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Interview with CEO of first clinical lab company from India to build and operate a lab in USA.

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

What Labs, Pathology Groups Can Expect in 2022

IN RECENT WEEKS, OUR EDITORIAL TEAM has been developing session topics and speakers for the upcoming *Executive War College Presents: Preparing Your Clinical Laboratory and Pathology Group for Post-Pandemic Success,* which happens on Nov. 2-3, 2021. It has been an eye-opening process because of how many forces for change are at work. This is true of the American healthcare system, as well as in the clinical laboratory marketplace.

To assemble our conference, we typically have 100 or more conversations with lab leaders, executives at IVD companies, and the attorneys, billing companies, and consulting companies who regularly interact with sizeable numbers of lab clients. Typically, these individuals are keen observers of market trends and disruptive technologies.

Each of these conversations gives us an inside perspective on a wide range of new and intriguing developments within the profession of laboratory medicine. Often, a single conversation can lead to a timely intelligence briefing in an issue of THE DARK REPORT where we are first to articulate and describe an important trend that will require an appropriate response by the executives and administrators of the nation's clinical laboratories and anatomic pathology groups. This issue provides several examples.

Our first briefing describes the intensifying efforts of health insurers to audit lab test claims. One significant aspect of these more frequent audits is that private payers are going back as much as six years in their audits. As our clients and regular readers know, payers have been slammed by a steadily-growing Tsunami of genetic lab test claims. Payers recognize that a substantial number of these claims are for genetic tests that have no clinical value. It is only natural for them to want to identify the most egregious offenders by the use of audits. But these same audits also ensnare labs with good ethics.

Our second briefing addresses the surging demand for pathologists, which far outstrips the supply of qualified candidates to fill these positions. At the same time, the pandemic, and greater acceptance of virtual clinical services, is changing how Millennial pathologists evaluate their job opportunities.

Our third briefing is an interview with a fast-growing lab company from India that has opened its first lab in the United States, demonstrating that globalization of laboratory medicine is underway. TDR

Insurers Get Aggressive with Years-Old Audits

Private payers are following Medicare's lead, reviewing lab payments made up to six years ago

CEO SUMMARY: Not only are health insurers looking back to find overpayments and funds paid erroneously, but payers also are requiring documentation for overpayments. If clinical labs and anatomic pathology groups do not appeal such claims quickly, they may be liable for any amount insurers deem to be overpayments, experts said. Health insurers also are taking any overpayments out of future funds to be paid to labs and pathology groups that did not provide adequate documentation, the experts added.

HEALTH INSURERS HAVE BECOME MUCH MORE AGGRESSIVE in pursuing what they call overpayments, even as much as six years after the fact. The actions being taken by private payers are significant.

Clinical lab managers and anatomic pathology groups need to recognize three new billing and collections challenges associated with these aggressive payer actions so that they can respond quickly. The amount of money at stake can be considerable.

"First, commercial payers are auditing lab claims following the example that the federal Medicare program set," said Ann Lambrix, Vice President of Revenue Cycle Management Consulting for **Vachette Pathology**, a division of **Lighthouse Lab Services** in Charlotte, N.C.

"When these audits are completed, payers then ask clinical laboratories, anatomic pathology (AP) groups, and other providers to return any funds the insurers classify as being overpayments or paid in error," she explained. "Several of the nation's largest health insurers have been doing these audits, including **Anthem**, **Blue Cross Blue Shield** plans, **Cigna**, and **UnitedHealthcare**, among others.

"Second, health insurers are asking for more documentation from labs and AP groups," Lambrix noted. "For example, once they audit past claims, health insurers are likely to request documentation on lab test claims they've already paid.

"We see payers also do internal audits on lab test claims paid going back two years and even as far back as six years," she added. "Should the labs or the AP groups not respond quickly to any requests for repayment, the payers then claw back payments associated with those claims.

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"Third, if the insurers determine that a lab test claim was paid incorrectly, then they do what they can to take that money back," she warned.

"The lab or the AP group can appeal. But when they do, health insurers will give them only 30 days to provide any supportive documentation for claims that were already paid. Providing that documentation is difficult for labs to do, especially given the need to respond in just 30 days," she added.

Legal Team Review

To protect themselves, clinical laboratories and AP groups should have their legal teams review their contracts with insurers to ensure that any time frames in current contracts are reasonable for the labs and AP groups involved. Any request requiring documentation within 30 days is unreasonable, Lambrix commented. *(See sidebar, "Non-screening COVID-19 Claims Should be Fully Covered," page 5.)*

"Technically, a pathology group and a clinical lab should have all the documents they need, unless they have switched their billing company or there is a change in ownership or corporate structure," Lambrix said. "Even a change in leadership can be a problem if the lab or AP group doesn't retain all the billing records it should keep.

"When a clinical lab or AP group switches to a new billing company or outsources its billing to a new company, many times the previous billing company will purge the files it had from that lab client after two years," she noted. "If the documentation the lab needs to support claims being audited or under review has been purged, then the lab may be unable to get the information needed to contest any payer's claim of overpayment.

"Ideally, clinical laboratories and pathology groups will want to pull the patients' medical records to review how those contested claims were paid and how they were posted in the billing system," she added. "If those records are unavailable for some reason, the lab will need to pay that money back to the health plan."

Looking Back Six Years

Another recent development in the way private payers are auditing payments to clinical labs and pathology groups is how they are pushing the review period for past lab test claims that go back as much as six years.

"The federal **Centers for Medicare and Medicaid Services** said it has six years to recoup repayment from the date of receipt of any overpayment or payment made in error," Lambrix noted. "That period is generally known as the look-back period to recoup overpayments. Now we see more private health insurers follow that same script."

Lab administrators and pathologists should understand how payers typically identify the claims they want to audit. "Typically, a payer will compare claims from one clinical lab or AP group against what they would say is normal utilization for a particular CPT code or a group of CPT codes," Lambrix explained. "Health insurers will then use that data to set benchmarks in their systems."

Automated Aggression

Using data they have collected, health insurers then will use automated tools to compare normal utilization against the lab or the AP group's utilization levels. In this way, payers can identify potential over-utilization.

"Once a payer establishes these utilization benchmarks, it will go back and pull the records from 20 or more particular patient cases to see what it has paid for those cases," Lambrix explained.

"If there were any overpayments, the health insurer will ask the clinical lab or AP group to provide the supporting documentation," she added. "To respond to that request, the group or clinical lab must provide the information about each patient's clinical history that supports the

Non-screening COVID-19 Laboratory Test Claims Should Be Fully Covered

WHILE SOME HEALTH INSURERS HAVE BEEN MORE AGGRESSIVE IN GOING AFTER OVERPAYMENTS, clinical laboratories and anatomic pathology groups should know that testing for the SARS-CoV-2 coronavirus falls under unique protections enacted as part of the Families First and Coronavirus Response Act (FFCRA), said Danielle Sloane, a member of the law firm **Bass, Berry and Sims PLC** in Nashville.

"Health plans are required to cover COVID-19 testing for patients who have been assessed by a healthcare provider," Sloane explained. "The government payment for COVID-19 testing is limited to individuals who do not have insurance coverage. Labs should note, however, that insurers do not have to pay for general workplace, school, or camp screenings, as the federal Centers for Medicare and Medicaid Services has noted.

"That said, I am aware of several audits that private payers have conducted involving COVID-19 test claims," she added. "From what I've learned, such audits primarily are focused on respiratory-panel testing that includes testing for COVID-19 and a number of other pathogens at the same time.

"However, private health plans also could be looking for COVID-19 test claims where the test is not based on a practitioner's individualized assessment that COVID-19 testing was necessary," Sloane noted. "In which case, insurers could take the position that such testing is screening in nature, and they are not obligated to cover it.

"In instances when a clinical lab or pathology group gets an audit notice from a health insurer, I'd be curious if any payers are trying to take the position that the COVID-19 tests the labs ran were not qualifying tests because they had not received or applied for an emergency use authorization (EUA) from the FDA," she added.

"Technically, the protections imposed under the FFCRA apply to COVID-19 tests with an actual or pending EUA," Sloane noted. "That said, I have not seen insurers take that position, likely because it could be a politically unpopular position given that **Health and Human Services** (HHS) issued a statement in the fall of 2020 telling clinical laboratories that they did not need an EUA to provide COVID-19 testing.

"My recommendation to clinical laboratories and pathology groups doing SARS-CoV-2 testing is to be prepared with a well-crafted response letter to any audit request," she advised. "Such a letter should state that the laboratory is aware of and understands the payer's obligations to cover COVID-19 testing provided during the public health emergency without cost-sharing and without any medical management.

"We have helped several lab clients craft such letters in response to the request of a payer's auditors," she added. "A little time and money spent on the front end to craft a good initial response may be able to help avoid a lot of denied claims and expenses later on."

lab test claims that were billed and now are being audited.

"Here is where labs often have problems. When payers go back a significant period—as much as six years—that alone is a challenge for labs and AP groups to retrieve the documentation needed to support the claims the payers are questioning," she said.

Clinical laboratories and AP groups can protect themselves from claims reviews and audits that can go back as far

as six years by reviewing language in their contracts with insurers and revising that language as needed.

"Labs and AP groups will need to work with their legal advisers to review the language in their contracts with all health insurers," she said. "If needed, the payer should be contacted and that language should be revised as soon as feasible.

Review Payer Contracts

"Such revisions may not be possible until the contract expires," Lambrix added. "That said, labs would be well-served to have their legal teams review all contracts with health plans before they expire and prepare new contract language for review.

"Typically, the language in the lab's contracts will say that health insurers or the insurers' designated auditors may notify the lab or anatomic pathology group of overpayments at any time," she warned. "That contract language will require the lab or group to return any overpayment or any payment made in error.

"Common examples of payments made erroneously include a payment that is a duplicate involving the same lab test claim or a payment issued on behalf of a patient who was not a member of that insurance company," Lambrix explained. "Such a notification will require repayment within a reasonable period.

What Is 'Reasonable Time'

In that case, the lab's reasonable period of time may be significantly different from that of the insurers," she advised. "Therefore, it's important for labs to review the language in their payer contracts and define the reasonable period of time as being within two years or less if possible."

If the health insurer is unable to get any overpayment or erroneous payment back within what it considers to be a reasonable period, the payer will reserve the right to offset that amount against any funds that the insurer would pay on pending or future claims, Lambrix advised. "If labs don't repay those funds right away, health insurers will claw back those amounts out of the money they owe your lab or AP group for future claims," she cautioned. TDR

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COVID-19 Test Claims Could Be Audited

NEWS THAT PAYERS ARE GOING BACK AS MUCH AS SIX YEARS when auditing lab test claims is a warning that labs should prepare in advance for audits that may lead to a sizeable overpayment demand.

Last fall, THE DARK REPORT published a special report, "Getting Paid for COVID-19 Lab Tests." The following are recommendations to help labs prepare for payer audits of COVID-19 tests:

Other common denial reasons are insufficient documentation errors. These include incomplete progress notes, unauthenticated medical records, and/or unsigned orders. Since many commercial payers follow Medicare guidance, it is important for providers to understand Medicare documentation requirements for the claims submitted; however, providers must still be sensitive to any payer-specific requirements. Due to the variety of guidance and requirements from payers regarding requirements for coverage and reimbursement of COVID-19 tests, clinical laboratories should, as a best practice, require signed requisitions for every COVID-19 test they perform. This is also a best practice for non-COVID-19 tests.

Record 600 Pathologist Jobs Open Nationwide

COVID-19 pandemic has had a dramatic effect on the job market for experienced, skilled pathologists

CEO SUMMARY: Demand for top-level pathologists is surging. A strong rise in the number of job openings for pathologists results from a combination of factors, some related to COVID-19. Now that physicians are seeing patients again, the number of specimens has risen after falling last year, creating demand for new hires, a consultant said. The average age of pathologists continues to rise, causing some to retire. At the same time, residency programs are training fewer pathologists.

FOR THE ANATOMIC PATHOLOGY PROFESSION, a good-news and bad-news story is developing. As demand for sub-specialized pathologists is increasing, the number of pathologists qualified to do complex diagnostic testing is inadequate to meet the demand.

For individual pathologists, it is good news that demand for their services is growing.

But it is bad news for pathology groups, academic institutions, and pathology companies seeking to hire more skilled pathologists to handle a rising number of tests while supporting growth in test volume and revenue.

Demand Exceeds Supply

"In today's job market, the demand for pathologists with director-level experience and with sub-specialty skills exceeds the available supply of pathologists," said Rich Cornell, President and founder of **Sante Consulting**, a pathologist and laboratory medicine recruiting firm.

"As the volume of diagnostic testing continues to grow, the number of pathologists available to do this work declines because older pathologists are retiring, and fewer pathologists are graduating from residency and fellowship programs," he added.

The imbalance in the supply of pathologists versus the demand for clinicians with those skills is changing the dynamics in the job market for anatomic pathologists. For pathology group practices and pathology lab companies actively recruiting pathologists, it is important to understand the current dynamics in the recruitment market.

Four Biggest Factors

Pathology groups and companies seeking to hire pathologists will want to understand the four biggest factors driving these trends.

First, data show that the number of jobs available for skilled pathologists exceeds the number of pathologists qualified and who are currently looking for positions.

Second, the economics of supply and demand mean that hiring labs must offer highly-competitive compensation and benefits packages when recruiting pathol-

ogists who have the requisite skills to meet the lab's needs.

Third, the pandemic has changed the way pathologists are recruited, interviewed, and hired.

Fourth, the coronavirus pandemic has caused some pathologists to restrict their job searches to regions of the country where they can be closer to family and to avoid the need to fly or commute over long distances.

Greatest Demand in 20 Years

In August, more openings existed for sub-specialized pathologists than at any time in the past 20 years, Cornell reported. Cornell's recruitment firm in Chesterfield, Mo., specializes in filling positions in anatomic and clinical laboratories at the director level and above, including those in molecular diagnostics, clinical chemistry, microbiology, and immunology.

In an exclusive interview with The Dark Report, Cornell noted that the shortage of pathologists nationwide is unprecedented.

"One popular website for jobs that pathologists use listed 600 pathology jobs as being open in early August," he said. "We often see that an advertised pathology job is filled within a few days and sometimes less than that."

Also, pathology groups seeking new talent to replace senior, retiring pathologists are recruiting virtually, meaning hiring groups are conducting interviews via **Zoom**, **WebEx**, and other online sites.

Virtual Negotiating Process

"Some current candidates looking for jobs have done all of the negotiating with hiring labs virtually," Cornell said. "That means that the first time the new hire meets anyone on staff is day one of the new job." *(See sidebar, "New Normal Is Real-Time Recruitment for Both Clinical and Anatomic Pathologists," page 9.)*

One reason for doing interviews online is the need to reduce travel time for desirable candidates. Another reason is to keep all parties safe during COVID-19.

"Also, a growing proportion of anatomic pathology work today can be done virtually via fully-digital pathology systems," Cornell commented. "That means some newly-hired pathologists can work remotely, and many may not need to move at all to take new jobs. Not having to sell a home or find a new one saves time, which enables new hires to often start right away."

In a presentation two years ago at the *Executive War College*, Cornell cited data from researchers showing that the workforce of pathologists in the United States is smaller relative to that of other countries that have experienced significant adverse events in clinical laboratory quality and delays in diagnosis.

At the time, the market for pathology jobs was already competitive, starting salaries for pathologists were rising, and AP groups were offering competitive benefits and hiring bonuses, he said. *(See, "Fewer Pathologists Means Tighter Market for Jobs," TDR, June 10, 2019.)*

'Looming Shortage' Predicted

Cornell's prediction was based on research published online by the *Journal of the American Medical Association* (*JAMA*) in 2019. "The *JAMA* workforce study showed that there would be a looming shortage of pathologists. That's exactly what we see now," he commented.

In its coverage of the pathologist workforce study published by *JAMA*, The Dark Report noted that the researchers had determined the number of pathologists practicing in the United States declined by 17.53% from 2007 to 2017. Using their definition of active pathologists, researchers found that the number of active pathologists in the United States in 2007 was 15,568. By 2007, that number had shrunk to 12,839 active pathologists.

Pathologist training programs are another factor contributing to fewer

New Normal Is Real-Time Recruitment for Both Clinical and Anatomic Pathologists

AMONG THE MANY WAYS THE CORONAVIRUS PANDEMIC HAS TIPPED THE SCALES in favor of anatomic and clinical pathologists seeking new jobs is that the pandemic itself helped to create a shortage of pathologists. That shortage has forced anatomic pathology (AP) groups and some clinical laboratories to change how they recruit new candidates.

Just as homes in some areas of the country have caused buyers to offer more than owners are asking, so too are AP groups and clinical labs competing for candidates by offering higher pay, more time off, and a strong work-life balance. Also, AP groups and some clinical labs have started adopting what Rich Cornell of Sante Consulting called a real-time recruitment methodology.

Recruitment Challenge

"Anatomic pathology groups have a big challenge recruiting candidates for open positions and in hiring those candidates," said Cornell, the President and Founder of Sante Consulting.

"Groups using the old method of inviting candidates for in-person interviews are struggling to recruit talent," he said. "The golden days of simply posting an ad on a job board and expecting to get 20 or 30 resumes are over. That's not the market today. By today's standards, if your group posts an ad and gets five to 10 applicants, you've done well."

Once an AP group or clinical lab identifies a viable candidate, those responsible for interviewing and hiring need to move with all deliberate speed. "Your lab needs to move any viable prospect through the hiring process expeditiously," Cornell cautioned.

"If the hiring team at your lab sits on a CV and does not respond quickly to each candidate, you could lose out," he stated. "Academic medical centers, for example, have layers of bureaucracy in their hiring processes. That slows everything down. They're going to lose candidates 90% of the time unless they react faster," he said.

Millennial Generation

Many of today's candidates were born between 1980 and 1995, meaning they are now in their late 20s to early 40s. These millennials are accustomed to getting what they want quickly. "This generation of pathologists is very demanding," Cornell noted. "Demographic data show that 75% or more of the physician workforce will be millennial physicians by 2025, just 40 months from today.

"Millennials think differently than older pathologists," he added. "Quality of life is very important to them, as is work-life balance. They want to be treated fairly and they want to have a voice in how their employer—meaning the AP group or clinical lab doing the hiring—treats staff."

All these factors mean anatomic pathology groups must be nimble, particularly in today's candidate-driven market. "If your AP group is hiring, you must let any top candidates know you're interested and what you'll do to land them," Cornell said. "If your group does not take these steps, somebody else will step in and snap up those candidates."

Virtual Interviews

The fastest-moving AP groups will hold virtual interviews in which several members of the group will meet with candidates being interviewed online via Zoom, WebEx, or other platform. "Anatomic pathology groups also may need to make competitive offers to candidates as soon after an interview as possible. Otherwise, the best candidates are likely to go elsewhere," Cornell warned.

active pathologists in the United States. In 2019, college and university pathology residency programs were training fewer pathology students compared with the number they had trained in earlier years.

The website **PathologyOutlines.com** showed on Aug. 6 that there were 600 job openings for pathologists. This number represents almost twice as many open positions as the site had shown on Aug. 3 last year.

"Those numbers are a good barometer for the pathology job market, and I don't believe they have ever had that many job openings for pathologists in their 20 years of tracking the market," he commented. "Here at Sante Consulting, our business has risen dramatically as well. Our clients are contacting us almost every day asking for help in recruiting pathologists."

Pandemic's Effect on Jobs

Multiple factors contributed to the rise in job openings for anatomic pathologists. "It's a combination of factors," Cornell noted. "One reason is that physicians are seeing patients again after not seeing the normal level of patients during the pandemic.

"All the patients who didn't see their doctors during the COVID-19 lockdown meant that physicians fell behind on the normal level of procedures they do," he explained. "Now those patients are getting biopsies done, which creates a rising demand for anatomic pathologists.

"A second reason is that many pathologists working today are nearing retirement age and leaving the profession as they retire," he added. "The *JAMA* study showed how the average age of pathologists was rising compared with other physician specialties.

"Also, for many years, pathologists tended to stay on the job, even past the typical retirement age that was common years ago," Cornell explained. "As long as their eyes were good and their minds remained sharp, they were inclined to continue working as long as possible.

"But then the pandemic hit, and now many older pathologists realized there's more to life than work," he continued. "They also may see that with COVID-19, life is short, particularly if they have lost loved ones, such as some front-line workers in healthcare. Many physicians—including pathologists—have lost colleagues due to the pandemic.

"All these factors cause pathologists to look at their priorities differently," he added. "In many cases, if they can afford to retire, they do just that. They're throwing in the towel on their careers and moving on to enjoy their lives.

"Another factor related to the pandemic is that pathologists are leaving groups, not because they're unhappy, but because they're moving to be closer to family," Cornell remarked. "Maybe they're reluctant to fly and want to be closer so that they can drive to be with their children and perhaps grandchildren too.

"If a pathologist has strong family ties in another region, there's probably going to be an opportunity to take a position that opens up near where they want to be," he commented. "Moving to that area may be more likely than it would be in a tight labor market.

Cost-of-Living as a Factor

"The booming market for pathologists seeking jobs gives candidates the option to move to a community where the cost of living is lower," Cornell stated. "We've seen the out-migration among individuals leaving areas where the cost of living is high. Those pathologists are moving to places where their money goes further, such as Florida, Texas, or the Carolinas.

"If a pathologist is getting closer to retirement, he or she is thinking about how to live on a fixed income," he continued. "If so, a state with a lower cost of living could be more attractive than staying in New England, New York, or California where the cost of living is higher." TDR

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Lab Market Update

Many Patients in United Kingdom Not Getting Speedy Diagnosis

About 4.2 million patients don't have diagnoses, average wait time for diagnosis is 10 months

RECENT NEWS REPORTS IN THE UNITED KINGDOM indicate that the COVID-19 pandemic has exacerbated the ongoing problem of lengthy delays in diagnosis of patients within the **National Health Service** (NHS). This is particularly true of delays for patients waiting on results of their cancer tests.

Currently, approximately 5.3 million patients are on a waiting list in the UK, noted the **Policy Exchange**, a UK-based think tank, in a report, titled, "A Wait on Your Mind." The report's authors determined that 80% of those 5.3 million patients (or about 4.2 million) are "waiting on a decision for treatment [no diagnosis] with an average wait time of 10 months."

For a better perspective on these numbers, the population of the United Kingdom is 67 million. Thus, the 4.2 million patients "yet to be diagnosed" represent 6.3% of the nation's total population. For context, if the United States had similar delays, it would mean that almost 21 million of this nation's 329 million citizens would be waiting for a diagnosis.

The Policy Exchange Report also described how current screening practices within the healthcare system are not capturing cancers early and quickly. "The statistics show that nearly a quarter of cancers—roughly 90,000 cases every year—are detected in patients who are referred on non-cancer pathways."

In fact, said the report's authors, "Around a quarter of cancer diagnoses occur following a non-cancer GP [general practice] referral to secondary care. Five times more cancers are detected through this route compared to all screening programs combined. Many of these patients will eventually be diagnosed in hospitals following a long delay, by which point their cancer will now be more advanced."

The Independent, an online news service in the UK, interviewed Sir Bruce Keogh, former National Medical Director of **NHS England**, who supports the Policy Exchange's reports and findings, He said, "Intolerable waiting lists are back. This is our next big test [after the pandemic], both the public and NHS staff have now seen better and expect better."

A Pathology Think Tank

One factor contributing to lengthy delays in the diagnosis of cancer in the United Kingdom is a shortage of histopathologists. This has been widely reported in the UK during the past three years.

One strategy in response to the shortage of surgical pathologists in the UK is a project to adopt digital pathology on a large scale. The NHS is now creating several regional centers where whole-slide images can be created, allowing these digital images to be more easily distributed to pathologists in different regions.

The expectation is that use of digital pathology systems can make the nation's histopathologists more productive. This would allow them to increase the number of cases they can diagnose each year and help shorten time to diagnosis. TDR

NEWSMAKER INTERVIEW

India's Neuberg Diagnostics Expands into U.S. Market

"Our idea is to enhance the access and affordability for next-generation techniques, meaning molecular diagnostics, genomics, pathology, digital pathology, proteomics, metabolomics, and all that. This is the spirit behind Neuberg Diagnostics.

—GSK Velu, PhD, BPharm

CEO SUMMARY: India is a nation where 50,000 pathology labs operate to serve the clinical laboratory testing needs of 1.4 billion citizens. U.S. investors have financed several of India's fast-growing lab companies. But now the tables are turned. One Chennai, India-based lab company is investing in the United States. It recently opened a sophisticated genetic and molecular testing laboratory in Raleigh, N.C.

INTRODUCTION: For more than 20 years, investors in the United States have looked to India as an opportunity for clinical laboratory testing. During this time, many pathologists considered India a potential threat involving anatomic pathology services.

For investors, clinical laboratory testing in India represents a huge opportunity. There are 50,000 pathology laboratories to serve India's population of 1.4 billion people. Since the late 1990s, private equity companies in the United States have regularly invested in certain bigger lab companies in India. In some cases, the capital was used to build new lab facilities in different cities. In other cases, the capital was used to buy independent labs and integrate their operations into acquiring the lab company's network.

It was also during the 1990s when some anatomic pathologists in the United States began to consider India as a threat.

The common perception was that the lower cost of doing business in India would allow histopathologists in that country to be a lowest-cost provider.

Thus, as use of digital pathology images increased, many predicted that specimens would flow from the U.S. to India. This would happen because of the belief that the lower cost of surgical pathology in India would successfully draw business away from pathology groups here in the United States. That fear proved unfounded because, as of this date, no substantial number of pathology specimens from the United States have moved to India for diagnosis.

Consolidation of Labs in India

What is true over the past 25 years is that several well-financed lab companies in India are consolidating clinical laboratory testing services in that country in much the same way public lab corporations in the U.S. consolidated lab testing between 1985 and the present. (In India, pathology laboratory is the common term for a clinical laboratory and histopathology is the common term for an antomic pathology laboratory. TDR is using the terms clinical lab and anatomic pathology in this story.)

During his trip to India to visit hospitals and clinical laboratories in 2018, our editor, Robert L. Michel, met with one of India's most respected entrepreneurs in the clinical laboratory section. He is GSK Velu, PhD, BPharm and he is the Chairman and Managing Director of **Neuberg Diagnostics**, headquartered in Chennai, India.

Labs in Four Countries

In 2018, Neuberg Diagnostics was only a year old and already one of India's fastest-growing clinical lab companies. Velu told Michel at that time that Neuberg Diagnostics had the goal of going international. Today, just 36 months later, Neuberg operates 109 labs in India, as well as 15 labs in South Africa, United Arab Emirates, and the U.S. It is preparing to open labs in several other nations.

In fact, Neuberg has turned the tables on the popular wisdom that lab specimens from the US would flow to India. In May, Neuberg announced the opening of its **Neuberg Centre for Genomic Medicine** (NCGM), a start-of-the-art esoteric and genetic testing laboratory in Raleigh, N.C. The lab is CLIA-certified. Neuberg is ready to compete with labs in this country on their home turf.

Neuberg may prove tough competition here in the US. The privately-held company closed the most recent fiscal year with revenue of 8 billion rupees, equal to $107.3 million in U.S. currency. Velu predicted that Neuberg would report more than US$150 million in revenue in fiscal 2022, according to reporting in India's *Business Standard* publication.

Worldwide, Neuberg has more than 4,000 employees working in more than 120 lab facilities and more than 1,200 collection centers.

"We are also planning to open diagnostics facilities in Kenya, Tanzania, Nigeria, and Ghana," Velu said. "In West Asia, we are looking at establishing clinical labs in a few middle eastern countries with the new lab in Dubai acting as a hub and anchor for lab testing in that region," Velu told the *Business Standard*.

As the first India-based lab company to establish itself in the U.S., it seemed appropriate for THE DARK REPORT to invite Velu to meet via Zoom for an interview with our editors. In June, Velu met with Editor-in-Chief Robert L. Michel and Senior Editor Joseph Burns.

During the interview, Velu outlined how he started Neuberg Diagnostics in 2017, his plans for growth in the U.S., and how Neuberg will follow strategies that some of the world's largest and most sophisticated labs have recently adopted.

He emphasized that leading diagnostic lab companies are focusing on delivering results at the higher end of pathology testing, including digital pathology, molecular diagnostics, genomics, proteomics, and metabolomics.

➤INTERVIEW:

EDITOR: Since its founding just a few years ago, your lab company has posted spectacular growth. Let's begin by having you give us a brief history of Neuberg Diagnostics, such as how you got started and what strategy your company uses to differentiate Neuberg from your lab competitors.

VELU: Neuberg Diagnostics is the third version of my pathology career. In 1991, when I was 21 years old, I started working at a small pathology lab in my home country of India. Then about seven years later, I founded a chain of laboratories in India called **Metropolis**. That was in 1998. By 2015, I sold off Metropolis to the **Carlisle Companies**, which is a U.S. company that has operations around the world.

EDITOR: What came next for you?

VELU: After my non-compete agreement with Carlisle expired in 2017, I founded Neuberg Diagnostics by combining five laboratory companies from Sri Lanka, South Africa, and the United Arab Emirates into one company.

EDITOR: What was the inspiration behind the name of your new laboratory company?

VELU: We chose the name Neuberg, which is a German word that means "new mountain." Since this company is my third time being an entrepreneur in pathology, we think it describes our objective in a way that indicates we are doing something different in laboratory medicine and diagnostics.

EDITOR: In May, you opened the **Neuberg Centre for Genomic Medicine** (NCGM) in Raleigh, N.C., that will focus on genomic and molecular testing based on next-generation sequencing. How do you envision NCGM competing in the U.S. market?

VELU: Our approach is similar to what some of the largest labs in the United States currently do, such as **Quest Diagnostics** and **Labcorp**, along with other large lab companies in different parts of the world. These lab companies are working at the higher end of pathology testing, particularly when it comes to digital pathology, molecular diagnostics, genomics, proteomics, and metabolomics. This is the strategy that sophisticated labs

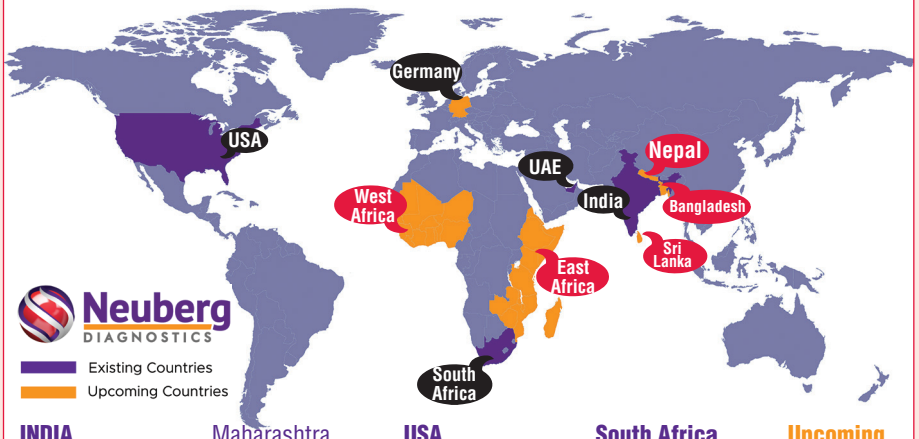
Neuberg Diagnostics of India Expands Steadily, Opening Labs in US, Africa, and Middle East

JUST A HANDFUL OF COMPANIES OWN AND OPERATE CLINICAL LABORATORIES IN MORE THAN ONE NATION. The newest lab player with a multinational strategy is Neuberg Diagnostics, founded in 2017 and headquartered in Chennai, India. This young lab company rapidly expanded across India, while also establishing lab facilities in the United Arab Emirates, South Africa, and the United States. The map below shows where Neuberg has existing labs and the countries it plans to enter soon.

Neuberg Diagnostics At-A-Glance

- Headquarters: Chennai, India
- Founded: January, 2017
- CEO: GSK Velu, PhD, BPharm
- 4,000 employees
- 120 laboratories
- 1,200 collection centers

Neuberg Diagnostics' Expanding Global Footprint



INDIA
Andhra Pradesh
Delhi
Gujarat
Haryana
Karnataka
Kerala
Madhya Pradesh
Maharashtra
Rajasthan
Tamil Nadu
Telangana
Uttar Pradesh
West Bengal

USA
North Carolina

UAE
Dubai
Sharjah
Ajman

South Africa
Cape Town
Durban
Johannesburg
Middleburg
Richards Bay
Shelley Beach
Umtata

Upcoming Countries
Bangladesh
East Africa
Germany
Nepal
Sri Lanka
West Africa

in the United States, Europe, and other advanced countries are doing.

EDITOR: That's understandable, because these newer, more complex diagnostic tests are the future of clinical laboratory testing.

VELU: True. What most pathologists and clinical lab executives in the United States often overlook is that many of these more sophisticated, newer diagnostic tests were not readily available, easily or at an affordable price, in developing markets. This is especially true for India, the Middle East, or in Africa.

EDITOR: Thus, your interest in establishing local labs in these regions, correct?

VELU: Correct, since most existing labs in South Asia, the Middle East, and Africa still do conventional testing while the new techniques in molecular and genetic

testing have been difficult to access and to afford. We saw that as our opening.

EDITOR: How would you differentiate your lab testing services?

VELU: Our idea is to enhance the access and affordability for these next-generation diagnostic techniques, meaning molecular diagnostics, genomics, pathology, digital pathology, proteomics, metabolomics, and all that. This is how the Neuberg idea was born.

EDITOR: That is an ambitious goal to launch a sophisticated clinical laboratory from the ground up. Is your plan to offer the full range of complex and new molecular tests, genetic tests, and digital pathology-based services from day one that your labs open? And in doing so, is that your way of getting an edge on your lab competitors?

GSK Velu, PhD, BPharm

➤"...many of these more sophisticated, newer diagnostic tests were not readily available easily or at an affordable price in developing markets. This is especially true for India, the Middle East, or in Africa."

VELU: We shaped this strategy in the following way. We wanted to offer all those different types of testing because there are two possibilities when you start a new lab company. One way is to establish a genomics- and proteomics-based laboratory in the communities to be served. That comes with challenges that I will describe in a moment. The second way is to set up a centralized lab facility as the hub serving a large region.

EDITOR: My guess is that having enough test volume to support economies of scale governs which of the two possibilities will work best.

VELU: We recognize that when you set up a specialized lab that is focused only on genomics, there may not be enough scale, enough test volume, to do that well. Many entrepreneurs who started labs focused on genomics did not survive their first few years. That's why we wanted to be more than just a genomics lab as we expand into new regions.

EDITOR: Please explain.

VELU: We needed to create a large-scale medical laboratory by acquiring multiple labs, while also upgrading them to do next-generation techniques. That was our vision when we started Neuberg in October 2017 and then began acquiring a few like-minded pathologists.

EDITOR: Did you have some real-world examples upon which to base this business approach?

VELU: Whenever large lab companies have been successful—such as Quest, the **IDEXX** lab in Europe, or **Unilab** in both Europe and the US—they have grown through acquisition. At Neuberg Diagnostics, we did the same thing by doing mergers and acquisitions. Since then, we have become the fourth-largest laboratory chain and soon we may be the third-largest chain of Indian origin. We operate 120 labs across India, the Middle East, Africa, and we now have a small but symbolic presence in the United States.

EDITOR: That's a sound strategy because your labs in India could do reference testing for your labs in South Africa and the United Arab Emirates. Is that right?

VELU: Yes, to a certain extent. But we also could do it the other way—the second option I mentioned earlier.

EDITOR: That would be the regional hub strategy that you have in play in several places.

VELU: One good example is that our lab in Dubai can be the headquarters for the Middle East region. Similarly, our lab in South Africa can be the headquarters for our operations in Africa. In each case, the two labs would be the most advanced lab facilities serving those respective regions because they provide the most advanced diagnostic testing services in

those areas. We wanted to have three hubs: India, of course, then our Middle East hub in Dubai and our Africa hub in South Africa.

EDITOR: How would you differentiate Neuberg Diagnostics in India from all the other lab companies in that nation?

GSK Velu, PhD, BPharm

"Right now, we might be India's largest genomics player. At the same time, we are doing the maximum amount of noninvasive prenatal testing and the maximum amount of clinical exome and whole genome sequencing."

VELU: If you look at our three largest competitors in India—**Dr Lal PathLabs**, **Metropolis**, and **SRL Diagnostics**—we are right behind them at fourth largest. When I started Metropolis back in 1998, those other two labs started almost at the same time.

EDITOR: Did they offer the same basic lab testing services?

VELU: Their focus was mainly routine testing, along with some standardized specialty testing. Each shared the major goal of having a presence everywhere in India. But as healthcare and physicians began to adopt clinical services like personalized medicine, these labs were not focusing on genomics, proteomics, metabolomics, digital pathology, and all of that.

EDITOR: That would be the opportunity you spotted in 2017.

VELU: At that time, we found that those areas were unexploited—meaning those areas were unmet needs in the marketplace. To succeed in the Indian market, you need to offer the full spectrum of routine, reference, and esoteric testing including molecular and genetic tests. That is how we started.

EDITOR: What has happened to Neuberg Diagnostics in recent years.

VELU: Right now, we might be India's largest genomics player. At the same time, we are doing the maximum amount of noninvasive prenatal testing and the maximum amount of clinical exome and whole genome sequencing. We've done all of that in the past three years.

EDITOR: What type of lab resources are devoted to next-generation sequencing?

VELU: We were the first company in the private sector in India to make an investment in **Illumina's** NovaSeq gene sequencing instrument. Today, we have 10 different sequencers in operation. We are starting a third sequencing lab in India, and we plan to start a sequencing lab in South Africa. We're doing that because genomics has become one of our fulcrum points for growth.

EDITOR: Are you developing other lines of specialty diagnostic testing?

VELU: In addition to genomics, we also are putting substantial effort into using mass spectrometry as a diagnostic technique. Currently, we offer the widest range of assays using mass spectrometry as a platform. These are some of the ways we have differentiate ourselves as a super-specialized player compared with the other pathology labs in the market.

EDITOR: I'll ask the same question about the U.S. market. How would you differentiate what your new Neuberg Centre for Genomic Medicine in North Carolina is doing versus what other lab companies do in this country?

VELU: What we are doing with NCGM is similar to what's happening with other lab companies in the United States that offer genomic testing services. Quest is growing in that way, along with **GeneDx** (a division of **BioReference Laboratories**) and **Invitae**. Basically, we will be doing what they're doing. NCGM aspires to be in the same developing market for genetic testing that Invitae and GeneDx are in. Also, we envision NCGM will be something like what Quest or Labcorp are now. Both of

those companies are focused on the developing market for genomics. That happens to be our market strategy too.

EDITOR: With so many existing competitors for genetic testing in this country, how do you plan to get to that level given that your lab in Raleigh just opened in May?

VELU: At the moment, our future plans for expanding our genetic testing program are on hold because the first tests we do in this lab are for COVID-19. That's where the demand was. We didn't start with that plan, but, for now at least, our Raleigh lab is doing a few hundred molecular COVID-19 tests per day and one or two other tests as well.

EDITOR: Did you have any delays in getting regulatory approval for your new lab and these specialized assays?

VELU: We got approval to do COVID-19 testing right away, and we expect to get FDA approval to do next-gen sequencing for COVID-19 possibly in the third quarter. For now, we are still waiting for our sequencers to be delivered.

GSK Velu, PhD, BPharm

➤"We expect that something will happen for us in the U.S. market, because even a small niche volume of tests in the United States could generate hundreds of millions of dollars in revenue over the long term. That's our immediate focus."

EDITOR: Are there other tests you are ready to launch at your Raleigh lab?

VELU: In addition to COVID-19 testing, we have identified one or two niche or unique tests that we want to run in the coming months. We don't want to compete with labs that are already well established and running the tests that we plan to run. That's not our first focus. We have a few ideas for niche or unique tests and we are reaching out to hospital groups to see if there is interest in having us run those tests for them.

EDITOR: What are your ambitions for your U.S. lab facility?

VELU: We expect that something will happen for us in the U.S. market because even a small niche volume of tests in the United States could generate hundreds of millions of dollars in revenue over the long term. That's our immediate focus.

EDITOR: Can you talk about what kinds of testing you plan to do in your CLIA-certified lab in Raleigh?

VELU: Yes. We are putting in a live-sequencing lab in North Carolina, so we'll be focused on next-generation sequencing (NGS)-based technology for niche testing. Initially, we're looking at newborn screening and pediatrics as our main areas of focus.

EDITOR: What other strategies are you considering?

VELU: Our aim is to focus on one type of diagnostic testing in the United States and try to offer some cost-effective and innovative solutions in that one area. For example, newborn screening in the United States is done by public screening laboratories, and they are all looking for partner lab companies to do genomics testing. Currently, **PerkinElmer's** genomics division is doing some of that, but beyond that, there's nobody else in that space.

EDITOR: That market sector is already competitive.

VELU: All the big laboratories are involved in prenatal testing. However, when it comes to newborn and pediatrics, there is no genomics laboratory that has that work exclusively. We're aiming at that space in the U.S. market. Of course, we are open to doing other kinds of testing, but for now, we will be very focused on niche testing.

EDITOR: What did you find attractive about Raleigh that led you to locate your lab there?

Despite Surging Volume, Labs in India Get Low Payment for COVID-19 Tests

ONE OF THE FIRST CLINICAL AND PATHOLOGY TESTING LABS IN INDIA to gain approval for COVID-19 testing was Neuberg Diagnostics. That approval came in the spring of 2020. Since then, Neuberg has started doing COVID-19 polymerase chain reaction (PCR) testing in 20 labs nationwide, said GSK Velu, PhD, MBA, BPharm, Chairman and Managing Director of Neuberg Diagnostics.

"When we wanted to do COVID-19 testing, we aimed to do it more for the social obligation than anything else because what the government was paying for this testing was very low. Plus, in those first few months, India was importing the testing kits and one of our companies, is one of the largest suppliers of COVID-19 kits here," he said.

"Still, we've been doing the PCR COVID-19 testing for over a year now in our Neuberg Diagnostic labs," he added. "Some days, we do as many as 80,000 to 90,000 tests per day in our network labs. That makes us the largest COVID-19 testing laboratory chain in the country.

Low Test Reimbursement

"In India, one of the challenges all labs face is that government has fixed the rate as low as maybe US$7 to $10 for one PCR test," he explained. "That's all you can charge, but it costs about $7 to do the test.

"If that's the maximum that labs charge a patient, how do we innovate? It's very difficult," said Velu.

"Fortunately, some of the suppliers we use have stepped up to give us a different price than they would normally charge," he noted. "Our suppliers are both international companies and companies based here in India.

"But even after that, we need to optimize our processes. Our average realizations—meaning what we collect—is only US$6 or $7 per test," Velu reported. "With that amount, we need to collect the samples, transport the samples to the lab, get the results and report them to patients. At the same time, of course, we must follow all the quality protocols that we normally follow. All those processes are very costly.

Success Through Innovation

"Initially, the government said we could charge patients as much as US$60 for each PCR test, but that was too high for many patients," he noted. "Therefore, what we can charge has come down to $6 now, and that's all been in the past year. The only way to succeed at such a low rate is through innovation, because in a country with a population of 1.4 billion people, and a high infection rate, we had to increase our operating efficiency.

"Fortunately, the infection rate and the number of deaths due to COVID-19 have both come down slightly as more people get vaccinated," he said.

"We are like a lot of countries in that we had a first wave and during that time India did reasonably well," he explained. "Then, there was a level of complacency and a lot of COVID-inappropriate behavior that probably led to the second wave, which was painful. Many labs in India—even our own labs—were overwhelmed to some extent. We could not meet the demand for testing in some cities, such as in Delhi and other places.

"In that time we had a real problem, meaning we had to stop taking samples, and that lasted for at least a week or two," he commented. "Now, as we come out of the second wave, I think we'll be fine."

Recent news reports from India indicate that the pandemic is moderating and has come down from earlier peak levels.

VELU: We had two reasons. One, Raleigh is in the Research Triangle and a substantial amount of research and development goes on there. All that research work has contributed to the legacy that the Research Triangle has of supporting the growth of large pathology businesses. Second, Labcorp is based there. Because of all this activity, there is a good supply of lab professionals and scientists who have hands-on experience with these complex testing technologies.

EDITOR: As a company focused on the whole range of pathology and clinical laboratory testing, including, genomics, metabolomics, proteomics, and digital pathology, would you consider acquiring any other successful lab company or companies that are working with those testing technologies?

VELU: Yes, but currently we are a very small player in the United States. That said, we are not opposed to acquiring smaller players. But our main interest in coming to the United States is not to play a huge nor a disruptive game—at least not yet.

EDITOR: It sounds like you are using this lab as a way to learn about the U.S. lab testing marketplace and build a base for expansion.

VELU: True. We opened our lab in North Carolina to gain an understanding about what's going on in the U.S. market and to see how our interests for technology innovation would fit there. That's why we went to North Carolina where Labcorp is based, and where there's so much activity in laboratory medicine in the Research Triangle. I'm sure people in the United States are looking for cost-effective testing options just as everyone around the world is seeking cost-effective testing.

EDITOR: When Neuberg Diagnostics announced the opening of the lab in Raleigh, the company said you were including capacity for large scale clinical and research projects. That raises the question of whether you anticipate that NCGM will work with pharmaceutical companies to do clinical trials across multiple populations in several countries.

VELU: Yes, we would like to be partners in companion diagnostics with pharma companies. We are currently looking at pediatrics and newborn testing as an area where pharma companies are developing drugs for inherited genetic disorders. We are currently in talks with some pharma companies about the cohort testing that we could do for them.

GSK Velu, PhD, BPharm

➤"...for pharma companies, we have a big base in India, the Middle East, Africa, and now we have a presence in the United States. We are in discussions with pharma companies and believe we can be a strong partner to do IVD testing for them."

EDITOR: Would you consider supporting pharma clinical trials as part of your strategy, since you're offering advanced genetics and you can do clinical trials in your labs in the UAE, South Africa, and India? In other words, would NCGM be interested in building a business such as what **Covance** and Labcorp are doing?

VELU: Yes, because for pharma companies, we have a big base in India, the Middle East, Africa, and now we have a presence in the United States. We are in discussions with pharma companies and believe we can be a strong partner to do IVD testing for them.

EDITOR: Is it in your plans to participate in pharma research and development with your Raleigh lab facility?

VELU: At the moment we are not interested in going beyond testing, but we can certainly offer testing solutions to all pharma companies. All our labs are CLIA-certified and our labs in India

and in South Africa are CAP-accredited. Soon, our Dubai lab will be going for CAP accreditation. In all those markets we have the accreditations we need, and we meet the necessary standards that a pharma company could use for testing a large population in a cost-effective way. For those reasons, our offerings compare well with what Covance, **Quintiles**, or other labs are doing.

EDITOR: To be a laboratory that does testing all over the world, are you getting your labs accredited to ISO 15189, because that standard is accepted in something like 90 countries?

VELU: All our labs are accredited to ISO 15189, although in India we call it NABL, which is the **National Accreditation Board for Testing and Calibration Laboratories**. This board is national and it uses ISO and other standards. All our major labs are accredited by NABL. In South Africa, we have CAP accreditation, and we have the ISO 15189 accreditation through the **South African National Accreditation System**. Our Dubai lab also is accredited to ISO 15189.

EDITOR: Looking ahead, how can you leverage Neuberg, not just in the other countries, but in the United States, as a value-added testing partner?

VELU: Even though the US spends a lot of money on healthcare, and it has all the clinical advancements in place, healthcare providers there are still looking for cost-effective solutions. Even some of the biggest names—such as **Massachusetts General Hospital**—are looking for cost-effective partners to work with on clinical trials. Otherwise, it costs a lot of money for them to go to these large players to do clinical trials or niche testing.

EDITOR: That means you believe Neuberg Diagnostics' menu of lab testing services in the United States will be fully competitive.

VELU: That's our niche: cost-effective clinical laboratory testing without compromising quality by having all our accreditations in place. That's how we can provide value-added laboratory testing to pharma companies, or any company doing clinical research activities, such as large hospital groups.

GSK Velu, PhD, BPharm

"We see a lot of opportunities in the United States and elsewhere to collaborate with pharmaceutical companies, clinical research organizations, and even large hospital groups. All those companies are looking for cost-effective niche testing."

EDITOR: What level of interest are you getting here in the United States?

VELU: Our team is having discussions about collaborating to do laboratory testing for clinical research with all of these potential partners. We see a lot of opportunities in the United States and elsewhere to collaborate with pharmaceutical companies, clinical research organizations, and even large hospital groups. All those companies are looking for cost-effective niche testing. Mostly, that testing will be NGS focused, and later we may think about using mass spec for such testing. But for now, most of our product offerings are going to revolve around NGS-based platforms.

EDITOR: Dr. Velu, thank you for providing us these insights into lab testing in India, Africa, and the Middle East, as well as your strategies for your new lab in North Carolina.

VELU: You are welcome. We are excited to have a clinical laboratory now operating in the United States and we welcome inquiries from anyone interested in our services. TDR

Contact Andy Bhattacharjee, PhD, at 978-821-6172 or Andy@neubergdiagnostics.com.

Managed Care Update

COVID-19 Lab Test Prices Give Some Health Plans 'Indigestion'

HEALTH INSURANCE PLANS CONTINUE TO BE UNHAPPY with the higher prices they are charged for COVID-19 tests by out-of-network clinical laboratories. That is one theme in a report on COVID-19 test prices published by a health insurance trade group.

In its report issued last month, the **America's Health Insurance Plans** (AHIP) wrote, "price gouging in COVID-19 testing continues as a significant problem." AHIP's report is titled "COVID-19 Test Prices: A Look-back on Trends in COVID-19 Testing Prices." The report can be viewed at *www.ahip.org/covid-19-test-prices/*.

12-Month COVID Test Study

AHIP's study of COVID-19 test prices looked at the 12-month period of April 2020, through March 2021. During this time, the study determined that the average price for a COVID-19 test in the commercial market was $130. "In contrast, out-of-network test providers charged significantly higher (more than $185) prices for more than half (54%) of COVID-19 tests in March 2021," the study noted.

The data used for this study came from a large proportion of the private health insurance industry. AHIP noted that the "the enrollment-weighted survey data includes 17 responses from plans representing 80% of commercial enrollment of AHIP member plans."

Out-of-network laboratories have increased their proportion of COVID-19 test claims. In March 2021, AHIP determined that 27% of COVID-19 tests in March 2021 were administered out-of-network. This is a 6% increase since the beginning of the pandemic in early 2020.

Fewer Hospital, ER Tests

Interestingly, researchers reported that the share of COVID-19 tests claims submitted from "high-cost locations"—identified as hospitals and emergency departments—declined from 18% in the first three months of the pandemic to only 5% during the first three months of 2021.

Another point that AHIP emphasized about the "price gouging" of out-of-network clinical labs was that "the share of tests charging 50% to 100% above the average costs has doubled in the same time period (April 2020-March 2021) from 18% to 36%. The overall share of high-priced COVID-19 tests costing more than $185 has increased from 42% to 54% in the same time period.

AHIP noted in the study that "when health insurers are working with the test providers in their own networks, they can bargain for lower prices." It then went on to say, "but when an insured patient gets medically-necessary testing from out-of-network providers, the federal Coronavirus, Aid, Relief, and Economic Security (CARES) Act of 2020 requires the insurer to pay the test provider's full listed cash testing price."

Suggestion to Congress

One recommendation AHIP made in the report was that "throughout the public health emergency, Congress should eliminate the ability for price gouging to occur by setting a reasonable market-based pricing benchmark for tests delivered out of network." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Elizabeth Holmes, the disgraced ex-CEO of the now-defunct **Theranos**, continues to be in the news. In the past several weeks, news reports indicate that she gave birth to a child, but whether it is a boy or a girl has not been reported. Also in recent weeks, attorneys have been in court arguing about unsealing certain court records. Included in the sealed records is the psychological evaluation of Holmes.

MORE ON: *Holmes and Theranos*

In July, *Wall Street Journal* reporter John Carreyrou, who wrote the stories that brought down Holmes and Theranos, told *CNBC News,* "A large part of her defense now looks to be blaming Sunny [Balwani, who was COO at Theranos, and Holmes' boyfriend] and basically saying to the jury that Sunny held her in his psychological grip. Her defense plans on making the case that Balwani was the older boyfriend—19 years older—who was really the puppeteer here, and she was the puppet. And obviously they're going to trot out a psychologist to help make that case." Holmes and Balwani face multiple federal criminal charges of wire fraud and conspiracy to commit fraud for her actions during her leadership of Theranos. Government prosecutors say she deceived investors, doctors, and patients about the performance of Theranos' lab testing capabilities.

RICHEST WOMAN IN HEALTHCARE

In July, *Forbes* published a list of the richest women in healthcare. Topping the list was Judith Faulkner, CEO of **Epic Systems**. Forbes estimated her net worth at $6.5 billion.

TRANSITIONS

• David Hickey joined **Illumina** of San Diego as Vice President of Regional Marketing. Formerly he served at **Pacific Biosciences**, **Affymetrix**, **Ingenuity Systems**, and **Incyte Genomics**.

• **Personal Genome Diagnostics** of Baltimore announced that Jamie Platt, PhD, is its new **Chief Operations Officer**. She previously served at **BRIDGenomics**, **Inivata**, **Molecular Pathology Laboratory Network** (MPLN), **BasePrime Gx**, and **Quest Diagnostics**.

• Maggie Rougier-Chapman was announced as the Senior Vice President of Marketing and Commercial Strategy at **Personal Genome Diagnostics**. Her prior positions were at **Footprint BioAdvisors**, **Invitae**, **ArcherDx**, **Bionano Genomics**, and **Agilent Technologies**.

• Charudutt Shah is the new Chief Business Officer and board member at **Genomtec** of Wrocław, Poland. Prior positions were with **BioFire**, **Spartan Bioscience**, **Luminex**, and **Life Technologies**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 7, 2021.

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