Volume XXXI, Number 1 Tuesday, January 16, 2024

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

FDA Has a Ticking Time Bomb with LDT Rule

PROPOSED REGULATION OF LABORATORY DEVELOPED TESTS (LDTs) by the federal **Food and Drug Administration** (FDA) may be the single topic of highest interest within the clinical laboratory and *in vitro* diagnostics (IVD) industries at this moment. If finalized in its draft form, the new regulation will radically transform a sector of laboratory medicine that uses LDTs to swiftly bring new diagnostic capabilities to the clinical market.

The FDA issued the rule, "Medical Devices; Laboratory Developed Tests," on Oct. 3, 2023. The public was invited to submit comments until Dec. 4, 2023. Now is the quiet period when FDA officials review public comments and decide how to move forward with their plans to regulate LDTs.

One sign that the proposed rule—at least as originally drafted—will dramatically alter the way many organizations in diagnostics and laboratory medicine work with LDTs is the number of public comments submitted to the FDA. The law firm of **Morgan Lewis**, based in Washington, D.C., issued a statement last month indicating that more than 6,900 public comments had been submitted during the comment period. If that number is accurate, this may be the largest number of responses to any proposed federal rule ever submitted by the clinical laboratory profession and its allies and opponents.

The FDA's initiative to move forward and issue a draft rule to give it regulatory power over LDTs means that the agency is getting ahead of **Congress**. That's because the Verifying Accurate Leading-edge IVCT Development (VALID) Act is again pending in this congressional session. Thus, the FDA is acting ahead of any decision Congress might make at changing the current legal status of LDTs.

It appears that, on its own initiative, the FDA created the proverbial ticking time bomb. It has put forth a controversial draft rule without specific guidance from Congress. On one hand, the FDA has said it will grandfather existing LDTs. If so, that means those inaccurate or medically-inappropriate LDTs can still be offered by the labs that developed them. On the other hand, given the number of new LDTs coming to market each month, the FDA potentially could be overwhelmed with premarket applications requiring its review. It would serve the FDA well to address these and similar issues in detail before proceeding to change the status quo with LDTs. TDR

British Columbia Ready for HPV Self-Collection

Shortage of medical technologists across Canada means longer turnaround times for Pap smear testing

CEO SUMMARY: Unacceptable delays of as long as six or seven months in reporting Pap smear test results is triggering a major change in how provincial health authorities screen for cervical cancer. For example, health officials in British Columbia announced that, going forward, cervical cancer screening will start with HPV tests, with patients collecting specimens at home.

NORTH OF THE BORDER, THE STEADILY GROWING SHORTAGE OF MEDICAL TECHNOLOGISTS and other skilled medical professionals is triggering changes in the standard of care for the diagnosis of certain diseases. The most recent example are new protocols for cervical cancer screening.

On Jan. 9, *Vancouver City News* reported, "In a news conference Tuesday, Premier David Eby and Health Minister Adrian Dix explained that the province will transition away from Cytology (lab tests looking for abnormal cells in swabs taken at doctor's offices [Pap smears]) to human papillomavirus (HPV)-based screening for cervical cancer."

Health officials are promoting the benefits of moving to HPV testing for cervical cancer screening, with specimens collected at home by the patients. "The B.C. government says the province will become the first in Canada and move from its current model of screening for cervical cancer to a far more accurate, accessible, and long-lasting test," the *Vancouver City News* reported.

The news outlet then explained, "The new tests are nearly twice as accurate as the screening done in B.C. now, the province says, with data from **BC Cancer** showing the test detects pre-cancer cells 96 percent of the time—current screening only 53 percent."

Another benefit mentioned in the news story was that "moving away from Cytology will mean that instead of having to go into a doctor's clinic for a Pap test—which takes cells to then be examined in a lab under microscope—the new tests come in a kit via mail, where you self-swab and then return by mail."

From one perspective, this change to emphasize HPV tests over Pap smears for cervical cancer screening can be viewed as recognition that greater understanding of

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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).

HPV's role in causing cervical cancer supports the move to using HPV testing as the first line of cervical cancer screening.

From another perspective, this same change reflects a well-known fact: Pap smear testing requires cytotechnologists and pathologists with a high level of training and proficiency. Both skilled professionals are in short supply throughout Canada.

Six Months for Pap Results

For example, in 2022, *CBC News* reported that patients in **Health Prince Edward Island** (Health PEI) had experienced a six-month wait for Pap smear test results. By moving to use of HPV testing, PEI said it cut test report times down to six or seven weeks by mid-2022.

"They've also told me that this is not unique to PEI," said Michael Gardam, MD, who was CEO of Health PEI in 2022. "That there's a backlog in cytology across the whole country, and it likely speaks to just all of the disruption that's been going on over the last two years."

This was also true in British Columbia. In Nov. 2022, *CBC News* published a story about delays in reporting cervical cancer screening test results, stating, "Vancouver-based family physician Dr. Anna Wolak said previously, her patients would get Pap test results back in four to six weeks. 'Now, we see Pap results coming back in four to six months,' she said."

Shortages of Lab Staff

Across Canada, there is recognition that the SARS-CoV-2 pandemic disrupted clinical laboratory services from normal testing volumes and turnaround times. But since the end of the pandemic, the shortage of medical technologists, cytotechnologists, and pathologists in many regions of Canada means—for certain types of tests—labs still struggle to hit target turnaround times for reporting results.

Another significant point in the decision of British Columbia to move HPV testing into the primary method for cervical cancer screening is how it will engage patients. The plan is for patients to self-collect the specimen at home, then send it to the lab where the HPV test will be performed and the results reported to physicians and their patients.

By creating a policy to have patients self-collect their HPV specimens at home, that means fewer patients coming into medical clinics in British Columbia for the purpose of collecting the specimen needed for the cervical cancer screening test. In turn, that eases the strain on any overloaded medical clinics in the province.

At the same time, the COVID-19 pandemic provided evidence that most consumers were comfortable with buying a SARS-CoV-2 test kit at the pharmacy, then collecting the specimen at home and returning the specimen to the lab for testing. In this sense, the new policy of health officials in British Columbia reflects the willingness of many consumers to be involved in collecting their own lab specimens and sending those specimens to the lab for testing and reporting.

Juggling Many Factors

Lab administrators and pathologists in the United States can use the Canadian experience with cervical cancer screening as an example of how a one-payer health system is juggling many factors.

News accounts about unacceptable delays in reporting Pap smear results to patients provide evidence that short-staffing in many laboratories throughout Canada continues to be a problem that can directly affect patient care.

To maintain service levels and credibility with the public, provincial health officials now want to use the HPV test as the primary tool for cervical cancer screening. Should patients in Canada become comfortable with collecting their own HPV test specimen at home, that could encourage similar health policies here in the United States. TDR

Lab Market Update

Google, Epic to Help Hospitals Migrate EHR Data to Cloud

Partnerships will advance AI and data analytics, goals are to reduce costs and drive innovation

GOOGLE CLOUD OF MOUNTAIN VIEW, CALIF., INKED A NEW DEAL with **Epic Systems** designed to encourage healthcare providers to move electronic health record (EHR) data to the cloud. This relationship will include efforts to step up use of artificial intelligence (AI) and data analytics.

The deal was announced in November and included news that 18-hospital **Hackensack Meridian Health** has begun migrating its EHR data to Google Cloud. As other hospitals decide to put their Epic EHR data in the cloud, their hospital laboratories—particularly if they use Epic's Beaker laboratory information systems (LIS)—will see their lab test data hosted on Google Cloud.

The agreement between Google Cloud and Epic essentially makes way for Epic's hospital customers to "run their Epic workloads" on Google Cloud, according to a blog statement.

Fierce Healthcare called the agreement (financial terms undisclosed) with Google Cloud a "major pivot" by Verona, Wis.-based Epic, which did not have interest in such an arrangement in 2020. **MEDITECH**, Westwood, Mass., has had an agreement with Google Cloud since 2021 to bring EHR data to cloud storage.

The objective of moving EHR data to the cloud is consistent with a broader business trend of cloud computing to allow healthcare organizations to realized their goals of cost reduction, innovation, and productivity. Experts say that, for the data-rich healthcare industry, having hospital and healthcare system data in a common and secure storage location is a step toward using AI to analyze data in ways that can enhance operations and improve patient care.

Recently in *Forbes*, Emil Sayegh, CEO of Austin, Texas-based **Ntirety**, a multi-cloud managed solutions provider, declared that cloud computing is at the "brink for transformation" in 2024.

Making Sense of EHR Data

Clinical labs at hospitals using Epic EHR and the Epic Beaker laboratory information system will likely see lab data migrate to Google Cloud as healthcare leaders decide to collaborate with Google Cloud.

"You need to understand the data, you need to see the pattern, you need to see the trends, and then we'll be able to predict. With Epic and Google Cloud, you will be able to bring that intelligence into the workflow," observed Aashima Gupta, Global Director of Google Cloud Healthcare Strategy and Solutions in a story published by *Fierce Healthcare*.

Epic Systems has 35.9% of U.S. EHR market share, ahead of Oracle Cerner (24.9%) and MEDITECH (16.3%), noted a report by **KLAS Research**, cited by *Becker's Health IT*.

Google Cloud says it leverages Google technology to deliver the "cleanest cloud in the industry." And, according to a video on the company website, Google's Healthcare Data Engine (HDE) uses AI and machine learning to help transform

unstructured, fragmented, and siloed data, while generating a "longitudinal patient record" for "smart and fast decisions" by healthcare providers.

HDE accelerators *(see sidebar on this page)*—created by Google Cloud in tandem with certain healthcare organizations—are intended to "solve a range of industry pain points, and they will unlock the truly transformative power of interoperable longitudinal patient records," Gupta added.

Providers Go Google Cloud

Hackensack Meridian Health has already moved data and EHR workload from an "on-premise" environment to Google Cloud. The Edison, N.J.-based provider sent EHR Playground—software used by onboarding residents and nursing students—to Google Cloud.

"Now that we've moved significant data, applications workload, and other IT resources from on-premise to Google Cloud, we see increased agility, improved reliability, and increased security," said Kash Patel, EVP and Chief Digital Information Officer, Hackensack Meridian Health, in a statement. "Data is at the core of how we are modernizing healthcare. Having all of our EHR workloads and other significant data sources on Google Cloud will help enable us to gain more insights from our data and introduce new services based on analytics and innovation," Patel added.

Meanwhile, 68-hospital **Lifepoint Health**, of Brentwood, Tenn., is in the second year of a multi-year partnership with Google Cloud to:

- Enhance data interoperability,
- Create new digital solutions and care models,
- Monitor patient care across the Lifepoint network of 60 acute care facilities and more.

Also, **Hartford HealthCare**, Hartford, Conn., has a five-year partnership with Google Cloud and expects moving data to the cloud will save $4 million annually, *CBIA Hartford* reported. It has these goals for partnership with Google Cloud, according to a news release:

- Increase patients' access to care.
- Give clinicians "data-driven" awareness about patients.
- Improve health outcomes.
- Find "undetected patterns in health data."
- Speed up availability of data needed for decision-making.

Pathologists and medical laboratory leaders will likely observe and participate in more collaborations between healthcare organizations and non-traditional partners like Google Cloud. In fact, *Becker's Hospital Review* called "partnerships" the buzzword in C-suites for 2024. TDR

Google Cloud Healthcare Data Accelerators

IN ADDITION TO ITS PARTNERSHIPS WITH PROVIDERS on migration of electronic health records, Google Cloud is developing Healthcare Data Engine (HDE) accelerators, aimed at fast forwarding response to industry challenges.

According to a Google Cloud blog post, these are the recently released accelerators within the HDE:

- **Patient Flow Explorer** aims at management of patient admissions, transfers, and length of stay.
- **Transition of Care Explorer** displays a review of a patient's journey including care in "different settings within the health system."
- **Social Determinants of Health Explorer** leverages data to help identify patients in "near-real-time and improve care in underserved communities."

Google Cloud says it worked on the accelerators with staff at Hackensack Meridian Health, Lifepoint Health, **Highmark Health**, and other providers.

Sept. Saw 153% Increase in Ransomware Attacks

Understanding new threats can help clinical labs become more resistant to malware and cyberattacks

CEO SUMMARY: Most ransomware attacks don't generate news stories because the victimized organizations don't want other threat actors to learn if they paid a ransom to regain access to their information systems. Experts point out that more cyberattacks are happening and that the attacks are becoming more sophisticated. That includes a new tool for the cyber thieves: Ransomware-as-a-Service (RaaS).

SEPTEMBER SAW A 153% INCREASE IN RANSOMWARE ATTACKS, including a 15% increase in attacks on hospitals and healthcare systems. "Ransomware attacks in the healthcare industry should be of particular concern, given how such attacks can directly affect patient safety," *ZDNet* reported.

These developments are timely reminders that clinical laboratories and pathology groups need effective defenses in place to protect against ever-more sophisticated ransomware attacks.

Labs Are Attractive Targets

Lab managers should also not overlook one reason why their labs are attractive targets for ransomware attacks. Patient health records are worth from $300 to $1,000 apiece on the dark web because of how much personal data is contained in a single record. *(See TDR, "Ransomware Attackers Target Health Providers, May 24, 2021.)*

"Ransomware is one of the most common types of cyberattack for organizations around the world, and it shows no signs of slowing down. According to our research, the number of ransomware attacks on organizations of all sizes across every sector has increased in the last 12-18 months by 45%," the **NCC Group** noted in its report, "Is Ransomware an Exponential Threat to Society?"

The NCC Group began in 1999 and now has offices in North America, Europe, Asia, and the Middle East. It defines itself as "a global cyber and software resilience business operating across multiple sectors, geographies, and technologies."

Healthcare is the fourth most targeted sector the NCC Group tracks, and it reports that attacks on hospitals and healthcare systems soared in September.

"NCC Group calculated a rise of 18 attacks [in September], which equals an 86% increase month on month. *TechTarget* editorial's ransomware database also showed persistent attacks against healthcare in September, including one that forced New York-based **Carthage Area Hospital** and **Claxton-Hepburn Medical** to divert emergency room patients," *TechTarget* reported.

"What stands out is the volume of these attacks and the emergence of new threat actors who have been major drivers of this activity," observed Matt Hull,

Looking at Recent Cyberattack Numbers

IN ITS REPORT, the NCC Group noted that for the month of September, "the top 10 (threat actors) are jointly accountable for a total of 362 cases representing 70% of the monthly output. This also represents 93% of the output recorded in the month of August, when we saw a total of 392 cases."

"This [third] quarter was the busiest in terms of ransomware activity that NCC Group saw since it started monitoring the threat three years ago," *TechTarget* reported, adding that the group was "taken aback by the volume of ransomware attacks it's seen last month and throughout the year."

"North America was once again at the top of the list with 258 attacks (an increase of 3%). Europe was listed second (an increase of 2%), with 155 attacks, and Asia in third place with 47 attacks (an increase of 8%)," *ZDNet* reported.

Global head of Threat Intelligence at NCC Group, in a story published by *ZDNet*.

The **American Hospital Association** (AHA) made similar observations. It recently warned its hospital members that "not only are cybercriminals more organized than they were in the past, they are also often more skilled and sophisticated. Those that conduct ransomware attacks as part of an ongoing criminal enterprise may reinvest some of their ill-gotten gains to develop more powerful malware and computer infrastructure to make their attacks harder to defend against, and make the perpetrators harder to catch."

Among the new threat actors are two new ransomware groups identified by NCC Group: LostTrust and RansomedVC. There was also "consistent activity across the board from established ransomware groups," Hull stated.

In an NCC Group news release, Hull noted that the tactics cyberattackers use are significant.

"These groups—including the likes of LostTrust, Cactus, and RansomedVC—are noteworthy for their approach: adapting existing ransomware techniques and introducing their own variations to add pressure for victims," Hull explained. "We've witnessed a growing number of groups utilizing the double extortion model as a strategy, piggybacking off this as a successful method used by more established threat actors.

➤ Ransomware-as-a-Service

"New threat actors are also increasingly embracing Ransomware-as-a-Service (RaaS) model, whilst diversifying their activities and creating 'unique selling points,'" he continued. "All signs point towards the newer groups increasing pressure on victims to comply with ransom demands."

In its report, the NCC Group outlined additional tactics. "Many attacks are manually deployed and targeted at specific organizations that are particularly lucrative or that threat actors believe will pay the ransom. These attacks use bespoke methods to cripple operations and exfiltrate sensitive information to use as leverage and as a threat to damage the organization (the double extortion attack).

"This dual approach means that any organization with money or data must consider a ransomware attack as inevitable and prepare accordingly," the report notes. "Practically, this means deploying good cyber hygiene by regularly patching vulnerabilities and increasing your [organization's] resilience against indiscriminate and targeted attacks."

Hull mentioned that the threat actors are ramping up pressure they apply during ransomware attacks, a tactic employed by groups like RansomedVC. Hull also believes new ransomware groups will explore the same methods of increasing

the pressure on victims to comply with demands.

In addition to the Carthage Area Hospital and Claxton-Hepburn Medical cyberattacks in September, another huge example of healthcare systems experiencing this trend occurred in early August.

Recent Cyberattacks

Prospect Medical Holdings, "a private equity-backed hospital owner based in Culver City, Calif., began dealing with a ransomware attack that caused emergency departments to shutter, ambulances to be diverted, and outpatient services to close," *Becker's Hospital Review* reported. The affected hospitals experienced "outages, disruptions, including moving to paper records, as a result of the attack," *Becker's* added.

Hospitals involved include:

- California: **Bellflower Behavioral Health Hospital**, **Foothill Regional Medical Center** (Tustin), **Los Angeles Community Hospital**, **Norwalk Community Hospital**, **Southern California Hospital at Culver City**, **Southern California Hospital at Hollywood** (Los Angeles), **Van Nuys Behavioral Health Hospital**.
- Connecticut: **Manchester Memorial Hospital**, **Rockville General Hospital** (Vernon), **Waterbury Hospital**.
- Pennsylvania: **Crozer Chester Medical Center** (Upland), **Delaware County Memorial Hospital** (Drexel Hill), **Springfield Hospital**, **Taylor Hospital** (Ridley Park).
- Rhode Island: **Roger Williams Medical Center** (Providence), **Our Lady of Fatima Hospital** (North Providence).

Targeting Clinical Labs

Clinical laboratories are not immune to this rising threat. As THE DARK REPORT noted last month, cyberattacks are the latest reminder that labs and anatomic pathology groups are at risk for two threats: One threat is a cyberattack that shuts down a lab's IT system while stealing patient data. The other threat involves lawsuits against the same lab by patients unhappy that their protected health information was stolen by hackers. *(See TDR, "Cyberattack Victims Sue Enzo Biochem and Labcorp, July 10, 2023.)* TDR

Six Steps to Protect Against Cyberthreats

TO STAY AHEAD OF RANSOMWARE ATTACKS, the NCC Group advises healthcare facilities to gather leaders in IT, operations, and security to decide together what the "most crucial assets" are in the business and align everyone's efforts.

These key personnel must identify steps to follow when an attack occurs, including which systems need to be restored first and how to do so. They should also consider what would be the most vulnerable times that their organizations or labs could be attacked.

For example, a retail store would be most at-risk during December when its retail sales increase dramatically. Attackers like to attack targets when they are most vulnerable.

In its report, the NCC Group recommended a minimum of these six steps to protect the organization against cyberthreats:

- Employ multifactor authentication on all external facing internet connections (remote access points).
- Segregate legacy operating systems from the network.
- Backup your files, ideally offline in multiple locations (and rehearse deploying them).
- Patch, patch, patch!
- Invest in your people to improve their awareness, culture, and behaviors.
- Write and rehearse your incident management plan.

The AHA recommends similar guidance for hospitals.

Legal Update

23andMe Says Big Data Breach Due to Customers' 'Negligence'

Last October, one high profile company that does genetics testing acknowledged it had experienced a data breach involving thousands of its customers. Then came an unexpected turn in this data breach event.

In subsequent public statements during December, **23andMe** stated that the original announcement of a data breach involving about 14,000 consumers was only the tip of a larger iceberg. Actually, some or all of the personal information of 23andMe's 6.9 million customers had been compromised.

For consumers affected by this data breach, the company added insult to injury when it stated the actions of its consumers were what opened the doors for the threat actors.

Unknown threat actors accessed data for approximately 14,000 of 23andMe's existing 6.9 million customers through a process known as credential stuffing to steal account credentials, typically consisting of usernames or email addresses, and corresponding passwords. The invader then utilizes those stolen credentials to gain unauthorized access to users' accounts.

23andMe Blames Customers

In a letter 23andMe sent to victims of the breach, the company maintained that its customers should have been more cautious when selecting login credentials.

"Users negligently recycled and failed to update their passwords following these past security incidents, which are unrelated to 23andMe," the company stated in the letter, initially reported by *TechCrunch*. "Therefore, the incident was not a result of 23andMe's alleged failure to maintain reasonable security measures under the [California Privacy Rights Act]."

The letter also states that the "information that was potentially accessed cannot be used for any harm" and notes that the breached data did not include social security numbers, driver's license numbers, or any payment or financial information.

30 Lawsuits Already Filed

To date, 23andMe has been hit with more than 30 lawsuits regarding the breach in US federal and state courts as well as courts in Canada. One suit involves more than 100 23andMe members who claim the company owes them compensation for loss of the value of their personally identifiable information, costs of remediating the impacts of the breach, and emotional stress.

Once 23andMe discovered the breach, it opened an investigation and notified customers based on applicable laws. The company also made minor changes to its terms of service to make it more difficult to take legal action against 23andMe.

"The breach impacted millions of consumers whose data was exposed through the DNA Relatives feature on 23andMe's platform, not because they used recycled passwords," said Hassan Zavareei, JD, a Partner in the law firm **Tycko and Zavareei**, in an email to *TechCrunch*. "Of those millions, only a few thousand accounts were compromised due to credential stuffing," he concluded. TDR

Lab News Briefs

Siemens to Explore Sale of Its IVD Diagnostics Unit

Siemens Healthineers, Erlangen, Germany, is reportedly looking into options for sale of its *in vitro* diagnostics (IVD) segment.

The company's "review could lead to sale of the [diagnostics] unit, but all options remain open," a source reportedly told *Reuters*.

Bloomberg Law said Siemens may be able to get $8 billion for sale of the IVD business.

In earlier coverage about IVD company earnings, THE DARK REPORT noted that, for the full year 2023, diagnostics division revenue at Siemens was $4.9 billion, down from $6.5 billion in 2022. Some of this decline is due to the lower volume of SARS-CoV-2 testing during that time. *(See TDR, "Most IVD Firms Increase Q3 2023 Base Business Revenue," December 4, 2023.)*

In an earnings call with financial analysts and investors, CEO Bernd Montag, PhD, said that a transformation program is "ongoing" and aimed at "right sizing" of the company's structure.

Also, Siemens filed in November with New Jersey's Department of Labor and Workforce Development a planned layoff of 300 employees at the Morris, N.J. site (to be completed by December 2024) as the company moves its Atellica Solution IM (immunoassay) manufacturing from New Jersey to Swords, Ireland, *MassDevice* reported.

Consolidation in Ireland "allows for greater operational efficiency and cost savings," according to a statement from Siemens in *MassDevice*. *(See TDR, "Siemens Healthineers Plans to Streamline Product Offerings," January 3, 2023.)*

Should Siemens Healthineers complete a sale of its IVD manufacturing business, it would mark the end of a 16-year strategy to be a major player in clinical laboratory automation, analyzers, tests, and consumables.

This strategy was launched in 2006. At that time, **Siemens Medical Solutions** paid $1.86 billion to acquire **Diagnostic Products Corporation** (DPC). Next, it paid $5.21 billion to acquire **Bayer Diagnostics** from **Bayer Healthcare AG**. *(See TDR, "Siemens' IVD Purchases Are a Major Investment," Aug. 14, 2006.)*

In 2007, Siemens purchased **Dade Behring** in a sale valued at about $7 billion. *(See TDR, "Siemens Acquires Dade Behring, Builds IVD Powerhouse," Aug. 6, 2007.)*

Siemens Medical Solutions spent $14 billion on these three IVD purchases and immediately became one of the world's three largest IVD manufacturers. At the same time, Siemens now needed to integrate three different corporate cultures. Each acquired company had a different menu of tests, supported by intellectual property and instruments designed for those technologies.

Whatever the grand vision was for Siemens back in 2006 when it spent billions to become a major player in the IVD market, the ensuing 16 years were a struggle. By 2016, the IVD business was part of the business unit known as Siemens Healthineers. The following year, in 2017, Siemens Healthineers was spun off as a separate company, with **Siemens Corporation** keeping a 75% interest.

Quest Acquires Outreach Lab Program

Quest Diagnostics Secaucus, N.J., announced it acquired select assets of the Pennsylvania and Ohio-based outreach laboratory services of **Steward Health Care System**. Steward operates 33 hospitals in eight states.

Quest's Pittsburgh, Penn., lab will perform the tests that were formerly done by Steward outreach labs in parts of Pennsylvania and Ohio.

The acquisition builds on a relationship Quest said it has had with Steward to provide lab management and outreach lab services.

The Business Journal, Youngstown Publishing Co. reported that the arrangement with Quest comes "amid reports that Steward Health Care System owes more than $50 million in unpaid leases to **Medical Properties Trust Inc**."

According to a news release from Steward shared with *The Business Journal*, "Steward's outreach laboratory operations in Ohio and Pennsylvania will gradually convert to Quest over the course of the next two months."

On its website, Steward Health Care System says it is "the largest private, tax-paying hospital operator in the nation."

Steward Health has been in the news regularly in recent years because of ongoing financial problems. For example, on Jan. 9, *WKBN News* in Warren, Ohio, published a story headlined, "Steward Health Having Problems Paying Its Rent" in which *WKBN* wrote "Steward Health, the owner of 346-bed **Trumbull Memorial Medical Center** in Warren and other facilities in the Mahoning and Shenango valleys, is having issues covering its rent payments and some loan obligations."

➤➤ Roche to Acquire LumiraDx POC Tech

Roche Diagnostics plans to acquire **LumiraDx's** point-of-care technology, giving the *in vitro* diagnostics (IVD) giant portable diagnostics.

The Basel, Switzerland-based Roche agreed to pay $295 million for the technology, along with an additional $55 million to support the London-based LumiraDx until the deal closes in mid-2024.

"The addition of LumiraDx technology to our diagnostics portfolio will enable us to transform testing at the point-of-care," said Matt Sause, CEO of Roche, in a statement.

LumiraDx, founded in 2014, says it offers 30 assays for infectious diseases, cardiovascular diseases, diabetes, and coagulation disorders. The point-of-care diagnostics platform works with microfluidic test strips and is used worldwide in labs, physician offices, urgent care centers, pharmacies, schools, and workplaces, according to LumiraDx.

MedTech Dive noted that the announcement of a deal comes as LumiraDx faces "potential [NASDAQ stock market] delisting amid declining revenue."

For six months ending June 30, 2023, LumiraDx reported revenue of $43 million, down 74.8% from $171 million in 2022.

In October, LumiraDx said it planned to appeal following its receipt of a NASDAQ notice that "the bid price of its listed securities had closed at less than $1 per share over the previous 30 consecutive business days." (Meaning it did not comply with "the Minimum Bid Requirement" to stay on the market.)

The plan is for LumiraDx to use proceeds from the sale to Roche to address its debt, *MobiHealthNews* reported.

➤➤ Gestalt, Sagis Ink Digital Path Agreement

Last week, Spokane, Wash.-based **Gestalt Diagnostics** and **Sagis DX**, a pathology laboratory in Houston, announced an agreement for Sagis to acquire and implement Gestalt's digital pathology workflow solution.

Sagis has 30 pathologists and the press release states that Gestalt's digital pathology platform "will be implemented for use in clinical and academic workflows, to include integrated artificial intelligence algorithms." 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.

Layoffs at Major Health Plans Slow Processing of Lab Claims

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.

HEALTH INSURERS WANT TO MINIMIZE HOW MUCH THEY PAY OUT TO HEALTHCARE PROVIDERS. Sometimes this means they are willing to deny clearly justifiable claims. This happens to all classes of providers, not just clinical laboratories.

But because labs submit large numbers of claims daily, and because there are now tens of thousands of different genetic tests, denials of even justifiable claims are a huge problem for clinical laboratories and anatomic pathology groups.

Medically Unnecessary Tests

Additionally, payers are aware that there are some clinical lab companies inducing doctors to order tests that are medically inappropriate or unnecessary. These labs then submit claims for those tests. Payers must sift through that stuff. This is why both sides come to the table wary of the other.

But now the thorny problem of dealing with claim denials, late payments, and other payer-related snafus is likely to get worse as commercial payers across the U.S. implement layoffs. News reports document how large and small health plans are cutting back staffs. The sidebar on page 15 covers some of these recent news items.

What happens when companies reduce their workforces? Often, they reorganize. They consolidate. They try to automate their processes. They might outsource support center operations to other countries where labor costs are lower.

Loss of Experience at Payers

This poses a twofold problem for providers, including lab companies. First, the payers may no longer have enough staff to respond to legitimate inquiries about claims that a provider submitted.

Second, the jobs most likely on the chopping block are often held by highly-paid senior personnel. Staffers who remain may lack the expertise needed to respond properly to anything beyond the most basic queries. These staffers also lack access to a higher authority that has the power to make decisions to resolve disputes about denied claims.

I already see this among the payers that have instituted cutbacks. Many folks with experience and understanding in the health plan business have been eliminated from their positions. Those who are left, in some cases, cannot answer even the most straightforward questions.

This affects all healthcare providers, but the fallout is likely to have a dispropor-

tionate impact on clinical laboratories and pathology groups. I've seen evidence of this.

Why are clinical laboratories more affected by these layoffs? Lab claims are a major puzzle for payers. Labs submit the highest volume of claims among healthcare providers.

A single physician might see 40 patients per day and order lab tests for 20-30 of them. But a lab company may be serving 5,000 physicians per day and submitting tens of thousands of daily claims. And when specimens arrive, labs are legally bound to run the tests without knowing for sure if they will be paid.

Payers consider labs to be on the managed care side of ancillary services. That includes ambulatory surgery centers, radiology, home health, transportation, and dialysis. Down at the bottom is the red-headed stepchild—the medical laboratory.

This doesn't make a lot of sense given the essential role a clinical laboratory test plays in diagnosing a patient's condition, selecting the right therapy for that patient, and monitoring the patient's progress. Most physician charts have lab results. A doctor isn't going to prescribe a therapeutic drug, for example, without first saying, "You need to get the following lab tests done. After I get those results, you'll get your prescription."

Labs as Ancillary Services

Nonetheless, payers see clinical labs as an ancillary service. And where does a payer most often go when it starts cutting? To the department that handles ancillary services.

In the past, these departments might have had a dedicated person the major laboratories could go to when questions arose about their claims. Even regional labs often had access to someone knowledgeable at the payer. Most information a lab needed from the payer to facilitate timely payments of claims would be readily available.

But after a health plan lays off a significant portion of its staff and restructures, a lab that has queries about claims might be told to go to a website and start a chat with someone in support—and the lab will get nowhere.

Inexperienced Staff at Payers

Consider this account I recently heard. A small regional lab needed information about its contract with a commercial payer. At health plans where I've worked, I could have pulled up that information in an instant. But this lab found itself in a 45-minute chat with a support person who clearly had no clue about the contract or where to get the information. The call went like this:

"Is this about a claim?" the support person asked.

"No," the lab replied, repeating that they needed to speak with someone who had access to their contract.

"I'll have to ask somebody else. Can you hang on?" [Ten minutes later.]

"We don't know what you're looking for."

When one of the big labs—the **Quests** and **Labcorps**—have an issue with a commercial payer, they can reach out to the payers' vice presidents. But the typical small regional lab? They struggle. When their test claims are denied, they cannot get access to an informed decisionmaker at the payer.

Is this happening across the board? Not necessarily. That same small regional lab might still have contacts at other health plans that have the needed information at their fingertips. But with substantial layoffs happening at a growing number of health insurers, it's doubtful this will last for long.

The sad reality for smaller labs is that the health plans would rather deal with the big players. The larger the provider, the more the insurer can negotiate a discount from the so-called market price.

Automation is another way to compensate for reduced staff. Some aspects of claims processing have been automated

Many of the Nation's Largest Health Insurers Are Announcing Layoffs and Staff Cutbacks

MANY HEALTH INSURERS ARE REDUCING THEIR WORKFORCES. Some managed care insiders say this is one reason why large numbers of claims are being denied, including claims for clinical lab tests. Consider these recent news items:

- **CVS Health**, parent company of **Aetna**, announced in July 2023 that it would cut about 5,000 jobs—mostly corporate positions—from its total workforce of 300,000, *The Wall Street Journal* reported. In October, nearly 600 positions were eliminated from Aetna alone, according to *Becker's Payer Issues*.
- **Elevance Health** revealed in October that it would take a $700 million charge due in part to an unspecified number of job cuts, *Reuters* reported. Those cuts were also attributed to a decline in Medicaid memberships.
- Former employees of **UnitedHealth Group's Optum** subsidiary turned to social media in August to state that the company had instituted layoffs worldwide, *Becker's Payer Issues* reported. UnitedHealth declined to reveal the scope or timing of the job cuts.
- **Centene Corp.**, a St. Louis-based payer, said in September that it would lay off approximately 2,000 employees, *Healthcare Dive* reported. The cuts were attributed to the payer's downgraded Medicare Star ratings and reductions in Medicaid enrollment.
- In October, former employees of **Cigna** turned to social media with claims of job cuts, *Becker's Payer Issues* wrote. Cigma did not confirm the reductions.
- **Blue Shield of California** filed a notice revealing it would cut 165 workers by the end of January 2024, mostly in its Oakland office, the *San Francisco Chronicle* reported. This follows a larger round of layoffs in January 2023.

for a long time. This is a necessity when a health plan gets hundreds of thousands of claims per day.

One thing that an automated system can do is to deny claims for legitimate reasons, such as when the doctor enters the wrong diagnosis code, or the test doesn't hold clinical value. However, there are times when claims are denied incorrectly.

Artificial Intelligence, ChatGPT

Now, automation across the board is poised to take a monumental leap with the emergence of generative artificial intelligence (AI). I'm referring especially to large language models such as ChatGPT that can interact with people in ways that seem almost human.

Proponents tout this technology for a wide range of potential applications across a multitude of industries. One of the most promising, they claim, involves the use of virtual assistants to augment customer support operations.

Speaking as someone who has worked within health plans for decades, I've watched the healthcare industry be relatively slow to adopt new technologies. Will that be the case with generative AI and health insurers? Can swift adoption of AI help payers make up for the loss of so much experience through these continuing layoffs and staffing cut-backs?

It may take years to learn the answer to those questions. In the meantime, I predict most health plans will struggle to properly accept, process, and reimburse legitimate claims.

The many news stories reporting staff cutbacks at major health plans, plus the continuing high rate of claims denials, are evidence that timely, accurate processing of legitimate claims will continue to be an intractable problem. TDR

IVD Update

OIG Reports Its Findings about CDC's First COVID Test Problems

OIG's findings confirm problems in development of the test, along with root causes of these issues

One major failure by federal agencies in the first days of the COVID-19 pandemic was the development and release of an inaccurate and unreliable SARS-CoV-2 test, intended for use by public health labs.

This was the finding of the U.S. **Department of Health and Human Services** (HHS) **Office of Inspector General** (OIG) in a report it issued in October. The OIG had conducted an audit of the failure of the federal **Centers for Disease Control and Prevention** (CDC) to develop a working molecular test for SARS-CoV-2 in the early days of the COVID-19 pandemic.

The OIG performed the audit to review the CDC's process for developing COVID-19 test kits and examine why the initial test kits were unsuccessful. The OIG's findings will be of interest to pathologists and clinical laboratory scientists, for two reasons.

Confirms Flaws in COVID Test

First, the OIG confirmed the specific flaws in the first COVID-19 test released by the CDC to public health labs. These flaws were publicized in news reports at that time. Second, the OIG's report goes deeper to identify and explain the root causes of the multiple failures that resulted in the development and distribution to public health labs of the federal agency's flawed COVID-19 assay.

The OIG discovered several factors that led to breakdowns during the test development process. These included inexperienced and insufficient staff, lack of quality safeguards, the lack of physical resources, and inadequate procedures and processes.

Specifically, the OIG report identified the following weaknesses in the CDC's SARS-CoV-2 test kit development process:

- CDC had inadequate policies and procedures for developing its COVID-19 test kit.
- The agency lacked established processes to prioritize the need for adequate personnel and medical laboratory space. (This is one reason why minimal resources were allocated to the lead laboratory developing the COVID-19 assay.)
- At the time when the CDC's response efforts escalated from an internal "center-led" response to an agency-wide response, there was insufficient oversight of the laboratory-based response.
- Similarly, lack of staff meant the lead scientist had to perform several tasks that should have been delegated to several other people.
- There was a lack of a laboratory document control system.
- Also absent was a laboratory quality management system (QMS).

In its report, the OIG noted that as the first cases of COVID-19 were reported in late 2019, the CDC began considering a molecular test for SARS-CoV-2. The agency's goal was to develop a test kit and make it available to public health labs as soon as possible to help curb the spread of COVID-19 infections.

Test development commenced in early 2020 and Emergency Use Authorization (EUA) was obtained from the **US Food and Drug Administration** (FDA) for the tests in February of 2020.

When the CDC first began sending test kits to public health laboratories, the intention was that public health labs would utilize the CDC test kits. Meanwhile, academic labs, industry clinical labs, and *in vitro* diagnostic manufacturers would create their own tests and submit them to the FDA to obtain an emergency use authorization.

Doomed Testing Capacity

However, problems during the production of the CDC's SARS-CoV-2 test kits caused many of the kits to produce inaccurate or unreliable results.

The OIG report indicates that the CDC distributed the test kits to public health labs before determining that all the kits worked properly. Consequently, this constrained the ability of public health labs to test for COVID-19 in the early days of the pandemic as the virus began its rapid spread.

The OIG's audit determined that the CDC's respiratory virus diagnostic (RVD) lab was primarily responsible for the establishment, production, and distribution of the COVID-19 test kits. But the RVD lab had little experience in test development.

The report states that the "RVD Lab was a research-focused laboratory that was not set up to develop and manufacture test kits, and therefore had no policies and procedures for developing and manufacturing test kits."

Clinical pathologists will also be interested to learn that "when the COVID-19 pandemic began the CDC's RVD Lab could not use CDC agency documents—such as the GRF (graduated response framework) and AHP (Advancing HIV Prevention)—for guidance in developing the test kits because neither contained information related to test kit development."

The OIG report noted that "without established policies and procedures at RVD lab, the lead (RVD lab) lead scientist had to create the processes and procedures for developing the COVID-19 test kit while the test kit was being developed" which "created a high-risk environment that allowed for incomplete processes to occur."

The OIG report identified another complication. The CDC's RVD lab had relatively limited resources, staff, and available lab space to perform such a task.

During planning meetings in January 2020, the lead scientist at the RVD lab requested assistance from the CDC's **National Center for Immunization and Respiratory Diseases** (NCIRD).

According to the OIG report, that scientist stated that the RVD lab would need "approximately 20 additional personnel with experience in project management, regulatory affairs, quality assurance, quality control, manufacturing, laboratory testing, and information management" to develop the SARS-CoV-2 test.

But the RVD lab only received assistance from 13 employees and some of them were only part time. A CDC employee interviewed for the audit "recalled RVD lab's lead scientist calling and pleading with individuals in other parts of the agency for help with development of the [SARS-CoV-2] test kit."

Lack of Requested Staff

Due to this lack of requested staff, the lead scientist at the lab had to manage and participate in the COVID-19 test kit development, along with troubleshooting and correcting any problems that were detected in the kits at the public health labs.

"Troubleshooting efforts consisted of identifying whether contamination of the test kit existed, recreating test kit components, and working with FDA to obtain an updated EUA for the corrected test kit," the report stated.

To further exacerbate the problems, the CDC had not obtained human samples of the SARS-CoV-2 coronavirus when the test development began. Thus, the RVD lab relied on manufactured viral material based on the SARS-CoV-2 genome sequence from China. The RVD lab received the viral material from the CDC's **Biotechnology Core Facility Branch** (CORE) lab. That lab was already making reagents for the RVD lab's test kits.

Ordinarily, the CORE lab would not produce test reagents and materials used for test verification in the same lab due to the possibility of contamination.

"RVD Lab, which was under pressure to quickly create a test kit for the emerging health threat, insisted that CORE lab deviate from its usual practices of segregating these two activities and fulfill orders for both reagents and viral material," according to the OIG report.

CDC Corrective Steps Taken

The report states that the CDC neither agrees nor disagrees with the OIG's suggestions. However, the CDC did respond to the draft report noting that the federal agency discussed actions and plans to implement the recommendations. Steps the CDC took include:

- Laboratory Quality Plan (LQP) developed.
- Publishing an annex to the GRF Concept of Operations.
- Developing a plan to create a new Center for Laboratory Systems and Response (CLSR).
- Electronic QMS (eQMS) implemented.
- Elevating the oversight of emergency response efforts.

The OIG report noted that without effective internal controls and corrections, the CDC may:

- Experience delay in the development of test kits when responding to future public health emergencies.
- Have difficulties identifying problems in a timely manner when developing test kits.
- Risk damaging public trust, which could undermine the agency's ability to accomplish its mission.

OIG acknowledged and commended the efforts the CDC took to address the weaknesses in their test kit development process. The OIG noted the CDC's ability to deliver a reliable test for COVID-19 shortly after the initial test failures. TDR

OIG's Recommendations for CDC Assay Creation

IN ITS REPORT ABOUT THE FAILURES of the federal Centers for Disease Control and Prevention (CDC) to create a reliable SARS-CoV-2 test for use by public health labs in the early days of the COVID-19 pandemic, the Office of Inspector General (OIG) made several recommendations for the CDC to streamline and improve its test creation processes to avoid a similar occurrence in the future. They include:

- Creating policies and procedures for developing test kits that include roles, responsibilities, and oversight.
- Ensuring that the finalized Graduated Response Framework (GRF) addresses the findings in the OIG's report.
- Develop and implement documented processes to ensure there is adequate staffing and laboratory space for future responses.
- Reevaluate the incident management system (IMS) structure at all levels of the CDC's response framework, and integrate positions or roles and responsibilities that provide effective oversight of a response effort.
- Implement a CDC-wide laboratory document control system.
- Ensure all infectious disease laboratories implement and periodically evaluate a laboratory quality management system (QMS).

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

If a patient's genetic test generates results that are actionable, will that patient move forward with treatment? That is one question asked by researchers in a study led by **Vanderbilt University Medical Center** that was published in the *American Journal of Human Genetics*. A pool of 16,218 research participants were genotyped. "Genetic counselors at six of the sites informed 477 of the participants that they were carrying pathogenic or likely pathogenic variants for one of five diseases and conditions: arrhythmia, breast cancer, cardiomyopathy, colorectal cancer, or familial hypercholesterolemia ... Among participants counseled about their risk variants, use of one or more of the services in question increased from 26% to 44% of participants, with average 12-month costs to insurers for these services increasing from $162 to $343.

MORE ON: *Genetic Results and Patient Action*

Meanwhile, the flip side to the findings of this study is that about half the individuals notified by genetic counselors that their genetic findings were actionable did not seek services for those conditions. Researchers noted that the individuals who did not seek care "may have previously known about and previously addressed their risks, preferred not to make changes to their healthcare, or were unable to afford follow-up."

FTC LOOKING INTO UPMC'S MERGER WITH WASH. HEALTH

Mergers between hospitals are catching the attention of the **Federal Trade Commission** (FTC). The latest deal to earn scrutiny from the federal agency is the agreement for the **University of Pittsburgh Medical Center** (UPMC) to merge with Pennsylvania-based **Washington Health System**. News reports say that FTC investigators are looking into this transaction. *Healthcare Dive*, in commenting on this development, wrote "The Federal Trade Commission and **Department of Justice** this summer released new guidelines that could give regulators new means to target healthcare deals, especially vertical and cross-market acquisitions. The Biden Administration has been increasingly cracking down on healthcare consolidation as deals have steadily increased and research has shown hospital consolidation to raise prices." It may be that hospital consolidation is now on the radar screen of federal antitrust regulators.

TRANSITIONS

- **Quest Diagnostics** announced that Yuri Fesko, MD, is now its Senior Vice President and Chief Medical Officer. He is an oncologist and previously served as Vice President of Medical Affairs at Quest and a number of positions at **Duke University Health System**.

- Gregory Critchfield, MD, is the new CEO of **EarlyDiagnostics** in Los Angeles. His prior executive positions were at **Sera Prognostics**, **Saladax Biomedical**, **Myriad Genetics**, and **Quest Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 5, 2024.

Publisher: Robert L. Michel *rmichel@darkreport.com*
Executive Publisher: Bob Croce *bcroce@darkreport.com*
Managing Editor: Michael McBride *me@michaelmcbride.com*
IVD Reporter: Donna Pocius *donna11019@att.net*
Legal/Compliance Reporter: Stephen Beale *sbeale58@gmail.com*
Regulatory Reporter: Jillia Schlingman *jpschlingman@yahoo.com*

29 YEARS JOIN US

EXECUTIVE WAR COLLEGE

April 30-May 1, 2024 • Hyatt Regency • New Orleans

CALL FOR SPEAKERS & TOPICS!


Robert L. Michel

JOIN US FOR THE 29TH EDITION of our *Executive War College on Diagnostics, Laboratory, and Pathology Management!* Prepare yourself for our biggest and best-ever line up of sessions and expert speakers. You'll get all the information you need to guide your lab to clinical and financial success.

You're invited to bring your lab's key leaders and managers to advance their skills.

You are also invited to send us your suggestions for session topics. We're now selecting speakers for the 29th Annual *Executive War College on Diagnostic, Laboratory, and Pathology Management.*

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- ***It's a trend: mobile phlebotomy services gaining favor with consumers and patients.***
- ***Digital pathology, generative AI, and ChatGPT are converging—but is this adding value?***
- ***VIRCHOW on: Why physicians are asking payers to restore local labs as in-network providers.***

For more information, visit:

www.darkreport.com

DARK Daily

Serving Clinical Labs & Pathology Groups

Sign Up for Our FREE News Service!

Delivered directly to your desktop,
***DARK Daily* is news, analysis, and more.**

Visit www.darkdaily.com