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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

Labs Face New Challenges in New Year, New Decade

TYPICALLY, PEOPLE CELEBRATE THE ARRIVAL OF A NEW YEAR and a new decade with optimism. That should be just as true for clinical lab managers and pathologists. After all, medical laboratory testing is fundamental to how physicians diagnose disease, select the most appropriate therapies, and monitor the progress of their patients.

Yet events of recent years have not been kind to the profession of laboratory medicine, as regularly chronicled on these pages. A careful reading of the events of the 2010s would demonstrate the multiple approaches used by government and private payers to reduce what they pay for clinical lab tests and anatomic pathology services. Year-after-year, in response to cuts in the prices payers reimburse for lab tests, labs have had to figure out how to cut costs in an intelligent way to balance their budgets without compromising the quality and integrity of the lab test results they produce.

This new decade of the 2020s is predicted to be one of major transformation of healthcare in the United States. The good news for medical labs is that knowledge of the many "omes" (genome, microbiome, proteome, transcriptome, etc.) is expanding swiftly and creating new, relevant biomarkers that can be incorporated into clinical practice to improve patient care.

But the challenge for clinical labs and anatomic pathology groups will be to maintain financial stability and still have access to the capital, the information technology, and the scientific expertise needed to set up and perform these new diagnostic assays. This is not an easy path forward.

The other major challenge labs will face during the decade of the 2020s is how to evolve and support the changing needs of physicians, payers, hospitals, and patients. It is now recognized that the U.S. healthcare system needs to focus on prevention and keeping patients healthy. There is pressure for prices to be transparent to patients in advance of service.

Hospitals, physicians, and other providers are realigning their organizations to be part of an integrated clinical care pathway. Government and private payers are shifting toward value-based payment models. Such changes to this country's healthcare system will require clinical labs and pathology groups to align their service offerings to meet these new needs. TDR

Labs May Be Excluded from Revised Stark, AKS Rules

The Stark Law and Anti-Kickback Statute are being revised to support value-based care

CEO SUMMARY: When CMS and the OIG issued proposed rules last fall to make it easier for providers to participate in value-based and coordinated care arrangements, they considered excluding clinical labs, pharma companies, and DME firms because of concerns that the proposed rules could promote lab test fraud. Now, labs will have to wait for the final regulations to see if they can engage in certain arrangements that will be protected under the revised rules if they are finalized as written.

FEDERAL OFFICIALS ARE REVISING TWO IMPORTANT ANTI-FRAUD RULES and may exclude clinical laboratories from proposed new safe harbors intended to support some value-based and care-coordination arrangements.

In October, the federal **Centers for Medicare and Medicaid Services** (CMS) and the federal **Office of Inspector General** (OIG) proposed rules to make it easier for healthcare providers to deliver coordinated and value-based care while complying with federal regulations against fraud. Healthcare providers and the public submitted comments through Dec. 31 and officials are reviewing those comments now. It is not known when the agencies will issue final rules.

The proposed rules call for clarifying the regulations under the Physician Self-Referral Law (commonly known as the Stark Law) and the Federal Anti-Kickback Statute (AKS). CMS said its proposed rules are part of its "Regulatory Sprint to Coordinated Care" initiative.

The OIG has proposed seven new safe harbors, the first three of which track the proposed Stark law exceptions. These proposed rules call for value-based exceptions (VBEs) for physicians, hospitals, labs, and other providers working in such arrangements. But the final rules could exclude clinical laboratories, pharmaceutical manufacturers, and companies that make and sell durable medical equipment.

Lawyers familiar with the proposed regulations said any such exclusions would be due to concerns that allowing labs more flexibility in how they get paid and receive referrals could lead to more fraud in testing.

In announcing the proposed rules, CMS acknowledged that incentives in a

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healthcare system that pays for value-based care are different from the incentives in a system that pays for volume under fee-for-service reimbursement. At the same time, CMS said it wanted to guard against over-utilization of tests and other services.

One way to guard against overuse in testing is to exclude medical laboratories out of concern that they depend heavily on referrals from physicians. Therefore, CMS warned that laboratories "might misuse the proposed safe harbors primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payers by improving the coordination and management of patient care, reducing inefficiencies, or lowering healthcare costs."

While labs could be excluded in any final rules that CMS and OIG issue, there are potential work-arounds for clinical lab directors whose labs have value-based or care-coordination contracts, according to Danielle Holley, a healthcare lawyer and partner with the law firm of **O'Connell and Aronowitz**, in Albany, N.Y.

"There are several new exceptions—meaning safe harbors—proposed under the Anti-Kickback Statute that could be beneficial for labs working in care coordination arrangements," Holley said. But the proposed rules also are a warning to labs to be aware of payment models that could be problematic, she added.

Impact of Revised Rules

Clinical lab directors will need to understand how the proposed rules could affect how labs get patient test referrals, how they get paid for testing in some value-based and care-coordination payment models, and how the rules governing current arrangements may change, she explained.

"One such arrangement that sticks out to me is the outcome-based payment and part-time arrangement safe harbor," Holley commented. "The proposed rules will make a change to the personal service and management safe harbor that potentially will add flexibility for certain arrangements that labs may have used previously, for example.

"Also, labs will need to know how the proposed rules would affect any work done by independent contractors or by someone consulting for a lab under certain management agreements," added Holley. The proposed rules also could affect some billing agreements with third-party payers that are based on outcomes.

Proposed Safe Harbors

"Under some arrangements, clinical labs might have more protections under a proposed new safe harbor than they had in the past," she commented.

"In some outcomes-based payment arrangements that labs had in the past, labs would need to set a flat fee in advance and that fee could not take into account any increase in volume or value," Holley explained. "But the new proposed rules allow for some outcomes-based payment and part-time arrangements that could be important for clinical laboratories.

"In addition, laboratories could benefit from the value-based proposed safe harbors. For example, we've seen scenarios where some laboratories wanted to provide feedback or training courses to physicians who order tests, or they wanted to provide reminders to physicians about how best and when to order tests," she said. "Those kinds of activities potentially could fall under the value-based safe harbor, or the patient engagement and support safe harbor, if the final rules do not exclude clinical laboratories."

Clinical labs and some genetic testing labs have heard complaints that referring physicians do not always order the most appropriate tests for patients or do not understand the results that labs produce, meaning that educating physicians on these issues might be useful.

But labs will need to be aware that in the commentary CMS and the OIG added to the proposed rules, the agencies said they were considering excluding clinical

laboratories from some or all of the safe harbors in the proposed rules that are designed to support payment for value-based and coordinated care.

"CMS and the OIG are concerned about fraud and abuse in some of the value-based or coordinated care programs and whether these programs are really providing a direct benefit to patients," Holley explained.

"Therefore, clinical labs should be aware that they could potentially have this great safe harbor that would be useful under the proposed rules. But to use that safe harbor, labs would need to have explained in the solicitation for comments how laboratories could participate in the outcomes-based or care-coordination payment program and benefit patients, so that the regulating agencies do not exclude laboratories in the final rule," she added.

Federal Advisory Opinions

The **American Clinical Laboratory Association** addressed this same issue in comments it sent to CMS about the proposed rules. In an Aug. 24 letter, ACLA recommended that CMS change the process labs and other providers would use to request an advisory opinion about whether an arrangement would comply with the Stark Law.

"In the two decades since the advisory opinion process was implemented in regulation, the agency has issued less than one opinion per year," wrote Sharon L. West, ACLA's Vice President, Legal and Regulatory Affairs.

"Currently, CMS accepts only those questions involving specific existing or planned arrangements and not those related to interpretation, hypotheticals, or proposed business arrangements," she said. "This limits the usefulness of the advisory opinion process tremendously."

In comments to CMS, the ACLA and the **College of American Pathologists** both recommended changes to the in-office ancillary services exception under the Stark Law. *(See sidebar at right.)* TDR

Calls to End AP Ancillary Service Exception

IN COMMENTS SENT TO THE CENTERS FOR MEDICARE AND MEDICAID SERVICES both the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP) called on CMS to end the in-office ancillary services (IOAS) exception for anatomic pathology testing.

Under the Stark law, physicians are prohibited from referring testing or other services to entities that they own or in which they have an investment interest.

"The IOAS exception to the self-referral prohibition allows a physician or group practice to self-refer and bill for anatomic pathology (AP) services that are performed in the physician's office or in a space in the same building or a centralized building," ACLA wrote in its letter to CMS. "Most non-pathology practices that self-refer and bill for anatomic pathology services use the IOAS exception to comply with the Stark Law."

In recent years, ACLA has told CMS that one way to limit self-referral for AP services is to exclude such work from the IOAS exception. The problem for CMS and for clinical lab and AP professionals is that including AP services in the IOAS exception can result in overutilization and worse outcomes for patients, ACLA wrote.

CAP had similar apprehensions about overutilization of AP services, writing that the IOAS exception to the Stark law provides a financial incentivize for physicians to self-refer AP services, CAP wrote in an unsigned letter to CMS dated Aug. 24.

Congress allowed the IOAS exception so that physicians and labs could offer non-complex ancillary services, such as simple blood tests, that a physician would need to diagnose a patient's condition and treat that patient during an initial office visit, CAP wrote.

—Joseph Burns

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In LabCorp Case, Judge Upholds Some Claims

➤Judges in two different lab-test pricing lawsuits have allowed both cases to move forward to trial

➤➤CEO SUMMARY: In a federal lawsuit against Laboratory Corporation of America, plaintiffs who were uninsured or underinsured charged the lab company with engaging in "business practices that trick and harass customers into paying excessive prices." Plaintiffs made this and other claims in court documents alleging that LabCorp overcharged them by two to five and as much as 10 times more than the lab company charged patients who had Medicare or commercial health insurance.

Third in a Series

LAST MONTH, IN THEIR LAWSUIT against **Laboratory Corporation of America**, plaintiffs began the discovery phase. The case is being tried in U.S. District Court for the Middle District of North Carolina, Greensboro Division.

The discovery phase of the trial began as a result of Chief District Court Judge Thomas D. Schroeder's ruling in August that the case against LabCorp could go forward on two issues.

The first issue is that the plaintiffs have an implied contract that allows them to know what they would be charged for lab testing before the testing is done. The second issue is that LabCorp's billing and collection practices violated consumer protection laws in eight states: Alabama, California, Florida, Maryland, New Jersey, North Carolina, Tennessee, and Texas.

➤Judge Dismissed One Claim

In the same decision, Schroeder ruled in LabCorp's favor when he dismissed the plaintiffs' claim that they had a right to recover the alleged overcharges based on their assertion that they had an implied contract with the publicly-traded laboratory company.

By dismissing one claim and upholding the other two claims, Schroeder's ruling is similar to one a judge in New Jersey made in a comparable case that other plaintiffs filed against **Quest Diagnostics**. In both cases, the plaintiffs' lawyer is Robert C. Finkel, an attorney with the law firm of **Wolf Popper** in New York.

➤Plaintiffs Sue Quest, LabCorp

Finkel filed the two cases on behalf of 33 plaintiffs in 19 states. In the case against Quest, Finkel brought the lawsuit in U.S. District Court in New Jersey on behalf of 19 plaintiffs in 11 states. In North Carolina, there are 11 plaintiffs from eight states. Each case is proceeding on a similar schedule in that discovery has begun and the cases will proceed throughout 2020.

In Quest's case, U.S. District Judge Esther Salas issued an order in September denying some of Quest's motions to dismiss plaintiffs' claims and granted some of Quest's motions to dismiss other claims. Salas' ruling is similar to Schroeder's in that she found that the plaintiffs alleged

sufficient facts to support their theory of unfair trade practices based on alleged excessive pricing.

The fact that judges in two different courts have issued rulings favorable to the plaintiffs on certain claims common in both lawsuits may be a sign that plaintiffs' claims of being overcharged have some merit. It's also noteworthy that the two lab companies have yet to persuade either judge to dismiss the lawsuits.

Both LabCorp and Quest denied the allegations of overcharging and moved to dismiss the cases. Quest did not respond to a request for comment. LabCorp said it does not comment on pending litigation.

In the first of two parts in this series, THE DARK REPORT covered the plaintiffs' charges in both federal lawsuits. *(See "Lawsuits Alleging Overcharges to Proceed in Two Courts in 2020," TDR, Dec. 16, 2019; and "Lawsuits Allege LabCorp, Quest Overcharged Uninsured Patients," TDR, Nov. 25, 2019.)*

One Claim Dismissed

In August, when Schroeder dismissed the plaintiffs' complaint about the right to recover any alleged overcharges, he noted that he had dismissed this claim in an earlier ruling. In response to that earlier ruling, the plaintiffs filed a 142-page amended complaint in August 2018.

"Plaintiffs once again assert a theory of unjust enrichment never before recognized by a North Carolina court," Schroeder wrote in his ruling last summer. Once a person has received the services in question and paid for those services, that person cannot sue for unjust enrichment unless there was a mistake or fraud, he added.

The significant issue in the LabCorp case is that the plaintiffs alleged that they did not have a prior agreement about price and that the lab company charged them the list price for testing services, which they claimed was too high.

What LabCorp charges patients varies greatly, and the list prices tend to be much higher than other rates LabCorp charges patients covered by Medicare, Medicaid, or through commercial insurance, Schroeder wrote in his ruling.

Judge Outlines Hurdles In Alleged Overbilling

AFTER DISMISSING ONE CHARGE AND ALLOWING OTHER CHARGES TO GO FORWARD in a lawsuit plaintiffs filed against **Laboratory Corporation of America**, a federal judge issued a caution about the merits of the remaining arguments in the case.

In a ruling in August, Chief District Court Judge Thomas D. Schroder wrote that the plaintiffs have a high bar to prove that LabCorp's practices amount to unfair or deceptive trade practices.

The case is in U.S. District Court for the Middle District of North Carolina, Greensboro Division, on two issues: First, that the plaintiffs have an implied contract that allows them to know what they would be charged for lab testing before the testing is done, and second that LabCorp's billing and collection practices violated consumer protection laws in eight states.

In an amended complaint, the 11 plaintiffs in the case claimed that they were overcharged, and that LabCorp sent them threatening letters if they did not pay. In his ruling, Schroeder said he did not hear any persuasive argument against the plaintiffs' claims that LabCorp violated the consumer protection laws in the eight states.

But then, Schroeder added a disclaimer of sorts. "To be clear, plaintiffs will ultimately have the considerable burden of showing that LabCorp's list prices were so excessive, and its billing practices so coercive, that—together with LabCorp's nondisclosure of price—LabCorp's billing practices were sufficiently 'egregious or aggravating' as to be an unfair or deceptive trade practice."

This issue is important for all clinical laboratories in that physicians often order lab tests for patients without an agreement about what the lab would charge.

"At the time the services were rendered, none of these plaintiffs had an express agreement with LabCorp to pay the list prices LabCorp subsequently charged," Schroeder wrote.

As a result, the plaintiffs never agreed to a price before the testing was done.

Therefore, Schroeder cited the plaintiffs' argument that LabCorp's right to charge what it charged "was limited to an implied-contract recovery of the 'reasonable value' of the services rendered."

In addition, Schroeder wrote, "Further, plaintiffs seek a declaration that LabCorp's list prices exceed the 'reasonable value' of its services." During the discovery and the trial itself, the two sides will argue over what is a reasonable rate to charge uninsured or underinsured patients.

In this case, an underinsured patient is one whose insurance does not cover the full cost of LabCorp's testing.

An Implied Contract

The plaintiffs claim they have an implied-in-fact contract or a quasi-contract, Schroeder wrote. LabCorp argued against this claim, saying that the plaintiffs' implied-in-fact contract theory fails because, "North Carolina law requires a meeting of the minds for formation of a valid and enforceable agreement."

In addition, LabCorp argued that to the extent that there was an agreement on price, that agreement only could have been on the list price that LabCorp always charges consumers who are uninsured or underinsured.

"Plaintiffs contend that it is possible to have an implied-in-fact contract absent agreement on price, and that the remedy for a breach of such an implied-in-fact contract is the 'reasonable value of the services' contracted for," Schroder explained.

In denying LabCorp's request to dismiss the claim, Schroeder said the lab company did not make a persuasive argument against the plaintiffs' charge.

Moreover, Schroder wrote, "In the amended complaint, plaintiffs' overcharging claim is not merely an accusation that LabCorp's prices are excessive, but that 'LabCorp has a number of business practices that trick and harass customers into paying excessive prices.'"

'Manipulative Billing'

The plaintiffs argued that in addition to charging excessive rates for lab testing, LabCorp used "aggressive and manipulative billing and collection techniques for services that are critical to a patient's health," Schroeder wrote.

As Schroeder explained, the plaintiffs' case hinges on several of LabCorp's practices. First, the plaintiffs alleged that LabCorp declines to disclose its prices until after patients have been tested, he wrote.

Then, the plaintiffs alleged, "LabCorp charges them amounts grossly exceeding the reasonable value of the services rendered and coerces them into paying the inflated prices by threatening to damage their credit ratings and to foreclose them from using LabCorp's services in the future," he added.

LabCorp had cited other cases in which businesses had similar practices, but Schroeder rejected that argument. "These additional elements distinguish LabCorp's alleged business practices from the transactions at issue in [another case], as well as from plaintiffs' arguments in the prior round of briefing, where the argument was simply that the prices at issue were too high," said the judge.

While the claims on these issues deserve a trial, Schroeder also explained that the plaintiffs' arguments against LabCorp represent a significant hurdle for the patients. *(See sidebar, page 7.)* TDR

—Joseph Burns

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Healthcare Trends/Strategy

Anti-Trust Regulators Opposed Illumina, Pacific Bioscience Deal

In two countries, regulators concerned about a possible monopoly of technologies and instruments used in human gene sequencing apparently were a major reason why the $1.2 billion acquisition of **Pacific Biosciences** by **Illumina Corporation** will not happen.

The two companies announced the termination of the transaction just weeks after the **Federal Trade Commission** (FTC) ruled the deal was anti-competitive and **Oxford Nanopore Technologies** complained to regulators in the United Kingdom that the deal would allow the combined company to dominate the market in the UK and worldwide.

"Considering the lengthy regulatory approval process the transaction has already been subject to, and continued uncertainty of the ultimate outcome, the parties decided that terminating the agreement is in the best interest of their respective shareholders and employees," the two companies announced on Jan. 2. Instead, Illumina will pay PacBio a termination fee of $98 million, as required by the preliminary agreement.

Sequencing Technologies

When the deal was proposed on Nov. 1, 2018, Illumina said it planned to combine the two companies' sequencing technologies, as The Dark Report explained. *(See "Illumina to Pay $1.2 Billion to Acquire Pacific Biosciences," TDR, Dec. 3, 2018.)*

Illumina's instruments are based on sequencing by synthesis, or short-read technology, in which machines analyze small fragments of DNA, allowing Illumina to drop the cost of sequencing an individual's DNA to about $1,000.

PacBio, however, pioneered the use of long-read technology to decode extended stretches of DNA with high accuracy. The drawback to PacBio's approach is the high cost ($12,000) to sequence a single human genome. After announcing the end of the deal, Illumina said it would seek to develop its own long-read technology.

A big blow to the deal came on Dec. 17 when the FTC announced it was seeking to block the merger by filing an administrative complaint. In the complaint, the FTC claimed Illumina aimed to unlawfully maintain a monopoly for NGS systems in the U.S. market by acquiring a competitor. Also, the proposed deal was illegal because it could reduce competition for DNA sequencing, the FTC charged.

The commission asked its legal staff to seek a temporary restraining order and a preliminary injunction in federal court, if necessary, to maintain the market status quo. In other words, Illumina was looking at a potentially protracted legal fight.

Because of ongoing improvements in its technology, PacBio had become a close alternative to Illumina, the FTC wrote. Given that the two companies drive each other's innovative expertise, the merger would eliminate that incentive, the agency added.

The UK's **Competition and Markets Authority** extended its inquiry into the proposed acquisition after Oxford Nanopore complained that the combined company would have a market share of more than 90% in the UK and more than 80% worldwide, enhancing Illumina's ability to foreclose other companies from the market. **TDR**

—Joseph Burns

In 2008, hospital administration considered sale of lab

How Northwell's Lab Team Demonstrated Value Over 10 Years

CEO SUMMARY: Among hospital administrators, the popular wisdom is that their clinical lab is a cost center. This thinking leads them to consider drastic cost-management strategies that include partnering with commercial labs to manage in-hospital lab testing and the outright sale of lab outreach programs. On the other side of this debate, innovative health system executives recognize clinical labs as strategic assets that can deliver substantial value in terms of patient outcomes and reductions to the overall cost of care. This latter approach is what evolved over 10 years at Northwell Health.

First in a Series

Whether correct or not, many hospital and health system executives tend to view clinical laboratories as cost centers. At the same time, clinical lab directors consider their operations to be strategic clinical and financial assets.

When the two sides diverge in this way, the narrow, expense-focused view of health system administrators may lead them to consider farming out clinical lab testing to commercial lab companies. After all, if the hospital laboratory is merely a cost center and lab testing itself is a commodity—identical in quality and service regardless of which lab performs the assay—then executives in financially-strapped hospitals will default to the lowest-cost method of operations. They may ask: Why not outsource the clinical lab, as is done with other services such as anesthesia, dialysis, imaging, hospitalists, and staffing for the emergency room?

When such thinking dominates the discussion, administrators often turn to the most expedient solution to the problem by asking an independent lab company to manage all operations and produce test results for the lowest possible cost. Viewing clinical lab testing in this fashion can thus become an existential threat to lab managers and pathologists.

The problem with this thinking is that those administrators who view the clinical lab in this way may miss the opportunity to leverage the value of their labs for improving patient care, increasing market share, as well as boosting profitability through reductions in the overall cost of care and improvements in their health system's quality performance under value-based payment systems.

In recent years, progressive and innovative health systems that worked closely with their clinical lab leadership have shown how lab testing can help hospitals, physicians, and other providers to provide greater value to health insurers and to patients by improving both clinical and financial results.

The work that **TriCore Reference Laboratories** has done in Santa Fe, N.M., is an example of a clinical lab that works closely with physicians throughout the state to improve results for patients and health insurers. Although TriCore is not an internal lab in a health system, it nonetheless functions as one in many ways. *(See "TriCore Forges Ahead to Help Payers Manage Population Health," TDR, May 20, 2019.)*

Now there is another success story from the laboratory organization of **Northwell Health**, in Lake Success, N.Y. In December, the leadership of Northwell Health Laboratories published the details of how over more than 10 years (2008 through 2019), the clinical lab added value to its parent health system. This report was published in December in the peer-reviewed medical journal, the *Archives of Pathology and Laboratory Medicine* (*APLM*).

Concept of Clinical Lab 2.0

Parts of this story have been published previously as the authors of the *APLM* report explained. "An overarching vision for valuation of in-system clinical laboratory services, termed Clinical Lab 2.0, was presented in 2017 by the Project Santa Fe group," the authors wrote in an earlier report published in *APLM*. "This vision emphasizes the favorable impact that clinical laboratories embedded within health systems can achieve, both for population health outcomes and for the financial performance of the parent health systems."

In this most recent APLM report, the authors described the strategies and implementation steps the Northwell lab team followed since 2008. For this reason, the article serves as a guide for senior lab administrators and laboratory directors to follow when developing similar strategies to boost the value of lab testing in their own health systems. Also, it is possible that CEOs and other hospital and health system administrators will want to emulate this lab-value success story.

The story of how Northwell Health retained the lab is particularly important today, given how payment for clinical and anatomic lab testing has declined in

recent years, and how many health system administrators continue to view clinical laboratory services simply as a cost center.

10-Year Lab Strategy & Plan

In this multi-part series, The Dark Report will describe the chronology of Northwell Health Laboratories from 2008 through last year, including steps Northwell corporate leadership took when they were considering a joint-venture partnership with a commercial lab company to run the Northwell labs.

This first installment in a series of articles The Dark Report will publish describes how Northwell Health administrators considered the advantages and disadvantages of outsourcing their clinical laboratory in 2008, before deciding to accept lab leadership's multi-year plan to retain the lab and enhance the value of lab testing for Northwell.

When discussions began in 2008 about selling the health system's lab assets, Northwell Health was a 15-hospital system based in Lake Success, N.Y., just outside New York City in the northwestern corner of Long Island. Today, the health system has 23 hospitals, and an extensive network of physician offices and other clinical assets that operate as one of the nation's largest and most respected health systems.

In the next parts of the series, The Dark Report will explain how Northwell's lab leadership and staff achieved the goals laid out in 2008, and how the lab and health system are positioned for success in the future. This narrative can be instructional for pathologists and clinical lab directors in other hospitals and health systems.

Northwell's Lab in 2008

Over the past 25 years, commercial lab companies have offered to hospital and health system CEOs the opportunity to lower lab test costs, increase efficiency, and grow outreach lab services by acquiring the clinical lab assets or forming joint-venture partnerships to operate the lab. When they announce these joint venture deals, the details often are reported widely.

Conversely, the details of negotiations between health systems and commercial lab companies that did not result in a sale or some form of lab collaboration agreement are rarely made public. For that reason, it's extraordinary that the details on the story of how one of the nation's largest urban health systems considered forming a joint venture with a commercial laboratory to run all its lab operations—yet did not execute the deal—has now come to light.

In *APLM's* December report, "Northwell Health Laboratories: The 10-Year Outcomes After Deciding to Keep the Lab," Crawford and colleagues explained that the story began in 2008. The senior and corresponding author was James M. Crawford, MD, PhD, the Senior Vice President for Laboratory Services, Northwell Health.

Sale of System's Lab Assets

At the time, health system executives considered monetizing the clinical lab by entering into a joint venture as a minority partner with one of two commercial laboratories. The offer under consideration involved accepting a multi-million-dollar payment for the health system's lab assets.

If accepted, this offer would have meant that Northwell would then hold a minority stake in a lab joint venture with the commercial lab company that would purchase those lab assets. Under this arrangement, the commercial lab company would operate the health system's inpatient, outpatient, and outreach lab services. Neither of the commercial laboratory companies that expressed interest in the JV opportunity in 2008 was named in the published story.

Following much discussion, the leadership of Northwell Health Laboratories persuaded the health system's administrators that retaining the lab as a significant clinical and financial asset was the best strategy. Their arguments were based on a vision for Northwell being able to lever-

How Health System Administrators Developed Criteria in 2008 for a Laboratory Joint Venture

WHEN THE CLINICAL LABORATORY TEAM AT NORTHWELL HEALTH published its peer-reviewed study of their lab's experience during the years 2008 to 2018, it listed the factors that the Northwell administration considered when it issued a request for proposal (RFP) in June 2008 for a laboratory joint venture with a potential commercial laboratory partner.

This list is presented below. It provides hospital lab administrators and pathologists with insights on the issues they must address when educating their administrators about why their lab is simply not a cost center that can be outsourced to the cheapest provider of lab tests to their hospital or health system, but is a strategic asset that can create value.

Goals for a Potential Laboratory Joint Venture

(JV to involve a commercial lab company with health system as a minority partner)

- Synergistic partnering/collaboration to establish a new entity as a national and international leader
- Equity opportunity (monetization of a system asset)
- Continued growth in laboratory services
- Increase margin from laboratory services
- Maintain and enhance service to the existing client base
- Further develop anatomic pathology service
- Further develop molecular and specialized testing
- Enhance academic mission

Arguments for Monetizing the Laboratory *(by sale to a JV)*

- Immediate short-term cash influx
- Relief from costs of salaries, benefits, employee management
- Access to larger geographic area through joint venture partner

Arguments for not monetizing the Laboratory *(keeping it)*

- Retaining complete control of a major clinical asset
- Maintaining one of the larger growth-oriented financial assets in the system
- Opportunity to grow into different revenue streams
- Access to laboratory data as a longitudinal resource for patient management

Source: "10-Year Outcomes After Deciding to Keep the Lab"—Jensen et al, Arch Pathol Lab Med. 2019 Dec;143(12):1517-153.

age the lab to expand its service offerings in the New York Metro, one of the largest healthcare markets in the nation.

One of the most persuasive parts of the argument was the lab's six-part, five-year strategic plan for lab growth for 2009 through 2014. *(See sidebar on page 15, "Lab Team's Six Ambitious Goals in 2008.")*

In the 10 years since (2009-2018), test volume in the core laboratory grew by 4.5% per year and revenue from testing rose by 16.0% each year, the authors wrote. Also during this time, hospital-based lab testing costs remained constant or grew in accordance with the development of strategic clinical programs. During this time, the lab developed innovative system-oriented clinical and value-based payment programs.

In addition, Northwell Health Laboratories developed a joint venture in

2014 with **New York City Health and Hospitals**. Under this arrangement, Northwell Health's lab organization worked with New York City Health and Hospitals to achieve substantial cost savings for laboratory services in both organizations.

Also, in 2011 and in 2016, the Northwell Health labs were called on to support two distressed hospital labs in the nearby borough of Brooklyn, New York.

Validating Northwell Health's decision to retain the laboratories as a wholly-owned system asset, the 10-year outcomes have exceeded projections, the *APLM* report authors added. "Northwell's clinical lab is now well positioned for leading innovation in patient care and for helping to drive a favorable posture for the health system under new payment models for healthcare," they wrote.

A Timely, Important Story

"This report comes at an auspicious time, since the not-for-profit sector of the laboratory industry faces challenges that threaten its status as in-system assets," the authors explained. "Inpatient laboratory services are a cost center for hospitals; key performance metrics are cost-per-test and total laboratory costs for the hospital."

Hospital and health system executives view cost efficiencies and laboratory test utilization management as significant indicators of performance and any perceived failure to achieve satisfactory clinical or financial results leads these executives to consider alternative management arrangements, the authors added.

When health systems consider such alternatives, the largest commercial laboratory companies, including **Laboratory Corporation of America** and **Quest Diagnostics**, have three factors in their favor:

1. They offer competitive lab test pricing wherever they have operations;
2. They are in-network through the national contracts they have with many national and regional health insurers; and
3. They have the size to withstand much of the reductions that health insurers and government payers have made in what they pay for laboratory tests.

Northwell Lab Had a Vision

As a result of the challenges that executives of not-for-profit health systems face, they are open to overtures from commercial laboratories for divestment (and one-time monetization) of their ambulatory laboratory assets, or entry into minority positions in joint ventures, while arranging for external managed services of their inpatient clinical laboratories, the authors explained. The decision Northwell Health made in 2008 to keep the lab gave Crawford and colleagues an opportunity to realize the vision they had put forth for achieving the value of in-system lab.

Their vision had included achieving in-system cost efficiencies for all clinical lab practice sites and unification of health information on patients from both the ambulatory and in-patient sectors of healthcare. For health insurers, such information has high value.

The lab staff's vision also included growth of outreach lab services to health-system affiliated physician practices and the establishment of pathology informatics to leverage the latent information present in the massive data streams the clinical laboratory generated.

2008 Decision-Making

In 2008, Northwell's lab had 50 pathologists on staff in various subspecialties. It also had professional PhD expertise in microbiology, virology, molecular pathology, and cytogenetics.

Because the lab was founded in 1997, its lab management team was experienced and highly qualified, given that they already had more than 10 years of experience running the Northwell Health Laboratories network successfully.

Also in 2008, the core laboratory occupied 60,000 square feet in a building in Lake Success and ran 5.90 million (or 98%) of the 6.02 million tests the health system generated each year from its hospitals, affiliated physician practices, nursing homes, in-system reference testing, and from clinical trials.

From the hospitals alone, testing generated $27.7 million in revenue from 2.12 million tests annually, representing 36% of the core lab's revenue.

The lab also ran 3.74 million tests that came from outreach testing, including physician practices, nursing homes, and reference testing. This volume generated $43.2 million in revenue and represented 59% of total net revenue.

Clinical Trial Revenue

At the same time, clinical trials ran 260,000 tests each year, generating $3.4 million in revenue, or 5% of the total net revenue, the authors explained.

For blood draws, the laboratory had 11 patient service centers, eight of which were in the surrounding communities and three of which were based in Northwell Health's physicians' offices. Each day, all lines of the labs' business generated about 5,000 requisitions and there were 30,000 laboratory test pick-ups per month. Primarily, the test pickups came from the Borough of Queens in New York and the two counties on Long Island, Nassau on the west end, and Suffolk on the east end.

In October 2008, lab executives projected revenue for the year would total $69.2 million, based on 5.9 million tests. It's important to note, however, that the projections fell slightly short of the actual total, which were $72.8 million in revenue for 6.0 million tests.

These numbers represented significant increases from the revenue numbers reported in the previous two years ($47.4 million in 2006 and $59.9 million in 2007). Over those three years, outreach revenue grew by 64% from $26.2 million in 2006 to $43.2 million in 2008, the authors reported.

In June 2008, health system administrators issued a request for proposals to commercial laboratories seeking a potential partner for the Northwell Health Laboratories. Two months later,

Lab Team Given Six Ambitious Goals in 2008

TO SHOW THAT IT COULD DELIVER VALUE TO THE PARENT HEALTH SYSTEM, the laboratory team at Northwell Health put forth six key goals for growth in 2008. This was at the same time that administration was considering selling the clinical lab and taking a minority share in the resulting clinical laboratory joint venture.

This was to be the laboratory's 6-part, 5-year strategic plan over the next five years, meaning 2009 through 2014. The goals were listed as follows:

1. Continue to support the health system's hospital-based clinical laboratory needs.
2. Generate incremental physician outreach revenue and increase regional market share.
3. Become recognized as a national reference laboratory through further development of test protocols and growth in areas of molecular diagnostics, anatomic pathology, and specialized testing.
4. Continue to grow clinical trials business focusing on high margin and high complexity testing.
5. Sustain the existing 18 nursing home clients while continuing to assess the effect of supporting nursing homes and the health system's efforts to provide care.
6. Enhance and drive the health system's brand.

Source: "10-Year Outcomes After Deciding to Keep the Lab"—Jensen et al, Arch Pathol Lab Med. 2019 Dec;143(12):1517-153.

a commercial lab company responded offering to form a joint venture to operate Northwell labs.

Under the proposal, Northwell Health would retain a minority interest and the commercial lab company would control the operation. Discussions ensued with this commercial lab from September through November 2008. Later in November, another potential commercial laboratory partner expressed interest in working with Northwell Health, although the authors provided no details about this second offer.

To evaluate the proposals, Northwell Health's administrators appointed members of the board of trustees to a subcommittee to assess how well the proposals met the goals outlined in the RFP for the joint venture. The subcommittee also considered the arguments for and against monetizing laboratory services. *(See "How Health System Administrators Developed Criteria in 2008 for a Laboratory Joint Venture," on page 13.)*

Assessing the Options

Lab leaders presented arguments to the subcommittee about the importance of retaining lab operations in full.

The discussion in October 2008 included the core lab's net revenue for 2006 and 2007 and the projected revenue for 2008 and 2009, along with actual test volume from 2007 and projected test volume for 2008 by source categories. Based on projected 2008 revenue of $69.2 million (representing a growth rate of 20%), lab leaders projected that revenue in 2009 would grow by 13% to $81.5 million.

Test volume from Northwell's hospitals was projected to be mostly steady (0.3% growth) at about 2.1 million tests. Growth in testing from nursing homes was expected to rise from 331,588 in 2007 to 359,312 in 2008 (growth of 8.4%), and from clinical trials, test volume would rise from 217,636 in 2007 to 237,223 in 2008 (9.0% growth).

Reference testing was expected to grow at a substantial rate from 24,430 tests in 2007 to 93,158 tests in 2008 (an increase of 281.3%). Outreach volume also was expected to rise significantly from 2.4 million tests in 2007 to 3.2 million in 2008 (growth of 31.2%), the authors wrote.

2009 Leadership, Structure

The combination of the 2008 positive numbers showing strong projected growth in test volume and revenue, and the projected growth for 2009 through 2014, helped to persuade the health system's administrators to retain the laboratory as a fully-owned system asset. The result was the administrators endorsed both the vision the lab's executives and staff offered and the necessary organizational structure to achieve that vision.

Specifically, in order to have Northwell Health Laboratories become a fully-integrated health system laboratory network, at the start of 2009 the health system's administrators approved the formation of a laboratory service line and appointed Crawford as both Chair of the Department of Pathology and Laboratory Medicine (DPLM) and as Senior Vice President for laboratory services.

New Clinical Programs

Reporting to both the Chief Medical Officer and Chief Operating Officer respectively, Crawford was asked to identify and develop new clinical programs consistent with market opportunities, patients' needs, and financial feasibility.

In the next installment of this series, The Dark Report will describe the steps Northwell's clinical laboratory team took to achieve the objectives the administration approved. TDR

—Joseph Burns

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Pathology Update

Pathology Groups Should Plan to Use Digital Pathology

Growing interest in digital pathology systems, whole-slide imaging comes with risks and rewards

When an anatomic pathology group considers implementing digital pathology and whole-slide imaging (WSI) for primary diagnosis, it must identify and understand a range of challenges and opportunities.

"Every pathology group should start by considering how it will use the related technologies of a digital pathology (DP) system and whole-slide imaging," said Liron Pantanowitz, MD, Vice Chair of **Pathology Informatics at the University of Pittsburgh Medical Center**. "This assessment needs to include an understanding of how these technologies can help pathologist improve clinical care and diagnostic accuracy and, at the same time, create opportunities that add value to the group's client physicians.

Changes to Workflow

"Another factor is how workflows change in the histology lab and with individual pathologists when DP and WSI are implemented by the group," he added. "Nearly all pathology subspecialties can benefit from a transition to digital, but often in different ways. It is also helpful to know that workflow efficiency is hard to prove in advance of actual implementation of a digital pathology system and whole-slide imaging.

"Your pathology group must look at the profile and practices of each user," stated Pantanowitz. "For example, different users and different pathologists will have unique workflow requirements that need to be accommodated by the system. These assessments will help your group identify what it wants to accomplish with DP and WSI, and what resources will be required to implement them."

Closed vs. Open Systems

Pantanowitz next took up the question of whether the digital pathology system, scanners, and associated software are "closed-box" products or based on open architecture. "DP technologies are new and evolving quickly," he explained. "This means means algorithms and modules will evolve and there may be add-ons.

"Open-architecture systems and products give your pathology group the capability to work with new tools that come along, especially in fields such as computational pathology and artificial intelligence," he added.

Going digital means that pathologists must also look beyond the simple function of image management. "Managing images is a basic function," said Pantanowitz. "It is even more important to look at how your pathology group wants to manage its cases and its patients.

"This can only be done by asking vendors specific questions about how their products support such functions as case management," he recommended. "Ask vendors to explain their experience in integrating their systems with your pathology group's particular LIS.

"Further, don't make the mistake of failing to anticipate future developments when choosing a system," said

Eight Tips for Preparing a Request for Proposal When Shopping for a Digital Pathology System

When anatomic pathology groups consider the purchase of digital pathology (DP) and whole-slide imaging (WSI) systems, Liron Pantanowitz, MD, Vice Chair of Pathology Biomedical Informatics at the **University of Pittsburgh Medical Center**, offers some suggestions and even a few red flags or deal breakers to watch for when requesting information from vendors and scheduling demonstrations:

- Not all vendors are accustomed to or prepared for addressing clinical needs. It can be useful to organize your questions by categories, such as application functionality, hardware and software requirements, vendor support and training, and infrastructure requirements.
- Ask whether the vendor can send a consultant out to fix problems the same day. DP and WSI workflows cannot function when a scanner jams or a scanned image does not appear in the practice's laboratory information system (LIS).
- Beware promises of features or functionality that will be available in the future.
- Don't get distracted by "bells and whistles." Features such as image analysis, algorithms, and molecular tools are not needed for routine digital pathology. At the same time, be sure the features you do need are available from day one.
- Beware vendors that seek consideration without completing the RFP.
- Beware vendors that cannot show how their product would integrate with your LIS.
- Beware vendors who do not offer to demonstrate their products onsite at the practice's location.
- Research the vendor's reputation. It's worthwhile to speak with other customers about their experiences and any challenges they had implementing the DP or WSI system. Some scanners can perform unreliably or image quality can be inadequate.

Pantanowitz. "This is the time to ask prospective vendors how they plan to incorporate new features and new capabilities going forward."

Pathology groups need to also acknowledge that the profession is moving away from simply reporting accurate test results within the accepted turnaround time. Instead, success will come from leveraging lab test data to create value for physicians, hospitals, payers, and patients.

"Laboratories are evolving into data companies," observed Pantanowitz. "Digital pathology will be a foundational technology that enables pathologists to help physicians achieve faster, more accurate diagnoses, identify the best therapies for the patient, and better monitor the patient.

"As pathology groups assess the value DP and WSI can bring to their group, they need to similiarly identify the different ways that these technologies can help them contribute to improved patient care—and be paid for that value," he added.

"It's important that pathology leaders and practice administrators understand digital pathology is undergoing steady improvement in its performance," said Pantanowitz. "For that reason, every pathology group should regularly assess how the current generation of digital pathology systems and whole-slide image has become more productive and cost-effective than earlier generations." TDR

—Pamela Scherer McLeod

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

On Dec. 19, Congress passed a year-end spending bill that included the Laboratory Access for Beneficiaries (LAB) Act. The bill went to the President for his signature. The bill mandates that the federal **Centers or Medicare and Medicaid Services** (CMS) delay by one year having labs report their private payer lab test data. This means no reporting will be required "during the period beginning Jan. 1, 2020, and ending Jan. 1, 2021," with reporting required "during the period beginning Jan. 1, 2021, and ending Mar. 31, 2021."

MORE ON: *LAB Act*

On Jan. 3, 2020, CMS issued a statement that it was implementing a one-year delay in the reporting of private payer lab test price data until Jan. 1, 2021. In its announcement, CMS also said that cuts to the 2020 Medicare Clinical Laboratory Fee Schedule (CLFS) would be implemented, capped at 10%, and that "the reduction cap is set to rise to 15% in 2021."

ADD TO: *LAB Act*

The second section of the LAB Act requires CMS, within 90 days of the LAB Act's enactment, to enter into an agreement with the **National Academies of Sciences, Engineering, and Medicine** to "conduct a study to review the methodology the Administrator has implemented for the private payer rate-based clinical laboratory fee schedule." The language in the LAB Act specifies that this study is to consider "how to implement the least burdensome collection process," while resulting "in a representative and statistically valid data sample of private market rates from all laboratory market segments, including hospital outreach laboratories, physician office laboratories, and independent laboratories." Clinical laboratory associations that supported passage of the LAB Act hope that an objective, third-party review of the methodologies used by CMS to collect, analyze, and determine the lab test prices paid by private health plans will address the multiple problems that industry experts have voiced to CMS officials. Meanwhile, CMS will enact the third year of 10% cuts based on 2017 data.

15 MILLION PATIENT RECORDS HACKED AT CANADIAN LAB

In Canada, on Dec. 18, **LifeLabs** disclosed a data breach involving 15 million patients. Stolen data was "patient name, address, email, login, passwords, date of birth, health card number, and lab test results," said LifeLabs. The company confirmed it paid a ransom fee to the unknown hackers. Canada's population is 37.5 million people, so this breach was significant.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 27, 2020.

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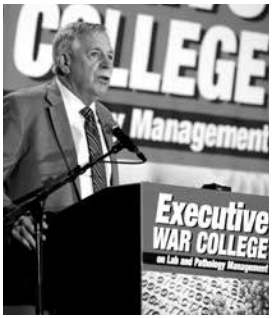

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