Account (MSA) plans, permit the employee to roll unspent monies into retirement accounts like IRAs.

Lab executives and pathologists should welcome this IRS decision. Anything that encourages consumer choice and takes arbitrary decisions affecting millions of patients out of the hands of Medicare bureaucrats or HMO officials has to be good for the clinical laboratory industry and the pathology profession. After all, a consumer-driven marketplace evolves in a much more rational way than a government-dictated marketplace. TDR

Two New Public Labs Launch Operations in FL

VitalLabs, Inc. to offer general lab testing; NeoGenomics, Inc. to serve OB/Gyn specialty

CEO SUMMARY: In 49 states, independent commercial laboratory companies are disappearing. But that's not the case in Florida. In recent months, two new public laboratory companies completed organizational steps and now offer diagnostic testing services. Both companies are starting small, but each is optimistic that the healthcare market will support steady growth in specimen volumes and revenues.

BOOM TIMES FOR PUBLIC LAB companies in recent years seem to have encouraged two new start-ups. Both laboratory companies are in Florida, just miles from each other.

One is called **VitalLabs, Inc.**, located in Clearwater, Florida. It is a general commercial laboratory that provides routine testing to physicians' offices in its service area. VitalLabs' stock trades on the NASD OTC Bulletin Board under the symbol VILB.OB.

The other new laboratory company is **NeoGenomics, Inc.**, based in Naples, Florida. This lab is organized to offer routine cytogenetics testing and high-end molecular genetics services. It is also building a bank of DNA and RNA samples. On the NASD OTC Bulletin Board, its shares trade as NOGN.

VitalLabs is a company which entered the lab business by purchasing **Med Tech Labs, Inc.**, based in Clearwater, then merging it into a public shell company. The purchase of Med Tech Labs by VitalLabs was closed on April 5, 2002.

During 2001, Med Tech Labs reported unaudited revenues of $10.9 million. Med Tech Labs was originally founded in 1957 and since its founding has competed for physicians' office business in 13 counties located along the west coast of Florida.

Officials of VitalLabs tell THE DARK REPORT that the company intends to grow by acquisition. It already has a contract to acquire one small lab company in Florida and is awaiting financing to complete the

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purchase. It will also build revenues and specimen volume through traditional methods of clinical laboratory sales and marketing.

VitalLab's central laboratory facility is 20,000 square feet and is located in Clearwater. It operates 20 patient service centers and has 133 full-time equivalent employees.

VitalLabs' Executive Team

Chairman and CEO of VitalLabs is Edwin B. Salmon. Much of his professional experience is in the fields of banking, finance, and computers. President of VitalLabs is Patrick Barmore, who has 25 years experience in clinical laboratories. He arrived at Med Tech Labs in 1999, at a time when the independent laboratory company was dealing with billing problems and issues related to long term care clients, a business the lab company exited in 2001.

VitalLabs has ambitious growth plans and believes there are many opportunities to acquire clinical labs in Florida. Last month, Salmon told the *Tampa Bay Business Journal* that "our objective is, by the end of next year, to be as close to $100 million as we can... At some point we would hope to get large enough so that one of the big conglomerates—like **LabCorp** or **Quest**—would want to acquire us."

Different Market Segments

The testing segment that underpins the business strategy at VitalLabs is routine clinical testing of specimens referred by physicians' offices. NeoGenomics has a different strategy. It is offering higher value lab tests, centered around genetic and molecular testing.

NeoGenomics was started by Michael T. Dent, M.D., a board-certified OB/Gyn who had earlier, in 1996, founded the **Naples Women's Center**. NeoGenomics was incorporated in June 2001. In November 2001, it was acquired by a public shell corporation and the enterprise reorganized itself under the NeoGenomics name.

This spring NeoGenomics opened a 2,200 square foot laboratory in Naples. CLIA certification was obtained on April 30, 2002. The laboratory is equipped to perform clinical cytogenetics, molecular, and flow cytometry. It is marketing its test services both within Florida and nationally. NeoGenomics' first clients were physician groups in the Naples area.

Dr. Dent is the Chairman, President, and CEO of NeoGenomics. The Clinical Cytogeneticist is Navnit Mitter, Ph.D., who has consulted or been employed by **DIANON Systems**, **IMPATH**, and **AmeriPath** in recent years. The Laboratory Manager is Debra L. Angel.

Unique Business Strategy

One unique aspect of NeoGenomics' business strategy is its planned activities in tisssue banking and research. Dr. Dent's OB/Gyn practice is a source of blood and tissue specimens for NeoGenomics. The company wants to conduct research and develop gene-based technology that would aid in the early detection and treatment of certain women's diseases and cancers.

It is an intriguing partnership between an OB/GYN practice and a clinical laboratory company. As a result of collecting tissue and specimens from Dr. Dent's practice, which numbers 8,000 patients, NeoGenomics believes it can "create what will be one of the largest and most comprehensive databases of female and neonatal phenotypic and genetic information in existence, spanning generations and allowing NeoGenomics to analyze and compare genetic alterations in individuals and within families."

One particularly interesting aspect about NeoGenomics is that its en-

At-A-Glance

VitalLabs

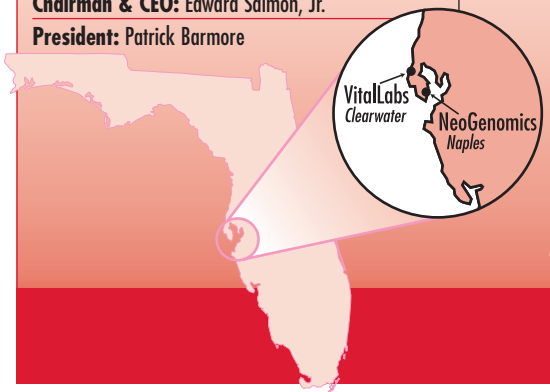
www.vitallabsinc.com

Target Market: routine clinical testing
Created: Med Tech Labs acquired by VitalLabs on April 5, 2002
Main Lab: Clearwater, FL
Size: 20,000 s.f.
Patient Service Centers: 20
FTEs: 133
Sales and Service: 15 FTEs
2002 Revenues: $12 million est.
Chairman & CEO: Edward Salmon, Jr.
President: Patrick Barmore

NeoGenomics, Inc.

www.neogenomics.org

Target Market: cytogenetics, molecular, flow cytometry testing, tissue banking
Created: 2002
Main Lab: Naples, FL
Size: 2,200 s.f.
CLIA Certified: April 30, 2002
Chairman, President, CEO: Michael T. Dent, M.D.
Clinical Cytogeneticist: Navnit Mitter, Ph.D.
Laboratory Manager: Debra L. Angel



Seldom does the lab industry see the birth of a new public lab company, so having two new public laboratory companies start up at almost the same time is a notable event, not to mention the coincidence that they are both located on Florida's west coast.

trepreneural vision did not involve a pathologist. Rather, it was an OB/Gyn who recognized that colleagues in his specialty had a real need for specialized laboratory testing that went beyond the offerings of labs serving his area. Further, this OB/Gyn was willing to shoulder the financial risk to translate his vision into reality.

As such, NeoGenomics represents an example of how the pathology profession, traditionally reactive and not proactive, is allowing "outsiders" to take a lead role in shaping its future. Certainly in a number of public laboratory companies, it has been non-pathologists who recognized opportunities and took the risks required to build thriving laboratory businesses.

These newest additions to the laboratory industry automatically become bellwethers worth studying. As **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have come to dominate the national marketplace, many business-minded laboratorians question whether new lab companies can enter the marketplace and successfully compete.

VitalLabs and NeoGenomics, although pursuing different segments of the laboratory testing marketplace, must also deal with meager reimbursement and the barriers to patient access so common with current managed care contracting policies. Both lab companies have considerable challenges to overcome on their road to success. TDR

Specialty Progresses With CA Lab Regulators

Besieged laboratory company turns feisty in executing its turnaround strategies

CEO SUMMARY: Earlier this month California laboratory regulators found Specialty Laboratories, Inc. to be "in substantial compliance with California clinical laboratory law." This is an important milestone in restoring the lab company to full compliance with both state and federal laboratory regulations. Meanwhile, at the CLMA convention in New Orleans, Specialty Labs mounted a major educational effort.

IT WAS A BIG WIN for beleaguered **Specialty Laboratories, Inc.**, which announced on July 3 that, following an inspection of the laboratory, California's **Department of Health Services** (DHS) had "found Specialty to be in substantial compliance with California clinical laboratory law."

This announcement indicates that Specialty Labs and lab regulators within DHS have agreed on a Plan of Correction (POC). Agreement with DHS is a significant milestone. Now that California lab regulators have deemed Specialty Labs to be again compliant, that would logically set up a similar review by federal lab regulators at the **Centers for Medicare and Medicaid** (CMS).

Review By Feds Is Next

That's because CMS relied on much of the DHS's findings of non-compliance in issuing its own set of sanctions, including revocation of Specialty Lab's CLIA-88 license, subject to a legal appeal which was filed. Because of the turmoil caused by the April 15th disclosure of the federal sanctions, it can be assumed that both Specialty Labs and federal regulators have plenty of motivation to expeditiously resolve these sanctions.

"Specialty Comes Out"

The timing of the July 3 announcement just missed the **Clinical Laboratory Management Association's** (CLMA) annual convention in New Orleans, which adjourned on June 29. But even without that important news, Specialty Laboratories served notice during the CLMA program that it will invest considerable resources to regain its standing as a major source of reference and esoteric testing.

Specialty Labs clearly came to CLMA with carefully-laid plans to address the issues and concerns of its clients. The public nature of the CLMA meeting put Specialty in full view of a wide cross-section of laboratory administrators.

The linchpin to Specialty Lab's public strategy to rebuild confidence in the company is the prominent role it is giving Douglas S. Harrington, M.D.,

its new Chairman, CEO, and Medical Director. At an evening event held for clients and special guests of Specialty Labs, Dr. Harrington earned high marks for his comments and commitment to the company's clients.

Evidence of Change

There is an interesting message in the fact that Specialty's executive team was able to prepare and execute this type of performance at CLMA. At a time when the company must devote considerable resources towards multiple—and highly stressful—management challenges, its ability to impress its client base in New Orleans may be the first visible evidence that, indeed, a different type of corporate culture is evolving within the company.

The challenges facing Specialty Lab's new executive team should not be underestimated. THE DARK REPORT has already observed that no public laboratory company has ever had to simultaneously: 1) work expeditiously to resolve a revocation of its CLIA-88 license and return to full compliance with both state and federal lab regulators; 2) deal with multiple shareholder class action lawsuits following the resulting decline in its stock price; 3) restructure lab operations due to ongoing revisions to the test menu, declining specimen volumes, and unexpected costs; and 4) operate under a suspension of Medicare and Medicaid payments even as new executives assume responsibilities during a time of high crisis. *(See TDR, June 24, 2002.)*

New Corporate Culture

To communicate the extensive changes in the way Specialty Labs will conduct business, new management's turnaround strategy is to use Dr. Harrington and his new executive team as the public face for this change. Under founder and former CEO James B. Peter, M.D., Ph.D., there was a distinct corporate culture. For all its good points, it was that corporate culture which led to the serious regulatory problems and the current difficulties at Specialty Laboratories. Thus, it is no surprise that Dr. Harrington is striving to establish a new corporate culture and a different public face for Specialty Laboratories.

Specialty Labs' Problems Cause Lawyers To Pile On

WHEN NEWS OF SPECIALTY LABORATORY'S regulatory woes caused its stock price to plummet, more than a few lawyers took notice.

During the past three months, at least seven law firms advertised the commencement of class action lawsuits against Specialty Laboratories. Several of these were simply efforts to attract disgruntled shareholders.

However, Specialty Lab's problems did attract the notice of one heavyweight law firm. **Milberg Weiss Bershad Haynes & Lerach** of San Diego, California filed their class action suit against the lab company on May 7, 2002.

Milberg Weiss has a well-deserved reputation for these types of class action lawsuits. Many corporations have paid it substantial amounts of money to settle allegations that they violated securities laws.

In fact, Milberg Weiss has already drawn blood from at least one laboratory company. When the stock price of **Laboratory Corporation of America** declined following its creation in 1995, Milberg Weiss filed a class action suit. As part of the settlement, LabCorp paid about $40 million.

Among the pending lawsuits, Specialty Laboratories' toughest legal opponent will be Milberg Weiss. At the least, if Specialty prevails, it will have paid a significant amount of money in legal fees to defend itself, not to mention the distractions such lawsuits cause to the executive team.

Even as the lab company awaits resolution of its negotiations with federal laboratory regulators, it has another hurdle to cross. On July 23, it will release its second quarter earnings on a conference call with analysts and others.

Early Warning To Analysts

To prepare the financial community, Specialty recently disclosed it expects to report a "significant net loss" for the quarter. It also plans to take a one-time charge of up to $3.8 million. It said revenue would be affected by a reduction in test volumes and because it was not billing for Medicare and Medicaid testing. Outsourcing certain tests was the source of additional costs during the quarter.

Any current concerns by the investment community would be reflected in Specialty Labs' stock price. However, through most of June and July it traded in the $7 to $8 range. One reason for this share price stability is that investors recognize the balance sheet strength of Specialty, which includes more than $70 million of cash and investments. It thus has ample capital to absorb losses and fund ongoing operations.

Changes In Test Volume

When Specialty Labs reports its second quarter financials, one important item will be the change in test volume. In the past, Specialty has reported this number as a percentage change from earlier financial periods.

Test volume will be affected primarily by two factors. One is the fact that Specialty reduced its test menu and referred certain lines of tests to other laboratories. The other is the impact of clients who decided, in light of many uncertainties, to redirect specimens to other sources.

In the three months since Specialty's regulatory sanctions were announced, there has been unease among many Specialty clients. Competing labs have used these events to aggressively court clients and it is known that plenty of new accounts have been opened.

But here is where the 80/20 rule may come into play. Once the state and federal sanctions were announced, Specialty Labs launched an intense effort to stay close to its largest clients and work with them through all the subsequent problems. Executives at the company represent that they have enjoyed great loyalty from these key accounts. Effectively, this could mean the 20% of their clients who generate 80% of the business have stayed loyal to Specialty.

If true, that means the many accounts opened by competing reference labs represent primarily the 80% of Specialty clients who generate just 20% of the business. It will take some months to better evaluate the economic value of those clients who did make a switch.

July May Be Pivotal

July may prove to be the pivotal month for Specialty Laboratories. It has the July 23 earnings release and another big lab convention when the AACC Annual Meeting convenes in Orlando on July 28 through August 1. Were it to have positive news about its federal sanctions by month's end, that would restore a degree of competitive strength.

Lab administrators and pathologists interested in the reference testing marketplace should carefully follow events over the next eight weeks. After three months of dealing with the consequences of its regulatory sanctions, Specialty Labs has accomplished three important objectives. First, it survived. Second, it was not acquired. And, three, it cleared one of two big regulatory hurdles. Combined with its rather fiesty attitude on display at CLMA, these are all signs that other chapters are yet to come in this saga. TDR

Lab Management Update

Two Major Hospital Systems First to Join Leapfrog Group

EXPERTS CONSIDER THE DECISION of two major hospital systems to join the **Leapfrog Group** to be a significant boost to the group's effort to improve patient safety.

HCA, Inc. of Nashville, Tennessee and **Promina Health System** of Atlanta are the first hospital systems to become members of the Leapfrog Group. Both organizations are large employers in their own right. HCA employs 168,000 people and Promina employs 13,000.

By joining the Leapfrog Group, both HCA and Promina sent a clear message to the hospital industry. Reduction of medical areas and measured improvement in the quality of healthcare are goals which must become part of every hospital's operating philosophy.

"We embraced Leapfrog's standards from the get-go and opened up a dialogue with them very early on," stated Robert Ryan, M.D., Chief Medical Officer of Promina. "It sends a strong message to our employees and patients that we mean business when it comes to quality and safety."

Spending Money On Quality

Both hospital systems have committed substantial resources to meeting the initial three safety standards specified by the Leapfrog Group. These include: 1) electronic prescription ordering capability; 2) board-certified intensivists in critical care departments; and 3) minimum volume requirements for certain high-risk medical procedures. Promina is spending $41 million to implement electronic ordering across its eight hospitals. HCA, with 200 hospitals, is working to implement electronic ordering, but still "has some issues" with the other two Leapfrog criteria.

New Management Methods

THE DARK REPORT was first to predict that the Leapfrog Group was the first major manifestation of an emerging trend. The nation's largest employers, who are also the nation's biggest purchasers of healthcare, are proactively working to push healthcare providers to adopt the same quality management principles which they use in their own business. *(See TDR, January 28, 2002.)*

Hospital laboratory administrators and pathologists tracking this trend will have a competitive advantage. There is much they can do to prepare their laboratory team for management methods which emphasize work processes that eliminate errors while improving quality and lowering costs.

One good "marker" for this unfolding trend are measurement systems introduced by third parties to evaluate the performance of hospitals, physicians, and other providers. The Leapfrog Group is only one example of such measurement efforts. Already there are at least five other credible Web sites that attempt to measure hospital quality, including *Hospitaliq.net, Qualitycounts.org, Healthgrades.com, Healthscope.org, Qualitycounts.org,* and *Healthcarechoices.org*. TDR

Known Locally as "Pathology Regionalization"

United Kingdom Soon to Tackle Consolidation of Hospital Labs

CEO SUMMARY: Consolidation and regionalization of hospital laboratory testing are not isolated phenomenons. Beginning in the late 1980s, individual provinces in Canada began to rationalize lab testing services by building core labs and consolidating lab services across multiple hospitals. By 1995, the same process of lab consolidation across multiple hospitals began mushrooming across the United States. Now it's the United Kingdom's turn. Serious planning for what's known as "pathology modernization" has reached the point where implementation of core labs and consolidated lab testing is about to begin.

BY JUNE SMART, PH.D.

DURING THE 1990S, Canada, followed by the United States, experienced hospital lab consolidation on a vast scale. Now the United Kingdom is planning an ambitious modernization program which includes several regional lab consolidation projects.

"The British government established the **National Health Service** (NHS) over 50 years ago and it is now the largest health organization in Europe," stated Professor Christopher Price, Vice President, Global Clinical Research, **Bayer Diagnostics**, Stoke Court, Stoke Poges, U.K. "The World Health Organization recognizes it as one of the best health services in the world, but there are significant improvements to be made to cope with the demands of the 21st century.

"To better utilize changing technology and meet the expectations of patients and providers, the NHS recently developed a ten-year strategy," noted Price. "Big changes are planned and several teams are spearheading the effort.

"First is the Modernization Board, a group of task forces working on priority areas that include cancer, cardiology, mental health, information technology, quality and related fields," Price explained. "Another is the Modernization Agency. Because patients and citizens have a vested interest in changes to the NHS, they are included in these teams."

First-Hand Experience

When it comes to pathology modernization (as used in the UK, the word pathology includes both clinical lab testing and anatomic pathology services), Professor Price has first-hand experience. Until December 2001, he was Director of Pathology for the **Royal London and St. Bartholomew's Hospitals**. In this position, he was heavily involved in orchestrating changes in the laboratory environment of East London.

"The NHS considers pathology modernization as a key component to improvements in the health system," observed Price. "Laboratory testing services underpin other parts of the program and are essential in delivering fast, accurate diagnoses for patients.

"In 1999 and 2000, the first two years, the pathology program directed about US$30 million for 35 local laboratory initiatives throughout the country," Price said. "This supported local rationalization of lab services, as well as technology upgrades to laboratories. It included innovations that, if successful at a local level, could be implemented by labs in other regions of the country.

"The biggest changes are coming in the second phase of the pathology modernization program," he added. "In 2001 another US$12 million was invested to fund the planning and implementation of four large-scale pilot projects aimed at re-configuring and rationalizing pathology services."

As a single-payer health system, the UK government is the source of funding. Money for healthcare services is disbursed to trusts. In simplest terms, each trust is a provider organization providing secondary and tertiary healthcare for between 100,000 and 300,000 people.

Lab Regionalization Goals

"In consolidating and regionalizing laboratory testing services, the goals are to better manage the way lab tests are performed within a region with an eye to reducing costs and eliminating service redundancies that were allowed to exist in prior years," stated Price.

"I should add that efforts by the previous government to improve the healthcare system included private sector incentives and more competition," he recalled. "That led to some unproductive situations, like a local general practitioner in Southeast England who sent lab work across the country to South Wales; it made no sense. Small

labs were running complex tests with limited staff and limited knowledge.

"Within the private sector, **Quest Diagnostics Incorporated** and **Unilab, Inc.** operated two hospital laboratories," he said. "Yet, due to the limitations of the business arrangements, several aspects of lab services, such as interpretation and training of physicians, remained the responsibilities of pathologists employed by the NHS.

> ***"Developing closer relationships with both our physicians and patients is a basic premise in our laboratory regionalization projects..."***

"Another area of cultural difference became noticeable in those two hospitals," Price stated. "Within NHS, we operate differently than labs in the United States. For example, within our health system, laboratorians will stop clinicians from doing tests if they are the wrong tests. Another example is that our labs will perform extra tests if they are applicable to the diagnosis and test results. UK labs operate differently from the United States in this respect. For reasons like these, the two hospital labs are now managed by the public sector."

Lab Regionalization Goals

Efforts to restructure laboratory testing services are part of the current government's drive to improve the quality of healthcare and patients' access to this care. "One difference is that, compared to past years, primary care physicians are now the major decision makers in the commissioning of hospital and laboratory services, not local health authority administrators," observed Price.

"The modernization plan is beginning to make a big difference and will bring significant changes to the laboratory sector," he added. "Plans are to expand the size of laboratories and their testing capabilities. Core labs are being designed to serve more than one million patients in their service area.

"Lab testing services will be organized in a multidisciplinary fashion and the work force will be multitasking," stated Price. "There is to be a greater emphasis on collaboration, rationalization, lab automation, POCT, new technology, and improvement in the management of labs.

"Professional staff will undergo mandatory re-accreditation every five years. This includes physicians, scientists, and the medical technologists," he said. "There is still a political desire to involve the private sector in the provision of laboratory services, but clear plans to allow this have yet to be developed.

Closer Relationships

"Developing closer relationships with both our physicians and patients is a basic premise in our laboratory regionalization projects," continued Price. "This will be accomplished by better integrating clinical labs to provide faster turnaround times, easy access to results, and more comprehensive lab services. Lab performance in all areas will be rigorously measured."

These goals can be seen in the specific regionalization projects. Price explains. "Take the East London project as an example. It involves six hospitals that are only about five miles apart. Two are teaching hospitals, two are district general hospitals, one was a children's hospital (now closed), and the **London Chest Hospital,** which will be integrated into St. Bartholomew's.

"To date, we've already consolidated microbiology, virology, histopathology, and cytology across these hospitals, generating immediate benefits," ex-

plained Price. "Histopathology was probably the biggest success.

"We brought 18 histopathologists together from the six hospitals and created teams of three, each team specializing in certain areas, such as urology, brain, or heart," he said. "Each team has a lead pathologist for every specialty, along with a backup. This allows them to specialize and this high-level expertise is equally available to all clinicians in the region.

Generating Large Savings

"Such arrangements improve patient care and create a better working environment for the pathologists," declared Price. "Besides boosting clinical training and research, it's generated large savings in real estate [facilities]. The East London laboratory regionalization project is now a model for other large urban areas."

"Prior to the East London modernization project, the six hospitals, representing about 1,000 beds, were run independently with separate management arrangements," noted Price. "These hospitals serve some 700,000 people. Their labs employed 295 med techs and 42 scientists, and were performing about eight million tests annually. That's now changed. Today we have a unified laboratory organization that runs in tandem with the hospitals.

"In fact, a new hospital is under construction in this region. It will offer rapid diagnosis and treatment. To support this, a US$52 million core laboratory is being built because it is recognized that the laboratory plays a key role in delivering better patient service.

Increased POC Testing

"In recognition of this, the laboratory is designed to 'go to the patient' rather than the other way around," revealed Price. "This directly translates into more point-of-care testing (POCT). Its effectiveness is measured by evaluating the cost per encounter. Large trauma units are making good use of POCT to better triage patients."

"In the East London pathology modernization project, the next step will be to establish a core laboratory at the Royal London Hospital and have satellite labs at the other locations," said Price. "These rapid response labs will perform rapid chemistry and hematology tests that require results in less than three hours.

"All test requests will be electronically entered at point of origin," he continued. "The core lab will have a single reception area for all samples, where they will be bar-coded. Tests will then be forwarded to multidisciplinary areas for automation (chemistry, hematology, immunology and virology), flow cytometry, mass spectrometry and molecular diagnostics.

"More complex or esoteric types of tests will be handled in specialty lab sections. Interestingly, these specialized labs are seen as vital to ensuring that the specialist knowledge is retained in a multidisciplinary environment," commented Price.

"In recognition of this, the laboratory is designed to 'go to the patient' rather than the other way around,"

"Within the East London area, the goal is to ensure that there is an expert in all areas at the clinical, scientific and MT level to support the clinical staff and development of services. The laboratory organization will be served by a US$3.5 million information system, but I am convinced there will be cost overruns, as this includes links to all primary care physicians, clinics and wards for both lab test ordering and results reporting access."

According to Price, there is some debate about the potential savings that will come from the different lab regionalization projects. "At one point, the Audit Commission estimated that, if all labs got their cost-per-test down to that of the lowest quartile, then the NHS would save over £40 million per year," he noted. "Despite the obvious savings in estate [facilities] and staffing, I believe the increased cost of logistics required to make these restructured lab organizations work properly have been underestimated."

Lab Regionalization Goals

Whereas East London is an example of an urban lab regionalization project, there are rural lab projects planned. "Lincolnshire is a good example of rationalizing and modernizing lab services in a rural setting," stated Price. "Lincolnshire has seven hospitals, which are as much as 35 miles apart. By American standards, that's not much distance, but it's a logistical nightmare on the narrow country roads of the UK.

"The laboratories are organized into a single network with a horizontal management board," he explained. "There was some consolidation of lab testing and a single information system network was implemented, along with procurement and a very complex transportation system.

"Logistics is proving to be more expensive than expected," he said. "Due to transportation limitations, each lab site must do more testing to provide necessary services in a timely manner."

Same Goals For Rural Labs

Price states that goals for rural pathology modernization projects are the same as for the urban lab projects—improved outcomes, faster turnaround times, enriched service menu, and lower overall cost-per-test. Because of the more limited ability to create a core lab, overall savings from rural lab consolidation are expected to be proportionately less than from urban lab projects.

Not unlike the experience of Canada and the United States, laboratory consolidation and regionalization in the U.K. has struggled to gain buy-in by laboratory professionals. "Although there is a vacancy rate as high as 25% in some areas, the MT's feel threatened," commented Price. "One goal of these lab rationalization projects is to more highly automate the labs, thus freeing up the med techs so they can become more involved in the clinical aspects of lab services.

"Post-implementation, the expectation is that med techs can become more involved in boosting the quality of testing in the automated lines. Another important aspect is to retain the link with the clinician, by providing education, auditing of services and proving knowledge for the clinical protocols," said Price.

Using Lab Expertise

"This is actually where laboratory professionals should want to use their expertise," he continued. "After all, the laboratory is a knowledge provider as well as a result producer. Our staff should have the ability to help physicians use tests more effectively.

"This is a more holistic approach to laboratory medicine, and helps move us away from the long-standing 'cost per test mentality.' We need to take a broader view and go to cost/stay, cost/episode, cost/life-year-gained, or cost/quality. Such approaches may increase lab costs, but they reduce the overall cost of healthcare.

Laboratory regionalization is happening even as changes are coming to the way NHS manages patient data. "Although somewhat behind schedule, implementation of a new patient data system is occurring," said Price. "Soon each NHS patient will have a unique

In the U.K., "Pathology Modernization" Means Lab Consolidation & Regionalization

Consolidation and regionalization of hospital labs is coming to the United Kingdom as part of a comprehensive modernization of the National Health Service (NHS). Plans call for creating unified regional laboratory organizations, each serving about 1 million people. About 400 existing lab sites will find themselves eventually operating as part of as many as 40 "regional lab clusters."

East London Pathology • *Urban Lab Regionalization Model*

In the urban setting of Metropolitan London, these four hospitals, representing about 2,000 beds, are about five miles or less from each other. Consolidation of microbiology, virology, histopathology, and cytology is completed. An automated core lab is in the design phase.

Post-Implementation Goals

- **Single employer**
- **Joint management board**
- **Single purchaser and procurement**
- **Consolidated, specialist services**
- **Critical mass of expertise**
- **Good training environment**
- **Major savings in estate (facilities)**

Lincolnshire Pathology • *Rural Lab Regionalization Model*

In the rural model, the five hospitals are each about 30 miles apart, with long transportation times on narrow country roads. Less consolidation of testing will occur and the emphasis will be on using common information system resources to improve how the lab adds value for clinicians

Post-Implementation Goals

- **Distributed lab testing network**
- **Horizontal organization**
- **Single management board**
- **Some consolidation of lab testing**
- **Single IT network between labs**
- **Single procurement and purchasing**
- **Effective logistics and transport**

identifier and every GP will have a terminal that allows the physician to electronically order lab tests and receive lab test results. This will provide continuity in our system."

Because the modernization program has a reporting schedule, Price has a way to track the ongoing progress of pathology consolidation and regionalization. "The most recent report issued by the Department of Health on pathology regionalization is now available at *www.doh.gov.uk/pathologymodernisation*," offered Price. "It provides overall guidance notes and suggested approaches to the needed changes, along with lessons learned in the process so far."

Has the United Kingdom looked at hospital lab consolidation in Canada and the United States for insights about the opportunities as well as the pitfalls? Price doesn't think so. "Not many laboratorians here are looking at the American or Canadian lab consolidation models," he said. "That may be because of poor reports on what happened, particularly in Canada.

"In the United Kingdom, laboratories will be accountable through quality indices and benchmarking for staff, budget, productivity and efficiency," he continued. "Because of the unique factors between countries, it is difficult to get data that offers a meaningful comparison."

Help From Canada & USA?

Price offered several concluding thoughts about lab consolidation in the United Kingdom. "We still have many questions to be answered on this modernization path. What are the optimal service models? What services should be planned nationally, supra-regionally and regionally?

"On the other hand, in the UK, laboratories now get positive attention from the media because of great value they provide in the clinical decision-making process. Such public recognition is a big step forward; public pressure often follows and that often leads to funds for additional improvements to the process.

"In our country, pathology modernization will be far-reaching," he added. "We have a population of around 60 million people and each regional lab organization is designed to serve between one and two million people. That means up to 40 regional lab consortia may eventually be established."

Possible Lessons For USA

For lab administrators and pathologists in North America, laboratory regionalization efforts in the United Kingdom may provide unexpected benefits. Although lots of lab consolidation is already complete in the United States and Canada, not every consolidation project was well-designed to capture all potential savings. There is still unrealized opportunity for further gains.

Thus, the more comprehensive perspective taken by the NHS modernization boards in executing lab consolidation may generate unappreciated benefits in how lab services can improve the overall quality per episode of care while reducing unnecessary costs.

The UK may also be a potential source of additional valuable experience for labs here in the United States and Canada. Rural pathology modernization projects represent a laboratory regionalization model which has been seldom tried in North America. Should the UK have considerable success at restructuring lab testing services in rural settings, this experience could have direct application in a number of regions around the United States.

However, as Dr. Price noted earlier, there is little transfer of laboratory management experience and thinking between countries. For that reason, the UK is bound to repeat some of the same basic mistakes in lab consolidation and regionalization that were made in North America. TDR

Contact Professor Christopher Price at chris.price.cp@bayer.co.uk.

Lab Industry Briefs

AETNA RECOMMENDS PAYERS SUPPORT GENETIC SCREENING TESTS

ALL LABORATORIANS SHOULD send a special note of thanks to **Aetna** Chairman and CEO John W. Rowe, M.D. for his recommendation that the health industry support the concept of genetic testing.

He made these recommendations as part of speech delivered at the *Inaugural Symposium on Genetic Privacy and Discrimination*, held at the **University of Rochester** in Rochester, New York on June 15, 2002. Dr. Rowe's comments made national headlines.

"Health plans can play an important role in promoting access to clinically useful genetic testing and the proper interpretation of test results," declared Dr. Rowe. "I believe there is a pressing need for the health insurance industry to establish guidelines for covering genetic testing in a way that promotes disease prevention and disease management, while at the same time respecting members' privacy.

"We have a responsibility to our members to keep pace with medical innovation," he added, "while preserving privacy and confidentiality. We believe there is also a good business case for health quality. A small investment in testing today can prevent or mitigate human suffering, while saving on health care costs in the future."

As the nation's largest health insurance company, Aetna's endorsement of a wider role for genetic testing will affect policymakers at all levels of government and business. Dr. Rowe called for state and federal lawmakers to adopt uniform laws that would ease the introduction and use of genetic-based medical procedures.

Aetna's endorsement of the economic benefits of clinically-proven genetic lab tests should help both diagnostic manufacturers and the clinical laboratory industry obtain adequate reimbursement for these types of lab tests as they are approved for use in clinical settings.

MEDICARE LAB BUDGET NOW CLOSELY SCRUTINIZED BY WALL STREET

IN ITS ONGOING BATTLES WITH CONGRESS to obtain adequate year-to-year funding for Part B laboratory testing services, the laboratory industry may have picked up an unexpected ally.

Earlier this month, the stock prices of several anatomic pathology-based companies began plummeting without notice. In the next several trading days, shares of **AmeriPath, Inc.** were down 30%, shares of **DIANON Systems, Inc.** fell 40% and **IMPATH, Inc.'s** stock price declined by 20%.

It turns out that certain hedge traders had been studying the latest draft proposals contained in the 2003 fiscal year funding legislation now winding its way through Congress. They noticed that the current draft legislation would reduce reimbursement for certain pathology technical services, as well as the scheduled reduction in the physician professional conversion factor.

In particular, DIANON announced that, if the current budget proposals remain unchanged, lower Medicare reimbursement would reduce its earnings by 10% during 2003. "When you do the math, the impact comes out to be a bit worse than anyone expected," noted Angela Samfilippo, an analyst at **U.S. Bancorp Piper Jaffray** who

tracks a number of clinical laboratory and anatomic pathology stocks.

Because lab stocks have been high flyers in recent years, the Wall Street investment community now takes a keen interest in any market variable which could affect the share prices of laboratory companies. Thus, each draft proposal for Medicare funding is now studied by investors seeking to determine its positive or negative impact on clinical laboratories. This is a change from past years, when such Congressional budget negotiations attracted little attention outside of the lab companies and diagnostic manufacturers who would be affected by Medicare funding levels.

The interesting speculation is whether certain professional investors, given their stakes in laboratory companies, might soon become a positive lobbying factor during budget negotiations. As such, these investors would be unexpected allies in the battle to maintain adequate reimbursement for Medicare Part B lab testing services.

JCAHO PREPARING "CONSUMER-FRIENDLY" HOSPITAL SURVEY RESULTS

IT'S ANOTHER PREDICTION by THE DARK REPORT coming to pass. **The Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) is revamping its publicly-available summaries of hospital accreditation survey results.

JCAHO announced this change in June. It is streamlining the performance reports it publishes for consumers following the surveys it conducts in hospitals and other healthcare organizations. The goal is to better relate the content of the summaries to consumers' interest in quality and safety.

In taking this step, JCAHO is responding to deep changes in consumer and employer attitudes toward hospitals and other healthcare providers. How profound is this shift? Read this comment by Charles Mowll, JCAHO Vice President of Business Development, Government, and External Relations: "The current reports *no longer reflect information that is meaningful* to the field or the public." *(TDR's italics.)*

What is equally revealing is the demand to access the existing survey reports. According to JCAHO's figures, between May 2001 and April 2002, the Web site section called "Quality Checks" was accessed 495,000 times and JCAHO received 117,500 requests for specific hospital performance reports.

Helping collaborate on the effort to revamp these survey result reports is the **American Hospital Association,** which is overcoming its long-standing resistance to public disclosure and rankings of hospital quality and safety measures. JCAHO expects the revised hospital-specific reports to be available by mid-2004. Long term care and home care reports will be introduced later.

JCAHO's recognition that consumers and employers want and need clearer information about the quality of individual hospitals and their safety record fulfills a prediction made by THE DARK REPORT earlier this year that public measurement systems that rank laboratories, physicians, and hospitals in quality measures are coming rapidly to the marketplace. *(See TDR, January 28, 2002.)*

Hospital laboratories and pathology group practices should carefully track this powerful and rapidly-evolving trend. As noted on these pages in earlier issues, buyers of healthcare—employers—are becoming more vociferous in their efforts to hold providers accountable for the double-digit increases in healthcare costs that have returned in recent years. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In many states, pathologists were hit by substantial increases in the cost of malpractice. In some states, like Pennsylvania, the market for medical malpractice insurance has deteriorated substantially. In the case of **AmeriPath, Inc.**, the nation's largest operator of hospital-based pathology groups, the increase in malpractice claims caused the company to budget an additional $6-$8 million for malpractice premium costs during the last six months of 2002.

SHOWDOWN BREWING ABOUT SUMMER EVENTS OF LAB ASSOCIATIONS

At this year's CLMA exhibit hall in New Orleans, several major diagnostics vendors did not have booths, but supported the CLMA Annual Meeting in other ways. It was a visible sign that the nation's largest diagnostics manufacturers are dissatisfied with the current status quo, which has CLMA and AACC producing annual meetings and exhibit halls within weeks of each other. Negotiations between all parties are ongoing.

INSURERS RAPIDLY MOVING BENEFICIARIES TO WEB SERVICES

Look for growing numbers of large health insurers to implement Web-based services for their beneficiaries in the next 18 months. Two examples show the speed of this transformation. Last month **CIGNA Corporation** launched a Web portal called *myCIGNA.com*. This portal allows CIGNA customers to see personalized information about both their health care and retirement accounts. This service is available to 16 million health and retirment plan participants. Meanwhile, **Humana Inc.** is preparing to roll out health insurance products that give employers and beneficiaries Web accesss to a variety of services and functions. Called "Emphesys," the system was implemented on trial basis in Memphis last October. It allowed the first six employers to reduce their health premium costs from a projected increase of 18% to an actual reduction of 12%. Web-based services triggered a 30% reduction in the year-to-year premium costs!

MORE INFORMATION ON COMPUNET LABS

• Two decades of lab executives involved in managing Moraine, Ohio-based **Compunet Clinical Laboratories** (CCL), came out of the woodwork following publication of TDR's assessment that joint ventures between commercial labs and hospital labs are on the decline. *(See TDR, June 3, 2002).* CCL is a three-way JV originally involving **Miami Valley Hospital**, **Valley Pathologists**, and **International Clinical Laboratories** (ICL). For the record, it was founded on January 1, 1986. During the life of the JV, it has had four General Managers: Louis Schnierer, Ph.D. (1986-1991), Bill Pesci (1992-1995), John Charles (1996-1998) and Edward Doucette (1998 to present). The JV survived two commercial partner acquisitions, when **SmithKline Beecham Clinical Laboratories** (SBCL) purchased ICL in 1988 and when SBCL sold to **Quest Diagnostics Incor-porated** in 1999.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 5, 2002.

UPCOMING...

- ***Exclusive First Interview with New Executive Team at Specialty Laboratories.***
- ***Updating Commercial Lab Collaboration in British Columbia: Physicians React to Combined Lab Test Data Base.***
- ***How Core Labs Serving Multiple Hospitals Are Moving Lab Test Services to a Higher Level—at Lower Costs.***

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