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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Did National Labs Sign Value-based Payer Contracts?

IT IS AN IMPORTANT SIGN OF THE TIMES when press releases about the two new national lab services agreements that **UnitedHealthcare** just announced with **Laboratory Corporation of America** and **Quest Diagnostics** emphasize how value-based programs will be an important element in the health insurer's relationships with the two national lab companies. *(See page 7.)*

In fact, the joint announcements issued by UnitedHealthcare (UHC) and LabCorp, and UHC and Quest, contain one identical paragraph that emphasizes the role of value-based programs involving lab testing. UHC wrote:

> *As part of the expanding relationship, UnitedHealthcare and [insert LabCorp or Quest here] will collaborate on a variety of value-based programs, bringing the same aligned incentives and enhanced patient experience to lab services as exist today in accountable care arrangements between UnitedHealthcare and more than 1,100 hospitals and 110,000 physicians. Working together, UnitedHealthcare and [insert LabCorp or Quest here] will strategically change the way we are able to support consumers' healthcare needs by using real-time data sharing to help better anticipate people's care options—and reducing gaps in care—similar to the model UnitedHealthcare already uses to integrate medical and pharmacy data.*

The decision to include the identical paragraph in both press releases demonstrates that UnitedHealthcare is actively seeking to leverage lab test data in ways that improve patient outcomes and contribute to a measurable reduction in the overall cost per healthcare encounter.

Stated differently, UnitedHealthcare is making a public statement that it intends to develop forms of remuneration that can replace the traditional fee-for-service reimbursement it has paid for clinical laboratory tests. All clinical laboratories and pathology groups should consider this an early warning to get their own houses in order and proactively develop clinical offerings that use lab tests to create more value for the physicians and patients they serve.

This goal is the target of the four health system labs involved in **Project Santa Fe**. They are working to demonstrate ways that the Clinical Lab 2.0 model can deliver value. At last month's *Executive War College*, the Project Santa Fe labs presented case studies on their early successes at delivering more value with lab tests. TDR

Why Lab Companies Buy Bankrupt Rural Hospitals

New twist on pass-through billing scheme targets small, financially-troubled facilities

CEO SUMMARY: Seeking the higher lab-test payment rates that insurers pay hospital labs, some lab testing companies are buying rural, financially-struggling hospitals in what may be the latest twist on the pass-through billing strategy that certain lab testing firms have found to be lucrative in recent years. Currently, two lab companies are seeking to buy struggling rural hospitals. One such pending purchase is in Cedarville, Calif. The other is in Jamestown, Tenn.

TWO DIFFERENT LAB COMPANIES want to buy, own, and operate small, rural, and financially-struggling hospitals in what appears to be the latest twist on a lab-billing strategy to use hospitals to bill for lab testing services in an effort to get the higher rates that hospitals charge over that of independent labs.

In one case, **Cadira Group Holdings**, of Denver, wants to buy the 26-bed **Surprise Valley Hospital** in Cedarville, Calif. (population: 514). In another case, **Rennova Health**, a lab testing company in West Palm Beach, Fla., plans to buy the 85-bed **Tennova Healthcare-Jamestown Hospital** in Jamestown, Tenn. (population: 1,959).

In both cases, the hospitals are in financial trouble with substantial debt, raising questions about the lab companies' motives. In buying these hospitals, both lab companies may see opportunities to use the hospitals' managed care contracts to bill health insurers at higher in-network rates than the labs would get otherwise.

Also, these lab companies may plan to use the hospitals they own to submit lab test claims for patients who are not in the hospitals' service areas, thus developing a new way to bill insurers under what's known as pass-through or hospital outpatient department (HOPD) billing arrangements. Insurers are challenging these billing strategies by filing lawsuits against operators of these schemes. *(See TDR, May 7, 2018.)*

In January, *Becker's Hospital Review* reported that the Surprise Valley Health Care District in Northeastern California filed for bankruptcy protection because the liabilities of the Surprise Valley Hospital that the district runs in Cedarville, Calif., greatly exceeded its assets. In its petition for

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bankruptcy, the district said it had assets of less than $1 million and liabilities of $1 million to $10 million.

In an effort to keep the hospital open, the district board agreed to partner with **SeroDynamics**, a lab testing company affiliated with **Cadira Group Holdings**. Under the agreement, Cadira will lend the healthcare district as much as $1.5 million if the district sells the hospital to Cadira, *Becker's Hospital Review* reported.

Next week residents of Modoc County, Calif., will vote on a measure authorizing the Surprise Valley Health Care District to sell and transfer the hospital and other district assets to Cadira Group Holdings LLC, or any other qualified buyer, according to *Ballotopedia*, an online encyclopedia of elections.

Lab Company Buys Hospital

In April, Dan Margolis of High Plains Public Radio in Garden City, Kan., reported that Beau Gertz is CEO of Cadira Group Holdings, a limited liability corporation registered in Delaware. Gertz also is the president of SeroDynamics of Denver, a lab company that lists itself as a wholly owned laboratory of Surprise Valley Hospital. SeroDynamics also lists Bill W. Massey, PhD, as its Medical Director and Chief Science Officer. His PhD is in Pharmacology.

Cadira loaned the hospital $1.5 million to keep the hospital open, Gertz added. "As part of the loan agreement with Cadira, we were provided the right to purchase the hospital in exchange for forgiving the $1.5 million loan and paying the hospital's then-outstanding debts, which are presently estimated to be about $3.85 million," he commented.

If voters approve the ballot measure on June 5, Cadira would remove as much as $5 million in Cedarville liabilities, he said. "It is presently believed that the $5 million will comprise all of Cedarville's liabilities so that there would be no additional taxes on the town," added Gertz.

In the article for KCUR radio, reporters Margolis and Bram Sable-Smith linked Gertz to Jorge Perez, CEO of **EmpowerHMS**, a company in Kansas City, Mo., that says it helps "distressed and underperforming hospitals." Margolis and Sable-Smith wrote that EmpowerHMS has affiliates that have been involved in taking over the operations of many rural hospitals.

The reporters also wrote about how Gertz described the business model he would use for the Surprise Valley Hospital. Margolis and Sable-Smith quoted Gertz as saying, "I'm trying to overcome my association with Perez and EmpowerHMS. I was a subcontractor of Empower and I ran away as fast as possible when I discovered how they were using hospitals to run offsite labs and that there was no common ownership between the labs and hospitals in Perez and Empower's business model."

Also, Margolis and Sable-Smith reported that Gertz added, "With Perez, there was no common ownership between labs and hospitals. Here [meaning with the Surprise Valley Hospital] it's different. There is common ownership between the Surprise Valley Hospital and SeroDynamics Laboratory. I do it the right way, I have legal advice from **Denton's**, the largest law firm in the world."

Millions in Liabilities

If voters approve the sale of the hospital to Cadira Group as Gertz proposed, the quotes from Gertz could mean that SeroDynamics would bill for lab tests done at Surprise Valley Hospital for any patient, whether in the Cedarville area or other states, as other labs operating pass-through billing arrangements have done. The fact that Gertz said he has legal advice from Denton's, a law firm that describes itself as the world's largest, may indicate that Gertz and SeroDynamics have discussed how to get the most value from the purchase of Surprise Valley Hospital. Using pass-through billing would be one way to boost hospital revenue.

Some Lab Companies Want to Own Rural Hospitals to Have Claims Paid at Hospitals' Higher Rates

ONE REASON PROMOTERS of pass-through billing schemes and HOPD arrangements have partnered with struggling rural hospitals in recent years is that the lab companies can get paid higher lab test payment rates from health insurers when they use the hospitals as the billing entities. This method of billing is called pass-through billing.

Reimbursement for lab services using the hospitals' favorable payer contracts can produce test payment rates as high as $2,000 per test, according to an article by Tara Bannow in *Modern Healthcare.*

In an article on how labs are partnering with hospitals, Tannow interviewed Brock Slabach, Senior Vice President of the **National Rural Health Association.** When hospitals are desperate financially, such arrangements may be their only option, Slabach said.

"When you're desperate, you're looking at bankruptcy or you're looking at some kind of dire situation you're facing financially, and one of these companies comes along and offers something that's too good to be true. It's tempting to listen to this presentation and say, 'Well, one answer is, what do we have to lose? We're going to close anyway,'" Slabach told Bannow.

The arrangement between the two companies in the proposed sale of Tennova Healthcare-Jamestown to Rennova Health, a lab testing company in West Palm Beach, Fla., is similar to other such arrangements in which lab companies bill through the clinical laboratories of financially struggling rural hospitals. One source Bannow cited said he had seen eight to 10 such lab test billing arrangements.

In recent years, Rennova's revenue has come from urine toxicology testing, CEO Seamus Lagan told Bannow. Believing that some labs have been overtesting, health insurers have cut back sharply on payments for such testing. In 2017, Rennova's lab test volume billed to health insurers dropped by 80% over the volume it recorded in 2016, Lagan told Bannow. Previously, Rennova operated five labs, and now runs only two, he added.

"Lagan said that acquiring the hospital to alter lab reimbursements is 'absolutely' not his intention in purchasing Tennova Healthcare-Jamestown," Bannow wrote. He's aware of the pass-through model, but said Tennova Healthcare-Jamestown would not bill in that way.

Rennova is proud of its record of compliance and does not plan to use the Tennova hospital to bill for toxicology or other lab tests for anyone who is not a patient in the hospital or who gets care from local doctors, Lagan told Bannow.

"That is not an area we have any interest in pursuing or looking at," Lagan told Bannow. "We see these hospitals as a good little business on their own with increasing the services that are required by the local community and absolutely without the need to get into any complicated or convoluted agreements with far-away companies."

THE DARK REPORT requested comment from Gertz by phone and email and made a similar request for comment from Perez but did not get a response as of press time.

As in the case of the California hospital sale, the acquisition in Tennessee also involves a financially-struggling rural hospital. **Community Health Systems**, of Franklin, Tenn., is selling Tennova Healthcare-Jamestown to Rennova Health, for $1 plus the amount of net working capital on the closing date, according to *Modern Healthcare* reporter Tara Bannow.

One of nation's largest operators of general acute care hospitals, CHS operates or leases 126 hospitals in 20 states. The deal

to sell Tennova Healthcare-Jamestown includes a physician practice, a medical office building, outpatient facilities, and ancillary services, she added.

In her article, Bannow wrote, "Rennova ended the year with no cash on hand from continuing operations, and has been sued by landlords and contractors alleging unpaid bills, according to the SEC filings. Three former employees have sued Rennova in Palm Beach County court alleging unpaid wages," she added.

The buyer of this rural hospital has other financial problems. In its recent filing with the **Securities and Exchange Commission**, publicly-traded Rennova reported a $51 million net loss from continuing operations last year and a $16 million operating loss on less than $5 million in revenue. On Feb. 2, 2018, the company was delisted from NASDAQ because of excessive stock-splitting. At that time, *Becker's Hospital Review* reported that Rennova started as a lab testing company.

Rennova's First Acquisition

Kristi Nelson reporting for *Knox News* of the USA Today Network wrote that the Tennova Healthcare-Jamestown facility will be the second hospital Rennova has purchased in recent years. In 2016, Rennova bought **Scott County Hospital** in Oneida, Tenn., from **Pioneer Health Services Inc.** of Mississippi after Pioneer filed for bankruptcy and closed the acute-care hospital in July 2016.

When Rennova announced an agreement to purchase Tennova Healthcare-Jamestown Hospital, *Becker's* wrote, "Evidently, Rennova CEO Seamus Lagan expects the addition of the new hospital to help stabilize the company's finances."

As Becker's reported, Lagan said, "This acquisition further demonstrates our commitment to expanding Rennova's rural hospital model to provide necessary services to patients while securing more predictable recurring revenues. This hospital is approximately 38 miles from our current hospital in Oneida and will benefit by receiving patients from Oneida who require operations and treatment not provided there. The synergy of management and services in a close geographic location creates numerous efficiencies for Rennova and will allow us to support a greater number of healthcare providers and residents in the local area."

Lab Services Provided

Rennova, which describes itself as providing diagnostic and support software for billing, record management, and lab services, agreed to pay as much as $450,000 of debt Pioneer Health Services owed, wrote Bannow in *Modern Healthcare.* Although the names Rennova and Tennova are similar, the two companies are unrelated, she added.

THE DARK REPORT has written about how a large number of lab testing companies—particularly those offering toxicology and pain management tests—have partnered with small rural hospitals in arrangements for these hospitals to bill for the lab tests that lab companies perform. Promoters of these schemes commonly use the term HOPD to describe the arrangement. *(See TDR, Oct. 30, 2017.)*

The new California and Tennessee examples of this trend show how promoters who own lab testing companies want to purchase financially-desperate hospitals that have substantial debt. In other examples of such arrangements, the operators have sent lab test volume from multiple states through the hospitals so they can submit test claims to payers at the higher rates health insurers typically pay to rural hospitals.

Could this sudden interest in having lab test companies buy failing rural hospitals be due to the lab owners' belief that having a hospital owned by the lab submit lab claims will make the arrangement compliant with federal and state laws and payer contracts? Time may provide the answer to that question. TDR

—Joseph Burns

Managed Care Update

Big Insurers Seek Value-Based Deals with LabCorp, Quest

Both UnitedHealthcare and Aetna ink new deals with two of the nation's billion-dollar lab companies

IT'S THE END OF AN ERA for the strategy of being the exclusive national lab provider for a major health insurer. Last week, the two largest clinical laboratory companies announced that the 10-year-old exclusive lab testing deals each had with a different big health insurer had crumbled.

In 2007, **Laboratory Corporation of America** locked up an exclusive national provider contract with **UnitedHealthcare**. Early that same year, **Quest Diagnostics** similarly won an exclusive national provider contract with **Aetna, Inc.** *(See TDRs, Oct. 16, 2006, and Feb. 19, 2007.)* That status quo held until last week, when both lab companies announced new non-exclusive deals with UnitedHealthcare and Aetna.

Starting next year, LabCorp will no longer be the exclusive national lab test company for UHC, but it will be able to serve Aetna's 20 million members. Also next year, Quest will lose its exclusive contract with Aetna, but will become one of UHC's preferred providers.

Labs' Share Prices Rise

Despite losing the exclusive contracts, the stock prices of both companies rose on Friday, according to Bertha Coombs of *CNBC*.

LabCorp and Quest each characterized their new contracts as positive developments even though both deals are aimed at keeping down the cost of clinical lab testing. The insurers said the deals are about delivering value-based care, a term that means the insurers expect low costs and high quality services for members.

"Insurers see ordering of unnecessary lab tests by doctors in a fee-for-service system that emphasizes volume of care delivered is in dire need of reform," explained Bruce Japsen in *Forbes*. "In the future, lab tests will increasingly be subject to quality and outcome measures via various value-based care models."

UHC Contracts

In its announcement of the LabCorp deal, UnitedHealthcare, one of the nation's largest health insurers, said LabCorp would continue participating as a national provider of laboratory services to all UHC plan participants. It's no surprise that, to Japsen's point, UHC added that the deal "will include a broad range of value-based programs." UnitedHealthcare wants high-quality, easily accessible lab services and lab test data "to drive more personalized care support."

For Quest, UHC's announcement is good news because Quest Diagnostics has been an in-network lab, but only for a limited number of UHC plans in some markets. Under its new agreement with UHC, Quest will be able to provide lab testing to UHC's 48 million members, helping to offset the loss of its exclusive arrangement to provide testing services to Aetna's 22 million members, wrote Japsen. TDR

—Joseph Burns

Near Real-time Data Helps Lab Save $500K Annually

➤586-bed Phoenix hospital lab uses analytics to optimize phlebotomy and boost productivity

➤➤CEO SUMMARY: After hospital labs and pathology groups implement lean and process improvement methods to harvest the easiest cost savings and boost quality, they often take the next step of introducing real-time analytics systems. Access to detailed data about workflows, productivity, and turnaround times then drives continuous improvement projects. At St. Joseph's Hospital and Medical Center, the lab team used an analytics solution to save $500,000 per year in phlebotomy costs.

WHEN IT COMES TO SOFTWARE FOR CLINICAL LABS, the hottest-selling category in recent years has been real-time analytics solutions. The need among labs to reduce costs and improve the quality of lab testing has fueled sales of these products.

Real-time analytics programs are effective enough to deliver a reliable return on investment, often in a remarkably short time. For Barbara Ballering, the Quality Assurance and Performance Improvement Manager at **St. Joseph's Hospital and Medical Center** in Phoenix, that ROI was one of the pivotal issues the lab considered before purchasing such a system.

Two years after installing software to analyze turnaround times in her lab and use that analysis to improve processes, Ballering said the outcome was impressive. In that time, the lab was able to eliminate 12 full-time phlebotomists through attrition, while saving almost $500,000 in annual spending.

In addition, Ballering stated, "We were able to beat our level of phlebotomy service from when we started this project, and this is a big point of pride for our administrative director. We now have a better phlebotomy service with fewer people because we use analytics to know where and when we need those staff. That wasn't possible before.

➤Room for Improvement

"Informed by better analytics, we could identify ways to use our phlebotomists more productively," she noted. "Using attrition, we were able to cut 12 FTEs while improving the key phlebotomy service measures.

"Assume about $20 an hour—including benefits—for each full-time phlebotomist," she continued. "By using 12 fewer phlebotomists, our lab saved approximately $499,000 per year. That produced an absolutely incredible return on investment of about 467%.

"In addition, we saw other benefits that are more difficult to measure," stated Ballering. "These include less staff frustration and more productivity, both of which are important aspects of this new system."

Ballering made her comments during a presentation at THE DARK REPORT's *Lab Quality Confab* in New Orleans in October 2017. The title of her presentation was, "Using Real-time Analytics to Improve TAT, Streamline Staff Scheduling and Identify Various Sources of Error, Both in the Lab and in the ED."

A Need for Useful Data

The 586-bed St. Joseph's Hospital and Medical Center is a division of **Dignity Health**, a 42-hospital system in Arizona, California, and Nevada. Although the clinical laboratory has little automation, it still runs more than four million tests each year in anatomic pathology, chemistry, hematology, microbiology, and in molecular testing and cytogenetics. The lab also runs a blood bank and supports point-of-care testing throughout the facility.

As the hospital was becoming part of Dignity Health two years ago, the lab had trouble generating useful and timely information on workflow, productivity, and other key factors.

"Our process for generating reports was cumbersome and sometimes impossible," recalled Ballering. "That's because it would often take so long to process the data that the system would time out and the desired data would be lost.

"Also, we couldn't compare staffing for one time period to another, which meant we couldn't identify staffing problems. If you can't identify problems, how can you address them?" she asked.

Greater Flexibility

"In addition, our lab team needed greater flexibility because we often can't use just raw data," she commented. "We wanted data available in a format that allows the lab staff to understand it and put it to use.

"In 2014, our administrative director heard a presentation at the *Executive War College* from Thomas Joseph about **Visiun's** Performance Insight System," stated Ballering. "One year later, our con-

From Baseball to Labs, Analytics Has Value

ACCESS TO REAL-TIME ANALYTICS in the clinical lab is akin to what the best general managers in baseball do, commented Barbara Ballering, Quality Assurance and Performance Improvement Manager at St. Joseph's Hospital and Medical Center. As depicted in the best-seller, *Money Ball*, by Michael Lewis, one of the best general managers in baseball is Billy Beane of the Oakland As.

The book tells the story of the small-market baseball team that lacks the money to overpay for high-priced talent, Ballering explained. "So, they had to figure a different way to find top players and they did so using analytics.

"With analytics, they got useful information on individual players," she explained. "Team managers used data to identify players who were otherwise overlooked and put them together to make a winning baseball team. That's what real-time analytics does.

"For labs, analytics deliver information that is available almost immediately after being entered into the system," Ballering said. "That makes it useful to lab managers.

"This is not like the laboratory information systems of the past, where the lab might wait a month to get performance information," she explained.

"With real-time analytics, our lab can use up-to-the-minute information to improve performance," she commented. "And, we don't just gather data. Rather, we get information that is meaningful to lab managers.

"Another way to think of analytics in the lab is that it's like having real-time business intelligence available all the time!" concluded Ballering.

tract to acquire this system was approved and we implemented the program in January 2016.

"Soon after that, lab staff were asking for a wide variety of specific kinds of data," Ballering said. "This told me that people recognized how this system can produce a lot of actionable information.

"At first, we focused on the ED, where we needed faster throughput from the time a test was ordered until the results were reported," explained Ballering. "Physicians in the ED were being pressured to move patients through quicker, to see more patients, and decrease patient wait time; all of which increases patient satisfaction. And of course, when patients are seen more quickly, that improves patient outcomes in many cases.

"In addition, we had complaints from physicians about how long they were waiting for stat lab results," she said. "We knew that test turnaround times were quite long in some cases.

Getting a Quality Specimen

"We also had specimen quality issues and, like many hospital EDs, nurses collect most of the samples," Ballering said. "We tried educating nurses about how to do patient draws, but decided it was best to draw our own specimens using phlebotomists managed by our lab. That's been successful, even though we needed more phlebotomists to do these draws.

"On top of these problems was the issue of poor communication between the lab and the ED," she added. "As is true in many hospitals, our lab staff tended to think the ED staff simply likes to complain and so the lab staff would reply in a way that didn't improve the problem.

"Further, when the ED staff called the lab, the lab services staff wouldn't know where to send these calls," she said. "That meant the ED staff would get transferred from one area to another without getting an answer.

"Things began to change once we had the data in place from the Visiun system," continued Ballering. "Now we could identify the source of problems in the lab.

"For example, every morning I now pull up the Turnaround Time Dashboard," she noted. "Overnight the Performance Insight software extracts the data from the day before, letting me send multiple reports automatically to the proper supervisors in the first seven minutes each morning. That is amazing!

"On the first page of our turnaround time report, we have all the lab tests that we monitor," she said. "We also get the average turnaround time. Recently, our medical director asked for a report on the percentage completed by a target time. So, we changed from 'average' to 'percentage completed.'

"Lab staff can now measure performance however they want," she added. "For blood specimens, we use order to verify. For urine specimens and blood gases, we use collect to verify. Also, we can set a target of 80% achieved by 70 minutes, for example, then monitor actual performance against that target.

"By doing so, we get the actual time, how our clinical laboratory did on a particular day, the number that passed, and the number that failed," Ballering explained. "We also get a list of outliers for each test, which lets our team focus on areas needing attention.

"Also, we get performance trend reports over time, whether by weeks or months," she said. "All that data is broken down by whatever department we want: such as the ED, the ICU, or microbiology.

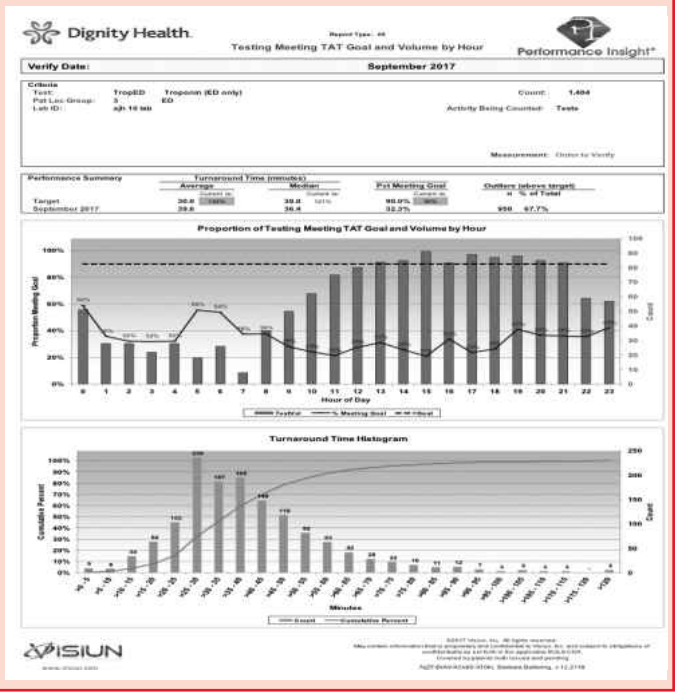
Comparison with Peers

"A large number of our reports are related to productivity, which allows us to compare how our phlebotomists perform against their peers," she explained. "This data is useful because we needed the right mix of phlebotomists in the ED, not just the right number.

Using Detailed Analytics to Improve Lab TAT

EACH MORNING, a full range of reports covering the previous day's lab operations are delivered to Barbara Ballering, Quality Assurance and Performance Improvement Manager at St. Joseph's Hospital and Medical Center.

At right is a sample report that shows tropinin turnaround times from the emergency department. These reports combine key statistics and data with charts and graphs that make it easy for lab staff to see the lab's performance against its goals.



"This report gives us the average activity and patient collections per phlebotomist," Ballering added. "Now we know the number of phlebotomy collections that occur each hour of the day, which phlebotomists worked in those hours, the total phlebotomies performed in each 24-hour period, and what percentage of the total our phlebotomists collected.

"We also can get information on the quality of each specimen broken down by patient location," she added. "That lets us know if someone needs retraining. Or, if a phlebotomist is new, perhaps that person shouldn't be in the ED yet.

"With these detailed daily reports, we know that average turnaround time decreased from a low of 6.5% in some areas to a high of 15.1% in other areas," she reported. "Our percentage of outliers decreased by a low of 11% to a high of 53%.

"Physician complaints also went down," she said. "At the start of the project, the lab got about 15 complaints a week. Today, we get about two complaints a week.

"That service improvement alone has increased satisfaction in the ED and for the lab staff as well," she commented.

"As a result of having performance data on so many aspects of lab operations, we saw when the ED is busiest, which was from noon each day until about 8 pm," Ballering concluded. "Now, our detailed reports deliver hard data that tell us daily when we need to beef up phlebotomy staff in the ED.

"Alternatively, when it's not so busy, we can recycle those phlebotomists from the ED to the floor to do in-house draws or to work on other projects," Ballering added. "Clearly, all of this has been positive for us because it allows us to fix problems as they arise." **TDR**

—Joseph Burns

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Lab company ran a 'giant unauthorized experiment'

WSJ Reporter Tells All About Downfall of Troubled Theranos

CEO SUMMARY: While Theranos was a darling of the business and national media, Wall Street Journal reporter John Carreyrou was hearing troubling reports about patients who got incongruent lab results that put them at risk for inappropriate medical treatments. His investigation of Theranos and its celebrated founder, Elizabeth Holmes, revealed that the company's much-touted lab testing technology was deeply flawed and that the company had misrepresented itself to government regulators, investors, patients, and the media.

IT IS OFTEN SAID THAT PRIDE GOETH BEFORE THE FALL. That phrase certainly applies to the story of **Theranos, Inc.**, and its much-touted founder and CEO, Elizabeth Holmes. While that story alone is fascinating, the work of an intrepid newspaper reporter from *The Wall Street Journal* is equally appealing, in part because he scooped all prominent news outlets while publishing multiple, well-researched exposés of Theranos, its many problems, and its various alleged fraudulent actions.

Acting on a tip from a former Theranos employee, *Journal* reporter John Carreyrou traveled to Arizona in April 2015 seeking doctors who had ordered blood tests from the Silicon Valley startup clinical laboratory. At the time, the two-time Pulitzer-prize winning journalist suspected the company's blood tests were putting patients at risk.

His first article on Theranos, published Oct. 15, 2015, was a blockbuster. In it, he described serious problems in the highly-touted lab testing company. Over the next several months, Carreyrou published additional detailed stories about the many problems that Theranos hid from government regulators, investors, patients, and the public. Since then, Theranos has been under close scrutiny from the federal **Centers for Medicare and Medicaid Services** and the **Securities and Exchange Commission**.

In March, the SEC charged Theranos Inc., its founder and CEO Elizabeth Holmes, and its former President Ramesh "Sunny" Balwani with raising more than $700 million from investors through what the SEC called "an elaborate, years-long fraud in which they exaggerated or made false statements about the company's technology, business, and financial performance." *(See TDR, March 26, 2018.)*

Theranos and Holmes agreed to resolve the charges and Balwani is contesting the charges. Last month, the company laid off all but about two dozen of its employees, Carreyrou reported for the *Journal*.

In a presentation in April at the annual meeting of the **Association of Health Care Journalists** in Phoenix, Carreyrou explained how the *Journal's* investigation unfolded, focusing on how the lab company's tests put patients at risk of harm.

Last week, Carreyrou's book about his work on Theranos, *Bad Blood: Secrets and Lies in a Silicon Valley Startup,* became available for sale from publisher **Alfred A. Knopf.**

"If you read my book, you'll see that it took me six more months after my Phoenix trip in April 2015 to expose what was essentially a giant unauthorized medical experiment," he said. "The resistance the company and its lawyers put up was like nothing I had ever experienced in 20 plus years of reporting.

"But in the end, the truth came out and Theranos voided or corrected nearly one million blood test results in California and Arizona," he continued. "There are some who believe that all 7-plus million of the blood tests the company returned to patients should have been declared 'unreliable.'"

Numerous Unreliable Results

In his presentation, Carreyrou described case after case of physicians in Arizona who found Theranos' test results to be not only unreliable but dangerous to patient care.

"The collateral damage from these false blood tests is hard to assess," Carreyrou commented. "Some patients have sued Theranos in federal court in Arizona, alleging medical battery and consumer fraud. One of them alleges that the company's test failed to diagnose his heart disease and led him to have a preventable heart attack.

"One thing is certain. The chances that people would have died from misdiagnoses or wrong medical treatments would have risen exponentially if Theranos had expanded its blood testing services to

Walgreens' 8,134 other U.S. stores, as it was on the cusp of doing when I started digging into the company in February 2015," he added.

Carreyrou's work on the story began early in 2015 with a tip from a former Theranos employee who suspected some of the company's tests were faulty. The former employee referred him to a nurse practitioner (NP) in Arizona who had complained about Theranos' test results, he said.

The NP told him three of her patients had questionable blood test results. "One was a 16-year-old girl who had a sky-high potassium result that suggested she was at risk of a heart attack," he said. "The results hadn't made sense given that she was a teenager in good health.

Providers Lose Faith

"Two other patients had received results showing abnormally high levels of thyroid stimulating hormone or TSH," he added. The nurse asked those patients to have their blood redrawn and retested. "The second time the results had come back abnormally low," he said. At that point, the nurse lost faith in Theranos' finger-stick tests," he added.

Seeking more sources, Carreyrou visited the online review site **Yelp**. "Sure enough, I found a woman who appeared to be a doctor," he explained. Using a Yelp feature to send messages to reviewers, Carreyrou sent the patient his contact information. She called him the next day.

A family physician in Fountain Hills, Ariz., the Yelp user was dissatisfied with her patients' test results from Theranos. "The previous fall she had sent one of her patients to the emergency room because of a frightening lab report from the company, only to learn it was a false alarm," Carreyrou explained.

On this same trip, he met the family physician and planned to drop in unannounced on other physicians sending patients' blood work to Theranos. During a meeting at **Starbucks** with the family physician's patient, he learned more about the patient's frightening episode.

"The lab report this patient received from Theranos showed abnormally elevated results for calcium, protein, glucose, and three liver enzymes," Carreyrou said. "Since she had complained of ringing in her ears, which was later determined to be caused simply by lack of sleep, her doctor was worried she might be on the cusp of a stroke and sent her straight to the hospital."

After four hours in the emergency room while doctors ran tests, including a CT scan, the patient was discharged after new blood tests done in the hospital's lab were normal. Also, she had two MRIs the following week and finally stopped worrying when results of those two scans were normal, Carreyrou said.

"This patient's case was compelling because it showed the emotional and the financial toll from a healthcare scare brought on by inaccurate results," he added. "As an independent real estate broker, this patient was self-insured and had a health plan with a high deductible. The ER visit and subsequent MRI's had cost $3,000, which she had to pay out of her own pocket."

Carreyrou also learned that the family physician doubted the accuracy of results for more than a dozen of her patients who tested suspiciously high for potassium and calcium, he said. "She had written Theranos a letter to complain, but the company hadn't even acknowledged it," he added.

Patients' Cost Soar

As a result of seeking other doctors who sent patients' blood work to Theranos, the reporter found three physicians in Scottsdale, Ariz. One doctor described a patient who had postponed a long-planned trip to Europe at the last minute because Theranos' test results showed she might have deep vein thrombosis. "People with DVT aren't supposed to fly because of the risks the clot will break lose, travel through the bloodstream, and lodge in the lungs,

Theranos Executives Used Silos to Operate in Ways that Kept the Real Facts Hidden

ONE QUESTION MANY THERANOS OBSERVERS have asked is how the company prevented outsiders from knowing about its operations.

"Theranos operated within silos," *Wall Street Journal* reporter John Carreyrou explained. "CEO Elizabeth Holmes and CFO Sunny Balwani set it up so that the various departments of the laboratory company didn't know what the other parts of the company were doing. That was enforced with key cards. The people who worked in engineering had their own key cards, and the people who worked in the lab couldn't set foot in engineering because they weren't authorized to do so.

"Eventually Theranos moved the lab rooms across San Francisco Bay to Newark, Calif., and installed fingerprint scanners there to limit access," he added. "The shenanigans were mostly going on in the lab, and they divided the laboratory into two rooms.

"One was called 'Jurassic Park,' which was the room that contained the regular off-the-shelf commercial analyzers, which they used for most of their tests," he recounted. "The conceit was that those machines were dinosaurs that would be rendered extinct by Theranos' groundbreaking new technology. Hence the name, Jurassic Park.

"Then, there was the other lab room that had the proprietary Edison devices and the hacked **Siemens** instruments," he added. "This room was called 'Normandy.' The analogy there was that they were going to take the lab industry by storm the way American and British troops took the beaches of Normandy in 1944.

"Essentially, the shenanigans were taking place in Normandy and no one who didn't work in Normandy or wasn't assigned to Normandy knew what was going on there," Carreyrou added.

"Therefore, when my first story came out in October 2015, many Theranos employees were angry at me and at the *Journal* because they thought they worked for a legitimate company," he said. "But they had no idea what was taking place in that part of the laboratory called Normandy."

causing a pulmonary embolism," he explained.

After ordering an ultrasound of the patient's legs and getting normal blood test results from another lab, the physician disregarded the Theranos results and was leery when Theranos sent a lab report showing an abnormally-high TSH value for another patient.

The patient was already on thyroid medication, and the results suggested that her dose should be raised, the physician explained. After sending the patient to get retested at **Sonora Quest Laboratories**, the physician got a normal test result.

If she had increased the patient's medication based on the Theranos result, the outcome could have been disastrous, the physician told Carreyrou. "The patient was pregnant and increasing her dosage would have made her thyroid hormone levels too high and put her pregnancy at risk," he said.

Yet another family physician told Carreyrou he stopped sending patients' blood work to Theranos after a bad experience with a patient who had high blood pressure. Knowing that one of the side effects of blood-pressure medications is high potassium, the physician monitored the patient's blood work regularly.

"After Theranos reported a near-critical potassium value for the patient, the nurse in his office sent that patient back to

Theranos to get tested again to make sure the result was correct," he said. "But during a second visit, the Theranos phlebotomist made three unsuccessful attempts to draw the patient's blood and then sent her home." Needing to confirm test results right away, the physician sent this patient to Sonora Quest for retesting.

"As it turned out, it was another false alarm. The potassium value Sonora Quest reported that evening was much lower than the Theranos results and well within the normal range," Carreyrou said, adding that the experience shattered the physician's trust in Theranos.

Doctors Question Results

While these physicians were questioning the results they got from Theranos, the clinical lab company itself was pursuing opportunities for growth, Carreyrou explained.

"Theranos went live with their blood tests in September 2013, first in a **Walgreens** store in Palo Alto, and then they expanded to Phoenix," he said. "By the time I started digging into the company not quite two years later, they had expanded to about 45 locations in Phoenix and had something like 47 locations in two states."

The Theranos partnership with Walgreens raised more questions. "How did the retail partner Walgreens not do its due diligence by asking more questions or having more supervision over this partnership?" asked Carreyrou. "In part, the answer to that question is that the people at Walgreens who were in charge of this partnership were just not very good people to have in charge.

"One had a drinking problem and been charged with driving under the influence and another was 'completely starry-eyed with Silicon Valley and Silicon Valley innovation,'" he said.

Another question Carreyrou wanted to answer is how Theranos avoided closer scrutiny from regulators. One reason is that the laboratory industry and blood testing itself are complex, and another reason is how Theranos used the lack of regulation for lab-developed tests (LDTs) to its advantage, he said.

"For decades, the FDA has not actively policed this part of the business, which technically falls under the jurisdiction of CMS, but CMS hasn't policed it either," he explained. "So, Theranos was operating in this gray area because it was using its own proprietary device for at least some of its tests, but didn't commercialize it. Therefore, it was avoiding close FDA scrutiny by not commercializing the equipment.

"Then when state inspectors enforcing CLIA would come by, Theranos would outright mislead them and not show them the part of the lab downstairs where they had their proprietary devices," he said. "So the state inspectors would just see a normal-looking lab with **Siemens** instruments.

"In addition, they lied," he added. "They outright misled CMS and the FDA. And so when you're being lied to, well, you can only blame the regulators so much."

Compared Two Labs' Results

Carreyrou's own experience also led him to distrust Theranos' test results. While in Arizona, he asked a family physician to write him a lab test requisition that he took to a Theranos Wellness Center at a Walgreens pharmacy. The family physician gave him two requisitions. One for Theranos and one for **Laboratory Corporation of America**. The family physician also planned to get two sets of tests so they could compare the results from both labs.

At Walgreens, Carreyrou learned firsthand that some of the tests on the physician's order required a venous draw. Previously, a former Theranos employee had explained that, of the more than 240 tests Theranos offered on its menu, only about 80 were performed on small fingerstick samples and about a dozen of those tests were performed on its Edison machine, a proprietary instrument Theranos used. "The other 60 to 70 tests were run on hacked Siemens machines," the employee said.

Silicon Valley's Business Ethos May Have Contributed to Theranos' Eventual Downfall

ONE PROBLEM THAT TAINTED THERANOS almost from its start was the environment inherent in Silicon Valley, reporter and author John Carreyrou explained.

CEO Elizabeth Holmes founded Theranos as a tech company in Palo Alto, Calif. "Palo Alto is the heart, the center of gravity of Silicon Valley and, as my book explains, Steve Jobs and **Apple** were her idols," he commented. "Obsessed with being the second coming of Steve Jobs, she lost sight of the fact that her company and her endeavor weren't a traditional tech venture. What she was building first and foremost was a healthcare company, a company that made a medical device.

"She conflated those two things and channeled the 'fake it until you make it' ethos of Silicon Valley," he said.

In the 1980s, workers in Silicon Valley coined the term "vaporware" to describe software or hardware that tech companies announced with great fanfare, but that never materialized or that fell well short of what was promised, he added.

"Ever since then, that 'vaporware' ethos has been part of the DNA of Silicon Valley," Carreyrou commented. The drive to innovate leads to hype that leads venture capitalists to fund projects that may not be worth such investments, he added. "To get funding, companies often exaggerate where they are and hope that reality catches up," he explained. "That's essentially what Elizabeth Holmes did."

At its height, Theranos claimed a value of more than $9 billion, and Holmes owned more than half of its shares, so that her net worth was almost $5 billion.

"Ironically, there's another part of San Francisco Bay—not far from Palo Alto—which is South San Francisco, and, along with San Diego, is the hub for the biotech industry," commented Carreyrou. "Real medical science takes place in this South San Francisco hub. Instead of basing her company there and emulating the people from the biotech industry, she chose to emulate what was essentially the computer industry. The result is this disaster."

After leaving Walgreens, Carreyrou took the second requisition to a LabCorp patient service center. A few days later, he got the results. "As I scanned my results, I noticed a number of discrepancies," he said. "Theranos had flagged three of my values as abnormally high and one as abnormally low. Yet on LabCorp's report all four of those values showed up as normal.

"Meanwhile, LabCorp had flagged both my total cholesterol and my LDL cholesterol—otherwise known as bad cholesterol—as high, while the Theranos report described the first as 'desirable' and the second as 'near optimal,'" he explained.

While those differences were alarming, the results the family physician got were more troubling. "According to Theranos, the amount of cortisol in the patient's blood was less than one microgram per deciliter," he commented. "A value that low is usually associated with Addison's disease, a dangerous condition characterized by extreme fatigue and low blood pressure that could result in death if untreated.

"Her LabCorp report, however, showed a cortisol level of 18.8 micrograms per deciliter, which was within the normal range for healthy patients," he said. "She had no doubt which of the two values was correct." **TDR**

—Joseph Burns

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How Many Patients Were Harmed at Theranos?

Physicians questioned some abnormal test results, while other results went unchallenged

CEO SUMMARY: Reporting in The Wall Street Journal shows that some physicians in Arizona were concerned about the harm from erroneous test results from Theranos Inc. But those physicians who expressed concern may have been only a small set of the number of physicians who were worried about patient harm. After reviewing the concerns about patient harm published by the Journal reporter, an expert in clinical lab quality issues said there may be no way to know how many patients were harmed.

DESPITE ALL THE FAVORABLE PRESS COVERAGE **Theranos Inc.** received in the fall of 2015, many in the clinical laboratory industry were concerned about the science behind Theranos' blood testing methods. In a new book out this month, investigative journalist John Carreyrou of *The Wall Street Journal* showed that many patients were harmed as a result of that lab testing. *(See pages 12-17.)*

"From his reporting, we can assume that many more patients were harmed," said George Cembrowski, MD, an expert in lab utilization and quality control. The former Director, Medical Biochemistry, at the **University of Alberta Hospital** in Edmonton, Canada, has followed the Theranos saga closely.

"What we learned from the story about Theranos is something we all knew earlier, and it bears repeating now: Before anyone puts huge amounts of money into new methods for clinical laboratory testing, they should do all of the required and rigorous methods of evaluation that are possible," he said.

"As the laboratory profession saw with Theranos, when you rely on unvalidated testing methods and untested machines, the result will be losses for investors and harm for patients," commented Cembrowski.

"Certainly when big investors lose money, it may not be a significant problem because they always seem to have more money," he added. "But the larger issue involves patient harm. And, for many of the patients harmed by Theranos' testing methods, that harm is lasting, whether it's financial or physical."

Faulty Test Results

In addition to financial and physical harm, patients who get faulty test results also may worry needlessly while they are taken on a diagnostic odyssey. "If results are flawed, then it leads a patient on this journey of more testing and overtesting to make sure the initial results were correct," stated Cembrowski.

"In many cases, abnormal results lead to overdiagnosis, overtreatment, and ultimately to significant morbidity and even mortality.

"Most clinical lab directors are happy the FDA and CMS have stringent quality standards in place because those standards are designed to ensure patient safety," he said. "But in this case, Theranos was doing whatever it could to get around those regulations.

Tip of the Iceberg

"We could also argue that what has been reported about patient harm is just the tip of the iceberg," Cembrowski added. "We know some physicians were using independent laboratories to verify the lab test results reported by Theranos on their patients. It's likely that other physicians were doing the same because they were puzzled or concerned about the results they got from Theranos.

"Some physicians agonized over the data they got, especially if a particular result showed the potential for patient harm," he said. "Take, for example, the prothrombin time and International Normalized Ratio (INR) test, which shows the action of warfarin, an important anticoagulant. In either direction, if the INR is too high or too low, it can indicate serious patient bleeding or clotting issues.

Sodium Testing

"Or, consider if a test result shows a problem with a patient's sodium," he added. "In most patients, the body regulates sodium flawlessly, and most lab instruments measure it well. But if sodium or any electrolytes are out of range in just a couple of patients the physician should be thinking that the lab has defective testing.

"In almost all healthy patients, if clinicians suspect sodium or electrolytes are out of range, they would be highly bothered because there's so little deviation in normal healthy people," he explained. "That alone could lead a physician to question almost all results from that lab.

"If a doctor gets a high frequency of clinically important outliers and reports those results to the lab, then the lab might

Mixing Distilled Water with Red Blood Cells Is Bad Idea

ONE ADVANTAGE TO ITS DIAGNOSTIC TECHNOLOGY THAT THERANOS TOUTED in its marketing and media interviews was its use of blood samples collected by fingerstick collections. Using fingersticks allowed the company to advertise itself as being patient friendly because its technology would allow it to avoid the need for venous blood draws.

News reports indicate that Theranos had been adding distilled water to these capillary blood samples in order to have enough specimen volume to run those samples on standard blood analyzers.

Problems arise, however, if there is insufficient blood volume for some tests, said George Cembrowski, MD. "Depending on how much water gets added to the blood sample, you could have a significant problem," he said. "In short, this is a really bad practice when testing clinical specimens.

"For example, consider how red blood cells react with distilled water," continued Cembrowski. "The red cells would swell up as more water is added and eventually break apart (lyse), thus releasing everything in the red cell into the plasma, which is then measured in addition to what was already in the plasma.

"When red cells break apart like this, it is called hemolysis and hemolysis is an issue which labs try hard to avoid when they collect and handle blood specimens," he added. "Many papers have been written on the effects of hemolysis. The basic issue is that, as the red cell contents leak out, that increases their apparent concentrations, which, in turn, affects all kinds of clinical laboratory tests.

"Sometimes, the test results decrease," added Cembrowski. "One example is when a lab tests for troponin in a patient suspected of having a heart attack. With hemolysis, on certain instruments, the troponin levels decline."

need to suspend testing and identify the problem," Cembrowski said.

"I would guess that physicians saw the outliers and reported those outliers, but it looks like Theranos' response was poor at best," he added. "It looks as if Theranos went into a mode designed to elude everybody. And they did a great job in eluding almost everyone.

Good Laboratory Practices

"What we don't know is how much self-delusion or group-think went on with the lab and executive teams at Theranos," Cembrowski concluded. "It could be there was a way of thinking in the lab that was counter to good laboratory practices, particularly if one or two people at the top were saying the system works fine. That can create a kind of a mass hypnosis. When that happens, everybody simply follows the leader.

"Just by the fact that Theranos had some of their proprietary Edison instruments in one place and other **Siemens** production instruments in a different place, implies that they were attempting to deceive inspectors or to keep employees in the dark," he said.

Potential for Patient Harm

The potential for significant patient harm was an issue that went unaddressed by nearly all the media accounts about Theranos and its founder Elizabeth Holmes during the years when it was being touted as the next Silicon Valley success story, a company likely to succeed on the same scale as **Amazon**, **Google**, or **Apple**, for example.

After Theranos began offering testing through **Walgreens** pharmacies in Palo Alto, Calif., and Phoenix, consumer review websites, such as **Yelp**, had postings from patients who reported serious issues with clinical laboratory test results they had recieved from Theranos and what they learned when they had the same tests repeated by another clinical laboratory.

During this time, did state and federal regulators of clinical laboratories fail patients in the regions where Theranos was offering lab testing services? It is not known how many physicians and patients may have complained to their state CLIA offices or CMS about discordant lab test results. But it is reasonable to expect that some medical professionals reported incidents of seriously-discordant lab test results to government bodies.

In several important ways, the story of Theranos' rise to fame and its subsequent collapse demonstrate why innovations in diagnostic technologies must be thoroughly vetted before they are used in patient care. **TDR**

—Joseph Burns

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Response to Bad Test Results? Offer to Retest for Free

ONE FACTOR SHOWS CLEARLY how Theranos was less than upfront in its dealings with regulators, referring physicians, patients, and the public, said George Cembrowski, MD. An expert in lab utilization and quality control, Cembrowski found it troubling that Theranos did not offer to retest patients when informed about bad test results.

"If Theranos truly wanted to improve, then when physicians had questions about test results, Theranos should have offered to do retesting for free," he stated. "The honorable way to respond to questionable results is to pay another clinical laboratory to do the retesting.

"As far as we know, that didn't happen," he said. "Instead, we know that Theranos voided the millions of blood test results."

In May 2016, reporter John Carreyrou reported in *The Wall Street Journal* that Theranos told federal regulators it had voided two years of results from its Edison blood-testing devices. But there is no evidence that Theranos provided or offered retesting to these patients.

Legal Update

In HDL Case, Judge Imposes Damages, Penalties of $114 Mill.

In DOJ and whistleblowers' cases, latest order starts the clock on when defendants can appeal

LAST WEEK, A FEDERAL JUDGE in South Carolina issued an order imposing civil damages and penalties of more than $114 million on Tonya Mallory, the former CEO of **Health Diagnostic Laboratory**, in Richmond, Va., and two owners of the lab's marketing partner, **BlueWave Healthcare Consultants Inc.** The damages and penalties were imposed on the defendants for violating the federal False Claims Act.

In January, a jury in Charleston, S.C., in U.S. District Court for the District of South Carolina, Beaufort Division, found the defendants guilty of civil fraud against Medicare and other federally-funded healthcare programs. *(See "Insights from Jury Verdict in HDL, BlueWave Case," TDR, Feb. 12, 2018.)*

The defendants in the case are Mallory, Floyd Calhoun Dent III, and Robert Bradford Johnson. Dent and Johnson own BlueWave Healthcare Consultants Inc., a marketing company in Alabama.

Defendants Ordered to Pay

In his ruling on May 23, Judge Richard M. Gergel ordered the defendants to pay more than $111 million in treble damages and penalties for fraud relating to HDL's arrangement with BlueWave to market HDL blood tests, in part by offering illegal kickbacks to physicians who ordered the tests, according to Peter W. Chatfield of the law firm **Phillips and Cohen LLP** of Washington, D.C.

The verdict and entry of judgment were the outcome of three whistleblower cases brought and litigated together. One of the whistleblowers was Michael Mayes, MD, an internist in Hilton Head, S.C., who was the only whistleblower to testify in court, Chatfield said. The DOJ joined the whistleblowers' case in which the plaintiffs alleged that the three defendants conspired to pay kickbacks to doctors in the form of unwarranted processing and handling fees for blood draws and testing referrals.

35,074 False Lab Test Claims

The payments provided a financial incentive to doctors to order expensive cardiovascular blood tests for federally-insured patients, Chatfield said. Often, the tests were unnecessary, he noted. The scheme by HDL and BlueWave involved paying doctors $20 in fees for processing and handling of specimens the physicians would send to HDL, Phillips and Cohen said in a press release. Under this scheme, HDL submitted 35,074 false claims, the government charged.

In a related kickback scheme, Dent and Johnson were found liable for paying a $10 processing and handling fee to physicians to encourage them to order unnecessary tests at another specialty blood lab, **Singulex Inc.**, the law firm explained. That scheme resulted in the submission by Singulex of 3,813 false claims to federally insured healthcare programs that cost the government $467,935, the press release said. Dent and Johnson were assessed more than $3 million in damages and penalties for this scheme, the firm added.

The jury ruled that the defendants owed the federal government single damages totaling in excess of $17 million, which were tripled under the False Claims Act, making the total combined liability $51.2 million, plus approximately $78.5 million in civil penalties. The amount of the penalties was calculated by imposing the minimum $5,000 penalty assessable under the False Claims Act at the time of the earliest misconduct to just 11,600 of nearly 39,000 false blood lab claims for reimbursement that the jury found the defendants caused the government to pay, Phillips and Cohen said.

Defendants May Appeal

"What Judge Gergel is doing is cutting the time it will take to get this case into (and thus also through) the appeals process," Chatfield explained in an email to THE DARK REPORT. "That helps limit the continued wasting of assets that could be used to repay the debt on unnecessarily prolonged appellate litigation."

The judgment against the defendants entitles the government to collect all known assets of the defendants, he added.

In effect, the judge's order starts the clock on the defendants' right to give notice if they intend to appeal, he wrote. "He does that by declaring them to be 'final' judgments within the meaning of the Federal Rule of Civil Procedure 54(b), which controls when an appeal can be taken," he added.

In a press release, Chatfield commented on Mayes' role in the case. "Dr. Mayes' strong sense of ethics compelled him to speak up, at a cost to his relationships with other doctors who had been enriching themselves by accepting the unlawful payments," Chatfield commented. "Dr. Mayes brought this case out of concern for Medicare patients, knowing that healthcare fraud can drive up Medicare premiums and Medicare costs, putting patients at risk of cuts in Medicare-covered services." TDR

—Joseph Burns

Former HDL CEO Sued HDL's Former Law Firm

ALTHOUGH ONE COURT CASE involving executives from Health Diagnostics Laboratory, Singulex, and BlueWave Healthcare Consultants, Inc., now has a judge's verdict, there is still ongoing litigation involving the former CEO of HDL, Tonya Mallory.

Last fall, Mallory sued the law firm that had provided HDL with legal advice at the time of HDL's formation and in the following years. Mallory is seeking $603 million in damages from **LeClairRyan**, based in Richmond, Va.

In an interesting twist to the HDL story, after HDL filed for bankruptcy protection in 2015, the bankruptcy trustee wrested a settlement agreement from LeClairRyan. In its coverage of this story, the *ABA Journal* wrote, "The law firm agreed to pay $20.375 million to resolve claims related to its legal advice to a medical lab company [HDL] that filed for bankruptcy after a federal investigation into whether it paid kickbacks to doctors."

Bloomberg Law reported that, in her lawsuit against LeClairRyan, "Mallory alleges LeClairRyan gave her 'incorrect legal advice' concerning processing and handling payments to physicians who sent testing samples to the now-bankrupt clinical testing provider."

The multi-million-dollar settlement negotiated with LeClairRyan by HDL's bankruptcy trustee, and Mallory's lawsuit against that law firm, demonstrate that law firms providing legal opinions about how various clinical laboratory business, sales, and marketing practices meet federal and state compliance statutes should consider their own exposure, should these opinions later be challenged in lawsuits or by government prosecuters.

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Ireland is dealing with a cervical cancer screening scandal that reaches back to laboratories in the United States. In recent months, the Irish public has learned that more than 200 women wrongly got negative Pap test results over a multi-year period. Many of these women did not learn of the erroneous test results for years after the government health service was aware of the problem. Ireland outsourced all of its cervical cancer screening in 2008 to **Quest Diagnostics** in the United States. *(See TDR, Aug. 31, 2009.)* In 2010, **Sonic Healthcare's Clinical Pathology Laboratories** division in Austin, Texas, won a contract to provide a significant volume of the cervical cancer screening tests for Ireland's **Health Service Executive**.

MORE ON: *Pap Testing in Ireland*

Back in 2008, it was a controversial decision for the Irish health system to outsource cervical cancer screening to labs in other nations. CervicalCheck is the name of Ireland's national cervical cancer screening program and, at its inception, CervicalCheck had critics who pointed out flaws in the plan to offer free cervical cancer screening services to Irish women. There are many important nuances to this story for pathologists in the United States. More detailed coverage will be provided by THE DARK REPORT in coming months.

SANFORD HEALTH OFFERS GENE TESTS TO PATIENTS SEEING THEIR PCPS

Sanford Health of Fargo, N.D., is preparing to offer a genetic test panel to patients visiting its primary care clinics. The test will cost $49 and will look for the patient's predisposition to 60 genetic diseases and 30 different drug-gene interactions.

TRANSITIONS

• **OPKO Health, Inc.** announced that Geoff Monk is the new General Manager of its **Bio-Reference Laboratories, Inc.** division. Monk formerly held executive positions at **Quest Diagnostics**, **Shering-Plough**, and **Glaxo-Wellcome**.

• **Aurora Diagnostics** of Palm Beach Gardens, Fla., promoted Bruce Walton to the position of President and COO. He was formerly Executive Vice President and COO at Aurora. Prior to Aurora, Walton served at **AmeriPath** and **CR Baird**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 18, 2018.