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EXCLUSIVE SERIES PART 2

CLIA laboratory directors testify in Theranos Trial!

In part two of our series, expert attorney looks at lab directors, lab owners and their risk for non-compliance, deficiencies

(See pages 12-21 inside.)

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

VALID Act vs. VITAL Act: Day of Reckoning for LDTs

TWO DISTINCTLY DIFFERENT BILLS HAVE SURFACED IN CONGRESS, each with the potential to have substantial impact on how laboratory-developed tests (LDTs) are regulated by agencies of the federal government. One bill even creates a new acronym for the lab industry: IVCT for *in vitro* clinical tests.

One bill is called the Verifying Accurate Leading-Edge IVCT Development Act of 2020 (VALID). It is 245 pages long and has bipartisan sponsors in the House and Senate. The other bill is the Verified Innovative Testing in American Laboratories Act of 2021 (VITAL). It is just seven pages long and is sponsored by Sen. Rand Paul, MD, (R-KY).

As you will read in our intelligence briefing on pages 3-7, The VALID Act is written to give the federal **Food and Drug Administration** (FDA) oversight of the class of tests currently known as LDTs. By contrast, the VITAL Act retains the role of the federal **Centers for Medicare and Medicaid Services** in overseeing LDT regulation under CLIA (Clinical Laboratory Improvement Amendments).

Clinical lab administrators and pathologists who currently utilize LDTs in their daily lab operations are advised to read both bills and study the positions issued by their laboratory associations and societies. They may want to express their opinions about each bill to their members of Congress.

My observation is simple and has two elements. First, no bill gets written in Congress unless some private individual, company, organization, or non-government organization lobbies individual Senators and Representatives and persuades them of the need for a specific bill to be written and passed into law.

Second, the more pages in a bill, the more significant the consequences for the industry to be regulated by the language of that bill. Clinical labs and pathology groups that use LDTs today will want to understand what is inside those 245 pages of the VALID Act and compare them to the content of the seven-page VITAL Act. Plenty of mischief can be hidden in 245 pages of lawmakers' prose.

As each of you develop your position on these two bills, remember that it was in 2014 when the FDA published draft rules that gave it the authority to regulate LDTs. That proposal was bitterly opposed by a large cross section of the clinical laboratory industry. Since then, opposing interests in the IVD industry and the clinical laboratory profession have been jockeying to advance their interests. That fact should motivate you to read the bills and speak to your elected officials. TDR

Congress May Soon Act on LDT, IVCT Regulation

Major changes in regulation of LDTs have the attention of many labs, IVD manufacturers

CEO SUMMARY: Congress is gearing up for a debate on how to regulate laboratory-developed tests (LDTs) and other in vitro clinical tests (IVCTs). The VALID Act sets the stage for the FDA to take a greater role in pre-market review of LDTs, and the VITAL Act proposes to keep those tests under CLIA while calling for a modernization of clinical laboratory test oversight. Some experts believe passage of the VALID Act would cause major changes in how labs are allowed to develop and offer LDTs.

TODAY'S STATUS QUO IN HOW LABORATORY-DEVELOPED TESTS (LDTs) are regulated may soon change if Congress passes a bill to give the federal **Food and Drug Administration** (FDA) oversight of LDTs and *in vitro* clinical tests (IVCTs).

And like many things in the clinical laboratory industry these days, there is a COVID-19 angle to this debate.

Depending on how a clinical laboratory manager views the landscape, the proposed heavyweight regulation—known as the Verifying Accurate Leading-Edge IVCT Development Act of 2021, or VALID Act—could bring about more needed test validations or crush innovation under regulatory burden.

Meanwhile, a smaller bill also has been proposed, called the Verified Innovative Testing in American Laboratories Act of 2021, or VITAL Act. This bill is largely an attempt to keep LDTs and other lab testing under the auspice of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

"COVID-19 has drawn new attention to this [issue]," said Tom Sparkman, Senior Vice President of Government Affairs and Policy at the **American Clinical Laboratory Association** (ACLA), in an interview with THE DARK REPORT.

"People need to be aware that there's a genuine chance that Congress will roll up their sleeves and take a real look at how oversight can be modernized," he added.

Debate over the passage of either bill is not imminent; expect to see congressional action in 2022.

Proposed by a bipartisan group of lawmakers, the 245-page VALID Act seeks to bring the regulation of IVCTs and LTDs

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under the FDA. Currently, these tests fall within CLIA oversight, but proponents believe FDA regulation is needed for *in vitro* diagnostic (IVD) tests because they are akin to medical devices and thus require extensive data collection.

Modernize IVD Law

"The bipartisan VALID Act is an important step toward the long-overdue modernization of the law for all diagnostic tests," Scott Whitaker, President and CEO of the **Advanced Medical Technology Association**, said in a press release.

"It calls for smart reforms that will incentivize and improve the development of the advanced, reliable tests patients depend on, regardless of where those tests were developed," he added.

The VALID Act has been introduced in the House of Representatives and Senate. Representatives Diana DeGette (D-CO) and Larry Bucshon, MD (R-IN) led the bill in the House, and Senators Richard Burr (R-NC) and Michael Bennet (D-CO) led it in the Senate. Senator Mike Braun (R-IN) cosponsored the bill.

On the other side of the argument is the VITAL Act, a seven-page proposal that calls for LDTs to remain under CLIA. The bill also seeks recommendations about how the federal government can modernize clinical laboratory oversight. Senator Rand Paul, MD (R-KY) is the bill's only sponsor.

The VITAL Act has support from dozens of lab industry groups and parties, including the **Association of Molecular Pathology** (AMP), **American Association for Clinical Chemistry** (AACC), and various departments of pathology at hospitals and universities, all of whom sent a letter to Paul in support of the bill.

"CLIA has served this country well for decades but has not evolved with science and medicine," according to the letter. "The advancements in laboratory medicine and pathology over the past decades warrant that this system be updated to align federal standards with those that most laboratories are already meeting or exceeding today. We are hopeful for the opportunity to work with CMS to modernize CLIA, which would be made possible by the VITAL Act." *(See the table on page seven for a comparison of the two proposals.)*

Although the CLIA-or-FDA debate over regulating tests has occurred for years, the COVID-19 pandemic amplified calls for keeping LDTs out the FDA's oversight. In early 2020, an FDA guidance indicated that emergency use authorization for LTDs to detect the presence of the SARS-CoV-2 coronavirus fell under the agency and not CLIA. Because of that, labs could not use LTDs for COVID-19 tests, which led to a decreased availability of initial testing, according to a November 2021 article in *The Yale Law Journal*.

In a related development, on Nov. 15, 2021, the federal **Department of Health and Human Services** reversed a Trump administration policy that prevented the FDA from requiring pre-market reviews of LDTs. The Trump administration intended its policy to speed up availability of COVID tests while under emergency use authorization.

More Regulations for Industry

Generally, manufacturers of *in vitro* test kits and large commercial labs support the VALID Act. The manufacturers argue that they are subject to FDA oversight, so it is fair that LDTs also come under the agency. The bill offers a rare case of big business endorsing more regulations for an industry.

"Clinical labs are used to dealing with the CLIA risks and being regulated by CLIA," Mark Birenbaum, PhD, executive director at the **National Independent Laboratory Association** (NILA), told The Dark Report. NILA has not taken a formal position on either bill, although the association did share detailed comments with the sponsors of the VALID Act when it was introduced earlier this year. *(Visit https://www.nila-usa.org/images/nila/2021/NILAVALIDActComments.pdf to read Birenbaum's full comments.)*

"Manufacturers who produce kits and reagents that are sold to and used by a wide

array of labs usually go through the FDA process and they're very familiar with the FDA, but not so much CLIA," Birenbaum added. "It's been a separation where if the organization sells a piece of equipment that does 20 chemistry tests, it goes through the FDA process to get cleared for clinical use, and if the organization is a clinical lab, its testing is performed in compliance with CLIA requirements.

Different Uses for LDTs, IVDs

"Clinical laboratories develop LDTs for a variety of reasons. Because IVD tests undergo FDA approval, test manufacturers might have a disincentive to refine them because modifications to an existing IVD test may require additional regulatory review," Birenbaum said. By comparison, LDTs do not require FDA approval, so laboratories are able to modify existing LDTs to meet patient needs.

"Manufacturers might feel that's unfair because they are required to go through the rigorous and expensive FDA process, but labs offering LDTs do not. These labs can validate their assays under CLIA and then offer those tests," Birenbaum said.

If FDA oversight is formalized, the associated user fees will become a major challenge for smaller laboratories. "These fees could impose unsustainable costs on community and regional laboratories and facilitate anticompetitive behavior within the laboratory and IVD industry," Birenbaum said.

Opponents of the VALID Act argue that the cost and time associated with FDA review would be out of reach of many academic and independent clinical laboratories. This would stifle innovation when it comes to LDTs. Some critics also contend that the VALID Act will protect the existing market share of larger lab companies by building barriers of entry for smaller lab competitors.

A major provision of the VALID Act would require laboratories that seek test review to provide clinical validity data,

Data Collection for Proposed FDA Review

THE VERIFYING ACCURATE LEADING-EDGE IVCT DEVELOPMENT ACT OF 2021, or VALID Act, proposes to bring clinical laboratory regulation under the Food and Drug Administration for a pre-market review process.

As part of the review, test developers would need to provide a variety of data as outlined in the bill:

- Description of the test's intended use;
- Explanation regarding test function and any significant performance characteristics;
- Details about a test's development and validation activities;
- Synopsis of any existing alternative practices or procedures for diagnosing the disease or condition for which the *in vitro* clinical test is intended;
- Brief description of the foreign and domestic marketing history of the test;
- Summary of any studies submitted for such test, including descriptions of the objective of the study, the experimental design of the study, how the data was collected and analyzed, the results of the technical data submitted, and any nonclinical or clinical studies;
- Risk assessment of the test;
- Details that show the data constitutes valid scientific evidence and a discussion of any adverse effects of the test on health and proposals to mitigate those risks, if any; and,
- Valid scientific evidence to support the analytical and clinical validity of the test, including raw data.

Proponents of the VALID Act contend that these data requirements bring laboratory tests more in line with other pre-market reviews, while critics argue that the provisions will be too burdensome for many labs to produce.

which is a significant change from what labs provide under CLIA.

"Establishing clinical validity for a new diagnostics test takes a lot of time and money, often millions of dollars," Birenbaum said. "The CLIA program doesn't review clinical validity. CLIA covers what it calls 'analytical validity,' meaning the technical aspect of the test. Is the test accurate? Is it reproducible? Does it test for the component for which it is intended to test?

"Whereas 'clinical validity' [means]: Is this test medically useful?" Birenbaum added. "A lab could have the perfect test that measures the target biomarker with accuracy 100% of the time. But the relevant next question is: Do the results from this lab test help in the clinical setting? Is it useful for physicians using the test results? The answer could be no, it's just not useful.

"So, clinical validity is a different standard," he noted. "To establish clinical validity requires the clinical lab or other test developer to conduct clinical studies and similar supporting reviews. These are very difficult for many labs to conduct because of cost, time, and resource issues."

Curbing LDT Development

The AACC—which supports the VITAL Act—worries that clinical laboratories will curb LDT development because it will become too expensive, should the VALID Act become law.

"Expanding oversight to include the Food and Drug Administration will divert limited laboratory resources from the provision of care to new, duplicative administrative requirements," AACC President Stephen Master, MD, PhD, wrote in a letter to the VALID Act's sponsors. "The additional costs associated with this bill may force many laboratories providing LDTs to discontinue this vital patient service."

The ACLA does not view the VALID Act as a big manufacturer versus small lab contest, but instead a debate about the complexity of tests that are offered.

"You might be a high-complexity lab, but it might vary on whether you're using high-volume IVD test kits or you're using laboratory-developed tests," Sparkman said. "And if you're using laboratory-developed tests, are those [assays] simple ... in-house modifications to test kits or are the assays more complex, from-the-ground-up development?"

Allow Modifications?

"There are proposals [to the VALID Act] to allow more modifications, and that's certainly what ACLA has been arguing—that there should be a greater breadth of modifications that should not require full-blown applications with months of [FDA] review and untold gigabytes of data," he said. *(See the sidebar on page five for further details about proposed data collection under the VALID Act.)*

Regardless of where they fall in the debate between the VALID and VITAL Acts, clinical laboratory executives and managers should take the opportunity to contact their state's Congressional members and express their thoughts.

"Don't underestimate the power of your own voice," Sparkman said. "Speak with legislators. All too often folks don't think enough about what is necessary for clinical laboratories to provide high quality tests for patients."

It is possible either proposal could become part of a larger bill. Congress often uses a major bill that is expected to pass as the vehicle to fix recognized issues, and to combine smaller bills which have widespread support among members of Congress.

The Medical Device User Fee Amendments will come up for reauthorization in 2022 and some veteran watchers of Congress consider that this legislation may be used to pass bills such as the VALID Act or VITAL Act. TDR

Contact Tom Sparkman at tsparkman@acla.com; Mark Birenbaum, PhD, at nila@nila-usa.org.

Comparison of VALID Act and VITAL Shows the Differences in Each Proposed Law

	VALID Act	VITAL Act
Full act name	Verifying Accurate Leading-Edge IVCT Development Act of 2021	Verified Innovative Testing in American Laboratories Act of 2021
Bill Numbers	House bill H.R.4128 Senate bill S.2209	Senate bill S.1666
Sponsors	Sen. Michael Bennet (D-CO), Sen. Mike Braun (R-IN), Rep. Larry Bucshon, MD (R-IN), Sen. Richard Burr (R-NC), and Rep. Diana DeGette (D-CO)	Sen. Rand Paul (R-KY)
Provisions	Developers shall apply for premarket approval of IVCTs if there is insufficient evidence of analytical validity or clinical validity or if it's reasonably possible an IVCT will cause serious adverse health effects. Applications shall include a summary of test data and scientific evidence to support analytical and clinical validity of the test. Through a technology certification, developers can submit an IVCT to the FDA for review, and if granted, the certification allows them to develop similar tests without going back for review each time. The FDA must establish a program for rapid review of breakthrough IVCTs that provide effective treatment of life-threatening diseases.	The federal government should work to ensure that regulatory oversight of laboratory tests does not limit patient access, impede innovation, or limit a test's sustainability as a result of being unduly burdensome or beyond the fiscal capacity of the laboratory to reasonably validate and perform. No aspects of LTDs shall be regulated under the FDA. No later than 180 days after enactment of the bill, the secretary of health and human services shall report to the Senate's Committee on Health, Education, Labor, and Pensions about recommendations to update clinical lab regulations and provide an assessment of LDT use during the 2020 pandemic response.
Exemptions	IVCTs being marketed before the VALID Act goes into effect. Low-risk tests. IVCTs that are granted emergency use.	No new exemptions.
Review timelines	The FDA shall make a decision no later than 90 days after an application is submitted.	No new requirements noted.

This chart's information is current as of November 24, 2021. As with any proposed bill before Congress, changes to requirements and provisions are possible and even probable.

Florida Laboratory Owner Gets 82-Month Jail Term

Executive-owned labs in two states participated in scheme to defraud Medicare using false claims

CEO SUMMARY: Federal prosecutors are sending a clinical lab owner to federal prison for almost eight years. Hopefully, this is a sign that the Department of Justice (DOJ) is ready to use criminal indictments more frequently against lab owners, lab managers, and lab sales reps who violate the federal anti-kick-back statute. Morever, this case is just one of several that the DOJ has filed against a number of laboratory owners. Some of this enforcement is related to false COVID-19 test claims.

FEDERAL PROSECUTORS SEEM MORE WILLING TO PURSUE CRIMINAL FRAUD CHARGES against clinical laboratory owners and others who work for them, based on recent announcements in November from various U.S. Attorney's Offices.

Across the country, individuals face trials or prison sentences for alleged wrongdoing with clinical laboratory testing and false claims:

- In Florida, a laboratory owner was sentenced to 82 months in prison for defrauding the federal **Medicare** program by paying illegal kickbacks to physicians.
- In New Jersey, a former medical laboratory sales representative faces a prison term after pleading guilty to conspiring to violate the federal anti-kickback statute.
- In Arkansas, a grand jury indicted a lab owner on charges of healthcare fraud allegedly in connection with over $100 million dollars in false billings for urine drug tests and COVID-19 tests.

These developments should serve as a warning to clinical lab administrators and pathologists to keep a close eye on their own operations and audit claims regularly.

Nearly Seven Years in Prison

On Nov. 9, Leonel Palatnik, the owner of clinical laboratories in Florida and Texas, was sentenced to 82 months in prison, a jail term that is one of the longest in the history of the clinical lab industry.

In May, Palatnik and Michael Stein were named in a 20-page indictment filed in **U.S. District Court for the Southern District of Florida**, according to the federal **Department of Justice** (DOJ).

In the nine-count indictment, the DOJ charged Palatnik and Stein with one count of conspiracy to defraud the federal Medicare program and to pay and receive kickbacks, four counts of solicitation and receipt of kickbacks in connection with a federal healthcare program, and four counts of offering to pay and paying kickbacks in connection with a federal healthcare program.

Palatnik was co-owner of **Panda Conservation Group**, which operated clinical labs in Florida and Texas, court documents show.

DOJ Recommends Clinical Laboratories Be Alert for 'Red Flags' Consistent with Fraud

IN RESPONSE TO QUESTIONS FROM THE DARK REPORT, an official from the federal Department of Justice (DOJ) said executives working in clinical laboratories should be wary of sudden large volumes of lucrative tests, particularly if telemedicine is involved.

"Lab executives—like all Medicare providers—have an obligation to submit only true and correct claims, and to refrain from billing for medically-unnecessary testing or treatment and services not rendered," the official said. "Billing large numbers of claims for often abused and highly lucrative tests, such as cancer genetic testing, could be considered a red flag."

Telehealth Waiver Fraud

The DOJ's Health Care Fraud (HCF) Unit thoroughly investigates entities or individuals who exploit regulatory changes designed to enable access to care during the COVID-19 pandemic, such as telehealth waivers, the official added. "The HCF Unit knows how to handle telemedicine cases involving clinical laboratory providers, and in recent years, has taken concrete steps to coordinate the prosecution of these and other multi-jurisdictional cases across the country."

The HCF Unit does not collect statistics on the number of clinical laboratory owners who have been sentenced to prison, the official added. However, the unit has been active since September 2019, when it announced Operation Double Helix, an effort that resulted in federal criminal charges against 35 defendants associated with telemedicine companies and cancer genetic testing laboratories.

The operation snagged six laboratory owners or operators charged with various healthcare fraud and kickback schemes involving at least $787 million in fraudulent billings to Medicare and other insurers. *(See TDR, "DOJ Charges 35 Individuals in Genetic Testing Scam," Oct. 14, 2019.)*

False Claims Fraud

Other healthcare fraud units in the DOJ have accused people of filing false claims worth hundreds of million of dollars. Targets of these units included:

- In September 2020, prosecutors charged three laboratory owners with healthcare fraud and kickback schemes involving approximately $639 million in fraudulent claims billed to Medicare, Medicaid, and private health insurance companies.
- In September 2021, the government charged three medical laboratory owners and operators who submitted $210 million in false claims.

Additionally, Palatnik also controlled a holding company called **Anucan LLC** in which he and others involved with Panda owned multiple clinical laboratories, including **Amerihealth Laboratory** and **MP3 Labs**.

The labs specialized in genetic testing for cancer and cardiovascular deficiencies, the DOJ said.

As a result of the scheme, Medicare paid Panda's laboratories more than $61 million for genetic testing orders procured by illicit kickbacks between April 1 and Dec. 31, 2020, the DOJ reported.

Palatnik Takes a Plea

On Aug. 31, 2021, Palatnik pleaded guilty to one count of conspiracy to defraud the United States and offer kickbacks and one count of paying a kickback, the DOJ said.

He also agreed to cooperate with prosecutors. Under the plea agreement's terms, Palatnik must repay $61.3 million. During his incarceration, however, Palatnik must

pay 50% of his wages, if any, from a federal prison job or $50 per quarter if he does not work while in prison, records show. Upon release from prison, Palatnik needs to pay 15% of monthly gross earnings to the government unless the court alters the repayment terms.

Palatnik's attorney, Brian Bieber, JD, a criminal defense attorney with the Miami law firm of **Gray Robinson**, did not respond to THE DARK REPORT's request for comment.

Telemedicine Kickbacks

Court documents listed Michael Stein as the owner of **1523 Holdings**, a company that conspired with Palatnik and Panda, the DOJ alleged.

On June 17, Stein was arraigned in the U.S. District Court for the Southern District of Florida. He pleaded not guilty and requested a jury trial. That trial is continuing.

Palatnik allegedly conspired with Stein and other co-owners of Panda to pay illegal kickbacks to Stein in exchange for having Stein arrange for telemedicine providers to authorize genetic testing orders for Panda's laboratories.

Panda and 1523 Holdings exploited temporary waivers to telehealth restrictions that the federal **Department of Health and Human Services** put in place during the COVID-19 coronavirus pandemic, the DOJ noted. Those amendments expanded access to care so that Medicare beneficiaries could get medical consultations from home.

"Palatnik and his co-conspirators took advantage of these waivers by using telehealth providers to authorize thousands of medically-unnecessary cancer and cardiovascular genetic testing orders," the DOJ charged. "In exchange, Panda gave these providers access to beneficiary information and the opportunity to bill for purported telehealth consultations with Medicare recipients, which often did not take place."

In a sentencing memorandum, DOJ prosecutors explained that Palatnik admitted in his plea agreement that Panda and its owners targeted Medicare beneficiaries with deceptive online advertising for genetic testing in order to obtain their insurance information and genetic material.

In that agreement, Palatnik acknowledged that starting in about April 2020, he and other Panda owners agreed to pay Stein's company a $50,000 monthly kickback in exchange for having Stein arrange for telemedicine providers to authorize genetic testing orders for Panda's medical laboratories.

Palatnik understood that the arrangement with Stein's company was illegal and, therefore, Palatnik and other Panda owners entered into a sham contract with Stein for purported IT and consultation services to disguise the purpose of the payments, court documents show.

Also, Palatnik acknowledged that he knew that Stein recruited and supervised telemedicine providers who had no pre-existing relationship with the recruited patients and typically did not speak with the patients before authorizing the testing.

Other clinical laboratory professionals also have dealt with criminal enforcement from prosecutors.

Genetic Test Kickbacks

In a New Jersey case, former clinical laboratory sales rep Terri Haines pleaded guilty on Nov. 17 to paying a kickback and bribe to Lee Besen, MD, a primary care physician in Pennsylvania.

Haines used Besen's name and medical credentials to order tests to detect genetic predisposition for cancer, also known as CGx tests, for Medicare patients she met at health fairs, according to the **U.S. Attorney's Office for the District of New Jersey**.

Haines faces up to five years in prison and a fine of $250,000, or twice the gross

gain or loss derived from the offense, whichever is greatest. Her sentencing is on March 22.

Haines owned **GenRx Testing Solutions**, which had a business relationship to provide DNA samples to a New Jersey laboratory that prosecutors did not publicly identify. In exchange for sales commissions, Haines sent the samples collected from Medicare patients at the health fairs to the lab, using Besen's credentials to order the CGx tests. Medicare reimbursed more than $341,000 for the tests, which were ordered from July 2019 through October 2019.

Besen never attended any of the fairs and never met the patients for whom the genetic tests were ordered, the U.S. Attorney's Office said. Besen previously pleaded guilty for his role in this and similar schemes involving CGx tests.

"He was also recorded saying that he hoped the money he made from CGx tests would help him 'retire early,'" according to the U.S. Attorney's Office.

In one example of the conspiracy, Haines paid Besen $1,500 sometime in July 2019 to use his name and credentials to order the CGx tests.

On July 19, 2019, Haines obtained a sample from a Medicare patient in Pennsylvania, and subsequently on August 19 caused the New Jersey lab to submit a claim for $10,280 for this patient's test. Medicare reimbursed the lab $7,223, and Haines received a commission for the test sample.

'Lavish Lifestyle'

Meanwhile, in Arkansas, prosecutors allege that laboratory owner Billy Joe Taylor filed claims for diagnostic tests that were not ordered by physicians and had not been performed. Taylor's labs submitted false Medicare claims worth more than $100 million.

"Taylor allegedly then used the proceeds of the fraud to live a lavish lifestyle, including purchasing numerous luxury automobiles, including a **Rolls Royce** Wraith, as well as real estate, jewelry, guitars, and other luxury clothing and items," according to the U.S. Department of Justice.

Taylor was charged with 16 counts of healthcare fraud and one count of engaging in a monetary transaction in criminally-derived property. He pleaded not guilty at his arraignment on Nov. 23 in **U.S. District Court in Fort Smith, AK**, according to the *Arkansas Democrat-Gazette*. A judge scheduled Taylor's trial for January 10, 2022.

Bought Existing Lab Firms

The fraud allegedly occurred from February 2017 through May 2021. During that time, Taylor purchased existing laboratories and misappropriated confidential Medicare beneficiary and provider data that previously had been used to submit claims to Medicare, according to Taylor's indictment.

He then used that information to repeatedly submit claims for urine drug tests and respiratory illness tests during the COVID-19 pandemic, prosecutors said. The indictment lists a variety of Taylor's personal property that was tied to the false claims, including:

- Dozens of motor vehicles and trailers,
- Personal watercraft,
- Luxury footwear,
- Various musical instruments, recording equipment, and amplifiers, including a baby grand piano,
- Jerseys signed by retired athletes Shaquille O'Neal, Troy Aikman, and Wade Boggs,
- Guns, and,
- Hundreds of thousands of dollars in bank accounts.

In addition to the possible forfeiture of the seized items and real estate, the government also seeks the forfeiture of $12.5 million, which is equal to the gross proceeds traceable to the alleged violations. TDR

Who's at fault? The lab director or Elizabeth Holmes?

In Theranos' Trial, CLIA Laboratory Director Has a Starring Role

Matthew J. Murer, JD

CEO SUMMARY: Most clinical lab directors understand the risks that come with running a CLIA-licensed lab. Such risks are at the forefront of the criminal trial of Elizabeth Holmes, founder of now-defunct Theranos. During the trial, federal prosecutors and defense attorneys questioned four of Theranos' former lab directors about inaccurate test results and failures to comply with CLIA's requirements. In this second part of our series, an attorney comments on the lab directors' testimony.

SECOND IN A SERIES

As the criminal fraud trial of Elizabeth Holmes unfolds in Silicon Valley, attorneys on both sides have focused on two key elements in particular: the role of the CLIA lab director and the CLIA regulations themselves.

Since the trial began Sept. 8, federal prosecutors and lawyers for the defense asked multiple questions about the responsibilities a laboratory director has under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and how the lab director can be held responsible for CLIA violations, particularly equipment failures and incorrect lab test results.

The case may be a first in the history of the U.S. criminal justice system in which trial lawyers have focused on the rules involving diagnostic testing and how pathologists could be held responsible for a lab's failures to comply with CLIA and any patient harm that results.

Since September, lawyers for both sides have questioned four former **Theranos** lab directors about their role as the person most responsible for ensuring that the lab meets all CLIA requirements at all times.

In many ways, the case offers multiple lessons for clinical pathologists and lab directors about how to properly run a clinical laboratory.

In the case of *United States vs. Elizabeth Holmes* in the U.S. District Court for the Northern District of California in San Jose, Holmes faces 10 counts of wire fraud and two counts of conspiracy to commit wire fraud. As of Nov. 15, the judge and jury had heard testimony for more than 11 weeks. Balwani faces the same 12 counts and will be tried separately in a case to be heard next year.

The government's case is based on the assertion that Holmes and Balwani knew that Theranos' analyzers did not work and should have informed investors about the poor reliability and accuracy of the testing equipment.

What Holmes and Balwani knew and when they knew it became linked to what the lab directors knew and were required to do under CLIA. Lawyers on both sides of the case spent days questioning four former lab directors who worked at Theranos before the lab closed in September 2018, just three months after a federal grand jury indicted Holmes and Balwani.

In that indictment, investigators from the federal **Department of Justice** (DOJ) alleged that the pair had "engaged in a multi-million-dollar scheme to defraud investors and a separate scheme to defraud doctors and patients."

Legal Issues in Theranos Case

To cover all these lessons, The Dark Report asked attorney Matthew J. Murer, JD, a partner with the Chicago law firm of **Polsinelli**, to review the issues that are most important for clinical lab directors.

Murer has more than 27 years of experience advising laboratory directors and managers about CLIA compliance. Often, hospitals, laboratories, and other providers have retained Murer's services in an effort to defend and maintain their CLIA certificates after the federal **Centers for Medicare and Medicaid Services** (CMS) has cited those labs for CLIA deficiencies.

In our earlier coverage of this case, The Dark Report showed how DOJ lawyers depicted why the actions of Holmes, other company executives, and clinical laboratory directors did not follow the CLIA rules when they had problems with the company's proprietary testing equipment.

"Also, those executives did not disclose the problems they had while continuing to promote to investors that their testing and equipment was reliable," Murer said. *(See TDR, "CLIA Lab Director Testimony Shows Risks to Pathologists," Nov. 8, 2021.)*

Compliance with CLIA

In part one of this series, we reported on the failure of the Theranos laboratory staff to conduct proficiency testing properly and the lab director's responsibilities to ensure

that PT testing was done in compliance with CLIA.

Also in part one of this series, Murer answered four questions about the case, mostly addressing the consequences of the actions of Adam Rosendorff, MD, a board-certified clinical pathologist and former Theranos lab director. Rosendorff served as laboratory director from April 2013 through December 2014 and spent hours on the witness stand over several days.

Four Questions

In this second installment, Murer answers the following questions:

- What obligation does a laboratory director have to notify regulators about problems in a lab?
- What problems arose over the CLIA laboratory director of record?
- Is it okay for laboratory directors to send company materials to their private email addresses?
- What possible punitive actions does Holmes face and, when CMS finds deficiencies at a lab, what punitive actions can the agency take against the CLIA laboratory director?

In addition to Rosendorff, three other former laboratory directors at Theranos have testified: Sunil Dhawan, MD, who testified that he was Balwani's dermatologist and accepted the position as laboratory director after Rosendorff resigned; Lynette Sawyer, PhD, who was added to Theranos' lab license in late 2014 and resigned six months later; and Kingshuk Das, MD, who was the last of the four laboratory directors.

What Lab Staff Knew

"The DOJ's attorneys seek to demonstrate that the lab's employees knew that the testing equipment did not meet CLIA's standards and that therefore, Holmes and Balwani knew that and did not disclose those failures to investors," Murer observed.

"Meanwhile, the defense also has used CLIA to shift responsibility away from Holmes," he said. "The defense asserts that Theranos' laboratory director is ultimately responsible for the failures to meet CLIA requirements, not Holmes and other Theranos executives. Therefore, the defense argument goes: So long as the clinical laboratory held a valid CLIA certificate, Holmes thought everything was fine. She was relying on the laboratory directors as the experts to make sure everything was compliant.

"As a result, neither the government nor the investors can claim she misled them, as she was just as misled as they were," Murer observed. "That's a tough argument to make, but the defense doesn't have a lot of cards to play in this case."

QUESTION 5:

What obligation does a lab director have to notify regulators about problems in a lab?

For Murer, the question of what obligation a laboratory director has when there are problems in the lab, and who is ultimately responsible, goes to the heart of the case the DOJ has brought against Holmes. "Also, this question will be one that will interest many CLIA laboratory directors because it leads to other important questions that are closely related," Murer commented.

"For example, what obligations do lab staff have to report CLIA violations or possible violations to authorities—particularly if they know or fear that the laboratory director has not done that reporting?" he asked.

"Another related question is: Should the lab staff have signed off on test reports that are inaccurate?" he added. "Should lab staff file anonymous complaints to the CLIA lab director, the executive team, or to regulatory authorities? What would happen if the lab staff filed complaints with the lab director appropriately but then the lab director did not respond or

How Claims of Fraud Resulting from Inaccurate Test Results Can Ensnare CLIA Lab Directors

DURING AN EXTENSIVE INTERVIEW ABOUT THE THERANOS TRIAL, attorney Matthew J. Murer, JD, warned lab directors of CLIA laboratories about the potential for criminal liability due to inaccurate test results.

Murer is a partner with the Chicago law firm Polsinelli and has more than 27 years of experience advising lab directors and managers about how to comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

"One lesson that's come from the Theranos trial is how inaccurate lab test results could trigger charges that a laboratory committed fraud," Murer noted. "This possibility affects clinical laboratories that do testing for any patients enrolled in government health programs, such as Medicare, Medicaid, TriCare, and others," he said. "This should also concern laboratory directors at labs that run tests for patients who have coverage from commercial insurers.

Accusations of Fraud

"Lately, we've seen a number of private insurers bring fraud cases against clinical labs, including against labs running tests for COVID-19," he warned. "U.S. attorneys have filed court cases against some labs on behalf of federal health programs. Lawyers have filed cases for commercial health insurers. The plaintiffs in these cases have accused the defendant labs of submitting false claims because the labs billed for tests that they knew were not justified as medically necessary.

"Therefore, under federal law, every unsupported claim submitted was a false claim and the plaintiff federal agencies and commercial health insurers are entitled to actual damages and to triple damages under the False Claims Act," he added. "That's a significant cudgel.

"In addition, if I'm a creative government prosecutor or a creative lawyer representing health insurers, I may add a claim of conspiracy because everyone in the clinical lab involved in such a money-making scheme is committing conspiracy because they agreed to commit an illegal act and they agreed to participate in the conspiracy," Murer warned.

Possible Conspiracy Charge

A conspiracy charge is possible when some or all of the owners, managers, CLIA laboratory director, and staff know that the testing in question is not accurate. When everyone goes along with it and submits those claims knowing that the testing is inaccurate or improper, then they're arguably part of the conspiracy.

"Recent court actions show such cases are becoming more common," he noted. "Anyone working as a CLIA lab director, in management, or as a staff member who knows that the lab has submitted false claims for inaccurate tests, should consider resigning from that position.

"By staying, these individuals run the risk of being named in that litigation," Murer continued. "If they are so named, they would need to pay for a defense attorney and they could be subject to monetary penalties and triple damages.

"Therefore, if you know that your laboratory's test results are consistently inaccurate or not medically necessary, and that your lab is billing for those tests and you don't report it, then you could face an allegation that you have participated in a conspiracy to commit fraud with others," Murer concluded.

did not act on those complaints? Would the lab director face consequences for failing to act on such complaints?"

The answers to these questions provide insights into how attorneys and judges interpret CLIA regulations and how they

assert that the lab director should be held responsible for failures to comply. "These questions are among the most interesting from the Holmes trial because some CLIA laboratory directors may face similar problems in their labs," Murer noted.

"We know from Rosendorff's testimony that both Holmes and Balwani opposed or overrode Rosendorff's recommendations about how to address the problems the lab staff encountered," he explained. "In rebuttal, the defense attorneys tried to show that some witnesses claimed Rosendorff did not fulfill his duties in a compliant manner.

Matthew J. Murer, JD

➤ "CMS and judges have asserted again and again that the buck stops with the lab director. CMS states clearly that laboratory directors have the ultimate responsibility."

"Those assertions should draw the attention of any pathologist serving as a laboratory director," Murer added. "The case shows how easy it is for a lawyer to argue that the CLIA laboratory director is responsible for that lab's failure to meet CLIA requirements."

As for what a lab director should do about problems with a lab, Murer focused on how the prosecution and defense characterized Rosendorff's responsibility as the lab director when he realized that the lab was reporting inaccurate results.

Inaccurate Lab Test Results

"Defense attorneys claimed that Rosendorff should be held responsible for any inaccurate lab results because inaccurate results put patients at risk of harm," Murer recalled. "The defense also presented testimony that Rosendorff should be held responsible for the lab's failure to perform proficiency tests properly and for the failure to follow federal and state lab regulations.

"Those claims from the defense make the case seem complicated by raising the issue of whether Rosendorff's warnings to management did not go far enough," he commented. "As a result, lab directors in similar circumstances may want to know what obligations a CLIA laboratory director has in such cases, such as, should Rosendorff have resigned?

"At the end of the day, Rosendorff, as the laboratory director, was responsible for everything that happened in the clinical lab, including the bad test results," Murer explained. "In these situations, the CLIA regulations make clear that lab directors are responsible for everything in the lab and what they should do in such situations."

Lab Director's Responsibility

When laboratory directors have been accused of similar failures to comply with CLIA, defense attorneys for those lab directors have argued against holding those directors responsible, Murer said.

"There have been a number of CLIA cases where laboratory directors have said they shouldn't be held liable when they've been in similar situations," Murer explained. "Some have said, for example, that they weren't involved in the day-to-day operations of the lab. Others have said they didn't have any knowledge of what was going on in the lab.

"But when those cases go before an administrative law judge, the judge almost always rules that the lab director has a responsibility to know everything that happens in the laboratory," he explained. "CLIA cases sometimes end up in court when a lab files a lawsuit challenging the findings of CLIA inspectors."

In some situations, lab directors contend that they knew about bad test results and reported those results to management, but then they argue that the lab's owners disregarded their recommendations. This argument is similar to the arguments defense attorneys have raised in the Theranos trial.

"In those cases, CMS and judges have asserted again and again that the buck stops with the lab director," Murer added. "CMS states clearly that laboratory directors have the ultimate responsibility. You can delegate and you can work with ownership, but CMS holds the lab director responsible for the quality and accuracy of all lab testing."

Resign in Some Cases

In its brochure seven, "Lab Director," CMS explains the clinical laboratory director's responsibilities.

"In situations when the lab director has tried to correct the issue and lab management or ownership refuses to listen or cooperate, then the lab director should resign," Murer asserted. "That's what should happen when lab directors find that any lab is not being run properly and ownership will not take the appropriate action. Under CLIA, laboratory directors cannot shift responsibility to management or to ownership. If they can't get the lab to a place where it needs to be, then they should walk away.

"In the case of Kingshuk Das, MD, Theranos' fourth and final laboratory director, that's what happened. He testified that after reviewing the data on the testing equipment, he concluded that these testing systems were nonperforming from the very beginning," Murer noted.

Lab Director Disagreed

According to Das' testimony, Holmes challenged his conclusion and said that it was not an issue of "instrument failure per se, but a failure of quality control and the quality assurance program around it."

Das testified that he disagreed with this conclusion because the validation data "had no bearing on the quality control or quality assurance program." He further testified that, "I found these instruments to be unsuitable for clinical use."

When CMS conducted an inspection of the Theranos laboratory, it issued extensive findings alleging that the laboratory failed to meet the CLIA standards in a variety of ways and that those failures posed immediate jeopardy to patient health and safety. Das drafted the laboratory's response to CMS and agreed with the agency's findings that the quality control tests of multiple assays run on the Edison blood testing device violated the "2SD rule" indicating that a test must be rejected if two consecutive control measures fall outside the two standard deviations.

Das also testified that he responded to CMS that the laboratory "had a global and long-term failure of the quality control program" and that, as a result, it would

Theranos Trial: Four Questions from Part 1

IN THE FEDERAL FRAUD TRIAL OF ELIZABETH HOLMES taking place in the U.S. District Court for the Northern District of California in San Jose, the prosecution and the defense have raised important questions for all clinical laboratory directors. As the founder of the blood-testing lab Theranos, Holmes faces 10 counts of wire fraud and two counts of conspiracy to commit wire fraud.

For the first part of this series, we interviewed Matt Murer, an attorney with Polsinelli in Chicago, on the first four of eight questions that CLIA lab directors may consider to be the most compelling from the Theranos trial. *(See TDR, "CLIA Lab Director Testimony Shows Risks to Pathologists," Nov. 8, 2021.)*

Here are those questions:

- Why is proficiency testing so important in this fraud trial?
- Who is responsible when a lab fails to use analyzers correctly?
- Who is responsible when a lab produces inaccurate test results?
- What obligation did the laboratory director have to issue warnings to management?

need to void more than 50,000 patient test results.

"But not all laboratory directors understand that CMS will hold them personally responsible for any problems in the lab," he added. "In some instances when CMS finds a lab failed to comply with CLIA, CMS can prevent that lab director from acting as a lab director for another lab for two years.

CLIA Compliance

"Even in cases involving a hospital lab, CMS considers that all responsibility for that lab falls on the laboratory director," Murer noted. "When they discuss CLIA compliance, CMS officials don't talk with the hospital CEO even though that CEO may want to be part of that discussion. Instead, CMS officials will go directly to the laboratory director.

"Of course, many hospitals have quality assurance committees, and the members of those committees may want to meet with CMS officials to discuss CLIA compliance," he added. "But, again, CMS officials will insist on meeting with the laboratory director. When they do, they will want documentation of the lab's efforts to ensure high-quality and accurate lab test results, and to ensure that PT testing is done appropriately. Too often, that distinction is lost on people in the lab, including laboratory directors."

Diverting Blame

It is possible that Holmes' defense attorneys raised the issue of Rosendorff's role in an attempt to shift blame away from Holmes, Murer noted. "Counsel for the defense is trying to distract the jury," he commented. "They're trying to get the jury to focus on the bad tests, and that those results were the responsibility of the laboratory director.

"But that's a distraction from the main question in this case, which is whether Holmes knew that the testing was inaccurate and continued to promote to investors that their tests were reliable," he added. "While it seems clear that the lab's owners knew the testing was inaccurate, the defense is raising questions about who caused the inaccurate test results.

"To me, it's clear that the lab ownership knew about the inaccurate results and lied to their investors about that," he noted. "That's a key point in this case."

What should laboratory directors do if management fails to address problems the lab director raises? "The answer is in the CLIA regulations and it should be in the lab's operation manual," Murer advised.

"In my experience with CLIA violation cases, CMS will ask to see that lab's policies—meaning its manual of standard operating procedures," he warned. "A good written policy and the CLIA regulations themselves will explain what's supposed to happen in the day-to-day operations of the laboratory, including what should happen if management fails to address problems the laboratory director raises.

Matthew J. Murer, JD

➤ "But not all laboratory directors understand that CMS will hold them personally responsible for any problems in the lab. In some instances when CMS finds a lab failed to comply with CLIA, CMS can prevent that lab director from acting as a lab director for another lab for two years."

"That means that if the facts in the laboratory don't match the lab's written policies, that laboratory director has a problem," he added. "CLIA regulations make the lab and the laboratory director liable for poor test results and for the failure to follow the lab's own written procedures."

Lab personnel need to follow those written policies. "When advising clients, I say: 'I didn't write your lab's policies and the government didn't write those policies. So, if your lab staff cannot follow

what you've written as the best practices for your laboratory, a jury will find you liable,'" Murer said.

"All well-run clinical laboratories have good standard operating procedures for handling every situation," he explained. "These procedures describe what to do when the laboratory has a quality-control issue, when test results are inaccurate, and when the lab has inconsistent results. If the laboratory's procedures don't tell staff what do in those situations, then the laboratory director has an entirely different problem.

"In addition, the lab's operations manual should address what happens if ownership or management repeatedly ignore the laboratory director's warnings about inconsistent or inaccurate results," he advised. "At a minimum, a lab should stop conducting testing that it knows to be unreliable or incorrect. A laboratory director should not continue working at such an organization. In such situations, the lab director, and perhaps other lab staff, have an obligation to resign."

QUESTION 6:
What problems arose over the CLIA lab director of record?

In 2014, Rosendorff resigned from Theranos, and early in 2015 the lab's management team named Sunil Dhawan, MD, as the new laboratory director.

A dermatologist by training, Dhawan did not have a degree or board certification in pathology or laboratory science, according to *The Wall Street Journal*. On Oct. 15, Dhawan testified that he got his position as Theranos' lab director because he was Balwani's longtime dermatologist.

The online news site *Ars Technica* reported that, "Dhawan testified that he went to Theranos twice and that he worked a total of five to 10 hours between November 2014 and June 2015.

"During that time, he basically signed whatever Balwani sent him. Theranos agreed to pay him $5,000 per month, though Dhawan says he never cashed any checks and once asked to be paid in stock options instead," said *Ars Technica.*

Court testimony indicated that Holmes, Balwani, and the management team at Theranos operated for months without a board-certified clinical pathologist as the laboratory director on the lab's CLIA license.

Theory of Negligent Hiring

"One issue that lawyers sometimes need to address is the legal theory known as negligent hiring," Murer noted. "In a clinical lab setting, if someone is hired who doesn't have the proper qualifications, and that decision leads to injuries or damages, that's negligent hiring.

"In the regulations, CLIA is very clear on the competencies and qualifications of lab personnel," he noted. "Laboratory directors should pay attention to this regulation on an ongoing basis. They should audit their personnel files to make sure that everyone's qualifications are up to date and that the competencies of each staff member are documented, meaning the lab keeps copies of licenses and course transcripts.

"Those documents need to be in every CLIA laboratory's files, because even well-run labs can run into this problem," Murer warned. "If a laboratory gets a complaint that leads to an investigation, that lab could lose its accreditation if CMS finds that the lab director's qualifications are improper or haven't been verified properly."

Unaware of Responsibilities

The most common reason why this happens is that the person maintaining the personnel files leaves the company and the position remains unfilled, or the new person is unaware of that responsibility. The hiring of Dhawan as laboratory director is a case in point.

"In my opinion, Dhawan's hiring could lead to a claim of negligent hiring from those who invested in Theranos

because the company hired an unqualified laboratory director and that action led to the loss of the money the investors put into the company," Murer said.

"The fact that Dhawan had absolutely no involvement in day-to-day operations is, in itself, a CLIA violation," he noted. "To meet CLIA's regulatory responsibilities, the laboratory director must demonstrate active involvement in all laboratory operations and must be available to the laboratory staff as needed.

"What's more, the lab director has a responsibility to review all of the lab's policies because he or she is fully responsible for ensuring compliance with every policy," Murer continued.

There is no minimum number of hours that the laboratory director needs to be present at the lab, but it certainly needs to be enough to demonstrate that the director is fully responsible for all operations and that all testing is accurate.

"I do not know if the lab staff has a responsibility to report on a negligent laboratory director," Murer noted. "I've never seen a case where the staff claimed the lab director was not present enough. But certainly, the lab's management or ownership needs to ensure that the laboratory director was physically in the lab for enough time each week."

➤➤QUESTION 7:
Is it okay for lab directors to send company materials to their private email addresses?

Rosendorff testified that he took some material home and that he sent some material to his private email address. Those materials documented management decisions that overrode his responsibility to fulfill his requirements as the CLIA laboratory director, Murer said.

"There's never a clear-cut answer of whether taking materials from work to home is a violation of law—or, in this case, CLIA—because the legality of doing so depends on company policies, employment agreements, confidentiality requirements, whether the laboratory director signed a non-disclosure agreement, and other factors," he commented. "Also, of course, in healthcare the Health Insurance Portability and Accountability Act of 1996 (HIPAA) limits which patient records, called personal health information, can be exposed to the public.

"Rosendorff may have decided, however, that he wanted to complain to the government, in which case there are certain protections for whistleblowers," Murer advised. "But when a person takes documents or other information, it's not always clear-cut that the individual will qualify as a whistleblower. That's why I can't say that what Rosendorff did was legal or illegal because we don't know all the facts."

Matthew J. Murer, JD

➤ "The fact that Dhawan had absolutely no involvement in day-to-day operations is, in itself, a CLIA violation. To meet CLIA's regulatory responsibilities, the laboratory director must demonstrate active involvement in all laboratory operations and must be available to the lab staff as needed."

When someone becomes a whistleblower by reporting to CMS or other agencies under federal laws, the lab or other healthcare provider cannot retaliate against that person. If the lab did so, it would face increased liability because the whistleblower would have a strong claim for retaliation under the law.

"But if a lab director sends work to a home email address with the intent of sharing that information with a journalist, that's not whistleblowing," he warned. "Instead, that employee may have some liability for breaching confidentiality if he or she is sharing that information with a reporter or other non-governmental party.

"In addition, a lab director can't send material from work to a private email address if he or she is seeking work at another lab and wants to use that information from home," he added. "Also, under HIPAA, taking any work from a healthcare facility to your home could be a problem.

"Sometimes people think they should send material to a home email or take that information home to protect themselves in case something goes wrong or because they might become a whistleblower," Murer continued. "If that's the case, you need to know your company's policies on confidentiality and what liability you might create for yourself. Unfortunately, the bottom line is that there's no clear answer to this question unless you know all the facts. Even then, a clear answer might be difficult."

➤➤QUESTION 8:

What punitive actions does Elizabeth Holmes face and, when CMS finds deficiencies at a lab, what punitive actions can the agency take against the CLIA lab director?

CMS does not have a lot of options in how it can respond to CLIA violations because Congress was specific when it wrote the law.

"If CMS determines that a lab has put patients in immediate jeopardy—which was the case at Theranos—and if the lab doesn't correct those deficiencies and then submits a credible description of compliance—which Theranos allegedly didn't do—then CMS is required to revoke the lab's CLIA certificate," he explained. "Once the CLIA certificate is revoked, it triggers the domino effect, meaning the owners of the lab and the lab director will be barred from owning and operating another lab for two years.

"In addition, that letter resulted in the revocation of the CLIA certificates for all the related labs under common ownership," Murer added. "Those steps are prescribed in the law, which some people say is Draconian. But it's not so much that CMS decided to impose those penalties on Balwani, Holmes, and Dhawan. It's more that those penalties are required under law. There's very little wiggle room."

➤Lessons from Theranos Case

Regardless of the result of the trial, lab directors can learn important lessons from the Theranos saga. "For me, the big takeaway from the Theranos case is that the testimony shows how, all too often, CLIA-laboratory directors do not realize all the responsibilities that come with this job," Murer noted.

"They are simply not aware of what they need to know. And that failure to understand the law can get them into deep trouble when CLIA comes to inspect their laboratory," he concluded.

Matthew J. Murer, JD

➤ "For me, the big takeaway from the Theranos case is that the testimony shows how, all too often, CLIA-laboratory directors do not realize all the responsibilities that come with this job."

This two-part series is important for all CLIA laboratory directors because it provides commentary and analysis as to how the actions of the lab directors hired by Theranos were questioned, challenged, or criticized by federal prosecutors and the defense attorneys in a criminal trial.

Pathologists who serve as laboratory directors in CLIA-certified clinical labs may want to use these two intelligence briefings as the basis of conversations about their responsibilities with their lab's legal advisors. This would be consistent with taking preventive actions ahead of any actual violations. TDR

Contact Matthew J. Murer at mmurer@polsinelli.com or 312-873-3603.

Regulatory Update

Major CLIA Deficiencies Found at Calif.'s COVID-19 Lab Facility

News reports point to a possible double standard in how California regulates its own COVID-19 lab

MIGHT THERE BE DIFFERENT STANDARDS IN HOW government regulators enforce CLIA requirements on privately-owned clinical laboratories compared to a government-owned lab?

This question is being asked after the **California Department of Public Health** (CDPH) finally made public the CLIA inspection report by state officials after they visited the state-owned **Valencia Branch Laboratory** last winter.

'Scathing Inspection Report'

Last week, *CBS13Sacramento* wrote, "Lab inspectors issued scathing reports following the state's routine initial inspection and a whistleblower complaint investigation that found lab practices [at the Valencia lab facility] posed a threat of 'serious injury or harm, or death to Californians.'"

Arguing that the state needed more COVID-19 testing capacity, last July, California officials awarded a no-bid contract worth as much as $1.7 billion to **PerkinElmer**. PerkinElmer built the COVID-19 laboratory, uses a SARS-CoV-2 assay it developed, and operates the lab under this contract, which was renewed in recent weeks.

News reports of poor operations, inaccurate COVID-19 test results, and poor staff work habits have plagued the Valencia laboratory since it opened in the fall of 2020. Early in 2021, whistleblowers went public with details about these issues, attracting more news headlines. *(See TDR, "Multiple Whistleblowers Disclose Issues in California's Big New COVID-19 Laboratory," Mar. 1, 2021.)*

Whistleblowers talking to the press provided many details that match the findings of the state inspectors. But the state did not make this report public last winter, as promised. Instead, *CBS13Sacramento* reported that, "in February, CDPH and PerkinElmer claimed the 'serious deficiencies' had 'long since been resolved.'

"However, inspectors issued a Notice of Intent to Impose Sanctions on October 21st for outstanding deficiencies—just 10 days before the lab's contract was renewed last month. ... not surprisingly, the agency did not issue sanctions against its own lab. Instead, the CDPH concluded, '(t)his blueprint can serve as a model for other states, and the federal government, in how to scale testing,'" said *CBS13Sacramento*.

California's Double-Standard?

These statements should catch the full attention of all clinical lab administrators and pathologists. This news report indicates that state officials do not appear to be enforcing federal and state laws with this state-owned clinical laboratory. Will these same regulators act tough with privately-owned labs that are inspected and found to have serious deficiencies, particularly deficiencies that put patients at risk of harm?

Expect more surprising revelations in this unfolding story of how government officials are assessing the compliance of the Valencia Branch Laboratory. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathologists interested in ways to automate the various manual steps in the histology laboratory may want to watch the progress of an emerging company. **Clarapath** of Hawthorne, N.Y., says it is "automating processes around the way tissue is processed onto glass slides via 'sectioning,' or cutting a cross-section of the tissue specimen." The company just announced a new infusion of $16 million in capital from a Series B Funding. One of the investors is **Northwell Health**. Clarapath has raised a total of $39 million to fund its efforts to develop its SectionStar system which "provides automated sectioning for non-clinical and clinical pathology laboratories."

MORE ON: *Clarapath*

Histology is one area of labortory medicine where much of the workflow is done manually. Eric Feinstein is CEO of Clarapath. In a press release, he said, "Clarapath's SectionStar consolidates many manual cutting, quality control, and decision-making steps into one piece of equipment, resulting in better quality tissue sections, faster processing efficiencies, and lower overall costs, all while providing richer data sets on those tissue specimens."

USE OF DRONES FOR BLOOD PRODUCTS

At Fort Pickett, Va., army researchers are working with **Near Earth Autonomy** and **L3Harris Technologies** to show how drones might be used to deliver whole blood, particularly on the battlefield. Success with this demonstration may help accelerate use of drones to move lab specimens.

TRANSITIONS

• Jason Newmark is now a Principal at **ECG Management Consultants**, owned by **Siemens Healthineers**. Newmark's prior positions were with **Baystate Health**, and **Stamford Hospital**.

• Andrew Lukowiak, PhD, will be the new President and Chief Scientific officer at **Epigenomics, Inc.**, of Seattle. Previously, Lukowiak served at **Millennium Health**, **AltheaDx**, **Hologix**, and **Third Wave Technologies**.

• **Prime Healthcare** of Ontario, Calif., announced that Carlton Burgess is its new Vice President of Laboratory Services. Burgess' career includes positions at **St. John Providence**, **California Laboratory Associates**, **Aspen Healthcare Metrics**, **Ambient ID**, **Quest Diagnostics Nichols Institute**, **SmithKline Beecham Clinical Laboratories**, and **Baxter Healthcare**.

• **Protenus, Inc.**, of Baltimore, appointed Michelle Del Guercio to be Chief Marketing Officer. She previously served at **Sunquest Information Systems**, **Atlas Development Corporation**, **Aspyra**, and **BMH Clinical Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 20, 2021.

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- ***More labs to sell microbiome tests directly to consumers: is this the first wave of fraud involving clinically-useless tests?***
- ***What every lab should know about adding latest-generation digital productivity tools to their core laboratory automation.***
- ***How increasing numbers of employers are ready to contract directly with hospitals, doctors, and clinical laboratories.***

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