



From the Desk of R. Lewis Dark...

THE R. LEWIS DARK REPORT

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

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R. Lewis Dark
Founder & Publisher



Wisconsin Provides Peek at Pathology's Future

BIGGER PATHOLOGY GROUPS AND METROWIDE OR STATEWIDE COVERAGE will be major characteristics in the anatomic pathology profession as health-care continues to transform in new ways. That is why the reasons for the substantial growth in case volume and revenue at **North Shore Pathologists (NSP)** in Milwaukee should be studied by pathology groups everywhere.

It was a practice with six pathologists as of 2017. Today, it has 21 pathologists and its case volume has quadrupled over the past 16 months. This success came because the pathologists at NSP were forward-looking and had strategies in place to help them win a statewide pathology services contract for **Ascension Wisconsin**, which operates 27 hospitals and 110 clinics throughout the state. (See pages 8-11.)

There are key insights to be gleaned from the successes of North Shore Pathologists.

First, this is an example of how, as health networks grow and expand their regional coverage, they need anatomic and clinical pathology services that are integrated and offer standardized clinical services with the required pathology subspecialty expertise.

Second, this trend toward regionalization means that small pathology groups are at a disadvantage. They are at increased risk of losing their independence, whether through acquisition, merger, or a decision to close the practice because of deteriorating finances and/or partners who are retiring.

Third, as regional consolidation happens, the same volume of pathology cases continues and there is need for the same number of pathologists to handle this work. But regional consolidation means that only forward-looking pathology groups will end up handling those cases on behalf of the regional health network.

The Wisconsin statewide pathology contract represents an excellent case study for any pathologist or pathology practice administrator who wants to understand today's healthcare marketplace and how they can keep their group positioned at the cutting edge of clinical excellence in a financially-sustainable manner. Effective strategy is always informed by a perceptive analysis of current market developments and ongoing trends. That's why the upcoming *Executive War College* on April 30-May 1 has sessions on what's changing in the pathology market and how pathologists are being paid. **TDR**

Respected Lab Exec Found Dead in Triple Homicide

➤ California's lab community stunned over death of Richard Nicholson, his wife, and a family friend

➤➤ **CEO SUMMARY:** *Police and the district attorney have released few details about the murders of well-known clinical laboratory executive Richard Nicholson, his wife, and a family friend. The crimes were committed in Nicholson's home in Newport Beach, Calif., and 27-year old Camden Nicholson, the family's youngest son, was arrested as the prime suspect in this case. Richard Nicholson owned and sold two successful clinical laboratory companies in recent decades.*

CALIFORNIA'S CLINICAL LAB COMMUNITY WAS STUNNED earlier this month when **Richard Nicholson**, age 64, was found dead along with his wife, **Kim Nicholson**, age 61, and their housekeeper, **Maria Morse**, age 57, on Feb. 13, in the Nicholsons' home in Newport Beach, Calif, according to reports in *The Los Angeles Times*.

Nicholson was the long-time owner and CEO of **Westcliff Medical Laboratories** and most recently was a part-owner of **Pacific Medical Laboratories**, both in Orange County. He had a well-deserved reputation for operating high-quality laboratories that were consistently profitable.

The suspect in the case is Nicholson's son, **Camden Burton Nicholson**, age 27, who was charged with three counts of murder. He did not enter a plea when he appeared in court on Feb. 15 and

was being held without bail pending a court appearance March 8, the newspaper reported.

After the murders were discovered, few details of motive and how the victims were killed were made public. However, on Feb. 20, *KTLA* television news reported that the Nicholsons had hired a private investigator because they were concerned that Camden Nicholson's behavior had become increasingly erratic.

Private investigator Michael Youssef of the investigation company **Blue Systems International** (BSI) told *KTLA* that Richard and Kim Nicholson contacted him earlier this month concerned about Camden Nicholson's behavior. On its website, BSI says it is "a team of former state and federal law enforcement investigators with combined experience of over 100 years."

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BSI's website also provides extensive details about the case, saying that Youssef, the firm's chief private investigator, met with Richard and Kim Nicholson in their home, where they said they were concerned about Camden's safety because he was missing and they wanted to get him medical assistance.

The Nicholsons asked Youssef to find Camden and "conduct surveillance on him in order to have physical evidence and proof that would help them get a conservatorship over their son because they knew that their son was suffering from extreme mental instability," the BSI site states.

The site also reported that in December, Camden Nicholson left his home suddenly and without reason and that his mother's attempts to reach him by phone and e-mail were to no avail.

"During the month of January 2019, Mr. Nicholson noticed that Camden was using his credit card at a Marriott [hotel] and giving excessive tips of \$1,000 in one transaction and in excess of \$15,000 in total," the site states. Richard Nicholson then cancelled Camden Nicholson's credit card, the site added.

► Visit to Nicholson Home

On Feb. 13, Newport police received a call from Irvine police requesting a welfare check at the Nicholson home. Irvine police were alerted after speaking with a man who was later identified as Camden Nicholson, in the emergency room of a medical facility, the *LA Times* reported.

"When Newport officers arrived at the house, they found the bodies of two women and a man. Authorities did not release details about the circumstances or manner of the deaths," the *Times* reported.

The news of Nicholson's murder came as a complete surprise to clinical laboratory professionals in Southern California. He was widely-respected for his contributions to the clinical lab industry. **TDR**

—Joseph Burns

Nicholson Family and Westcliff Med Labs

FOR ALMOST FIVE DECADES, one of the most-admired clinical lab companies in Southern California was Westcliff Medical Laboratories. It was founded in 1963 in Newport Beach by Edward L. Nicholson, father of Richard Nicholson.

Richard Nicholson assumed the role of President and CEO of Westcliff and came into his own during the 1990s. This was the time when closed-panel HMOs and independent practice associations (IPAs) began negotiating capitated, full-risk prices with labs in the Golden State.

However, Richard refused to play that game. He understood that these capitated rates (as low as 20¢ per member-per month) did not pay labs for the full cost of testing. This was counter-intuitive at a time when the popular wisdom in the clinical lab market was that a lab needed that capitated contract in order to "pull through" the Medicare and other fee-for-service patients from physicians.

Nicholson refused to bid for the capitated HMO and IPA contracts. He organized his lab so that it truly offered a noticeably higher level of service, accuracy, and quality. Physicians recognized this difference and happily split their lab specimens. They sent the fee-for-service specimens to Westcliff and capitated specimens went to the contracted labs.

Nicholson's success with this strategy was admired by his peers. Unfortunately, Westcliff Med Labs came to a sad end. He sold the lab to a private equity company in 2006. In the following years, Westcliff's new executives went after all the money-losing capitated contracts—even though they already had the profitable fee-for-service referrals from these same physicians. Westcliff filed for bankruptcy in 2010 and **Laboratory Corporation of America** bought Westcliff's assets.

PAMA Price Cuts Reduce Revenue at LabCorp, Quest

➤ On quarterly earnings calls, both labs reported revenue declines attributable to Medicare cuts

➤➤ **CEO SUMMARY:** *In their respective earnings reports for the fourth quarter and the full year of 2018, executives at both Laboratory Corporation of America and Quest Diagnostics told financial analysts that the Medicare fee cuts of 2017 and 2018 were reducing revenue and operating margins. More significantly, both lab companies told analysts they expect greater acquisition activity as hospital administrators respond to lower Medicare prices by selling some or all of their lab businesses.*

DURING THEIR LATEST QUARTERLY CONFERENCE CALLS with Wall Street analysts, the nation's two largest publicly-traded clinical lab companies reported this month that the effects of the federal Protecting Access to Medicare Act (PAMA) of 2014 are rippling through the clinical lab industry in four significant ways.

Executives from **Laboratory Corporation of America** and **Quest Diagnostics** said the following:

- PAMA has cut into the earnings of the nation's two largest clinical lab companies, LabCorp and Quest Diagnostics.
- PAMA will have a negative effect on earnings this year.
- PAMA is having an even more adverse effect on the revenue of smaller labs and hospital labs, causing some to report no profit at all.
- Those smaller labs and hospital labs may be forced to sell out to larger labs, LabCorp and Quest reported.

In essence, this fourth effect is a silver lining for LabCorp and Quest because both reported that they expect to acquire more lab test volume by striking deals with these smaller labs and hospital labs. Some deals may be an outright purchase

of the lab organization. In other deals, the national lab may take over some of the testing those labs now do.

➤ Drop in State Medicaid Rates

In addition to these four known PAMA effects, executives from Quest said PAMA could be causing a decline in payments from Medicaid plans. Medicaid payments dropped in 2018, they added, and they assumed that this reduction resulted from Medicaid payers following Medicare's lead. Under PAMA, Medicare cut payments for many lab tests by 10% last year, by 10% again this year, and Medicare is due to cut what it pays labs by 10% again next year.

One result of all these negative effects is the potential shift of lab market share away from smaller labs and hospital labs to larger lab companies, executives from LabCorp and Quest said.

To emphasize this point, Quest CEO Steven Ruszkowski said the pressure that lower payments under PAMA put on all labs is a "catalyst for structural change in the lab business."

"The impact of these [PAMA] cuts will be more significant on smaller indepen-

dent hospital outreach laboratories which we believe could eliminate the majority of their profit, and will provide a catalyst for market consolidation,” he added. “Most hospital CEOs and CFOs are still not fully aware of how PAMA impacts hospital outreach labs.

“We believe that as this impact of PAMA becomes increasingly more visible, hospitals will be more motivated to work with us on their lab strategy,” he commented. By harming all labs—particularly those that are not market-leading labs—PAMA will cause smaller labs to sell to larger ones, he said.

But as these smaller labs struggle, Quest could benefit by acquiring lab test volume from smaller labs to offset the decline in revenue from PAMA, he explained. “When you go through the math, we believe there’s an opportunity for us to pick up [market] share in 2019, and that will continue in 2020,” he said.

► Financial Pressure

Later, Ruscowski returned to this theme. “Hospitals and health systems face unprecedented financial pressures, and are therefore motivated to discuss ways we can help them with their lab strategy,” he commented. “We recently signed two new professional lab services agreements in the Southeast region. In both relationships we will provide full lab management employing technical lab staff, providing operational lab oversight, and maintaining responsibility for the lab supply chain.”

Reporting on PAMA’s effect on finances, Ruscowski said revenue declined in the fourth quarter by 1.4% to \$1.84 billion versus 2017, reflecting what he called “increased reimbursement headwinds.” In all of 2018, revenue rose by 1.7% to \$7.53 billion.

Quest said requisition volume in 2018 increased 3.4% over 2017 and organic requisition volume rose by 1.1%. Organic requisition volume comes from sales and not by acquiring volume from other labs.

This year, Quest expects net revenue to rise by 1% to 3%. Much of this revenue will come from adding 43 million lives and about \$1 billion in revenue as a result of being in-network with **UnitedHealthcare**,

Horizon Blue Cross Blue Shield of New Jersey, and **Blue Cross Blue Shield of Georgia**. (See TDR, “Lower Prices, More Data in UHC’s New Lab Network?” TDR, Feb. 4, 2019.)

“We have already seen encouraging volume growth early in 2019 resulting from this expanded network access,” Ruscowski commented.

► LabCorp’s PAMA Experience

While Quest reported extensively on the effects of PAMA, LabCorp’s CEO David King and CFO Glenn Eisenberg had similar comments, but LabCorp’s executives did not offer as much detail as Quest did.

“Although we continue to see judicial and legislative relief on the second round of PAMA price reductions, there is increasing industry-wide awareness about PAMA’s true impact,” King commented. “This presents us with a number of attractive tuck-in lab acquisition opportunities, which typically deliver significant synergies and high return on invested capital.”

Both Quest and the diagnostic testing business of LabCorp reported a decline in revenue in the fourth quarter of 2018 but an increase in revenue for the full year. For LabCorp in 2018, fourth quarter revenue for the diagnostic-testing segment was \$1.69 billion, a decrease of 2.8% from \$1.74 billion in the year-earlier quarter. For the full year, LabCorp reported revenue from its lab-testing business of \$7.03 billion, an increase of 2.5% over the \$6.86 billion it reported in 2017. For the fourth quarter, Quest reported revenue of \$1.84 billion, down 1.4% from the \$1.87 billion it reported in the year-earlier quarter, and full-year revenue of \$7.53 billion, an increase of 1.7% from the \$7.40 billion it reported in 2017.

► Declining Income, Margin

PAMA had the biggest effect on LabCorp’s lab-testing business. Adjusted operating income from laboratory testing was \$279 million (or 16.5% of revenue) in the fourth quarter compared with \$357 million (or 20.5% of revenue) in 2017, Eisenberg said. The decline in operating income and mar-

gin was primarily due to the impact from the PAMA cuts to lab test prices of about \$18 million in the fourth quarter and about \$20 million for the year, he added.

In addition, revenue per requisition decreased by about \$8 million in 2018 and was partially offset by test mix, he said, without explaining how test mix affected revenue.

LabCorp reported that revenue per requisition in 2018 dropped by 0.4% as a result of PAMA. And, total volume rose by 0.3% in 2018, including an increase of 0.4% in acquisition volume and a decline of 0.1% in organic volume.

Later, during the call with analysts, LabCorp's CFO Eisenberg predicted that revenue in 2019 would be flat or would decline by 2% "primarily due to the impact from PAMA." LabCorp said PAMA will reduce its lab-testing revenue by about 1.6% this year as a result of lower direct Medicare payments of some \$85 million, and, the company's executives said, there will be an indirect effect that will lower other payments, primarily from Medicaid-related plans, by \$30 million.

➤ Medicaid Program Payments

Quest's executives also mentioned that Medicaid payers may be cutting payments for lab tests as a result of PAMA. And, they added that Medicaid plans have been more aggressive in denying payment for certain tests, such as those for vitamin D, cystic fibrosis, and for panels of tests. Also, Medicaid plans have added more prior authorization rules, which often lead to denials, they added.

These earnings reports are a first look at how the Medicare Part B price cuts for lab tests are affecting the financial performance of the nation's biggest lab companies. If operating margins have fallen by 4% to 5% for a billion-dollar lab company with Medicare testing making up about 15% to 20% of total testing, then the financial consequences for a small laboratory generating 50% to 80% of revenue from Medicare patients means such labs are operating at a loss. Closure of these small labs will affect access for many Medicare patients.

TDR

—Joseph Burns

Sonic's Half-Year Revenue Growth is 6%

ON FEB. 20, Sonic Healthcare USA reported revenue results for the last two quarters of 2018 and so reflect only six months of the company's annual results. As a division of Sonic Healthcare in Australia, the company's fiscal year ends on June 30.

For the six months ending Dec. 31, Sonic Healthcare USA generated US\$441.8 million. That projects to annualized revenue of US\$883 for its U.S. lab operations. The U.S. division represents about 21% of the company's total revenue worldwide, making the U.S. operations the second largest division after Sonic's operations in Australia. In its operations worldwide, the company reported a net profit for the half year ending Dec. 31 of US\$159.3 million on revenue of US\$2.076 billion.

Unlike Quest and LabCorp, Sonic Healthcare USA reported that the federal Protecting Access to Medicare Act of 2014 had a relatively minor effect on revenue. Sonic said the effect of reimbursement under PAMA is expected to be only about 1.3% reduction of total revenue for its lab U.S. lab division.

In the last two quarters of 2018, revenue from U.S. operations rose by 6%, the company said. Revenue from U.S. operations would have been higher by about \$9 million if Sonic had not contributed to a joint venture with **ProMedica** in Toledo, Ohio, effective Sept. 1. (Sonic now owns 49% of that joint venture. (See *ProMedica, Sonic Form Lab Outreach Joint Venture*, "TDR Aug. 20, 2018.")

In the U.S., Sonic said other hospital lab opportunities and acquisitions are in the pipeline. On Jan. 30, Sonic completed a significant acquisition in the United States, paying \$540 million for **Aurora Diagnostics**, a company that had annual revenue of \$310 million, Sonic said.

Patient Care Focus Helps Path Group Win Contract

► North Shore Pathology's contracting strategy emphasized patient care via the quadruple aim

►► **CEO SUMMARY:** *When Ascension Wisconsin wanted one pathology group to serve its needs statewide, North Shore Pathologists responded to the request for proposal by focusing on how pathologists can improve patient care through a patient-centered model. Other pathology groups responded with proposals that emphasized the financial aspects of the relationship. Focusing on patient care won the statewide contract for North Shore, quadrupling its case volume.*

ONE CHALLENGE THE ANATOMIC PATHOLOGY PROFESSION FACES IS how pathologists who get paid fee-for-service for each case will be paid as healthcare adopts value-based reimbursement more widely.

In Milwaukee, **North Shore Pathologists** (NSP) is demonstrating a way for pathologists to thrive amid the changeover to this new form of payment. But doing so involves what might be called the marriage of preparation and opportunity.

► Preparing for Opportunity

This was the theme **THE DARK REPORT** covered in 2015 when reporting on how NSP had gained a seat at the table in 2012 when executives in the state's health systems were forming the first accountable care organizations. (See, "Pathologists Contribute to Care in Wisconsin ACO," *TDR*, March 30, 2015.)

Two years later, preparation met opportunity again, but this time, the opportunity for NSP was much bigger and so was the reward. In an interview with **THE DARK REPORT**, NSP President

Guillermo G. Martinez-Torres, MD, explained what happened in 2017 when **Ascension Wisconsin** wanted a single pathology group to serve its needs throughout the entire state.

► Statewide Health Network

Ascension is one of the largest nonprofit healthcare providers in Wisconsin, with 23 hospitals, more than 110 physician clinics, and about 900 clinician employees. Thus, their request for proposal (RFP) two years ago was a big growth opportunity for the different pathology groups that wanted the contract.

When Ascension issued the RFP to provide pathology services statewide, North Shore Pathologists responded. NSP won the contract by focusing on how pathologists can improve patient care through a patient-centered approach and by following the tenets of the quadruple aim.

Years ago, the **Institute for Healthcare Improvement** adopted the triple aim, saying providers should aim to improve the health of populations, enhance the experience of care for individuals, and reduce

the per capita cost of care. Since then, other organizations have added a fourth aim: attaining joy in work.

By contrast, other pathology groups responded to the same RFP by addressing the potential financial aspects of the relationship. In other words, NSP's competitors focused on what most pathologists and other providers would assume to be most important to a large, statewide health system: cost control and revenue enhancement.

➤ **Response to the RFP**

But the emphasis in NSP's proposal as to how pathologists could contribute to improving patient care through the quadruple aim was not the only factor that helped them win the Ascension contract. Martinez-Torres surmised that NSP was chosen, in part, because Ascension's executives were familiar with them through NSP's support of the system's ACO. Ascension knew the six-physician group could serve its needs in an environment where value-based care was becoming the predominant form of reimbursement.

It didn't hurt NSP's chances that Martinez-Torres was Chair of Pathology and Laboratory Medicine and Medical Staff President at **Columbia St. Mary's Hospital**, an integral part of the Ascension system.

Also, it was timely in November 2017 that Martinez-Torres received the first Raymond C. Zastrow Award from the **Wisconsin Society of Pathologists** for his leadership, service, and efforts advocating for pathologists, not only in Wisconsin but nationwide.

➤ **Statewide Pathology Service**

As Martinez-Torres explained, Ascension recognized that providing pathology services in such a large state with different pathology groups would be challenging.

"Ascension knew that having different groups throughout the state with different voices and different agendas would

be more difficult than having one group for all of its pathology needs," he said. "Instead of multiple groups, it wanted a single provider of pathology services for the entire state.

"Early in 2017, Ascension put out an RFP and North Shore Pathology responded," he added. "The review process took months. At the end, in September 2017, we were awarded the exclusive contract for pathology services for the entire Ascension Wisconsin ministry. At that point, Ascension had 27 hospitals and more than 100 physician clinics, doctors' offices, and other providers throughout the state.

"In 2017, NSP was a mid-size pathology group," noted Martinez-Torres. "Thus, to win that kind of a contract was very exciting, but also a bit scary because it was and is an amazing opportunity to work with such a wonderful partner.

"To meet Ascension's needs, our pathology group had to handle quadruple our existing volume," he added. "We needed to quadruple our staff from where we were before winning this RFP."

➤ **Need for More Pathologists**

Prior to submitting its answers to Ascension's RFP, the group had six pathologists, three PAs, and a practice manager. "But to respond effectively to the RFP we needed more than three times the number of pathologists and a much bigger staff," Martinez-Torres explained. "Right now, we have 21 pathologists, seven PAs, and a practice manager."

Four of those pathologists came from **Racine County Pathology Associates** in Racine, Wis., and three more came from the **Butte des Morts Pathology** group in Appleton and Oshkosh.

NSP has since added eight pathologists to the staff, four of whom came from **AmeriPath**, and it plans to add more pathologists to serve the remaining northern portion of Ascension Wisconsin, he said.

“During the entire RFP process, we reached out to the other independent groups that were providing services to Ascension Wisconsin and they agreed to join us and participate in responding to the RFP,” explained Martinez-Torres. “That is how North Shore Pathologists was able to integrate those other groups.

► Swift Response Required

“To prepare for the quadrupling of our pathology volume, we needed to act swiftly,” he continued. “So, we brought those pathology groups in, and as of Jan. 1, 2018, those other groups became part of North Shore Pathologists. Because they already worked at Ascension hospitals, there was little disruption.”

Ascension didn’t share with NSP why it was chosen over the other pathology groups that responded to the RFP. Also, Ascension did not respond to THE DARK REPORT’s request for comment.

“All we know is that Ascension reviewed the proposals and assigned a numeric score to each of the responses and awarded the contract to the group with the highest point total. Beyond that, they didn’t share their reasoning with me,” said Martinez-Torres.

But after NSP won the contract, Martinez-Torres heard informally from some of Ascension’s administrators that NSP not only focused on improving patient care, but the administration also thought that NSP shared Ascension’s mission, vision, and values, and that this aspect of NSP’s response was a winning strategy.

► Evaluation of Presentations

“I heard comments about how Ascension evaluated the presentations that our team and the other groups made,” he stated. “Feedback was that there was a very stark difference in the way the pathology groups responded.

“Outside of that comment, I don’t know why we were chosen,” Martinez-Torres admitted. “But I will say that when you make a patient-centered argument,

there is still a financial component to that point of view, which I thought resonated with the administrators, perhaps because Ascension is a nonprofit organization.”

In looking back on why NSP was chosen, Martinez-Torres acknowledged that he considers himself blessed to be working for an organization that focuses on providing care that leaves no one behind, especially in this age when so many health-care providers have a narrow focus on cost control and revenue enhancement.

But then he added this comment, which may be the key lesson for all pathologists: “Of course we’re going to make money. However, at the same time, we cannot forget about why we’re here,” he said. “We are in healthcare because everything we do revolves around the patient. Patients count on us to be their advocates to the best of our ability.

“Most patients don’t know who pathologists are,” concluded Martinez-Torres. “But they put all their trust in us because everything we do and say drives their treatment and can change their lives forever.”

► Strategic Lessons

Pathologists throughout the United States should recognize the strategic lessons to be learned from how North Shore Pathologists successfully won the contract to provide pathology statewide services to Ascension Wisconsin. This is the future of healthcare in the United States.

First, Ascension Wisconsin is responding to a major trend: the need for an integrated healthcare system that covers an entire metropolitan area or even a state. Employers and health insurers want to contract with providers who can deliver clinical care that eliminates silos and helps patients manage chronic conditions while reducing healthcare costs.

Second, in assembling its statewide network of hospitals and clinics, Ascension Wisconsin wants providers who are integrated and can provide uniform, quality services everywhere that Ascension

North Shore Pathology's Involvement in an ACO Helped It Win Statewide AP Services Contract

IT PAYS PATHOLOGISTS TO BE READY FOR OPPORTUNITY. When 27-hospital **Ascension Wisconsin** issued a request for proposal (RFP) for a statewide pathology services contract, North Shore Pathologists (NSP) of Milwaukee was ready and had an established track record with Ascension.

That track record dated back to 2012 when NSP worked with other health-care executives to form a large integrated delivery network and an accountable care organization (ACO) in Wisconsin. Today, Guillermo Martinez-Torres, MD, President of North Shore Pathologists, said that if NSP was not involved in that process six years ago, the group might not have had the success it has seen since then.

At that time, Martinez-Torres was preparing to make a presentation to a national meeting of pathologists about how pathologists can and should participate in ACOs. To help him prepare, he met with the president of Columbia-St. Mary's Hospital, a 300-bed hospital in Milwaukee that is part of Ascension Wisconsin.

➤ Integrated Care Network

On that day in 2012, the hospital president happened to be reviewing plans for a new ACO. "At the time, few people knew about this proposed integrated care network and ACO," Martinez-Torres told *THE DARK REPORT* in 2015. "So, for me, it was an opportunity to get involved at an early stage." (See, "Pathologists Contribute to Care in Wisconsin ACO," *TDR*, March 30, 2015.)

"It was serendipity that I happened to walk into his office at that time, but I knew from my work with the **College of American Pathologists** that it was vitally important to have a laboratory representative at the table when discussing the formation of an ACO," he explained. "I simply needed to take advantage of the opportunity."

➤ Pathologists in the ACO

As a result of being well-prepared even for such a chance encounter, Martinez-Torres earned a place for the lab in the formation of the ACO by acknowledging that pathologists have a unique value proposition to offer ACOs: the ability to collect and interpret lab data for population health management.

He also explained that the NSP pathologists were prepared to engage in value-based contracting and to move away from payment based on test volume, he said. He also commented that pathologists needed to identify future trends and prepare for them.

The experience in working with Ascension since 2012 in its integrated care programs and ACO certainly was a positive factor when NSP responded to Ascension's RFP for a statewide pathology services contract in 2017. By winning that contract, North Shore Pathologists quadrupled its case volume and now serves a larger share of the Wisconsin market for anatomic pathology services.

Wisconsin has facilities and patients. To meet the RFP's requirements for integration and regional coverage, North Shore Pathologists had to approach its colleagues at other pathology groups serving the system at that time and develop an integrated pathology service that could be run as a single business entity.

Third, Ascension Wisconsin appears to have recognized that North Shore Pathology's patient-centered approach would be a valuable asset. **TDR**

—Joseph Burns

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Pathologist's Errors Associated with 12 Deaths at Arkansas VA

IN AN UPDATE TO A CASE REPORTED LAST YEAR, the investigation at the Arkansas **Veterans Health Care System of the Ozarks** and the **Veterans Affairs Medical Center** in Fayetteville, Ark., now shows that as many as 12 veterans died as a result of this one pathologist's errors, according to a report by Arkansas *KFSM 5 News*.

Investigators have now reviewed 33,902 cases that one pathologist handled and of these—3,007 (8.8%) involved an error or misdiagnosis—local media reported in January. The pathologist in question is Robert Morris Levy, MD, whom the VA fired in April 2018 after saying that Levy had been working while “impaired.” During a preliminary review, investigators found that he gave incorrect diagnoses to three veterans who later died. (See “*Pathology Errors a Factor in Three Deaths at VA Hospital*,” TDR, Oct. 1, 2018.)

Kelvin Parks, Director of the VA health system, reported on Levy's high rate of errors and said the rate was more than 12 times that of the standard in pathology practice. The *Northwest Arkansas Democrat Gazette* reported that the normal error rate for pathology results nationwide is 0.7%.

During a meeting in Fayetteville on Jan. 28, the health system released the latest findings in the investigation. News media said about 100 veterans attended the meeting. The Veterans Health Care System of the Ozarks serves veterans in 23 counties in Northwest Arkansas, Southwest Missouri, and Eastern Oklahoma.

As TDR reported earlier, Levy had been Chief of Pathology at the Veterans Health Care System of the Ozarks before he was fired. At that time, media reports said Levy “denied he was impaired on duty.”

VA officials said it was necessary to review the 33,902 cases, prioritized by level of risk, because that was the number of cases Levy had been involved with since he was hired in 2005, the newspaper reported.

The case review was expected to last until the end of last year because the **University of Arkansas for Medical Sciences** had sent nine pathologists to work at the Fayetteville Veterans System site fulltime, the newspaper reported. By Oct. 1, the beginning of the federal fiscal year, the VA system wanted to bring in more pathologists from outside of Arkansas, it added.

► Working While Impaired?

One of the most pressing questions in the case was whether Levy worked while impaired at the **Fayetteville Veterans Administration Hospital**. The pathologist confirmed that he had worked while impaired by alcohol in 2016 but said he did not work while impaired after that, the newspaper reported.

The Inspector General for the Veterans Affairs Office is investigating why Levy was retained at the VA system as a pathologist after his first reported impairment, officials said. As TDR reported, Levy was suspended in March 2016 for being impaired, but, after counseling, returned to work in October 2016. In October 2017, Levy was no longer involved in clinical work after the hospital discovered a second instance of working while impaired, and after a review by staff in the personnel department, Levy was fired, the newspaper added.

The newspaper reported that the U.S. Attorney for the Western District of Arkansas also was investigating. **TDR**

For Labs, Blockchain Offers New Opportunities

➤ **Aetna, Humana, Multiplan, UnitedHealthcare, Ascension, and Quest are working with blockchain**

➤➤ **CEO SUMMARY:** *Some of blockchain's proponents view its potential uses in health information technology to combat cybersecurity threats and improve the secure exchange of health information through electronic medical record systems. But for clinical laboratories, blockchain could be the key to improve payment processes and help eliminate errors in payment and allowed amounts. In theory, it could do so by allowing both parties to track claims from origin to payment.*

FOR CLINICAL LABORATORIES looking to solidify their relationships with health plans, blockchain may provide a new opportunity. Surprisingly, labs may be positioned to offer substantial value to health plans, providers, and others developing blockchain for a variety of purposes in healthcare.

Take, for example, when a new medical office opens. Clinical laboratories are among the first to know about such openings because physicians need to contract with at least one lab in order to manage patient care on the first day. As part of that contract, the lab is likely to bring supplies to the physician's office and set up a way to collect specimens and test requisitions.

➤ **Case for Blockchain**

A more compelling case might be made for using blockchain to reduce errors and improve the speed and accuracy of payments from public and private health insurers, proponents say.

One of the first problems proponents say blockchain could solve is the one involving out-of-date provider directories. Because labs are among the first to know

when a new physician group is opening, the lab can alert the physicians and the health insurers for which it is in-network that both should list the other as a partner.

That way, the health insurer can keep its physician directory up to date, thus helping to solve one of the health insurance industry's toughest problems. To date, health insurers have been notoriously bad at keeping their provider directories up to date.

Failing to do so causes patients to get surprise medical bills, which is another big problem that health insurers face. By visiting a doctor whom a patient believes is in-network, but who is in fact out of network, the patient may get a large surprise medical bill for healthcare services the patient may have believed should have been covered.

One way to address both of these problems is by having health insurers and clinical labs use blockchain, which is a data structure that can be timed-stamped and signed using a private key to prevent tampering. One of its widespread uses to date has been with the cryptocurrency Bitcoin.

Some of blockchain's proponents view its potential uses in health information technology to combat cybersecurity threats and advance the secure exchange of health information through electronic health record systems. Proponents say that when blockchain is used with EHRs, it can protect sensitive medical records from hackers and can be updated quickly and inexpensively. If so, it could be an effective tool for updating provider directories.

In a recent *Dark Daily* e-briefing about blockchain, Jason O'Meara, Senior Director of Architecture at **Quest Diagnostics**, noted how blockchain could be useful for clinical labs.

Although health plans collect the information they need for provider directories many months after a new practice opens, Quest and other labs often know about such new operations weeks in advance because of the need to order lab tests for patients on the first day, O'Meara explained.

"Each of our organizations expend a tremendous amount of energy and effort trying to get this data as good as it can be," O'Meara said. "The challenge is—when we're doing this in independent silos—it leads to duplication of efforts."

► **New Blockchain Alliance**

In December, Quest joined health insurers **Aetna**, **Humana**, **Multiplan**, **UnitedHealthcare**, UHC's data division **Optum**, and the health system **Ascension** in just such an effort, called the **Synaptic Health Alliance** (SHA).

"The alliance is exploring how blockchain technology could help ensure that the most current healthcare provider information is available in health plan provider directories, providing consumers looking for care with the most accurate information when they need it," Quest said when it joined the alliance. "Maintaining up-to-date health plan provider directories is a critical, complex, and challenging issue facing organizations across the healthcare system."

Under federal and state laws, health insurers are required to maintain directories that are accurate and up to date. To do so, insurers and their vendors spend some \$2.1 billion annually acquiring and maintaining provider data, Quest said.

The SHA defines blockchain as "a shared, distributed digital ledger on which transactions are chronologically recorded in a cooperative and tamper-free manner [such as a] spreadsheet that gets duplicated multiple times across a network of computers, which is designed to regularly update the spreadsheet."

► **Track Claims in Real Time**

In a recent article in *Modern Healthcare*, reporter Shelby Livingston explained that **Change Healthcare** is using blockchain to allow providers and insurers to track claims in real time—from the point of filing the claim to when each provider is paid. If blockchain technology can be harnessed in this way, does it have the potential to allow providers and payers to sort out all the issues they have currently over rejected payments and allowed amounts?

Change Healthcare already has a division that works with independent and hospital-owned labs to reduce the costs of medical billing and coding services.

If Quest and other lab companies can successfully demonstrate how blockchain can be used to improve the cumbersome and error-prone payment processes that most insurers and labs use today, they will have made a big step toward solving one of the most challenging problems that clinical labs face when seeking payment.

As Livingston explained, providers and health insurers maintain their own separate payment data. This means the insurer's idea of the status of a claim could be quite different from the lab's view. "But blockchain would allow both parties to have a shared understanding of where that claim is in the life cycle and automate the claims adjudication process," emphasized Livingston.

TDR

—Joseph Burns

Northwell Health Builds Two Big Lab Facilities

➤ **NYC Health and Hospitals is partner in one lab; the other is a new core clinical laboratory facility**

➤➤ **CEO SUMMARY:** *At Northwell Health, the clinical laboratory team has been busy building and opening two new, large laboratory facilities. First to open was the lab in Little Neck, Queens, a shared lab with NYC Health and Hospitals. This lab will handle 36 million tests annually. The second lab to open is Northwell's new core lab facility in Long Island, at Lake Success. This lab is designed to perform 55 million tests annually. Projects like these point to a building boom in the clinical lab industry.*

TWO MORE LARGE CLINICAL LABORATORIES ARE SCHEDULED TO OPEN this month, bringing to five the number of new facilities that big lab organizations have opened or announced throughout the United States since September.

The new labs are in New York City and Long Island. Early this month, **Northwell Health** and the **NYC Health and Hospitals** corporation opened a new 36,000-square foot facility in the Little Neck section of Queens. Then, later in the month, Northwell Health opened a second, larger new lab facility in its hometown, Lake Success, N.Y.

➤ **Two Partners in NYC Lab**

In Little Neck, the two partners are sharing the \$47.7 million cost of the new lab, which is expected to save NYC Health and Hospitals more than \$20 million annually. On the first day, the lab began operations with 176 employees, a number that is expected to rise to 210 as testing volume increases.

NYC Health and Hospitals runs 11 acute care hospitals, five post-acute and long-term care facilities, a federally qual-

ified health center clinic, a home health agency, and a health plan, among other operations. As the nation's largest public health system, the NYC Health and Hospitals corporation serves more than one million New Yorkers annually in more than 70 patient care facilities across the city's five boroughs.

➤ **Largest Non-Profit**

The new laboratory facility in Little Neck is an integral part of what Northwell and NYC Health and Hospitals call the **Clinical Laboratory of New York Alliance** (CLNY), which the partners formed in 2014. As the largest nonprofit hospital-operated lab in the nation, CLNY is designed to enhance quality and patient care and cut costs for both health systems and their hospitals. Also, CLNY aims to integrate laboratory services through a shared reference lab and to standardize information systems and equipment.

Later in February, Northwell Health opened a second CLNY lab when it moved its core lab operations from one location in Lake Success, N.Y., to Northwell's **Center for Advanced Medicine**, also in

Lake Success. Located across the street from the health system's headquarters in the village of New Hyde Park, the Center for Advanced Medicine includes a cancer institute, the **Smith Institute for Urology** and the **Monter Cancer Center**, the *Long Island Newsday* newspaper reported.

► Space for Clinical Lab, AP

The laboratory facility at the Center for Advanced Medicine will include space for clinical lab and anatomic pathology testing. Built at a cost of \$59.6 million, the new Center for Advanced Medicine lab will measure 101,000 square feet—including 84,000 square feet for clinical lab work—and contain the largest chemistry and hematology automated line of its kind in North America, Northwell said.

Newsday reported that Northwell Health planned to move 520 employees to its new lab in Lake Success, and that the new facility will be able to run 55 million tests annually. Many of those tests will come from the health system's 23 hospitals and its medical group, **Northwell Health Physician Partners**. Other tests will come from nonaffiliated hospitals and physicians, the newspaper added.

To manage the additional lab test volume from the new labs in Little Neck and nearby Lake Success, Northwell has hired about 90 new employees over the past year. In total, Northwell Health Labs has a workforce of more than 1,300, the partner said.

► Prior Use of Lab Building

The renovated building in Lake Success has an interesting history from when **Sperry Gyroscope Corp.** manufactured weapons there during World War II. When the war ended, Sperry didn't need as much space and the **United Nations** located its headquarters there from 1945 to 1951, when the UN opened its new facility in Manhattan.

The construction of these two sizeable new laboratory facilities comes in the

midst of an interesting building boom in the clinical laboratory industry. In recent months, three major laboratory companies began building very large lab facilities. (See *TDR*, Feb. 4, 2019.)

In Salt Lake City, **ARUP Laboratories** has construction underway on a 200,000 square foot lab building. It will be the fifth building at the company's headquarters.

In DeLand, Fla., **DaVita Labs**, a division of **DeVita Kidney Care**, opened a 150,000 square foot laboratory facility. This expands the capacity of the existing laboratory at that site.

In Clifton, N.J., **Quest Diagnostics** is in the design stage to build a new laboratory facility of 250,000 square feet. It expects the new lab to be operational by early 2021.

► Lab Automation

Collectively, the investments by major organizations to expand the capacity of their clinical lab facilities demonstrates that the healthcare system is using more lab tests. Two trends fuel this activity.

First, physicians need to order more clinical laboratory tests. One factor is the ongoing increase of population and the number of patients. Another factor is that physicians are participating in care models that require them to apply the same care algorithms to every patient, as appropriate. For example, every diabetes patient should get an annual hemoglobin A1c test. These algorithms include lab tests.

Second, there are more types of clinical laboratory tests that physicians can use to diagnose and treat different diseases and medical conditions. This increases the volume of lab tests ordered each year.

Of course, both trends described above work against the single most disruptive trend in the clinical lab industry today: the successive and deep cuts to lab test payments that Medicare and private health insurers are implementing. **TDR**

—Joseph Burns

Pathology Firm Pays \$63M to Settle Qui Tam Case

➤ **Inform Diagnostics faced three whistleblower lawsuits alleging illegal inducements to clients**

➤➤ **CEO SUMMARY:** *Inform Diagnostics, formerly Miraca Life Sciences, settled the federal qui tam case while denying wrongdoing. The \$63.5 million settlement will be paid by the former owner, Miraca Holdings, a Japanese company. The federal Department of Justice alleged that the company—then known as Miraca Life Sciences—violated the False Claims Act by engaging in what federal lawyers called “improper financial relationships with referring physicians.”*

On Jan. 30, federal prosecutors announced an agreement with **Inform Diagnostics** of Nashville, (formerly known as **Miraca Life Sciences**) to settle allegations that the company violated the False Claims Act by engaging in what **Department of Justice (DOJ)** lawyers called “improper financial relationships with referring physicians.”

Inform Diagnostics agreed to pay \$63.5 million to settle the claims in the case, but did not admit to any wrongdoing. There are two twists in this case. The first twist is that the current owners of Inform will not pay the settlement amount. Instead, it will be paid by the company’s previous owner, **Miraca Holdings**.

The second interesting twist in this case is that pathology laboratory companies competing against Inform Diagnostics and its earlier owners complained about business practices that violated the federal anti-kickback statute. These claims commenced within years of the company’s launch in the late 1990s.

Founded in 1998 in Nashville as a venture capital-funded physician practice management company named **Pathology**

Partners, the company moved to Dallas shortly thereafter. In 2005, **Caris** acquired a majority interest and renamed the company **Caris Life Sciences**. In 2011, **Miraca Holdings**, a Japanese firm, bought the company and changed the name to **Miraca Life Sciences**.

After its move to Dallas in 2000, lab competitors of Pathology Partners began to claim that the company was illegally inducing physicians by subsidizing, in various ways, how client physicians purchased and used EHR systems. These allegations continued as the company was renamed Caris and then Miraca Life Sciences and operated by new owners.

➤ **Avista Acquired Miraca**

In 2017, the company changed hands once more when **Avista Capital Partners** acquired Miraca and changed the name to Inform Diagnostics. In a statement to **THE DARK REPORT**, Inform Diagnostics said Miraca Holdings will pay the settlement of \$63.5 million and Inform will not be subject to a corporate integrity agreement. Inform also said it was pleased to reach the agreement with the DOJ to settle the dispute and admitted no wrongdoing.

In announcing the results of its investigation, the DOJ added this important caveat: “The claims asserted are allegations only, and there has been no determination of liability.”

In November 2017, Miraca Life Sciences amended its merger agreement with **Avista Capital Partners** after the pathology company lost value in the two months since the agreement was signed in September 2017, THE DARK REPORT reported. Among the factors that led to the revision were a significant decline in reimbursement rates, stiff competition from physician-office labs, and a loss of specimen volume to POLs and hospital labs, Miraca said. (See, “*Value of Miraca Falls by 92% from 2011 to 2017*,” TDR, Dec. 11, 2017.)

In the announcement, the DOJ said the allegations in the case stem from three lawsuits filed under the *qui tam*, or whistleblower, provisions of the federal False Claims Act. The first of these cases was filed in 2013 and amended twice. The second was filed in 2016 and the third was filed last year. A former Caris employee is believed to have filed the lawsuit in at least one of the whistleblower lawsuits.

When the government reaches such settlements, plaintiffs can share in the proceeds. In this case, the whistleblowers’ share of the settlement has yet to be determined.

► **Claims of Illegal Subsidies**

U.S. Attorney Don Cochran for the Middle District of Tennessee and U.S. Attorney Maria Chapa Lopez for the Middle District of Florida announced the settlement, saying it resolves allegations that the company violated the Anti-Kickback Statute and the Stark Law by providing subsidies for electronic health record (EHR) systems, and free or discounted technology consulting services to referring physicians and physician groups.

The Anti-Kickback Statute and the Stark Law restrict the financial relationships that healthcare providers, including laboratories, may have with doctors who refer patients to them, the DOJ said.

In 2006, the federal **Department of Health and Human Services** adopted regulations allowing laboratories to provide EHR donations to physicians under certain conditions, the DOJ said. But the DOJ alleged the pathology company violated the conditions of the regulations. In 2013, HHS withdrew those exemptions for laboratories, the DOJ added.

► **Pathology Service Menu**

Inform Diagnostics provides AP services primarily in the fields of GI pathology, dermatopathology, hematopathology, and GU pathology. The company has some 1,000 employees and laboratories in Irving Texas, Boston, New York, and Phoenix.

Regarding steps the company will take toward compliance, Inform said new senior executives and board members have taken over the management and made compliance a priority. “A full-time chief compliance and ethics officer reports to the board and manages a new team of compliance staff,” the company said. “External consultants perform regular compliance and billing audits. As we move forward, we are committed to meeting and exceeding the expectations of our clients and other stakeholders.”

When commenting on the case, Assistant Attorney General Joseph H. Hunt of the DOJ’s Civil Division said the settlement may deter similar conduct. “The Department of Justice has longstanding concerns about improper financial relationships between healthcare providers and their referral sources, because those relationships can alter a physician’s judgment about the patient’s true healthcare needs and drive up healthcare costs for everybody,” he added.

Court documents and public statements make it clear that the new owners of Inform Diagnostics have had strict compliance programs in place since the date when they acquired the company. **TDR**

—Joseph Burns
Contact David Boling at the DOJ at 615-736-5956 or david.boling2@usdoj.gov.

INTELLIGENCE

LATE & LATENT
 Items too late to print,
 too early to report



Quest Diagnostics sold its clinical laboratory business in India last December, thus ending a 12-year effort to build a thriving business in that nation of 1.3 billion people. The buyer was **Strand Life Sciences** of Bengaluru, India. The transaction was announced in a press release issued by Quest Diagnostics and no purchase price was disclosed.

MORE ON: Quest India

It was back in 2007 when Suriya Mohapatra, then CEO of Quest Diagnostics, announced ambitious plans to open a Quest Diagnostics laboratory business in India. At that time, Quest executives regularly predicted that the company could rapidly grow that business to US\$1 billion per year. Paul Rust, who had worked at **SmithKline Beecham Clinical Labs** and then Quest after it acquired SBCL, was named country manager and given the unenviable task of building the business in India. In 2007, **UnitedHealthcare** gave **Laboratory Corporation of America** a 10-year exclusive national contract and excluded Quest from national provider status. Many

in the lab industry thought Mohapatra's decision to build a lab business in India was one way to divert attention away from his company's loss of the **UnitedHealthcare** contract.

SWISS POST DRONE CRASHES WITH LAB SPECIMENS

After announcing it intended to transport medical lab specimens by drone last year, **Swiss Post**, the postal service of Switzerland, was doing pilot tests of the drones when on Feb. 20, a drone carrying "non-relevant" blood samples crashed in Lake Zurich. Swiss Post announced it would stop drone flights while it analyzed this failure.

TRANSITIONS

- As of Jan. 1, Jerry Hussong MD, MBA, became the new CEO of **Sonic Healthcare USA**. Previously, Hussong has worked at **ARUP Laboratories**, **Cedars-Sinai Medical Center**, **Laboratory Medicine Consultants**, **University of Utah**, and **Northwestern Medical Center**.

- Steve Schumpert retired as CEO of **Sonic Healthcare**, USA, of Austin, Texas, on

Dec. 31, 2018. Schumpert had previously held executive positions at **Clinical Pathology Laboratories**, **Louisiana Reference Laboratories**, **SmithKline Beecham Clinical Laboratories**, and **International Clinical Labs**.

- **Providence Health Care** of Spokane, Wash., appointed Bill Remillard as Director of its laboratory operations. He formerly held executive positions at **TriCore Reference Laboratories**, **PAML**, and **ARUP Laboratories**.



DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the closure of rural, for-profit hospitals at an "alarming rate." This trend, coupled with Medicare lab price cuts that are eroding the finances of community labs serving rural areas, means patient access to quality lab testing is diminishing.

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 18, 2019.***



SPECIAL SESSION

How Labs Can Support Precision Medicine and Shared Saving Initiatives

Philip C. Chen, MD, PhD

Chief Healthcare Informatics Officer,
Sonic Healthcare USA, Austin, Texas

Using Data, Lab Results, and Analytics to Support Office-Based Physicians in Managing Patients with Diabetes and Chronic Diseases

Here is one of the more important sessions for lab leaders who want their labs to deliver added value...and be paid for that value. Dr. Chen and his team have the capability to combine lab test data with clinical and demographic data in ways that allow physicians to identify which patients in their practice are at risk and which patients may be progressing toward diabetes or chronic kidney disease, for example.

This is actionable intelligence rooted in lab test data, presented so that physicians, ACOs, and payers can intervene in a timely fashion to help patients avoid acute events, keep them from developing a chronic condition, and maintain peak health. You'll learn different ways your lab can be paid for these added-value services. This session is a valuable road map your lab can follow to generate revenue from new sources to offset the ongoing declines in fee-for-service payments. Guarantee your place at this presentation by registering today!

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- Update on Diagnostic Management Teams: New Success at Speeding Diagnosis, Treatment.**
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