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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

Arguing in Favor of Regional Laboratory Networks

TWO STORIES IN THIS ISSUE OF *THE DARK REPORT* DEMONSTRATE why regional laboratory networks are a business model which should be revisited by hospital laboratories with outreach programs.

Seattle provides a great example of how an existing laboratory network gives hospitals in that region an additional business option. **PACLAB**, an eight-hospital laboratory network, has steadily grown in size, professionalism, and market impact. When two hospitals went shopping for a commercial laboratory partner, PACLAB was able to provide a credible proposal in both cases. *(See pages 10-14.)*

Plans in Florida to select a single laboratory to do all testing statewide for Medicare beneficiaries is a direct threat to independent laboratories and hospital lab outreach programs. Laboratories in that state are scrambling to develop a lobbying coalition that can stop this proposal. A regional laboratory network would help in this effort. *(See pages 5-7.)*

What is ironic about the situation in Florida is that the state's major hospital laboratory outreach programs actually did have a network. The **Florida Reference Laboratory Network** (FRLN) was developed to help these lab outreach programs bid and service large managed care contracts in the state. However, as closed-panel HMO contracts became less of an issue in recent years, the lab network's organizers allowed it to languish.

In contrast, Detroit's regional laboratory network is probably "best in class." Over a ten-year period beginning in 1992, **Joint Venture Hospital Laboratories** (JVHL) successfully captured almost every significant managed care contract in Michigan. As many as 150 Michigan hospital laboratories participate in certain contracts. Like PACLAB, JVHL is a work in progress. Each year additional resources are developed and put in service to the benefit of member hospital laboratories and their physician-clients.

Current developments in Seattle and the State of Florida remind us that hospital lab outreach programs can accomplish more by collaborating than by working alone. If payers continue to develop contracting models which cover larger regions, then lab outreach programs should respond by creating a regional laboratory resource. Let me also add that anatomic pathologists would benefit from the same kind of regional collaboration. But that's another opinion for another column! TDR

MT Contracts HIV & HCV In Hospital Lab Scandal

Maryland state health officials uncover numerous serious violations

CEO SUMMARY: An extraordinary story is unfolding in a Baltimore hospital laboratory. Maryland state health officials have uncovered serious operational deficiencies, particularly with HIV and HCV testing performed over a 14-month period. During this same time, a medical technologist now infected with both HIV and HCV claims a malfunctioning laboratory instrument was the source of her infection.

IT'S THE LABORATORY MANAGEMENT nightmare always lurking in the backs of the minds of laboratory administrators and pathologists.

On March 10, 2004, first news broke in Baltimore about problems in the laboratory at **Maryland General Hospital**. The *Baltimore Sun* reported that state health officials had determined that, during the period June 2002 through 2003, HIV and HCV testing performed at the hospital's laboratory had produced unreliable results.

Within days of this disclosure, public health officials estimated that at least 460 individuals tested for HIV and HCV had been given potentially inaccurate results during the 14-month period of flawed testing. "I'm really quite disturbed. They [laboratory personnel] apparently knew there was a problem," stated Baltimore Health Commissioner Peter C. Beilenson.

Beilenson and Secretary of the **Maryland Department of Health** Nelson J. Sabatini both stated that two inspections of the laboratory by state officials in January had uncovered other potential problems in how the laboratory was operated.

Two days later, on March 12, came another startling disclosure. A medical technologist formerly employed by the hospital laboratory had sent a letter to state health officials in December describing serious safety and accuracy problems in the Maryland General Hospital laboratory. Moreover, this med tech was now infected with both HIV and HCV, which she attributed to expo-

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sure while operating the HIV/HCV testing instrument in the laboratory.

Public news that hundreds of patients may have received inaccurate results from their HIV and HCV testing created a public relations disaster for Maryland General Hospital. Timothy D. Miller, President of the hospital, offered free testing for patients affected by the lab's problem. He also explained that an internal review and the report of an outside consultant had identified no other problems in the laboratory. His explanation for the HIV/HCV testing deficiencies was a combination of "human error and equipment problems."

Lab Management Lessons

From a laboratory management perspective, many lessons will emerge from this still-unfolding story. THE DARK REPORT is in communication with a range of individuals with knowledge of specific elements of the situation at Maryland General Hospital, a 245-bed hospital.

What is known at this point is that the hospital laboratory acquired an instrument called the LABOTECH Open Microplate Blood Testing System to do HIV, HCV, and other similar tests. It is manufactured in Italy by **Adaltis Inc.** Worldwide, more than 2,000 of these instruments are in labs. In the United States, between 200 and 240 instruments are in labs.

Maryland General's lab put its instrument into operation in June 2002. Problems with the instrument surfaced immediately. A preliminary nine-page state inspection report states that staff at Maryland General Hospital's laboratory did not follow the manufacturer's standards for the LABOTECH instrument. Whenever tests on known samples fell outside the acceptable limits, laboratory staff edited the data to bring results within normal ranges. Such specimens were not retested and the suspect test results were reported to patients.

The report also noted that "there were no records to show that correction of errors were made in a timely manner; and no records to show that testing personnel, both past and present, were trained properly and evaluated for competency."

State health officials further noted that, during a meeting in late January, laboratory staff had acknowledged their failure to heed another warning sign of inaccurate test results. When certain HIV and HCV samples were sent to a reference laboratory for confirmation testing, the results reported often conflicted with the hospital lab's test results.

In August 2003, the laboratory ceased using the Adaltis LABOTECH instrument. "We were having challenges with the instrument itself," explained Miller. He again affirmed that his laboratory's problems with HIV and HCV testing were the result of a combination of both "human error and equipment problems."

Maryland General Hospital has tried to put a positive spin on this situation. But as of early December 2003, it had taken no internal action to address the testing problems generated on HIV and HCV tests performed during the 14-month period ending August 2003.

Alerted By Whistle-Blower

Action to rectify this situation did not occur until a whistle-blowing med tech, who, after failing to get the attention of hospital administration to these problems, then sent letters to the Maryland Department of Health in December. Alerted by her letters, state officials inspected the laboratory in January 2004.

The medical technologist is Kristin S. Turner, 32. She filed a $30 million

lawsuit against Maryland General Hospital, laboratory director Dr. James Stewart, and Adaltis. In a public interview, Turner stated she began working at the laboratory in October 2002. She noticed problems with the Adaltis LABOTECH immediately.

"Every run had different errors. three of every five tests were wrong. The machine failed its own self test," observed Turner. She also noted that the instrument, an automated "load and walk away" microplate system, would often skip required steps during testing. As a result, lab techs had to constantly watch the machine during operation to catch such events. "None of the techs had confidence in the machine," she declared.

Turner estimates that about 150 tests for HIV, HBV, and HCV were done weekly, which would represent about 8,400 tests during the 14 months that the LABOTECH was in use in the laboratory. Turner stated that Adaltis was contacted several times each week about problems and sent technicians into the laboratory regularly. Turner said that she provided warnings and complaints to laboratory management, but there was no response to her efforts. "Every single test that came off that machine should be in question, from its first day in use," stated Turner.

More Competition Ahead

Turner believes that she became infected with HIV and HVC as a result of operating the LABOTECH instrument. On March 12, 2003, she responded to an error message on the machine. She opened the top and during the repair procedure, the washer-head fell off the control arm. It fell on the plates and material from both specimens and controls splashed up onto her face, running down behind her protective mask and protective goggles.

Turner was rushed to the emergency room and tested negative for HIV and HCV. However, by June, Turner tested positive for both diseases.

One issue which disappointed state health officials in Maryland is the fact that neither laboratory management nor hospital administration had taken steps, as of early December 2003, to accurately evaluate the problems with testing integrity. Nor did the hospital attempt to contact patients who potentially were given inaccurate results to offer retesting until after government authorities ordered the hospital to take corrective action.

New Revelations Ahead

Indications are that more trouble areas in the management and operation of this hospital laboratory will be made public in coming weeks. It is known that the hospital has retained **Park City Solutions** to operate the laboratory on a interim basis, evaluate operational deficiencies, and bring the laboratory back into full operational compliance.

The *Baltimore Sun* has already singled out hospital administration for criticism, writing in an editorial that "it was dismaying that hospital executives have sought to minimize this tragedy and blame it on low-level workers—one of whom was the whistle-blower who alerted city and state officials."

Along with the medical technologist who now tests positive for HIV and HCV, it is known that, among the first 60 patients retested, at least one individual was found to be HCV-positive, even though his original test result was negative. This extraordinary episode is a reminder that the human cost is immeasurable anytime things go wrong within any of the nation's clinical laboratories. TDR

Florida Issues State RFP For Sole Medicaid Lab

Effort to award $100 million contract using a 28-day RFP process is criticized

CEO SUMMARY: If competitive bidding for Medicare business is something universally viewed as bad by the laboratory industry, then the lab services RFP issued by Florida's Medicaid program must be considered a serious threat to the status quo. Further, the fact that Medicaid officials in Florida designed a 28-day RFP process to award a single lab with an exclusive, 3-year, $100 million contract earned criticism from both labs and employers.

IF FLORIDA IS A BELLWETHER STATE for healthcare developments which are adopted in other states, then Florida's Medicaid RFP for lab testing services should be closely scrutinized by lab managers and pathologists throughout the country.

"Without prior notice and without notification to all but a few laboratories in Florida, on March 2nd the state's Medicaid agency commenced a 28-day process to award one laboratory with a three-year contract to perform 100% of laboratory testing on Medicaid patients statewide," stated Philip Chen, M.D., Ph.D., CEO of **Cognoscenti Health Institute**, based in Orlando, Florida.

The contract, estimated to be worth $100 million, will cover all laboratory testing done on Florida's 1 million Medicaid beneficiaries, except for inpatient testing. The **Agency for Health Care Administration** (AHCA), which administers the Medicaid program in Florida, originated the Medicare laboratory services RFP in response to legislation passed in Florida during the past 24 months. The Legislature mandated that AHCA implement cost-saving initiatives in the Florida Medicaid program.

"We estimate that 160 laboratories currently provide testing to Medicaid patients in Florida," noted Chen. "Should Florida Medicaid actually award all lab testing to a single laboratory, the financial effect on these small labs will be devastating."

Laboratories Have Allies

Labs in Florida have allies concerned about the negative potential of a single, statewide contract for Medicaid laboratory testing. "We adamantly oppose the idea of one laboratory vendor to provide lab tests for all Florida Medicaid beneficiaries," declared Becky Cherney, President and CEO of the **Florida Health Care Coalition** (FHCC). This coalition is made up of large employers, like **Disney Corporation**, **Lockheed Martin, Siemens Westinghouse**, and the **City of Orlando**.

"The motto of our coalition is 'Quality First—*Always*!' The Medicaid

laboratory services RFP fails to deliver quality in several ways," noted Cherney. "This RFP fails to include quality requirements for the winning laboratory. There are no minimum standards for clinical quality. Nor are there any standards for laboratory testing services, such as an adequate number of well-placed patient service centers or timely courier pick-up of specimens.

Oppose Lab Monopoly

"Medicaid should provide services above some level of minimal quality," she added. "There is no need for anything as poor as this Medicaid laboratory testing RFP to go forward. This proposal, and its award process, make me feel like my state is about to go from 'hanging chads' to 'hanging labs.' Our residents should not be forced to accept a monopoly. They deserve better!"

Laboratories in opposition to the Medicaid lab testing RFP are fortunate to have the Florida Health Care Coalition in their corner. FHCC represents employers with more than 2 million employees. Lawmakers and state officials do listen to its views on a variety of issues.

Florida's independent laboratories are obviously concerned about the negative impact of awarding a single laboratory the right to do all laboratory testing for the state's 1 million Medicaid beneficiaries. That's one reason why there are numerous criticisms about the fairness of the RFP process and AHCA's motives in designing the Medicaid RFP and awards process.

28-Day Bidding Process

"AHCA issued the RFP on March 2. The deadline for labs to file a letter of intent was March 16," said Chen. "The RFPs themselves were due on March 30. It is remarkable that AHCA is willing to award this contract with just a 28-day bidding process. Such a compressed RFP cycle makes it difficult for smaller labs, with limited staff resources, to respond quickly to such a comprehensive RFP."

"Further, the first inkling any laboratory had about this RFP was on March 9," noted Chen. "We can identify five laboratories which got letters from AHCA notifying them about the Medicaid laboratory service RFP. Most interesting, four of those laboratories received addressed envelopes with no contents! It was not until they called AHCA that they learned about the RFP."

The concept of a single laboratory winning the right to do all the state's Medicaid lab testing for three years is generating lots of criticism.

The concept of a single laboratory winning the right to do all the state's Medicaid lab testing for three years is generating lots of criticism. But there are additional flaws in the RFP. "This RFP emphasizes lowest cost over all other variables," Chen observed. "There are absolutely no requirements for a minimum level of quality in the clinical results. As well, there are no requirements for service levels. Physicians in Florida would be forced to accept whatever the winning laboratory offers. Under the RFP, there are no penalties for lapses in quality."

"Another area of concern involves pricing," stated Gary Onofry, Administrator at **Palm Beach Pathology** in West Palm Beach, Florida. "Florida Medicaid has its own fee schedule. It pays for both clinical laboratory testing and anatomic pathology services on a schedule of fixed rates. This is different than Medicare's use of RVUs.

"This Medicaid RFP specifies that prices are to be discounted based on the existing, flat-rate Medicaid price schedule," he continued. "Not only does this fail to take into account the specific and unique needs that accompany testing provided to specialized providers, such as long term care facilities and dialysis testing centers, but it maintains and increases existing distortions in Florida Medicaid's already complex pricing scheme."

$20 Million Bond

Bond requirements are another source of criticism. "As spelled out in the RFP, any laboratory bidding for this contract must post a $20 million performance bond," said Chen. "That's not all. Any laboratory seeking to file a formal protest to any aspect of this RFP must post a $1 million bond. These are onerous requirements that automatically prevent all but a handful of laboratories in Florida from even entertaining the idea of submitting a bid, individually or as part of a consortium."

THE DARK REPORT observes that the Medicaid laboratory testing RFP in Florida represents a real-world example of two important concerns repeatedly voiced by the laboratory industry over the concept of competitive bidding in the Medicare and Medicaid programs. The first concern is whether the bidding model used to evaluate and select a winning laboratory is properly designed and supports the concept of "any willing provider." Can and will the bidding model establish fair pricing for the government health program, while allowing an adequate number of laboratories to opt in and provide services at that price?

The second issue is one which gets less attention, but which is no less important. Is the process of selecting a winning laboratory free of bias? Is it free from manipulation, either by bureaucrats inside the program or by laboratories or other vendors seeking favorable advantage in the awards process?

The laboratory industry now has a front row seat to watch whether Florida's Medicaid program runs afoul of either or both of these concerns. The outcomes have real consequences. If Florida gets this first attempt at a single lab, three-year, exclusive contract wrong, many people within the healthcare system will be disadvantaged.

Further, a statewide-contract for Medicaid lab testing services in Florida, regardless of the impact it has on the quality of lab testing services, can be expected to encourage other state Medicaid programs to adopt a similar, single-lab contracting model. It can also be expected to encourage Medicare to finally implement a demonstration project involving the competitive bidding for laboratory testing services.

THE DARK REPORT reminds readers that it was Arizona's Medicaid program which launched capitated, shared-risk contracts. This happened in the early 1980s. As this contracting technique was adopted by other states and private payers, the financial impact on the laboratory industry proved devastating during the following decade. So there is a precedent for a state Medicaid program to innovate and have its innovation copied by both government and private health plans.

As this issue of THE DARK REPORT went to press, AHCA had exended the date for submission of proposals by an additional 30 days, from March 28 to April 28. Forces in opposition to this single-lab RFP are beginning to emerge and it appears that groups outside the lab industry will join the fight. TDR

Contact Philip Chen, M.D. at 407-882-0212; Becky Cherney at 407-425-9500; Gary Onofry at 561-659-0770.

LabCorp Buys MDS Labs In New York and Georgia

MDS concedes U.S. lab market and its lab automation strategy

CEO SUMMARY: It's the final chapter of the "Canadian Invasion" of the U.S. laboratory testing market. In the mid-1990s, both MDS and Dynacare built a sizeable presence in the United States as they both worked to develop joint ventures with hospital laboratories. Dynacare was acquired by LabCorp in 2002. In selling two U.S. lab operations, MDS has taken the first steps to reposition its business in this country.

BY SELLING TWO of its U.S. laboratories to **Laboratory Corporation of America**, Toronto, Canada-based **MDS Diagnostic Services** served notice that it was ready to pursue a different business strategy in the United States.

MDS announced on March 16 that it had sold its laboratories in Atlanta, Georgia and Poughkeepsie, New York to LabCorp. The change of ownership was effective March 15. LabCorp did not issue a public statement on the acquisition and neither company disclosed a sales price or terms.

The decision by MDS to sell some of its U.S. laboratory operations was not a surprise. During 2003, Toronto, Canada-based **MDS Inc.**, parent company of MDS Diagnostics Services, indicated it was reviewing strategic options for its laboratory testing operations in the United States. It stated these operations were failing to meet corporate goals for revenue growth and profitability.

"There's a simple reason why MDS sold these two laboratories," stated Cam Crawford, President of MDS Diagnostics. "Given their existing size and regional market, it was our evaluation that neither laboratory could deliver revenue growth and operational scale that would support our corporate objectives."

Three MDS Lab Operations

Following the sale of its Poughkeepsie and Atlanta laboratories, MDS is left with three laboratory operations in the United States. They are **Memphis Pathology Laboratories** (MPL), in Memphis, Tennessee, a joint venture that includes **Baptist Memorial Healthcare Corp.** and **Methodist Healthcare** as partners; **Integrated Regional Laboratories** in Fort Lauderdale, Florida, a joint venture with **HCA**; and **Duke University Health System Clinical Laboratories**, which MDS manages under contract.

"We consider the three remaining laboratory operations in the United States to be solid partners with MDS," noted Crawford. "Each is an example of how a hospital-centric regional laboratory organization can attain sus-

tained improvements in clinical and operational performance."

The sale of these two laboratories marks the end of a long-running business strategy. It was almost ten years ago when MDS announced that it would open a headquarters office in Brentwood, Tennessee and use that as a base to develop partnerships with hospital laboratories in the United States.

MDS believed it had a unique asset to offer potential hospital lab partners. In Canada, it had developed a viable line of total laboratory automation (TLA) equipment. Part of its business proposition to U.S. labs called for MDS to install and operate its TLA system as part of the laboratory partnership.

Interest in Joint Ventures

The arrival of MDS on the national U.S. laboratory scene came almost at the same time that **Dynacare, Inc.** was boosting its presence in the United States. Like MDS, Dynacare also wanted to cultivate joint ventures with hospital laboratories.

However, this "Canadian Invasion" neither gained much traction nor generated many hospital joint venture agreements. In the case of Dynacare, it grew mostly by acquiring laboratories. With MDS, its biggest potential was with HCA, the for-profit hospital corporation. However, to date, the Atlanta and Fort Lauderdale laboratory projects have not encouraged both partners to replicate the business model in other regions of the United States.

"Joint ventures are tough. It's not easy to be a partner because it requires more work," observed Crawford. "It's a source of pride that relations with our hospital partners have generally been great. We believe strongly in the future of diagnostics, as demonstrated by our pharma and proteomics businesses.

"Selling two laboratories reflects our recognition that the lab testing market continues to evolve," Crawford added. "However, we remain committed to the concept of partnering and the importance of diagnostic testing to healthcare.

"These sales clear our decks for the next healthcare cycle, he said. "We want to absorb the lessons we've learned in the marketplace and develop a business strategy that allows us to continue our participation in laboratory testing in the United States." TDR

Contact Cam Crawford at 416-675-6777.

Sale Reinforces Two Lab Industry Trends

VALIDATION OF TWO IMPORTANT trends within the lab services marketplace can be seen in MDS' decision to sell two of its U.S. laboratories to LabCorp.

First, this sale is additional evidence that joint ventures between commercial laboratories and hospital laboratories continue to be a difficult concept to execute successfully. In the case of Poughkeepsie, the laboratory joint venture evolved through several forms over three decades until the hospital owners sold their interest in order to raise capital. In Atlanta, the hoped-for benefits with HCA never materialized and MDS never developed a second phase business plan on its own that could take maximum advantage of its laboratory infrastructure in that city.

Second, one key element in MDS' proposition to potential hospital partners was that it would install and maintain a total laboratory automation (TLA) program as part of the joint venture. The fact that, after almost ten years of effort, MDS had only five active laboratory ventures demonstrates that TLA is still not a high priority in most hospital laboratories. It is a sign that the market demand in the United States for total laboratory automation systems by larger hospitals is still unable to support more than a limited number of TLA vendors.

Seattle Hospital Lab JVs Involve Quest & LabCorp

One victory and one loss provide insight into blood brothers' hospital lab strategies

***CEO SUMMARY:** Joint ventures and collaborative business relationships between hospital laboratories and commercial laboratories continue to be a difficult business model. Recent events in Seattle demonstrate the challenges and frustrations of establishing such ventures, then making them successful. One footnote to the Seattle story is the success of a regional laboratory network at grabbing market share.*

MAJOR CHANGES HAPPENED in recent months to hospital laboratory joint ventures (JV) operated by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** in Seattle, Washington.

It was a "renew one–lose one" scorecard. The big news was that LabCorp convinced 900-bed **Swedish Medical Center** to renew its long-standing laboratory operations agreement. Across town, Quest Diagnostics was unable to get **Evergreen Hospital Medical Center** to renew the agreement for the JV which started in 2001.

Dynacare's Biggest Lab

The Swedish/LabCorp deal was closely-watched for an important reason. When LabCorp bought **Dynacare, Inc.** in 2002, the Northwest laboratory division was Dynacare's crown jewel. With annual revenues in excess of $100 million, it contributed the lion's share of Dynacare's net income.

Wall Street is tough on labs which buy other labs, then lose the business they just bought. Along with other reasons, this is why LabCorp needed to retain this particular relationship.

With so much at stake in the Swedish/LabCorp relationship, a little history is useful to understand recent events. Until 1994, all inpatient and outpatient laboratory services at Swedish were provided by a pathologist-owned commercial laboratory called **Laboratory of Pathology** (LOP). LOP was one of the premier local laboratories in Greater Seattle and had an iron grip on the outreach market around Swedish Hospital.

LOP's lucrative business was finally threatened in 1994. That was when Dynacare approached the CEO of Swedish and offered to perform the hospital's laboratory testing for several millions of dollars per year less than Swedish was currently paying LOP. It was rumored that Dynacare offered Swedish inpatient testing prices that were one-third lower than what Swedish was then paying LOP.

Having received Dynacare's offer, the Swedish CEO offered LOP's

pathologists the same deal. Dismayed at the revenue loss they faced, the pathologists opted to sell LOP to Dynacare, who followed through on the price reduction to Swedish and continued to do its testing.

In the years following that acquisition, Dynacare's Seattle lab was one of its most successful regional operations. LabCorp became the joint venture partner with Swedish Medical Center when it acquired Dynacare in 2002.

Another Fascinating Twist

Along the way, another fascinating twist develops in the Swedish story. In 2002, Swedish purchased a nearby hospital from the **Sisters of Providence**. Known as **Providence Seattle Medical Center**, the laboratory of this 376-bed hospital was a member of **PACLAB**, a statewide regional laboratory network owned by nine hospitals and **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington.

There was an interesting consequence from this new arrangement. Even as LabCorp provided all laboratory testing for Swedish Medical Center, Swedish was receiving profit checks from PACLAB. These checks reflected Swedish Providence's share of outreach testing activities conducted from its participation in PACLAB.

Opportunity To Learn

Administrators at Swedish had the opportunity to see the financial consequences of Providence Seattle's participation in PACLAB. The lessons they learned triggered a different approach when it came time to consider renewing the joint venture with Dynacare/LabCorp.

Swedish Medical Center retained a laboratory consulting firm, the **Nichols Management Group**, to help it evaluate its options. "Since Swedish Providence Hospital was now part of our health system, our needs for laboratory testing services had expanded," stated Brian Kuske, Vice President of Ambulatory and Ancillary Services at Swedish. "We decided to consider three business scenarios for our extended laboratory organization.

"First, should we rebuild and operate our own lab?" Kuske asked. "Second, would it make sense to have PACLAB as a partner? Third, how might Dynacare/LabCorp propose to change our existing relationship?"

Swedish Medical Center proved to be a tough negotiator. During 2003, both PACLAB and LabCorp aggressively developed multiple options to provide a competitive package. The bidding process was lengthy and intense. Last summer, LabCorp Chairman and CEO Thomas Mac Mahon flew to Seattle and met personally with Richard H. Peterson, President and CEO of Swedish. Some sources say that meeting "sealed the deal." In any event, within a few months, Swedish decided to accept the LabCorp proposal.

Lots Of Folks Know A Little

Few details of the final package were disclosed in public statements about the new agreement. However, after polling a number of individuals familiar with different aspects of the transaction, THE DARK REPORT has determined that Swedish Hospital obtained significant benefits from the new pact with LabCorp.

Collectively, the opinions of lab industry veterans in Puget Sound support several broad assumptions about the recast agreement. One, the initial term is probably five years, or slightly longer. However, with options, this agreement can extend as far out as 2015.

Two, estimates are that Swedish was paying about $20 million per year to LabCorp for lab testing. Kuske

acknowledges total annual savings for the recast lab testing package (with outreach) in the range of 20%, with much of the savings coming from lowered costs in the Providence Hospital lab. However, THE DARK REPORT constantly heard the number of $6 million per year as the savings negotiated. If true, that would generate razor-thin profits for LabCorp, since hospital inpatient testing in these types of arrangements is typically already priced close to marginal cost.

Consolidating Lab Sites

Three, LabCorp has committed to lease as much as 75,000 square feet in a medical office building next to Swedish Providence Hospital. Although it has not announced that it would close its existing lab in Kent, Washington, informed sources bet that LabCorp intends to do just that and consolidate all its Seattle-area testing into this new laboratory facility.

Four, Kuske told THE DARK REPORT last week that Swedish intends to enter the outreach business sometime in the next 18 months. Its agreement with LabCorp includes a joint venture arrangement that allows it to share in the outreach business.

Smaller Profit Pie

If these four assumptions come reasonably close to the actual situation, they indicate that LabCorp's profit contribution from the Swedish lab testing business will be significantly less than under the original joint venture. That also may be true of the outreach business around the Swedish Medical Center campus, because, for the first time in decades, Swedish will finally participate in the profits from outreach testing around its own campus. But that reduces the revenue yield for LabCorp.

In addition to the above, LabCorp must incur the cost of building a new laboratory, as well as the cost of closing two existing laboratories (the ones operated by LabCorp and Dynacare, respectively, prior to the acquisition). It must also deal with union contracts covering employees connected with the Dynacare and Swedish laboratories.

Thus, to keep the Swedish relationship intact, LabCorp will have to accommodate lower pricing and higher costs. At the same time, its existing business around the Swedish medical campus will be at increased risk. That's because a new lab competitor recently moved into the neighborhood: PACLAB.

"I'm proud to say that PACLAB's newest laboratory is now open and conducting business. In a 'can do' spirit, it took just six weeks from signing the lease to a fully-licensed, operational laboratory," said Adelman.

"PACLAB aggressively made its case to Swedish Medical Center," stated Stewart Adelman, COO and Gen-eral Manager of PACLAB. "We were disappointed when Swedish Medical Center decided not to become a member and withdrew the Swedish Providence Hospital laboratory from PACLAB.

"As part of this change, Swedish retained the right to provide laboratory services to those Providence physicians owned by the Swedish health system," noted Adelman. "That was about 50% of the existing outreach business around that hospital. To service the remaining 50% of those clients, PACLAB decided to build a laboratory in that neighborhood.

"I'm proud to say that PACLAB's newest laboratory is now open and conducting business. In a 'can do' spirit, it took just six weeks from signing the lease to a fully-licensed, operational laboratory," noted Adelman. "Staffing the new laboratory was not

difficult. As the Swedish Providence hospital laboratory was consolidated into the LabCorp/Swedish joint venture, 160 laboratory employees were laid off. That put a large number of highly-skilled med techs into the job market—just as we were hiring!

"We expect the competition for business in this sub-market to be intense. For the immediate future, non-compete agreements govern marketing to specific clients of LabCorp/Swedish and PACLAB. However, that still leaves a substantial number of business prospects that PACLAB can pursue from its new laboratory location."

Changes At Evergreen

Across Lake Washington from downtown Seattle, the joint venture contract between Quest Diagnostics and Evergreen Hospital Medical Center was approaching renewal time last year. Evergreen Hospital is located in Kirkland, Washington. The arrangement, which became effective in 2002, was designed to fully integrate inpatient, outpatient, and outreach laboratory testing activities at Evergreen with those of Quest Diagnostics.

Evergreen ended its laboratory joint venture with Quest Diagnostics on January 5, 2004. On that same day, it launched a business relationship with PACLAB.

Hoped-For Benefits

Evergreen Hospital Medical Center is a 240-bed public hospital. In doing a joint venture with Quest Diagnostics, it expected to see a reduction in the overall cost of inpatient testing and better laboratory testing services because of an expanded test menu done locally, supported by Quest's national esoteric testing capabilities.

Of equal importance, it was expected that Quest Diagnostics would be more effective at sales and marketing. This would expand the outreach market and Evergreen would benefit from more specimens flowing into its core laboratory, along with a share of profits from expanding outreach revenues.

Similar benefits were expected at Quest Diagnostics. It was rumored that Evergreen was the single largest client for Quest's Northwest laboratory region.

During the course of the joint venture contract, Evergreen became disappointed. The collaboration proved unsatisfactory in a variety of performance areas. "In simplest terms, this joint venture failed to meet the expectations of our mutual customers," stated Ron Brown, Director of Laboratories at Evergreen. "The voice of the customer was one of frustration.

"Why didn't this JV succeed? Without becoming a Monday-morning quarterback, it was probably two main reasons. First, Quest Diagnostics seemed to be organized to meet business objectives originating from the East Coast. That meant local needs and customers were often not well-served in this business model.

Right Incentive Needed

"Second, the joint venture itself was flawed in its original design," he continued. "Financially, it was a cost-plus contract. Our hospital ended up with a relatively high average cost-per-test and there was no incentive for our partner to reduce costs and share those savings with Evergreen.

"This arrangement taught us lots of lessons about the do's and don'ts of a laboratory joint venture," added Brown. "It's been Evergreen's strategy to venture with a commercial laboratory partner to achieve a number of goals. Based on our experience, we established new parameters for our venture. Following a review process, Evergreen selected PACLAB to be our venture partner. This relationship started on January 5."

The laboratory joint ventures at Swedish Medical Center and Evergreen Hospital Medical Center demonstrate some useful insights about this business model. First, hospital administrators remain intensely focused on the goal of cost reduction. Both hospitals wanted their joint venture structured so as to deliver a sustained annual reduction in the average cost-per-test.

High-Quality Lab Services

Second, the joint venture must deliver a high level of service and quality to the hospital and physicians. Hospitals are cautious about ceding control of inpatient laboratory testing. Because of that, a laboratory joint venture must demonstrate that the managing partner can provide better quality inpatient testing services than a standard, in-house hospital laboratory.

Third, hospital administrators remain skeptical about the joint venture throughout its life. Thus, a commercial lab-hospital lab joint venture must deliver services which go above and beyond. Even then, the two examples in Seattle demonstrate that there doesn't seem to be much loyalty when the time comes to renew the operating agreement.

JVs in Today's Marketplace

These two joint venture stories in Seattle show how today's marketplace is handling the commercial lab-hospital lab joint venture concept. It is still a complicated process and no single business model seems to provide all the right answers. It will be interesting to see, in coming years, if continued cost pressures combine with expensive new molecular diagnostics technology, to make these types of joint ventures more attractive to a greater number of hospitals. TDR

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PACLAB Plays Spoiler In Seattle Lab Market

REGIONAL LABORATORY NETWORKS ARE even more difficult to organize and operate than a laboratory joint venture involving a commercial lab and a hospital lab.

Yet, as recent events in Seattle demonstrate, a professionally-managed regional laboratory network brings substantial benefit to member hospitals. It also represents a viable competitive force to counter the sales and marketing strategies of national laboratories competing in that regional market.

PACLAB was a credible participant in both laboratory joint venture situations which recently came up for renewal in Seattle. In the case of Swedish Medical Center, PACLAB's proposal was not accepted. But the fact that PACLAB provided a credible option probably aided Swedish Medical Center in negotiating better terms from its commercial lab partner than might otherwise have been true. For Evergreen Hospital, which had rejected PACLAB's proposal in 2001 when it first entered into a laboratory joint venture, PACLAB was a welcome option in 2004.

Since its founding in 1997, PACLAB has steadily increased its outreach revenues, improved its management capabilities, and built credibility with payers. Its track record means that this regional laboratory network can grow in any number of strategic directions. For member hospital laboratories, it provides the enhanced services and regionwide visibility needed to sustain a competitive outreach program.

PACLAB in Seattle and **Joint Venture Hospital Laboratories** (JVHL) in Detroit show that the regional lab network business model can be viable over the long haul. Each often plays the role of spoiler in its market—for the right reasons. What may be an important next step for these two networks is to develop a much closer relationship with anatomic pathology (AP) groups. To date, pathologists in each city have resisted the idea of creating a parallel AP network. But that may change in the next couple of years.

Pathology & Oncology Update

Welsh Carson Pays $1.14 Billion To Acquire U.S. Oncology, Inc.

It's another billion-dollar Wall Street bet on the future prospects in oncology services

EVEN AS THE LAST ISSUE of THE DARK REPORT was reaching clients with news of **Genzyme Corp.'s** offer to buy **IMPATH Inc.**, another big oncology deal was announced.

On March 22, 2004, **Welsh, Carson, Anderson & Stowe** announced an offer of $15.05 per share to purchase all remaining shares of **U.S. Oncology, Inc.** which it currently does not own. This was a premium of 18.5% over US. Oncology's closing share price of $12.70 the previous trading day. Welsh Carson already holds 14.5% of U.S. Oncology's common stock.

As part of the deal, U.S. Oncology will become a private company. Welsh Carson will pay $1.14 billion. U.S. Oncology has a major presence in cancer treatment. Its affiliated practices include 875 physicians who practice at 470 sites in 32 states. Estimates are that U.S. Oncology provides care to about 15% of the nation's new cancer cases each year.

Big Money Chases Oncology

For the laboratory industry, this is one more billion-dollar play in oncology. As detailed in the last issue of THE DARK REPORT, transactions involving laboratory companies with a significant presence in oncology diagnostics attracted $1.65 billion of investment capital during the past 14 months. *(See TDR, March 15, 2004.)*

Welsh Carson's acquisition of U.S. Oncology should interest laboratory administrators and pathologists for another reason. Welsh Carson, a private equity firm, has sizeable investments in **Lab*One*, Inc.** of Lenexa, Kansas and owns **AmeriPath, Inc.**, headquartered in Riviera Beach, Florida. It obviously sees a profitable future in laboratory medicine and diagnostic testing services.

Because Welsh Carson owns Ameripath and is now buying U.S. Oncology, one logical conclusion is that it sees potential synergy. That's because AmeriPath has anatomic pathology capabilities essential to the diagnosis and treatment of cancer. On paper, these capabilities perfectly match the clinical needs of U.S. Oncology's physicians.

However, executives familiar with Welsh Carson's involvement in Lab*One* and AmeriPath tell THE DARK REPORT that it is unlikely that any close synergy will develop between AmeriPath and U.S. Oncology. That's because Welsh Carson views each company as a stand-alone investment.

What is notable about the acquisition of U.S. Oncology is that it provides one more example of the close attention Wall Street is paying to the oncology marketplace. Anatomic pathologists should take notice of this fact and prepare for more intense competition. TDR

Dark Index

AmeriPath Reports on 2003, Its First Year as a Private Firm

Company reports that Quest is internalizing anatomic pathology contracts at a steady rate

WILL BUSINESS BE BETTER for **AmeriPath, Inc.** as a private company than it was as a publicly-traded firm? Its 2003 financial report indicates some interesting challenges, many common to all laboratories.

First, a look at basic numbers. AmeriPath's net revenues grew from $478.8 million in 2002 to $485.0 million in 2003. That's a growth rate of less than 1%. Net income for 2003 was $5.4 million compared to net income of $44.6 million in 2002. The company attributed the decline in net income to higher interest expenses, merger-related expenses, and restructuring costs,

Many of the challenges facing AmeriPath are common to the laboratory industry at large. From labor shortages to managed care contracts, a variety of issues are impacting the company's operations.

Managed Care Contracts

One challenge is access to managed care patients. As it acquired anatomic pathology practices, AmeriPath also became owner of the managed care contracts held by these group practices. In a number of cases, pathology groups were doing sub-contract work for national laboratories like **Quest Diagnostics Incorporated** and **Laboratory Corporation of America.**

As clients and regular readers of THE DARK REPORT know, in recent years Quest Diagnostics has steadily internalized anatomic pathology (AP) work it formerly contracted out to local anatomic pathology groups. Because AmeriPath held a substantial number of these subcontracts, it has lost a significant chunk of revenue.

In 2003, AmeriPath reports it was paid $3.3 million for its Quest work. That is a decline of 85.4% from 2002, when AmeriPath's revenues from Quest contracts totaled $23.3. million. That shows the speed with which Quest Diagnostics is building its AP capacity.

Significant Volume

As an aside, it is worth noting this fact. Whenever Quest Diagnostics (or LabCorp) internalizes revenue like this, it is included in the net revenue growth calculations. In 2003, Quest Diagnostics also internalized much of the send-out testing formerly referred by **Unilab Corporation** to **Specialty Laboratories, Inc.** Specialty has acknowledged that the Unilab testing represented about $17 million per year in business. Add that to the $20 million Quest picked up by internalizing work formerly done by AmeriPath, and the numbers get significant for Quest during 2003.

Shortages of trained technical labor are a concern at AmeriPath. In a financial filing, it stated that "in many markets, because of competition for techni-

cians, periodic salary increases and retention bonuses have been necessary to retain and attract employees." Just in the area of histology, AmeriPath states that its costs increased by 18.4% between 2001 and 2002.

Bidding For Scarce Labor

Hospital laboratories and pathology group practices should take notice of this fact. As a for-profit corporation, AmeriPath will bid as aggressively as necessary to attract labor. If it can't do the work, it can't generate the revenue. Thus, AmeriPath is a major factor in establishing the level of salaries and benefits for technical labor in many markets. Because hospitals are not as market-responsive, their compensation packages will probably lag behind those of the national laboratory companies.

AmeriPath similarly acknowledges the challenges in maintaining adequate numbers of pathologists, particularly those with subspecialty expertise. It doesn't discuss the specifics of pathologist compensation, but it does provide some statistics for pathologist turnover.

As of December 31, 2003, AmeriPath employed 408 pathologists. AmeriPath states that, for the years 2001, 2002, and 2003, the turnover rate for pathologists in the company was 10.0%, 8.8%, and 13.3%, respectively. The number of pathologists turning over in each of those same years was approximately 40, 35, and 53, respectively. As a result, in the past three years, about 128 of AmeriPath's 400 pathologists have left the company.

Pathologist Turnover

The financial impact of this should not be underestimated. Replacing each pathology generates substantial expenses. First, there is the cost of recruiting and any headhunter fees. The second source of additional costs involve relocation, signing bonuses, and similar up-front concessions.

Third, and most importantly for the AmeriPath business model, the incoming pathologist will probably have a higher salary than his/her predecessor. A large number of AmeriPath pathologists became employees of the company when their group practice was acquired. Often, as part of the generous acquisition price, pathologists from the acquired group agreed to work at a compensation package reduced from the amount they earned as partners in a private practice.

Whenever these pathologists decide to leave AmeriPath, the pathologist hired as a replacement may need to be paid more compensation. Unlike the departing pathologist, who has a financial nest egg from his or her share of the group's purchase price, the incoming pathologist wants to be paid at a competitive market rate. Thus, pathologist turnover will tend to raise AmeriPath's existing cost to do business.

Allowances For Bad Debt

One additional challenge AmeriPath must address is bad debt and contractual allowances. In its 2003 financial report, AmeriPath indicates that, under new ownership, it changed its estimates of contractual allowances "resulting from the analysis of our managed care contracts."

Based on this analysis, AmeriPath increased its reserves by $4.5 million. One reason for this increase in reserves may be that AmeriPath's new owners are taking a conservative position and using this year to write down as many items as possible. Then, in subsequent years, if the company performs better than estimated, its profit margins will be greater.

Finally, anatomic pathologists will want to know whether AmeriPath is buying pathology practices. For 2003, the company acquired four anatomic pathology group practices. That compares to seven acquisitions in 2002 and just one acquisition in 2001. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's a new national lab company ready to compete. This week **American Esoterix Laboratories, Inc.** (AEL) announced it was open and ready for business. Based in Brentwood, Tennessee, it has already completed two lab acquistions (**ThromboCare Laboratories** and **Viral Diagnostics, Inc.**, both in the Dallas, Texas area). Chairman and CEO is Brian Carr. President and CEO is Jim Billington. AEL received $70 million of equity funding from private equity firm **ABS Capital Partners**. Look for extensive information on AEL in April 26 issue of THE DARK REPORT.

Esoterix, Inc. has a new Chief Financial Officer. Frank J. Spina is assuming duties as Executive Vice President and CFO for the Austin, Texas-based lab services company. Spina was formerly CFO at **Specialty Laboratories, Inc.**, where he helped Specialty prepare for its IPO (initial public offering) four years ago. Spina's arrival might be a sign that Esoterix is taking active steps to prepare itself for an IPO within a year or two.

EMPLOYERS DEVELOP "DOCTOR SCORECARDS" AS QUALITY MEASURE

Within 24 months, large employers may be able to purchase healthcare from physicians using "Care Focused Purchasing." Development work is already under way to create "scorecards" that would allow employees to select physicians based on cost-effectiveness and quality measures. At least 28 large employers, with two million employees among them, are driving this effort. The companies include **BellSouth Corp.**, **J.C. Penny Co.**, **Morgan Stanley**, **Sprint Corp.**, **Lowe's Cos.**, and others.

ADD TO: Scorecards

With the help of **Mercer Human Resource Consulting**, the companies want to use claims and pharmacy data provided by their insurers to create a rating system which is "quantitative and unassailable." The format would resemble the type of ratings (stars or points) used in consumer publications like the *Zagat Guide*. "We have an obligation to give our employees more information. We can't just say, 'You are responsible for your health care, now go at it," stated Sharon Leight, Benefits Manager at J.C. Penny. Employers want the doctor "scorecard" to eventually spur higher quality, reduce inconsistencies in care, and help clinicians provide recommended care in a more consistent fashion. Since pathologists don't see patients directly, it will be interesting to see what types of quality measures are eventually developed for clinical pathology and anatom -ic pathology.

Pathologists fighting to retain compensation for Part A professional services will want to read the March 2004 issue of *CAP Today*. Attorney Jack R. Beirig of Chicago-based **Sidley Austin Brown & Wood** has authored a story called "Spirit of the Law: The Little-Known History of Part A Payments—and Why They Belong to You!" In one of the finest analyses done on this subject, Beirig provides a step-by-step history of Part A payments. He includes references from Medicare going back as far as 1980. Kudos to *CAP Today* for helping document the legal foundations for Part A pathology compensation.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 26, 2004.

PREVIEW #6

EXECUTIVE WAR COLLEGE

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UPCOMING...

- ***Birth of a New National Lab: First Look Inside "American Esoteric Laboratories."***
- ***Update on the Unfolding Story about HIV and HCV Testing that Went Wrong in a Maryland Hospital Laboratory.***
- ***ASCP's new "Technologist in Molecular Pathology" Certification: Market Demand Grows for Different Med Tech Skills.***

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