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BREAKING NEWS! **INDICTED**
Elizabeth Holmes
Ramesh 'Sunny' Balwani
Ex-Theranos Executives each charged with 11 counts of fraud
(See pages 3-6 inside.)

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

Theranos' Elizabeth Holmes Prepares to Meet Justice

IT'S NOW CLEAR THAT TWO CLINICAL LABORATORY EXECUTIVES COMMITED one of the largest corporate fraud schemes in the past century.

Reading the federal indictments against Elizabeth Holmes and Ramesh "Sunny" Balwani unsealed Friday provides insights into the extensive scale and wide scope of the alleged fraud the two **Theranos** executives perpetrated against patients, doctors, and investors.

When combined with the media reporting on Theranos, the information in the federal indictments provides compelling evidence that Theranos would at least equal, if not exceed, most of the biggest business frauds, Ponzi schemes, and accounting scandals that have occurred since 1900.

If we view who was hoodwinked in this dark story of deception and intrigue, the list is impressive. It starts with some of the smartest investors in the Silicon Valley, who, after being among the first to invest in Theranos, noticed that the lab testing products Holmes was developing did not function properly, that Holmes was turning over staff and executives who challenged her with the reality of how these systems were failing, and that Holmes was misrepresenting the performance of these products when she presented them to potential customers and investors.

Then in 2013, there was the illustrious and ballyhooed board of directors. Comprised of multiple former cabinet officers, generals, and admirals from the highest ranks of the military, they lent their names to—and bet their reputations on—Theranos. Next were the executives of **Safeway** and **Walgreens**. Both companies made sizeable investments in Theranos without fully understanding whether Theranos could deliver on its promises. During this time, many in the mainstream media were eagerly leading cheers for Holmes without seriously investigating her company's representations.

Following the media hype, once-shrewd investors rushed to put hundreds of millions of dollars into Theranos. We should not overlook the thousands of physicians and their patients who trusted Theranos with their lab tests, only to learn months later that these test results were fraudulent.

Theranos is a business scam of unprecedented scope. It may not have ripped off billions as Bernie Madoff did, but Holmes and her company certainly took advantage of wide array of people and institutions. TDR

Holmes, Balwani Indicted by Department of Justice

Each defendant charged with two counts of conspiracy and nine counts of wire fraud

CEO SUMMARY: Federal criminal indictments were unsealed last Friday in San Francisco against Elizabeth Holmes and Ramesh "Sunny" Balwani for their actions as executives at Theranos, Inc., the once high-flying lab test company. Officials at the Department of Justice said the counts against Holmes and Balwani are based on the alleged actions of each to defraud investors and to defraud both the physicians and patients who ordered clinical laboratory tests from their company.

TWO HIGH-PROFILE EXECUTIVES associated with **Theranos, Inc.**, were indicted last week. Elizabeth Holmes and Ramesh "Sunny" Balwani were arraigned before U.S. Magistrate Judge Susan van Keulen on Friday in U.S. District Court for the Northern District of California, San Jose Division. Each one was charged with two counts of conspiracy to commit wire fraud and nine counts of wire fraud.

If convicted, Holmes and Balwani could face prison sentences that would keep them behind bars for the rest of their lives and fines totaling $2.75 million each, the **Associated Press** reported.

Under a federal grand jury indictment returned June 14 and unsealed Friday, the charges stem from allegations Holmes and Balwani engaged in a multimillion dollar scheme to defraud investors, and a separate scheme to defraud doctors and patients. Both schemes involved efforts to promote the lab company Theranos of Palo Alto, Calif., the federal **Department of Justice** announced.

In the indictment, the DOJ charged that Theranos, Holmes, and Balwani not only defrauded investors, but also defrauded consumers who trusted and relied on Theranos' blood-testing technology that Holmes and Balwani claimed was revolutionary and would change the clinical lab testing business in significant ways.

"This indictment alleges a corporate conspiracy to defraud financial investors," said FBI Special Agent in Charge John F. Bennett. "This conspiracy misled doctors and patients about the reliability of medical tests that endangered health and lives."

The indictment contains at least one new development in the alleged fraud

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scheme that Holmes and Balwani perpetrated. The indictment states Holmes and Balwani sent to patients and doctors test results that they knew contained—or were likely to contain—data that were inaccurate and unreliable, came from improperly adjusted reference ranges, and were generated from improperly validated assays. Also, the indictment states, the results contained or were likely to contain improperly removed 'critical' data.

Prison, Fines, Restitution

If convicted, Holmes, age 34, and Balwani, 53, face a maximum sentence of 20 years in prison, and a fine of $250,000, plus restitution, for each count of wire fraud and for each conspiracy count, the DOJ said.

The DOJ's indictment follows by three months charges the federal **Securities and Exchange Commission** filed March 14 in the same court. The SEC charged that Theranos, Holmes, and Balwani raised more than $700 million from investors through an elaborate, years-long scheme that involved exaggerating or making false statements about the company's technology, business, and financial performance. The SEC's charges are similar to those in the DOJ's indictment.

'Deceived Investors'

In the SEC case, the federal agency said Theranos, Holmes, and Balwani deceived investors into believing that the company's portable blood analyzer could do comprehensive laboratory blood tests from drops of blood collected via a fingerstick. *(See TDR, March 29, 2018.)*

In fact, the company's proprietary analyzer could complete only a small number of tests while the company conducted most patients' tests on modified, industry-standard commercial analyzers, the SEC said.

To settle the SEC's charges, Holmes agreed to pay a $500,000 fine and she agreed to surrender almost 19 million shares of Theranos stock and voting control of the company, the SEC said. Also, she was barred from running a public company for 10 years. At the time, Holmes did not admit to nor deny the charges. Balwani said he would contest the charges.

After dropping out of Stanford University at age 19, Holmes founded Theranos in 2003 with the idea that the company would revolutionize medical laboratory testing through allegedly innovative methods for drawing blood and testing blood and for interpreting the resulting patient data, the DOJ said. At one time, Theranos was valued at more than $9 billion and because Holmes owned almost 50% of the company's stock, her personal wealth was valued at more than $4 billion, making her the youngest self-made female billionaire, the AP said.

Balwani's Role at Theranos

From 2009 through 2016, Balwani served the company in several roles, including as president, chief operating officer, and as a member of the board of directors.

The Wall Street Journal's John Carreyrou reported Friday night that Holmes had stepped down as CEO and that the indictments were the culmination of a 30-month investigation by the U.S. attorney's office in San Francisco that was sparked by Carreyrou's reporting on Theranos since October 2015. *(See "WSJ Reporter Tells All About Downfall of Troubled Theranos," TDR, May 29, 2018.)*

Sara Ashley O'Brien at *CNN* reported that minutes before the charges were made public, Theranos announced that Holmes stepped down as CEO and that the general counsel, David Taylor, would assume the role of CEO. Holmes will stay on as chair of the company's board.

The indictment explained in detail how Holmes and Balwani used advertisements and solicitations to doctors and patients to get them to use Theranos' blood testing services, even though both Holmes and Balwani knew the technology

was incapable of producing accurate and reliable results for certain blood tests consistently and that the tests were likely to contain inaccurate and unreliable results, the DOJ said.

Defrauded Potential Investors

Also, the indictment alleges that Holmes and Balwani defrauded potential investors through direct communications, marketing materials, statements to the media, financial statements, and other means. "Specifically, the defendants claimed that Theranos developed a revolutionary and proprietary analyzer that the defendants referred to by various names, including as the Theranos Sample Processing Unit (TSPU), Edison, or minilab," the DOJ said. Holmes and Balwani claimed the Theranos analyzer could perform a full range of clinical tests using only small fingerstick samples of blood and that the analyzer could produce results faster, more accurately, and more reliably than conventional testing methods could produce, the DOJ explained.

In their presentations to investors, Holmes and Balwani knew that their statements about the analyzer were false, the indictment alleged. "For example, allegedly, Holmes and Balwani knew that the analyzer, in truth, had accuracy and reliability problems, performed a limited number of tests, was slower than some competing devices, and, in some respects, could not compete with existing, more conventional machines," the DOJ said.

Doctors, Patients Defrauded

Doctors and patients were defrauded because Holmes and Balwani made false claims about the ability of Theranos' testing systems to provide accurate, fast, reliable, and low-cost blood tests and test results, the DOJ said. Also, Holmes and Balwani failed to disclose the limits of that technology and the problems they had developing those testing systems, the DOJ explained in its announcement.

Indictments Are a Warning to Silicon Valley and All Labs

IN ITS PRESS ANNOUNCEMENT about the indictments of Elizabeth Holmes and Ramesh "Sunny" Balwani, the federal Department of Justice outlined how it will pursue cases against those who misrepresent the technology they are developing.

That announcement for the DOJ's district office in San Francisco serves as a warning to companies in Silicon Valley where Theranos is based, as well as to clinical and genetic testing labs.

In addition, lab directors and pathologists should note that the federal **Food and Drug Administration's** Office of Criminal Investigations assisted the FBI and DOJ in its pursuit of fraud charges against Holmes and Balwani.

"This district, led by Silicon Valley, is at the center of modern technological innovation and entrepreneurial spirit; capital investment makes that possible. Investors large and small from around the world are attracted to Silicon Valley by its track record, its talent, and its promise," the DOJ said. "They are also attracted by the fact that behind the innovation and entrepreneurship are rules of law that require honesty, fair play, and transparency.

"The conduct alleged in these charges erodes public trust in the safety and effectiveness of medical products, including diagnostics," the DOJ added.

"The defendants knew Theranos was not capable of consistently producing accurate and reliable results for certain blood tests, including the tests for calcium, chloride, potassium, bicarbonate, HIV, HbA1C, hCG, and sodium," the DOJ said. "The defendants nevertheless used interstate electronic wires to purchase advertisements intended to induce individuals to purchase Theranos blood tests at **Walgreens** stores in California and Arizona."

In its advertisements, the company explicitly represented that Theranos' blood tests were cheaper than blood tests from conventional laboratories, the DOJ said. As a result of Holmes and Balwani's misrepresentations and omissions, many hundreds of patients paid for blood tests and test results or had their health insurers pay for blood tests and results following referrals from their "defrauded doctors," the DOJ said.

Scheme to Mislead Investors

Holmes and Balwani also used various schemes to mislead investors, the DOJ said. "For example, with respect to investors, defendants performed technology demonstrations during which defendants intended to cause potential investors to believe blood tests were being conducted on Theranos' proprietary analyzer when, in fact, the analyzer really was running a 'null protocol' and was not testing the potential investor's blood," the DOJ said.

"Similarly, defendants purchased and used commercially-available analyzers to test patient blood, while representing to investors that Theranos conducted its patients' tests using Theranos-manufactured analyzers," the DOJ explained.

'Negligible' Revenue

In addition, Holmes and Balwani misrepresented Theranos' financial condition and its future prospects, the DOJ said. The defendants claimed Theranos would generate over $100 million in revenue and break even in 2014, the DOJ said. Also, the defendants claimed that the company expected to generate $1 billion in revenue in 2015. "In truth, the defendants knew Theranos would generate only negligible or modest revenues in 2014 and 2015," the DOJ said.

In addition to making false claims about how the DOD was using its technology, Holmes and Balwani also misrepresented to investors its relationship with Walgreens, the DOJ said. "The defendants represented to investors that Theranos would soon dramatically increase the number of Wellness Centers within Walgreens stores when, in truth, Holmes and Balwani knew by late 2014 that Theranos' retail Walgreens rollout had stalled because of several issues, including that Walgreens' executives had concerns with Theranos' performance," the DOJ explained TDR

—Joseph Burns

Holmes and Her Mother Both Had Fear of Needles

TWO OFT-TOUTED BENEFITS of the proprietary Theranos lab test technology were that it needed just a tiny amount of blood as a specimen and that blood could be collected with a finger stick, thus avoiding a venipuncture. Nearly all pathologists and clinical laboratory scientists recognized the dubious nature of these claims.

In his book about Theranos—"Bad Blood: Secrets and Lies in a Silicon Valley Startup"—that was published last month, author John Carreyrou, *The Wall Street Journal* reporter who exposed the fraud at Theranos, wrote about the origin of these two benefits. On page 19, he wrote:

The main difficulty stemmed from Elizabeth's insistence that they use very little blood. She'd inherited from her mother a phobia of needles; Noel Holmes [Elizabeth's mother] fainted at the mere sight of a syringe. Elizabeth wanted the Theranos technology to work with just a drop of blood pricked from the tip of a finger. She was so fixated on the idea that she got upset when an employee bought red Hershey's Kisses and put the Theranos logo on them for a company display at a job fair. The Hershey's Kisses were meant to represent drops of blood, but Elizabeth felt they were much too big to convey the tiny volumes she had in mind.

Hospital Lab Outreach Still Effective Revenue Strategy

When payment rates decline, hospital laboratory outreach programs help bring in needed income

CEO SUMMARY: Despite the challenges hospital and health system laboratory outreach programs face today, there are many ways they can remain viable, according to an outreach expert from Mayo Medical Laboratories. By taking specific steps to increase volume and the value they provide, lab outreach programs can keep their costs down while bringing in more revenue and staying relevant to their parent hospitals, health systems, and clients at the same time.

HOSPITAL AND HEALTH SYSTEM LABORATORIES running outreach programs face unprecedented challenges today as payers cut reimbursement levels and exclude many local labs from their networks.

Despite these challenges, however, outreach programs can remain viable by taking specific steps to increase volume and the value they provide to hospitals and health systems, said Jane M. Hermansen, MBA, MT(ASCP), Manager of Outreach and Network Development for **Mayo Clinic**, in Rochester, Minn. She made her remarks at THE DARK REPORT'S *Executive War College* in New Orleans earlier this month.

Hermansen made her assessment that outreach programs can provide significant value to hospitals and health systems based on her experience working for **Mayo Medical Laboratories**, which consults with some of the best hospital lab outreach programs in the nation. She offered examples from many of these best-in-class outreach programs and found they shared three similarities.

"All of these programs want to do one of three things," she said. "First, they want to save money. Second, they want to make money, and third, they definitely want to stay relevant in the lab testing services they provide to referring physicians.

"Another important benefit is that lab outreach programs can help hospital labs keep costs down by adding volume to the hospital's laboratory that the hospital might otherwise not have," she added. *(See sidebar, page 9.)*

Support for Care Continuum

One way clinical labs can remain relevant to parent hospitals or healthcare systems is to do testing that supports the entire continuum of care. "Doing so means the clinical laboratory will have clinical lab test data on every patient in the healthcare system—whether inpatient, outpatient or outreach," stated Hermansen. "This complete and longitudinal record of patient lab test results is a critical component for labs today.

"To support the entire continuum of care, every hospital and health system lab should consider it essential to perform 100% of the testing ordered within its parent organization," she advised. "Once a

lab achieves that level, the lab and the health system will own the clinical lab data on those patients. That creates a competitive advantage over health systems that do not have that same data.

"In addition, your lab will own that patient interaction, which is important because—compared with other clinical services in the healthcare continuum—laboratories have four to five times more interactions with patients than does any other clinical service," she said.

"What's more, much of the medical record data on each patient comes from clinical lab data," Hermansen added. "That means hospital labs have an opportunity not only to deliver results, but also to manage that patient's impression of the healthcare system. Further, if their interaction with the hospital lab is favorable, they're more likely to remain as patients in the system."

Nursing Home Opportunities

Supporting the entire continuum of care means lab directors at hospitals and health systems now serving nursing homes may need to rethink any ideas they may have about abandoning that business.

Understandably, lab directors are worried about the deep cuts in payment that the Medicare program established in the 2018 Clinical Laboratory Fee Schedule, implemented Jan. 1 under the Protecting Access to Medicare Act. However, even before those low payment rates went into effect, many labs serving nursing homes considered exiting the nursing home business.

Leaving that business would be a critical mis-step, despite the inherent challenges, Hermansen advised.

"Hospital labs should think about serving nursing homes as respecting and supporting the continuum of care," she explained. "If your lab provides integrated test results across the continuum, your parent hospital's chances of caring for that patient effectively are much better. But if your lab stops serving nursing homes, your hospital could lose access to that patient's continuum of care data.

Big Value in Big Data

"Then, if that patient is readmitted, the hospital would be on the hook for the costs of care and for any readmission," she added. "Doing a cost-benefit analysis that compares the cost of a laboratory test with the cost of a readmission would clearly show the benefit of having the hospital lab continue to serve its nursing home patients."

Instead of leaving the nursing home business, hospital and health system labs should analyze their contracts with these facilities to ensure that payment for these testing services reflects the lab's actual costs, Hermansen suggested.

"When one East Coast hospital lab did this analysis, it found that it had discounted contracts for some work under Medicare Part A for patients in skilled nursing facilities," explained Hermansen. "Under those discounted contracts, the lab was getting paid about 50% of what Medicare would normally pay for those tests—meaning the lab was barely covering its costs.

"In addition, those contracts had expired, but this hospital lab had continued to operate under those expired payment rates," she said. "At that point, the hospital lab had to raise its rates, and the nursing home accepted that change.

"That example suggests that hospital and health system labs have an opportunity to renegotiate their contracts with nursing homes in this payment environment," Hermansen said. "In addition, it might be time to renegotiate with other payers as well."

In any negotiation, a hospital's lab outreach program should consider the inherent strength it has in negotiations with nursing homes today because the large national lab companies are unwilling to serve nursing homes, she said.

"Managers of hospital labs need creative ways to work with their customers because nursing homes need laboratory services for this population. If the local hospital lab doesn't serve nursing homes, who will?" Hermansen asked. "Are there other laboratories pounding on their doors, begging at the opportunity? No.

Covering Phlebotomy Costs

"At Mayo Medical Laboratories, we work with a hospital lab that had two nursing home clients recently offer to cover the lab's phlebotomy costs," she reported. "One nursing home offered to pay $500 per month if the hospital lab would do the phlebotomy draws and bill separately for the testing.

"A second, larger nursing home offered to pay $1,000 a month for the phlebotomy service," Hermansen added. "The hospital laboratory is no longer on the hook for those phlebotomy costs and can still do the testing.

"At a third health system lab we know, a nursing home offered to do the phlebotomy draws if the lab would train its nursing staff to do so," she said. "Then all the laboratory needed to do was pick up and transport those specimens."

Add Tests; Cut Send-Outs

Another way hospital lab outreach programs can increase revenue is by changing the type of testing the lab does. "Some health system lab outreach programs are expanding their test menus and thereby reducing the number of send-out tests they do," Hermansen suggested. "Doing so means going through the make-versus-buy process to justify not sending some laboratory tests out, but it's a relatively easy calculation.

"When your lab shifts its test mix correctly, it will likely add more esoteric tests," she said. "That means your lab may no longer be doing mostly $10 CBCs. Instead, it may be doing many more $30 esoteric tests.

"A hospital lab also can make it a priority to do more work for other hospi-

Hospital Labs Could Serve Large Local Employers

ONE OF THE LARGEST EMPLOYERS in Central Florida is the **Walt Disney Company**, which has a well-earned reputation for aggressively seeking the best healthcare deals for its 70,000 workers.

In February, Naseem Miller reported for the *Orlando Sentinel* that the Disney company introduced a health insurance plan for its Central Florida employees that bypasses insurance companies and instead relies on two local hospital systems. Disney contracted directly with the area's two largest health systems, **Orlando Health** and **Florida Hospital**.

By eliminating the insurance middlemen, Disney jettisoned the contracts those insurers had with large national labs. **Cigna**, for example, has a contract with **Quest Diagnostics**, which stood to lose some of that lab test business it had previously, said Jane M. Hermansen, MBA, MT(ASCP), the Mayo Clinic's Manager, Outreach and Network Development.

"This is the perfect example of how hospital lab outreach programs can be included in these types of arrangements," she added. "Do you think Disney got the very cheapest laboratory testing it could get? Probably not, but they are supporting the local community and creating an opportunity for the clinical labs of those hospitals.

"Now those 70,000 Disney employees and other covered lives under that health insurance plan will be using the hospital laboratories because Quest is carved out," she said. "Other employers are likely to be interested in doing so as well.

"If your hospital lab has a local employer sending testing out of your community, you should do whatever you can to bring that testing into the community," she urged. "Other employers are likely to be interested in following Disney's example."

tals," Hermansen recommended. "In that way, your lab will shift more testing to a hospital-client bill, which means it would be easier to send out and collect when compared with an insurance bill."

Marshfield Clinic's Lab

One stellar example is the lab that is part of the **Marshfield Clinic** in Marshfield, Wis. "This lab has three lines of business, two of which are outside of traditional insurance billing," explained Hermansen. "One line of business is the typical clinical lab testing for outreach patients. The second is for veterinarians, for which the lab has dedicated equipment and veterinary pathologists on staff.

"The third line of testing is for industry clients such as organizations involved in biotech, medical devices, animal health, pharmaceutical companies, universities, and contract research organizations," she said.

"Adding pathologists who specialize in veterinary work may not be possible, but hospital and health system labs certainly can add sub-specialist pathologists, such as hematopathologists," Hermansen advised. "If your hospital lab has hematopathologists on staff, you can reach out to oncologists in the community to bring in those additional samples.

Opportunities with Mass Spec

"Mass spectrometry MALDI-TOF is another example of lab testing that can help expand market share, particularly if your lab serves rural areas," she said. "With the right equipment, your lab could become a regional core laboratory for microbiology.

"This strategy can be effective in rural communities, especially in highly-regulated states such as New York," Hermansen commented. "In those states it's difficult to find technologists to do microbiology testing.

"But if your hospital lab has the right equipment, and is within an hour or so drive by courier, your lab could offer core microbiology testing and deliver those results quickly," she concluded. "That could be a differentiator in a rural market and contribute to greater market share and larger outreach lab revenue."

These examples of how hospital and health system lab outreach programs are succeeding using different strategies demonstrate that opportunities still exist for hospital and health system labs. TDR

—Joseph Burns

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Economics of Successful Hospital Laboratory Outreach

AS VALUE-BASED REIMBURSEMENT METHODS become more common, managers in hospital and health system labs must be on the alert to demonstrate that a cost center analysis of their labs may fail to capture all the revenue they produce, said Jane M. Hermansen, the Mayo Clinic's Manager, Outreach and Network Development.

For this reason, hospital laboratories need to know how much they generate in revenue and how much it costs the lab to produce that revenue. "Knowing these numbers is incredibly important," she added.

A study Mayo Medical Laboratories did showed that removing outreach testing from a hospital laboratory had a significant effect on the lab's overall costs. "For example, at one particular hospital, our study showed there was a 24% increase in costs if the outreach volume was removed from the laboratory cost structure.

"Stated differently, these economic facts support the strategy of building hospital laboratory outreach programs," noted Hermansen. "The additional outreach volume brings down the average cost per test for the entire laboratory, even as it brings in additional revenue."

In Lawsuit Against HHS, ACLA Has Strong Positions

Case hinges on data collection process, and whether ACLA has a legal right to sue

CEO SUMMARY: Rulings from Judge Amy Berman Jackson of the U.S. District Court in Washington, D.C., are expected soon in the ACLA's lawsuit against HHS concerning the PAMA final rule that set the course for the new Medicare CLFS rates implemented in January 2018. One lawyer following the lawsuit explains that ACLA has presented strong arguments. How quickly the case will move beyond the initial motion stages is unknown.

CLINICAL LABORATORIES NATIONWIDE are coping with the financial consequences of the new lower payment rates the Medicare program imposed on Jan. 1. Meanwhile, the civil case that the **American Clinical Laboratory Association** (ACLA) brought against the federal **Department of Health and Human Services** (HHS) puts forth reasonably strong arguments in its favor, says a lawyer following the case.

Late last month in U.S. District Court for the District of Columbia, federal Judge Amy Berman Jackson denied a request from the ACLA to schedule oral arguments in its case against HHS Secretary Alex M. Azar. In response to the ACLA's request, Jackson wrote, "The court is well aware of the parties' interest in expedition and will set a hearing if and when it deems it necessary to do so." Jackson also is hearing arguments in Special Counsel Robert Mueller's investigation into Russian meddling in the 2016 election.

For clinical laboratories, any delay may mean more clinical labs will close, as ACLA argued in its request to move the case to oral arguments. While ACLA awaits a court date for oral arguments, clinical lab directors may want to know the strength of the ACLA's case. To address this issue, THE DARK REPORT turned to Charles C. Dunham, IV, a partner in the Houston and New York offices of the Health Care and Life Sciences practice of the national law firm **Epstein Becker Green, PC**.

Statutory Bar in Question

Dunham acknowledged that both sides in the case have good legal arguments. While HHS has the strength of agency discretion and favorable case law on its side, the ACLA, however, has strong positions on at least two of the most important issues in the case, he said.

First is a preliminary issue of whether the ACLA is precluded from seeking judicial review of the actions HHS took based on language in the Protecting Access to Medicare Act (PAMA) of 2014. The act specifically precludes "administrative or judicial review of the establishment of payment amounts under Section 216 of PAMA."

ACLA argued that the statutory bar is limited and does not preclude the right to

challenge HHS acting outside of its statutory authority, Dunham explained. In rebuttal, HHS argues that the ACLA's challenge is nothing more than a challenge to the payment amount, and the reporting of the private payer rates is integral to the establishment of the payment amount.

HHS Authority Questioned

In legal terms, this first issue revolves around whether ACLA has legal standing to challenge what HHS calls its PAMA final rule that resulted in the 2018 CLFS rates. In his analysis of the case, Dunham said that the legal arguments, as presented, favor the ACLA. *(See sidebar, next page.)*

The second significant issue involves whether HHS has the statutory authority and followed the intent of Congress when it essentially redefined the term "applicable laboratory" by defining the terms "laboratory" and "revenue."

HHS argues that the agency was tasked with crafting a definition for applicable laboratory because it believes the "statute left unspecified the precise meaning of a laboratory and how to determine its received revenue," Dunham explained. ACLA argues that there is no ambiguity in the statute with regard to these terms, and instead of clarifying any questions concerning how to calculate the Medicare revenue a laboratory receives, HHS effectively rewrote the statutory definition in contrast to the statute's plain text and inconsistent with Congressional intent, added Dunham.

Review of Legal Briefs

After reviewing the legal briefs on both sides of this issue, Dunham said the legal arguments more favor ACLA but HHS dropped the ball on its approach to arguing its position.

"There is no disagreement that the term 'laboratory' under PAMA was meant to include all laboratories—hospital, physician, and independent," Dunham explained. "The statute even makes reference to hospital labs in clarifying that Medicare payments to hospital labs will be affected when a hospital lab provides test services that are paid for separately.

"Clearly, there was congressional understanding of the distinction and how hospital labs in particular were paid," he said. "The logical conclusion would be that a laboratory is any entity licensed under CLIA. That's very clear.

"Then, the real question HHS faced was: How does a laboratory calculate the Medicare revenue received from activities that labs perform, especially for hospital and physician office labs," Dunham said. "HHS admittedly struggled to address these issue, but instead of providing a framework for hospitals to attribute Medicare bundled payments under PPS to laboratory services, it chose to redefine a laboratory by its NPI."

Congressional Intent Debate

"Doing so affected which labs are deemed an 'applicable laboratory' and required to report the private payment-rate data that HHS collected, and, in fact, HHS acknowledged in its analysis that it had data from some labs but not from others," noted Dunham. "For example, more than 90% of all hospital labs were not included when HHS collected the payment-rate data. Given that health insurers and the federal Medicare program pay hospital labs more than they pay independent labs for the same tests, leaving out hospital labs skews HHS' results."

How HHS attributed revenue to hospital labs may have been part of the problem. "Because HHS pays for laboratory services in many different ways, how do you attribute payments under the Hospital Outpatient Prospective Payment System (OPPS) or other bundled payment arrangements?" Dunham acknowledged. "And how do you pull out the lab portion of those payments? Do you define it by a percentage, for example?"

HHS' decision to argue that the statute was ambiguous and required HHS to

PAMA Language Precludes Review, But Lawyer Says ACLA Can Proceed with Its Legal Case

ONE ARGUMENT the federal Department of Health and Human Services (HHS) raised in this case is whether the American Clinical Laboratory Association (ACLA) has standing to bring the case at all.

"In this case, Congress included language in PAMA that precludes a challenge to certain HHS actions, and Congress was explicit on what was barred," stated Charles C. Dunham, IV, of Epstein Becker Green. "The statutory bar removes the ability to challenge HHS' establishment of payment amounts. HHS cited supporting case law that reinforces the concept that Congress can prevent judicial review, including the ability of the federal agency to define a payment formula and choose specific data.

"In my opinion, however, that's not what ACLA is challenging in its case," he noted. "ACLA points out there is a difference between the process of making rules that are inconsistent with the statute and the process under PAMA of HHS taking the information that's received and calculating it based upon the weighted median formula to establish payment rates based on those calculations. For example, whether HHS received all applicable information available to calculate the Medicare rate would likely not be challengeable based on the statutory bar.

"What could be challenged is the fact that HHS didn't receive all the information required under statute to make an accurate assessment of payment rates because it redefined statutory definitions and thereby altered Congressional intent," Dunham said.

"In addition to those questions, ACLA is arguing that HHS didn't follow the statute," he added. "That's an important distinction: whether, in fact, HHS acted beyond its authority in promulgating these final rules, and in doing so, may have excluded data in conflict with PAMA. That's what ACLA is saying, and that's a point that should certainly be subject to challenge."

After he explained the judicial review issue, Dunham added two additional legal points, both of which appear to favor the ACLA's case, he said. "First, I would add that HHS had minimal discretion in what laboratory was an 'applicable lab,'" he explained. "In other words, the formula for determining an applicable laboratory was defined in the statute except for the ability of HHS to define the minimum threshold of Medicare revenues from CLFS and PFS.

Hospital Labs Carved Out

"In the way it promulgated the rules under PAMA, HHS did, in fact, carve out almost all hospital labs," he said. "That's the issue ACLA is challenging, and it's a decent legal argument."

Dunham's second point related to whether ACLA has legal standing to bring this case, and HHS has argued that ACLA does not have such standing. "Standing is the ability of ACLA to bring a suit on behalf of its association members," he explained.

"HHS has argued that there has been no injury to labs and no demonstration that Medicare rates are impacted because many hospitals were not required to report," he said. "Oddly enough, HHS also argues that administrative remedies were not exhausted, which contradicts what HHS has been saying: that the establishment of the payment amounts could not be challenged under the statutory bar.

"Therefore, the standing issues are more in favor of the ACLA," he said. "HHS doesn't have strong arguments on lack of standing.

"ACLA made it clear by stating bluntly that HHS didn't cite any case in which a court concluded an association lacked standing," he said. "ACLA also said it was not aware of any such case. So on the standing issue, this is not likely to be a hurdle that will stop ACLA from moving forward."

define the terms 'laboratory' and 'revenue' may prove to be harmful to its case, Dunham suggested. Instead, HHS may have been better served to refocus the argument, not on whether the statute was ambiguous, but on the practical problems that required HHS to establish a framework for calculating Medicare revenues related to lab services, he said.

"ACLA did a nice job arguing this point when it said that, instead of clarifying the term 'laboratory,' HHS effectively replaced the term 'laboratory' with 'any entity within an NPI that has at least one component that is a laboratory,'" Dunham commented. "The problem with this method is that hospitals get so much Medicare revenue and if that's how HHS is defining a 'laboratory' for calculating 'revenue', then HHS is not actually focused on the laboratory portion of that revenue.

"That's a very strong argument on ACLA's part," he added. "ACLA argues that, essentially, HHS has now redefined the term 'laboratory' from what the Congressional intent was. In addition, ACLA should be able to challenge the fact that HHS did not have the statutory authority to redefine the term 'laboratory' and thus change the whole construct.

A Weakened Argument

"HHS could have easily resolved this problem with an adjustment factor," Dunham suggested. Hospitals could have attributed payments from Medicare OPPS for lab services using a formula that accounts for the share of payments that should be apportioned for lab testing, he explained. Doing so likely would have been an easier task than following the reporting obligation under PAMA.

"That was an available option and none of the case law that HHS cites in its motion papers indicates HHS was precluded from doing so," Dunham explained.

"These calculations can be performed without the need to redefine what 'laboratory' and 'revenue' mean under PAMA," he added. "That is ACLA's argument: that this can be done without carving out significant portions of laboratories in the market.

"HHS asserts that its data-collection efforts resulted in fair representation from all clinical labs, and in doing so, HHS weakens its case, because HHS' own data show that only 21 out of 7,000 hospitals reported to CMS," Dunham suggested. "HHS might have a stronger argument if it established an equitable process for collecting data from all or most laboratories," he concluded.

THE DARK REPORT provided these legal perspectives from Dunham to help pathologists and clinical lab executives understand that the plaintiff, ACLA, has several points to argue in support of its position in this lawsuit. TDR

—Joseph Burns

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Other Important Issues in ACLA vs. HHS Lawsuit

IN HIS REVIEW OF THE LAWSUIT FILED by the American Clinical Laboratory Association against the Secretary of Health and Human Services, attorney Charles C. Dunham, IV, identified two more issues of relevance in this case.

Along with the issues of Statutory Bar and Standing discussed in the accompanying story, Dunham mentioned two other underlying issues.

First, did HHS violate its statutory authority in promulgating the final rules (*ultra vires*)? Second, if HHS did not, should HHS be afforded agency discretion (**Chevron** case) in its approach to define how a laboratory calculates its Medicare revenues by its NPI? Space limitations prevented THE DARK REPORT from providing Dunham's detailed comments on these two legal issues in this lawsuit.

Lab Billing Update

Inconsistent Billing Causes Patients to Find New Providers

High deductibles, confusion over payments are reasons why patients leave providers of care

THERE IS A NEW SOURCE OF LOST BUSINESS for physicians, clinical laboratories, and others. Patients are losing patience with confusing bills from their providers and opting to find new providers who offer simple, clear, and consistent bills. This turnover in patients was one key finding in a recently-published report.

The report, issued by **InstaMed**, a national payment network based in Philadelphia, determined that, as healthcare costs rise and there is increased confusion about what patients owe, consumers become dissatisfied and increasingly are willing to choose new providers.

"The consumer voice will become harder to ignore as dissatisfaction takes the shape of customer attrition and lost revenue for providers," wrote the authors of InstaMed's "Trends in Healthcare Payments Eighth Annual Report: 2017."

For clinical laboratories, the InstaMed report made four points. *(See sidebar on page 16.)*

1. Consumers are unhappy;
2. Digital transactions have consequences in healthcare;
3. Using paper creates friction; and,
4. Security is a growing concern.

Two factors influencing how providers, including labs, bill and collect from patients are the sustained rise in healthcare costs and the growing number of consumers enrolled in high-deductible health plans (HDHPs). It is smart business for clinical labs and pathology groups to acknowledge that the steady increase in patients with high deductibles means it is necessary to update and increase the accuracy of the lab coding, billing, and collections process. Of equal importance, labs need to rework their billing procedures in ways that improve the customer experience.

An Experience-Revenue Link

The InstaMed report states that patients who have a poor, confusing, or frustrating experience [with how they are billed by their providers] will move to other providers, leading to "damage to healthcare brands and ultimately lost revenue."

"Consumer loyalty is increasingly tied to the healthcare payments experience, as 65% of consumers would consider switching healthcare providers for a better healthcare payments experience," the report said.

Consumers are attracted to HDHPs because the premiums for these plans are lower than they are for other health plan options. However, HDHPs require consumers to pay more at the point of care, including when they need clinical lab testing and other services. Therefore, clinical labs would do well to make payments easier and less confusing whenever possible, the report showed.

"For provider organizations, there is a direct connection to patient collections and their bottom line as payers cover less of the amount due for services rendered," the report states. "As consumer responsibility and frustrations increase, that con-

nection, and the [financial] impact to providers, becomes more prevalent."

In 2016, hospitals delivered $38.3 billion in uncompensated care. "This could be why 58% of providers report their top revenue cycle concern is related to patient collections," the report said.

Medical bills from providers confuse 70% of consumers, and the explanation of benefits that health insurers send to members confuse 72% of consumers, the report showed. What's more, only 9% of consumers can define such common terms as a premium, deductible, co-insurance, or out-of-pocket maximum.

For evidence of the depth of consumer confusion, the report states 73% of providers say it takes a month or more to collect a patient payment, while 80% of consumers report they pay their bills within three weeks.

Causes of Dissatisfaction

Among the experiences that cause dissatisfaction are: More than 50% of consumers received a bill for an amount they expected their health plan to cover or had an amount due for more than was expected. And, more than 25% of consumers had a medical bill turned over to a collection agency last year.

"These experiences could be why consumers not only feel healthcare does not deliver good value, but are also becoming fearful and frustrated with the industry," the report states. "Indeed, 40% of consumers fear the costs associated with an illness. That is more than the percentage of consumers who fear an illness itself."

InstaMed made four recommendations. One, consumer demands must be a top priority. Adopt best practices from other industries so providers can reduce friction in the consumer experience.

Two, resisting the digital world will backfire. "The data is clear: Consumers want automated and electronic payment options while clearly understanding what they owe and how to pay," the report said.

Consumers Are Unhappy with Unclear Provider Bills

TODAY'S HEALTHCARE CONSUMERS are dissatisfied with the lack of value they get from healthcare. This is one key finding in the reported issued by InstaMed. As healthcare costs rise, consumers want providers to offer more electronic transactions, eliminate paperwork, and beef up security, the report said. In the report, InstaMed highlighted the following four points.

First, consumers are not happy. While consumers spend more on healthcare every year, education and outreach to them about these payments have not kept pace with the rise in payment responsibility, leading to frustration and fear among consumers. "The consumer voice will become harder to ignore as dissatisfaction takes the shape of customer attrition and lost revenue for providers and payers alike," the report states.

Second, it is time to fully embrace digital transactions. Consumers demand convenient, frictionless payments and will turn to social media when experiences do not meet their expectations.

Third, paper is like sandpaper in healthcare. Overwhelmingly, healthcare remains loyal to paper, especially for payments. Heavy use of paper costs all industry stakeholders.

Fourth, security concerns aren't going away. Compromised data causes financial losses, reputational damage, and customer attrition.

Three, retire paper and embrace digital payments so providers can reduce overhead and collect more from consumers.

Fourth, security and compliance must be a priority. Providers need to recognize that the issue with data breaches is not if, but when. "Any organizations unsure if their data is at risk should assume the worst," the report states. TDR

—Joseph Burns

Lab Acquisitions Update

Myriad to Buy Counsyl, to Gain Presence in NIPS Test Sector

In women's health testing market, Myriad Genetics will have a commanding presence

LATE LAST MONTH, **Myriad Genetics Inc.** announced a definitive agreement to acquire **Counsyl, Inc.**, an innovative genetic testing company in South San Francisco, Calif., for $375 million. In a deal that is expected to close by early next year, Myriad will use a combination of cash and common stock.

Founded in 2007, Counsyl offers carrier and non-invasive prenatal screening (NIPS) tests. Over the past 12 months, the company did 280,000 reproductive genetic tests, generating $134 million of revenue, the companies said.

Counsyl has three products in women's health: Foresight, an expanded carrier screening test; Prelude, an NIPS test; and Reliant, a hereditary cancer test.

"Over Myriad's last three fiscal years (ending June 30), Counsyl has reported a 22% revenue compound annual growth rate—largely driven by volume," wrote Amanda Murphy, an analyst and partner with **William Blair and Company**.

For Myriad, the deal allows the laboratory testing company in Salt Lake City to position itself as a leader in genetic testing for women's health, expanding the customer base for Counsyl's reproductive tests by almost 300%, the companies said.

The deal also gives Myriad an innovative company that has commercial insurance coverage for its genetic tests, and room for more insurance coverage of its Foresight test for expanded carrier screening and its Prelude test for non-invasive prenatal testing, *Zacks* reported. THE DARK REPORT has covered the story about Counsyl's patient-friendly innovations. *(See "How Price Transparency Increased Lab's Revenue," TDR, Aug. 3, 2015.)*

By combining sales forces, the two companies will have a total of more than 300 sales professionals calling on the nation's 40,000 ob-gyns, the companies said. Myriad said it has a women's health sales force of about 225 representatives and Counsyl has about 80.

Strong Market Potential

In her analysis of the market potential behind Myriad's acquisition of Counsyl, Murphy wrote, "In aggregate, Counsyl is approximately 13% penetrated in the total women's health market for reproductive testing. Each additional 5% gain in market share translates to $50 million in revenue and $25 million in incremental earnings before interest, tax, depreciation, and amortization (EBITDA)."

Genetic testing labs serve only about 25% of the full market potential for reproductive health testing, a market that could grow at a compound annual rate of 15% to eight million tests annually, Murphy predicted. Counsyl's three tests represent a $5 billion market, she added.

In addition, there is strong potential for growth if health insurers cover more of these tests, she said. Most patients who get carrier screening tests do so for a limited number of genes, such as those for cystic fibrosis (CF), spinal muscular atrophy (SMA), and Fragile X, Murphy wrote.

While health insurers do not broadly cover expanded carrier screening tests, the **American College of Obstetricians and Gynecologists** (ACOG) last year recommended universal screening for CF and SMA, she said.

Value in Payer Coverage

"In addition, the [ACOG] committee pointed to use of expanded carrier screening panels as an acceptable strategy for prenatal screening," she wrote. "Finally, the use of non-invasive screening is moving into the average-risk market, which could further accelerate growth."

To bolster this point, she wrote that one of the strengths of the deal is Counsyl's strong relationships with health insurers. The company is in-network with about 90% of the nation's commercial payers. What's more, several professional organizations representing physicians providing women's health have guidelines that strongly support expanded carrier screening and non-invasive prenatal screening tests, Murphy said. Among these organizations are ACOG and the **Society for Maternal-Fetal Medicine**.

Expanded Carrier Screening

"Given that these guidelines have increasingly moved toward recommending expanded carrier screening and NIPS as the standard of care tests recommended for patients, management believes it is possible that the ACOG could strengthen its endorsement of NIPS in its 2018 professional guidelines," commented Murphy in her report.

In addition, although Medicaid pays for about half of all births in the United States, more than 90% of Counsyl's revenue comes from commercial insurance. "Thus, there is significant potential to expand Medicaid reimbursement," she explained. TDR

—Joseph Burns

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Buyers Pay Good Multiples to Buy Genetic Test Companies

TWO FINANCIAL ANALYSTS see an emerging trend involving genetic lab companies. In a report issued by Adam Abramowitz and Jonathan Bluth of **Intrepid Investment Banks**, Myriad Genetics' plan to acquire Counsyl exemplifies a possible trend in consolidation among diagnostic testing companies, such as **Konica Minolta's** acquisition last year of **Ambry Genetics** for $1 billion. *(See TDR, July 17, 2017.)*

The two analysts noted that Myriad is an established company that has been disruptive in the market for noninvasive prenatal screening (NIPS) tests, thus providing "a strong entry point and foothold in the large NIPS market with well-established reimbursement to fill out its test portfolio."

In addition, Abramowitz and Bluth said the purchase price represents about 2.8 times Counsyl's revenue of the previous 12 months. What Myriad is paying to acquire Counsyl is at the same dollar value that **Laboratory Corporation of America** paid when it acquired **Sequenom** less than two years ago, they added. In September 2016, LabCorp spent $302 million to acquire Sequenom, a competitor to Counsyl in the NIPS testing market.

In their report, Abramowitz and Bluth characterized the 2.8-times-revenue number as being a "relatively low" multiple when contrasted with that of **Invitae**, another genetic testing company that trades at a revenue multiple of more than five times its last 12 months' revenue, they said. They added that Invitae forecasts substantial revenue growth that translates into a revenue multiple of 2.9 times over the next 12 months, which, they added, is similar to the valuation of Counsyl.

"But, for other genetics diagnostics businesses, does this deal suggest that a nearly three-times-revenue multiple should be the new threshold for a flat revenue company in this sector?" they asked.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In New Jersey last week, David Nicoll, 44, the former owner of **Biodiagnostic Laboratory Services** (BLS) of Parsippany, N.J. was sentenced to 72 months in a federal prison. On the same day, his brother, Scott Nicoll, 37, who also worked at BLS, was sentenced to 43 months in prison. Both had previously pled guilty to U.S. District Judge Stanley R. Chesler. Each defendant was charged with one count of conspiracy to violate the Anti-Kickback Statute and the Federal Travel Act, and one count of money laundering.

MORE ON: *Biodiagnostic Lab Fraud Case*

Biodiagnostic Laboratory Services received more than $100 million in payments from Medicare and private payers. The federal attorney in New Jersey has successfully convicted 53 defendants, including 38 physicians. The *Parsippany Focus* said that "It is believed that this is the largest number of medical professionals ever prosecuted in a bribery case."

WORLD HEALTH ORGANIZATION'S LIST OF ESSENTIAL DIAGNOSTICS

There is now an international list of "Essential *In Vitro* Diagnostics (EDLs)." This list was published by the **World Health Organization** (WHO). The list has two tiers: Tier I for primary healthcare and Tier II for healthcare facilities with clinical laboratories. Included in the last are about 50 tests for the detection and diagnosis of common conditions, and over 50 tests for the detection, diagnosis, and monitoring of priority diseases. Priority diseases include HIV, tuberculosis, malaria, hepatitis B and C (HBV/HCV), HPV, and syphilis infections.

TRANSITIONS

- Lisa-Jean Clifford is the new COO and Chief Strategy Officer at **Gestalt Diagnostics** of Spokane, Wash. Clifford has held executive positions with **Psyche Systems**, **IDG**, **MathSoft**, **Ebusiness Technologies**, **McKesson HBOC**, and **IDX Systems**.
- **Cancer Genetics, Inc.,** of Rutherford, N.J., announced the appointment of Michael McCartney as its Chief Commercial Officer. McCartney has previously served at **SciKon Innovation**, **Carolina Life Sciences**, **BioAgilytix Labs**, **Roche Diagnostics**, **Siemens**, and **Abbott Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 9, 2018.