Volume XV, Number 3 Monday, March 3, 2008

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Citizens Taking on the Government

IT WAS P.J. O'ROURKE WHO SAID THAT "giving money and power to government is like giving whiskey and car keys to teenage boys." I think of that quote when I ponder the Medicare Laboratory Competitive Demonstration Project and the twisted reasoning of the faceless bureaucrats at the **Centers for Medicare & Medicaid Services** (CMS) who created this byzantine scheme.

P.J. O'Rourke is one our nation's foremost political satirists. He is currently the H. L. Mencken Research Fellow at the **Cato Institute** and regularly contributes to *The Atlantic Monthly*. Some of our erudite readers will likely recall that, in his day, H. L. Mencken was an acerbic commentator on government and culture in the United States. So, O'Rourke's observation above is in keeping with a long American tradition of pointing out the nonsensical and often counterproductive actions that regularly emerge from our government.

The Medicare Laboratory Competitive Bidding Demonstration Project certainly meets that description. It is a bad idea made worse by a bureaucracy that has an agenda which directly conflicts with the needs of the patients that the Medicare program is chartered to serve. As designed, the bidding demonstration violates the spirit of the laws that called it into life. Further, recent court documents filed in the lawsuit by the three San Diego laboratories attempting to get a federal judge to review this demonstration project are laying open to public scrutiny the willingness of federal officials to ride roughshod over the law.

To read these documents, informed by an understanding of the design of the competitive bidding demo, is to see, firsthand, the exercise of power, with little respect to the full constitutional rights of the healthcare providers to be affected by the demonstration project, nor the negative effects likely to be foisted upon those Medicare beneficiaries in the San Diego area who will be denied their choice of laboratory.

That is why the lawsuit filed in federal court by **Sharp HealthCare**, **Scripps Health**, and **Internist Laboratory** is a worthwhile step by the laboratory profession. Too often, it is only through the courts that citizens and private companies are able to constrain government power. As the public documents in this court case now reveal, Medicare officials overstepped their bounds. Now it is up to a federal judge to study the law and make a ruling. Whatever the outcome, it was important for the laboratory profession to take this step and serve notice to CMS officials that they should carefully follow the law. TDR

Judge Rules Against Labs In Medicare Lab Bid Case

Three San Diego Labs lose round one and come out swinging at the start of round two

CEO SUMMARY: On February 14, Federal District Judge Thomas J. Whelan denied the request for a temporary restraining order (TRO) by three San Diego labs that would have stopped the Medicare Laboratory Competitive Bidding Demonstration pilot project until several legal challenges were adjudicated. It is believed that CMS received bid applications from an unknown number of laboratories by the February 15 deadline. Now round two in this federal lawsuit is about to get under way.

SCORE ROUND ONE for the federal government in the federal lawsuit filed by three San Diego laboratories seeking an injunction to prevent the Medicare Laboratory Competitive Bidding Demonstration pilot project from going forward.

On February 14, Federal District Court Judge Thomas J. Whelan issued an order denying the request by **Sharp HealthCare**, **Scripps Health**, and **Internist Laboratory** for a temporary restraining order (TRO) to stop the the Medicare Lab bidding demonstration from going forward until certain legal issues are resolved. In requesting the TRO last month, the three labs challenged the procedural steps used to implement the bidding demo project by **Department of Health and Human Services** (HHS) Secretary Michael Leavitt.

Because the judge ruled against the three laboratories, the Medicare lab competitive demonstration pilot went forward as announced. The next day, February 15, was the deadline for the submission of bids by those laboratories meeting the criteria of "eligible bidders" and wanting to participate in the demonstration pilot.

Since February 15, officials at the **Centers for Medicare & Medicaid Services** (CMS) have made no statement about the number of laboratories that submitted bids, nor the names of laboratories which submitted bids. Next on the bidding timetable is for CMS to engage bidding laboratories in a "Stage Two" round of negotiations it will use to select which laboratories will be eligible to provide lab testing and what price level will be paid to participating labs over the three

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

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

year period of the demonstration pilot in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area). If CMS sticks to its timetable, it will announce the labs selected to participate in the bidding demonstration pilot on April 11, 2008. Implementation of the competitive bidding demonstration pilot is scheduled to commence on July 1, 2008.

Labs' Request Denied

In his February 14 ruling, Judge Whelan denied the request for a TRO and said the plaintiff labs should explain why the case should not be dismissed. Essentially, Whelan upheld CMS' arguments in its challenge to the TRO request. In its response to the lawsuit, *CMS said the three labs had no legal standing because they could file an administrative appeal if they were not named winning bidders in the demonstration project.* (See next column on this point.)

That sets up round two in this lawsuit. Last Thursday, February 28, Attorney Patric Hooper of **Hooper Lundy & Bookman**, in Los Angeles, the law firm representing the three San Diego laboratories, filed papers in response to Judge Whelan's ruling. In this filing, Hooper Lundy argues that federal officials misrepresented legal principles and misled the court when they argued against a request for a temporary restraining order (TRO).

Pathologists and laboratory executives have watched the high-handed actions of CMS officials in recent years as they shaped the form and structure of the Medicare Laboratory Competitive Bidding Demonstration project with little meaningful input from the laboratory profession. That attitude shows in the filings by government lawyers in this case. There are legal contradictions in their arguments.

A couple of extracts from the Hooper Lundy filing hint at the government's flawed legal arguments. For example, to answer the right of the three labs to challenge aspects of the bidding demo, Hooper Lundy wrote "The Secretary well knows that 'losers' under the Demonstration Project will have no appeal rights to challenge the project's very policies that caused them and their patients to become losers. *Under the Secretary's own rules, losers are prohibited from submitting claims to Medicare altogether and have no appeal rights. [TDR emphasis.]* Moreover, there are also no appeal processes for "winners" to present the challenges presented here. Thus, the Secretary's discussion of jurisdiction is based on an entirely contrived premise."

The CMS "Catch 22" on non-winning labs being required to provide services to Medicare patients, *knowing that they will not be reimbursed*, was addressed by Hooper Lundy as follows: "As the Secretary concedes in his Opposition brief, required bidders who lose under the Demonstration Project 'may not bill Medicare directly for any of the laboratory tests involved in the project'...Nonrequired bidders who chose to bid and lose also are 'precluded from billing Medicare directly...' ...Indeed, in a February 1, 2008 release to providers, the Secretary expressly states that 'non-winner laboratories... have no appeal rights'...In fact, by telling this Court in his opposition papers that losers may simply file claims and then pursue administrative remedies, the *Secretary was not only misleading the Court but was also inviting plaintiffs and others to file claims for which they know they are not entitled to any Medicare reimbursement. The Secretary and the Department of Justice typically regard such claims as fraudulent." [TDR emphasis.]*

Citizens Fighting Back

THE DARK REPORT observes that, regardless of the power, clarity, and reason in the arguments provided by the three laboratories in this case, its outcome lies in the hands of a federal judge. It is a reminder that government power is often wielded arbitrarily and in ways that are tough for average citizens to restrain. TDR

ISO 15189 Accreditation Program Offered by CAP

ISO 15189 Accreditation remains voluntary for laboratories here in the United States

CEO SUMMARY: Two strong trends in laboratory management can be seen in the College of American Pathologists' (CAP) move to offer accreditation to ISO 15189:2007. The first trend is the movement toward quality management systems such as Lean and Six Sigma. The second trend is the global convergence of laboratory operations. Also, a growing number of countries are basing laboratory accreditation on ISO 15189, which is another reason why CAP is adding this new service.

BY ANNOUNCING A SUPPLEMENTARY NEW LABORATORY ACCREDITATION PROGRAM that incorporates the ISO 15189 quality management system for medical laboratories, the **College of American Pathologists** (CAP) is helping to move ISO 15189 closer to becoming a global standard in accreditation.

Scheduled to be available to U.S. medical labs in the fourth quarter of this year, CAP's program accredits laboratories that conform to ISO 15189:2007 from the **International Organization of Standardization** (ISO). ISO 15189:2007 uses medical lab-specific accreditation criteria, procedures, and processes to evaluate a lab's technical competence and its management system.

The accreditation to ISO 15189:2007 will be separate and distinct from the CAP Laboratory Accreditation Program (LAP) and will be done in addition to CLIA accreditation. It does not replace LAP. A laboratory that chooses to become accredited to ISO 15189:2007 will have an ISO assessment by professional assessors separate from LAP inspection.

ISO will account for quality management systems throughout the laboratory and other parts of an organization that interact with the laboratory. Any clinical lab can apply for this new accreditation.

"Laboratories accredited to the ISO 15189:2007 standard will be well positioned to rapidly respond to the changing health care environment and to demonstrate measurable quality to their customers," said pathologist Cordelia Sever, M.D., FCAP, Chair of the CAP ISO Program and Accreditation Committee. "Currently ISO 15189:2007 is a complement to what CAP offers. It is not in lieu of any CAP program and it is voluntary. The CAP LAP is a prescriptive, CLIA-based standard, whereas ISO is an international standard that is not based on CLIA (the Clinical Laboratory Improvement Act).

"ISO 15189:2007 is an internationally recognized standard, and in some countries, it is the standard by which laboratories are reimbursed," Sever added. "Although it is not currently a standard in the United States, we believe that a laboratory working to achieve best practices in quality management systems will want to be ISO 15189:2007 accredited.

"Since CAP already accredits labs in more than 40 countries, this ISO-based program supports developments internationally," Sever continued. "We recognized the importance of having an ISO-based laboratory accreditation option as we expand into Canada and into other nations. Medical laboratory accreditation is a core competency at CAP.

"CAP has extensive experience with ISO 15189," Sever noted. "Back in 2003, when the ISO 15189 standards were developed, CAP was a significant contributor. This new ISO 15189 accreditation program was developed to help reinforce ISO's goals and standards while supporting CAP's mission of advocating excellence in the practice of pathology and laboratory medicine.

Key Differences

"Here are the key differences between ISO 15189:2007 accreditation and LAP accreditation," Sever added. "Accreditation to ISO 15189:2007 is strictly voluntary in the United States. In contrast to LAP's annual cycle, the ISO accreditation follows a three-year timeline. The time it will take to attain initial accreditation to ISO depends largely on a lab's readiness, internal resources, and the laboratory's level of commitment. In the first and second years of this program, two surveillance assessments are scheduled. During the third year, a reaccreditation assessment takes place onsite."

THE DARK REPORT observes that CAP is getting involved with ISO 15189:2007 accreditation at the right time. As the lab industry becomes more global in nature, a steady convergence in the organizational structure of laboratories can be seen. ISO 15189:2007 is one factor that supports this ongoing international convergence in clinical laboratory operations. TDR

Contact Keith Pierson at CAP: 847-832-7051 or kpierso@cap.org, and Sue Masaracchia-Roberts at 847-832-7319 or srobert@cap.org.

ISO 15189 Incorporates Quality Systems for Labs

ISO 15189:2007 IS AN ACCREDITATION PROGRAM AND QUALITY MANAGEMENT SYSTEM for medical laboratories that focuses on the continuum of care directly connected with improved patient safety and risk reduction.

The ISO system outlines standards for quality and competence specific to medical laboratories. It is a road map to help clinical labs develop their quality management systems and assess their own competence. It provides guidance regarding the structure of a lab's quality management system. It integrates both preventive measures and improvement opportunities with a focus on patients. There is no tie to the federal Centers for Medicare & Medicaid Services (CMS) for reimbursement.

Any laboratory conducting medical testing such as private medical centers, hospitals, and commercial reference labs should consider applying for the accreditation program to help achieve accreditation to ISO 15189:2007.

ISO 15189:2007 uses criteria and procedures specifically developed to determine technical competence. Assessors will conduct a thorough evaluation of all factors in a laboratory that affect the production of test or calibration data. ISO 15189:2007 uses standards (best practices or benchmarks) to assess factors, including:

- Customer satisfaction and quality of care
- Quality management system
- Validity and appropriateness of test methods
- Traceability of measurements and calibration to national standards
- External services and suppliers
- Technical competence of staff
- Testing environment
- Suitability, calibration, and maintenance of test equipment
- Sampling, handling, and transportation of test items

Mich. Dermatologist Gets 10.5 Years in Fraud Case

Federal prosecutors cite five-year pattern of fraud totaling an estimated $1.9 million

CEO SUMMARY: In a federal case involving billing improprieties and insurance fraud, a federal judge sentenced Michigan dermatologist Robert W. Stokes, M.D., to 126 months in prison and ordered him to pay $178,100 in fines and assessments, with the amount of restitution yet to be determined. Stokes was tried in federal court last April facing 73 counts, including 38 counts of fraud relating to marking up anatomic pathology services that he did not perform, but which he presumably purchased from a third party.

"DOCTOR SENTENCED to hard time for health care fraud scheme." That was the headline on the day in December when the U.S. Attorney's office announced the sentence of dermatologist Robert W. Stokes, M.D., of Grand Rapids, Michigan, in a federal case of healthcare billing fraud.

This sentence is the latest development in the Stokes case, a federal case first revealed to the pathology and laboratory industry last year by THE DARK REPORT. This case is notable because the federal attorney had indicted Stokes in April 2006 on 73 counts of violating federal health laws. What made this significant for the laboratory industry (and for physicians who mark up purchased pathology and laboratory tests when billing private payers) was that 38 of these counts involved fraud in how Stokes billed for lab tests in claims submitted to **Blue Cross Blue Shield of Michigan**, **Aetna**, and **TriCare**. *(See TDR, August 27, 2007.)*

This is an extraordinary event in pathology and laboratory compliance. First, the U.S. Attorney from the Western District of Michigan was both willing to prosecute a physician for fraudulently billing purchased anatomic pathology services. Second, the U.S. Attorney successfully convinced a grand jury to return a bill of indictment on 31 counts of laboratory test billing fraud. Both of these developments should not go unnoticed by pathology and laboratory providers, their physician customers in states that allow physicians to mark up purchased pathology and laboratory services when billing private payers, and the attorneys who advise them.

Convicted On 31 Counts

Following a weeklong trial, on April 27, 2007, Stokes was convicted on 31 counts, each count involving fraud in how Stokes upcoded dermatology procedures and filled claims for his professional services. Through communications with the U.S. Attorney's office and conversations with several individuals who had involvement in the Stokes case, THE DARK REPORT learned what happened to the 38 counts of lab billing fraud.

Early in the trial, the federal attorney altered his original strategy. He recognized

that he had a compelling and relatively easy case to convince the jury of Stokes' guilt in the counts relating to upcoding and false claims for dermatology procedures. That was not the situation with the counts involving Stoke's alleged fraudulent billing of insurers for anatomic pathology services that he did not perform. The federal attorney decided that presenting the complex details of laboratory billing fraud was likely to distract—if not outright confuse—the jury.

No Jury Ruling On Lab Counts

For that reason, the federal attorney chose not to pursue the 38 counts of anatomic pathology billing fraud at the trial. Thus, the jury never heard the evidence relating to these indictments nor did it rule on Stokes' guilt or innocence relating to those 38 counts of pathology billing fraud.

"As I understand the facts, the U.S. attorney's strategy at trial makes sense," said Jane Pine Wood, attorney at **McDonald Hopkins**, a law firm based in Cleveland, Ohio. "On the counts of upcoding and wrongful coding for dermatology services, he probably believed that he had a clear, easy-to-understand case with compelling evidence. Proof of that is the jury's decision to convict Stokes on 31 of those 35 counts.

"However, because of the complexities of billing for purchased pathology services, the lack of prior case law on billing for such services, and the need to present lots of detailed procedural evidence to convince the jury to convict Stokes on the pathology billing fraud charges, it should be no surprise that the federal attorney decided to not pursue those specific 38 counts at trial," explained Wood. "He went after the low-hanging fruit and let go of the pathology billing fraud counts so as not to confuse or distract the jury.

"Since the federal attorney persuaded the jury to convict Stokes on 31 of 37 counts of fraudulent upcoding and filling fraudulent claims, I would say the federal attorney made the right decision," she continued. "Not only did he convince the jury to convict Stokes, but the federal judge was also convinced and sentenced Stokes to an unusually stiff sentence of more than 10 years in jail! That's another sign that Stokes' actions were egregious."

Stokes was sentenced on December 27, 2007, to 126 months (10.5 years) in prison and ordered to pay $175,000 in fines and pay $3,100 in special assessments. In addition, he was ordered to serve 36 months of supervised release upon completion of his prison term. The amount of restitution is to be determined later this spring and will be based on an estimated $1.9 million that was fraudulently paid to Stokes.

After initially indicating THE DARK REPORT that it would make an official available to discuss the specifics of the Stokes case involving the 38 counts of billing fraud for the purchased pathology services, once Stokes was sentenced, the U.S. Attorney's Office has yet to make good on that promise. That means THE DARK REPORT has not been able to get more specifics about how Stokes violated the billing statue involving marking up laboratory tests, what evidence was used to obtain the federal indictments, and what legal principles supported this aspect of the Stokes case.

Nonetheless, the Stokes case should become part of the legal compliance program for all pathology and laboratory providers and all physicians marking up purchased pathology and laboratory services. It shows that federal prosecutors will bring a criminal case against a physician for inappropriately marking up such purchased services.

Indicted For Lab Billing Fraud

That's precisely what happened to Stokes in this case. The prosecutor, U.S. Attorney Charles R. Gross of the U.S. Attorney's office for the Western District of Michigan, in Grand Rapids, filed 38 charges of lab billing fraud along with 35

other charges of billing fraud. Stokes was indicted in April 2006 on a total of 73 charges of various types of billing fraud. The evidence against Stokes was voluminous and the case showed that the dermatologist's behavior was egregious. Along with billing fraud and performing procedures not medically necessary, federal prosecutors showed that Stokes did not sterilize his surgical instruments and regularly reused sutures and other single-use disposable medical equipment.

Although the federal attorneys who brought this case to trial have yet to provide a more detailed explanation about how and why Stokes' actions violated federal laws on filing false claims for purchased pathology services and marking up for pathology services he did not perform, there are still important compliance lessons to be drawn from this case.

"None of this should distract from the primary lesson here," warned Wood. "Physicians involved in billing for purchased pathology and laboratory services want to avoid the indictment itself! This case is a warning to physicians and laboratories that U.S. attorneys may consider billing for purchased services as a violation of federal or state law. This may signal a more strict interpretation of existing rules for billing for purchased services."

Wood also calls attention to another important point. "These indictments were under United States Code 1347, which is for obtaining money under false pretenses," she noted. "USC 1347 is the general health care fraud statute that the government uses in such cases. This statute includes violations involving upcoding, miscoding, and filing claims for services not rendered.

"It is disappointing that the federal attorney is not willing to talk to the pathology and laboratory providers and physicians about the pathology billing elements in this case," added Wood. "However, that does not alter the essential message, that a federal prosecutor was willing to indict a physician for marking up purchased services. And, it is important to note that these counts were not dismissed. To the contrary, it's just that they were not pursued." TDR

Contact Jane Pine Wood at 508-385-5227 or at jwood@mcdonaldhopkins.com.

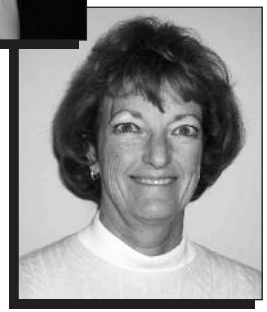
Stokes Regularly Billed Services Not Performed

FEDERAL PROSECUTORS BUILT THEIR CASE against dermatologist Robert W. Stokes, M.D., by demonstrating a pattern of fraud over five years. The case is important to pathologists, lab directors, and physicians who mark up laboratory tests they bill to payers because it shows that a federal prosecutor is willing to indict a physician for fraudulently marking up and billing for tests he/she did not perform.

Court records show that Stokes executed his scheme by billing Blue Cross Blue Shield of Michigan (BCBSM), Aetna, and Tricare for laboratory services that he did not render. "In order to receive reimbursement for a service, a participating provider, such as Stokes, must certify that he personally performed the service and that the service was performed at this office," the records show. "Stokes routinely billed BCBSM, Aetna, and Tricare for laboratory services that were rendered by independent outside laboratory facilities and then billed to Stokes. Moreover, Stokes not only billed for the services that he did not perform, but he inflated the cost of the services by adding a 'mark up' to his costs."

However, because the U.S. Attorney's office that prosecuted the Stokes case has declined to discuss the indictment counts dealing with fraudulent billing for laboratory services, THE DARK REPORT is unable to provide further understanding and guidance to the laboratory industry. Thus, a very important opportunity to further improve compliance with federal healthcare laws has been lost to the laboratory testing profession.

Matt Dixon



Jane Newhall, MT

NEWSMAKERS INTERVIEW

Hospitals Saw Several Benefits In Forming Laboratory Joint Venture

"We expect our lab venture with PAML will help us realize several goals. By expanding the number of physicians utilizing our lab, not only will we enjoy more specimen volume and greater revenues, but the laboratory relationship also gives us the opportunity to encourage these same doctors to refer more patients to our other hospital services."

—Matt Dixon, *COO, St. Mark's Hospital, MountainStar Healthcare Network*

CEO SUMMARY: For the past eight years, growing numbers of hospitals and health systems have launched laboratory outreach programs. Hospital CEOs are recognizing that laboratory outreach programs generate worthwhile operational gains, along with steadily-increasing revenues. However, laboratory outreach programs also require a significant capital investment, because the hospital laboratory needs to match the service levels of other laboratory competitors in the community. At MountainStar Healthcare Network in Salt Lake City, Utah, senior hospital administrators decided on a business strategy of partnering with Pathology Associates Medical Laboratories (PAML) of Spokane, Washington. PAML would bring the necessary capital and management expertise to the laboratory joint venture. MountainStar would provide the laboratory testing resources.

FOR MORE THAN 25 YEARS, the overwhelming majority of hospital CEOs and administrators have proven decidedly resistant to the concept of laboratory joint ventures involving their hospital laboratories and outside lab companies.

Among the nation's 4,800 hospitals, examples of a laboratory testing joint venture involving a hospital laboratory and an independent lab company are scarcer to find than the proverbial "hen's teeth." Despite the excellent service and financial performance sustained by a handful of successful laboratory joint ventures, it is a business opportunity that hospital CEOs and their administrators are reluctant to embrace.

That's why the recent decision to launch a laboratory joint venture by leaders at two of the hospitals in the **MountainStar Healthcare Network** in Salt Lake City, Utah, deserves closer study and understanding. MountainStar is an eight-hospital health system owned by **Hospital Corporation of America** (HCA), of Brentwood, Tennessee.

Called **MountainStar Clinical Laboratories LLC**, the new laboratory joint venture consists of the labs of 297-bed **St. Mark's Hospital** of Salt Lake City, Utah, and 116-bed **Lakeview Hospital** of Bountiful, Utah, in partnership with **Pathology Associates Medical Laboratory, Inc.** (PAML) of Spokane, Washington. In the interview that follows, hospital administrators from MountainStar discuss how they evaluated the opportunity and why they supported the creation of the laboratory joint venture. This complements an earlier interview that THE DARK REPORT conducted with executives from PAML about the joint venture. *(See TDR, December 10, 2007.)*

Participating in the interview from St. Mark's Hospital were Matt Dixon, Chief Operating Officer, and Jane Newhall, M.T., Director of Laboratory Services.

EDITOR: What was it about a laboratory joint venture that caught your attention back in 2003? Also, what triggered the momentum that sustained the joint venture concept through a proposal and into a working venture?

DIXON: Initially, we saw two significant opportunities. First, we recognized that a growing outreach program would feed steady increases in specimens to our clinical laboratories. Obviously, that had the potential to generate economies of scale, particularly because our lab instruments could be used more productively.

EDITOR: Was the fact that this increased outreach volume would lead to a lower average cost per test for both inpatient and outreach tests considered to be a direct benefit?

DIXON: Yes. Further, we knew our lab had excess capacity and our instruments were available to handle the outreach testing as it came in later in the day and in the evenings. Second, we knew that the outreach volume would translate into increased earnings. Both of those factors made the laboratory joint venture an attractive proposition.

EDITOR: Were there any other important factors that helped in this decision?

DIXON: One other big opportunity helped sell the deal and it was probably just as important as the direct financial advantages. This other

opportunity was the chance for the hospital to sustain and improve physician relations and to have a presence with those physicians in their offices that we did not have at the time. We did not have a dynamic outreach program and so were losing out on the opportunity to have that daily relationship and establish electronic links into the physicians' offices.

EDITOR: It is widely recognized among hospital lab directors that the outreach lab program is usually the hospital's first clinical service to establish these electronic ordering and reporting bridges, and the daily relationship the lab has with office-based physicians strengthens the relationship the physicians have with the hospital.

DIXON: We agree with that point. In our area, the national lab companies have used connectivity as a competitive edge. We knew our hospital would have to do better. Plus, we knew that we could not develop a state-of-the art informatics and connectivity solution on our own. We placed significant value on PAML's connectivity services to physicians' offices.

EDITOR: Is another primary goal in this joint venture is to use the outreach lab program as a bridgehead to build stronger relationship with physicians?

DIXON: Yes. We believe the joint venture will help us achieve this in several ways. For example, the joint venture's sales reps will be gathering intelligence on what the physicians need and we want to react in ways that meet those needs. As physicians look at our hospital, it is easier for them and their patients if they have a one-stop shop. That eliminates the cost and confusion of attempting to coordinate patient care across four or five different entities. We want to provide all those services in a seamless fashion from one hospital. That is all part of a broader strategy that we our hospital is looking to execute. We believe a successful laboratory outreach program can support this primary business strategy.

EDITOR: This is good background for your interest in laboratory outreach. Describe how you evaluated the laboratory joint venture proposal.

DIXON: Well, we see two opportunities in lab outreach. One, we have 600 physicians on staff. We serve their inpatients very well. The real growth opportunity is to expand our laboratory outreach services to those 600 physicians' offices and to physicians who are not affiliated with our hospital. The new lab joint venture is focused on these two opportunities.

EDITOR: Besides the income generated by the lab outreach program, is the hospital's more global strategy to use the laboratory to build inpatient admissions?

DIXON: Definitely. We want these physicians to see our hospital as a partner for their needs. If our lab serves them effectively and efficiently, it makes them confident that they can refer their patients to our hospital. We want to leverage that relationship with our lab to generate more outpatient referrals and inpatient admissions. This is one way our lab outreach program can benefit other areas of our hospital.

EDITOR: As you describe this, it sounds like you were wrestling with a fundamental decision, should you build the outreach program by yourself, or should you ally with a partner, like PAML, who can contribute capital and expertise?

DIXON: That hits the nail on the head. However, this decision included one more dimension, because our hospital is owned by **Hospital Corporation of America** (HCA), of Brentwood, Tennessee. HCA is a large company and owns more than 160 hospitals nationwide. At any one time, there are numerous projects competing for resources at the corporate level. When PAML approached us in 2003, many of the issues associated with a laboratory joint venture had to be addressed at the corporate level. As you can imagine, it is difficult at the hospital level in our company

to simply say, "Let's go out and develop a lab interface that we can use to link with a physician-office EMR." If that's our goal, it has to be proposed to corporate and reviewed. Corporate must determine whether they want to fund it, which requires time since our request for resources is jostling for attention with other important initiatives and priorities that HCA is pursuing.

EDITOR: This is interesting, because many of our readers know that HCA is a for-profit company. Thus, how and why they favorably reviewed this laboratory joint venture will be of high interest.

Matt Dixon

➤"We want to leverage that relationship with our laboratory to generate more outpatient referrals and inpatient admissions."

DIXON: That is true, because, as your readers know, labs don't always get a lot of attention, since clinical laboratories lack much visibility within a hospital. For lack of a better word, it's not as sexy as some other services we offer, such as outpatient imaging or the ambulatory surgery center.

EDITOR: So what made the difference at HCA corporate?

DIXON: Administrators here realized that PAML was offering an opportunity for St. Mark's to address several challenges it had in its local market. These included an existing outreach program that had the potential to produce much more, plus the lack of a connectivity solution for office-based physicians.

EDITOR: What was attractive about PAML's laboratory joint venture proposal?

DIXON: PAML has a track record in building outreach business, as demonstrated with other hospitals in other places. In many ways, PAML was offering to help us address some of our own weaknesses. We already had in-house lab testing facilities that have turnaround times that can't be beat. We already had the equipment and we are a well established hospital with a long history of more than 130 years in Salt Lake City. PAML offered to give us some of those missing pieces, among which is the ability to interface with the physician office EMRs. And PAML already had effective systems to handle the couriers, the ordering, and the logistics. In effect, PAML had all the ingredients to energize our laboratory outreach program and help it achieve a much higher level of success.

EDITOR: Having recognized the potential benefits from a laboratory joint venture, what were the next steps in selling this idea up the line to HCA?

DIXON:: At that point, we needed to introduce the idea to the different departments. PAML had developed the concept of the lab joint venture and it did pro forma financials about our current market. So, we took the financial pro forma and business concept to a number of corporate departments for their review. The goal was to ensure that the laboratory joint venture structure was sound and legal. We also had to introduce it to our billing and compliance departments to make sure that we could operate within the design of the joint venture.

EDITOR: Was this a complicated process?

DIXON: No, rather, it was a healthy give-and-take. HCA has smart, experienced, and well-qualified individuals in these departments. As we described how we intended to make the joint venture work—from an operations point of view—the idea was met with a healthy dose of skepticism. As questions were answered and due diligence took place, it was seen that the laboratory joint venture was a good idea. It was also recognized that the upside benefits from capturing more business in our market far outweighed the downside risks.

EDITOR: What other elements helped in this evaluation process?

DIXON: Another important factor in helping to sell this idea to corporate was PAML's experience with hospital laboratory joint ventures. PAML's history of having done this in multiple markets and having a track record of success adds to the argument that this venture would succeed. We visited several of the other joint ventures that PAML developed to see their operations and get a feel for what to expect going forward. That certainly helped in getting the approval from corporate.

EDITOR: Changing course, who were the internal champions of the idea at St. Mark's and what specific benefits did they recognize that kept the proposal moving toward implementation within HCA?

Jane Newhall, M.T.

➤"PAML was looking for a joint venture partner and they were going to find one in Salt Lake City. My biggest concern was that, if we did not join with them, they would become another competitor. "

DIXON: Our laboratory director, Jane Newhall, championed it from start to finish. She was integral in keeping it in front of everyone. About two years ago, I joined St. Mark's as Chief Operating Officer. Along with other members of our administrative team, we took the time to study the laboratory joint venture proposal and understand its upsides and downsides. Throughout this time, Jane, as the director of our laboratory, did a very good job of explaining the strengths of the idea and pitching it to us as we went through our skepticism and did our due diligence. So, she should be the one who addresses that issue.

NEWHALL: Basically, from start to finish, from when PAML first approached us about four years ago, it was a matter of explaining it to everyone who was involved. We started discussing the possibilities of the lab JV with our previous administration before they moved the proposal to the division level. That was to our benefit, because then we had people at the division level who understood the issue and this understanding helped us in the long run. When Matt came on board, it was my job to push it from the lab standpoint. HCA has furnished our lab with top of the line equipment, including dual analyzers in every department. So we had analyzers with plenty of capacity that were not being fully used. Utilizing this capacity was another reason we found the lab joint venture to be advantageous.

EDITORS: Did any other factor play a role in these decisions?

NEWHALL: We also recognized that PAML had the marketing and sales capability to more than double the specimen volume that we have now. We can accommodate those specimens without adding people because of the equipment in our fully automated lab. When you look at it from that perspective, it makes perfect sense. We said, "Let's get these machines running at full capacity and make them pay for themselves." In the lab business, the more work I do, the less it costs.

EDITOR: How did St. Mark's view its ability to compete against other labs?

NEWHALL: That question needs to be answered in two ways. On one hand, the Salt Lake Valley is a unique market and I was concerned about our ability to compete against **Quest Diagnostics** and **LabCorp**. They have a strong presence here. On the other hand, we recognized that PAML, which had recently acquired a lab in Salt Lake City, is an extremely aggressive company in a good way.

EDITOR: Explain that, please.

NEWHALL: PAML was looking for a joint venture partner and they were going to find one in Salt Lake City. My biggest concern was that, if we did not join with them, they would become another competitor. So, if

you look at it realistically, that means we really would have had three competitors: Quest Diagnostics, LabCorp, and PAML.

EDITOR: I can see how this assessment of the competitive balance in the Salt Lake Valley would encourage further discussions with PAML.

NEWHALL: Certainly. I like to say that, "It's important to keep your friends close and your enemies closer!" Not that PAML is our enemy, but we knew they could easily be our competitor and we would rather have them on our side. We decided early on that we didn't want to let them partner with any other hospital in our region. But that was not the major consideration.

EDITOR: What other elements came into play?

NEWHALL: We recognized from the start that PAML offered us an opportunity to work with people who could contribute operational and strategic business services in lab outreach that we could not provide on our own, as Matt explained earlier. In fact, from the time Matt joined St. Mark's, he recognized the advantages of the proposed laboratory joint venture and was dedicated to the cause. He was constantly in front of corporate pushing this project forward. Plus, at the corporate level, his credibility and commitment helped to bring this business concept to fruition.

EDITOR: We understand that St. Mark's had done its own studies about the lab outreach market. How did these internal studies influence the evaluation of the proposed joint venture?

NEWHALL: We knew from the PAML projections that we would see increases in our lab testing volume and the St. Mark's laboratory could accommodate that increased work without adding to staff or adding equipment. In fact, we already had first-hand experience with PAML's ability to sell its lab testing services in a new market.

EDITOR: Had you done referral testing for them?

NEWHALL: Yes. For two years previously, under a separate agreement, PAML had contracted with St. Mark's to do all of its microbiology testing for PAML. When this micro arrangement first started, we processed roughly 20 specimens a night. Over the past two years, that number grew to about 100 specimens. That's a five-fold increase just in microbiology! For our laboratory joint venture, the projections are that our main lab, meaning chemistry and hematology, coag, and urinalysis, will see a 50% increase from current volume.

EDITOR: With increased test volume comes the ability to expand the in-house test menu and improve turnaround time. Did St. Mark's recognize this as a benefit in the joint venture?

NEWHALL: The answer is yes. The agreement allows us to regularly determine whether it makes sense to set up tests in-house rather than sending them out. This is another big advantage. Not only can we increase our volume, but we can also increase our in-house menu of tests. That is positive for physicians and patient care because, when we do tests in-house, we deliver faster turnaround time for results and have greater control over the tests.

DIXON: To put the issue into context, as we worked with PAML to put this deal together, several market studies were done on lab volumes and where the lab volumes were going. In the immediate vicinity of St. Mark's Hospital, meaning the five blocks surrounding the hospital, we hold about a 20% market share of the outreach volume. But within this five-block area, many of those medical office buildings are physically attached to the hospital and that's significant. Few physicians in those five blocks have to walk outside and cross the street to get to our hospital. Their office building is physically connected to our hospital.

EDITOR: That's quite a built-in marketing advantage for your hospital laboratory outreach program.

NEWHALL: That's why we believe it is a reasonable goal to capture 80% to 90% of the market share from this medical campus. It gives us lots of confidence that, over the next five years, this joint venture is going to be a big win for us.

EDITOR: Could you speak to the general benefits identified by St. Mark's that would result from this laboratory joint venture?

NEWHALL: On the revenue side, this laboratory joint venture will make a significant contribution that will increase as our market share expands. From an efficiency standpoint, there will be significant improvements. One, the lab will enjoy continuous increases in economies of scale because we will get more from our fixed investments in assets such as analyzers and lab equipment. Two, it will make lab labor more productive. Together, these two items will contribute to reducing the cost of laboratory services, on a per patient basis.

EDITOR: Strategically, I've picked up that the decision to develop the laboratory joint venture also stems from a general willingness of St. Mark's and HCA to use market-driven opportunities to move forward.

DIXON: We believe that to be true. For example the business model developed by PAML is one that involves using healthcare dollars in a responsible way. When you consider some of the macro concerns of the healthcare system—such as the cost of care and how to increase efficiencies in the system—collaborations like this are what the healthcare system needs. These are the types of market-based solutions that can help control the rising cost of care while helping to achieve improved outcomes for patients.

EDITOR: Please continue.

DIXON: As health care administrators, we all have to ask ourselves, is there a need for us to invest in infrastructure and then for PAML to invest in very similar infrastructure, only to have both of use operate at only half capacity? If we can come together avoid duplicate investments, and put these fixed dollars in the system, then we can work together to do what we are both good at. In that way, we will be spending our healthcare dollars more wisely.

EDITOR: That leads to the last question. How do you think HCA corporate will evaluate the success of this laboratory joint venture? Will the success of this laboratory joint venture motivate them to consider the business concept for other HCA hospitals?

DIXON: That is very much a possibility and, of course, it is contingent on how we execute it here in our market. But, clearly we have blazed the trail with the legal, regulatory, compliance, and billing issues that we have resolved with PAML. So, for HCA to do this in another market should be a lot easier. It is possible that if the venture succeeds and generates the earnings that we anticipate in terms of physician relations, then this could be scaled to other HCA hospitals, absolutely.

NEWHALL: And I would add one other comment. The mission statement of the hospital is to provide care for patients in harmony with our long tradition of quality and caring and compassion. To me, it is a big benefit for our patients when their laboratory testing is performed here in our laboratory and not sent hundreds or thousands of miles away. By allowing us to expand and improve our laboratory services, this joint venture will help us further the long-standing mission of our hospital.

EDITOR: Thanks for sharing the process by which you evaluated this laboratory joint venture. It will help other hospital administrators rethink and reassess their strategies for using laboratory services to advance patient care.

NEWHALL: Thank you! On behalf of Matt and myself, we appreciate the opportunity to tell our story. **TDR**

Contact Jane Newhall at 801-268-7190 or jane.newhall@mountainstarhealth.com.

Market Trends

Lab/Path M&A Day Explores High Prices Paid to Lab Owners

May 15 program brings together lab buyers, lab sellers, and financial experts to discuss trends

IF YOU HAVEN'T NOTICED, there's a gold rush in diagnostics! Prices paid for clinical laboratories, anatomic pathology group practices, and *in vitro* diagnostic (IVD) companies have soared recently.

This is good news for pathologists and laboratory owners interested in putting their laboratory on the market. All the trends in laboratory testing point to a bright future and new investors are looking for ways to buy labs and participate in this market growth cycle.

To assess the current state of the merger & acquisition market for clinical laboratories and pathology group practices, THE DARK REPORT has organized a special, full-day program. It will bring together laboratory sellers with laboratory buyers.

"Mergers & Acquisitions in Pathology and Clinical Laboratories" will take place on Thursday, May 15, 2008 at the Intercontinental Hotel in Miami, Florida. It will follow the 13th annual *Executive War College on Lab and Pathology Management*, which will be conducted on May 13-14, 2008.

A Lab Industry First

"To our knowledge, this is a first in the laboratory industry. Never before has there been any attempt to invite both laboratory sellers and laboratory buyers to gather together to discuss market trends, and share the secrets of a successful acquisition," stated Robert L. Michel, Editor of THE DARK REPORT and Founder of the *Executive War College.*

"There will be more than 30 sessions during the day with as many as 50 speakers and panelists," he continued. "Lab owners who have sold their labs will share lessons learned and we've confirmed that **Laboratory Corporation of America** and **Sonic Healthcare, Ltd.** will conduct sessions on 'What Clinical Lab Buyers Want in an Acquisition Candidate.'

Buyers & Sellers Roundtable

"This is a rare opportunity for owners of laboratories and pathology group practices to network with many of the lab buyers and investors who are active in today's merger & acquisition marketplace," noted Michel. "There will also be experts in law and finance discussing how to prepare your lab for market so that it can come to market properly valued and attractive to buyers."

Another innovation will be five learning tracks tailored to the specific needs of: clinical laboratories, anatomic pathology group practices, hospital/health system lab outreach programs, specialty/niche labs, and a track for all lab owners on contract, valuation, and personnel issues. *(See full session listings on next page.)*

"Even lab owners and pathology group partners who are not ready to sell their laboratory are encouraged to attend," stated Michel. "This is the time and place to come, listen, learn, and meet the experts you will need down the line when retirement looms and you are ready to bring your laboratory to market."

(Continued on next page)

Bringing Together Lab Buyers and Lab Sellers

Mergers & Acquisitions in Pathology & Clinical Laboratories

Thursday, May 15, 2008 • Intercontinental Hotel • Miami, FL

Designed specifically to bring laboratory sellers face-to-face with laboratory buyers, it is a lab industry first. Hear from owners who successfully sold their lab or pathology group practice. Meet buyers and investors. Network with the experts in law, financial, and valuation who package laboratories and help owners come to market and negotiate a successful sale at a winning price. For details and to register, visit www.executivewarcollege.com.

Thursday, May 15, 2008, Miami
Following the opening session, these special breakout events:

Clinical Laboratory Learning Track

- Capital and Financial Opportunities for Clinical Labs
- What Clinical Lab Buyers Want in an Acquisition Candidate
- Case Study by a Seller: PA Labs, Muncie, IN
- Panel: Critical Issues in Selling a Laboratory

Anatomic Pathology Group Practice Learning Track

- Key Considerations for Professional CP and AP Service Agreements Post-sale
- What Anatomic Pathology Lab Buyers Want in an Acquisition Candidate
- Case Study by a Seller: To Be Announced
- Panel: Critical Issues in Selling an Anatomic Pathology Group

Hospital/Health System Laboratory Outreach Program Learning Track

- How Hospital Administrators Are Using Laboratory Outreach to Build Cash Flow and Capital Value
- Business Strategies for Developing Hospital Laboratory Outreach with an Eye to Eventual Sale
- Case Study: PAML with Multiple Hospital Lab Outreach Joint Ventures
- Panel: Selling, Joint Venturing, and Collaborating with Hospital Lab Outreach Programs

Specialty Testing Labs/Intellectual Property Learning Track

- Legal & Business Issues for Intellectual Property Involved in Diagnostic Testing
- Sources of Capital at Each Stage in Technology Development & Business Formation
- How to Package the Technology and the Business Plan to Launch in the Market
- Case Study of Specialized Lab Testing Firm that Has Come to Market: To Be Announced
- Panel: Do's & Don'ts for Building the Profitable Specialty Testing Laboratory

Sellers' General Knowledge Learning Track

(*Topics are universal and have application across all lab business models)*

- For Owners: Personal, Tax, & Estate Planning Prior to the Sale—Essentials for Shareholders before any Purchase Offer is Ever put on the Table
- Legal Aspects of the M&A Transaction. Nuts and Bolts of the M&A deal. What is the Deal Flow? Who Contributes at Each Stage?
- How to Keep Key Employees Pre-Acquisition and Post-Acquisition.
- Basics of Valuation and Establishing a Reasonable Expectation of Sales Price for Laboratory Businesses

For program details & to register, go to: www.executivewarcollege.com

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another laboratory company is suing the federal government. On January 24, **UroPath, LLC** and three urology groups filed a lawsuit in the U.S. District Court for the District of Columbia. UroPath, the largest operator of anatomic pathology (AP) condo/pod laboratory complexes, is suing the Department of Health and Human Services (HHS) to roll back the anti-markup provisions of the 2008 Medicare Physician Fee Update that specifically target AP services performed in centralized, multi-laboratory buildings. The prohibition affecting condo/pod labs was implemented on January 1, 2008, while implementation of other anti-markup provisions were deferred until January 1, 2009.

MORE ON: Lawsuit

UroPath has brought out the big guns for its lawsuit. It is represented by the law firm of **Fulbright & Jaworski**. The first positive development for UroPath is that the judge agreed to defer the UroPath preliminary injunction motion, and in exchange the Court confirmed that Medicare laboratory claims for the period February 1 until April 1 in centralized building labs may be submitted for reimbursement.

QUEST BULLISH ON ITS PROSPECTS IN INDIA

By the end of March, **Quest Diagnostics Incorporated** expects its first clinical laboratory operation in India to be operational. The company is optimistic about its future in India. Chairman and CEO Surya N. Mohapatra recently told analysts that market for laboratory testing in India is currently about $1 billion per year, and growing at 15% to 20%. Further, Mohapatra stated that "we are expecting $1 billion [in yearly revenue] from international in five years. So India is going to be our largest investment outside the United States."

ADD TO: Global Labs

As Quest Diagnostics builds its international revenue base, it will mark a significant change. Until now, public lab companies in the United States have generally not had much of a presence in foreign countries. Currently, **Sonic Healthcare, Ltd.** of Sydney, Australia is the world's most global laboratory company, with laboratory businesses operating in Australia, Europe, and North America.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from Dark Daily? Then you'd know about...

... how efforts to ban animal testing in the cosmetics industry have encouraged development of lab-on-a-chip technology as a substitute. This technology is likely to find its way into clinical laboratory testing.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 24, 2008.

Preview #3

Executive War College

May 13-14, 2008 • Intercontinental Hotel • Miami

Spectrum Lab Network CEO Nate Headley on...

Building a Laboratory Testing Powerhouse from a Hospital Lab Outreach Program

During this decade, one of the nation's best-performing laboratory organizations has been Spectrum Laboratory Network of Greensboro, North Carolina. Created from the combination of three hospital laboratory organizations, Spectrum's strategy has been to offer top service, supported by sophisticated information technology, to office-based physicians. Its professional sales and marketing team has now expanded into states such as Tennessee, Georgia, and Virginia. Learn what was done to convert an underperforming hospital lab outreach program into one of the nation's top-performing regional laboratories.

Check for program details and to register!

visit www.darkreport.com

UPCOMING...

- ***Legal Challenge to Medicare Laboratory Competitive Bidding Demonstration Project.***
- ***Next Wave of Informatics Integration Will Challenge Clinical Lab and AP Status Quo.***
- ***Surprising Developments in Microbiology: Lab Automation Establishes a New Beach Head.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE New Service!

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

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends