Volume XXXI, Number 6 Monday, April 29, 2024

Congressional Subcommittee Hears Testimony on FDA LDT Rule

Lab groups argue against proposed rule.

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BREAKING NEWS!

DOJ Antitrust Probe of UnitedHealth *(see pages 9-12)*

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Artificial Intelligence and Executive War College

BY THE TIME YOU READ THIS our 29th annual *Executive War College on Diagnostics, Laboratory, and Pathology Management* conference will be underway in New Orleans. As noted in previous issues of THE DARK REPORT, three topics will be of keen interest.

First is the FDA proposed rule for laboratory developed tests (LDTs). Second is private payer requirements that certain genetic test claims include a Z-Code. Third is the work underway by the Clinical Laboratory Improvement Advisory Committee (CLIAC) to reform and update the Clinical Laboratory Improvement Amendments (CLIA) of 1988 regulations. Most of the nation's clinical laboratories and pathology groups will be impacted by all three.

However, another technology trend that will require a response by most labs will also be front and center at the *Executive War College*. It is the growing role of artificial intelligence (AI) in lab operations, diagnostic medicine, and data management. Of the 13 Corporate Benefactors giving presentations on topics of their choosing, six are centering their content around artificial intelligence and how their services incorporate AI to deliver value to lab customers.

This is significant. It demonstrates that the most important message major vendors to clinical labs and pathology groups want to deliver is the role their firm's artificial intelligence solutions have in: 1) Helping lab clients operate more efficiently; 2) Delivering more effective lab testing services to referring physicians; and 3) Mining sets of data to identify opportunities to deliver more value to physicians, parent hospitals, patients, and payers.

That's why this year's *Executive War College* has already scheduled a full plenary session centered solely on artificial intelligence. Plus, there will be a full-day optional workshop organized to provide lab leaders with an understanding of different AI technologies, which technologies are ready for use in lab settings, and what to expect next as AI solutions become more robust.

Thoughtful lab managers and pathologists will want to consider these developments in the context of their lab's current strategic plan. The evidence above demonstrates that the rate of adoption of AI-powered solutions is accelerating. Now is the time for labs to ride this wave to success! TDR

Change Health Cyberattack Breaches PHI Here at TDR!

Labs should be on the alert for attempts to use the PHI of employees and their lab organization

CEO SUMMARY: It was Feb. 21 when cybercriminals attacked Change Healthcare's claims processing systems. On April 22, UnitedHealth Group issued a statement that PHI for "a substantial proportion of people in America" was breached. We believe the PHI of our employees and THE DARK REPORT itself was breached because fraudsters recently attempted to use employees' credit accounts and open bank accounts under THE DARK REPORT name.

MANY CLINICAL LABORATORY MANAGERS BREATHED A SIGH OF RELIEF following last February's national headlines about the hugely disruptive cyberattack against **Change Healthcare**, the business unit of **Optum**, itself a division of **UnitedHealth Group**.

That relief stemmed from the details of the Feb. 21 cyberattack, which shut down the prescription ordering and prescription payment functions of Change Healthcare. But the cybercriminals had not attacked the systems that processed other types of claims, including clinical lab and genetic test claims. *(See TDR, "Change Healthcare Hit by Major Cyberattack," March 18, 2024.)*

However, even if clinical laboratories and anatomic pathology groups were unaffected by this cyberattack—which was unprecedented in its scope and disruption to the U.S. healthcare system—they are still at risk from another consequence of this cyberattack.

That risk is unauthorized use of personal and corporate protected health information (PHI) by cybercriminals who come into possession of the millions of data files Change Healthcare kept on patients, providers, and the employers who purchase health insurance coverage from **UnitedHealthcare** (UHC).

Here at THE DARK REPORT, we believe we are victims of two attempted cybercrimes directly resulting from the breach of personal and company PHI held by Change Healthcare. The purpose of this intelligence briefing is to inform other laboratory professionals and lab organizations about our experiences so they can be alerted to the specific frauds attempted against us. These fraud actions and their timing appear to be consistent with bad actors accessing the type of information that would be held in the computers of UnitedHealthcare, Optum, and Change Healthcare.

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

There is ample evidence in the public domain that the data stolen from Change Healthcare by the cyberattackers flowed into possession of two or more entities.

ALPHV/BlackCat are the Russia-based cybercriminals who took credit for the ransomware attack against Change Healthcare. Here is where the story takes a unique twist. Within days of Change Healthcare paying a $22 million ransom in Bitcoin, a second hacker issued a public statement.

One Hacker Was Not Paid

This hacker claimed that it was he who discovered the way to compromise Change Healthcare's computer systems and that he partnered with ALPHV/BlackCat to enable the ransomware attack to succeed. He then said that he was owed a portion of the $22 million ransom paid to BlackCat. But it was reported ALPHV/BlackCat had ceased operations without paying him his share.

Next, this hacker declared that he had his own copy of the data captured from Change Healthcare's computer systems. Unless he was paid his cut by ALPHV/BlackCat, he had a motive to expose the data on the web or sell it to other bad actors.

The fact that more than one fraudster had copies of the Change Healthcare data was reported by multiple news outlets in the weeks following the Feb. 21 ransomware attack on Change Healthcare.

Early Cost Estimates

Fraudulent use of the PHI of our employees and THE DARK REPORT itself appears to be connected with the Feb. 21 cybercrime. On April 23, one of the executives at THE DARK REPORT was called by his bank. The fraud officer at the bank informed him of a $50 purchase on his debit card. The bank had rejected the charge. It blocked the debit card and issued a new debit card with overnight delivery.

Then, two days later, another fraud officer of the same bank used by THE DARK REPORT called to report that an individual had walked into a branch in another state and had opened up a corporate checking account using THE DARK REPORT's employer identification number (EIN) and the name of the same employee whose debit card had been compromised two days earlier.

Two business days later, a letter from this bank arrived at THE DARK REPORT's office. It was the form letter that our executive was to sign for the bank's records, giving it a live signature for this new commercial checking account. This letter had been put in the mailstream before the bank's fraud department closed that corporate bank account in the name of THE DARK REPORT.

What linked these two events is how the same executive was connected to the fraudulent use of his debit card, followed by the attempt to open a corporate checking account with his name as the signatory.

Link to UnitedHealthcare

In assessing these remarkable events, it was recognized that THE DARK REPORT's employee health plan is administered by UnitedHealthcare. Further, as a beneficiary of the plan, this executive has a number of prescriptions under the UHC health plan.

The team here deduced that the ransomeware attack that stole the data from Change Healthcare's prescription ordering and reimbursement systems meant that our executive's debit card and credit card information were probably breached. And with that theft came the records of THE DARK REPORT's health plan with UHC—records that included this same executive's name as the contact for our group insurance plan.

This experience is shared with our clients and regular readers because many clinical laboratories and pathology groups may either have health coverage by UnitedHealthcare or are providers of lab testing to UHC beneficiaries.

The timing and the details of these two attempted financial crimes make it rea-

sonable to consider THE DARK REPORT's experience as evidence that bad actors are probably using the data stolen from Change Healthcare to commit fraud against both patients and the companies with health plans administered by UnitedHealthcare.

Filing Reports with UHG

As a postscript to these events, the team here is attempting to file reports with Change Healthcare, UnitedHealth Group, the **FBI**, and the **Department of Justice**. On April 22, UnitedHealth Group posted a page on its website that directs individuals to call a toll-free telephone number. It says that it "will offer free credit monitoring and identity theft protections for two years to anyone impacted."

It should be noted that UnitedHealth Group—like other healthcare organizations—must follow the steps required by HIPAA when a breach of protected health information occurs. Those steps include:

- When the breach of PHI involves 500 or more individuals, the organization must notify federal and state officials.
- When 500 or more individuals are involved in the breach, the organization must issue a public statement describing the breach to the media, with some exceptions.
- The organization must notify individuals affected by the breach, "without unreasonable delay and in no case later than 60 days following the discovery of a breach."

Heighten Lab Cybersecurity

THE DARK REPORT is sharing this experience to alert lab managers that it would be prudent to heighten their lab's cybersecurity. Today, it is possible that any breach of PHI and personally identifiable information (PII) may involve a patient or a provider whose data was stolen during the Change Healthcare ransomware attack.

Further, THE DARK REPORT is interested to hear from other clinical laboratories and pathology groups that may have discovered similar attempts at financial fraud using the PHI of its employees and patients. Having a public record that describes the types of attempted fraud can help all labs better protect themselves, their employees, and their patients in the wake of the Change Healthcare ransomware attack. TDR

Huge Cyberattack Breaks New Ground

IT MAY TAKE YEARS TO SORT THROUGH ALL THE CONSEQUENCES of the Feb. 21 ransomware attack directed at Change Healthcare, which is owned by UnitedHealth Group's Optum subsidiary.

As reported by *SC Magazine* on April 23, "The case has led to an alleged $22 million ransom payment to BlackCat/ALPHV as well as news that a second threat group, **RansomHub**, had leaked a portion of stolen Change Healthcare data on the dark web."

In a public statement, UnitedHealth Group said, "Based on initial targeted data sampling to date, the company has found files containing protected health information (PHI) or personally identifiable information (PII), which could cover a substantial proportion of people in America. To date, the company has not seen evidence of exfiltration of materials such as doctors' charts or full medical histories among the data."

In that statement, the company also said, "The company, along with leading external industry experts, continues to monitor the internet and dark web to determine if data has been published. There were 22 screenshots, allegedly from exfiltrated files, some containing PHI and PII, posted for about a week on the dark web by a malicious threat actor. No further publication of PHI or PII has occurred at this time."

UnitedHealth now has a dedicated website at *http://changecybersupport.com/* to provide additional information.

Wisc. Diagnostic Lab's Alternative Staff Solutions

College students and recent graduates learn the lab while working toward MLS ASCP certification

Mike Baron
Wisconsin Diagnostics Lab

CEO SUMMARY: *Even as clinical laboratories and pathology groups around the nation cope with a sustained shortage of qualified staff, the team at Wisconsin Medical Laboratories has successfully kept staffing at 96% of authorized levels. One effective strategy they use is to go into the community to educate recent college graduates and high school students about the benefits of a career in laboratory medicine.*

AMID UNPRECEDENTED CHALLENGES IN RECRUITING AND RETAINING LAB PROFESSIONALS, **Wisconsin Diagnostic Laboratories** (WDL) is using alternative staffing solutions to develop qualified and certified employees to meet its workflow needs.

WDL managers and technologists share responsibilities for guiding college student apprentices and recent graduates on their way to certification as laboratory professionals. The WDL team also now reaches out to high schools and more venues to spread the word about the benefits of a career in laboratory science.

All the hard work is paying off in a low staff vacancy rate and other achievements by WDL, which was recently named a 2024 Lab of the Year Runner-Up by *Medical Lab Observer*.

"We are making a connection. There are a lot of programs and initiatives we are doing. We don't have any temporary staff or traveling staff working in the lab. We have been able to develop our own team and average a 4% vacancy rate," said Mike Baron, WDL's Executive Director, Clinical Laboratory Operations, in an interview with THE DARK REPORT.

WDL's unique recruiting, staff development, and education initiatives include:

- Non-certified technical staff program.
- Apprenticeship program.
- Outreach to high schools, job fairs, and school counselor conferences.
- Clinical laboratory leaders education collaborative.

Serving Froedtert Health

Based in Milwaukee with patient service centers throughout southeast Wisconsin, WDL is a full-service clinical reference lab employing more than 400 people. It performs more than 6.5 million tests a year and specializes in anatomic pathology, chemistry, cytogenetics, cytology, flow cytometry, hematology, microbiology, and molecular biology.

WDL is the main lab for **Froedtert Hospital**, a 735-bed teaching hospital in Milwaukee. It also functions as the central reference lab for the **Froedtert Health** network. Through its partnership

with the **Medical College of Wisconsin's** Pathology Department, WDL's reach extends throughout Wisconsin and northern Illinois.

"We are pushing to create a high quality lab with a patient-first focus," Baron said. "We have three priorities. Priority one is patient care. Priority two is teamwork and supporting the team and being a team player. And priority three is individual wellness."

Filling Vacancies

The creation of a unique environment is important, as clinical labs and pathology groups nationwide struggle to recruit and retain employees.

"Medical laboratory scientist candidates are in the driver's seat," Baron stated. "They are interviewing with several labs. They will go where they can get more money or they may make their decision based on the lab's environment."

The central northeast area (which includes Wisconsin) has the second highest vacancy rate with 15.2% (behind the northeast with 15.8%), according to an article summarizing a 2022 vacancy survey of medical labs published in the *American Journal of Clinical Pathology*.

With its 4% vacancy rate, WDL appears to be doing well. So, why all the work on alternative staffing programs? "Even though we are able to fill jobs, we still see a lot of people coming and going. We are constantly filling vacancies with non-certified techs," Baron said.

Learning the Lab

Non-certified technologists (NCTs) are recent college graduates who hold bachelor's degrees in molecular or microbiology, chemistry/biochemistry, neurology, or another advanced science degree.

At WDL, they receive entry-level pay for a position usually on the second or third shift.

Importantly, they get on-the-job experience in the lab department relating to their **American Society for Clinical Pathology** (ASCP) certification interest: chemistry, hematology, microbiology, or molecular biology.

The NCTs are eligible to pursue ASCP certification in a year, but actually have up to 30 months to do so from WDL.

Following WDL's launch of this NCT program in 2022 for areas beyond microbiology (which had a previous program):

- 14 NCTs earned ASCP certification: two in chemistry, three in hematology, and nine in microbiology.
- 28 NCTs are about to be certified or awaiting eligibility to sit for exams: seven in chemistry, seven in hematology, and 14 in microbiology.

WDL provides the NCTs with classroom instruction, certification support, as well as on-the-job training by WDL's clinical lab trainers. The lab and NCTs follow ASCP certification requirements and paths, which are published on the organization's website. The steps include determining an exam route, submitting an application, scheduling a test, and participating in exam day.

"An ASCP Board of Certification (BOC) credential can result in improved job prospects, higher salaries, and greater career satisfaction. … BOC offers a variety of professional certifications, and each one has its own set of requirements," the ASCP website states.

"Classroom instruction is not necessarily required since [the college graduates] come in with a bachelor's degree and have a strong foundation already," Baron added. "The classroom instruction does provide a better foundation for the NCTs' success."

In fact, Baron got his start in the laboratory profession at **Rockford Memorial Hospital**, Rockford, Ill., armed with a bachelor's degree in biology and a minor in chemistry. He has since added

advanced degrees in biology and business administration.

"I worked in the chemistry laboratory with many hours of classroom instruction from the medical director. I achieved my ASCP certification as a technologist in chemistry and have since took on leadership roles in the clinical laboratory," said Baron, who also served as a **U.S. Army** Reserve Officer, retiring as a Lieutenant Colonel in 2016.

Partnering with Students

Another unique way WDL staffs the lab while giving others a gateway to the profession is the Medical Laboratory Scientist Apprentice Program, a partnership with **Wisconsin Workforce Development** and **Milwaukee Area Technical College** (MATC).

College students work in the lab and also attend classes at MATC. WDL covers the students' tuition, books, and parking fees. "Like the NCTs' path, the goal for apprentices is pursuit of ASCP certification in the area they support in the lab," Baron said.

One challenge in running the Medical Laboratory Scientist Apprentice Program is balancing the lab's need for students and their on-the-job training with the time they need to spend in classes.

Plans to Grow

Baron wants to grow the WDL Education Collaborative and encourage more exchange of ideas on recruitment, retention, and education of technical laboratory staff.

WDL also plans to increase awareness of the clinical lab profession by reaching out to more high school students and to sponsors of career-related events. It plans to build on NCT Program participation, and to support more apprenticeships while also evaluating how newly certified employees are helping to solve the lab's staffing challenges.

WDL Lab Team Goes into the Community

TO GENERATE MORE AWARENESS OF THE CLINICAL LABORATORY AS A CAREER PATH, Wisconsin Diagnostic Laboratories (WDL) wants more people to begin thinking of a career in the clinical laboratory profession early-on—before they attend college classes.

"It's important to reach out to a variety of ages," emphasized Mike Baron, WDL's Executive Director, Clinical Laboratory Operations, in an interview with THE DARK REPORT. "We regularly have team members speak about medical laboratory careers at area high schools and during conferences attracting guidance counselors."

To get invitations to high schools, WDL staff may tap their personal contacts, calling on teachers they happen to know. Baron said he visits school websites and searches instructors of biology, chemistry, and anatomy and physiology classes to inquire about their interest in the lab's presentation.

In another type of outreach, he welcomes lab leaders to the WDL Education Collaborative. Baron hosts speakers who share their lab staffing solutions and education ideas during monthly Webex teleconferences with colleagues.

"We are not always the highest paying diagnostic laboratory. But we are starting to make a name for ourselves for the environment we have created here. And that is part of the reason we have a low vacancy rate," Baron said.

Baron will speak on ISO 15189 medical laboratory accreditation to advance patient care, sustaining lab staff's quality culture, and being CLIA inspection-ready, at the upcoming *29th Annual Executive War College* set for April 30 through May 1 in New Orleans. TDR

Contact Mike Baron at 414-805-7938 and mbaron@wisconsindiagnostic.com.

UnitedHealth Group Faces DOJ Antitrust Probe

Nation's largest health insurer faces challenges on several fronts, with implications for clinical labs

CEO SUMMARY: Recent events have not been kind to UnitedHealth Group and its subsidiaries UnitedHealthcare and Optum. In February, just as UHG's Change Healthcare division was hit with a major cyberattack that disrupted billions of dollars in medical claims, news leaked out that the federal Department of Justice was investigating the firm for antitrust violations.

News of a federal **Department of Justice** (DOJ) antitrust investigation has added to the headaches at **UnitedHealth Group Inc.** (UHG), whose **Change Healthcare** subsidiary is still dealing with the fallout from a massive ransomware attack in February.

The Wall Street Journal reported that federal investigators have been speaking to "healthcare industry representatives in sectors where UnitedHealth competes, including doctor groups."

The investigation is reportedly focusing on UHG's acquisitions of physician practices, as well as relationships between UHG's two major divisions: **UnitedHealthcare** (the insurance arm) and **Optum**, which operates a large network of medical groups in addition to other businesses. *(See sidebar on page 11.)*

Clinical laboratory administrators and pathologists may want to follow this intriguing story. The different business divisions of UnitedHealth Group touch the laboratory profession in multiple ways:

- UnitedHealthcare is the nation's largest health insurer, with about 40 million beneficiaries. It contracts directly with clinical labs, genetic testing companies, and anatomic pathology groups. Its guidelines, pricing, and network contracting policies involving lab testing typically impact a large proportion of labs in the United States.
- Optum Health employs 90,000 physicians and controls the choice of clinical labs that provide testing to the patients of these physicians.
- Optum Insight is positioned to impact clinical labs in two ways. One, it develops coverage policies for other health insurers and self-insuring employers. Two, with its 2021 acquisition of Change Healthcare, it is reported that Optum Insight now has a claims clearinghouse that handles about 40% of all medical claims annually in the U.S.

Pervasive Influence

Few lab managers appreciate the pervasive influence that UnitedHealth Group has on healthcare in general and clinical lab testing specifically. For this reason, the federal antitrust probe has the potential to change the healthcare landscape if federal officials successfully pushed for a break-up of UnitedHealth Group as it now exists.

"I do think the DOJ is starting to wake up and see how vertical integration or vertical consolidation is affecting the healthcare

industry. … When you have an insurer buying physician practices or hospitals, they're paying themselves for the care that is being provided," stated Adam Brown, MD, an emergency physician and founder of **ABIG Health** in an interview with *MedCity News*. "That creates a challenge for anyone who's not underneath that umbrella. But it also creates a challenge for those stakeholders underneath that umbrella, such as physicians, where they have inability to compete, negotiate for wages, benefits, etc."

Irony in Antitrust Probe

There is some irony in the fact that the DOJ is investigating UnitedHealth Group for antitrust violations. Over the years, DOJ has allowed UHG to swallow one healthcare entity after another to become a dominant player.

The initial reporting of the investigation came from an unlikely source: *The Examiner News*, a small news organization in the Hudson Valley region north of New York City. Adam Stone, the owner/publisher, has been running a series of investigative reports about Optum's takeover of local medical groups, including problems such as double billing of patients and aggressive collection efforts.

After acquiring the practices, Optum made them part of a regional operation known as **Optum Tri-State.** Citing "internal company correspondence," Stone reported in February that UHG received notice of the DOJ antitrust investigation last October.

UHG Acts to Retain Records

Rupert Bondy, JD, UHG's chief legal officer, alerted other high-level executives about the DOJ's action, which included a "document preservation notice" requiring UHG to retain materials that could serve as evidence. However, Bondy noted at the time that the probe was at an early stage and that the DOJ notice did not allege any specific wrongdoing.

Stone also reported that the **New York State Health Care Bureau**, part of the Attorney General's office, was looking into the high volume of patient complaints about Optum Tri-State.

The DOJ and UHG declined to comment about the investigation, *The Wall Street Journal* reported. However, citing individuals who have talked to investigators, the paper suggested that the DOJ is looking into these questions:

- Does UnitedHealthcare, the insurance arm of UHG, favor Optum-owned medical practices in contracting and payment arrangements?
- Does Optum's ownership of medical practices pose problems for payers that compete with UnitedHealthcare?
- Are UnitedHealthcare and Optum using their relationship to get around federal rules that limit the percentage of premiums that can go to administrative costs and profits?
- Are Optum doctors documenting patients' illnesses in a way that would inflate Medicare claims? Such practices can be "lucrative for insurers such as UnitedHealthcare," the paper reported.

Antitrust Déjà vu for DOJ

The federal government has already attempted action against UHG on antitrust grounds. In February 2022, the DOJ filed an antitrust lawsuit seeking to block UHG's $13 billion acquisition of Change Healthcare.

Change is the nation's largest clearinghouse for electronic submissions of insurance claims. At the time, the government said the deal would give UHG access to "vast amounts of competitively sensitive data about United's rivals—data that reveals how their plans are designed and how they calculate payments to providers, for example."

Also, "the proposed acquisition would also allow United to use its control over Change's technologies to disadvantage

Taking a Closer Look at UnitedHealth Group and Possible Antitrust Action by Dept. of Justice

IN 2023, THE AMERICAN MEDICAL ASSOCIATION RANKED UNITEDHEALTHCARE as the largest commercial health insurer in the U.S., with a 14% market share. It's the largest **Medicare Advantage** insurer by far, with a 28% market share, compared with 18% for second-place **Humana**, according to the AMA.

But UnitedHealthcare is just part of **UnitedHealth Group** (UHG), a publicly-traded behemoth that also owns Optum, Inc., which is also a giant in the markets where it competes. According to UHG's annual report, UnitedHealthcare—the insurance arm—and Optum each accounted for roughly half of the company's $32.4 billion in earnings in 2023.

That was an increase of 14% from the previous year.

Three Lines of Business

UHG reported total revenue of $371.6 billion, up 15% from 2022. Optum has three lines of business:

- **Optum Health** operates medical groups and ambulatory care centers in many locales. A report from **Darwin Research** described Optum as the largest physician employer in the U.S., with nearly 90,000 physicians and 40,000 other clinicians.
- **Optum Rx** provides pharmacy benefit management services for employers and health plans. *Becker's Hospital Review* ranked it as the third-largest PBM with a 22% market share.
- **Optum Insight** provides data, analytics, consulting, and technology services to payers, healthcare providers, and other entities. This unit was bolstered by Optum's $13 billion acquisition of **Change Healthcare**, which closed in October 2022 after the **U.S. Department of Justice** (DOJ) failed to block the deal on antitrust grounds.

There are two reported numbers about the value of the deal. Apparently it's $8B in cash and $13B with debt included. The *Associated Press* and *The Wall Street Journal* have reported both numbers at different times. *Reuters* said $8B.

Optum Health and Optum Rx accounted for more than 90% of Optum's revenue in 2022 and 2023, according to UHG's annual report. However, while it brings in far less revenue than the other businesses, Optum Insight accounted for more than 25% of the division's annual earnings.

UHG a Serial Acquirer

How did UHG and Optum grow so large? In its 2022 complaint seeking to block the Change Healthcare acquisition, the DOJ described UHG as a "serial acquirer that has purchased more than 35 healthcare companies over the last 10 years."

And it isn't finished. In March 2022, Optum announced a $5.4 billion deal to acquire **LHC Group**, a provider of home healthcare services.

Last June, the company said it planned to acquire **Amedisys**, a large provider of home health and hospice services, in a deal valued at $3.33 billion.

The Wall Street Journal reported that the DOJ is eyeing the latter deal for possible antitrust action.

its health insurance rivals by raising their costs and denying or delaying their access to innovations and quality improvements to products and services supplied by Change," the complaint alleged.

Later, when the case went to trial, UHG CEO Andrew Witty testified that Optum had a "strictly arm's length relationship" with UnitedHealthcare, a point that is likely to come up again if the new

DOJ investigation leads to another antitrust suit.

Federal district judge Carl J. Nichols ultimately rejected the government's attempt to block the deal and the acquisition closed in October 2022.

Ransomware Attack

Fast-forward to February 2024, when cybercriminals launched a massive ransomware attack against Change Healthcare, forcing the Optum subsidiary to disconnect many of its computer systems.

"We cannot say this more clearly—the Change Healthcare cyberattack is the most significant and consequential incident of its kind against the U.S. healthcare system in history," said **American Hospital Association** President and CEO Rick Pollack in a March 5 statement. "For nearly two weeks, this attack has made it harder for hospitals to provide patient care, fill prescriptions, submit insurance claims, and receive payment for the essential healthcare services they provide."

Since then, Optum has been bringing systems back online. However, as of early April, the company had confirmed that full restoration of the systems had been achieved.

Protected Health Information

UnitedHealth Group did, on April 18, issue a statement about the breach of patients' protected health information (PHI). "At this time, we know that the data had some quantity of personal health information and personally identifiable information," UHG said. "We are working to determine the quantity of impacted data, and we are fully committed to providing notifications to impacted individuals when determinations are able to be made—and will work with the Office for Civil Rights and our customers in doing so."

Is UnitedHealth Group a corporation under siege? It is dealing with the consequences of probably the largest cyberattack and data breach known to have occurred to the United States' healthcare system.

UHG is being investigated for antitrust violations by the DOJ. It is also reducing staff. Starting in the first half of 2023, UnitedHealth Group and its various operating divisions have cut personnel in successive waves of layoffs.

Lab managers should be on the lookout for the consequences of these developments, particularly in the timely processing and payment of lab test claims. TDR

Lawsuit Describes Optum's Tactics

CLINICAL LABORATORIES ARE NOT THE ONLY CLASS OF PROVIDERS that have reason to be unhappy with the policies and practices of UnitedHealth Group and Optum.

In California's San Gabriel Valley, **Emanate Health** serves one million patients and operates a network of care facilities. Emanate Health filed a lawsuit against Optum in November 2023, alleging violations of antitrust laws. The action stems from Optum's acquisition of a medical clinic in the area. After several physicians left the Optum-owned clinic to join Emanate facilities, Optum instructed staff not to inform patients of the move, in one case terminating an employee who truthfully responded to a patient's inquiry, the lawsuit alleged.

Optum also placed "facially unlawful restrictions in the physicians' contracts" to prevent them from going to competitors, the plaintiffs alleged. The lawsuit also claimed that Optum tried to force Emanate out of the primary care business. When Emanate chose not to do so, the lawsuit alleged, Optum retaliated by declining to renew contracts with Emanate hospitals.

An Optum spokesperson described the allegations as "baseless" in a statement to *Becker's Hospital Review*.

Regulatory Update

Congressional Subcommittee Hears Testimony on FDA LDT Rule

Lab industry stakeholders warn members of Congress about the flaws in the FDA's plan to regulate LDTs

During a March 21 hearing convened by the **U.S. House Energy and Commerce Subcommittee on Health**, key members of Congress came under fire from representatives of clinical laboratory groups over the **Food and Drug Administration's** (FDA's) proposed rule to regulate laboratory developed tests (LDTs). The participants also disagreed over whether the Verifying Accurate, Leading-edge IVCT Development (VALID) Act was an appropriate alternative.

Warnings to Lawmakers

Testimony given during this hearing allowed many lab industry stakeholders to warn lawmakers about serious flaws in the FDA's plan to regulate LDTs. That was true of Donald S. Karcher, MD, FCAP, President of the **College of American Pathologists** (CAP) when he told the committee, "We believe the [FDA's] proposal as written would reduce the number of highly accurate LDTs available to patients, and delay medical innovation and timely patient care."

The proposed rule "would result in reduced patient access to critical diagnostic testing services," said Susan Van Meter, President of the **American Clinical Laboratory Association**. "Laboratory developed testing services would be removed from testing menus, not because they don't yield reliable and accurate results, but because seeking FDA approval can be prohibitively expensive."

The FDA proposed the rule in October. According to the agency, the rule clarifies that IVDs made by laboratories are subject to regulation under the federal Food, Drug, and Cosmetic Act. Historically, the FDA has exercised enforcement discretion in which it declined to regulate most LDTs. The rule, as proposed, would phase out the discretion in multiple stages over four years.

The FDA proposed the rule after **Congress** failed to vote on the VALID Act, which would have established a statutory framework for FDA regulation of LDTs. First submitted in Congress in 2020, the VALID Act was reintroduced in each subsequent Congress, but has yet to be passed. *(See TDR, "Congress May Soon Act on LDT, IVCT Regulation," Nov. 29, 2021.)*

"VALID creates a new pathway for FDA approval of *in vitro* diagnostics, including LDTs," said Rep. Larry Bucshon, MD, (R-Indiana) Bucshon, co-sponsor of the bill in his opening remarks during the hearing. "Under its framework, tests would be categorized as low-, medium-, or high-risk, and treated in a manner that is appropriate for each risk level.

"For example, low risk tests could bypass FDA's premarket approval process altogether, and even most medium-risk tests could obtain a technology certification that would allow them to immediately enter the market," Bucshon added.

He also noted that the Act included a grandfather clause that would exempt LDTs currently in use.

"For many reasons—ones that we've already heard and will continue to hear—these unique tools should not be evaluated in the same way that FDA reviews machines, implants, and other kinds of devices," Bucshon noted. "But it's not just LDTs that are ill-suited to be evaluated as medical devices. The entire category of *in vitro* diagnostic tests should be differentiated from devices and provided with their own, less burdensome pathway for review and approval."

In their testimony, both Karcher and Van Meter expressed support for the VALID Act. Witnesses also included **AdvaMedDx** executive director Zach Rothstein, JD, and **Friends of Cancer Research** president and CEO Jeff Allen, PhD, both of whom said they supported FDA oversight of LDTs. But even Rothstein, whose organization represents IVD manufacturers, voiced concern about the FDA rule.

"Regulatory certainty is a critical element to encourage a favorable innovation environment for diagnostic tests," he observed. While the FDA rule "would bring about at least some level of certainty," he said it would likely lead to litigation to block its enactment. "We would prefer regulatory certainty through VALID," he added.

➤'LDTs Are Not Devices'

However, Dara L. Aisner, MD, PhD, Medical Director of the **Colorado Molecular Correlates Laboratory**, said the FDA has no business regulating LDTs, whether it's through a rule or legislation.

"LDTs are not devices, they are processes performed with expertise," she said. "Knowledge of all the steps combined with an understanding of the scientific and clinical data allows for nuanced care that simply cannot come from an assay kit. The use of the FDA's device infrastructure is quite simply forcing a square peg into a round hole."

Aisner spoke as a representative of the **Academic Coalition for Effective Laboratory Developed Tests**. The group formed in 2021 to oppose legislation like the VALID Act that would enable FDA regulation of LDTs. It includes pathologists from 100 academic and hospital-based laboratories in the U.S.

Instead of empowering the FDA to regulate LDTs, she said lawmakers could look at other pathways to ensure the quality of tests. For example, "a pathway that asks laboratories to undergo proficiency testing prior to launch achieves the endpoint without the burden," she said.

➤House Members Weigh In

Speaking against the rule, committee chair Rep. Cathy McMorris Rodgers (R-Washington) observed that LDTs play an important role in testing for rare diseases, cancers, pediatric illnesses, and other conditions that affect relatively small patient populations.

"Under the proposed rule, clinical laboratories will incur significant costs to come into compliance," she said. "New administrative and clerical burdens, along with oppressive submission fees, will be a substantial drain on a lab's limited resources." The rule, she said, extends "far beyond any of the legislative proposals that Congress has considered."

Speaking in favor, the committee's ranking Democrat, Frank Pallone, Jr. (D-New Jersey), cited the growing complexity of LDTs and questions about their reliability. "We have a responsibility to provide patients with greater certainty over the tools that are used to guide their medical decisions," he said. "It's my hope that [the rule] will help eliminate patients' harm from unnecessary treatment, or under treatment from inaccurate LDTs."

"The lack of action by Congress really forced the FDA's hand to come up with their proposal," said Rep. Anna Eshoo (D-California). "I think it's fashionable, at least in some quarters, to just bash the FDA. But it's up to Congress to act." TDR

Virchow

Medicine Money Managed Care

This column is named after the famous German pathologist Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Payer Contracts with Labs: Getting the Contract Is Just the Start

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

IT IS COMMON FOR MANY CLINICAL LAB MANAGERS TO THINK, "Oh, if I could just get those key managed care contracts, that would solve everything for my business." But if a lab is fortunate enough to get a contract from a health plan, the real work has just begun.

Labs often underestimate the time and expense required to deal with payers, and they overestimate the reimbursement rates. Each health plan has its own policies and procedures and these can be changed after the plan gives sufficient notice. If the lab handles billing in-house, someone has to monitor the health insurer's bulletins to stay on top of those changes.

It's crucial to have a good partner relationship with a managed care plan, so the plan can assist with problems that inevitably occur. But what happens if a lab is not paying attention to how claims are being adjudicated and reimbursed? Say a lab bills $100,000 in claims and its paid $30,000. One reaction may be, "Something's wrong. The payer is not processing my claims correctly. It must be the plan's fault."

It is common for the payer to get a call from someone at the lab who may scream, "What are you doing? You're not paying our test claims!" After the excitement of a network contract with the plan, the reality of daily claims processing is now apparent.

Reverse Sticker Shock

We've all experienced sticker shock. We see a shiny product on a retail shelf and dream of taking it home until we see the price tag. When it comes to reimbursement for diagnostic tests, a lab's reaction when it finally gets a contract can be more like sticker shock in reverse.

I've seen labs win new contracts—say from **Medicare Advantage** plans—and then make revenue projections based on getting 120% of **Medicare** reimbursement. But I've never seen a payer reimburse a lab even at 100%. Generally speaking, it's going to be 45% to 60% for a commercial plan.

With some tests, Medicare Advantage plans are supposed to reimburse at the Medicare rate, but that doesn't always happen. The health plan will say, "This is not straight Medicare. This is managed Medicare, and we don't have to abide by 100% of Medicare."

Sometimes one of the larger labs will get their attorneys involved. They will pull statements from the federal **Centers for Medicare and Medicaid Services** (CMS) and overturn some of the rates. But that doesn't happen often.

Once the lab gets over reimbursement shock, it might then discover that it can't balance bill a plan member. Say a patient gets a $300 test and the health plan reimburses $100. The lab can't turn around and bill the patient for the other $200, so the lab has to write that off.

Navigating the Policies

Each plan has specific policies. With so many variables, they're all a bit different. Maneuvering the complexities of each health plan's policies can be plenty of work.

For example, each payer has policies for genetic testing. Plan A might say the lab can bill an unlisted CPT code or that it needs a Z Code, whereas Plan B might say the opposite. Plan A might reimburse for a certain genetic test, whereas Plan B regards that same test as experimental and not eligible for reimbursement.

Drug screen testing is another example. Plan A might say it will reimburse for only one drug test per day within a certain category, whereas Plan B might state that tests must be medically necessary and not ordered excessively for the same member.

Lab test claims are almost always filed electronically, and each plan also has nuances in claim submissions that may require different IT configurations.

Staffing Up

If a lab chooses to perform billing in-house, it will need sufficient staff to handle the workload brought on by the new contract. This can be particularly challenging for smaller labs, which typically don't have robust staff.

For example, if a health plan chooses to change its policies, it is required to give 30 or 60 days notice. These changes are noted in periodic bulletins distributed to providers. In some cases, changes in policies are dictated by CMS, which sends out its own monthly bulletin.

If labs don't have someone checking bulletins and staying on top of changes, they might unknowingly send claims that don't comply with new policies.

Health plans can provide assistance or host meetings to discuss issues related to contracts. But this requires participation from the lab's staff. It is why labs need people experienced in handling the work associated with submitting test claims.

Some labs might be best served by outsourcing lab test billing. These services have experience with every health plan and the expertise to deal with billing issues that are likely to arise. TDR

Negotiating Contracts with Health Plans

HERE ARE KEY POINTS THAT A CLINICAL LABORATORY should keep in mind when evaluating a contract with a health plan:

- What lines of business are covered by the contract?
- What services are not covered?
- How much notice is required for policy changes? Changes are usually noted in the plan bulletin.
- How does the lab connect electronically to the payer?
- How much time does the lab have to file claims?
- How much time does the lab have to correct a claim that's been denied?
- What is the appeals process for denied claims?
- What are the policies related to prior authorization and lack of medical necessity?
- What is the length of the contract?
- What are "hold harmless" provisions?
- How much notice is required to terminate the contract?

Labs should also pay attention to a contract's regulatory appendices and the payment appendix and fee schedule.

Lab Market Update

Labcorp to Acquire Only Certain Lab Assets of OPKO's BioReference

Transaction gives Labcorp specific lines of business, BioReference keeps its New York/New Jersey labs

Following **Labcorp's** announcement that it will acquire "select assets" of **BioReference Health's** laboratory testing businesses, experts shared insights on what led up to the deal. They also speculated why Labcorp will purchase some testing assets but not other testing assets.

Labcorp of Burlington, NC, will pay $237.5 million. It will purchase only BioReference's testing businesses throughout the United States that are focused on clinical diagnostics and reproductive and women's health—areas that return $100 million in annual revenue, according to a news release. This transaction will include the BioReference facilities outside New York and New Jersey.

BioReference Retains Testing

BioReference is a diagnostics company and subsidiary of **OPKO Health, Inc.**, itself a biopharmaceutical and diagnostics company. BioReference will continue to offer oncology and urology diagnostic services nationwide and full routine clinical lab testing operations in New York and New Jersey. The Elmwood Park, NJ-based company currently operates 10 laboratory facilities throughout the United States, performing more than 12 million tests annually.

OPKO paid nearly $1.5 billion for BioReference in an all-stock transaction in 2015, reports stated.

"This transaction is part of our previously announced effort to reestablish profitability of our lab business while at the same time better positioning OPKO as an innovative biopharmaceutical company," said Phillip Frost, MD, OPKO Chairman and CEO, in a news release.

Typically, when one of the nation's two largest clinical laboratory companies acquires an independent lab, it buys all the assets. Thus, it is notable that OPKO will only sell certain pieces of its BioReference business, while keeping the majority of its lab testing business, including the routine clinical laboratory operations in the New York/New Jersey markets.

"I think this sale of BioReference (select assets) is something that has been discussed by OPKO with potential acquirers for a few years now," said Richard Faherty, JD, **RLF Consulting LLC**, in an exclusive interview with The Dark Report. "OPKO is primarily a biotechnology company accustomed to biotech methodologies, and I think they realized the best thing for them to do was to sell off selected pieces of the clinical lab testing business and hopefully make some money off the original investment they made when they acquired BioReference in 2015."

Faherty was Chief Information Officer for BioReference Laboratories from 1995-2017. He was responsible for information technology, investor and external relations, and government affairs.

With a well-established approach to oncology performed at its Elmwood Park facilities, BioReference probably sought to keep that testing business, according to Faherty, who acknowledged Labcorp may

not have been interested in the oncology category anyway. "Oncology is where BioReference always had a differentiated product. And it is a very, very manual-oriented service, which probably does not fit the Labcorp preferred model for developing business," Faherty said.

Hematopathology Expertise

BioReference employs many hematopathologists—physicians who specialize in bloodborne pathology liquid cancer tests and make complex diagnoses enabled by their specialized training and certification—Faherty explained. "It is a labor-intensive approach, because a hematopathologist needs to look at slides and supplementary tests to make a diagnosis."

It was BioReference's ownership of intellectual property for the 4Kscore test, a blood test to determine a man's risk for developing aggressive prostate cancer, that originally attracted OPKO to BioReference, Faherty said. He added that the test is part of urology diagnostics.

"The exception of urology services in the planned deal with Labcorp is probably the result of OPKO's interest in urology because of 4Kscore," Faherty said. In fact, during a fourth quarter 2023 earnings call, OPKO President Elias Zerhouni, MD, said, "The 4Kscore test volume has continued to perform, and we expect these volumes to continue."

Likely Regulatory Hurdles

Faherty was not surprised to see that the New York and New Jersey market was omitted from the BioReference and Labcorp agreement. "Acquisition of BioReference by either Labcorp or **Quest Diagnostics** in the New York metropolitan area would likely have Hart-Scott-Rodino Act (HSR) issues," Faherty said.

Under the HSR Act of 1976, "parties to certain large mergers and acquisitions must file premerger notification and wait for government review.

The parties may not close their deal until the waiting period outlined in the HSR Act has passed, or the government has granted early termination of the waiting period," the Federal Trade Commission explained in a Premerger Notification and Merger Review Process statement.

"BioReference also has a very strong sales presence in the New York area," Faherty explained. "Any company that tries to buy BioReference is going to have to deal with that strong sales team—a sales team that performs and has entrenched itself in this market."

For BioReference, the deal may enable growth and profits, as OPKO has a lift in its cash position, *Zacks Equity Research* reported.

Labcorp Seizes Opportunity

For its part, Labcorp is seizing an uncommon opportunity to build its business in clinical diagnostics, reproductive, and women's health by purchasing a large, publicly-traded clinical laboratory, according to Faherty.

"It is hard to find a hundred million dollars of independent clinical laboratory business anywhere in the country. There are not many potential targets that have the size and quality of business that BioReference Laboratories has," Faherty noted.

Michael Cherny, an analyst with financial services company **Leerink Partners** in Boston, wrote in a statement to investors, "Deals of this kind tend to generate strong (and predictable) ROIs (returns on investments)," *MedCity News* reported.

Labcorp aims to "expand access and convenience to patients across the country," said Mark Schroeder, Labcorp's EVP, President of Diagnostic Laboratories, and COO, in a news release announcing the acquisition. TDR

Contact Richard Faherty at rfaherty@mindspring.com or 201-803-9095.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It may be that the genetic data cat is out of the bag already. Nonetheless, lawmakers in Delaware are considering a bill that—among other things—would prevent life insurance companies from buying or using genetic testing data if it was obtained from ancestry companies and not from medical records. Lawmakers and reporters recognize that **Ancestry.com** and **23andMe.com** are the nation's two largest genetic testing companies offering ancestry testing. House Bill 286 was introduced by Rep. Jeffrey Spiegelman, R-Clayton, who said that life insurance firms would not be able to request, require, or purchase information from these genetic-testing businesses.

MORE ON: *DELAWARE BILL*

Another goal of the proposed law is to address a gap that exists in the federal Genetic Information Nondiscrimination Act of 2008. This law prevents health insurance companies from using genetic information to alter an individual's eligibility, coverage, or premiums. The federal law specifically applies these protections to private health insurers, Medicare, and Medicaid. But this federal law does not apply to life, disability, or long-term care insurance.

LABCORP BUYS WESTPAC LABS FROM SONIC

On April 7, **WestPac Labs** (formerly **West Pacific Medical Laboratory**) with labs in Santa Fe Springs and Bakersfield, Calif., sent a client letter announcing that its parent, **Sonic Healthcare**, was selling the lab company to **Labcorp**. This transaction was not announced by either the seller or the buyer.

TRANSITIONS

- Global software company **BYG4lab, Inc.** named Tim Bickley to the position of U.S. Vice President of Sales. Bickley previously served at **Visiun**, **Sunquest Information Systems**, **DCH Health System**, **Novartis Diagnostics**, **Chiron**, **SCC Soft Computer**, and **Columbia/HCA**.

- Mike Mosunic is the co-founder and CEO of the newly formed **Alder Brooks**, a search firm focused on healthcare (including diagnostics and laboratory), based in Denver. Mosunic previously held positions at **Slone Partners**, **Wolf Hill Group**, **WestPac Labs**, **Pathology Inc.**, and **Labcorp**.

- **NorDx Laboratories** of Scarborough, Maine, announced the retirement of James McAvoy from the position of Chief Financial Officer. McAvoy joined NorDx in December, 1999.

- Paul Kortschak was appointed CEO of Louisville, Kentucky-based diagnostics company **NX Prenatal**, effective April 1. He previously held executive positions at **Roche Diagnostics**, **Qiagen**, and **Bio-Rad Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 20, 2024.

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