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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Northwell and Memorial Health: A Tale of Two Labs

SOMETHING VERY UNUSUAL HAPPENED IN THIS ISSUE OF THE DARK REPORT. We analyzed the entirely opposite fates of two clinical laboratories owned by different healthcare systems. With apologies to author Charles Dickens and his opening sentence in his novel, a *Tale of Two Cities*, it can be said that, "for one lab, it was the best of times and for the other lab it was the worst of times."

The clinical lab at **Northwell Health** of New Hyde Park, N.Y. is enjoying "the best of times." On pages 10-17, you'll read the second of two parts in our coverage of its 10-year journey to support its parent organization's financial and clinical goals by delivering increased value to physicians, patients, and payers.

And on Jan. 27, "the worst of times" began for the clinical laboratory at **Memorial Hermann Health System** (MHHS) in Houston. On that day, Memorial Hermann announced it was selling its outreach laboratory business to **Quest Diagnostics** and contracting with Quest to manage the inpatient laboratories at MHHS' core lab and 17 hospitals. *(See pages 3-6.)*

Each intelligence briefing allows you to better understand why it's essential for managers and clinical pathologists in charge of hospital labs to recognize the powerful opportunity they have to deliver value in patient care to their parent organizations—and how that achievement becomes a win for everyone in the healthcare continuum, from the lab's owners to physicians, patients, and payers.

The decision by Northwell Health's lab leaders to prepare a compelling strategy and plan for their lab underpins the importance of that opportunity. After gaining the support of administration, lab managers worked diligently to better manage costs. They then collaborated with physicians to leverage lab test data to improve patient care and to expand outreach test volume and revenue. That in turn financed the implementation of new assays and the enrichment of the lab information system, so that lab data could be converted into actionable clinical intelligence, available in real time to physicians at the point of care.

By contrast, it appears that the laboratory division of Memorial Hermann Health was unable to gain similar support from their health system executives. The end of MHHS' lab "story" is that its outreach business was sold and a commercial lab company will now manage its inpatient lab testing. TDR

Memorial Hermann Sells Outreach Lab to Quest

Health system to sell outreach lab business, Quest gets contract to manage inpatient, other labs

CEO SUMMARY: Need for more capital is probably one reason why Memorial Hermann Health System decided to sell its large clinical laboratory outreach business to Quest Diagnostics in a transaction both organizations announced on Jan. 27. Although terms of the sale were not announced, lab executives in Houston believe that Memorial Hermann will be paid several tens of millions of dollars by Quest. Still to be determined is the post-closing staffing needs for pathologists and lab professionals.

At the end of January, **Quest Diagnostics** continued a two-month run of acquisitions when it announced it would buy the outreach laboratory division of **Memorial Hermann Health System** (MHHS) in Houston and other assets of **Memorial Hermann Diagnostic Laboratories** (MHDL).

In the deal, Quest gets two other assets. First, under a multi-year agreement, it will manage all the remaining Memorial Hermann labs, including the core lab, the inpatient laboratories in 17 hospitals, and the labs in four other facilities. Memorial Hermann will continue to own those labs, many of which provide onsite rapid response testing.

Second, Quest will serve the **Memorial Hermann Health Plan** (MHHP) as the only preferred lab provider. The MHHP has a three-star rating with Medicare and has a 25% share of the HMO market, making it the second largest insurer behind Aetna, which has a 29% share. MHHP does not have a significant presence in the preferred provider, point-of-service, or exchange markets, according to data from the **American Medical Association**.

As the largest health system in the nation's fourth-largest city, the nonprofit Memorial Hermann includes 17 hospitals and more than 300 care delivery sites in Houston and its suburbs. MHDL itself has 60 physician office labs and more than 30 patient service centers.

When the deal closes, Memorial Hermann will transfer MHDL's assets, including its outreach testing business, to Quest, which will use its own Houston lab facility for such testing. MHDL will cease to exist and has no plans to open a new outreach testing business, MHHS said.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Quest announced the Memorial Hermann contract on Jan. 27, just five days after saying it would buy **Blueprint Genetics** in an all-cash transaction. Based in Helsinki, Finland, Blueprint has operations in Seattle. In December, Quest announced it acquired some of the clinical laboratory assets of **Boston Clinical Laboratories**, a privately held lab company in Waltham, Mass. *(See sidebar, "In Addition to Getting Memorial Hermann's Lab Assets, Quest Diagnostics Made Two Other Acquisitions," page 5.)* Financial terms were not announced for any of these three deals.

In a letter to patients, Memorial Hermann touted the benefits of the deal, saying Quest has some 80 patient service centers in Greater Houston and that the transition to Quest will give patients, "Broad health plan access that includes all major payers," although how a clinical lab can provide broad access to health insurers was not explained. Patients also get access to what Memorial Hermann called "a comprehensive test menu," without explaining the differences between the two companies' test menus.

Memo to Physicians

In a memo on Jan. 27 to **Memorial Hermann Physician Partners**, Memorial Hermann's President and CEO David L. Callender, MD, said physicians were not required to refer patient testing to Quest Diagnostics. The memo made no other reference to lab referrals. He also wrote that MHHS' pathology groups would not be changing as a result of the agreement and that they would continue to have clinical oversight.

Neither Quest nor MHHS will make any immediate changes to laboratory operations until the deal closes in the spring, Callender added, in part because the relationship was in its early stages.

For physicians who have in-office lab services or are clients of MHDL, he wrote, the Quest Diagnostics Commercial team in Houston would be in contact to discuss preparations for the transition.

As all health systems shift away from volume and toward value-based payment, Callender emphasized this point in his memo to physicians. Memorial Hermann is shifting toward value-based care, he wrote, and, "this agreement serves as a natural extension of our vision and strategy for the future."

Value of Lab Test Data

That statement may lead clinical lab employees and managers to wonder what will happen to the lab test data Memorial Hermann collected on its patients. In value-based payment arrangements, labs collect extensive data on patients' conditions that health systems can use to increase the value of services they deliver to payers. *(See, "How Northwell's Lab Team Demonstrated Value Over 10 Years," TDR, Jan. 27, 2020, and "TriCore Forges Ahead to Help Payers Manage Population Health," TDR, May 20, 2019.)*

According to Otto Schaefer, founder and president of **Advanced Pathways Consulting**, among clinical lab professionals and pathologists in Houston the Quest-Memorial Hermann announcement was "ground shaking."

Schaefer, who advises pathologists and pathology groups on business strategy, said one of the biggest concerns about the deal is how it will affect pathologists, clinical lab staff, and the managers and directors of Memorial Hermann's labs.

Path Groups to Lose Income?

The effect on pathologists may be the most significant, he added. "My main concern is what will be the effect of this deal on the revenue that currently goes to the pathology groups in the Memorial Hermann system," he commented.

As one of the largest integrated delivery networks in Houston, Memorial Hermann employs at least three different pathology groups. "That's likely by design because they don't want any one pathology group to have a monopoly within the system," said Schaefer. The pathologists in those groups

In Addition to Getting Memorial Hermann's Lab Assets, Quest Diagnostics Made Two Other Acquisitions

IN AN EFFORT TO ACQUIRE A USEFUL TECHNOLOGY PARTNER AND ELIMINATE A COMPETITOR, **Quest Diagnostics** announced on Jan. 22 that it acquired **Blueprint Genetics** in an all-cash transaction. Blueprint has operations in Helsinki, Finland, and Seattle.

The Blueprint deal was Quest's second acquisition in as many months. On Dec. 2, Quest announced it acquired some of the clinical laboratory assets of **Boston Clinical Laboratories**, a privately-held lab company in Waltham, Mass. BCL's services will move to Quest's lab in nearby Marlborough, Mass., a facility that serves New England and other states.

No Disclosure of Terms

None of the companies disclosed the financial terms of these deals. BCL's COO, Hossein Bayat, PhD, said the sale to Quest was driven in part by apprehension about revenue.

"Given increasing reimbursement pressures on today's labs, now is the right time for BCL to transition the business," he said in a Quest press release.

Note that Quest's acquisition follows a model that big tech and other large companies have used to eliminate competitors. By buying a competitor, the purchaser gains the competitor's technology and its market share and expertise in that business, something **Microsoft** and **Apple** have done for years.

While the BCL deal is important for Quest's operations in New England, the acquisition of Blueprint is perhaps more significant for Quest.

Blueprint serves customers in more than 70 countries, mostly in North America and Europe. Its growth is based on detecting and interpreting variants in more than 3,900 genes. It offers more than 200 panel tests covering 14 medical specialties.

For Quest, Blueprint provides a platform in specialty genetics, especially gene variant interpretation and reporting, said Carrie Eglinton Manner, Quest's Senior Vice President for Advanced Diagnostics.

Blueprint is expected to support Quest's efforts to serve providers specializing in rare disease and neurology, especially those physicians in pediatric and academic hospitals. Also, Blueprint's tests will benefit Quest's pharmaceutical and *in vitro* diagnostics offerings.

Blueprint's Vice President and General Manager Tommi Lehtonen agreed, saying that working with Quest will allow Blueprint to extend its work in the United States, Canada, and in other countries.

He added that Blueprint considered working with several organizations but accepted Quest's offer because of its work in genetics, national infrastructure, and good cultural fit.

While Blueprint will operate largely independently from its lab in Helsinki, Quest said, the company now says it is based in Helsinki and Seattle. In July, Blueprint moved its sample accessioning, client services, and billing operations in North America to its new Seattle lab and began hiring to fill open positions.

Blueprint Partnership

On September 24, Blueprint announced a partnership with **ARCHIMEDlife Medical Laboratory** of Vienna, Austria, to do biochemical testing for rare diseases in North America.

Starting early this year, Blueprint and ARCHIMEDlife will test for genetic disorders using mass spectrometry and NGS.

In addition to testing for rare disease, the combination of biochemical and genetic testing is used for personalized medicine and clinical research.

serve as medical directors of lab services in Memorial Hermann hospitals, he added.

Lab Staff, Pathologist Jobs

Lab staff and pathologists in Houston have told Schaefer they are concerned that Quest will replace the current laboratory operations managers and directors in Memorial Hermann laboratories.

"They can apply for the positions they're in now through Quest's direct hiring process," he reported. "But Quest may not retain most of those department heads or managers. Instead, Quest will probably want to have their own people manage hospital laboratory operations."

Both parties will benefit from having Quest take over some positions, because MHDL will no longer be responsible for paying the salaries and benefits of those management employees, and Quest will be able to cut staff as needed, he commented. "In addition to the management staff changes, most med techs in the core lab will probably be let go," he added.

"Also, what will happen with the key parts of hospital labs such as histology and cytology?" he asked. "I don't know how the core lab at MHDL manages histology or cytology, but all the regional Memorial Hermann laboratories have their own histology labs.

Will Lab Billing Be Affected?

"I wouldn't be surprised if a lot of that work was moved to MHDL's core laboratory," Schaefer commented. "If so, that work is not in Quest's wheelhouse because it's labor intensive and not scalable. That raises the question about what's going to happen to pathology services.

"In the announcement, both Quest and Memorial Hermann said pathology services will remain the same," Schaefer confirmed. "I read that memo to mean that the pathology service groups would be unchanged. But if you look at the economics of it all—which is what I do with the groups I consult with—you see an unsettling trend.

"The clinical pathology billing in most hospitals includes the medical director's fees that get tacked onto all the clinical laboratory work in those labs, meaning every CBC and every chem panel," he explained.

"In most cases those fees for clinical pathology billing are equal to or very close to the anatomic pathology billing. So, for a pathologist serving as a medical director, the income from both AP and CP are about equal.

"But at the same time, reimbursement for AP and CP is declining as more insurance companies scale back reimbursement for CP fees for pathologists," he said. "Medicare and Medicaid don't pay for it anymore. Those fees are trending downward even more drastically than anything else. Still, CP fees are a large portion of every pathology group's total income," he added.

Core Lab Testing

So, what does that mean now that the core laboratory work at Memorial Hermann will go to Quest's core lab? "A lot of that income will be lost to Memorial Hermann, which will affect those pathologists working as medical directors in those hospitals," Schaefer said. "Without numbers or data, it's difficult to estimate how much of an effect the Quest deal will have, but it's likely that the biggest impact will be on the core lab and on the labs that send their CP and AP work to the core lab.

"Can those pathology groups take that hit to revenue and retain the pathologists they have now?" he asked. "We don't know that, but we can say that Quest will get a lot of the revenue that has been going to Memorial Hermann.

"And, we can say that Quest will be able to bill for the technical component and the professional component of any CP or AP work," Schaefer added. TDR

—Joseph Burns

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First EKRA Guilty Plea Involves Lab Kickback

Only 15 months after enactment of EKRA, prosecutors win first case involving a lab and bribe

CEO SUMMARY: Federal investigators wasted little time in using the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) to prosecute fraud involving clinical laboratories and providers. The manager of an opioid treatment center in Kentucky pleaded guilty last month to three counts: soliciting a bribe, making a false statement, and attempting to tamper with evidence. Prosecutors announced the plea and conviction, but the laboratory company remained unnamed.

Word is spreading around the clinical laboratory industry that federal prosecutors recently won their first conviction under the federal Eliminating Kickbacks in Recovery Act (EKRA) of 2018. The case in Kentucky involved a provider requesting a bribe from a clinical laboratory in exchange for referring patient specimens to the lab.

The enactment of EKRA into law in October 2018 created compliance risks for all healthcare providers—especially for clinical labs and anatomic pathology groups—because the law's language conflicts with practices historically permitted under the federal Anti-Kickback Statute (AKS). *(See TDR, Dec. 3, 2018.)*

In the Kentucky case, the first count was filed under EKRA, which is part of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act signed into law on Oct. 25, 2018. The law is aimed at addressing the opioid crisis and prohibits the solicitation or receipt of kickbacks in exchange for the referral of urine drug testing services, among other acts.

On Jan. 10, Robert M. Duncan, Jr., the U.S. Attorney for the Eastern District of Kentucky, filed the plea agreement in which Theresa C. Merced, a manager at an opioid treatment center, pleaded guilty to three counts: soliciting a bribe, making a false statement, and attempting to alter evidence in the case, the plea agreement showed.

Possible Jail Term, Fine

Merced faces a potential prison term of 20 years, and a fine of $250,000, and restitution, if applicable.

In court documents, Duncan said Merced was a manager of **St. John Neumann's Extended Hours Clinic**, in Jackson, Ky., where patients underwent urine drug testing as part of their care and Merced was involved in referring urine drug testing to clinical toxicology laboratories. Merced's husband, a physician at the clinic, provided substance abuse treatment to clinic patients, the agreement said without naming the husband.

The *Lexington Herald-Leader* identified Merced's husband as Pablo Merced, MD, a family physician.

In the first count, court documents showed Theresa Merced solicited and received remuneration in return for referring patients to a laboratory that was not named.

In the second count, documents showed Merced told an agent of the federal **Department of Health and Human Services**, Office of Inspector General (OIG), that a $4,000 check from a toxicology lab owner was a loan to Merced's husband. The statement was false because Merced knew that she had solicited the $4,000 check as a kickback in exchange for referring urine drug testing services from the clinic to the toxicology lab, the plea agreement showed.

In the third count, Theresa Merced attempted on Sept. 12, 2019, to alter financial records relating to her receipt of a kickback, court documents explained.

Plea Agreement Facts

In the plea agreement, Duncan said the case began in December 2018 and continued through August 2019. The Lexington newspaper reported Theresa Merced wanted cash and asked the lab company's CEO to pay for hiring clinic employees and to cover utility costs.

"On or about Dec. 13, 2018, the defendant telephonically contacted R.C., the CEO of a clinical toxicology laboratory located in Lexington, Ky.," the plea agreement showed. "The defendant solicited kickbacks from R.C. in exchange for her referral of urine drug testing to his laboratory; the solicited kickbacks included cash payments, the hiring of employees to work in the clinic, and the payment of certain utilities."

The lab was not named and R.C. was not identified. In this case, no other charges have been filed publicly. Through a spokesperson, Duncan told THE DARK REPORT that he would not comment on whether the lab or any lab employees would be charged because the case is ongoing. The Lexington newspaper reported that Theresa Merced's attorney, Darrell A. Herald, said it appeared R.C. cooperated in the investigation.

"Between Dec. 13, 2018, and Aug. 15, 2019, the defendant engaged in multiple conversations with R.C. in which she requested both cash and in-kind payments in exchange for the urine drug test referrals," the plea agreement said. "The defendant knew the proposed arrangement was illegal. On at least one such phone call, the defendant cautioned R.C. to be discreet because she did not want 'to be in trouble with the law.'"

On Aug. 15, 2019, R.C. gave Theresa Merced a $4,000 check, court documents showed. R.C. called the check "earnest money" toward a total payment of $14,000, the plea agreement said. In addition, court documents showed that R.C. would "hire five employees as requested by the defendant."

On Sept. 12, 2019, agents from OIG and the Kentucky Attorney General's Office Medicaid Fraud Control Unit (MFCU) interviewed Merced. The agents warned Merced that making false statements in the interview could result in prosecution.

"The agents asked the defendant why she or her husband cashed a $4,000 check from R.C.," the plea agreement showed. "The defendant repeatedly denied having seen or knowing anything about the check. The defendant told the agents that her husband was careless with money and that, in anticipation of an upcoming vacation, he probably borrowed the money from R.C. The defendant acknowledges that these false statements about the $4,000 check were material and were made knowingly and willfully."

The Lab's Involvement

One month after that interview, Theresa Merced spoke on the phone with R.C. "On Sept. 12, 2019, after being interviewed by the MFCU and HHS-OIG agents, the defendant communicated with R.C. by telephone," the plea agreement said. "The defendant expressed concern about the investigation and told R.C. that she had explained away the check as a 'loan.'

"When R.C. informed the defendant that the memo line of the check said 'rent,' and that his laboratory's internal accounting records also classified the kickback as 'rent,' the defendant asked R.C. to alter the internal accounting records to say 'rent/loan,' the documents showed. "The defendant told R.C., 'we'll synchronize ... so we won't incriminate each other.'"

On Jan. 10, Merced appeared in U.S. District Court for the Eastern District of Kentucky with her lawyer and pleaded guilty. Duncan recommended releasing the defendant on an unsecured bond pending sentencing, and that she could self-report to prison if she did not violate the plea agreement or bond conditions.

Chief Judge Danny C. Reeves imposed conditions of Theresa Merced's release pending sentencing and denied her request to modify the conditions relating to travel restrictions and possession of firearms. Sentencing was scheduled for May 1.

Labs Have Compliance Risk

Since EKRA was enacted in 2018, some of the lab industry's marketing and sales practices, which either meet a safe harbor of the Anti-Kickback Statute or have historically presented low risk on an analysis of the facts and circumstances, now may be considered illegal.

Lawyers familiar with the law have said all clinical laboratory managers and pathologists need to be aware of provisions in EKRA that appear to eliminate the ability of laboratories to compensate sales personnel (including W-2 employees and 1099 contractors) on a commission-based formula related to any business they generate, whether covered by a government health program or a private health insurer. For this reason, the lab industry has asked federal agencies to address the conflicting language of EKRA and the Anti-Kickback Statute. TDR

—Joseph Burns

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Lawyer Says More Charges Are Possible

DANIELLE SLOANE, a member of the law firm **Bass, Berry, and Sims** in Nashville, said more charges are possible in the federal criminal case involving the treatment center manager charged in Kentucky under the Eliminating Kickbacks in Recovery Act of 2018 (EKRA).

Sloane said, "I wouldn't be surprised if we saw some charges involving the lab in the coming months.

"It's interesting that the plea agreement doesn't even name the laboratory company." she continued. "In many kickback cases, federal prosecutors will go after both sides of the transaction. I don't see why prosecutors would treat this case any differently, unless the lab thought the payments were for a legitimate purpose.

"It's possible that the lab reported this defendant's request for a kickback in exchange for test referrals to state or federal authorities," she added.

One question left unresolved is how EKRA's wording appears to conflict with the Anti-Kickback Statute.

"Federal authorities have yet to resolve discrepancies where the two laws overlap. There's a provision in EKRA that says the statute doesn't apply to anything prohibited by the Anti-Kickback Statute," she added. "Given EKRA does not apply to conduct prohibited by the Anti-Kickback Statute, it's interesting that the prosecution did not include a violation of the Anti-Kickback Statute in addition to EKRA."

Sloane cautioned lab directors and lab staff to be aware of EKRA's prohibitions and, with respect to sales, ensure they have an adequate compliance program in place to prevent, detect, and deter inappropriate sales tactics.

➤➤ ***CEO SUMMARY: In 2008, the administration at the Northwell Health system on Long Island considered selling its inpatient and outpatient laboratory services to a commercial laboratory company. In response, the leaders of the Northwell Health Laboratories proposed a plan to show how the health system would benefit clinically and financially by retaining the laboratories. Ten years later, the lab team published the details of how that strategy was successful in boosting outreach lab revenue from $46.1 million in 2008 to $236.4 million in 2018.***

Lab Achieved Complementary Goals of Improving Patient Care and Increasing Revenue

Northwell Health Labs Produce Value-Added Outcomes, Growth

Second of Two Parts

To survive and thrive as healthcare transforms away from delivering care based on volume, clinical laboratories and anatomic pathology groups need strategies to deliver value.

In 2008, the leadership at **Northwell Health**, and in the system's medical laboratories, recognized the need for the laboratory to add value in how it served the health system, its patients, and its physicians and other providers.

To do so, the lab developed a multi-part strategy in the fall of that year to increase lab test volume and revenue from lab testing while also improving patient care and controlling costs. At the time, Northwell Health in New Hyde Park, N.Y., was a 15-hospital system. Today, the health system has 23 hospitals and an extensive network of physician offices and other clinical assets.

In part one of this multi-part series, we explained the steps the leadership of **Northwell Health Laboratories** began in the fall of 2008 and continued through 2018 to add value to support the growth of its parent health system. *(See, "How Northwell's Lab Team Demonstrated Value Over 10 Years," TDR, Jan. 6.)*

This series is based on a report published in December 2019 in the *Archives of Pathology and Laboratory Medicine* (APLM), a peer-reviewed medical journal, titled, "Northwell Health Laboratories: The 10-Year Outcomes After Deciding to Keep the Lab."

In part two of this series, we report on how the lab integrated a pan-system structure in the Department of Pathology and Laboratory Management (DPLM) to deliver value consistent with the concept that all healthcare is local, along with how the lab's leadership rigorously tracked quantitative data to demonstrate how the lab contributed to improved patient outcomes and cost management.

These two steps were critical for the lab to increase test volume and revenue, while making clear to health system leadership that the lab was an essential system asset.

Beginning in January 2009, James M. Crawford, MD, PhD, Senior Vice President, Laboratory Services at Northwell Health, worked with other lab leaders to integrate the structure of the DPLM.

➤54 Pathologists in the System

At the time, 50 of the lab's 54 pathologists were paid salaries as employees of their respective hospitals, and those hospitals were responsible for the professional component revenue cycle.

During the year, the DPLM converted 52 of those pathologists to department employees, and five years later, the DPLM hired the other two away from their positions in private practice. Each of the hired pathologists was added as a department employee.

Over the same period, the DPLM acquired all professional component billing from the hospitals. This step was a key factor in the lab's success in the following years because it allowed the lab to manage all claims-coding, billing, and collections.

By managing these functions more closely, the lab could submit more clean claims and devote more resources to documenting claims, successfully appealing rejected claims, and improving collections, particularly for the small dollar amounts characteristic of laboratories.

These early actions paid dividends. "The 2009 restructuring of pathologist employment increased professional Part B revenue by 78% when compared to 2008 ($69.04 collected per work relative value unit (wRVU) in 2009, versus $38.86 per wRVU in 2008), through better performance of the revenue cycle," Crawford and colleagues wrote in the APLM article.

Also at that time, the lab named two system vice chairs (one for Anatomic Pathology and one for Laboratory Services), hired one departmental division chief from the outside, and promoted six other departmental division chiefs from within the department.

Two years later (in 2011), the lab integrated the central region anatomic pathology services, meaning those serving **North Shore University Hospital**, **Long-Island Jewish Hospital**, and the core lab outreach program.

In 2012, two regional associate chairs were appointed to oversee community hospital pathology practices in the health system's eastern and western regions. When Northwell Health acquired other hospitals in subsequent years, the pathologists from those facilities were hired into the department after they completed any prior contractual arrangements.

The management of the laboratory service line also was streamlined and integrated into the DPLM. By integrating these services, the DPLM created what the authors called "pan-system divisions" that enabled standardization and delivery of clinical services in cytopathology, hematopathology, pediatric pathology, autopsy, blood banking and transfusion medicine, cytogenetics and molecular pathology, and infectious disease diagnostics.

In 2012, point-of-care testing was added as the Near-Patient Diagnostics division. In 2014, Pathology Informatics was added as a division. This pan-system structure allowed the lab to develop strategies throughout the department to support the health system's goals of improving patient care, increasing revenue, and controlling costs.

Single Service Line

A significant step in the process of streamlining departmental operations was having all laboratory practices adopt a coordinated administrative and performance structure. This structure ensured that all lab staff and leaders interacted with health system and local hospital-based leadership as members of a single service line, instead of operating as separate clinical practices.

"The purpose of the systemwide service line was to support local care, and, specifically, to support the ability of local hospital-based clinical laboratory staff and pathologist leadership to provide local care (ambulatory as well as inpatient), as well as to support their working relationships with local clinical staff (physician, nursing, and other), patients, and their communities," the authors wrote.

"The service line was a resource for provision for local care, not a mechanism for pulling test volume out of local sites," the authors added. "The core lab was both an in-system reference lab and an engine for driving the necessary infrastructure for pan-system operations and management of the laboratory service line."

Integration of Pathology

A key step in enhancing service line operations came in February 2011 when DPLM integrated the anatomic pathology services of two tertiary hospitals with the core laboratory's anatomic pathology outreach service: **North Shore University Hospital** (738 beds) and **Long Island Jewish Hospital** (583 beds).

Integrating pathology services from the two hospitals allowed the DPLM to boost pathologists' productivity by 30% by converting 27 pathologists in three separate generalist practices into an integrated single group practicing subspecialty anatomic pathology. This step allowed Northwell to expand its outreach market share.

"By making available a fully subspecialized practice group for the core laboratory outreach program, 'full service' subspecialty support of physician practices throughout the market region became more attractive to potential clients," the authors explained.

At the same time, this central subspecialty anatomic pathology unit functioned as a real-time in-system "stat" consultancy for pathologists reading local cases, particularly those in community hospitals.

These streamlined operations fueled laboratory service-line growth through 2018, the authors reported. Including testing for in-system hospitals and outreach, net revenue in the core laboratory grew from $73 million in 2008 to $320 million by 2018. *(See table on page 17 for finan-*

Authors Explain Three Concerns As To How a Hospital Lab Could Fall Short of Its Potential

PERFORMANCE OF THE LAB, AS DEMONSTRATED BY THE DATA, show that Northwell Health Laboratories achieved the goals lab leaders set in 2008 when presenting a plan to Northwell Health administrators to retain the lab as a health system asset.

It is also true that there could be some areas in which the Northwell Health Laboratories may be falling short of potential, the authors explained in the report published in December in the *Archives of Pathology and Laboratory Management*.

It's highly unusual for lab executives to publicly express concerns about the strategies they implement. That fact alone makes the disclosure of these three areas instructive for lab directors and pathologists.

The three areas of concern involve the use of the lab's quantitative data, the lab's use of healthcare resources to support value-based payment, and whether consumers recognize the value they get from lab tests.

First, the authors wrote, clinical laboratories have a vast reservoir of quantitative clinical data. A health system such as Northwell Health can combine that lab data with data from the following sources:

- Northwell's electronic health record system,
- The pharmacy department, and,
- Billing, revenue, and managed care contracting.

"That combination of data should be a powerful driver for innovating healthcare delivery, they wrote. "Moreover, innovation is a team effort, which requires the clinical lab to work closely with medical, nursing, pharmacy, administrative, financial, and other health system teams," they added.

"The Northwell Health Laboratories staff feel we have not achieved our potential for the pace of innovation and consider this gap in pace-of-innovation as an ever-present challenge," they wrote.

The second concern is that the market for healthcare services is trending away from volume-based payment and toward value-based models. "While Northwell Health Laboratories have made early inroads on clinical wellness programs to improve patient outcomes, we again feel that we have not yet harnessed the full potential of the clinical laboratory for effective utilization management of healthcare resources," the authors commented.

The third concern is that Northwell Health's consumers may not recognize the value the lab delivers. "Regardless of the 10-year outcomes, the threats to Northwell Health Laboratories remain," they explained. "In particular, the financial benefits provided to the parent health system may not be sustainable, owing to downward pressure on laboratory revenue, and competition from regional and national laboratories.

"Managed care agreements with Northwell may not respect the in-system posture of Northwell Health Laboratories," they wrote. In addition, Northwell's consumers may not recognize the value the Northwell laboratories provide as opposed to other alternatives.

"We hope that our continued efforts to develop evidence in support of the value-added contributions of the in-system laboratory through 'Clinical Lab 2.0' activities will continue to provide strong justification that we are a laboratory of merit to all of our stakeholders," they conclude.

cial performance and volume growth from 2008 through 2018.)

Again, the lab's strategies paid dividends. From 2008 through 2018, revenue grew at an annualized rate of 16%, and the lab's net financial margin grew more than 10-fold. During this time, the lab managed expenses tightly.

As measured in professional wRVUs, anatomic pathology (AP) services for

How Lab Achieved Multiple 10-Year Goals

Few hospital or health system clinical laboratories are willing to publish the metrics that provide insights about their effectiveness at capturing additional market share, generating more specimen volume, and increasing revenue.

However, this is exactly what the lab team at Northwell Health's Department of Pathology and Laboratory Management did when it published a paper in the *Archives of Pathology and Laboratory Medicine* that described the lab's 10-year strategy to deliver more value to its parent health system. Presented below are some of the lab's achievements from the years 2008 through 2018.

Northwell Lab's Goals:

Generate Outreach Revenue

2008 Actual:
3.7 million billable tests;
$46.1 million revenue

2018 Actual:
9.8 million billable tests;
$236.4 million revenue

Increase Market Share

2008: estimated 5% market share
2018: estimated 9% market share

Grow Clinical Trials Business

2008 Actual: 258,000 tests
2018 Actual: 118,000 tests

Sustain Nursing Home Client Base

2008 Actual: 360,000 tests
2018 Actual: 473,000 tests

NOTE: The actual outcomes for 2008 to 2018 are given for the strategic goals declared by Northwell Health laboratory leadership at the time of decision-making in October 2008.

community hospitals remained stable, although there was some variation due to changes in the network affiliations of multispecialty physician groups. AP volume at three tertiary hospitals grew mostly as a result of increases in cancer service volume at **Long Island Jewish Hospital, Lenox Hill Hospital** (652 beds) in New York, and **Southside Hospital** (300 beds) in Bay Shore, N.Y., the authors reported.

Eight-fold Increase in Work

From 2009-2013, AP work from outreach sources increased more than eight-fold. Subsequent fluctuations from 2014 to 2018 reflected the entry or departure of multispecialty physician groups that changed their laboratory network affiliations.

As measured against goals lab leaders outlined in 2008, performance improved. Leadership predicted an increase in outreach revenue, for example, and did so as a result of more than doubling the number of billable tests from 3.7 million in 2008, generating $46.1 million in revenue, to 9.8 million billable tests in 2018, producing $236.4 million in revenue.

Not only did performance improve, but the lab met the overall goals declared in 2008. The lab also increased outreach market share in its service area from an estimated 5% in 2008 to 9% in 2018. "In particular, core laboratory outreach volumes grew at an annualized rate of 10.3%, and revenue grew at an annualized rate of 17.8%," the authors wrote.

In 2008, laboratory leadership had predicted it would sustain its nursing home client base of 360,000 tests in 2008. By 2018, it had increased that volume to 473,000 tests. The one exception to this growth was a decline in clinical trials business from 258,000 tests in 2008 to 118,000 tests in 2018, the authors reported.

By January 2018, the DPLM consisted of a centralized core lab with the associated subspecialty anatomic pathology services unit; 16 hospital-based clinical laboratories of which 13 were rapid-response laboratories, and three were full-service laboratories; plus one clinical laboratory for a stand-alone combined ambulatory

Results from Northwell Lab's Value Initiatives Offer Lessons for All Hospital Laboratories

WHAT THE NORTHWELL HEALTH LABORATORIES ACCOMPLISHED OVER THE 10 YEARS from 2009 through 2018 is useful to other health systems considering the option to sell their inpatient or outreach clinical laboratory services to commercial lab companies.

The authors of the report in the *Archives of Pathology and Laboratory Medicine* (APLM) made this point in, "Northwell Health Laboratories: The 10-Year Outcomes After Deciding to Keep the Lab."

"The lab's 10-year outcomes are presented as an example for other health systems that are facing such decision-making in the current time frame," the authors commented.

Over those 10 years, Northwell Health's lab's leadership demonstrated that an in-system laboratory can be a strong asset, as James M. Crawford, MD, PhD, Senior Vice President, Laboratory Services at Northwell Health, explained at an industry conference in 2018.

During a presentation at the *Executive War College* in New Orleans in 2018, Crawford reported how the lab transitioned from a high-performance Clinical Lab 1.0 model with a transactional and volume-based approach to laboratory operations to becoming a leader of the Clinical Lab 2.0 model of delivery value-based care. Also, Crawford explained, the improvement over those 10 years represented an evolutionary process from the inception of the Northwell Health laboratory in 1993.

All of the accomplishments are important for clinical labs that other hospitals and health systems operate, the journal authors commented. "Corporate decisions to monetize the clinical laboratory are of high interest in the current laboratory industry," they wrote. "The emerging trend has changed from binary (divest or not) to somewhere in between, with some health systems choosing joint ventures with commercial laboratories."

The outcomes the Northwell Health Laboratories achieved could provide a template for quantitative assessment of the outcomes of laboratory relationships with commercial entities that health systems have established, the authors wrote. Alternatively, the APLM report could provide a benchmark for health systems assessing how to retain their clinical laboratories as a wholly-owned system asset.

center and emergency department. The department had an operating budget in 2018 of $521 million and 2,100 employees, including 108 employed pathologists and eight clinical PhD scientists.

Not including the tests the Northwell Health Laboratories managed for outside labs, the clinical lab at Northwell handled 30 million billable tests in 2018, including 200,000 surgical pathology case accessions, and 150,000 cytology case accessions.

The lab also operated 51 patient service centers. That same year, it did 430,000 ambulatory blood draws, 220,000 nursing home blood draws, 84,000 home phlebotomy blood draws, and 500,000 courier pick-ups. The lab staff answered one million customer service calls, supported 1,000 client result-and-order electronic health record interfaces, and supported 200 physician office laboratories.

The process of streamlining the DPLM included providing support for hospital-based laboratory services. By 2018, the substantial growth in core lab test volumes enabled cost-effective performance of in-system reference testing for system hospitals.

Starting in 2012, the lab began routine collection of hospital performance data for the pan-system laboratory service. These data demonstrated the success of

DPLM's support of hospital-based lab services in three ways:

- Hospital-based costs-per-test (minus blood) rose from only $10.31 in 2012 to $12.22 in 2018 for an annualized rate of 4.5%.
- Billable laboratory tests-per-adjusted-discharge rose from 32.9 in 2012 to 38.1 by 2018, an annualized rate of 2.5%. From these increases, the authors used the 451,808 adjusted discharges system-wide in 2018 as the basis for calculating that the lab held costs to an equivalent of just a $4.5 million rise in the annual cost of hospital-based laboratory testing system-wide from 2012 to 2018.
- Blood costs per adjusted discharge remained essentially unchanged at $67.72 in 2012 versus $68.48 in 2018.

2% Annual Rise in Costs

"Overall, the imputed systemwide increases of $4.5 million in the unit costs of laboratory services per discharge from 2012 to 2018 were compared with total hospital laboratory spending of $242 million in 2018," the authors wrote. "This is less than a 2% rise in laboratory costs per adjusted discharge during a six-year period."

In addition, this rise in hospital laboratory costs was linked on a site-by-site basis to growth in high-acuity clinical programs at specific hospitals including cancer services, cardiothoracic surgery, trauma care, and transplantation, and thus was appropriate given the health system's goals, the authors explained.

One metric important to all labs is productivity as measured by billable tests per technical fulltime equivalent (FTE) staff, which has remained constant at DPLM. A modest increase in productivity in billable tests per total laboratory FTE reflects improved efficiencies among non-technical staff, the authors added.

The authors also addressed the how the lab's quality improvement and cost control program affected patient care. The authors addressed this issue clearly. "The fundamental mission of a clinical laboratory is delivering high-quality patient care," they wrote. "A default premise of the entire laboratory industry is that clinical laboratories provide accurate, safe, and timely results, and there are extensive regulations and compliance requirements to ensure that this premise is true.

Evidence Base

"The question is, therefore, does a wholly-owned in-system laboratory network enable better patient care than an alternative arrangement?" they asked. "Establishing an evidence base to answer this question remains a challenge because the lab industry has focused extensively on the evidence base of quality and safety, without necessarily addressing whether one model of lab service delivery is better than another in support of clinical care.

"In these 10 years, Northwell Health Laboratories has attempted to provide strategic in-system leadership for innovation and enhancement of patient care, and responsiveness to challenges and operational difficulties," they wrote.

The authors gave three examples of improvements the lab made in patient care:

- Showing national and international leadership in responding to the H1N1 influenza virus pandemic in 2009.
- Demonstrating how in-system consolidation of AP services can help drive sub-specialization to support high-acuity patient care.
- Improving diagnostics for respiratory virus infections.

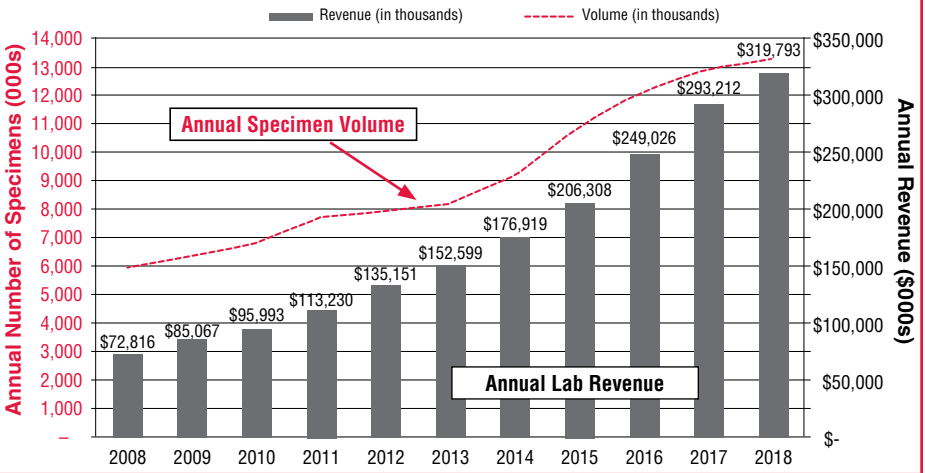
"The consistent year-to-year effort to advance the delivery of healthcare is an essential element of being an effective in-system laboratory," the authors commented. "Patient care is also served through leadership and volunteerism provided by pathology medical and managerial personnel at all levels of the

Ten-year Outcomes for Northwell Health Lab's Financial Performance and Volume Growth

BELOW IS TABLE SHOWING the annual increase in both the number of specimens and revenue at the laboratory division of Northwell Health during the years 2008 through 2018.

The lab strategies used to accomplish this growth were described in the peer-viewed journal, *Archives of Pathology and Laboratory Medicine*, where the authors (members of the Northwell Health laboratory team), wrote "The 2009 creation of a system-wide Department of Pathology and Laboratory Medicine, and its integration into the operations of Northwell Health Laboratories (the Core Laboratory), enabled 'full service' growth in Core Laboratory outreach programming. The increased rate of revenue growth, compared to volume growth, is a reflection of the increased contribution of Anatomic Pathology Services outreach, growth in molecular pathology and infectious diseases diagnostics testing, and insourcing of reference laboratory testing when justified by increasing test volumes." *(Archives of Pathology & Laboratory Medicine 143:12, 1440-1441.)*

Northwell Health Clinical Laboratory
Growth in Specimen Volume and Revenue (2008-2018)



Source: Archives of Pathology and Laboratory Medicine; 143:12, 1440-1441. Online publication date: 25-Nov-2019.

institution and throughout its extensive geography."

In the APLM report, the authors concluded that the metrics the lab published support the lab leaders' premise that retaining the Northwell Health Laboratories as a wholly-owned system asset was a good decision, they wrote. "It is therefore a reasonable statement that the decision to retain Northwell Health Laboratories as a wholly-owned health system asset was justified by outcomes in the 10 years after 2008," they explained.

Looking ahead, Northwell Health's lab team seeks to leverage their labs' assets to drive a higher level of system performance in the delivery of cost-effective healthcare while the parent health system adapts to newer models of payment for healthcare services, the authors concluded. **TDR**

—Joseph Burns

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Legal Update

Judge Rules in Theranos Case, Elizabeth Holmes Again Is News

Attorneys for former **Theranos** CEO Elizabeth Holmes and former President Ramesh Balwani are in court maneuvering before the federal case starts the trial phase this summer. Last week, Judge Edward J. Davila ruled that prosecutors from the federal **Department of Justice** (DOJ) cannot argue that physicians and insured patients were victims of fraud that Theranos committed, as prosecutors had argued in an indictment.

In 2018, a federal grand jury indicted Holmes and Balwani. Each defendant was charged with two counts of conspiracy and nine counts of wire fraud, stemming from allegations that they engaged in a multimillion-dollar scheme to defraud investors, and a separate scheme to defraud doctors and patients. *(See "Holmes, Balwani Indicted by Department of Justice," TDR, June 18, 2018.)*

'Revolutionize Lab Testing'

In the indictment, the DOJ charged that Theranos, Holmes, and Balwani defrauded investors and consumers who trusted Theranos' technology after Holmes and Balwani claimed the company's blood-testing methods would revolutionize clinical lab testing, *The Wall Street Journal* (*WSJ*) reported. Holmes and Balwani have pleaded not guilty.

On Feb. 11, Davila dismissed counts accusing Holmes and Balwani of defrauding doctors or nonpaying patients, such as those with health insurance. Davila ruled the indictment didn't show Holmes and Balwani intended to obtain money from nonpaying patients or that the doctors were victims of fraud, the *WSJ* reported.

The effect of the judge's decision was unclear, because prosecutors haven't disclosed to the public how many victims were paying or nonpaying patients, the *WSJ* added. The case will continue because Davila denied motions from Holmes' and Balwani's attorneys to dismiss the indictment, the *WSJ* said. The defendants' attorneys had argued that the DOJ failed to establish that alleged statements and omissions from Holmes and Balwani were materially false, the *WSJ* reported.

During an earlier hearing in the case, a lawyer for Holmes made the unusual claim that incorrect blood tests are a fact of life. Prosecutors had argued that some of Theranos' blood tests were unreliable. At that point, Holmes' lawyer Amy Saharia said, "That's not true," reported the *San Jose Mercury News*. "There were no problems with them whatsoever," Saharia added. "All tests have error rates. The government should not be permitted to try a case with anecdotes when incorrect blood tests are a fact of life."

In January, the *Mercury News* reported Holmes has had between seven and nine attorneys representing her in the case. But in a civil case in Arizona, Holmes has represented herself and phoned in her appearance in that case, according to published reports.

In the Arizona case, court records showed that Holmes had two lawyers defending her. Last fall, three lawyers representing Holmes quit, saying she hadn't paid them for more than a year and probably never would, the newspaper wrote. "Now, the court docket shows Holmes representing herself in the civil case," it added. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last month, *TechCrunch* reported that a data breach at **Laboratory Corporation of America** had exposed the protected health information (PHI) of thousands of patients. *TechCrunch* published its findings on Jan. 28, 2020. It wrote, "This latest security lapse was caused by a vulnerability on a part of LabCorp's website, understood to host the company's internal customer relationship management system." *TechCrunch* is an online publisher focusing on the tech industry.

MORE ON: *PHI Breach*

In its story about the breach, *TechCrunch* said "Of the handful of files we examined to understand what kind of data was exposed, the documents largely appeared to affect cancer patients under the laboratory's Integrated Oncology specialty testing unit. The documents contained names, dates of birth and, in some cases, Social Security numbers of patients. The documents also contained lab test results and diagnostic data, a class of data considered protected health information under the Health Insurance Portability and Accountability Act (HIPAA). A couple of the documents we reviewed contained a footer notice, which said: 'This document contains private and confidential health information protected under state and federal law.'" *TechCrunch* did report that the source of the breach had been closed, writing that "The vulnerability was found in-house at *TechCrunch* and was reported to LabCorp, which later pulled the server offline. Although the web address remains in **Google's** search results, the link is now dead. 'I can confirm that we have terminated access to the system,' stated LabCorp spokesperson Donald Von Hogan ... [who] said in a call that the company would not confirm the documents found on the exposed server 'are in fact LabCorp information.'"

TRANSITIONS

- **Personal Genome Diagnostics** of Baltimore, Md., promoted Megan Bailey to the position of Chief Commercial Officer. Bailey held prior positions at **Roche Diagnostics** and **Ventana Medical Systems**.
- **Interpace Biosciences** of Chevy Chase, Md., announced the selection of Jeff Salzman as its new Vice President, Managed Care and Payer Relations. He formerly worked at **CareDx**, **Transplant Genomics**, **diaDexus**, **Vermillion**, **Monogram Biosciences**, **Quest Diagnostics**, **Becton Dickinson**, **Prudential Healthcare**, and **Humana**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 9, 2020.

SPECIAL SESSION

Lab Value-based Contracting & Risk Adjustment Arrangements with Payers, ACOs, Medicare Advantage

Matthew M. Modleski
Vice President, Development
Orchard Software, Carmel, Ind.

Steps to Make Your Lab an Essential Resource: Data Requirements, Different Payment Options

It's been discussed and debated for years. Now it's here! Value-based payments and risk adjustment arrangements are dominating the actions of providers and payers alike. The good news is that your lab can play in this new game by helping your client physicians and the health plans in your region in two important ways.

First, your lab has both the data and the clinical expertise to help physicians more accurately diagnose patients with chronic conditions, thus helping these providers qualify for higher risk-adjustment payments. Second, your lab can identify gaps in care in real time for specific patients—which has immense benefit to payers and providers alike.

Modleski will show you the simple steps your lab can take to engage both client physicians and health insurers in arrangements that reward your lab for delivering clinically-actionable intelligence. You'll learn what lab data has the highest value and how to structure a reimbursement arrangement that creates a new revenue stream for your lab. Register today to guarantee your place!

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- ***How Innovative Labs Are Benefiting from Use of Real-Time Analytics, Machine Learning, and A.I.***
- ***Are There Too Few or Too Many Pathologists? New Survey Says Job Market, Demand Is Robust.***
- ***Steps One Lab Took to Hit a Clinical and Financial Home Run with Precision Medicine Services.***