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Lab Staffing Crisis & 'Great Resignation'!

(See pages 3-5.)

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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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Despite the Challenges, Labs Are Prevailing

EVENTS IN THE WORLD, THE UNITED STATES, AND THE U.S. HEALTHCARE SYSTEM over the past two years have challenged clinical laboratories and anatomic pathology groups in unprecedented ways.

Stand back for a moment and consider what has unfolded since Jan. 1, 2020. Cases of SARS-CoV-2 exploded across the globe. At the same time, nations locked down their entire populations for months at a time. During these early months of the pandemic, clinical laboratories saw the daily volume of regular lab specimens fall by as much as 60% from pre-pandemic levels. Some pathology groups reported an 80% decline in tissue referrals during this same time!

This severe drop in regular testing volume deprived labs of essential revenue, just when they needed it most to ramp up their ability to process large volumes of COVID-19 tests. Simultaneously, it was nearly impossible to access an adequate supply of lab analyzers, kits, and consumables. Complicating that problem was the federal government, which arbitrarily redirected supplies away from labs ready to receive them so as to send those materials to the labs and communities the feds deemed in greater need.

Today, most of us would agree that the pandemic has released its tight grip on society. After a full two years, Farr's Law seems to be playing out. William Farr is the British epidemiologist, who, in 1840, postulated that "diseases of the epidemic class follow laws of their own; they remain nearly stationary during months, years, and, as we learn from medical history, centuries; then suddenly rise, like a mist from the earth, and shed desolation on nations—to disappear as rapidly or insensibly as they came."

Whether SARS-CoV-2 disappears or becomes endemic—much like influenza or the common cold—we have arrived at a moment when COVID-19 is not the dominant challenge in clinical lab testing. Rather, the biggest source of stress these days is the shortage of medical technologists, pathologists, and the other types of laboratory scientists. *(See pages 3-5.)*

The staffing shortage still needs a solution, whether it is more training programs or new automation that can eliminate many manual processes. That said, the good news is that, collectively, many of the nation's hospital/health system labs, independent labs, genetic testing labs, and anatomic pathology labs are strong, adequately financed, and poised to go forward. TDR

'Lab Workforce Crisis Takes Top Spot'–CAP Today

Clinical laboratories of all types and sizes report the difficulty of maintaining adequate staffing

CEO SUMMARY: ***Just weeks ago,*** **CAP Today** ***characterized the current crisis in staffing clinical laboratories as going "from simmer to rolling boil." Demand for medical technologists and other certified laboratory scientists far exceeds the supply. Consequently, many labs now use overtime and temp workers to handle daily testing. But that is a strategy that leads to staff burnout and more turnover. It may be that yet-to-exist automation will be the ultimate answer.***

THROUGHOUT THE TWO-PLUS YEARS OF THE COVID-19 PANDEMIC, clinical laboratories struggled to adequately staff all types of positions. Today, as the pandemic eases, lab staffing shortages continue and is the number one issue at a majority of the nation's labs and pathology groups.

The nature of this dire situation was best described by writer Anne Paxton. In a story in this month's issue of *CAP Today*, titled, "Lab Workforce Crisis Takes Top Spot," her lead paragraph states:

> *April 2022—There are sudden crises like the SARS-CoV-2 pandemic. And then there are the simmering crises that can be temporarily overshadowed but inevitably re-emerge to command notice. In New York and in many other states, the decades-long shortage of laboratory staff—especially medical technologists and histotechnologists—has gone from simmer to rolling boil.*

Of course, labor shortages are widespread across all industries in the United States. This major trend is known as the "Great Resignation" because so many employees are quitting their current employers. At the same time, employers desperate to fill open positions are finding no takers, despite offering higher wages and increased benefits.

Clinical laboratories and anatomic pathology groups are not exempt from this trend. Lab employees may be quick to resign, with the resulting full-time positions impossible to fill.

Another factor exacerbating staff shortages at labs is the willingness of hospitals and health systems to pay sizeable signing bonuses to medical technologists,

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clinical laboratory scientists, and other technical lab positions. This encourages lab employees at one hospital to quit and go across town to accept a position at a competing hospital that offers a substantial signing bonus or similar benefit, such as paying down the candidate's student loans.

Harvest Sown in 1990s

Even as most industries suffer staffing shortages and the Great Resignation grabs news headlines, when it comes to having enough trained and certified lab professionals, the relevant truth is that clinical labs and pathology groups today are reaping the staffing harvest that was first sown during the 1990s.

Throughout that decade, the trend was for hospitals and other lab organizations to shut down training programs for medical technologists (MTs) and other lab scientist training positions. This was done primarily to save money because of the multi-year squeeze on reimbursement from health maintenance organizations (HMOs), Medicare, and state Medicaid programs that marked the 1990s.

Demographics allowed lab organizations to shutter these training programs. After all, there were abundant numbers of baby boomers who, at the start of the 1990s, were entering the most productive years of their careers.

Challenge to Staff at 100%

Thus it was that, in the decade of the 2000s, shortages in the available numbers of MTs, medical laboratory technicians (MLTs), histotechnologists—even phlebotomists—made it challenging for many lab organizations to staff at 100% of authorized FTEs. At this time, it was often pointed out that, by the end of the decade, 60% or more of certified medical technologists would be eligible for retirement within the next five years.

Those demographics were even more critical during the decade of the 2010s. The ongoing retirements of aging baby boomers steadily eroded the staffing numbers. At the same time, the retirement of experienced baby boomer MTs and other types of lab scientists deprived labs of the valuable institutional knowledge these employees had developed during their tenure with lab organizations.

In its coverage of the lab staffing shortage, *CAP Today* wrote, "In the 1970s there were about 800 accredited medical technology programs in the U.S., compared with [estimates of] fewer than 300 today ... But despite the chronic need for trained technologists, programs today typically are filled at a capacity of only 80%. On average only about 250 medical technologists each year graduate from the four-year programs for medical technology in New York State."

For medical lab directors, this gap means they must not only meet increasing test volume with less workers, but also strive to be more competitive when recruiting and retaining new employees.

Concerns for Lab Directors

Job openings for employers in the lab market is one of the key themes at this year's *27th Executive War College Conference on Laboratory and Pathology Management*. The event is taking place this week in New Orleans.

"In my 30 years covering the clinical laboratory industry, I have never seen such a scramble by labs to hire and retain the needed talent than what is happening today," noted Robert Michel, Editor-in-Chief of The Dark Report and Founder of the *Executive War College*.

"Only the leaders of the nation's largest health system labs and independent lab companies fully recognize the remarkable achievement it was for the clinical laboratory industry to ramp up the huge volumes of COVID-19 testing," he added. "This feat was accomplished at the same moment in time when lockdowns made it incredibly difficult to hire the phlebotomists, accessioners, and med techs needed to perform this testing."

Specialization Among Lab Scientists Is One Factor in Ongoing Laboratory Staff Shortage

RECRUITING AND RETAINING ENOUGH CLINICAL LABORATORY SCIENTISTS (CLSs) AND OTHER TECHNICAL POSITIONS to keep labs at 100% of authorized staffing levels has challenged administrators, executives, and pathologists at labs throughout the United States for 10 years or more.

The ongoing shortage of adequate numbers of certified CLSs, medical laboratory technologists (MLTs), microbiologists, histotechnologists, cytotechnologists, and related positions is regularly attributed to the inadequate number of training programs in the United States.

That is certainly a major factor, particularly because the closure of a local lab tech training program is remembered by local lab professionals for years after the event. But another factor contributes to the current shortage of certified medical technologists (MTs) and other lab scientists. That factor is specialization.

Tara Luellen is Vice President of Laboratory Director Services at the consulting and recruiting firm of **Lighthouse Lab Services**. She works daily with labs that need to hire and retain staff. In a recent interview, she observed that, besides the pandemic and early retirements, there is another contributing factor in the shortage of experienced certified lab scientists. It is the increased specialization with clinical laboratories.

"Today, younger workers who do go into the clinical lab and pathology industry tend to be trained in specialty areas more so now [than] compared to the broader [generalized medical technologist] training programs of the past," Luellen stated. "Today, clinical laboratories don't have as many staff members who are more broadly trained [across different disciplines of lab testing].

"Instead, many of this younger generation of laboratory scientists are very specialized," she added. "So, it takes them years working at labs that do a full range of clinical laboratory testing for these individuals to gain real-life, hands-on experience with those other kinds of testing, compared to the training program that prepared them for a specific specialty in the lab."

Luellen also identified another factor when recruiting MTs and laboratory scientists. "We see a big shift in what people want in a lab technical position," she said. "The compensation still must be there, but these people are also seeking a whole community within the lab organization.

"Today's candidates look for more than just a 9-to-5, punch-the-clock and go-home gig," she continued. "They want the job to enrich their lives. They want to experience a community at work. It's a different paradigm in how they look at what work means for them."

It isn't just med techs and technical staff that are in short supply. The same is true for pathologists. For example, in August 2021, there were 600 pathologist jobs open in the U.S. It may have been the largest number of open positions for that specific position in two decades, a clinical laboratory and pathology practice recruiter noted to THE DARK REPORT at that time. *(See TDR, "Record 600 Pathologist Jobs Open Nationwide," Aug. 16, 2021.)*

THE DARK REPORT regularly hears of stories about hospital labs that are operating at anywhere from 65% to 90% of the authorized number of FTEs. To get by, these labs must authorize plenty of overtime hours and bring in temporary MTs. Both are expensive staffing solutions. If there is a positive side to this dilemma, it is that many developers are working to automate manual processes in lab testing. Such solutions cannot come to market soon enough. **TDR**

Lab Market Update

U.K.-based CliniSys Acquires Nashville-based ApolloLIMS

Consolidation in the clinical laboratory informatics industry took another step forward with the announcement that **CliniSys** (the parent of **Sunquest Information Systems**) was acquiring Nashville-based **ApolloLIMS**.

This move may also further muddy the line between classic laboratory information systems (LIS) and traditional laboratory information management systems (LIMS). The result may be a stronger LIMS market, a fact which lab managers and pathologists will want to consider whenever they evaluate their information systems.

In an April 12 press release, CliniSys said that the ApolloLIMS solution supports testing activities in clinical, public health, toxicology, and molecular diagnostics settings.

LIS Versus LIMS

An LIS is a patient-centric system that usually complies with HIPAA and generally is used within clinical diagnostic laboratories, such as those in hospitals. It typically needs to integrate with electronic health record systems, billing software, and physician ordering platforms.

An LIMS, however, manages workflows in batch-specific environments, often in non-clinical labs, such as for food testing. By design, an LIMS is self-sustaining without add-on integrations.

An interesting twist is that commercial diagnostic labs—because of their large specimen batching—tend to use an LIMS. Also, smaller clinical labs, including start-ups, may gravitate to an LIMS because of its more independent functionality.

In fact, a quick review of ApolloLIMS' case studies on its website reveals several stories about labs, including COVID-19 diagnostics sites, ramping up within weeks by taking advantage of the flexibility of an LIMS.

Long-Term Goals

In January, CliniSys, a U.K.-based division of **Roper Technologies**, reported that it had acquired **Horizon Lab Systems** in Raleigh, N.C. CliniSys also announced at the time that it planned to combine the Horizon LIS with the LIS of its Sunquest Information Systems division, located in Tucson, Ariz.

Horizon develops lab tests outside of healthcare in areas such as environmental management and agriculture. The ApolloLIMS deal fits nicely with Horizon's business line.

"The announcement confirms a significant step toward fulfilling our vision to enable a new wave of digital diagnostics and community laboratories, spanning environmental, water quality, public health, toxicology and agriculture lab testing markets," CliniSys noted in a statement.

ApolloLIMS' employees will stay with CliniSys. "Not only will [ApolloLIMS employees] help expand our knowledge of diagnostics within and beyond the clinical laboratory, but they share our deep belief that the future of digital diagnostics lies in the cloud," said Michael Simpson, CEO at CliniSys, in a press release about the acquisition of ApolloLIMS.

CliniSys said that over time it will integrate the ApolloLIMS platform into its software suite. TDR

Problems at Theranos Described in Balwani Trial

Balwani case again raises questions of when CLIA laboratory directors should act on suspicious results

CEO SUMMARY: ***Former Theranos President and COO Ramesh Balwani is now being tried in federal court in San Jose, Calif. As with the earlier trial of Elizabeth Holmes, questions will arise about whether executives or clinical lab directors bear ultimate responsibility for lab test results. Balwani's lawyers have painted him as an investor who ceded decisions to Holmes, but testimony and his own text messages contradict that argument.***

CLINICAL LABORATORY DIRECTORS MONITORING THE FRAUD AND CONSPIRACY TRIAL against Ramesh "Sunny" Balwani—former President and Chief Operating Officer at now-defunct **Theranos**—may find themselves experiencing déjà vu.

Balwani's trial, which started on March 22 in San Jose, Calif., has echoed the prior proceedings against Theranos' founder, Elizabeth Holmes. Balwani is charged with 10 counts of wire fraud and two counts of conspiracy to commit wire fraud—the same charges Holmes faced.

So far, Balwani's proceedings have received far less media fanfare and public attention than Holmes' blockbuster trial. However, eyebrows raised during Balwani's trial when a former Theranos laboratory director testified that getting accurate results from the company's Edison blood analyzer was akin to a coin toss.

Readers of THE DARK REPORT should focus on testimony in the Balwani case that concerns duties required under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

As with Holmes, the government alleges that Balwani knew that the Edison analyzer did not work and that he should have informed investors about the poor accuracy of the equipment.

Undoubtedly Balwani is hoping for a different outcome than Holmes given she was convicted on four of 11 counts in January. *(See TDR, "Jury Finds Elizabeth Holmes Guilty in Four of 11 Criminal Counts," Jan. 10, 2022.)*

Holmes faces up to 20 years in prison for each conviction when she is sentenced in September.

'I Am Responsible'–Balwani

The big question for the jury will be whether Balwani made decisions hand-in-hand with Holmes—his girlfriend during much of their time together at Theranos—or whether he was merely an investor who let Holmes steer things, as his defense team has postulated.

Jurors saw text messages between Balwani and Holmes that seem to bely his defense strategy. In one text to Holmes, Balwani wrote, "I am responsible for everything at Theranos," *NBC Bay Area* reported.

"While many questions remain about Balwani's role in the Theranos scheme, he definitely wielded a lot of power at the

company," according to a March 2022 profile on Balwani by *The Cut*, a website affiliated with *New York* magazine.

"Most former Theranos employees and investors didn't seem to know he and Holmes were dating, but they did know him as an overbearing manager with little knowledge of the science behind Theranos' machines," *The Cut* added.

On the other hand, Constance Cullen, an immunology expert who helped lead test development at pharmaceutical firm **Schering-Plough**, testified during the trial that she never met or spoke to Balwani.

Cullen was asked by her superiors in 2009 to evaluate Theranos' technology, in theory to potentially help Theranos approach investors. Cullen said it was Holmes whom she interacted with. Schering-Plough was acquired by **Merck** in 2009.

During the Holmes trial, THE DARK REPORT noted eight areas that CLIA lab directors should pay close attention to based on testimony. *(See TDR, "CLIA Lab Director Testimony Shows Risks to Pathologists," Nov. 8, 2021, and "In Theranos' Trial, CLIA Laboratory Director Has a Starring Role," Nov. 29, 2021.)*

One of those concerns surfaced again early in the Balwani trial: Under CLIA, what obligation does a laboratory director have to notify regulators about problems in the lab?

Inaccurate Lab Test Results

During Holmes' trial, prosecutors sought to prove that lab employees knew Edison results were inaccurate, and thus executives also must have known. Her defense pushed back that the lab director holds ultimate responsibility for test results and that executives rely on their laboratory director's CLIA expertise.

How those opposing views will play out in the Balwani trial is not yet clear.

Nevada State Public Health Laboratory director Mark Pandori, PhD, who served as Theranos' lab director from December 2013 to May 2014, took the stand during Balwani's trial. He testified that receiving accurate results for some tests run through the Edison machine was like "flipping a coin."

"When you are working in a place like Theranos, you're developing something new. And you want it to work," Pandori stated, according to *KRON-TV*. "Quality control remained a problem for the duration of my time at the company. There was never a solution to poor performance."

Pandori noted double-digit failure rates for common blood tests in March 2014, including for:

- Vitamin D tests—18% failure rates.
- Total T4 thyroid test—23%.
- Free T4 thyroid test—20%.
- Prostate-specific antigen test—29%.

Lab Director Obligations

Clinical laboratory directors may want to ask themselves what they would do in similar circumstances. Try to convince the lab's owners, perhaps in vain, that the results are inaccurate or, instead, file complaints with lab regulators?

Perhaps more importantly, what would a lawyer's response to the director's actions be in the event of legal action against a clinical laboratory?

CLIA puts all aspects of a lab's operations under a director's responsibility, according to a 2006 **Centers for Medicare and Medicaid Services** publication, titled, "Laboratory Director Responsibilities," known as Brochure #7.

"Even though you have the option to delegate some of your responsibilities, you remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met," the brochure states. "It is your responsibility to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results."

Medical lab directors should consider how their own view of CLIA responsibilities meshes with testimony on how Theranos operated. TDR

Regulatory Update

DOJ: EKRA Governs Lab Sales and Marketing Commissions

Prosecutors contend that weakening EKRA would 'immunize' conduct that drives up medical costs

By filing a motion in a U.S. District Court recently, officials from the federal **Department of Justice** (DOJ) took steps to oppose an earlier ruling by a federal judge in Hawaii dealing with the way the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) governs how percentage-based commissions can be paid to clinical laboratory sales and marketing reps.

Lab directors and pathologists should continue to pay close attention to how they pay their sales and marketing representatives, as the issue of compensation under the EKRA law and the Anti-Kickback Statute (AKS) is confusing and fraught with risk. At the core of the matter is the question of whether reps can be paid commissions based on the volume or value of tests they refer to labs.

As The Dark Report noted previously, the U.S. District Court of Hawaii surprisingly concluded that EKRA did not prohibit labs from paying sales reps percentage-based renumeration. However, that decision went against how EKRA is viewed by many in the lab industry. *(See TDR, "Labs Should Be Cautious about 'Surprising' EKRA Ruling," Feb. 22, 2022.)*

DOJ Focuses on Kickbacks

As expected, the DOJ does not support the ruling in the Hawaii case: **S&G Labs Hawaii** vs. Darren Graves.

"EKRA's prohibition on kickback payments does extend to payments made to marketing employees or independent contractors, where those marketers' commission-based compensation is based on the number of patients referred for testing or the number of tests performed," the DOJ wrote. The federal agency was responding to an argument made by defendant Mark Schena, a biochemist who has been indicted on various healthcare fraud charges.

"Criminalizing kickback payments from a clinical laboratory to a marketer, who in turn induces physicians to refer individual patients to that laboratory for testing, thus fits comfortably within EKRA's broad statutory framework," the DOJ added in its Feb. 28 motion. Schena filed a motion to dismiss some of the charges against him based on the Hawaii ruling.

Violation of EKRA?

Schena is president at **Arrayit**, a microarray laboratory in Sunnyvale, Calif. Prosecutors allege he paid one or more marketers to recruit physicians to order blood-based allergy testing from Arrayit for their patients.

On Feb. 3, 2022, Schena's lawyer filed a motion to have some of the counts against his client dismissed. Schena cited the Hawaii ruling in that motion, saying, "Based upon the analysis in S&G Labs [and] the text of EKRA itself … this court should dismiss counts four through six of the superseding indictment because the conduct that is alleged in those counts is not cognizable as an offense under EKRA."

The DOJ took umbrage with Schena's position. It responded by saying "Defendant's contention that it is legal for a clinical laboratory owner to pay kick-

backs to marketers to induce doctors to refer patients to a laboratory for testing is as astonishing as it sounds on its face," the DOJ wrote in its motion.

"Such a reading would immunize a vast array of conduct that Congress criminalized for good reasons: because it drives up medical costs, deprives patients of freedom of choice, leads to unfair competition that disadvantages those who do not pay kickbacks, and results in medically-unnecessary services, the very harm that allegedly resulted from defendant's kickback payments in this case,'" stated the motion."

A judge has yet to rule on either motion from the DOJ or Schena.

EKRA and Kickbacks

Federal prosecutors are including violations of EKRA in cases involving kickbacks paid by labs to providers in exchange for referrals of clinical laboratory tests. The first such prosecution was in January 2020. An office manager of a substance abuse treatment clinic pleaded guilty to soliciting kickbacks from a toxicology lab in exchange for referrals.

In this case, the defendant pleaded guilty to one count of violating EKRA, along with one count of making false statements and one count of attempted tampering with records. On May 11, 2020, she was sentenced to ten months imprisonment for soliciting kickbacks and obstructing justice.

Another early EKRA prosecution happened in 2020. Two defendants in California were charged and admitted to participating in a multi-state scheme to broker patients to recovery homes in exchange for kickbacks. One man faced a maximum potential penalty of 10 years in prison and a $250,000 fine (or twice the gross gain or loss from the offense). The other man faced a maximum potential penalty of five years in prison and a $250,000 fine (or twice the gross gain or loss from the offense). TDR

How EKRA Creates Criminal Exposure

IT WAS IN LATE 2018 THAT CONGRESS PASSED THE ELIMINATING KICKBACKS IN RECOVERY ACT (EKRA) as part of a larger legislative package intended to address the opioid epidemic.

It was immediately recognized by the clinical laboratory industry that the language in the EKRA law dealing with the payment of sales commission in exchange for lab test referrals was in conflict with the long-established safe harbors for payment of sales commissions under the federal Anti-Kickback Statute (AKS). *(See TDR, "New Opioid Law Hits Labs Paying Sales Commissions," Dec. 3, 2018.)*

Equally troubling were the penalties written into the EKRA statue. Violations could lead to fines of $200,000 along with a maximum sentence of 10 years in prison. Like the AKS, these penalties can be applied per occurrence.

On its website, the Houston law firm of **Hendershot Cowart PC** describes the "common medical lab referral and compensation arrangements that could lead to criminal charges under EKRA," such as:

- Marketing deals that involve multiple LLCs owned by the same party or parties to get around annual compensation limits fixed in advance.
- A physician directing patients to a particular medical testing laboratory in exchange for routinely waiving or discounting co-pays for that physician's patients.
- A medical lab that pays its sales team based on volume of new patients.
- Referrals to privately paid services in exchange for fees or kickbacks.
- Marketing arrangements that involve direct marketing to patients that do not fall within one of EKRA's exceptions.
- Services that are accepted at below fair market value in exchange for special consideration.

Anticipating Change in COVID-19 Test Volume

With emerging COVID-19 variants causing surges in cases and testing, clinical labs must remain nimble

David Dexter

CEO SUMMARY: ***New and more easily transmitted variants of SARS-CoV-2 are causing surges and declines in both the daily number of COVID-19 tests and new cases. This presents pathologists and lab administrators with two common problems: how to scale a COVID-19 testing program and how to staff that program. David Dexter, CEO at Sonora Quest Laboratories, shares his lab's lessons learned after dealing with intense COVID-19 surges in Arizona.***

TWO YEARS INTO THE SARS-CoV-2 PUBLIC HEALTH EMERGENCY, the pandemic continues to provide lessons in how to speedily right size a clinical laboratory as testing for COVID-19 surges, retreats, and surges again.

Even as the daily number of new COVID-19 cases and hospitalizations has declined in the past month, the pandemic continues to produce new variants that are more easily transmitted. Another factor that can directly lessen demand for SARS-CoV-2 PCR tests is the growing competition from at-home/consumer self-test COVID-19 antigen tests.

Because of this situation, many labs are scrambling for strategies and operational approaches that allow them to swiftly right-size the lab, whether COVID-19 test volumes are increasing or decreasing. This must be done at the same time that test services for the regular volume of routine, reference, and esoteric testing referred by physicians is sustained in a timely manner.

This is true for **Sonora Quest Laboratories** (SQL), which had the unique challenge of meeting the SARS-CoV-2 testing needs of its extensive lab outreach business while at the same time sustaining inpatient and outpatient care at the hospitals and clinics of its health system parent. For this reason, when it comes to managing the ups and downs of demand for COVID-19 testing in recent years, the strategies employed by SQL's management team have something to offer for both independent clinical lab operators and hospital/health system laboratory administrators.

SQL is a clinical laboratory joint venture between **Banner Health** (51% owner) and **Quest Diagnostics** (49% owner). It is a major provider of testing services to office-based physicians and other providers throughout Arizona and the surrounding markets it serves.

SQL's executive team also operates **Laboratory Sciences of Arizona** (LSA), owned by Banner Health. LSA employs and manages the lab staff in all the hospitals and satellite labs operated by Banner Health. Thus, LSA's team is responsible for maintaining COVID-19 and other lab testing for the 30 hospitals operated by Banner in six states.

In an exclusive interview with David Dexter, CEO at Sonora Quest

Laboratories, he shared several innovations and business strategies that were responses to the testing waves generated by new variants of SARS-CoV-2. The strategies include:

- Surges come and go quickly—such as from the Omicron variant—that mandate a lab be nimble about adjusting testing capacity on short notice. Doing so is essential for lab leaders who align operations to sustain service levels while at the same time working to maintain stable lab finances.
- Clinical labs must be ready to hire workers quickly if testing volume must be quickly ramped up.

Dexter noted that, despite the prevalence of at-home rapid testing, clinical laboratories must stay vigilant about protecting communities. That includes recognizing the capabilities of different types of COVID-19 tests.

"Labs do need to maintain a PCR testing safety net," he observed. "An antigen test is not nearly as sensitive as a PCR test, and you can't really determine what variant it is from an antigen test." Dexter noted that the PCR methodology does allow a genetic analysis that can identify the COVID-19 mutations of interest.

Demand Rises and Falls

Sonora Quest tackled significant testing demands in its home state of Arizona during the early months of the pandemic in 2020. Dubbed "Operation Catapult," Sonora Quest's program eliminated a testing backlog at the time and taught the company how to scale testing capacity in the future. *(See the sidebar on p. 13 for more details.)*

Fast forward to late 2021. Like the rest of the country, Arizona experienced a sudden surge from the Omicron variant. "This second surge caused us to ramp up Operation Catapult again around Dec. 1 as it became obvious that Omicron was fueling a major surge in the daily number of new COVID-19 cases," Dexter recalled.

"Our lab team continues to get better at ramping up and ramping down Operation Catapult. It takes a considerable number of people to build the capacity that we need when demand calls for it," he noted.

Highest-Ever Positivity Rate

At its height in Arizona, Omicron infected nearly half of the people who received testing. "By the time we hit the third week of January, the virus surveillance topped out at 46.5% in Arizona," he said. "That was the PCR positivity rate, and that's the highest ever measured in Arizona. At that point, Sonora Quest was performing 37,000 PCR tests a day. That was a substantial volume of work flowing through our labs.

"However, just as fast as Omicron rose, it dropped off a cliff on the other side," he continued. "Now, as of late March, our positivity rate has fallen as low as 4% and we're doing about 2,500 PCR tests daily."

At peak capacity, Sonora Quest has eight COVID-19 diagnostic lines available. During times of low community infection, several lines are not running. To bring a dormant line back on takes time, so it's important for the company to monitor increases in infection rates.

"If a line is not up, it takes a week, possibly as much as two weeks, to get one to two lines up and running at full capacity," Dexter explained. "Our operations people have done a great job with that. As of late March, we're doing about 2,500 tests per day. If we get another surge from the BA.2 variant [a lineage of Omicron], it will take us about a month to ramp up to that full capacity of 37,000."

Sonora Quest has also been able to fine-tune the testing process on the lines to reduce errors, such as quality control lapses or mix-ups with specimens.

"We've got the number of failures down to less than 1%," Dexter said. "When we first started with those

In Early Days of Pandemic, Arizona State Officials Wanted 60,000 Tests/Day from Sonora Quest

AS WITH MANY CLINICAL LABORATORIES IN THE U.S., at the start of the pandemic the need to expand testing volume for SARS-CoV-2 was a pressing problem at Sonora Quest Laboratories in Phoenix.

In June 2020, Sonora Quest CEO David Dexter met with officials from both the State of Arizona and Banner Health. Sonora Quest's labs were maxed out at about 10,000 PCR tests daily and the backlog at the moment was more than 67,000 tests.

State officials and executives from Banner Health, the largest health system in Arizona, threw a surprise at Dexter—Arizona needed 60,000 tests run per day from Sonora Quest.

"At the time, I didn't see a way to go from 10,000 COVID-19 PCR tests each day to 60,000," Dexter recalled. "It would be fair to say I was a bit shell-shocked when I walked out of that room."

COVID-19 cases slammed Arizona in the spring and summer of 2020. Maricopa County—home to Phoenix—saw more than 2,000 cases per day in late June. The problem was compounded by a dearth of testing in the state. Arizona was near the bottom of the 50 states in per capita testing, the *Arizona Republic* reported on May 17, 2020.

Steps to Increased Volume

Dexter and his lab team had to find new ways to increase COVID-19 PCR testing volume. Three steps were taken to eventually bring Sonora Quest's capacity to 60,000 tests per day.

The first step was financial: He pushed to spend $10 million for additional equipment and reagents, roughly 10 times over his spending authority at the time. Soon after, Sonora Quest Laboratories launched "Operation Catapult" to meet the goal that Arizona and Banner Health set.

Once the funding was in place, SQL's second step was to reach out to large purchasers of equipment and supplies in Europe in hopes of grabbing additional stock of needed resources.

"We knew that the supply of reagents and other supplies was tight at the time because every lab in the United States was short of equipment and supplies," he explained.

Opening a 24/7 COVID Lab

Once equipment arrived, Sonora Quest's third step was to open a new 24/7 clinical laboratory that the company had been planning to open for some time.

The company hired about 300 employees for Operation Catapult to work in this new 250,000-square-foot facility. The larger labor force and added equipment helped Sonora Quest aggressively tackle its backlog while keeping turnaround times for new COVID-19 PCR tests in the 12- to 24-hour range.

"Shipments of test kits and supplies arrived the weekend of July 4, and by August 3, the backlog of 67,000 tests was eliminated. And this new inventory extended our testing capacity going forward," Dexter said. The company also hit the goal of 60,000 tests daily.

By mid-August 2020, COVID-19 cases dropped 75% in Arizona, thanks to a combination of mask mandates, community education, and increased testing, the *Washington Post* reported on Nov. 2, 2020.

"The rates of infection had calmed down a bit, so some of that capacity was taken down," Dexter noted. "Then, we got hit with a second wave around November that lasted into the early days of 2021. But we were able to accommodate high levels of testing again, which meant Operation Catapult was still paying dividends."

SARS-CoV-2 lines, our failure rate went up to about 15%.

"However, with our culture of Lean, Six Sigma, and Quality Management, we knew our medical lab team had the operational and the technical expertise to continuously identify and reduce the sources of failure. That's essentially what we've done over time."

Hiring Follows More Capacity

Dealing with that ebb and flow of heightened testing capacity requires clinical laboratories to quickly hire staff members—and just as quickly reduce labor if necessary. Each of the eight COVID-19 testing lines that Sonora Quest runs employs six people.

"It takes a significant number of full-time equivalents. We've used a lot of temporary workers and that's required us to be effective at training them quickly and thoroughly," Dexter noted. "As each wave of COVID-19 test volumes dropped, it was necessary for us to reduce the number of temporaries we employed in specimen processing as well as in molecular."

Finding temporary workers quickly presents difficulties for any lab that experiences a rapid surge in test volume that requires a significant increase in the lab's testing.

"This is a challenge, particularly in a tight market for lab labor, but our lab has managed to be successful at recruiting and hiring the needed staff," Dexter noted.

Lab hiring managers must be aware of what's needed for COVID-19 testing procedures. For some duties, such as accession, it's possible to quickly train temp workers with little clinical experience.

However, analyzing COVID-19 PCR test results and entering them into medical records requires the skills of certified medical technologists (MT). During a surge of COVID-19 testing, hiring those people on a temporary basis may not happen as rapidly because the labor pool of MTs is limited.

Clinical laboratories can avoid those problems, by establishing networks ahead of time with health systems and med tech school programs.

Future of the Pandemic

Seen from the perspective of a social need, Dexter considers lab-based COVID-19 testing to be a cornerstone that protects communities as the pandemic inevitably becomes endemic.

"It's concerning that the current administration is flooding the market with hundreds of millions of antigen tests," Dexter commented. "One reason is because the sensitivity of these consumer self-test kits is not comparable to a PCR test done in a CLIA-accredited laboratory.

"A second reason is that few people who receive a positive result from an antigen test are going to call the state and report they got a positive result. That means the public health data reported daily may under-report the true number of positive COVID-19 cases."

Dexter added that it is impossible to track variants from at-home antigen tests while clinical laboratories are set up to provide PCR specimens to determine variants.

"Working closely with the state of Arizona, and also with health systems in Arizona, SQL tracks the variants very closely," he explained. "We take the positives from our PCR tests and we share them with the TGen—the **Translational Genomics Research Institute**.

"TGen determines what variant is there. This ongoing surveillance allows our lab and the public health officials in Arizona to determine what SARS-CoV-2 variants exist county by county."

However, Dexter noted, "I think we're going to be handicapped going forward if we have another surge. Use of antigen test means we're not going be able to track new variants as effectively," he added. **TDR**

Contact David Dexter at Dave.Dexter@sonoraquest.com.

Intelligent Use of COVID-19 Pooled Testing Helps Clinical Lab Serve Schools in Arizona

SONORA QUEST LABORATORIES USED ITS COVID-19 TESTING CAPACITY to aid schools in Arizona with pooled testing as students returned to in-person learning.

Initially in early 2021, there was little funding for such surveillance testing, said David Dexter, CEO at Sonora Quest. But he got introduced to the National COVID-19 Testing Action Plan (NTAP), a program run by philanthropic organization **Rockefeller Foundation** in New York. NTAP worked collaboratively with federal agencies and the White House to seek funding sources for the safe return to classrooms for K through 12 students.

Use of Pooled COVID Testing

One key to school-based pool testing is the ability to scale pool sizes based on infection rates in a community or the occurrence of a surge.

Research from the **University of Nebraska Medical Center** and the **University of Nebraska-Lincoln** conducted in 2020 showed that five specimens was the ideal number to batch in a COVID-19 testing pool. Researchers also said pooled testing works best in areas with an infection rate below 10%. *(See TDR, "COVID-19 Pooled Testing: Good for Labs? Not for IVDs?" July 13, 2020).*

"When the incidence rate of SARS-CoV-2 infection is 10% or less, group testing will result in the saving of reagents and personnel time with an overall increase in testing capability of at least 69%," researchers wrote in the June 2020 edition of the *American Journal of Clinical Pathology*.

"Our lab did validations of pooled samples of five, 10, 15, 20, and 25 specimens at a time," Dexter explained. "We understood that we would need a range of pools, depending on the prevailing infection rate. If that rate is high, the size of the pool of specimens being tested in batch will need to be smaller.

"The goal was to ensure that we weren't diluting the sensitivity of our PCR tests so much that we wouldn't pick up any infections," he explained. "What we got was virtually the same result in all those different validations. We also wanted to make sure that we had levels of pools, depending on the size of the classroom or what the school or local school district wanted."

To handle logistical issues—such as parent opt-out activities—the **Arizona Department of Health Services** hired **Ginkgo Bioworks**, a biotech company in Boston. DHS contracts with Ginkgo and Ginkgo pays Sonora Quest.

Using Ginkgo on Front End

The objective was to simplify the entire collection process.

"This included how parents could opt out, and effective ways to explain to teachers and administrators how the collection process would work," Dexter noted. "Ginkgo has done all of that on the front end. Frankly, that's not the core competency of Sonora Quest. We specialize in testing and reporting results.

"We signed an agreement with Ginkgo which did not include the Arizona Department of Health Services," he continued. "Ginkgo has a sole-source contract with the Arizona DHS for the $219 million that the state will spend on in-school testing.

"That contract has worked very well for our lab," Dexter added. "Under this contract, SQL is allowed to do COVID-19 testing in 500 of the state's 1,200 K through 12 schools. We've adjusted our testing capacity and we now have ability to do the COVID-19 testing in all 1,200 schools in Arizona."

Legal Update

In Civil Suit, DOJ Seeks Triple Damages for Lab Test Fraud

CERTAIN CLINICAL LABORATORY EXECUTIVES AND LAB SALES PROFESSIONALS may soon be made to pay where it hurts most—in their wallets.

The **U.S. Department of Justice** (DOJ) announced on April 4 that it had joined a civil complaint against 18 defendants, all of whom are alleged to have violated the False Claims Act, Anti-Kickback Statute, and the Stark Law. The DOJ is asking for triple damages in the civil lawsuit, which, if successful, could mean defendants would have to pay back tens of millions of dollars to the federal government.

The complaint stems from clinical laboratory tests conducted by **True Health Diagnostics** in Frisco, Texas, and **Boston Heart Diagnostics** in Framingham, Mass. THE DARK REPORT has been reporting on these entities since 2015. *(See TDR, "True Health to Buy HDL Pending Court Approval," Sept. 14, 2015.)*

Warning to Lab Executives

The latest court action serves as clear warning to medical laboratory executives and lab sales teams about the risks of allegedly offering inducements to refer lab tests. It is evident the DOJ is devoting more attention to individuals' accountability in such cases.

Many of the alleged violations occurred in Eastern Texas, which has been a hotbed of DOJ action in 2022 against lab kickbacks. In March, 10 physicians and one healthcare executive agreed to pay back $1.68 million to the government for alleged lab kickbacks. *(See TDR, "Another 10 Doctors Settle Laboratory Kickback Cases, Pay Back $1.68M," April 4, 2022.)*

Just a few months earlier in January, another seven Texas physicians and one hospital executive agreed to pay back $1.1 million. *(See TDR, "Seven Doctors Settle Lab Test Fraud Case," March 14, 2022.)*

Fraud and Conspiracy

According to the DOJ, lab executives and employees at True Health and Boston Heart allegedly conspired with **Little River Healthcare**, which ran several small hospitals in Southeast Texas, to pay doctors to induce referrals to the hospitals for clinical laboratory testing. True Health and Boston Heart then allegedly performed those tests.

Court documents allege that the hospitals paid a portion of their lab test profits to recruiters, who in turn kicked back those funds to the referring physicians. The recruiters allegedly set up companies known as management service organizations (MSOs) to make payments to referring doctors that were disguised as investment returns.

However, those payments were based on, and offered in exchange for, the doctors' referrals, said the DOJ's lawsuit.

"Executives and sales force employees [from Boston Heart and True Health] leveraged the MSO kickbacks to doctors to increase referrals and, in turn, their bonuses and commissions," the DOJ stated.

The lawsuit further alleged that lab tests resulting from this referral conspiracy were billed to various federal healthcare programs. The claims, in many cases, also involved tests that were not medically necessary.

Defendants Range from Lab CEOs to Sales Reps in the DOJ's Civil Lawsuit, Filed on April 4

APRIL 4TH'S CIVIL COMPLAINT FILED BY THE U.S. DEPARTMENT OF JUSTICE lists the following people accused of various clinical laboratory fraud misdeeds:

- Peggy Borgfeld of Lexington, Texas, former Chief Financial Officer and Chief Operations Officer, **Little River Healthcare**.
- Jeffrey "Boomer" Cornwell of McKinney, Texas, former Vice President of Sales for the Southwestern Region, **True Health Diagnostics**.
- Christopher Gonzales of McKinney, Texas, a management service organization (MSO) recruiter.
- Christopher Grottenthaler, of Frisco, Texas, True Health's founder and former CEO.
- Thomas Gray Hardaway of San Antonio, MSO recruiter and co-owner and operator of **LGRB Management Services**.
- Susan Hertzberg of New York, former CEO of **Boston Heart Diagnostics**.
- Laura Howard of McKinney, Texas, former Area Sales Manager and MSO recruiter, Boston Heart Diagnostics.
- Ginny Jacobs of Magnolia, Texas, MSO recruiter and co-owner and operator of defendants **S&G Staffing LLC** and **Jacobs Marketing**.
- William Todd Hickman of Lumberton, Texas, owner and operator of defendants **Ascend Professional Management**, **Ascend Professional Consulting**, and **BenefitPro Consulting LLC**.
- Scott Jacobs of Magnolia, Texas, MSO recruiter and co-owner and operator of S&G and Jacobs Marketing.
- Stanley Jones of San Antonio, MSO recruiter and co-owner and operator of LGRB Management Services.
- Stephen Kash of Beaumont, Texas, former Director of Strategic Accounts and MSO recruiter, True Health.
- Courtney Love of Dallas, former True Health Account Executive.
- Jeffrey Madison of Georgetown, Texas, former CEO, Little River Diagnostics.
- Ruben Marioni of Spring, Texas, MSO recruiter and co-owner and operator of defendant **Next Level Healthcare Consultants LLC**.
- Jeffrey Parnell of Dallas, MSO recruiter and co-owner and operator of LGRB Management Services.
- Jordan Perkins of Conroe, Texas, MSO recruiter and co-owner and operator of Next Level Healthcare Consultants.
- Matthew Theiler of Mars, Pa., former Vice President of Sales, Boston Heart.

In addition, to increase reimbursement from lab test claims, Little River allegedly falsely billed tests as hospital outpatient services. As described in the lawsuit, Little River allegedly paid out the following amounts from 2014 through 2018:

- $30 million to Boston Heart for MSO kickbacks.
- $18.5 million to various MSOs to induce referrals.
- $15.9 million to True Health for MSO kickbacks.

True Health filed for bankruptcy in 2019 after the government stopped Medicare and Medicaid payments to the lab. *(See TDR, "After Two-Year Battle with CMS, True Health Diagnostics on Verge of Collapse," August 12, 2019.)*

Boston Heart agreed that same year to pay back nearly $27 million to resolve a variety of False Claims Act allegations, the DOJ stated. Little River closed in 2018.

For the last decade, MSOs have been notorious for their connections to alleged lab test fraud. *(See TDR, "Why the Management*

Services Organization May Be Healthcare's 'Scam of All Scams,'" April 4, 2022.)

According to lawsuits and information previously uncovered by THE DARK REPORT, it was clear that MSOs generated plenty of cash for fraudsters. The general MSO setup was as follows:

- Organizers sold MSO shares to, say, 10 doctors, who each invested $20,000. That gave the organizers $200,000 in cash with little to no upfront costs.
- The MSOs commonly passed lab tests referred by their shareholder physicians to a rural hospital, which then billed payers for the tests. Because rural hospitals are allowed to charge health plans more for lab tests, the pass-through billing arrangement let the fraudsters and physician shareholders in the MSO reap large profits.

In one example cited in the DOJ's April 4 civil complaint, Little River allegedly funded MSO kickbacks to physicians "with the knowledge and approval" of former CEO Jeffrey Madison and former Chief Financial Officer Peggy Borgfeld.

Madison and Borgfeld, who are among the defendants in the civil suit, allegedly developed a business growth plan for Little River that centered on increasing referrals for toxicology lab tests.

"[Little River] paid recruiters to generate commercial and federal laboratory testing referrals; the recruiters transferred a portion of the funds to the recruiters' MSO entities," the lawsuit stated.

From there, the MSOs paid the referring providers to induce their referrals to Little River. The hospital system then submitted the resulting claims to Medicare, Medicaid, and TRICARE, the federal health insurance program for military members and their families.

Lower Proof Standard

It's important to note that the lawsuit is a civil complaint, not a criminal complaint. As such, the burden of proof on the plaintiffs is based on a "preponderance of evidence"—a lower standard than in a criminal case, in which a guilty verdict must be beyond a reasonable doubt.

"Under the preponderance standard, the burden of proof is met when the party with the burden convinces [the jury] that there is a greater than 50% chance that the claim is true," according to the **Legal Information Institute at Cornell Law School** in Ithaca, N.Y.

Also, while a defendant can be found guilty of a crime in a criminal case, if a defendant loses in a civil complaint, that party is considered liable. Prison time is not a punishment under civil cases.

The clinical laboratory kickback civil lawsuit provides few details about the original whistleblowers, Chris Riedel and Felice Gersh, MD, who prompted the complaint. The DOJ joined the *qui tam* suit after its filing. TDR

Federal Laws Involved in the DOJ Lawsuit

IN ITS CIVIL LAWSUIT AGAINST SEVERAL LAB EXECUTIVES AND LAB SALES REPS, the Department of Justice cited violations to the following federal laws:

- The **Anti-Kickback Statute** prohibits providers from soliciting, providing, or receiving any payment to induce either the referral of an individual or furnish a service for which payment may be made under a federal healthcare program.
- The **False Claims Act** imposes penalties for any person who submits or causes the submission of fraudulent claims for payment to the federal government.
- The federal **Stark Law** prohibits the referral of Medicare and Medicaid beneficiaries by a physician to an entity for health services if that physician (or the physician's immediate family member) has a financial relationship with the entity.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In a sign that awareness of medical diagnostic testing continues to grow during the SARS-CoV-2 pandemic, the **Mayo Clinic** announced it will invest $49 million to build a new laboratory space on its campus in Rochester, Minn. As part of the multi-year project, several clinical labs will eventually relocate to an expanded area of an existing building. The move will allow the labs to have more workspace and more modern facilities. Construction is expected to be completed in 2025. The project will enable **Mayo Clinic Laboratories** to provide more access to its testing catalog for patients around the world.

MORE ON: *Laboratory Expansion*

Meanwhile, **Summit Health** based in Berkeley Heights, N.J., opened a 50,000-square-foot pathology laboratory in April. The lab, located in Woodland Park, N.J., will serve Summit Health's more than 2,500 providers practicing at over 340 locations in New Jersey, New York, Connecticut, Pennsylvania, and Central Oregon. It will be one of the few physician-group-owned laboratories in the U.S., according to Summit Health. With 80 employees staffing the site, the laboratory expects to process eight million test specimens in its first year, reported *NorthJersey.com*.

DIGITAL PATHOLOGY SETS STAGE FOR PHARMA PARTNERSHIP

Digital pathology continues to blaze new paths. Pharmaceutical giants **Roche** and **Bristol Myers Squibb** have announced they will use the digital technology as part of a new collaboration. In one project under this partnership, **Roche Digital Pathology** is developing an AI-based image analysis algorithm to aid pathologists in interpreting an immunohistochemical assay. Bristol Myers Squibb then will use this algorithm to generate biomarker data from clinical trial samples. In a second project, Roche will use its recently announced collaboration with image analysis technology firm **PathAI** to integrate a PathAI algorithm with Roche's NAVIFY digital pathology software. Subsequently, Bristol Myers Squibb will use the PathAI algorithm to analyze clinical trial samples.

TRANSITIONS

- Julie Ramage is now the new Global Director, Biopharma, at **Ambry Genetics** in Aliso Viejo, Calif. Previously, Ramage served at **AstraZeneca**, **Pfizer**, **PhenoPath Laboratories**, **Neogenomics**, **AD Path Labs**, **TriPath Imaging**, **US Labs**, and **Quest Diagnostics**.

- **Madison Core Laboratories** in Huntsville, Ala., named Jeff Wisotzkey, PhD, as Chief Scientific Officer and Laboratory Director. Prior positions were with **Phase2 Labs**, **Diatherix**, **Health Network Laboratories**, as well as the **Central PA Alliance Laboratory**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 16, 2022.

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