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Balwani Convicted!

It's a sweep for federal prosecutors in two trials of ex-Theranos Executives

(See pages 7-9)

Ramesh Balwani
Photo copyright David Paul Morris, Fortune

Elizabeth Holmes
Photo copyright The Guardian

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Important Court Rulings & Pending New Federal Law

IMPORTANT THINGS ARE HAPPENING WITH COURT DECISIONS AND PROPOSED FEDERAL LEGISLATION that will affect a substantial number of the nation's clinical laboratories and anatomic pathology groups. In this issue of THE DARK REPORT, you'll be alerted to those developments we think will have the biggest impact on laboratory compliance and legal risk.

The first of these developments is presented on pages 3-4. The Verifying Accurate Leading-edge IVCT Development (VALID) Act is a bill pending in Congress that would give the federal **Food and Drug Administration** (FDA) oversight for laboratory-developed tests (LDTs). In recent weeks, a large number of academic pathologists have expressed their opposition to this law as currently written. Some proponents are hoping to attach this bill to the pending bill to reauthorize FDA user fees. If that happens, there would be no Congressional debate about the language of the VALID Act.

The intelligence briefing that follows analyzes Advisory Opinion 22-09 recently issued by the **HHS Office of the Inspector General** (OIG). This opinion finds that a proposed plan to pay hospitals a "fair-market rate on a per-patient basis to collect, process, and test specimens" would be considered a violation of the federal Anti-Kickback Statute. *(See pages 5-6.)*

Next, we cover the jury decision in the trial of Ramesh "Sunny" Balwani, the ex-COO of **Theranos** and paramour (at that time) of former Theranos CEO Elizabeth Holmes. Balwani was convicted on all 12 counts of conspiracy and wire fraud. He and Holmes will be sentenced later this year. *(See pages 7-9.)*

Every lab relies on *in vitro* diagnostics (IVD) manufacturers for instruments, analyzers, test kits, and other products. On pages 10-15, we present the insights from four experts on the current state of the IVD industry. This includes supply chain issues and a shortage of managers and service reps, along with a disruption in the development of the next generation of products because of the pandemic.

The remaining intelligence briefing in this issue covers an important ruling by a federal judge in California in the case of *United States vs. Mark Schena*. The judge ruled that payment of percentage-based sales commissions for marketing to physicians and referral sources is a violation of EKRA. This has significant implications for many laboratories. *(See pages 16-18.)* TDR

Might VALID Act Support Be Waning in Congress?

New developments on LDT oversight include pushback from academic center pathologists

Jeremy Segal, MD, PhD

CEO SUMMARY: Just weeks ago, events seemed to indicate that the Verifying Accurate Leading-edge IVCT Development (VALID) Act was going to sail through Congress as part of a bill to reauthorize the FDA. However, momentum has shifted, at least in part because pathologists from academic medical centers spoke up in opposition to the VALID Act.

SURPRISINGLY, SUPPORT WITHIN CONGRESS FOR GREATER REGULATION of laboratory-developed tests (LDTs) may be wavering based on a variety of factors, including strong opposition from academic medical center pathologists.

The proposed Verifying Accurate Leading-edge IVCT Development (VALID) Act, which seeks to move oversight of LDTs to the **U.S. Food and Drug Administration** (FDA), is attached to the Senate's proposed FDA Safety and Landmark Advancements (FDASLA) Act. The bigger bill would reauthorize the FDA's drug and medical device user fee agreements. *(See TDR, "Passage of FDA LDT Regulation Inches Closer in the Senate," June 6, 2022.)*

The FDASLA Act went to the Senate floor on June 14 for potential amendments. However, that same day, a prime supporter of the VALID Act, Senator Richard Burr (R-NC), introduced updated legislation that stripped the VALID Act and other provisions from the larger bill. Without mentioning LDTs, Burr noted in a statement that the original FDA bill would "threaten Americans' access to breakthrough treatments and cures and deter private sector innovation."

The final decision on which version of the FDA bill will be voted on remained pending in Congress as of July 15. The House of Representatives passed its own version of the bill without the VALID Act.

Opponents of the VALID Act have long argued that moving LDT oversight under the FDA would endanger future innovative lab tests from coming to market because of the expenses and time involved with agency review. Currently, LDTs are regulated by the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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VALID Act supporters believe FDA pre-market approval is needed for *in vitro* diagnostic (IVD) tests because they are similar to medical devices and thus require extensive data collection.

Losing Momentum?

It's not clear if the VALID Act is losing momentum because of larger concerns about ensuring the FDA user fee bill passes on time, or whether pushback from pathologists influenced members of Congress enough to force a change.

Pathologists opposed to the VALID Act have had at least 30 phone calls with lawmakers in recent weeks, according to one insider. Also, a June 1 grassroots letter to a Senate committee from more than 290 pathologists and clinical laboratory directors asked for a series of concessions to be made for academic medical center labs under the VALID Act.

"You're talking about huge amounts of money and effort to get a single test through a system like that," said Jeremy Segal, MD, PhD, Associate Professor of Pathology at the **University of Chicago**, who was among those who attached his name to the letter.

"If that's the system the VALID Act proposes, it's going to be unapproachable for our labs," Segal told THE DARK REPORT.

Academic Pathologists' Letter

In the letter, the pathologists proposed several actions to loosen the regulatory burden on academic medical center labs:

- Remove the VALID Act from the FDASLA Act to allow more time to debate LDT oversight.
- If that removal isn't possible, enact low-cost application processes for laboratories in academic medical centers and hospitals, as well as simplified technology certifications for those labs.
- If those changes aren't possible, then exempt academic medical center labs from the VALID Act.

"We believe that the current proposed legislation fails to recognize the notable differences between testing at patient-centered, research-focused institutions versus commercially-based testing laboratories/kits and will dramatically impact patient access to critical diagnostic tests," the letter stated. "The onerous financial and administrative demands VALID will place on our laboratories threatens to leave us insolvent and incapable of achieving our mission to provide the highest quality healthcare."

Other influences also appear to be raising questions about whether the VALID Act is in the best interests of clinical laboratories and pathology groups.

FDA Performance

The Senate's Health, Education, Labor, and Pensions (HELP) Committee reviewed and marked up the FDASLA bill on June 14, and it was approved by the committee by a bipartisan vote of 13-9, according to a summary from the **Association of American Medical Colleges** (AAMC). The AAMC also sent a letter to the committee on June 2 opposing parts of the VALID Act.

In an unexpected twist, opposition to the VALID Act may have been bolstered by the infant formula shortage in the country. Burr has questioned the FDA's ability to handle any more regulatory oversight given its widely panned response to the formula crisis. Burr told fellow HELP Committee members on June 14 that the agency may not deserve additional authority, including oversight of LDTs.

Laboratory leaders and pathologists should note that at this point the VALID Act continues to have bipartisan support. Burr's future stance on the larger FDASLA bill will be an important one to watch given his prior support of the VALID Act and his dissatisfaction with the FDA. TDR

Contact Jeremy Segal, MD, PhD, at jsegal5@bsd.uchicago.edu

New OIG Advisory Opinion Dubious of 'Fair Market'

Clinical lab network requested opinion based on proposal to pay hospitals for specimen collection

Charles Dunham IV

CEO SUMMARY: There is a new advisory opinion from the Office of the Inspector General (OIG). It reviewed a proposal in which a clinical lab network would pay fair market value to hospitals for specimen collection based on volume of patients tested. The OIG said this arrangement would violate the federal Anti-Kickback Statute, because hospitals still had a financial incentive to refer patients to the lab network.

While a new opinion from the federal government about compensation based on lab test volumes may not be surprising, it does for the first time put a specific stance about the matter on the record.

Clinical laboratory managers and pathologists responsible for regulatory compliance will want to read through the the "Advisory Opinion 22-09" recently issued by the **U.S. Department of Health and Human Services' Office of the Inspector General** (OIG).

The OIG's overall message has long been echoed by compliance experts: Any sort of remuneration from a testing lab to a hospital or physician's office on a per-test or per-patient basis is likely to run afoul of the Anti-Kickback Statute—notwithstanding circumstances where the payment reflects fair market value for the services.

"Even though someone needs to collect that blood sample, and even though the amount being paid to collect the sample might be fair market value, the OIG has now expressly stated that the laboratory paying the ordering provider is at a high risk of fraud because it could be used as a way to induce referrals to that particular laboratory," said healthcare attorney Charles Dunham IV, a shareholder at law firm **Greenberg Traurig LLP** in Houston. "That's the first time that the OIG has actually come out and said it after the fraud alert in 2014."

Dunham was referring to the 2014 OIG document, "Special Fraud Alert: Laboratory Payments to Referring Physicians."

Proposed Arrangement

The operator of a clinical laboratory network, which is not named, requested the OIG's opinion on a proposed arrangement involving paying hospitals for specimen collection activities based on volume of patients tested.

Under the proposal, the lab would sign contracts with hospitals around the U.S. and pay those facilities a fair-market rate on a per-patient basis to collect, process, and test specimens. The lab would bill Medicare and private insurers for the tests.

The collection services would be performed on the patients by hospital-employed or contracted phlebotomists at the hospitals. The lab would only pay the hospitals for work done on individuals who aren't inpatients or registered outpatients.

In the proposed arrangement, none of the hospitals' employed or contracted physicians would be required to refer tests to the lab in question, and those physicians would not receive any remuneration from the hospitals for any test referrals to the laboratory network.

OIG Examines Incentives

The OIG took a hard stance against the proposed arrangement between the lab network and contracted hospitals.

"We conclude that the proposed arrangement, if undertaken, would generate prohibited remuneration under the federal Anti-Kickback Statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions," the OIG stated.

The OIG made clear that the arrangement would not meet a safe harbor—in other words, a business practice not considered an offense under the Anti-Kickback Statute—because the payment was volume-based. The agency further dissected the proposed arrangement with these observations:

- **Financial incentives exist**. Even if the lab in question was not named on test order forms, the contracted hospitals could be motivated to refer patients to the lab for tests, the OIG said. "Indeed, because of the per-patient-encounter fees paid by requestor for the services (which contract hospitals agree to receive in lieu of any reimbursement for the services from a third-party payer), contract hospitals have a financial incentive to direct any such specimens to requestor for the furnishing of laboratory services," the agency commented.
- **Fair market value is not a safety net**. Regardless of the lab proposing to only pay the hospitals fair market value for the collection and processing of specimens, the OIG noted such arrangements present a risk for fraud.
- **It's hard to mitigate steering tests toward the lab**. Even if the hospitals verified that no physicians would be directed to order tests from the laboratory network, it would be difficult to stop the physicians or the hospitals from steering business toward the lab because the hospitals have an incentive to grab payments from the lab to offset costs, the OIG stated.

Dunham noted the gap between the 2014 Special Fraud Alert and the recent OIG opinion. In this latest Advisory Opinion, "the OIG came to a definitive position now—eight years later—that even if a lab only paid for what it collected under fair market value, there's too much inherent risk in there and it will likely be deemed fraudulent by the government," he said.

Concerns Go Far Back

The Special Fraud Alert outlined OIG concerns about payments from clinical laboratories to physicians in excess of fair market value and payments that reflected the volume or value of referrals of federal healthcare program business. The alert came at a time when the DOJ was beginning to heavily investigate certain organizations for kickbacks—in particular, **BlueWave Healthcare Consultants** and **Health Diagnostic Laboratory** (HDL).

The Dark Report has written extensively on those cases, including recent court actions that tie back to those labs. *(See TDR, "DOJ Charges Execs over Alleged Lab Kickbacks to Obtain Restitution," June 6, 2022.)*

However, observant lab managers and pathologists shouldn't shrug off the latest OIG opinion just because their organizations would never go as far as BlueWave and HDL did, Dunham warned.

"Even if a laboratory is paying fair market value and the arrangement doesn't compare to what BlueWave and HDL were doing, the OIG is saying, 'We still don't like it,'" he added. "The OIG still thinks that it's a high risk. That's where they've finally come out and been clearer." TDR

Contact Charles Dunham IV at 713-374-3555 or dunhamc@gtlaw.com.

Balwani Guilty! Sentencing Is Next for Theranos Execs

Jury finds ex-Theranos COO Ramesh Balwani guilty on all 12 counts of wire fraud and conspiracy

CEO SUMMARY: The trial of former Theranos President and Chief Operating Officer Ramesh "Sunny" Balwani ended with convictions by a jury on 12 counts of wire fraud and conspiracy. Now all eyes are looking ahead to the sentencing of Balwani and Elizabeth Holmes, the founder and former CEO of Theranos, who was found guilty on four charges earlier this year. Both face significant prison time for their crimes.

Juries have spoken: Two Silicon Valley executives at disgraced blood testing company **Theranos** orchestrated one of the biggest corporate fraud conspiracies in U.S. history.

Now, those executives—Elizabeth Holmes and Ramesh "Sunny" Balwani—will spend the coming months pondering their fate as they both prepare for possible prison time.

Their sentencings will once again capture the attention of medical laboratory directors and pathologists who have followed the strange saga of Theranos, which may be entering its final chapter.

Text Messages Sway Jury

On July 7, a jury in San Jose, Calif., found Balwani—the former president and chief operating officer at Theranos—guilty of two counts of conspiracy and 10 counts of wire fraud.

Holmes, the founder and former CEO at the blood testing lab, was convicted in January on one count of conspiracy and three counts of wire fraud, and she was acquitted on seven other charges. Wire fraud is the use of electronic communications, such as email, to further a crime. *(See TDR, "Jury Finds Elizabeth Holmes Guilty in Four of 11 Criminal Counts," Jan. 10, 2022.)*

ABC News Correspondent Rebecca Jarvis, who extensively chronicled the Theranos story, appeared on the *ABC News* Start Here podcast on July 8 to talk about Balwani's verdict. She said text messages between Holmes and Balwani that prosecutors showed to the jury were powerful.

"They presented a text message from Sunny to Elizabeth, and it read, 'I am responsible for everything at Theranos,'" Jarvis observed. "Well, that was in the context of a lot of other text messages, but it very likely made a big difference with jurors at this trial."

Sentencing is Coming Up

Holmes will learn her punishment on September 26, while Balwani's sentencing date is Nov. 15. Each count for which they are guilty carries a maximum 20 years in prison and $250,000 fine. Both individuals also face possible restitution to victims.

Federal judges do not have to sentence defendants to the maximum prison term. Also, the judge can decide that multiple terms may be served concurrently.

Meanwhile, Holmes has appealed her verdict; a hearing is scheduled to occur

Ramesh "Sunny" Balwani Convicted of 12 Crimes

BALWANI WAS CONVICTED ON 12 COUNTS during his Theranos trial. Here are more details about those charges:

- Count one: Conspiracy to commit wire fraud against Theranos investors.
- Count two: Conspiracy to commit wire fraud against Theranos patients.
- Counts three through eight: Wire fraud (electronically transferring $154.7 million from various investors' bank accounts to Theranos' bank account).
- Counts nine through 11: Wire fraud (electronically transmitting questionable blood test results to three patients).
- Count 12: Wire fraud (electronically transferring $1.1 million from Theranos' account to a media company's account to purchase ads for Theranos Wellness Centers).

Among the investors noted above were **Lakeshore Capital Management** (a firm owned by the family of Betsy DeVos, former U.S. Secretary of Education); **PFM Health Sciences** (a healthcare investment firm); a company associated with Daniel Mosley (former estate attorney for former U.S. Secretary of State Henry Kissinger, who introduced Mosley to Theranos CEO Elizabeth Holmes); the Walton family (heirs to the **Walmart** fortune, who were introduced by Mosley to Holmes); and former U.S. Secretary of Defense James Mattis (who also became a Theranos board member).

in July, *CNN* reported. Balwani also will likely file an appeal. Both remain free on bond until their sentencing.

At the core of both trials were dubious claims that Theranos' proprietary technology worked properly. The company said it could take a few blood drops of blood from a patient and successfully analyze the specimen using a machine called Edison.

During both high-profile trials, THE DARK REPORT and its sister publication, DARK DAILY, provided clients and regular readers with exclusive insights as to how lawyers from prosecutors and defendants were questioning the actions and responsibilities on the role of laboratory directors as governed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). *(See TDR, "CLIA Lab Director Testimony Shows Risks to Pathologists," Nov. 8, 2021.)*

➤ Lab Director's Obligations

For example, attorney Matthew Murer, JD, a partner at Chicago law firm **Polsinelli**, told THE DARK REPORT last year that clinical lab employees should consider it their responsibility to report failures to use analyzers correctly to the CLIA laboratory director. Subsequently, the lab director should report that failure to lab owners and management.

Under CLIA, the laboratory director is ultimately responsible for a lab's operations and testing accuracy. Further, if executives ignore a lab director's concerns, that director should leave the company, Murer warned.

"In my opinion, as a lawyer who has represented labs and lab directors in these cases, when a lab director believes the lab is not being run properly, and he or she cannot get ownership to agree that the lab is not being run properly, those lab directors should resign," he told THE DARK REPORT.

The government alleged that Holmes and Balwani—who were romantically involved during their time at Theranos—began a multi-million-dollar scheme to defraud investors and patients in connection with operations at the company.

For several years, Holmes and Balwani benefited from the incredible news coverage that Theranos generated within the healthcare industry and the media.

By 2014, Theranos, which Holmes founded in 2003 at age 19, was valued at more than $9 billion as a private company. However, by 2015, the public began to learn about serious problems in the company. At least some employees at Theranos doubted that the Edison analyzer performed accurately, but Theranos executives shrugged off those concerns.

"For example, Holmes, Balwani, and others knew that the analyzer 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," according to the **U.S. Department of Justice** (DOJ).

Whistleblowers from the company talked to the *Wall Street Journal* and federal investigators. In 2018, the **U.S. Securities and Exchange Commission** accused Theranos, Holmes, and Balwani of raising more than $700 million from investors by making exaggerated or false statements about the company's technology. That same year, Balwani and Holmes were indicted by the DOJ. Within months, Theranos shut down.

Balwani Deceived Patients

Holmes and Balwani were both found guilty of defrauding Theranos investors. However, an interesting point for laboratory directors to note is that unlike Holmes, Balwani also got convicted of defrauding patients.

Those charges stemmed from a deal Theranos struck with **Walgreens Boots Alliance** in 2012 to offer specimen collection and testing in some stores in California and Arizona. According to the indictment, Balwani's actions induced patients to pay for blood testing under the false pretense that the Theranos technology produced accurate results.

It's not yet clear why the jury convicted Balwani of more crimes than Holmes, given the two faced the same charges. It could simply be two juries reached different conclusions, or perhaps Holmes garnered more sympathy when she took the stand in her own defense.

In her trial, Holmes, 38, took the stand and alleged that Balwani, 57, was abusive to her while they dated. He denied this claim. Balwani never testified during his trial. "The biggest difference is that he didn't take the stand to say, 'I didn't do this,' or to raise his own objections to the claims against him," Jarvis noted.

The New York Times postulated that the government was able to present a more polished case against Balwani given his trial occurred after Holmes' trial.

"Since Mr. Balwani went to trial after Ms. Holmes, prosecutors essentially got a do-over and honed their case," *The Times* reported in July. TDR

Another Former Lab CEO Sentenced to Prison

IN OTHER FRAUD-RELATED NEWS, the former CEO of a now-defunct clinical laboratory will spend the next two years behind bars.

Executive Jae Lee must also pay restitution of $7.6 million, according to the U.S. Department of Justice (DOJ).

Lee previously pleaded guilty to charges that he helped **Northwest Physicians Laboratory** in Bellevue, Wash., obtain more than $3.7 million in kickback payments by referring urine drug test specimens to two labs that billed the government for the services. This resulted in government payments to those two labs of more than $6.5 million, the DOJ noted.

To conceal the payment of the kickbacks, Lee described the fees paid to the lab as being for marketing services. However, the DOJ argued that no marketing activity occurred.

Lee's sentencing is one more recent example of federal prosecutors cracking down on individual responsibility stemming from clinical lab fraud. *(See TDR, "DOJ Charges Execs over Alleged Lab Kickbacks to Obtain Restitution," June 6, 2022.)*

Renewing lab automation contracts to be one focal point

In Post-COVID-19 Market, IVD Manufacturers Face Supply, Staff Challenges


Bruce Carlson


Debra Harrsch


Bob McGonnagle


Larry Worden

➤➤CEO SUMMARY: After making billions during the COVID-19 pandemic, in vitro diagnostics (IVD) manufacturers must now adjust their strategies and relationships with clinical laboratory customers. Because many contracts for automated instruments are coming due, some IVD companies have the opportunity to grab additional market share at the expense of their competitors. IVD firms are also dealing with supply chain shortages and inadequate staffing because of the "Great Resignation."

If the SARS-CoV-2 pandemic was "kind" to any one sector of healthcare, that would be the *in vitro* diagnostics industry. Demand for COVID-19 test kits, analyzers, and automation skyrocketed and most of the world's largest IVD manufacturers reported record sales and earnings during the first 24 months of the pandemic.

However, that's not the case today. As the coronavirus morphs into what some epidemiologists predict will be an endemic disease, IVD manufacturers and their clinical laboratory customers are learning to live with an ongoing number of new SARS-CoV-2 infections.

To assess the current state of the IVD industry and identify the challenges facing these companies, a special panel of experts was convened at the the *Executive War College Conference on Laboratory and Pathology Management* that took place last April in New Orleans. The panel included:

Chair: Debra Harrsch, President and Chief Executive, **Brandwidth Solutions LLC**, Lansdale, Pa.

Panelists:

- Bruce Carlson, Senior Vice President, **Kalorama Information**, Part of **Science and Medicine Group**, Arlington, Va.
- Bob McGonnagle, Publisher, *CAP TODAY*, Northfield, Ill.
- Larry Worden, Principal, **IVD Logix LLC**, Dallas

In this session—aptly titled "Current State of the IVD Industry and How Lab Vendors are Responding to the Pandemic, the Supply Shortage, and Great Resignation"—the four experts agreed that IVD firms are facing the pressing need to replace fleeting COVID-19 revenue while also kickstarting stalled innovation.

As panel chair, Harrsch launched the discussion by inviting the panelists to identify the specific ways that the pandemic has altered or reshaped the IVD industry.

Carlson responded immediately by observing that "COVID-19 'giveth' and 'taketh' away. IVD revenue came at a price for staffing and expansion of manufacturing facilities."

Kalorama, Carlson's company, has published estimates that IVD companies—from large manufacturers to small start-ups—together made $33 billion in revenue during 2021 from COVID-19-related instruments and molecular and antigen tests. Kalorama pegs the current size of the global IVD industry overall as $120 billion per year.

The Arlington, Va.-based publisher covers medical research in the biotechnology, diagnostics, medical devices, and pharmaceuticals industries.

Carlson continued, noting that the IVD industry transitioned, "from an industry that—pre-pandemic—needed to convince its marketplace that a diagnostic test is needed, to an industry with a 'war mentality mindset' that emphasized increasing production of COVID-19 tests as fast as possible."

That approach produced benefits during the pandemic, but now consequences are being felt that make it imperative for IVD companies to take stock of their businesses.

As the pandemic exploded across the world, "some of the big IVD companies had no molecular platform and got caught short," explained Worden. "Those companies are now incurring costs as they re-evaluate who they are."

➤Automation Pacts Coming Due

The panelists agreed that one challenge about to confront IVD firms—as they estimate sources of non-COVID-19 revenue during 2022 and beyond—is the need to renew a substantial number of lab automation agreements. Many manufacturers' contracts for automation in medical laboratories will expire in 2023 and 2024, so IVD companies will be pressed to keep their instrument brands in clinical laboratories.

This is true at **Roche Diagnostics**, for example. Carlson pointed out that "Roche indicated over 60% of contracts

will soon expire, and it will make a major effort to nail down contracts for its instruments and automated systems in clinical labs."

The surge of lab automation contracts that expire in the next 24 months could be an important opportunity for savvy lab administrators and pathologists. The panelists were in agreement that IVD manufacturers were likely to offer attractive terms to their lab customers, either to renew existing agreements or to win the business of a new lab buyer.

In particular, they recommended it would be timely for lab managers to review their existing automated instrument contracts now with the goal of developing useful negotiating points. Then, as these contracts mature, the labs can enter negotiations as knowledgeable buyers.

New Products Push

In discussing the ways that the COVID-19 pandemic has changed IVD companies, Worden said this varied by manufacturer size, location, and market segment.

"Much of the work we do involves infectious disease and molecular technologies," he said. "From the start of the pandemic, my IVD clients' resources were dedicated to gearing up and creating SARS-CoV-2 tests.

"This came with a cost to these companies because development of other types of analyzers and products stopped," Worden explained. "Even if their diagnostic products were ready for regulatory review, IVD companies couldn't get a meeting with the **U.S. Food and Drug Administration** (FDA) because the agency was on hold. IVD companies could not implement the clinical trials that were planned and ready to commence because patients were not available."

For medical device manufacturers, product innovation has stalled, too, he added. "At this point, most companies have not started new product development. It is stagnant, and things are still very much focused on COVID-19 and on roles for diagnostic testing systems that are in place," Worden said.

The panelists next addressed the situation with smaller IVD companies that successfully rode the COVID-19 testing wave. "Small IVDs companies need to watch out if they are primarily reliant on their sales of COVID-19 tests," Carlson warned. "It will be hard for smaller companies to develop products and assays to replace those COVID-19 tests amid intense competition."

Sustained Supply Chain Woes

Two other important topics were addressed by the panelists. One involved the supply chain. The second involved staff recruitment challenges. The experts agreed that recruitment challenges may further slow instrument and product development and launches.

"IVD manufacturers learned during the pandemic that they were not the masters of their own fate," explained Bob McGonnagle, Publisher of *CAP Today* and a panelist. *CAP Today* is a publication of the **College of American Pathologists**.

"From the onset of the pandemic, some of the IVD companies' biggest laboratory customers were calling them, having long conversations, and questioning, 'Why can't we get our normal allocation of test kits?'" he noted.

Lab administrators, understandably, have preferred not to take on costs associated with carrying inventory, McGonnagle commented. But the trade-off was that during the pandemic, clinical labs became dependent on a lot of imported goods.

"It is also important to realize that IVD companies have the same issue as labs when it comes to an aging workforce—especially in service and installation staff," he added. "Those are big factors in terms of what IVD firms are able to do going forward."

Emerging New Asia-Pacific IVD Companies Stretched Out Internationally During Pandemic

OUTSIDE THE UNITED STATES, ONSET OF THE COVID-19 PANDEMIC spurred an emerging class of *in vitro* diagnostic (IVD) companies in the Asia-Pacific region to develop and bring SARS-CoV-2 tests to their local markets. Many of these tests were accurate, fast to administer, and low cost. This well-positioned these brands for a new, international audience, according to IVD Logix.

Two South Korean companies—**Seegene** and **SD Biosensor**—reacted to the pandemic early, making significant incremental revenue gains in 2020, according to Larry Worden, Principal at IVD Logix, a Dallas-based consulting and market research firm.

Seegene developed one of the first SARS-CoV-2 tests two weeks after China released the genetic profile for the virus. Seegene was responsible for nearly all COVID-19 clinical laboratory testing in Europe during the initial months of the pandemic, Worden added.

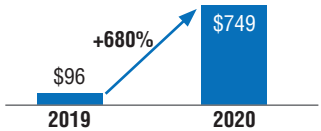
Meanwhile, SD Biosensor partnered with **Roche** to distribute point-of-care COVID-19 assays worldwide, he noted. That global teamwork helped SD Biosensor to attribute nearly all its 2020 revenue to COVID-19 sales. IVD Logix shared these two examples of market expansion by Asian IVD firms, presented below.

Lasting Changes in Global IVD Market: Emergence of Asia-Pacific Companies

These two South Korean companies reacted to the pandemic early and made significant incremental revenue gains in 2020.

Seegene

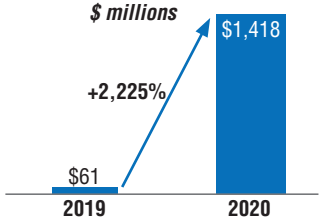
Annual Revenue
$ millions



- Developed the first SARS-CoV-2 test just two weeks after China released the genetic profile
- Responsible for nearly all the early testing in Europe
- One of the first to introduce variant-focused tests in 2021

SD BIOSENSOR

Annual Revenue
$ millions



- Received FDA EUA for a molecular test in April 2020
- Entered into a partnership with Roche to distribute its point of care COVID assays worldwide
- Nearly all its 2020 revenue from COVID sales

Charts provided by IVD Logix, LLC.

From that perspective, U.S. IVD firms and clinical laboratories should be watching their IVD counterparts in the Asia-Pacific region that were able to develop SARS-CoV-2 tests at a low cost and position their brands on an international stage, according to **IVD Logix** research. *(See above sidebar for further details.)*

The panel also took up the topic of what IVD firms might do with the profits generated from sales of COVID-19 tests and instruments. Some leading IVD companies are flush with cash. This is prompting speculation by Wall Street investors about future mergers and acquisitions that might alter the IVD marketplace.

Investors Direct More Scrutiny to IVD

In vitro diagnostics (IVD) piqued investor interest over the last couple years, but that attraction may be wearing off.

"We have said that the IVD industry is an under-looked industry for investors. IVD, in general, is favored by venture capitalists," said Bruce Carlson, Senior Vice President at medical publishing company **Kalorama Information** in Arlington, Va. "But there has been a plateau in investor interest in the IVD industry segment."

That cool-off may be due to COVID-19 test revenue falling in 2022 for some IVD firms. However, other business lines are regaining steam. *(See TDR, "IVD Firms Grow During 2022, But COVID-19 Revenue Dropped," May 16, 2022.)*

"My feeling is IVD companies are taking a deep breath after two long years," Carlson said. "Part of that reflection will be to compare performance numbers and determine how they will explain to investors why they are off on revenue.

"Often, during conference calls, IVD executives are warning investors up front that today's COVID-19 revenue won't be tomorrow's," he added.

"There is investor pressure for the larger IVD manufacturers to come up with a strategic plan for investment for that cash," Worden stated. "Many are actively looking at start-up companies and investing in co-development or acquisition."

Panelists recognized one such IVD acquisition as an example of this trend. Harrsch mentioned that **QuidelOrtho** in San Diego is the new name of an IVD company that formed following **Quidel's** $6 billion acquisition of **Ortho Clinical Diagnostics** in December. Combined revenues of the two companies totaled more than $3.5 billion during 2021. *(See TDR, "Ortho Clinical Diagnostics to be Acquired by Quidel," Jan. 10, 2022.)*

Over the next two to five years, Carlson sees more consolidations coming. "Consolidation within the IVD industry will be accelerated by inflation," he asserted. "There will be at least one big acquisition about the size of Quidel's and lots of smaller ones."

History may be clinical laboratory leaders' best teacher about what to expect in the next 24 to 48 months, McGonnagle suggested. "We have had various clinical events with big inflection points for the lab industry," he stated. "Organ transplantation was one of them. At first, these procedures could only performed in a handful of sites. Then, it became possible to do them widely and labs got involved.

"Another example is AIDS," he continued. "AIDS made an incredible difference to the public's consciousness of infectious disease and the role of diagnostic testing. I have a feeling that COVID-19 will have the same impact, particularly as many consumers became comfortable with buying their own COVID-19 test, collecting their own specimen, and performing the test in their own home. "

It will take a while for the global giants in IVD solutions to reboot. "The companies are trying to figure out who they are," Worden said. "Only now are IVD companies beginning to refocus on other development areas and restart clinical trials."

Expected Changes

In response to Harrsch's question about what will change in the IVD industry in the next three to five years, the consensus was that there would be more IVD consolidation; that the labor shortage would continue to move faster than improvements in automation; and that inflation would increase the cost of products and salaries, both for IVD companies and their clinical laboratory customers. TDR

Contact Bruce Carlson at bruce.carlson@kalormainformation.com; Bob McGonnagle at bmcgonn@cap.org; Larry Worden at lworden@ivdlogix.com; Debra Harrsch at dharrsch@brandwidthsolutions.com.

Reimbursement for COVID-19 Testing Totaled Tens of Billions of Dollars to Labs, IVD Firms

BOTH CLINICAL LABORATORIES AND THEIR *IN VITRO* DIAGNOSTIC (IVD) SUPPLIERS rose to the single biggest public health challenge of the last 100 years after the outbreak of SARS-CoV-2. In the United States, both sectors were adequately reimbursed for their efforts to deliver hundreds of millions of COVID-19 test results.

But "adequate reimbursement" understates the true cost in human effort and use of resources required daily during the pandemic by companies that supplied the tests, analyzers, transport media, primers, personal protective equipment and other supplies needed to perform unprecedented numbers of COVID-19 tests.

The website of the **Centers for Disease Control and Prevention** (CDC) has useful data. Here are some basic numbers that the CDC is reporting for the "daily number of COVID-19 Nucleic Acid Amplification Tests (NAATs)" performed since the onset of the pandemic. The data start on March 1, 2020, and were complete through July 11, 2022.

Total number of NAATs:

- 921,423,930 tests

Highest daily total of NAATs:

- 3,134,008 tests on Jan. 5, 2022

Current seven day average of NAATs:

- 293,878 tests as of July 11, 2022

It should be noted that these statistics are only for COVID-19 NAAT results reported to the CDC. From the onset of the pandemic, the results of some NAATs performed were not reported to the CDC.

Further, these numbers do not include antibody tests for COVID-19. There were significant numbers of point-of-care antibody tests for COVID-19 used by healthcare entities and employers. COVID-19 antibody tests were also sold directly to consumers so they could test themselves.

THE DARK REPORT did some back-of-the-envelope calculations to estimate how much reimbursement flowed to the nation's clinical laboratories for COVID-19 testing throughout the course of the pandemic, starting in March 2020 and continuing through July 11, 2022.

Estimating Test Payments

Assume reimbursement at the Medicare price of $100 for a COVID-19 NAAT. Here are some estimates of payments to labs in the United States.

Total reimbursement:

- 921,423,930 tests times $100 equals $92.1 billion

Highest daily total of NAATs:

- 3,134,008 tests on Jan. 5, 2022, times $100 equals $313.4 million

Current seven day average of NAATs:

- 293,878 tests as of July 11, 2022, times $100 equals $29.4 million per day

These estimates show that the nation's labs were paid close to $100 billion for COVID-19 NAATs. That's about what the nation normally spends for one year of medical laboratory testing. Moreover, at the height of the outbreak last fall and early this winter, labs in the United States were collectively being reimbursed at close to $200 million to $300 million per day for COVID-19 testing.

Assume that IVD companies were paid an average of about $40 per NAAT kit. Using the numbers above, in the United States, that would produce an estimate of $38.9 billion in COVID-19 test kit revenue to IVD companies during the course of the pandemic.

The estimates help clinical lab managers and pathologists better understand one dimension of the financial impact the pandemic had on the nation's clinical labs and IVD companies.

New Percentage-Based Commissions Ruling

Latest decision from California federal court conflicts with earlier EKRA ruling in Hawaii

Robert Mazer

CEO SUMMARY: In denying a motion to dismiss certain charges against a clinical laboratory owner, a federal court in California has declared that the Eliminating Kickbacks in Recovery Act (EKRA) of 2018 applies to payments for marketing to physicians and other referral sources. This ruling diverges from a prior EKRA-based decision in a Hawaii court.

Danielle Sloane

CAN CLINICAL LABORATORIES PAY PERCENTAGE-BASED COMMISSIONS to marketing and sales employees of clinical laboratories? Since passage of the Eliminating Kickbacks in Recovery Act (EKRA) of 2018, conflicting language with that and another federal law has unsettled labs. Now, things have gotten even muddier with a new court ruling that conflicts with an earlier ruling.

However, in response to the newest court ruling, advice from healthcare attorneys is simple: If labs are going to pay commissions, make sure the compliance infrastructure is strong.

"There is some risk in paying commissions under EKRA, even for employees. If labs are going to use volume-based commissions, they should have good compliance training and compliance checks on what those sales and marketing reps are doing," warned attorney Danielle Sloane, a member at law firm **Bass, Berry and Sims** in Nashville.

"Ultimately, it is the bad behavior that garners attention from federal officials, so the best labs can do to reduce the risk is to maintain compliance processes that reduce the likelihood of aggressive and inappropriate sales tactics," she added.

The latest court decision arose from a case in California, *United States vs. Mark Schena*. Schena, who is president at **Arrayit Corporation** in Sunnyvale, Calif., was indicted on various charges of healthcare fraud. In part, the federal prosecutors alleged Schena and others paid one or more marketers to recruit physicians to order blood-based allergy testing from Arrayit for their patients.

Motion to Dismiss Charges

In February, Schena asked a judge to dismiss some of the charges against him based on an October ruling from a judge in Hawaii. That earlier ruling, a civil case, concluded that payments of percentage-based sales commissions to a laboratory sales employee did not violate EKRA. The **U.S. Department of Justice** (DOJ) opposed Schena's motion to dismiss. *(See the sidebar on p. 17 for more details about both cases.)*

On May 28, **U.S. District Court in the Northern District of California** sided with the DOJ and denied Schena's motion. "Schena tried the same argument in his

In Different Federal Civil and Criminal Cases, the Scope of EKRA is Debated by the Courts

TO UNDERSTAND THE LATEST COURT RULING regarding the Eliminating Kickbacks in Recovery Act (EKRA) of 2018, it helps to look at two cases that have prominently raised questions about the law.

The first case—***S&G Labs Hawaii*** *vs. Darren Graves*—is a civil court matter that centers on an employment contract dispute. Defendant Graves was a sales account manager at S&G. Beyond his salary, he received percentages of monthly net profits generated by his client accounts and by the accounts of the sales reps whom he managed, according to court records.

In early 2019, concerned that EKRA prohibited S&G from paying sales reps based on the number of tests performed for client accounts, the company's CEO unsuccessfully tried to renegotiate Graves' contract. In September of that year, the CEO fired him, at least partially because Graves had contacted a competing lab about working there and urged other S&G reps to also leave.

S&G sued Graves in March 2020 for breach of contract. He filed a counterclaim against S&G for unlawful termination and for not paying his agreed upon compensation.

Surprising Decision

A hearing was held in July 2021 about the applicability of EKRA to the case. U.S. District Judge Leslie Kobayashi ruled in October that EKRA did not apply to Graves' employment arrangement.

"The commission-based compensation provisions of Graves' employment contract with S&G did not violate EKRA, and therefore S&G's failure to pay him according to those provisions constituted both a breach of contract and a violation of Hawaii [law]," Kobayashi concluded.

That decision surprised many observers because it went against the general belief that volume-based sales commissions did not meet the intent of EKRA.

Motion to Dismiss

It didn't take long for an unrelated case to jump on the Hawaii ruling.

On February 3, a lawyer for defendant Mark Schena filed a motion in U.S. District Court in the Northern District of California to have some counts against his client dismissed based on the Hawaii ruling.

"Based upon the analysis in S&G Labs [and] the text of EKRA itself … this court should dismiss counts four through six of the superseding indictment because the conduct that is alleged in those counts is not cognizable as an offense under EKRA," according to the motion to dismiss.

Schena, president at Arrayit in Sunnyvale, Calif., was criminally charged by the U.S. Department of Justice (DOJ) for allegedly paying one or more marketers to recruit physicians to order blood-based allergy testing for patients from Arrayit.

In an original indictment filed in November 2020, Schena was charged with healthcare fraud for allegedly taking part in a scheme to submit $69 million in false claims for allergy and COVID-19 tests, according to the DOJ. A superseding indictment filed in May 2021 added new charges involving conspiracy to pay kickbacks. The alleged conspiracy centered on inducing orders of COVID-19 tests and bundling them with a medically unnecessary allergy test. Additionally, the government charged that the COVID-19 tests were not reliable in detecting SARS-CoV-2.

The California court ruled against the motion to dismiss on May 28, 2022, arguing the Hawaii decision was flawed and that EKRA did indeed apply to Schena's case. He is set to go to trial on July 26.

motion to dismiss as the Hawaii case: that EKRA doesn't apply to a situation where a lab pays people to market to doctors," explained Robert Mazer, senior counsel at law firm **Baker Donelson** in Baltimore. "But the California court didn't agree with the Hawaii ruling."

EKRA is contentious for lab leaders. Originally it targeted sales practices at sober homes and substance abuse treatment centers. In a later draft passed by Congress, clinical laboratories were added to the list of providers named in the act. *(See TDR, "New Opioid Law Hits Labs Paying Sales Commissions," Dec. 3, 2018.)*

EKRA's anti-kickback provisions cover all payers, while the Anti-Kickback Statute (AKS) applies just to federal healthcare programs, which creates conflicts. The conflict in the language to the two laws means that some conduct protected under the AKS is instead a criminal violation under EKRA. That includes the common lab practice of compensating sales employees on a commission-based formula related to any third-party-payer business they generate.

Individual vs. Organization

The Hawaii decision made a distinction between a marketing employee receiving commission to refer an individual to a lab for testing versus receiving commission for getting client organizations to use a specific lab. But the California ruling did not agree with this logic within EKRA's framework.

"There is no requirement of 'directness' in the text of EKRA. Rather, by its terms, it applies to situations where someone 'pays or offers any remuneration' to 'induce' an individual into using laboratory or clinical services," according to the Schena ruling. "Notably missing is any requirement of direct interaction between the marketer and the individual."

The court also noted that EKRA fairly applies to the alleged conduct of Schena. "EKRA reaches the conduct at issue in the superseding indictment, namely defendant's alleged scheme to influence marketers by paying them illegal kickbacks to induce the referral of patients to Arrayit," the ruling stated.

"It is irrelevant that some of the marketers caused the referral of patients by conveying defendant's allegedly false representations about Arrayit to physicians, instead of to the patients directly," the ruling continued. "The physicians referred the patients based on the misrepresentations, and the marketers received a kickback to 'influence' the physician's referrals. This conduct squarely falls within the text of EKRA."

Differences in the Two Cases

Sloane noted that the two cases are quite different, and that the California case is a better indicator of the likely interpretation in the context of enforcement actions.

"In the Hawaii case, a sales employee is trying to enforce his contract in a civil dispute with his former employer to get paid amounts he feels due," she said. "There are no allegations of wrongdoing or impropriety in any way; rather, the employer is saying, 'This arrangement doesn't comply with EKRA, so I can't pay you.'

"However, in the Schena case, if you read the indictment, there's a litany of allegations of wrongdoing, and importantly, the DOJ weighs in on what it thinks the law means," she added.

Wise clinical laboratory directors should not look at the California decision as a panacea to any questions about EKRA.

"The Schena ruling addresses only one threshold question about whether EKRA applies to payments for marketing to physicians and referral sources," Mazer noted.

"Clinical labs might mistakenly read more into it, such as what compensation arrangements are permissible under EKRA, but the ruling really didn't touch on that," he added. "So, to the extent that those issues were fuzzy before, they remain fuzzy now because only a very narrow issue was addressed by the court." TDR

Contact Robert Mazer at 410-862-1159 or rmazer@bakerdonelson.com; Danielle Sloane at 615-742-7763 or DSloane@bassberry.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Given that monkeypox cases continue to rise, the federal government likewise is ramping up its response. In June, the federal **Centers for Disease Control and Prevention** (CDC) began shipping monkeypox tests to five commercial laboratories: **Aegis Science**, **Labcorp**, **Mayo Clinic Laboratories**, **Quest Diagnostics**, and **Sonic Healthcare**. The government has also been building up its supply of vaccine as part of a national response plan.

MORE ON: *Monkeypox Testing*

The following commercial labs began testing for monkeypox in July, as announced by the CDC:

- Mayo, Labcorp, and Aegis each have the capacity to perform 10,000 tests per week.
- Quest expects to be able to test up to 30,000 specimens weekly by the end of July.

As of July 15, the CDC reported 1,814 monkeypox cases in the country across 41 states, Puerto Rico, and Washington, D.C. That's up significantly from just June 1, when 19 monkeypox cases had been detected in the U.S.

NEW PUBLIC HEALTH LAB COMING IN NYC

New York City has begun construction on a replacement for its **Public Health Laboratory**. The project, which comes with a price tag of $454 million, will bring a 10-story, modern laboratory to the city's Harlem neighborhood, across the street from **Harlem Hospital**, according to NYC.gov. The city's current public health lab has been operating since the 1960s.

MACHINE LEARNING ASKS ABOUT LAB TEST RESULTS

Researchers at the **Massachusetts Institute of Technology** (MIT) are working to build a database of questions that physicians typically ask when reviewing health records, with the hope of training a machine-learning model to ask similar questions. Researchers found that most follow-up questions asked by physicians focused on symptoms, treatments, or the patient's diagnostic test results, according to MIT. Early results show that the model asked high-quality questions, as compared to questions from medical experts, more than 60% of the time.

TRANSITIONS

• The **University of Texas MD Anderson Cancer Center** in Houston named Donna Hansel, MD, PhD, as new Division Head of Pathology and Laboratory Medicine starting Sept. 12. She currently serves as Chair of Pathology and Laboratory Medicine at **Oregon Health and Science University** in Portland, Ore. She previously was Chief of the Division of Anatomic Pathology at the **University of California San Diego School of Medicine** and Associate Professor of Anatomic Pathology at **Cleveland Clinic**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 8, 2022.

Executive Publisher: Bob Croce *bcroce@darkreport.com*
Editorial Director: Scott Wallask *swallask@darkreport.com*
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*
Managing Editor: Michael McBride *michaelmcbride58@gmail.com*
Senior Editor: Joseph Burns *joeburns@capecod.net*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*