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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Another Whistleblower Lawsuit: Why Care?

IN READING THIS ISSUE, YOU MAY LEARN, FOR THE FIRST TIME, how a former CEO of a public lab has filed two whistleblower lawsuits. His most recent *qui tam* lawsuit names **Laboratory Corporation of America** as defendant. The earlier *qui tam* lawsuit was filed against **Quest Diagnostics Incorporated**. *(See pages 3-8.)*

To my recollection, this is unprecedented! To have anyone who was once CEO of a public laboratory company turn around and file whistleblower cases involving possibly billions of dollars in potential settlements against the nation's two biggest lab testing companies strikes me a bit like a "man bites dog" story. After all, public company executives are "in the club." They tend not to turn on each other in this fashion.

From that perspective, something special is unfolding in a federal court. Even if the **Department of Justice** has not yet joined the most recent *qui tam* case filed against LabCorp, this lawsuit was noticed by two senators. It was on November 9, 2011, that Senator Max Baucus (D-Montana) and Senator Chuck Grassley (R-Iowa), issued a press release stating they had sent letters to the two big lab companies and three national health insurers requesting documents and information concerning the role of deeply-discounted lab test pricing in managed care contracts. The two Senators specifically mentioned the business practice of "pull through" as a source of their concern and a possible violation of Medicare False Claim laws.

It is unclear how these events will play out. But wouldn't you agree it is an extraordinary development to have an ex-public lab company CEO be so bold as to file whistleblower suits that claim the practice of giving private payers highly-discounted prices for lab tests is a violation of certain Medicare laws, in part because the contracting lab needs access to reimbursement from Medicare patients to offset the losses from the service contracts with the private payers?

Of course, this ex-lab CEO faces many banana peels on the path to either a favorable judgement in federal court or gaining a favorable settlement because—at some future point—a federal regulatory agency joined the case and negotiated in a tough manner with the defendant. Why should we care? Remember that whistleblowers C. Jack Dowden and Chris Riedel, in their respective *qui tam* actions, were each given a small chance of success by some smart lab industry lawyers. Yet, each case ended up with government officials negotiating a settlement and changing lab industry practices. Déjà vu, anyone? TDR

'Pull Through' Is Key Issue In Lab Whistleblower Suit

Question is whether low test prices to payers are a violation of federal anti-kickback statutes

CEO SUMMARY: Now comes a whistleblower lawsuit in federal court with the claim that, in the 2007 contract between UnitedHealth Group and Laboratory Corporation of America, LabCorp's discounted lab test prices were a kickback that violated Medicare law. LabCorp has denied the allegations and says it complies with all laws. Legal experts wonder if the Department of Justice will decide to join the case. Billions of dollars are at stake. In 10 years, LabCorp alone has billed Medicare for $5.4 billion.

IF THERE IS ANY SINGLE TOPIC that is guaranteed to raise the dander of many clinical lab industry executives, it is the "pull through" sales tactic used most aggressively by national lab companies when contracting with health insurers.

Now comes a federal whistleblower lawsuit that asserts such business practices violate federal laws governing the Medicare program. Unsealed in September, 2011, in New York's Southern District Court, this *qui tam* action claims that **Laboratory Corporation of America** violated the federal False Claims Act when it provided kickbacks to **UnitedHealth Group, Inc.**, in the form of deeply-discounted prices for laboratory tests. LabCorp denied the allegations in the case and stated that it complied with all laws.

The plaintiff is **NPT Associates** and includes a former public laboratory company CEO. Andrew Baker served as Chairman and CEO of **Unilab Corporation** in Tarzana, California, from 1992 through 1997. **Quest Diagnostics Incorporated** acquired Unilab in 2003.

The **Department of Justice** (DOJ) has yet to join this *qui tam* action—but Baker and his colleagues seem to have caught the attention of two influential senators. Just a month after Baker's whistleblower lawsuit was filed, on November 9, 2011, Senator Max Baucus (D-Montana) and Senator Chuck Grassley (R-Iowa) issued a press release from their offices revealing that they had sent letters to the two biggest public laboratory companies and three big health insurers.

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Baucus and Grassley stated that they were requesting "information about a practice where insurers receive discounted pricing from labs in exchange for referrals, including testing for Medicare beneficiaries." In these letters, the Senators described this pricing practice as "pull-through." The letters were sent to: Quest Diagnostics Incorporated, LabCorp, UnitedHealth, **Aetna, Inc.**, and **Cigna Corporation**.

"Pull Through" Scheme

Across the nation, lab administrators and pathologists took notice of these events. Many in the lab testing industry believe that use of the "pull through" scheme is a violation of federal law. In fact, most hospital and health system attorneys interpret federal law to prohibit their laboratory outreach programs from offering deeply-discounted prices for lab testing—prices that are significantly below the Medicare Part B lab test fee schedule—to referring physicians. Further, it is common for these hospital attorneys to prohibit their lab outreach programs from offering any lab test price to a client that is less than the Medicare Part B fee schedule.

Given these facts, it is no understatement to say that there is a major schism in the lab testing industry on this marketplace practice. National lab companies, with ample money to hire top-flight lawyers, assert that the discounted prices they extend to health insurers are in full compliance with all federal and state laws.

Federal Guidance

For their part, federal healthcare regulators in the Medicare program, the Office of the Inspector General, and the DOJ have not issued objective and detailed guidance on these points. Nor have they taken enforcement action that provides useful guidance to pathologists and laboratory managers.

What may be significant is that Baker's *qui tam* case opens the door to increased federal scrutiny of discounted lab test pricing practices in much the same way that the whistleblower case filed in California by **Hunter Laboratories** and Chris Reidel caused the state Attorney General to assess whether similar discounted lab test pricing activities violated California Medi-Cal statutes.

California collected more than $300 million in settlements from defendant lab companies in that case. But the stakes for the Medicare program are much higher because the largest laboratory companies that offer discounted lab test prices bill the Medicare program for more than $1 billion each year. TDR

Lawsuit Alleges Inducement In Managed Care Contract

IT WAS LAST SEPTEMBER when plaintiff NPT Associates' whistleblower lawsuit against defendant Laboratory Corporation of America was unsealed in the Southern District Court of New York. The following paragraph is how the defendants described the way the "pull through" scheme was used to allegedly induce business.

3. The Defendants violated the Anti-Kickback Law through their operation of an ongoing "pull-through" scheme wherein Defendants paid remuneration to UnitedHealthcare, an operator of managed care plans nationwide, in the form of prices for laboratory tests that were so low as not to be commercially reasonable, in order to induce UnitedHealthcare to arrange for or recommend that their in-network physicians send their Medicare-reimbursable tests to the Defendants. In order to insure that this remuneration would not be diminished by other costs that UnitedHealthcare might incur by making these arrangements or recommendations, the Defendants agreed to reimburse UnitedHealthcare up to $200 million for any such additional costs.

Laboratory Corporation of America denied that it had violated the law.

Former Lab CEO Explains Why He Filed Lawsuit

Whistleblower case alleges lab used discounts in effort to win Medicare 'pull-through' business

CEO SUMMARY: It may be the first time that a former public laboratory CEO has turned whistleblower. Andrew Baker, formerly Chairman and CEO of Unilab Corporation in the 1990s, filed a* qui tam *case in federal court last year that centers on the practice of lab companies offering private health plans deeply-discounted lab test pricing in order to win "pull through" lab test referrals, including those of Medicare patients, which will be reimbursed at higher prices. Laboratory Corporation of America is the defendant in this case and denied all the allegations, stating it complies with all laws.

FEDERAL LAW ON LABORATORY BILLING is broken every day, according to Andrew Baker. In a case filed by the former CEO of **Unilab Corporation** and unsealed in federal court last year, Baker makes an effort to prove this point.

The lawsuit is a whistleblower case against **Laboratory Corporation of America.** It was filed in New York's Southern District Court by **NPT Associates** and was unsealed in September 2011. A plaintiff along with other former medical laboratory industry executives, Baker was the Chairman and CEO of Unilab in Tarzana, California, between 1992 and January 1997. Unilab was acquired by **Quest Diagnostics Incorporated** in 2003. (Quest is not a party to the NPT Associates suit.) Baker has filed a separate and similar *qui tam* lawsuit against Quest Diagnostics.

In the federal complaint, NPT alleged that LabCorp violated the federal False Claims Act because the discounted laboratory test prices it offered in 2007 to **UnitedHealth Group, Inc.,** were kickbacks. In January 2007, UnitedHealth made LabCorp its exclusive national provider of laboratory testing services. That contract was renewed last year. Baker's *qui tam* suit alleged that, in return for the discounts, UHC had physicians in its network send all UHC patient lab tests to LabCorp.

LabCorp denies these allegations. The company says that it fully complies with all applicable federal and state laws.

Tests From Network Doctors

In an interview with THE DARK REPORT, Baker alleged that LabCorp is charging UnitedHealth less for lab tests than it charges the federal Medicare program for those same tests and that it is illegal to do so under federal law. "The reason LabCorp charges less in this way is to win the 'pull through' Medicare business from those doctors in UnitedHealth's network who send their lab tests to LabCorp," stated Baker.

Baker is raising a high-stakes issue for the two national laboratory companies. "Over the past 10 years, Quest Diagnostics and LabCorp have generated a cumulative $14 billion in payments from the Medicare program," he noted. "During this 10-year

period, Quest billed Medicare $8.7 billion and LabCorp billed Medicare $5.4 billion."

Baker has brought his evidence to the U.S. **Department of Justice**. "If the government were to prevail in this case and win a ruling that the use of 'pull through' contracts with health insurers violates federal anti-kickback law, it could collect a multi-billion dollar sum in fines and penalties from these two companies," noted Baker.

Seeking a Safe Harbor

"My belief is that these two companies willingly exploited a way of getting business in total willful disregard of a federal law on the books right now," explained Baker. "In particular, they have disregarded an interpretation of the law about how the law was to be implemented. The law clearly states that all providers must offer to the government (meaning the Medicare and Medicaid programs in the states) the best price possible.

"Back in the early 1990s, when HMOs and managed care plans started working closely with lab companies, they sought a safe harbor," Baker explained. "The industry asked government health regulators for an interpretation of the Medicare law and they got it. The interpretation said there is nothing wrong with package pricing, capitation, or potentially a discounted price.

"This interpretation included a commentary that the safe harbor was not intended to apply in situations where a provider used discounts purely to get Medicare business without that discount being passed onto Medicare," he continued. "However, on the basis of this safe harbor language, national lab companies continued to use discounts to win business.

Discounted Lab Test Prices

"The situation we have today is that these two national lab companies have willfully used discounts—sometimes at a price that was less than the marginal cost of performing the test—for no other reason than to get Medicare business," he said. "To me, that is breaking the law, which is the basis of our lawsuit.

"'Pull-through' is a simple scheme," observed Baker. "It is a marketing practice that essentially uses the higher fee-for-service payments from the Medicare program to offset the financial losses incurred by the discounted prices the lab company gives to the health insurance plan.

"Lab companies offer health plans a very low price for lab tests performed on the plans' beneficiaries," he stated. "The health insurer then gives the lab contract access to solicit physicians and win their lab test referrals for the patients covered by these health plans.

"Of course, the physicians tend to use that same lab for all of their patients covered by other health plans—including Medicare," Baker said. "That additional business is the 'pull-through' and the Medicare program is reimbursing these labs at a much higher price per test than what the health insurance plan is paying the same lab for the same test!

Need To Offset Losses

"In this scheme, a lab uses the higher payments from the Medicare patients to offset the losses incurred because it has given the private health plan a cut-rate price that is all-too-often below cost," noted Baker. "It is important to understand that these lab companies weren't offering discounts because they were good guys.

"This was Medicare being exploited by knowing, intelligent operators. That's my view," he declared. "When you know how this works, you come to believe that no one is innocent.

"When a lab company sells lab tests below cost, it does so specifically for the purpose of getting access to other specimens, including Medicare, that will be reimbursed at higher prices," commented Baker. "After gaining access to a physician's practice because of its exclusive contract with the private health plan, the lab knows it must 'pull-through' patients in

Baker's Experience with 'Pull Through' Started During California's Heydey of HMOs and IPAs

ANDREW BAKER'S THOROUGH UNDERSTANDING of the "pull through" issue goes back to the days when he was CEO of Unilab Corporation.

"In September 1992, I was named Chairman and CEO of Unilab after I bought it from **Corning's MetPath** subsidiary," he said. "At that time, I discovered that, in California where Unilab was located, the 'pull through' practice was in place. Some lab companies were using deep discounts to win business.

"I disliked this practice, and after studying it, I decided to stop it," he recalled. "In fact, I sent termination notices for contracts Unilab had with the health insurance companies and told them that we would no longer do these transactions. We followed the steps outlined in the contracts and gave notice that we were ending this arrangement.

"After that, the board of directors fired me in 1996 from my job as Unilab CEO," Baker said. "The board didn't like what I had done and the revenue numbers at Unilab weren't improving. Around that time, we issued a bond and the bond holders started asking questions. I became a scapegoat.

Discount Pricing Continued

"The discounting practice continued in a half-hearted way until a new owner of Unilab was found and the company was sold to **Kelso & Company**," he continued. "The new owners disregarded my belief about how this practice was illegal. Instead, they wholeheartedly went back to it. And that practice of using deeply-discounted lab test prices to obtain new contracts with HMOs, managed care plans, and IPAs (independent physician associations) led to the company doing extremely well.

"When I sold my ownership stake in the company, I sold for $5.85 per share," he said. "But three years later, Kelso sold Unilab to Quest for $26.50 per share. That was quite a difference in three years and I wanted to know why. I suspected that it was due to this practice of using discounted lab test prices to win new business and capture additional market share.

"I talked with people I still knew there" noted Baker. "I learned that they had blatantly pushed this discount program to health insurance companies, private Medicare health plans, and IPAs.

California *Qui Tam* Case

"This marketing practice led to a whistleblower case that was filed in California under a similar state law governing the prices providers must extend to Medi-Cal, the state's Medicaid program," he recalled. "That whistleblower case is similar to our lawsuit. It involved the use, by certain lab companies, of deep discounted pricing for lab test services to private payers as a way to gain access to the fee-for-service payments from the Medi-Cal program."

Both Quest and LabCorp paid settlements in that whistleblower case last year. In its settlement with California Attorney General, Quest agreed to pay $241 million last spring. When LabCorp settled with the California Attorney General last summer, it paid $49.5 million. In both settlement agreements, Quest and LabCorp denied all the allegations of the *qui tam* lawsuit, including that their pricing practices were improper. *(See TDRs, June 13, 2011 and September 26, 2011.)*

"When I was in California, there were clinics or programs that managed patients for a fee, and I believe these clinics or programs were billing illegally," Baker said. "You could argue that these clinics had nothing to do with lab testing but, in fact, they sent lab specimens to the commercial labs that offer them deeply-discounted prices—and there was an element of impropriety to it. These labs would offer the clinics a deeply discounted price on the lab tests so that the clinic made a profit from its global fee and the labs got the 'pull through' work. In fact, the 'pull through' work was mainly the fee-for-service Medi-Cal patients. The labs actually made out very well."

the Medicare program to financially offset the losses generated by the discounted lab test prices it is contracted to deliver to the private health insurance companies."

Asked why the U.S. **Department of Justice** has been reluctant to bring enforcement actions against labs that used discount lab test pricing to win business and gain the "pull through," Baker could not explain the lack of federal action by regulators. "As to our *qui tam* complaint and why we have not enjoyed a positive reaction in Washington, I'm perplexed," he commented.

Abuse Of Health Program

"At the same time, there is also a degree of conservatism and caution that doesn't quite embrace the issue," said Baker. "Why wouldn't the federal government pursue this case? This is a situation where an important government program is being abused, and the amount is significant, totaling billions of dollars annually!

"I have been told that some lawyers in the Justice Department think it is a difficult case," he noted. "What is interesting is that the people who think this case is difficult are not the decision makers. Every legal case has its challenges for both plaintiffs and defendants.

"But you could also view a case like this with an aggressive attitude where you say, 'Our government program is clearly being taken advantage of and we have every reason to be able to prove it.' If you don't take that more aggressive attitude, then you have an abrogation of responsibility. That's the way I see it.

"Plus, I believe that if you're paying the bill, you are allowed to ask any question you like at any time," he added. "That's how it works in business. That's how it should work here.

"Further, many in the lab testing industry know that it is whistleblowers who tend to show government prosecutors the road map to prosecute both criminal and civil violations of Medicare and Medicaid laws," Baker said. TDR

Two Lab Firms Collected $14 Billion in 10 Years

OVER THE PAST 10 YEARS, the nation's two largest lab companies were reimbursed a total of $14 billion by the Medicare program. Were Andrew Baker's allegations in his whistleblower lawsuit to be upheld by the court, the federal government could consider some or all of these claims to be "false claims" under Medicare False Claims laws.

Quest Diagnostics Estimated Medicare Revenues

Year	Total Rev.	Est. % Medicare	Medicare Revenues
2010	$7.4 bil	15%	$1,105,338,000
2009	$7.5 bil	15%	$1,118,286,000
2008	$7.2 bil	15%	$1,087,417,000
2007	$6.7 bil	15%	$1,005,736,000
2006	$6.3 bil	15%	$ 940,298,850
2005	$5.5 bil	15%	$ 818,508,900
2004	$5.1 bil	15%	$ 760,047,900
2003	$4.7 bil	15%	$ 702,904,500
2002	$4.1 bil	15%	$ 609,813,900
2001	$3.6 bil	15%	$ 544,165,650
TOTAL			**$8,692,516,700**

Source: Form 10-Ks filed with the SEC

LabCorp Estimated Medicare Revenues

Year	Total Rev.	Est. % Medicare	Medicare Revenues
2010	$5.0 bil	15%	$750,585,000
2009	$4.7 bil	15%	$704,205,000
2008	$4.5 bil	15%	$675,780,000
2007	$4.1 bil	15%	$610,230,000
2006	$3.6 bil	15%	$538,620,000
2005	$3.3 bil	15%	$499,140,000
2004	$3.1 bil	15%	$462,720,000
2003	$2.9 bil	15%	$440,910,000
2002	$2.5 bil	15%	$376,155,000
2001	$2.2 bil	15%	$329,970,000
TOTAL			**$5,338,315,000**

Source: Form 10-Ks filed with the SEC

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Lab Informatics Update

HIMSS Says 46% of Hospitals Are at Stage 3 EMR Usage

Path toward a complete, paperless patient record requires eight stages as defined by HIMSS Analytics

ADOPTION OF ELECTRONIC MEDICAL RECORD (EMR) SYSTEMS by hospitals is occurring at a steady pace. That's one recent finding by the **Health Information and Management Systems Society** (HIMSS).

In a statement made on February 17, HIMSS officials said that 46% of the nation's hospitals had achieved Stage 3 in their use of EMRs. This stage requires: a) nursing/clinical documentation (flow sheets); b) a clinical decision support system (CDSS); and, c) a PACS that is available outside the radiology department.

Survey Of 5,299 Hospitals

These findings were based on a third quarter, 2011 survey of 5,299 hospitals. The data was gathered for the EMR Adoption Model (EMRAM) that is maintained by **HIMSS Analytics**.

At the extremes, the survey determined that only 1.1% of hospitals have achieved Stage 7 of EMR use. This is full adoption as defined by the EMRAM's eight stages (0 through 7) and is recognized only after a site visit from officials of HIMSS Analytics.

At the other extreme, there are about 10% of the nation's hospitals which have yet to start with EMR adoption—or are still in Stage 0, according to EMRAM findings.

Adoption of EMRs by hospitals represents a major operational development which requires the hospital's laboratory to integrate its laboratory information system (LIS) to the needs of the institution's EMR system.

Implementing a full-function EMR is a daunting challenge, and the EMRAM data demonstrates that. "It is clear, from looking at the model, that Stages 4, 5, 6 and 7 are the more difficult ones," observed John Hoyt, Executive Vice President of HIMSS Analytics. "The numbers drop off drastically from Stage 3, which is 46% of the hospitals, to Stage 4, which is just 13% [of hospitals]."

Hoyt says that the major jump comes when hospitals implement computer physician order entry (CPOE). The next milestone is physician entry of notes. He says that it is best for hospitals not to attempt that until the nurses are supportive of the EMR and good users of the system.

Achieving Paperless Records

Achieving the eighth stage of the HIMSS Analytics' EMR adoption model would mean that the hospital is operating with a true paperless patient record. In these situations, pathologists and laboratory scientists would benefit from having real time access to the complete patient record as they review clinical laboratory test results and prepare the release of lab test reports or provide consultative support to the referring physicians. The HIMSS Analytics' findings show that most hospitals still have much implementation work to accomplish before achieving full adoption of their EMR. TDR

➤➤➤ NEWSMAKER INTERVIEW—Part 2

Jack Shaw

Stu Adelman

Shaw & Adelman

Successful Lab Networks Need Support of Hospital Leadership

➤➤➤ CEO Summary: In the second installment of our exclusive two-part interview, the executive directors of two regional laboratory networks formed in the 1990s (one in Michigan and one in Washington State) share their assessment of why their respective lab networks have performed strongly over the past two decades. They also identify the reasons why it is more challenging for anatomic pathology groups to form regional networks. The executive directors discussed how hospital administrators often lack a true understanding of the powerful economics of laboratory outreach programs and why it is essential to educate these administrators about those benefits.

Second of Two Parts

INTRODUCTION TO INTERVIEW: Since their founding in the 1990s, two regional laboratory networks have had sustained success. Each regional lab network has grown to become a major player in its respective service area.

Joint Venture Hospital Laboratories (JVHL) was founded in 1992 in Detroit, Michigan. Today it has 128 hospital labs in a network that covers all of Michigan and parts of Ohio and Indiana. It has 23 managed care agreements covering 2.8 million members for outpatient and physician office laboratory services.

PACLAB Network Laboratories became operational in 1996. It is based in Seattle, Washington. Today it has 13 hospital members.

To identify the reasons behind the success of these two networks, THE DARK REPORT interviewed their executive directors: Jack Shaw of JVHL and Stu Adelman of PACLAB. Last summer, Adelman resigned from PACLAB to take an executive position at **Puget Sound Institute of Pathology**.

Part one of this interview was published by THE DARK REPORT in its January 30, 2012, issue. In part two of this interview, Shaw and Adelman each speak further about the factors that contributed to the success of their respective regional laboratory networks.

They also address an interesting phenomenom that occurred in parallel between Detroit and Seattle. In both metro areas, the anatomic pathology groups based in the hospitals and health systems that were members of the JVHL and PACLAB networks neither joined these networks nor formed their own anatomic pathology networks to piggyback on the activities of their region's existing clinical laboratory network.

Shaw and Adelman next describe the challenges of having to educate incoming administrators at the hospitals and health systems which are members of these two networks about the powerful economics that result from a professional laboratory outreach program. Shaw and Adelman both agree that it is essential that administrators fully understand how a laboratory outreach program can advance clinical care and generate substantial revenue to the member hospitals. *—Editor*

THE INTERVIEW:

EDITOR: For nearly two decades, JVHL and PACLAB have been successful at increasing specimen volume and revenue from clinical laboratory testing services in ways that have clear benefit to the networks' member hospitals and health systems. So why is it that the anatomic pathology component of these member institutions never organized themselves into networks in Detroit and Seattle? It would seem to make sense to have a common sales and marketing effort that offered office-based physicians both clinical lab testing and anatomic pathology services.

ADELMAN: That's a good question and let me discuss what unfolded in Seattle concerning the pathology groups in that region. In its second or third year, PACLAB helped the pathology groups at the member hospitals come together and create a limited liability corporation (LLC). The strategy was that the LLC could contract for anatomic pathology if this option became available as future opportunities presented themselves.

EDITOR: What was the outcome to this effort?

ADELMAN: Unfortunately, after forming the LLC, no contracts came up. Another year or two later, the LLC disbanded, mostly because pathology groups across Seattle began to compete more aggressively against each other.

EDITOR: Did that come about because of the consolidation of several pathology groups in the area?

ADELMAN: In part yes. That was one factor that changed the long-standing "gentleman's agreement" about the territory around each hospital. It was understood that the pathology group at each hospital basically "owned" that local outreach business. It was as if there were invisible barriers around each group's territory.

EDITOR: Would you say that, when it comes to anatomic pathology, local groups are much more competitive against each other today than, say, back in 2000?

ADELMAN: Most definitely. In Seattle, there were some pathology groups that never stepped across those barriers. But now—after a decade of increased competitiveness—those barriers have dropped in the past three or four years.

EDITOR: Your point is that it is competition among pathology groups across Seattle which has been one reason why they could not come together and work collaboratively with PACLAB in some sort of regional sales or business development arrangement, correct?

ADELMAN: Certainly that is a factor. It is interesting to listen to them. They are great pathologists who know the pathology part of their operations very well and they are confident that they know how to run a business. But no single leader emerged who could foster the trust and collaboration needed that would bring their different groups together in their own network or collaboration with PACLAB. That's how it's turned out in Seattle.

SHAW: We have some of those same dynamics in Detroit, but with important differences. Until recent years, in our market, the pathologists working within each of the JVHL member hospitals and health systems could make a very comfortable living just by being affiliated with a health system.

EDITOR: Has there been any structural shifts in anatomic pathology in Detroit during these past two decades?

SHAW: There has been one big shift. In the 1990s, the market for pathology services generally saw pathologists employed by hospitals. Today, most pathologists in Detroit have incorporated their own professional corporations and then contracted with their hospitals to provide anatomic pathology (AP) services.

EDITOR: Does the "gentleman's agreement" about not competing in another AP group's neighborhood exist in Detroit?

SHAW: Recall that Stu said, in Seattle, there was not much crossover by pathology groups in that region. Each pathology group affiliated with one hospital and each one stayed in its own little cocoon. That has largely been the case in Detroit, at least until recent years.

EDITOR: What changed?

SHAW: Competition for anatomic pathology specimens in Detroit is intensifying. We now see independent dermatopathology groups and national pathology companies, such as **Aurora Diagnostics**, marketing in our metro area. Until recently, there had not been much pressure from physician in-office histology labs in this market—even though Michigan's largest urology practice has an in-office pathology laboratory. There was a day when the Michigan market was not fertile ground for national pathology groups. That is changing at a swift pace.

EDITOR: It seems that competition for anatomic pathology specimens is intensifying in Detroit, just as it has in Seattle.

What is the history at JVHL in trying to collaborate or incorporate anatomic pathology testing within its managed care contracting program?

SHAW: In 2000, JVHL acquired its first statewide lab services contract—after tough negotiations with the managed care plan to rip it away from the national lab company that held it. This statewide contract covered both outpatient and outreach services. It also included professional pathology services at the plan's insistence. With that contract and with one other that followed shortly afterward, we had to find a way to persuade the pathology groups to participate in the JVHL network model. That proved to be a very difficult process.

Stu Adelman

"In its second or third year, PACLAB helped the pathology groups at the member hospitals come together and create a limited liability corporation (LLC)."

EDITOR: Why were the pathologists so resistant to these contracts, assuming that it would help them market their services to office-based physicians and win new clients that refer more volume of AP specimens?

SHAW: The major hurdle was that—although the hospitals were willing to take discounts in order to get the contract and the opportunity to win more business—the pathology groups absolutely would not accept discounts to service beneficiaries covered by these managed care contracts. Over the past two decades, they rarely embraced the opportunity to gain market share. In fact, several pathology groups were against having to perform the additional outreach work.

EDITOR: Please explain how you handled these developments.

SHAW: It became a real economic challenge for those two contracts. In order to meet the reimbursement requirements, JVHL had to take capitation risk for the professional pathology services. But because the pathologists were almost universally unwilling to take a discount on reimbursement, their affiliated hospitals ended up taking a loss on many anatomic pathology claims. Fortunately, the hospitals saw the long term benefit of the contracts and continued to work with JVHL. That helped give us control over this situation and we eventually addressed it through increases in the capitated rate.

EDITOR: What was the final resolution to this situation?

SHAW: To better balance the economics and manage this situation required much effort to work with the pathologists to collaborate with JVHL and their affiliated hospitals. As many as 40 different pathology groups were involved in these discussions. Strategically, after we acquired that second contract in 2002, JVHL refused to include professional pathology services in any future contracts. JVHL has also worked to remove these services from the existing two contracts. Finally, in 2011, we were able to remove the professional pathology services from one of the two contracts.

EDITOR: Am I correct in suspecting that pathologists were unhappy to see any aspect of professional pathology services discounted as part of a managed care contract?

SHAW: Almost universally, that is true. Very few of the pathology groups recognized the positive market share opportunity that came with these managed care contracts, in exchange for discounting fees. Although it opened the door for them to develop more client relationships with office-based physicians in their service area, it was rarely seen as an even trade.

EDITOR: It doesn't sound like the pathology groups in Detroit were willing to develop a professional sales and marketing program to expand their group's share of the market in their target service area.

SHAW: That turned out to be true. Coincidently, JVLH found, as PACLAB did, Stu, that the pathologists tend to think they are good business people, but with a few notable exceptions they seemed satisfied with the volume of work that the hospitals brought to them.

EDITOR: The two of you have identified common themes in Seattle and Detroit in regards to a reluctance by anatomic pathology groups to collaborate in some form of regional network. In both markets, the pathologists sought to protect their in-patient professional services work and their outpatient professional business. Perhaps the experiences in Detroit and Seattle demonstrate that it is difficult for pathology groups within a community to band together and contract for outreach services because—when they do—payers recognize that it may open the door for them to seek discounts in inpatient fees as well.

SHAW: That is a reasonable conclusion. However, there is another element to consider as well. In Michigan, the commercial labs will bill globally for outreach services—including anatomic pathology. But when JVHL started to service these managed care contracts with national payers in 1997, we explained that the hospital would bill for the technical component (TC) and the professional component (PC) bills would come from the professional pathology groups. At that point, the heath plan administrators looked surprised, and they said, "We never had that with **Quest Diagnostics Incorporated** or **Laboratory Corporation of America**; from them we get a global bill." The health plans thought separating the TC and PC added a degree of difficulty and they did not want to deal with this added complexity and additional paperwork.

ADELMAN: This is another useful insight. Many community hospital-based pathology groups use the technical laboratory of the hospital. So having the TC billed by the hospital and the PC billed by the pathology group is quite common in Seattle. Here is where the "one stop shop" approach of the national lab companies is considered to be an advantage by the national health insurance companies.

EDITOR: It was fascinating to hear each of you explain why JVHL and PACLAB—successful in many ways—were each unable to engage local pathologists in collaborative ways. Now it is time to switch the conversation. Can we conclude with each of you offering three points about what value you believe your networks delivered to your member hospital labs and their parent organizations?


Jack Shaw

➤"For JVHL, first, it delivered additional revenue by creating an organization that competed successfully with commercial lab companies. "

SHAW: That certainly cuts to the essential point. For JVHL, first, it delivered additional revenue by creating an organization that competed successfully with commercial lab companies. One way JVHL achieved this is that it welcomed all hospitals—even if they didn't always recognize that value.

EDITOR: What is your next point?

SHAW: Second, JVHL gave its member hospitals a way to support their fixed costs in the laboratory that would not have existed without JVHL. We continue to deal with many hospitals where administrators do not understand that we deliver that value. They don't con-

sider the additional tests brought in to their institution though JVHL contracts as an incremental activity. They should really view these specimens based on their marginal or incremental cost, instead of carrying a fully allocated cost burden.

EDITOR: Your third point?

SHAW: Third is the value of information transferred and stored within JVHL by its member hospitals. There is substantial value inherent in the information. It is comprised of the millions of lab test results on millions of patients, stretching back for many years. As healthcare advances toward the information age, JVHL is now starting to deliver data—not just to health plans, which we have done for a long time—but also to physicians and to physician organizations. These providers are using this data for pay-for-performance programs or for value-based reimbursement.

EDITOR: Does JVHL give a community hospital capabilities in this regard that it would not have on its own?

SHAW: Most definitely! The transfer of lab test data I just described would, in many cases, require additional cost and resources that hospitals often don't have for this type of program. And, because JVHL collects results and other data from all its member hospitals, its cumulative value is even greater. In addition, JVHL is embarking on a program to improve the economics and logistics of connecting hospitals to multiple physician EMRs. We hope this will provide substantial value to our hospitals in the data arena.

EDITOR: Please explain.

SHAW: As EMRs becoming increasingly common in physician offices, we hear from our hospitals—especially small or mid-sized facilities—that the financial and support costs may become too burdensome to compete effectively in the outreach market. We need to address that on behalf of our network hospitals and for the network as a whole.

EDITOR: Stu, what are your three points about PACLAB's value?

ADELMAN: Jack, my thoughts are similar. First, PACLAB provides enhanced revenue back to the hospitals and that revenue has been very substantial. If the hospitals had to develop these systems on their own in support of their own laboratory outreach programs, they would never have generated that revenue.

EDITOR: What is the second point?

ADELMAN: PACLAB helps hospitals achieve a much-reduced unit cost for laboratory tests compared with that of an individual stand-alone hospital.

EDITOR: Is this based on some "before PACLAB" and "after PACLAB" examples?

ADELMAN: It is. In fact, that data is compelling. PACLAB worked with several hospitals that had laboratory joint venture or lab management agreements with a national laboratory immediately before they became PACLAB members. When the unit-cost-per-test was compared 18 months after they joined PACLAB, in most cases the hospitals had a 50% reduction in unit costs! That is tremendous because it translates to the inpatient side of lab testing as well.

EDITOR: What is your third point?

ADELMAN: Point three is a great illustration of the value PACLAB delivers as a regional laboratory network. About three or four years ago, PACLAB conducted a meeting with the chief information officers (CIO) of each of our hospitals. The CIOs said their physicians were asking for EMR connections between the hospital labs and the physicians' offices. But at the time, they had no money, no funds budgeted for such a program, and they had no idea how to do EMR connections. But PACLAB already had several hundred connections with physicians'

EMRs and so we were able to step in and show them how to get it done quickly and easily. That's three examples of how PACLAB delivers value to the hospitals: increased revenue, lower unit costs, and the ability to provide physician EMR connectivity when they didn't have a clue about how to begin that project.

EDITOR: There's one more point we need to address before we conclude and that's the market power that results from having a regional laboratory network. This is an organized, unified presence from a number of hospitals working together in one market. Put simply, it's strength in numbers, isn't it?

SHAW: Yes, I believe that's correct. People have observed that JVHL's regional laboratory network model is interesting because we have hospitals working together and yet they are often in fierce competition with each other. In this one clinical service area, JVHL's founding members have come together and stayed together for almost 20 years because of the ongoing value JVHL delivers. To be honest, the organization has not been without tensions because some of the hospital administrators believe they could do what we do without the network framework.

ADELMAN: Jack, I couldn't agree more. The one challenge PACLAB always had was the need to constantly make presentations to the new players who were hired at each of the hospitals. It was necessary to explain to each one why PACLAB was important to them and why they had to be an active member. It is essential to regularly remind the hospital administrators of all the benefits they get from participating in a regional laboratory network.

SHAW: That sounds familiar because I regularly do the same thing here in Michigan with any new hospital administrator. I always say that JVHL is like a chain in that it is only as strong as its weakest link. In other words, JVHL is only as good as all its members who are willing to participate. Each laboratory needs to understand the importance of participating.

EDITOR: It appears you both consider it important to educate new hospital administrators about the value of the regional laboratory network.

SHAW: That's true. New CFOs ask similar questions. "Why am I taking this work at a discount?" they ask. "Why am I giving away 80% of my charges?" The difference between outpatient and non-patient/outreach work is still a mystery to many finance people. As you said, Stu, it requires constant education and reeducation because hospital leaders change regularly.

ADELMAN: Yes, they do, and hospitals change administrators much more frequently than you would think. In addition, there's the new wrinkle of accountable care organizations (ACO) being formed. Just in the past six months PACLAB saw hospitals that had been arch competitors for years now in negotiations about an affiliation. It will be very interesting to see how these partnerships develop and what they will mean for the future of PACLAB.

EDITOR: Jack and Stu, thank you for sharing your thoughts about the history and success of your regional laboratory networks. At a time when healthcare is moving toward new models of integrated clinical care, it would be smart for hospital laboratory leaders in many cities to revisit the benefits and value of organizing their own regional laboratory networks. TDR

—By Joseph Burns

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Lab Briefs

GENOME SEQUENCING TO BE OFFERED BY NORWAY IN NATIONAL HEALTH PLAN

HERE'S A MILESTONE ON THE PATH TO PERSONALIZED MEDICINE. Norway is the first nation to announce that its national health system will incorporate whole genome sequencing.

Cancer is the target of Norway's first genome sequencing program. What sets the Norwegian program apart from gene testing activities in other countries is that Norway is building a new laboratory specifically designed to utilize next generation genome sequencing technologies.

The **Norwegian Cancer Genetics Consortium** announced that, as part of a three-year pilot, it will sequence the genomes of tumors from 1,000 patients. The study will also take 3,000 tumor biopsies that exist from other cases and seek to identify mutations associated with specific types of cancer.

The goal of the genome sequencing project is to identify which treatments may be most effective for cancer patients, using an analysis of the mutations in their tumors. Norway has a population of 4.8 million people. About 25,000 Norwegians are diagnosed with cancer each year.

Health officials in Norway say the budget for this effort will be about U.S.$6.3 million. This includes the cost of the new genome sequencing laboratory facility, along with the associated clinical and computing infrastructure.

MEDTOX SCIENTIFIC POSTS ANOTHER YEAR OF STRONG GROWTH

IT'S A LAB COMPANY ON A ROLL. In St. Paul, Minnesota, **MedTox Scientific, Inc.**, reported its fourth quarter and full year 2011 financial results. Growth hit double digits in revenue and operating income.

For the full year 2011, MedTox said revenue was $108.1 million, compared to $97.1 million in 2010. This is a growth rate of 11.4%.

MedTox has four core business lines. For the full year, its drugs-of-abuse business grew 4.3%, to $41.3 million. Its diagnostic division makes and sells test kits. In 2011, this business line grew 11.1% and achieved revenue of $22.3 million. The clinical trial business posted revenue of $9.6 million, representing a growth rate of 28.9%.

The interesting evolution at MedTox is happening with its clinical laboratory testing business division. In 2011, MedTox posted revenue of $34.9 million, compared to 2010 clinical lab revenue of $29.9 million. This growth rate of 16.5% shows that MedTox is capturing market share from the office-based physicians in its service area.

Known primarily as a company with expertise in therapeutic drug testing and drugs-of-abuse testing, MedTox launched its clinical laboratory division just a few years ago to diversify its revenue sources and better utilize its laboratory testing facilities. Since that time, the clinical laboratory testing business has grown to where it currently represents almost one-third of the company's annual revenue.

CLEVELAND CLINIC OPENS NEW LAB FACILITY, PLANS TO GO NATIONAL

OVER IN CLEVELAND, OHIO, the **Cleveland Clinic** is ready to throw its hat in the ring as a reference and esoteric testing laboratory that has a national presence. In recent months, it officially opened its new, $75 million facility that is designed to help it achieve this and other strategic goals.

The state-of-the-art laboratory building is 135,000 square feet. It will support the **Pathology and Laboratory Medicine**

Institute and **Cleveland Clinic Laboratories**. Cleveland Clinic says that this division employs 1,300 people and performs about 12 million tests annually.

In recent years, administrators at the Pathology and Laboratory Medicine Institute have laid out a vision that includes an expanded presence as a national source of reference and esoteric testing. Although this is already a very competitive marketplace, the Cleveland Clinic brand is highly respected. That gives its growing sales force a strong card to play when soliciting laboratory test referrals from prospective clients.

APOLLO PACS, DELL INK AGREEMENT TO ADD APOLLO'S IMAGE SOLUTION

IT'S ANOTHER FORWARD STEP TOWARD FULL INTEGRATION of the patient health record. Earlier this month, **Dell, Inc.**, and **Apollo PACS, Inc.**, announced an agreement that forms a strategic alliance between the two companies.

Apollo, of Falls Church, Virginia, will provide its "complete solution to manage, retrieve, and share clinical multimedia images, and data" to Dell for use in Dell's Unified Clinical Archive (UCA). UCA is designed to be "a data management and archiving solution that makes every diagnostic image for a patient available from one device at the point of patient care."

Dell is working to solve the "Tower of Babel" that surrounds the multitude of healthcare information products that each handle different pieces of a patient's clinical record. James Coffin, Ph.D., Vice President and General Manager of Dell Healthcare and Life Sciences, emphasized that goal when he described the addition of Apollo's Enterprise Patient Media Manager (EPMM) to Dell's UCA as "an important step toward providing a truly patient-centric view for every medical specialist and provider across the healthcare enterprise.

"The management of both clinical and diagnostic images and related data across multiple specialties is vitally important in the healthcare arena today," added Coffin.

For pathologists who recognize Apollo PACS as one of the pioneers in solutions to handle and archive digital pathology images, this new strategic collaboration with Dell shows the rapid progress being made toward a unified patient electronic health record (EHR). Providers and payers are demanding integrated solutions for archiving and accessing clinical information. At the same time, advances in information technology are making it easier for companies like Apollo to develop systems that can handle images across the full range of medical specialties—not just anatomic pathology and radiology.

LAB CONSULTANTS: BRITISH COLUMBIA NEEDS YOUR EXPERTISE!

HERE IS AN OPPORTUNITY for talented laboratory management and operations consultants. In Canada, the Province of British Columbia (BC) has issued a request for proposal (RFP).

In response to a 27% increase in the cost of laboratory testing over the past five years (representing C$130 million), provincial health officials are looking for a management consulting firm. In a 10-week contract, it wants the winning bidder to "compare lab services in Canada and other jurisdictions to identify strengths and best practices."

Meetings will be conducted with stakeholders, including health authorities in the province, the **BC Medical Association**, the **BC Association of Laboratory Physicians**, unions, and private laboratory companies operating in the province.

Cost reduction is a major goal. The final report is to include options that will allow the health authority to strengthen the province's laboratory system, along with recommendations on cutting costs, improving access, and increasing efficiency. The RFP documents can be accessed at *www.bcbid.gov.bc.ca*. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In its effort to change how code stacking is used to bill for certain genetic and molecular tests, **Palmetto GBA** announced changes to its Molecular Diagnostic Services Program (MolDx). Earlier this month, the Medicare carrier announced that the effective date for claim submissions under MolDx would move from March 1, 2012, to May 1, 2012. Laboratories will also have the option of applying for a **McKesson** Z-Code or using the Palmetto Test Indicator (PTI), an alternate test identifier developed by Palmetto. These changes affect the J1 Region.

MORE ON: *Palmetto*

Where labs will be unable to implement systems to meet the information timetables for MolDx, Palmetto has amended its electronic claims fax cover sheet to incorporate the test identifier. This fax "attachment" can accompany an electronic claim. In situations where no test identifier (Z-Code or PTI) has been issued, Palmetto has released a MolDx test information form.

CRM SOLUTION FOR LABS COMES TO MARKET

Few labs have implemented some type of customer relationship management (CRM) system. CRMs generally act as an integrator of data that resides in the multitude of information systems typically used by a busy clinical laboratory organization. This month, **hc1.com**, a division of **Bostech Corporation**, announced the release of a CRM-type of system designed for use by clinical laboratories. It is called "hc1.com Opportunity Management System." It is designed to integrate what are currently silos of information within a lab.

ADD TO: *Lab CRM*

Bostech says that this system pulls together information that allows the lab's team to watch, in real-time, all activities involving clients. Among other functions, it uses links to internal lab processes to compare actual client volume with forecasted volume. Enterprise-wide software systems —such as that sold by **SAP** of Mannheim, Germany—are widely used by non-healthcare companies. Within the lab industry, one of the first lab companies to implement a robust CRM solution was **Pathology Associates Medical Laboratories** (PAML), of Spokane, Washington. It began using a CRM about six years ago and later sold this customized CRM and the related suite of integrated solutions it had developed to **Sunquest Information Systems**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 12, 2012.

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*Preview–**Adam Slone** and **Tara Kochis,** Slone Partners:*

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UPCOMING...

- ***More Competition in Anatomic Pathology May Increase Financial Pressure on Local Path Groups.***
- ***How Did 2011 Treat the Two Blood Brothers? What Their Successes and Setbacks Say about Market.***
- ***Hospital CEO Speaks Out about How His Patients Are Inconvenienced When His Lab Is Excluded by Payers.***

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