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Federal Prosecutors Sue Lab Execs, Lab Sales Reps to Win Restitution for Alleged Medicare Fraud.

See pages 10-14

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THE DARK REPORT

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

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R. Lewis Dark
Founder & Publisher

Halfway Through 2022, More Changes Come at Labs

APPROACHING THE MIDWAY MARK OF 2022, some clinical laboratory directors and pathologists might feel like they've already experienced enough changes to last the whole year.

For example, since the start of 2022, we've seen SARS-CoV-2 testing surges come and go, as well as changes to the No Surprises Act's out-of-network billing procedures. At the same time, supply chain issues continue and the acute shortage of medical technologists, pathologists, and lab staff is ongoing. That's just for the first half of 2022. More significant changes are coming—and THE DARK REPORT guides you through them in this issue.

A change in how federal prosecutors enforce lab fraud statutes has caused certain lab executives and sales managers to find themselves named as defendants in federal court cases. On pages 10-14, we describe how the **U.S. Department of Justice** (DOJ) is more aggressively targeting individuals accused of Medicare fraud and abuse. As you will read, in one large civil suit, lab executives have been taken to court even *after* corporate settlements with their lab company were reached. This is a one-two anti-fraud punch that has not been seen before from the DOJ. Anyone responsible for lab compliance will want to note this shift.

Meanwhile, changes may be imminent to allow the federal **Food and Drug Administration** (FDA) to regulate laboratory-developed tests (LDTs). We've discussed the Verifying Accurate Leading-edge IVCT Development (VALID) Act in past issues. As you will read on pages 7-8, observers believe Congress is poised to pass this legislation as part of a larger FDA authorization bill. If the VALID Act goes forward, oversight of LDTs will shift from the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and move to the FDA. Once the VALID Act becomes law, it is expected that the process of obtaining FDA clearance for an LDT will become expensive and time-consuming. Many pathologists believe this will discourage academic medical centers and researchers from developing and validating new biomarkers that could diagnose disease earlier and more accurately.

For the remainder of 2022, this collective list of changes will continue to affect clinical labs and the healthcare systems of which they are part. Ironically, the one change that is of greatest importance—to improve quality of patient care—will probably not be advanced by these developments. TDR

Atrium, Advocate Aurora Merge into $27b System

It's the latest example of two large IDNs merging, confirms trend of consolidation of hospital ownership

CEO SUMMARY: ***Integrated delivery networks continue to consolidate in the U.S., with the latest example being the merger of Atrium Health and Advocate Aurora Health. The deal forms a 67-hospital system across two distinct geographic areas in the Southeast and upper Midwest. IDN mergers raise the value of longitudinal test records for patients, with IDNs reaping the benefits of that data for healthcare goals, including value-based care.***

YET ANOTHER MEGA-MERGER HAS OCCURRED IN THE HOSPITAL INDUSTRY and this transaction provides the latest evidence that integrated delivery networks (IDN) will play a large role in healthcare's transition to value-based care.

A deal to consolidate has been struck between 40-hospital **Atrium Health** in Greensboro, N.C., and 27-hospital **Advocate Aurora Health**, which is co-headquartered in Downers Grove, Ill. and Milwaukee.

Pathologists and clinical laboratory administrators working in hospitals and IDNs should consider this merger of two sizeable health systems to be a bellwether transaction. There are reasons to expect additional merger deals between other large IDNs will occur in coming years.

Just as individual hospitals underwent major consolidation of ownership in the 1990s as a market response to the managed care contracting practices of health maintenance organizations (HMOs), there are market forces today that encourage multi-hospital health systems to combine into a single, much-larger IDN.

This new merger, announced May 11, results in a conglomeration of 67 hospitals and more than 1,000 ambulatory clinics across the states of Illinois and Wisconsin (Advocate Aurora's region) and Alabama, Georgia, North Carolina, and South Carolina (Atrium's area).

The new company will be known as **Advocate Health** and—with $27.1 billion in combined revenue—will become one of the largest health systems in the United States. No financial exchanges were described as part of the deal, and no assets from either company will change hands. Advocate Aurora and Atrium will also not transfer any liabilities.

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It's not clear if layoffs will occur, although the systems noted plans to create 20,000 new jobs as part of the merger.

Different Type of IDN Merger

One interesting aspect to this merger is that the Advocate Aurora-Atrium deal combines two geographically-separate IDNs. Advocate Aurora's hospitals are spread across two Midwest states. Atrium's hospitals are based in four Southeastern states.

Historically, IDN mergers have been created in adjoining states or regions. For example, in April, **Intermountain Health** and **SCL Health** completed a merger that created a giant IDN of 35 hospitals and 365 clinics that spans seven contiguous states in the Rocky Mountain region. *(See TDR, "Intermountain Health Merges with SCL Health," May 16, 2022.)*

Meanwhile, in February, IDNs **Beaumont Health** and **Spectrum Health** merged in Michigan. Post-merger, this enlarged IDN has 22 hospitals and more than 300 outpatient clinics.

Similarly, a deal is in the works to merge Morgantown, W.Va.-based **Mon Health System** (three hospitals) and Charleston, W.Va.-based **CAMC Health System** (four hospitals). The two IDNs signed a letter of intent to create a single new system named **Vandalia Health**, the organizations announced March 31.

FTC Opposes Two Mergers

Two other planned IDN mergers have been opposed by the **Federal Trade Commission** (FTC). Following a 2020 agreement to merge, the FTC just last week filed a court case against the planned merger of **Saint Peter's Healthcare System** (one hospital) and **RWJBarnabas Health** (12 hospitals). Both entities are based in New Jersey.

Separately, the FTC is opposing the planned acquisition of five Utah hospitals owned by **Steward Health Care** by for-profit **HCA Healthcare** in a deal that was announced in 2021. HCA intends to roll those five hospitals into its mountain division, which currently has 11 hospitals throughout Utah, Idaho, and Alaska.

Thus, just in the past 24 months there have been at least six multi-hospital IDN merger transactions announced. Data show there are approximately 474 integrated delivery networks that own and operate hospitals. (There are IDNs that do not include acute care hospitals.)

Last summer, research and intelligence firm **Clarivate** in London cited IDN growth as "one of the most dynamic changes in U.S. healthcare." The six IDN merger deals described above support Clarivate's analysis about the dynamic developments in the mergers and acquisitions of hospital-based IDNs.

In discussing their merger, Advocate Aurora CEO and President Jim Skogsbergh told the *Charlotte Business Journal* that the two systems' shared values outweighed any benefits of geographic size, but he acknowledged that size does bring business advantages.

Strength to Serve Patients

"All of our metrics improve as we scale because we execute around that," Skogsbergh said. "It isn't just big for bigness' sake, right? That's not what gets it done. It's using that to become stronger, and then using your strength to serve your patients, your communities, and your team members.

"Our work is done in the field, and at the bedside and in the laboratory," Skogsbergh told the *Milwaukee Journal Sentinel*. "We don't think headquarters is significant."

Skogsbergh and Atrium Chief Executive and President Eugene Woods will act as co-CEOs for 18 months, after which Skogsbergh will retire and Woods will assume sole leadership.

In any merger of two different IDNs, one early priority for lab services is to rationalize them and standardize analyzers, tests, and test methodologies across

Advocate Aurora Merger with Atrium Health Combines Service Providers in Six States

FOLLOWING THE MERGER of Advocate Aurora Health and Atrium Health, the new organization boasts a clinical laboratory network that will serve 5.5 million patients in the six states where the newly-named Advocate Health operates 67 hospitals and more than 1,000 ambulatory clinics. The map below shows how the merger spreads across wide areas of the United States.

At-a-Glance

AdvocateAuroraHealth

CEO: Jim Skogsbergh

Founded: Aurora 1984; Advocate 1995 (merged in 2018)

Number of hospitals: 27

Number of employees: 75,000

Revenue: $14.1 billion

Market reach: 2.6 million patients in two states

At-a-Glance

Atrium Health

CEO: Eugene Woods

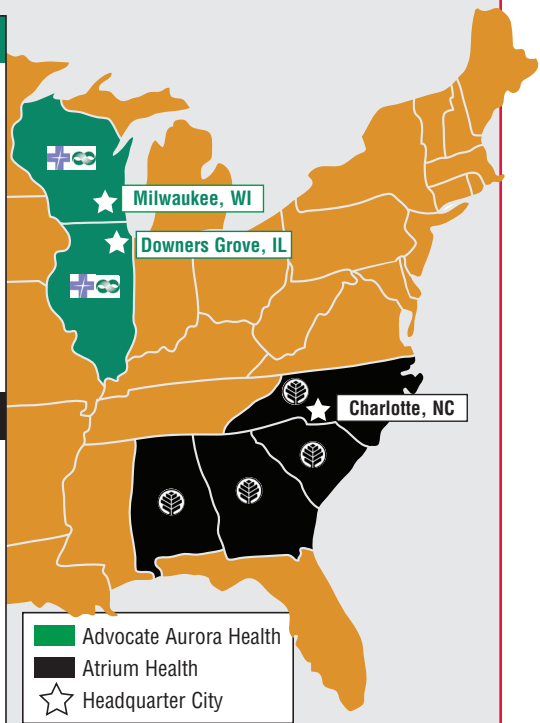
Founded: 1940

Number of hospitals: 40

Number of employees: 73,000

Revenue: $13 billion

Market reach: 2.9 million patients in four states



Sources: Advocate Aurora Health; Atrium Health.

all the lab facilities within the two merged IDNs. This brings economies of scale, supports performing more assays in-house to cut turnaround times for inpatients, and makes it easier to move medical technologists to different lab testing sites as needed.

Atrium's Unique Lab Asset

What will be interesting to watch as the new Advocate Health enterprise begins to integrate its clinical laboratory services is whether administration recognizes one unique asset associated with the Atrium Health clinical lab division.

Atrium's clinical laboratory division has one of the nation's best-developed cultures of quality management. Lean and Six Sigma methods are fully integrated into the daily operations of the larger labs within the health system. This includes methods that address continuous improvement, system of prevention, small batch/single piece workflow, and the identification of non-conforming events that negatively affect patient care.

The Atrium Health laboratory team is recognized nationally for its accomplishments at creating a quality culture

throughout the lab organization. This includes presentations by its leadership at recent *Executive War College* conferences.

Further, the lab teams at Advocate Aurora and Atrium have the potential to make important contributions that go beyond the usual issues of rationalization, consolidation, and regionalization of clinical lab testing services across the two merging IDNs.

Potential of Clinical Lab 2.0

There is a unique opportunity for lab administrators and pathologists serving within the merged IDNs' laboratories. It is to move past Clinical Lab 1.0 (accurate and timely test results, produced at lowest cost) to Clinical Lab 2.0 (converting lab test data into clinically actionable intelligence that improves patient care and creates value for which the lab and its parent health system can be paid.) *(See TDRs, "Lab Innovators Advocate Need for Clinical Lab 2.0," Jan. 9, 2017; "Message to Labs: Improve Outcomes,Get Paid More Money!" June 5, 2017.)*

The financial analysts at Clarivate recognize this opportunity for the two merging IDNs. "Through electronic health records (EHRs), patient information can be stored, tracked, and shared within the network, providing a comprehensive view of a patient's health," Clarivate wrote.

Big Data, Precision Medicine

In fact, converting healthcare data into actionable clinical intelligence is an opportunity recognized by the leadership at the newly-combined Advocate Health.

At the macro level, healthcare big data requires huge amounts of data, including patient health records, demographic data, geographic data, etc. Analysis of these data pools makes it possible to understand trends and identify geographical pockets where patients are underserved or specific clinical interventions can pay big dividends.

At the micro level, big data enables personalized medicine—the ability to diagnose a patient and tailor a treatment precisely to that individual's unique needs. Both uses of healthcare data play to the strengths of clinical laboratories.

As lab test data is standardized within both sides of the newly-combined IDN, lab administrators and pathologists have the opportunity to ensure every patient has a full longitudinal record of lab test results.

To achieve maximum value, the goal would be for every patient record to have current and past inpatient, outpatient, and outreach test data with consistent test methodologies and reference ranges. This would allow the Advocate pathologists and lab managers to contribute added value to the IDN. TDR

Advocate Aurora Earlier Looked for IDN 'Partners'

IT WAS IN 2018 WHEN ADVOCATE HEALTH CARE OF CHICAGO MERGED WITH AURORA HEALTH CARE OF MILWAUKEE. The newly-combined integrated delivery network (IDN) quickly went on the hunt for another IDN that would be interested in merging.

Less than 24 months later, Advocate Aurora thought it had a likely merger partner with **Beaumont Health** of Detroit. The two IDNs signed a non-binding letter of intent to merge. The resulting merger would have created a $17 billion nonprofit health system across the states of Michigan, Wisconsin, and Illinois. But four months later, the deal was canceled. News reports blamed the break-up on "the COVID-19 pandemic and concerns raised by physicians and a former Beaumont Health trustee."

In the announcement of the recent merger of Advocate Aurora Health and Atrium Health, the two IDNs stated their belief that the combined organization would focus on six areas: clinical pre-eminence and safety, health equity, affordability, next-generation workforce, learning and discovery, and environmental sustainability.

Regulatory Update

Passage of FDA Regulation of LDTs Inches Closer in the Senate

Congressional lawmakers add the VALID Act onto a major FDA reauthorization bill

CONGRESSIONAL LAWMAKERS ARE MOVING A BILL FORWARD that would give the federal **Food and Drug Administration** (FDA) the power to regulate laboratory-developed tests. There are many in the clinical laboratory profession who oppose any proposal to give the FDA regulatory oversight of LDTs.

FDA Would Approve LDTs

The bipartisan Verifying Accurate Leading-Edge IVCT Development (VALID) Act would require the U.S. Food and Drug Administration (FDA) to review and clear LDTs—with some exceptions.

Proponents of the VALID Act 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.

Opponents feel the administrative burden of seeking FDA approval will stifle LDT innovation for smaller clinical laboratories that don't have the resources to meet the proposed new requirements.

"If enacted, the VALID Act will take years to fully implement but could have far-reaching consequences for diagnostics development and the standards for diagnostic tests in the U.S.," the *National Law Review* wrote on May 8.

An LDT is a proprietary diagnostic test developed and performed by an individual clinical laboratory. LDTs often address unmet clinical needs. Currently, LDTs are generally regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The VALID Act's proposed language has been included in the Senate's proposed FDA Safety and Landmark Advancements (FDASLA) Act. The full legislation would reauthorize the FDA's prescription drug, generic drug, biosimilar, and medical device user fee agreements.

The bill was formally introduced on May 27. Potential amendments to the language will occur in June based on feedback from FDA officials and other interested parties who provided comment earlier to a draft version of the bill. A date when senators will debate the full bill has not been made public.

The VALID Act was originally released as a standalone bill in 2021. *(See TDR, "Congress May Soon Act on LDT, IVCT Regulation," Nov. 29, 2021.)* It had some momentum before other legislative and geopolitical issues temporarily pushed it aside. However, now that it is part of the FDASLA Act, its passage into law becomes more likely, the *National Law Review* noted.

The VALID Act takes up 263 of the 433 pages in the FDASLA proposal—more than 60% of the legislation. That figure alone should alert clinical laboratory directors and pathologists of the weight behind what the VALID Act proposes.

Lab Groups Write Congress

The **National Independent Laboratory Association** (NILA) sent a letter on May 21 to a Senate committee that had reviewed the VALID Act. NILA's letter took a strong stance in expressing its concerns about the draft language in the bill.

"Regulations that require LDTs to go through burdensome FDA approval processes will prevent patients from accessing accurate LDTs, harming or delaying patient care and limiting response to current and future public health threats," wrote Mark Birenbaum, PhD, executive director at NILA.

Suggestion to Amend Fees

However, NILA did not call for the VALID Act to be pulled from the FDASLA, but rather that amendments be made to the Act's provisions. Those amendments included establishing a sliding scale of user fees to accommodate smaller clinical labs and allowing web-based test menus to count as part of the submission to the FDA.

The **American Society of Microbiology** also issued a statement on May 17 calling for changes to the VALID Act's provisions, largely echoing NILA's suggestions.

Meanwhile, the **College of American Pathologists** (CAP) argued that while no legislation is perfect, the bill is a viable approach that addresses LDT regulation. Further, the CAP noted the labs must remember that patients are at the core of the proposed changes.

"While some may think the VALID Act goes too far, many patient advocate groups believe it doesn't go far enough and are actively pushing for more restrictive LDT oversight," wrote CAP President Emily Volk, MD, FCAP. "Indeed, these groups are frustrated that strengthening the oversight of LDTs has taken so long," she added.

New Business Opportunities?

In its review of the amendments being proposed to the VALID Act provisions, *National Law Review* noted, "The changes in law will create investment opportunities, as new FDA legislation of this magnitude often results in business exits and consolidations (e.g., mergers between laboratories, or between laboratories and currently FDA-regulated IVD manufacturers), as well as growth of service industries that would support new regulatory efforts.

"Also, there could be strong opportunities for growth for those businesses that can anticipate, effectively advocate for, and navigate the final path of regulation as it is translated from statute to FDA regulation and guidance," noted the *National Law Review*.

Should the VALID Act become law as written, it will add another complex layer of regulation for those clinical laboratories that perform LDTs. It is possible that existing LDTs may be grandfathered under the law, but labs wanting to introduce new LDTs may find the FDA's process of review and clearance to be both expensive and time-consuming. TDR

Bill Would Allow FDA Oversight of LDTs

SINCE 2014, THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) has several times issued proposed regulations and position papers discussing why and how it should be given authority to regulate laboratory-developed tests (LDTs). *(See TDR, "FDA Notifies Congress That It Will Regulate LDTs," July 21, 2014.)*

Were Congress to pass the bill titled "Verifying Accurate Leading-Edge IVCT Development (VALID) Act," a new category of lab test would be created, known as "*in vitro* clinical tests" (IVCL). In this category would be the commercial test kits manufactored by the *in vitro* diagnostic (IVD) companies and LDTs.

Medical Device Network stated that this law would, "by creating a risk-based framework ... require high-risk tests, like novel assays, to go through premarket review, while lower-risk tests, like cholesterol tests, could go to market after passing 'technological certification.' This would be a significant change to the way IVDs are regulated right now. The law will grandfather in LDTs currently in use."

Lab Market Update

Amazon to Close Employee COVID-19 Testing Lab in Ky.

In a move that may surprise some observers, **Amazon** announced it will close its COVID-19 employee testing laboratory in Hebron, Ky., which is just across the Ohio River from Cincinnati.

This is the second large COVID-19 clinical laboratory to publicly announce it will cease operations instead of transitioning to conduct other non-COVID testing for either its employees or the public.

In early April, the state of California announced it would close its **Valencia Branch Laboratory**, which was built to handle COVID-19 tests in that state. *(TDR, "State of California Cancels COVID-19 Test Contract with PerkinElmer," May 16, 2022.)*

In a letter to Kentucky officials, Jennifer Detmer, Amazon Pharmacy's Director of Human Resources, noted that 150 people would lose their jobs within the next few months because of the closure.

Clinical laboratory positions that will be eliminated include:

- Forty medical laboratory associates.
- Twenty-nine medical lab assistants.
- Nine medical lab managers.
- Seven medical lab technologists.
- Two bioassay scientists.
- One senior medical lab manager.
- One lab engineer.

Lab testing at the Kentucky site is expected to end in the summer. "Active operations are expected to cease effective July 2, 2022, with wind-down operations continuing through and until Aug. 31, 2022," Detmer wrote. Detmer did not provide any reasoning for the lab's pending closure. The letter's intent was to update Kentucky officials about the upcoming layoffs.

Generally, the clinical laboratory and pathology industry is adjusting to a lower demand for on-site polymerase chain reaction (PCR) testing given the reduction in COVID-19 cases across the country, compared to the surge in cases at the beginning of the year.

In addition, many people are becoming accustomed to taking rapid antigen COVID-19 tests at home, and federal and state governments have promoted such serological testing to prevent infection.

Amazon's CLIA Lab Facility

The Dark Report was among those surprised to learn that Amazon planned to close this CLIA-certified clinical laboratory facility. In recent years, Amazon's plans and actions to expand its presence in healthcare were widely-publicized.

Amazon's reputation for disrupting multiple industries looms as a threat over the U.S. healthcare system. Its acquisition of **PillPack** in 2018 triggered major responses by retail pharmacy chains, for example.

Thus, the willingness of Amazon—in the early months of the pandemic—to build the COVID-19 CLIA-certified clinical lab large enough to provide SARS-CoV-2 testing to its one million employees was seen by some as a way to learn more about the clinical laboratory industry. It was reasonable to assume that, once the pandemic had ended, Amazon might repurpose the COVID-19 lab facility to provide routine clinical lab tests to its employees under its health benefits plan.

Amazon's announcement of the closure of its COVID-19 lab facility means that the company may want to develop alternative ways to deliver clinical laboratory tests, whether to consumers or physicians and their patients. TDR

Feds to pursue individual accountability in civil fraud lawsuits

DOJ Charges Execs over Alleged Lab Kickbacks to Obtain Restitution

CEO SUMMARY: Multiple executives and sales representatives at True Health Diagnostics and Boston Heart Diagnostics have been named as defendants in a civil suit filed by the U.S. Department of Justice. The complaint centers on alleged kickbacks in return for clinical laboratory test referrals. The companies and employees involved have been associated with allegations, a settlement, and for one of the people, a guilty plea.

Executives and other employees who once worked at diagnostic companies dogged by fraud allegations have been named by the **U.S. Department of Justice** (DOJ) in a civil complaint.

The lawsuit seeks damages for alleged fraudulent clinical laboratory test claims. One of those people—Jeffrey "Boomer" Cornwell—pleaded guilty in January to a prior related criminal indictment on Anti-Kickback Statute charges.

Cornwell was the former Vice President of Sales for the Southwestern Region at **True Health Diagnostics** in Frisco, Texas. He and Christopher Grottenthaler, former CEO at True Health; Susan Hertzberg, former CEO at **Boston Heart Diagnostics** in Framingham, Mass.; and Matthew Theiler, former Vice President of Sales at Boston Heart, are the highest-ranking employees among 18 defendants listed in the DOJ's civil complaint.

The lawsuit was unsealed on April 4 in **U.S. District Court in the Eastern District of Texas**. *(See TDR, "In Civil Suit, DOJ Seeks Triple Damages for Lab Test Fraud," April 25, 2022.)* The suit was originally filed by whistleblowers Chris Riedel and Felice Gersh, MD. The DOJ eventually joined the filing. Aside from the Anti-Kickback Statute, the complaint also notes alleged violations of the False Claims Act and the Stark Law.

One fact makes this federal court case of high interest to clinical laboratory managers and pathologists. It is an example of federal prosecutors pursuing charges against individuals associated with a laboratory company that had earlier entered into a settlement with the DOJ.

Prior Settlement

Essentially, federal prosecutors want to hold individuals in these lab organizations personally accountable by seeking penalties and restitution from the executives, sales reps, and other staff associated with lab organizations that previously settled allegations of fraud with the DOJ.

In the case of Boston Heart, federal prosecutors entered into a settlement agreement with the company back in 2019. Boston Medical agreed to pay back nearly $27 million to settle False Claims Act allegations. Now the DOJ has filed a civil case against employees of Boston Heart.

In the past, once the DOJ obtained a settlement agreement with a lab company accused of violating one or more federal laws, the federal agency seldom took the additional step of initiating a civil court case against former executives and employees of that company as a way to obtain additional repayment.

Individual Accountability

Because the latest actions by the DOJ are occurring in civil court, the government will have a lower burden of proof to find the defendants liable compared to a criminal case.

The Dark Report previously reported on the DOJ's rekindled interest in individuals' responsibility in fraud cases. *(See TDR, "Federal Healthcare Fraud Enforcement Turns to Emerging Areas," April 4, 2022.)*

In a virtual keynote address in October to the **American Bar Association's National Institute on White Collar Crime**, U.S. Deputy Attorney General Lisa Monaco announced a renewed focus on individual accountability in cases of corporate fraud and abuse, including clinical laboratory testing.

"Accountability starts with the individuals responsible for criminal conduct," Monaco said in the keynote. "Attorney General [Merrick] Garland has made clear it is unambiguously this department's first priority in corporate criminal matters to prosecute the individuals who commit and profit from corporate malfeasance."

Attorney Randy Jones with Boston-based law firm **Mintz** previously said that medical laboratories and others that run into potential trouble with the False Claims Act should pinpoint who was responsible for the problems.

"This renewed focus on individual accountability is going to cause companies under investigation by the DOJ to be prepared to conduct more fulsome internal investigations, to identify all wrongdoers, and to provide the government with all non-privileged information about individual wrongdoing," Jones explained during a February webinar. "There is no partial credit for incomplete disclosures."

CEO Under Fire from DOJ

Grottenthaler worked at True Health from 2014 to 2019. In 2015, True Health acquired the assets of **Health Diagnostic Laboratory** (HDL), the latter of which was under scrutiny following a $47 million settlement with the DOJ for alleged violations of the Anti-Kickback Statute and False Claims Act. *(See TDR, "True Health to Buy HDL Pending Court Approval," Sept. 14, 2015.)*

At the time of the acquisition, Grottenthaler said in a statement that True Health would adopt "an exacting corporate compliance program."

According to the DOJ, the opposite ended up happening. "Aware of the financial success and astronomical growth of a prior laboratory known as HDL, Grottenthaler sought to adopt the illegal practices used by HDL," the lawsuit stated.

Specifically, Grottenthaler allegedly entered into a conspiracy with **Little River Healthcare**, which ran several small hospitals in Southeast Texas, to commit lab test fraud. A True Health affiliate company later operated an onsite lab for Little River.

Little River "agreed to pay [True Health] per laboratory test that was performed, and [True Health] allowed [Little River] to bill the tests to any public or private insurer," the lawsuit stated. The DOJ stated that Grottenthaler allowed True Health to submit two fraudulent reimbursement claims for laboratory testing. In a statement given to The Dark Report, Grottenthaler's lawyer, Andrew Wirmani at the law firm **Reese Marketos** in Dallas, said his client is not liable for the allegations.

"Mr. Grottenthaler adamantly denies the allegations unsealed [on April 4]. The truth is True Health, at his direction, invested millions to develop a rigorous compliance program, hired top-of-the-line compliance professionals, and even went so far as to volunteer to have the government monitor its operations," Wirmani stated. "Whatever misconduct the government believes occurred did not involve my client. We are confident that the facts will demonstrate that he should never have been a part of this lawsuit."

Wirmani filed a motion to dismiss Grottenthaler from the lawsuit on May 13.

According to the DOJ, part of Grottenthaler's motivation for the alleged scheme was to prevent losing business to Boston Heart Diagnostics, which was a competitor. That notion of competition has been disputed by some, as each company focused on different diagnostic tests, according to a source familiar with the case.

From 2006 to 2011, Grottenthaler was Vice President of Finance at **Ameritox**, a drug testing company that closed in 2018 after being sued by **Humana** for allegedly filing false claims with the insurer. In 2010, Ameritox settled a federal whistleblower lawsuit and agreed to pay $16.3 million. *(See TDR, "Facing Lawsuit Filed by Humana, Ameritox Closes Lab, Sells Assets," March 26, 2018.)*

Grottenthaler left True Health after the company entered bankruptcy. His LinkedIn account does not indicate where he currently works.

VP Had HDL Connections

Cornwell was hired by True Health after a stint on the marketing team at **BlueWave Health Consultants**. BlueWave at one point served as a contracted sales company for HDL.

HDL ended its relationship with BlueWave after HDL's leaders believed a BlueWave executive recruited BlueWave salespeople to work for True Health, The Dark Report noted in 2015.

Sales Reps' Roles in Alleged Lab Fraud Resulted in Inducements and Cash Payments

AMONG THE OTHER DEFENDANTS IN THE FEDERAL GOVERNMENT'S CIVIL LAWSUIT alleging clinical laboratory fraud are three sales representatives who worked in various roles: Stephen Kash, True Health's former Director of Strategic Accounts; Courtney Love, Account Executive at True Health from January 2015 to September 2019; and Laura Howard, a Sales Manager for Boston Heart.

The suit alleged that Kash recruited providers to refer patients to Little River for testing in return for payments from an MSO called **Quick Diagnostics**.

In an alleged conversation, Kash offered MSO kickbacks to a Texas doctor. The physician indicated he knew the kickback income would not be for medical services provided to the MSO.

"In an attempt to hide his role in the kickback scheme, Kash had his payments funneled through a shell company named **Tigerlily LLC**, of which he was the beneficial owner," the lawsuit stated.

In 2016 and 2017, two companies that recruited for MSOs as part of the Little River scheme allegedly paid Kash via Tigerlily more than $862,000.

Processing and Handling

Meanwhile, the federal lawsuit painted Love as being deeply involved with setting up kickbacks, including at Oakmont Wellness Center. Oakmont was enrolled as a healthcare provider under Medicare and Medicaid.

Oakmont was owned by a physician whose parents worked in administrative roles there. One parent formed Onsite Draw Station in April 2015. That same month, Love went to Onsite Draw Station to pick up taxpayer forms as a prelude to a compensation arrangement, the suit contended. Love allegedly knew the parents worked for Oakmont and had a financial interest in Onsite Draw Station.

The next month, an alleged agreement was reached in which True Health would pay Onsite Draw Station "processing and handling fees" of $25 per specimen sent to True Health for testing. From 2015 to 2017, True Health allegedly paid Onsite Draw Station kickbacks worth $260,000 to induce laboratory referrals to True Health, stated court documents.

'Cash in a Bag' Deliveries

Aside from her sales duties for Boston Heart, Howard was also a recruiter for MSOs that allegedly paid kickbacks.

For example, in October 2015, she allegedly induced a physician in Plano, Texas, to order Boston Heart tests through Little River. "Before being offered the kickbacks, [the physician] had never referred to [Little River], a hospital nearly 200 miles away," the suit stated.

To conceal Howard's actions, a fellow recruiter's company allegedly received payments for her fraud-related work. "Approximately monthly, from May to December 2016, [the fellow recruiter] delivered to Howard the cash in a bag," the suit said, adding that, "Each month, after Howard received the bag of cash … she placed it in the safe in her home." In total, Howard allegedly received $250,000 in cash from various MSO schemes.

Cornwell's alleged troubles started during his time at BlueWave. While there in 2013, Cornwell offered purported "processing and handling fees" to **Oakmont Wellness Center** in Fort Worth, Texas, to induce their laboratory referrals to HDL, according to the DOJ. Later, while at True Health, Cornwell arranged for lab test referrals from Oakmont to True Health. The owner of Oakmont later started **Onsite Draw Station**, a Fort Worth phlebotomy lab.

On Jan. 5, 2022, Cornwell pleaded guilty in a criminal case to conspiring with one or more persons to violate the Anti-Kickback Statute in connection with True Health's payments of processing and handling fees to Onsite Draw Station. The payments were to induce Oakmont laboratory referrals to True Health, according to the DOJ.

Cornwell also allegedly pushed True Health to get involved with kickbacks from management service organizations (MSOs), the civil lawsuit states. MSOs are legal healthcare setups that help providers and practices with administrative operations. But some MSOs have been associated with fraudulent activity.

Cornwell worked at True Health for about a year. His LinkedIn profile indicates he is currently owner at a hormone replacement therapy and wellness clinic in Texas.

Hertzberg is accused by the DOJ of working with Little River to set up kickbacks for tests performed by the diagnostics firm.

'Buy and Bill Contract'

"Described as a 'buy and bill contract,' Hertzberg allowed [Little River] to bill [Boston Heart] tests to insurers, including federal healthcare programs, in return for a fee paid to [Boston Heart]," the DOJ lawsuit states.

Boston Heart's sales force, allegedly with Hertzberg's approval, worked with Little River and MSO recruiters to induce referrals to the hospital system for Boston Heart testing, the lawsuit contended.

Unnamed vice presidents at Boston Heart seemed to be aware of potential fraud occurring, and they allegedly warned Hertzberg about this problem to no avail, the DOJ stated.

Hertzberg is currently CEO at **BrainScope** in Bethesda, Md., according to BrainScope's website.

Theiler was the former Vice President of Sales at Boston Heart. He worked there from 2012 to 2017. As a vice president, Theiler was a right-hand executive to Hertzberg, the lawsuit stated.

DOJ Lawsuit Notes Three Federal Laws

IN ITS CIVIL LAWSUIT AGAINST SEVERAL LAB EXECUTIVES AND LAB SALES REPS, the Department of Justice cited violations to the following federal laws:

- The **Anti-Kickback Statute** prohibits providers from soliciting, providing, or receiving any payment to induce either the referral of an individual or furnish a service for which payment may be made under a federal healthcare program.
- The **False Claims Act** imposes penalties for any person who submits or causes the submission of fraudulent claims for payment to the federal government.
- The federal **Stark Law** prohibits the referral of Medicare and Medicaid beneficiaries by a physician to an entity for health services if that physician (or the physician's immediate family member) has a financial relationship with the entity.

Theiler and Hertzberg knew that, as a critical access hospital, Little River could submit claims at higher Medicare rates. Such hospitals receive higher rates to ensure access to care in rural communities, and thus, they cannot submit claims for services provided to people who are not inpatients or outpatients at the facility.

Theiler allegedly knew that individuals receiving Boston Heart testing through Little River were not patients at the hospital and had been referred via MSOs. From 2015 to 2018, Little River allegedly paid Boston Heart more than $30 million as part of the MSO-based fraud.

According to Theiler's LinkedIn profile, he works as Vice President of U.S. Sales at **ZOLL Medical's** LifeVest division in Pittsburgh. However, LifeVest's website lists another person in that position.

Attempts to reach Hertzberg, Cornwell, and Theiler were unsuccessful. TDR

Lab Vendors Adjusting to Changing Sales Practices

Clinical laboratories and pathology practices shifted buying patterns since onset of the pandemic

Debra Harrsch

Deborah Hewett-Smith

CEO SUMMARY: Important changes are happening in how lab managers research and buy new lab analyzers, automation, test kits, and consumables. Today, a large proportion of a lab buyer's research and interaction involving new products is done digitally. This includes virtual sales calls, say two IVD lab marketing experts.

When it comes to marketing and selling clinical laboratory automation, analyzers, and test kits, it's a brave new world for the leading *in vitro* diagnostics (IVD) companies. Because of the pandemic and related factors, traditional sales channels no longer work as they did before. At the same time, new paths to lab customers have emerged.

One consequence of these developments is that IVD manufacturers are scrambling to adjust to the new realities of marketing and selling in the clinical laboratory marketplace. They recognize that their lab customers now research and shop for new lab instruments, automation, tests, and consumables in significantly different ways than before the pandemic.

Front and center in these developments was the lockdown in the early months of the pandemic. Businesses closed. Employees stayed home. If any business was done during this time, it was primarily by telephone, email, Zoom conferences, and similar.

Simultaneous with the government-ordered lockdown, hospitals, physician clinics, and clinical labs restricted access to their facilities. These restrictions on visitors (including the sales and service reps of IVD suppliers) continued throughout 2020 and even into 2022 because of the surge of Omicron cases at that time.

Given lemons, IVD companies set about making lemonade. "The pandemic gave IVD marketers the opportunity to try something different because they could not go to trade shows and they could not walk into hospitals for sales meetings," Debra Harrsch, President and CEO at **Brandwidth Solutions** in Lansdale, Pa., told The Dark Report.

Digital Sales Visits

"Marketers really had to get their digital houses in order during the pandemic because they could not rely on things they normally did to reach their lab buyers," she added.

As the pandemic forced closures for nonessential visits, business-to-business (B2B) marketers within IVD firms learned that lab customers and prospects liked being contacted remotely. With most labs short-staffed, lab buyers had little time for on-site visits with IVD sales reps.

"This is a dynamic shift that we see continuing. It is something to embrace. The real question is: How will marketers harness this new normal in marketing and sales in the B2B space?" said Deborah Hewett-Smith, Principal at **Talking Laboratories** in Tucson, Ariz., during the presentation she made with Harrsch at the *Executive War College Conference on Laboratory and Pathology Management* in April.

The session was titled, "How the Pandemic Permanently Changed the Way Lab Buyers Respond to Marketing Messages and Make Buying Decisions."

Hewett-Smith's observations are consistent with a 2020 analysis by management consulting firm **McKinsey & Company**. It found that the SARS-CoV-2 outbreak propelled buyers and sellers into digital "in a massive way."

Most B2B interactions have moved to remote or digital from in-person, the analysis showed. In its survey, 70% to 80% of decision-makers indicated preference for "remote interactions or digital self-service," McKinsey said. Respondents cited reasons such as ease of scheduling, savings on travel, and safety.

"This same internal transition also occurred at clinical laboratories because of the sudden shift to remote marketing and selling—whether for IVD equipment and tests or other lab services," Hewett-Smith noted. "For today's lab buyers, personal, curated content is in high demand from IVD companies—such as digital messages from credible leaders."

Benefit to Digital Sales Mode

Hewett-Smith, who served in marketing for several IVD manufacturers, pointed out that there is a unique benefit when working in a digital sales mode. "Digital sales interaction enables organizations to involve more of their internal experts in the selling process," she stated.

"'Team selling' is starting to take off as compared to a one-on-one sales call," Hewett-Smith explained. "This changes the dynamic of sales to more of a hybrid model. IVD companies will not eliminate in-person interactions. They just won't be the primary way—and maybe not the best way—to further an opportunity to develop a lab prospect into a buyer.

"Lab buyers want it. They like it because it demonstrates to them that the IVD company understands their lab's unique needs," she added. "The walls have come down. With digital engagement tools, an IVD company can deliver better access to its experts. In turn, it creates the opportunity for IVD marketing teams to create curated content and develop useful engagement with lab thought leaders."

Detailed Customer Persona

With more sales development now based on digital engagement, it is important that IVD companies and lab vendors develop a detailed customer persona—i.e., a firm understanding of the individual or people the seller is attempting to reach.

The COVID-19 pandemic created new challenges and responsibilities in the clinical laboratory. Among the top challenges are maintaining adequate lab staff and managing the supply chain. That is why pathologists and lab manager are tapping new sources of information about IVD products and using this information to make informed decisions.

"Most lab buyers are scientists. They like data, and they will look for information to solve patient challenges," Harrsch observed. "They will do their homework. They will go through a consideration phase and look at all the data available.

"It is important that IVD marketers be prepared to take a targeted lab customer on a journey that could lead to an initial purchase and future upsells," she continued. "It is not just saying, 'Here is the instrument and it is great, or here is a new assay.' Customers want more information to take them on their journey to buy what their lab needs."

McKinsey & Co. Survey Determines That B2B Omnichannel Sales May Be Here to Stay

MCKINSEY & CO. CONDUCTED A SURVEY LAST YEAR TO DETERMINE HOW COMPANIES WERE CONDUCTING B2B SALES more than a year into the pandemic. The survey team determined that a large majority of B2B customers now want to access information about products using multiple, digital channels. For *in vitro* diagnostics (IVD) companies, this signals that the era of reliance on face-to-face selling is winding down and virtual access to information, experts, and sales professionals will be the dominant way to communicate with clinical laboratory and pathology customers. Below are key findings from the McKinsey & Co. survey.

Omnichannel selling has soared during the COVID-19 crisis, permanently reshaping the role of the B2B sales rep

85% of B2B organizations expect hybrid reps (who interact with customers more remotely than in person) to be the most common sales role over the next 3 years.	**64%** of B2Bs intend to increase the number of hybrid sellers over the next six months, making this model the lead sales role.	**15%** of B2Bs expect in-person sales meetings to be the norm by the start of 2022.	**41%** of leaders say e-commerce is their most effective sales route, compared to 37% in-person and 31% video.
8 in 10 B2B decision makers now say omnichannel is as or more effective than traditional methods.	**83%** of B2B leaders say omnichannel selling is a more successful way to win new business.	**2 in 3** B2B buyers prefer remote human interactions or digital self-service.	**20%** of buyers would spend more than $500K on a fully remote/digital sales model.

Source–B2B Pulse: How B2B decision makers are responding to the coronavirus crisis, McKinsey & Co.

As before the pandemic, a customer lifecycle loop revolves around various phases of awareness, research, consideration, selection, buying, satisfaction, retention, and advocacy.

"The big four steps continue to be awareness, consideration, buying, and retention," Harrsch said. "A lot of lab vendors do the awareness, consideration, and buying phases, but then they drop the other lifecycle steps.

"A current lab customer may not remain a future customer if the IVD company fails to continue marketing to them through the product lifecycle."

Engage Customers after Sale

Looked at another way, IVD companies need to continue to engage with their customers after a sale occurs, Hewett-Smith added.

"How is your company going to keep your lab customers satisfied? You want the sales team to get back in the organization and hunt for new opportunities," she noted. "But what are the sales and marketing teams doing to make that lab customer the company's advocate?"

Because of the shift away from personal sales calls as a primary method to a digital-based sales process, it is important for IVD companies to send a clear marketing and sales message, Harrsch suggested.

"It's noisy out there. Get the sales message in order, because if it is not in order, the lab customer does not know who you are and how your company's product or service can help them," she noted.

One key is content that addresses customer challenges. "What's the value to the customer? Lab buyers want to know the value proposition at the beginning of the

sales cycle," Harrsch said. "It is really about the customer experience, and digital over the last few years has reinforced that."

IVD marketers have many digital tools available to them: podcasts, videos, webinars, and social media. They can also turn to traditional means, such as news releases, blogs, white papers, and case studies. Regardless of the method, all messaging needs to be integrated.

"Don't create advertising or content in isolation," Harrsch said. "Don't create public relations in isolation. If a message is well integrated, it will cost the company less to market."

She encouraged IVD firms to develop blog content that drives more traffic to the organization's website. The process for doing so is known as search engine optimization (SEO), a web buzzword that refers to using content keywords and related tactics that play into a browser's algorithms for search results.

Using Social Media Channels

"The blog is a place to branch out to all social media channels and develop thought leadership. People respond to thought leadership in articles, news releases, and white papers," Harrsch added.

Potential buyers are curious about what is out there, Hewett-Smith added. "Now is a good time. Buyers are receptive to digital interactions. How can an IVD marketing team ramp that up?"

Increased marketing comes at a cost, and results need to be tracked. "Marketers are being held accountable for return on investment. ROI cannot be shown on everything, but a lot of this is measurable," Harrsch noted.

"For example, if I do a webinar, I know how many people were on the call and how many followed up. And now marketing automation tools show how customers or prospects are engaging with the company.

"So, an IVD sales team can have information about what topics are of interest to lab customers before it initiates the sales call, because these marketing automation platforms now tell them what areas of interest were engaged by the customer," Harrsch explained. "It remains true that nothing is more important to a sales person than knowing what is of greatest interest to a customer."

Marketing Effectiveness

Another benefit to remote sales interactions is that this channel allows IVD companies to monitor the receptiveness of marketing messages by lab customers and the effectiveness of the marketing and sales teams, according to Hewett-Smith.

"Real-time feedback from a recorded, remote sales interaction is a way to help ensure that messages are understood and meet their mark," Hewett-Smith emphasized. "Digital platforms give marketing and sales teams direct access to the voice of the customer to see how messages resonate. It's a gold mine of marketing data that would not be available from an in-person interaction."

Modern sales call software can transcribe and annotate conversations with prospects, allowing for post-call reviews that can better pinpoint topics or wording that promoted follow-up discussions. The software can also aggregate call data to pull out keywords that are mentioned most often during calls, offering another opportunity to tailor future marketing and sales messages to customers.

Competitive Advantage

IVD companies that are keen on maintaining a competitive advantage should evaluate these new marketing and sales tactics as more clinical laboratories and anatomic pathology practices resume normal operations. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Monkeypox is the latest disease showing up in the United States. That means hospital laboratories will want to be ready to diagnose monkeypox cases that show up in their emergency departments. An official from the **Centers for Disease Control and Prevention** (CDC) says it is exploring the possibility of expanding capacity for monkeypox testing if it becomes necessary. Currently, a state or local laboratory performs an initial test to determine if a case is an orthopox virus (the genus that includes monkeypox) and a CDC laboratory later confirms whether it is monkeypox, according to *STAT*.

MORE ON: *Monkeypox Testing Capacity*

At least two *in vitro* diagnostics companies are preparing to meet any increased demand for monkeypox testing. **Roche** announced on May 27 that it had rolled out a new suite of tests to detect the monkeypox virus and that the tests are available in most countries. Meanwhile, *CNN* reported that **Abbott Labs** plans to introduce a polymerase chain reaction test for monkeypox. As of June 1, 19 monkeypox cases had been detected in the U.S., according to the CDC. The disease is rare in this country, so the increase in cases is puzzling. The CDC reported two monkeypox cases in the U.S. in 2021.

CDRH RESUMES IVD PRE-SUBMISSIONS

It was good news for lab test developers when, as of June 1, the **U.S. Food and Drug Administration's Center for Devices and Radiological Health** (CDRH) began accepting non-COVID-19-related *in vitro* diagnostic (IVD) pre-submissions. Since April 2021, the CDRH had declined some pre-submission requests as it sought to prioritize pandemic work, according to *MedTech Dive*. Due to the continued elevated workload related to the pandemic, it's likely that upcoming IVD pre-submissions will initially be reviewed under an extended timeline, CDRH noted.

TRANSITIONS

- **XIFIN** has appointed John Kelly as the company's first Chief Information Officer (CIO). He comes after stints as Chief Technology Officer (CTO) at software company **PatientKeeper** and as a Segment CIO and CTO at **Cigna**.

- Sharon Bracken is the new Head of Diagnostics at **Siemens Healthineers**. Bracken was most recently President at **Perma Pure**, a moisture management company. She previously spent 14 years at **Abbott** and four years at **Ortho Clinical Diagnostics**.

- Funda Suer, PhD, has joined **Quadrant Biosciences** as Executive VP of Clinical Diagnostics and CLIA Laboratory Director. Suer previously served as Division Head of Molecular Diagnostics at **Sema4** and Lab Director at the **Icahn School of Medicine at Mt. Sinai.**

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 27, 2022.

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