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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Preparing Your Lab for Post-Pandemic Success

MOST OF US WOULD CONSIDER IT GOOD NEWS that the number of Americans vaccinated continues to grow even as the daily number of new COVID-19 cases and deaths has fallen since its peak last winter.

Data from *USAFacts.com*, a website developed by teams from **Penn Wharton** and **Stanford University**, show that as of May 3:

- At least 147,894,586 people or 44% of the population received at least one dose of the COVID-19 vaccine.
- Overall, 96,246,540 people or 29% of the population are now fully vaccinated.
- Currently, the seven-day moving average for daily new COVID-19 cases and deaths is 49,128 and 675, respectively, as reported by *USAFacts.com*.

Of equal importance, the medical profession now has a better understanding of what factors put certain individuals at highest risk for a severe case of COVID-19. Compared to the onset of the pandemic, today, physicians also have experience at treating the most serious cases, which is a contributing factor in helping reduce deaths from the SARS-CoV-2 coronavirus.

Collectively, these developments are a reason to be optimistic that the pandemic is on a downward course, at least here in the United States and a number of other countries around the world. The unanswered question, which only time can answer, is whether SARS-CoV-2 disappears, as did SARS back in 2003. Or will SARS-CoV-2 become endemic? In either case, the nation's hospitals, physicians, and clinical laboratories will return to a more normal state of operation because people continue to need the full range of care for chronic conditions, cancers, and other infectious diseases.

The facts above provide evidence that it is reasonable to expect that some type of return to normalcy is not too far into the future. Accepting that premise, it is timely for lab administrators and pathologists to chart a path back to a more normal delivery of routine lab testing services.

To help in this effort, THE DARK REPORT surveyed lab leaders about their institution's travel bans, and whether, as individuals, they are ready to fly on airplanes and attend live conferences again. At least two-thirds of respondents are ready for business travel and educational conferences. That is encouraging and we are exploring how to organize a lab management conference for this fall. Stay tuned for details. TDR

Millennials Set to Reorder Healthcare & Lab Testing

Generation Y leads the consumer revolution, labs should develop testing services to serve them

CEO SUMMARY: In just 42 months, Millennials will make up 75% of the workforce, according to U.S. Department of Commerce statistics. As consumers and patients, they are already triggering changes, reforms, and innovation in healthcare. It is timely for clinical lab administrators and pathologists to understand how and why Millennials expect to experience healthcare services in a very different way than Generation X and Baby Boomers. Here's a look at key developments.

CONSUMERS ARE BECOMING A POWERFUL FORCE OF CHANGE as the nation's healthcare system continues to transform. This has profound implications for those clinical laboratories that want to stay at the cutting edge with their lab testing services.

As consumers radically alter the way they access medical services, clinical laboratories will need to reconfigure key aspects of their services to properly serve the "new healthcare consumer" and meet their very different expectations for service, for quality, and for price.

For example, as more patients grow comfortable using telehealth to do virtual office visits with their physicians, how will clinical labs get access to that patient to collect the samples needed to perform the lab tests ordered by that physician as a result of the virtual office examination?

Today, the clinical laboratory industry is oriented around the primary specimen collection model of:

a) having phlebotomists in physician offices, and,

b) maintaining a network of patient service centers, typically located in physician office buildings.

Will this existing infrastructure of specimen collection sites be viable if a greater number of patients stop traveling to their doctors' offices and instead see their caregiver using a telehealth service? Labs should ask this question in their strategic planning and develop new approaches to collecting specimens from those patients using telehealth services to consult with their physicians.

Millennials—Generation Y—are the front wave in this change in the way

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healthcare is accessed and delivered. They are comfortable accessing their physicians via telemedicine and virtual office visits, especially if it saves time.

Similarly, the Millennials want to use their smartphones and digital devices to have immediate access to their health records. A high proportion of Millennials also track their own health metrics with a fast-growing product category known as "wearable fitness technology." These devices range from **FitBits** and **Nike** Fuelbands to **Apple** watches.

The consumer revolution in healthcare is not limited only to Millennials. Growing numbers of Gen X'ers and Baby Boomers are becoming comfortable seeing their physicians virtually, having 24/7 digital access to their health records, and using wearable devices to monitor their diabetes, deliver insulin, and track the function of their heart, among other uses.

Insurers Support Telehealth

Health insurers are jumping on the virtual physician visit trend. Not only do telehealth services meet the wants of Millennials for quick access to their doctors, but telehealth sessions are a way for payers to reduce healthcare costs without compromising the quality of care. Just this year, **Oscar Health**, **UnitedHealthcare,** and **Kaiser Permanente** launched or expanded virtual-first care plans.

Humana started similar health plans in the Southeast U.S. two years ago that require the patient to start a care encounter with a virtual physician visit in exchange for very low monthly premiums. Last year, Humana invested $100 million in telehealth company **Heal** specifically to help the insurer expand into new markets.

This trend of expanded acceptance and use of telehealth and virtual office visits was intensified by the outbreak of COVID-19 in the winter of 2020. From the start of the pandemic, even senior citizens proved willing to see their doctors virtually.

The **American Medical Association** published a report quoting Jared Augenstein, a Director at **Manatt Health**. He said that "between mid-March and mid-October of last year, nearly 25 million Medicare beneficiaries received services via telehealth, while Medicaid and CHIP beneficiaries received nearly 35 million services via telehealth last year."

Convenience as a Driver

Another important driver of change in healthcare shared by all consumers—regardless of their generation—is the desire for convenience. Today's healthcare consumer wants a smooth, fast, and easy experience with any retailer or service provider.

That is why patients are increasingly frustrated with how they are forced to interact with hospitals, doctors' offices, clinical laboratories, and other providers. It is still common for a patient with an appointment for a health service to walk into the facility and be handed a clipboard with a form to fill out with pen or pencil. Patients must sit in the lobby and fill out forms before they can access their doctor or have a procedure performed.

This example shows why patients—as consumers—are frustrated with the healthcare system. They understand that, if they are buying from **Amazon**, **eBay**, or any number of other web retailers, they may be just two clicks away from completing a purchase. That is not true for healthcare.

Labs Emulating Starbucks?

Similarly, these patient know they can walk into a **Starbucks**, give the barista the order, and then hold their smartphone up to the reader to complete the transaction wirelessly and instantly. Furthermore, digitally-connected consumers can use the Starbucks app on their smartphone to order and pay before they even entered the store! This allows them to walk through the door and find their order ready and waiting to be picked up.

Four Ways That Consumers Are Encouraging Change and Transformation in Healthcare

IF CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS want to continue to meet and exceed the expectations of consumers and their patients, they need to recognize how consumers are changing many aspects of healthcare. Below are several primary trends in consumerism as they relate to how consumers want to be served by their healthcare providers, including hospitals, physician offices, and laboratories.

Convenience:

Consumers want fast access to personal services. In healthcare, think of the growth of medical clinics in retail stores, the big shift to put lab patient service centers in retail pharmacies and grocery stores.

Examples: Walmart's healthcare supercenters, branded as "Walmart Care Clinic." CVS Pharmacies' "Health Hubs" and "Minute Clinics."

Personalization:

Consumers turning to the web for information before seeing their physicians and to find providers; they want their doctors and care providers to know them and their unique needs.

Examples: Amazon Prime Members recognized at log-in and have just two clicks to purchase. Starbucks mobile app handles the order and payment before customer gets to the store.

Technology:

Consumers want to track their own exercise and health factors in real time. Think consumers using wearable monitors for exercise, monitoring blood glucose levels (for diabetics), using remote monitoring devices prescribed by their physician; digital access to health information that alerts them digitally to test results, etc.

Examples: Fitbits, Apple Watches, Abbott Laboratories' FreeStyle Libre device, cardiac rhythm remote monitoring devices.

Transparency:

Consumers, particularly those with high-deductible health plans, want to know the price of service before choosing a provider.

Examples: Growth of benefit investigation (BI) for expensive genetic tests, prices posted publicly at Walmart's healthcare supercenters, CMS Medicare website with provider prices, Castlight Health's website with provider prices.

Imagine how different the experience of your lab or pathology group's patients would be if your team streamlined and automated as much of the specimen collection process as possible. Your lab would create a loyalty bond with each patient that would be difficult for competing laboratories to break. It could be the ultimate competitive advantage.

Different Generations

Changes in healthcare and other segments of business attributed to the different interests and needs of Millennials can be better understood when compared to earlier generations.

For example, the "Greatest Generation" (those Americans who fought World War II and parented the Baby Boomer generation) were typically recognized to be compliant patients. They usually accepted their doctor's diagnoses and recommendations with few questions.

This is generally not true of Baby Boomers. They are the generation of patients who do deep-dive research into their health conditions. They then arrive for their appointment carrying a stack of published clinical studies and press the doctor to absorb this information and incorporate it into their treatment plans.

Generation X

Generation X continued the research trait of the Boomers, but also began adapting to new models of primary care. Urgent care centers could be considered a response to Gen X patients who want 24/7 access to healthcare whenever they have earaches, sore throats, and sniffles.

All this changed with Millennials because they grew up with computers, mobile communication devices, and the Internet. Millennials tend be more demanding consumers of healthcare.

Thus, clinical laboratory leaders would be well-served to understand Millennial lifestyle preferences and meet those expectations. TDR

Identifying Other Forces Shaping Healthcare

FORTUNATELY FOR THE CLINICAL LABORATORY AND PATHOLOGY PROFESSION, the pace of healthcare's transformation will allow adequate time for labs to identify and understand key trends, then develop appropriate strategies in response to those changes.

Healthcare's transformation in this country includes discrete elements. These are elements that THE DARK REPORT tracks regularly. They include:

- New emphasis on proactive care, compared to the reactive care of past decades.
- Continued efforts to shift care from inpatient to outpatient settings because hospitals are the most expensive sites for medical care.
- Tighter integration of both clinical services and the organizations that provide those services.
- Digital health records that are truly interoperable, allowing data to move freely across all classes of providers.
- Emphasis on reducing variation in care provided by different doctors so that the treatment delivered to every patient is consistent with the care protocols for their health conditions.
- Telehealth/Virtual physician visits.
- Value-based payment to providers.
- Consumer-driven change.
- Primary care's move toward clinics based in retail pharmacies and in neighborhood shopping centers.
- For labs, what TDR describes as distributed testing, enabled by a coming generation of small, miniaturized instruments that deliver accurate results inexpensively at the point of care and in near-patient settings.

Federal Judges: Paying Commissions Violates AKS

Federal appeals court ruling affirms finding by the lower court that defendants violated AKS

CEO SUMMARY: Health Diagnostic Laboratory and its marketing partner, BlueWave Consultants, were back in the news recently after a three-judge panel of a federal appeals court denied a challenge from the former principals of those companies to an earlier court ruling that required them to pay more than $100 million for violating the False Claims Act. The appeals court judges affirmed that the Anti-Kickback Statute does not allow labs to pay sales commissions to contractors.

PAYING SALES COMMISSIONS TO INDEPENDENT CONTRACTORS working as sales professionals for clinical laboratories and anatomic pathology groups continues to be illegal and in violation of the federal Anti-Kickback Statute (AKS). This was affirmed by a recent federal appeals court ruling.

The ruling itself describes how the federal appeals court judges reviewed issues considered by the lower court. For that reason, it is a document that pathologists and clinical laboratory managers may want to review with their legal advisors as part of their laboratory's ongoing compliance program.

Appeals Court Ruling

In particular, one aspect of the trial court's verdict and the appeal court's ruling that may be useful and relevant for other lab organizations is centered around how the defendants disregarded legal advice regarding the legality of sales compensation arrangements.

This element of the appeals court decision describes how the lab company and its officers and principals received advice from different attorneys about their sales program. On this point, having assessed the government's charge that the defendants "'knowingly and willfully' violated the Anti-Kickback Statute," and the defendant's response, the appeals court found that the defendant's arguments lacked merit.

The ruling was issued by the **U.S. Court of Appeals for the Fourth Circuit** in Richmond, Va., and upheld an earlier decision in which a federal district court awarded more than $100 million in damages against the owners of a lab company and its marketing partner consultants. The names of the defendants in these federal cases are likely to be familiar to readers of THE DARK REPORT.

Last December, a three-judge panel heard arguments in the Fourth Circuit case, and the judges issued their ruling on Feb. 22.

The earlier trial court verdict and the federal appeals court ruling in February went against the defendants, including former CEO LaTonya Mallory of **Health Diagnostic Laboratories** (HDL) and two executives (Floyd Calhoun Dent

III and Robert Bradford Johnson). The appeals court's decision indicates that Dent and Johnson's marketing company (**BlueWave Healthcare Consultants**) had received a percentage of lab revenue for their services, according to Robert E. Mazer, a health law attorney and senior counsel with the national law firm of **Baker Donaldson** in Baltimore.

HDL's Bankruptcy in 2015

HDL had operated as an independent clinical lab company in Richmond, Va., until it filed for bankruptcy protection in 2015 and its assets were sold to another lab company, **True Health Diagnostics**. *(See "Insights from Jury Verdict in HDL, Bluewave Case," TDR, Feb. 12, 2018.)*

"What started as a False Claim Act (FCA) suit focused on payment of 'process and handling fees' to referring physicians has resulted in an appellate decision confirming that payment of sales commissions to independent contractor marketing agents violates the Anti-Kickback Statute (AKS)," Mazer wrote in a story on his LinkedIn page.

"It is useful to note that the appeals court ruling didn't offer much in the way of any new analysis of the Anti-Kickback Statute," said Mazer in an exclusive interview with THE DARK REPORT. "I thought the appeals court decision was consistent with the **Office of the Inspector General's (OIG)** general view that the Anti-Kickback Statute doesn't allow a provider, like a clinical laboratory, to pay commission to an independent contractor selling that provider's services."

Mallory, Dent, Johnson

It was in January 2018, when a jury in the **U.S. District Court** in Charleston, S.C., found Mallory, Dent, and Johnson violated the False Claims Act that covers Medicare and other federally-funded healthcare programs. Four months later—in connection with the false claims—a federal judge in South Carolina imposed civil damages and penalties totaling more than $114 million against the same three defendants.

The verdict and judgment were the result of three separate whistleblower or *qui tam* cases. One of those whistleblower-litigants was Michael Mayes, MD, a physician in Hilton Head, S.C., who testified in the South Carolina case. Other whistleblowers in the case were Scarlett Lutz, Chris Riedel, and Kayla Webster.

Riedel is well known among lab professionals as a whistleblower and former president of **Hunter Laboratories** in Campbell, Calif. *(See "National Group Names Riedel 'Whistleblower of the Year,'" TDR, Sept. 26, 2011.)*

He's also the author of the book, "Blood Money—One man's bare-knuckle fight to protect taxpayers from medical lab fraud," which was published last fall.

Sustaining Jury's Finding

"In sustaining the South Carolina jury's finding that the parties had violated the FCA, the appeals court rejected the defendants' principal argument that the government had not proven that they 'knowingly and willfully' violated the Anti-Kickback Statute (AKS)," Mazer wrote.

In fact, the appeals court found that the defendants had numerous warnings from their attorneys that the payment arrangements that HDL and BlueWave had made regarding sales compensation violated the AKS or was legally risky, he explained.

In the appeals court case, the appellants [defendants Mallory, Dent, and Johnson] argued that the sales commissions [paid by HDL to BlueWave] did not violate the AKS, that the AKS statute was ambiguous, and that attorneys had helped prepare the marketing contracts, Mazer added. The appeals court rejected these arguments.

But then Mazer went further in explaining the nature of the Anti-Kickback Statute violations.

"According to the court, previous court decisions had held that commis-

Anti-Kickback Statute and EKRA: How They Differ in Ways Labs Can Pay Sales Commissions

CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS must review their sales and marketing programs for compliance with two federal laws. One is the Anti-Kickback Statute (AKS), first passed in 1972 and updated with revised safe harbor rules that took effect this January. The other is the Eliminating Kickbacks in Recovery Act (EKRA) that was passed in 2018.

There are significant differences in how each law defines acceptable sales compensation and whether providers, including clinical labs, may pay commissions to employee sales agents or independent contractor sales agents. The table below provides a basic overview of each law's requirements.

Attorneys knowledgeable about AKS and EKRA speculate as to whether the Department of Justice would view all arrangements that might be said to violate either law as the same, or whether it might more favorably view some long-standing arrangements that were legally compliant until EKRA's enactment, particularly if there were no known abuses.

Anti-Kickback Statute

Employee

- Laboratory uses a bona fide employee as a sales agent and can pay commissions based on the volume of specimens, volume of tests, or amount of revenue generated.

Contractor

- Under the recent revision of the AKS rule, the payment method must be set in advance, reflect fair market value, and take into account the volume of value of referrals of business generated between the two parties. Conventional thinking is that revised AKS safe harbor effectively continues to forbid the payment of commissions to non-employees of the lab.

Note: *Anti-Kickback Statute only applies to government health programs, such as Medicare, Medicaid, TriCare.*

EKRA Law *(Eliminating Kickbacks in Recovery Act of 2018)*

Employee

- EKRA allows the employer to pay a fixed salary to an employee working as a sales agent or using any other method that is not prohibited by the statute, as outlined below.
- EKRA exception for payment to an employee prohibits payments that reflect: the number of individuals referred to lab, the number of tests or procedures performed, or related amounts billed or received by the laboratory.

Contractor

- EKRA treats an independent contractor sales agent the same as an employee sales agent.
- EKRA exception for payment to an independent contractor prohibits payments that reflect: the number of individuals referred to lab, the number of tests or procedures performed, or related amounts billed or received by the laboratory.

Note: *It is important to understand that EKRA applies to government health programs and to all types of private health insurance plans.*

Lawyer Offers Insight on Prohibitions Defined by Anti-Kickback Statute and EKRA Law

BEFORE 2018, CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS could be relatively confident about how to compensate sales professionals without violating the Anti-Kickback Statute (AKS), according to Robert E. Mazer, Senior Counsel with Baker Donaldson, a national law firm.

In an interview with THE DARK REPORT, Mazer noted that, until three years ago, clinical laboratories and AP groups that wanted to use commission-based payments to compensate sales and marketing staff would need to employ the individuals providing those services. But as of 2018, this would no longer result in compliance with federal law, he noted.

"In 2018, the Eliminating Kickbacks in Recovery Act (EKRA) became law and generally extended federal kickback prohibitions to clinical laboratory services covered under a private insurance plan or contract," Mazer explained. "In addition, those prohibitions apply to public plans as well, such as Medicare and Medicaid."

For clinical lab directors and AP groups, it is important to understand that EKRA is much different from the Anti-Kickback Statute in significant ways, he noted.

"EKRA's exception for payments to employees prohibited compensation based on the number of individuals referred to the laboratory, the number of tests performed, or related amounts billed or received for laboratory services," Mazer wrote in a story posted on his LinkedIn page. "Therefore, absent any statutory amendment, EKRA appears to prohibit longstanding commission-based payment arrangements between independent laboratories and employed sales representatives that have been permitted under the AKS."

That said, EKRA does not necessarily prohibit labs or pathology group from paying all individuals employed as sales representatives on a fixed annual salary or any other basis that does not violate one of EKRA's three prohibited payment methods.

sion-based payments to independent contractors violated the AKS, the AKS safe harbor permitting commission-based payments applied only to employees, and while sales representatives may not make direct referrals, they unlawfully receive compensation for 'recommending' health care services," he wrote.

'Knowingly Violated AKS'

"The court stated that a reasonable jury could conclude that Defendants willfully paid commissions to independent contractors and, accordingly, that they knowingly violated the Anti-Kickback Statute," Mazer added.

Now that the appeals court case has been decided, Mazer speculated that it is possible the appellants could take the case to the U.S. Supreme Court.

When crafting compliance programs for their own labs, lab executives should take note of several important facts about this case. First, the Department of Justice was successful in bringing Mallory, Johnson, and Dent into federal court and winning decisions that require them to repay more than $100 million. This shows the risk of a lab executive violating AKS and later facing federal court action when the federal government seeks to recover those funds.

Second, the appeals court ruling has important insights into how the defendants were advised by attorneys as to the compliance of their sales program. These elements in the court ruling can help labs and their lawyers develop appropriate compliance policies. **TDR**

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IVD Update

BioReference Labs to Use Gestalt for Digital Pathology

Goal is to expand use of digital pathology, AI, particularly in the analysis of breast cancer cases

One of the nation's largest public clinical laboratories is moving forward with plans to expand its use of digital pathology and whole-slide imaging. On Mar. 30, it was announced that **BioReference Laboratories, Inc.** would move forward with **Gestalt Diagnostics'** PathFlow digital pathology solution.

For the agreement with BioReference, Gestalt is partnering with **MindPeak**, of Hamburg, Germany, for digital image analysis algorithms that incorporate artificial intelligence (AI) and deep learning, and with **Leica Biosciences** of Buffalo Grove, Ill., as the provider for the whole-slide imaging scanners.

BioReference is based in Elmwood Park, N.J., and is an **OPKO Health** company. The company operates 11 lab sites and serves about 19 million patients annually. It will begin deploying PathFlow in the second quarter of this year.

Difficult Diagnostic Cases

"BioReference is initially launching our PathFlow DP solution with breast cancer cases," stated Lisa-Jean Clifford, COO and Chief Strategy Officer at Gestalt. "In this specialty, we will support their most difficult diagnostic cases with fully-integrated artificial intelligence (AI) algorithms."

Gestalt Diagnostics, based in Spokane, Wash., is a software and services company offering PathFlow, a digital workflow platform that provides pathologists with a comprehensive automated workflow engine, a full image-management solution and universal viewer. Its open digital pathology technology integrates with image analysis software and AI algorithms for cancer scoring and diagnosis support. PathFlow is compatible with existing pathology lab information systems.

For BioReference, the agreement with Gestalt Diagnostics is a forward step to implement a pathologist workflow and productivity solution while also moving to the latest generation of digital scanner and AI image analysis technologies.

Expand Pathology Offerings

"This is an upgrade from what we currently use in surgical pathology, and we view PathFlow as an enhancement of technology and software," said Ellen Beausang, Senior Vice President, Advanced Diagnostics, BioReference, Elmwood Park, N.J., in an exclusive interview with The Dark Report. "This will enable us to expand our offerings to current and new customers."

Ongoing advances and improvements in digital pathology tools and systems triggered this decision at BioReference.

"We have a pathology platform that we are sunsetting and we needed to do some upgrades and updates," Beausang noted. "This was an opportunity to look at the market, assess the digital pathology solutions, and identify what was best for us.

"We felt Leica had many years of experience with digital pathology, and pairing their hardware system with Gestalt's

pathology workflow platform will give us one of the most innovative workflows in the market today. Plus, the artificial intelligence tools for digital image analysis give us new capabilities."

BioReference has short-term and long-term strategies for how it wants to leverage digital pathology to deliver more value to referring clients while expanding market share.

Client Collaborations

"In the near-term, we will predominantly use the new digital pathology (DP) resources for our current digital customers," Beausang explained.

"For the long-term, we want Gestalt's open-workflow solution because it has value in enabling potential collaborations with the client laboratories and hospitals that BioReference supports. This system gives us the ability to add new services in digital pathology—should we decide to do that."

In the first phase of this agreement, BioReference will give priority to its breast prognostic testing. "In the Elmwood Park site, we perform our IHC (immunohistochemistry) prognostic testing. We run about 20% of the IHC tests on the whole-slide imaging instrument," she noted. "As part of bringing this new DP program up, we are sunsetting our current whole-slide imaging platform.

Tweak the AI Algorithms

"Both our chief medical officer and our internal medical team were very involved in our initial package from Gestalt," Beausang added.

"We gain the ability to tweak the algorithms (developed by Gestalt) and change the AI offering for breast that they have (AI breast diagnostic algorithms ER, PR, Ki-67, HER2, and P53 in partnership with MindPeak)." TDR

Contact Ellen Beausang at media@bioreference.com; Lisa-Jean Clifford at 508/868-6827 or ljclifford@gestaltdiagnostics.com.

Image Analysis Can Add Value in QC

With its latest steps to acquire and deploy the newest generation components of digital pathology—scanners, a pathologist workflow solution, and image analysis algorithms—the team at BioReference decided on the PathFlow system.

Because it planned to buy the components from different companies, BioReference needed an open system to operate them. It chose Gestalt Diagnostics' PathFlow for that open system.

"Our system has the ability to support multiple different scanners (vendors and models) in multiple locations," explained Lisa-Jean Clifford, COO and Chief Strategy Officer at Gestalt. "PathFlow can integrate with a lab's LIS or with multiple LISs simultaneously. It provides that same interoperability with EMRs and EHRs and reporting systems, as well as artificial intelligence vendors and algorithms."

Clifford also mentioned that the ongoing improvement in the current generation of image analysis algorithms means that laboratories have another way to reduce malpractice lawsuits and reduce malpractice premiums. "Pathology laboratories—when considering the cost of lawsuits—see that there is significant value in deploying algorithms for specific use cases, such as QC (quality control) or second reads," she noted. "This can more than pay for a labs' investment in the AI.

"In first read or diagnostic aid algorithms—if the algorithm draws a pathologist's attention to the potential area of interest or region of interest and identifies abnormal or high potential for malignant cells—that helps narrow down the scope, improving diagnostic accuracy," Clifford said.

Amazon Makes Big Play into Health, Diagnostics

Tech giant offers grants for COVID-19 testing and other diagnostic tests, adds primary care services

CEO SUMMARY: Amazon is prepared to award $12 million in grants and is soliciting proposals for developing diagnostic technologies for detecting SARS-CoV-2 and other infectious diseases. This is the latest indication that the multi-billion-dollar enterprise would like to disrupt healthcare in the United States. Amazon has built clinical labs to provide COVID-19 testing to its one million employees. It is now collaborating with a primary care provider to establish clinics near its distribution centers, and these are just a few of its activities involving clinical care.

EVIDENCE CONTINUES TO BUILD that **Amazon** wants to become a big and disruptive player in healthcare. Significantly, there is growing evidence that clinical laboratory testing is one element in this company's strategic plans.

Given Amazon's track record at disrupting one industry after another since its founding in 1994, this is a threat that clinical laboratory administrators and pathologists should take seriously.

Just last month, Amazon announced that it would distribute $12 million this year to fund COVID-19 testing and to pay for diagnostic assays for other infectious diseases. In its announcement on April 12, Amazon said it was launching the next phase of its **Amazon Web Services** (AWS) Diagnostic Development Initiative (DDI), a project it started in March 2020.

In addition, the tech giant has developed a partnership with **Crossover Health**, a company in San Clemente, Calif., that provides primary care, mental health, and other healthcare services to self-insured employers and health plans.

Under this partnership, Amazon and Crossover will develop health centers near Amazon's fulfillment and operations centers. These health centers will provide primary care and other health services to Amazon employees. *(See sidebar, page 15).*

In addition, since the start of the pandemic, Amazon has built clinical laboratories near its distribution centers. These lab facilities provide SARS-CoV-2 testing for its almost one million employees. *(See, "Amazon Building Labs to Do COVID-19 Testing," TDR, Aug. 3, 2020.)*

Operates Its Own Labs

With Amazon operating its own clinical labs for COVID-19 testing, the Diagnostic Development Initiative project serves as a case in point in assessing the company's plans to be disruptive in healthcare. According to announcements from Amazon, the AWS DDI effort is designed to accelerate research and innovation and to promote the development of testing for the SARS-CoV-2 coronavirus that causes COVID-19.

Amazon also said the DDI is designed to accelerate research and innovation to advance the collective understanding and detection of COVID-19 and other infec-

tious diseases in an effort to mitigate current and future outbreaks.

In its announcement of the DDI last year, Amazon said it would invest $20 million over two years in diagnostic-related projects from accredited research institutions and private entities that use AWS. The funds are to support research for such work as molecular, genetic, and other testing projects that generate vast amounts of data requiring extensive storage on the web.

Diagnostic Technologies

Notably, *Modern Healthcare* reported that funding provided by Amazon could be used for research-oriented projects aimed at developing point-of-care testing that consumers could do at home or that could be used in health clinics to produce same-day results.

Of that initial $20 million in grants, AWS invested $8 million in a variety of companies and organizations to develop molecular tests and data analytics tools that use artificial intelligence and machine learning to detect the SARS-CoV-2 coronavirus. The company also invested in diagnostic imaging and wearables.

Now, the company is preparing to review applications for the remaining $12 million and is accepting proposals at *www.aws.amazon.com* from clinical diagnostics companies, research institutions, and other organizations.

This year, AWS said it is particularly interested in early disease detection to identify outbreaks at the individual and community levels, tools that can be used to understand disease trajectory, and efforts to bolster viral genome sequencing worldwide. Among the projects the company will consider from diagnostic testing companies and other institutions are proposals in four areas:

- **Diagnostics**. In this category, eligible projects could include molecular tests for nucleic acids or tests for antibodies and antigen. Other projects in this category could include imaging diagnostics, methods that put connected medical devices such as wearables to use, and predictive analytic tools such as artificial intelligence and machine learning systems.
- **Early disease detection**. In this category, eligible projects include early warning systems for outbreaks; connected medical devices such as stethoscopes, devices for electrocardiograms and for measuring oxygen levels in patients' blood; and wearables that can detect pre-diagnostic factors such as body temperature associated with infections or potential outbreaks.
- **Public health genomics**. In this area, eligible projects can include efforts to sequence viral genomes, initiatives to conduct viral genomic surveillance, and sequences made available on open data systems.
- **Prognosis**. In this category, eligible projects could include tools that would assess or analyze a patient's molecular factors, such as genetics, inflammatory response, metabolism, or co-morbidities. Other projects include those that report on a patient's ethnic, demographic, or socioeconomic factors, which could be useful in guiding treatment to improve patient outcomes.

The initiative's top priority is to evaluate COVID-19 diagnostic projects. However, Amazon said it also will review projects focused on other infectious diseases.

Transformative Innovations

"We have seen transformative innovations in how we diagnose disease over the past year, from machine learning-powered X-ray imagery analysis to new developments in rapid, high quality, and direct-to-consumer tests," said Vin Gupta, MD, Chief Medical Officer of Amazon's COVID-19 Response. Gupta also is an Affiliate Assistant Professor of Health Metrics Sciences at the Institute for Health Metrics and Evaluation (IHME) at

Can Amazon's Moves involving Health Services Be a Plan to Become a Healthcare Behemoth?

IN 2020, AMAZON FORMED AN ALLIANCE WITH CROSSOVER HEALTH to launch health centers near its fulfillment centers and operations facilities. Crossover Health specializes in delivering primary care, mental health services, and other forms of care in neighborhood health centers to serve Amazon workers and their family members in Detroit, California, Dallas-Fort Worth, Phoenix, and Louisville, *Fierce Healthcare* reported in March.

Since beginning their partnership last year, the two companies have started 17 health centers to provide services to more than 115,000 Amazon workers and their dependents after the program started late last year. The companies say they offer "full-spectrum acute, chronic, and preventive primary care, same-day pediatrics, prescriptions, vaccinations, behavioral health services, physical therapy, health coaching, and care navigation for specialty referrals and diagnostic services," *Fierce* added. "Crossover fully operates and staffs the centers and also provides virtual care to employees."

More than 75% of Amazon's workers in the United States are within 10 miles of one of these centers, the companies said.

Founded in 2010, Crossover works to cut employers' healthcare costs by ensuring that workers get well-coordinated care aimed at improving outcomes and reducing costs. One of its earliest customers was **Apple**. Later, it added **Microsoft** and **LinkedIn**.

To optimize availability and access to care, each center operates on extended hours during the workweek and weekends, and offers 24x7 on-call services to accommodate the various employee work and family schedules.

Crossover also is registering to be a vaccination provider participating in the U.S. COVID-19 Vaccination Program. Once registered, Crossover will be able to administer state-supplied vaccines to Amazon employees who meet eligibility criteria based on state and local health agency guidelines, the company said.

"Access to convenient comprehensive primary care is essential for all employees and we are proud to see the Neighborhood Health program with Amazon continue to expand throughout the country," said Sally Larwood, RN Chief Nursing Officer at Crossover Health, in a statement.

Last year, Amazon announced it was working with another primary care company, called **Care Medical**, to develop a virtual health benefit service for employees and their families in the Seattle region called **Amazon Care**. In this program, the company aims to offer virtual and in-person visits at patients' homes or offices, as well as prescription delivery.

the **University of Washington**, according to his LinkedIn profile.

"We have already seen inspirational results from the Diagnostic Development Initiative, and we look forward to supporting broader uses of cloud technologies to enable organizations and communities to identify and respond even faster to future outbreaks," he added.

In one DDI-funded project, **Illumina** used next-generation sequencing to improve the identification of viral mutations. Illumina uses a variety of Amazon services on the web to keep its computing and storage costs low.

In another DDI-funded project, researchers at the **Stanford University School of Medicine** developed a smartwatch-based diagnostic system that flags signs of a person's immune system fighting a potential COVID-19 infection.

The Stanford researchers aim to increase the system's ability to detect signs of COVID-19 in real time. TDR

Lab Briefs

Lighthouse Lab Services Acquires Vachette Pathology

LAST MONTH, it was announced that **Lighthouse Lab Services** of Charlotte, N.C., had acquired **Vachette Pathology** of Sylvania, Ohio. Price and terms of the acquisition were not disclosed.

Vachette Pathology was founded in 2002 by its current President, Mick Raich. The company describes itself as a "consulting firm specializing in revenue cycle auditing, refining revenue cycle processes and negotiating managed care contracts" for anatomic pathology groups and laboratories. It does not provide claims billing and collections services.

Lighthouse Labs was founded in 2002 by current President CEO Jon Harol. Originally focused on medical technologist recruiting and placement, Lighthouse expanded and currently offers a full range of lab consulting services that include assisting new labs with start-up, meeting CLIA requirements, and providing medical directors.

The addition of Vachette Pathology gives Lighthouse new capabilities in revenue cycle management consulting services to offer to laboratories.

Hologic to Buy Mobidiag for $795 Mil.

IN A MOVE TO STRENGTHEN ITS PRESENCE in multi-plexed point-of-care molecular testing, **Hologic** will pay approximately $795 million to acquire **Mobidiag**, which described itself as a Finnish-French company with offices in both countries.

Hologic's Chairman, CEO, and President, Steve MacMillan, said the acquisition would strengthen his company's market position in a post-COVID-19 world. Mobidiag offers two testing platforms. One is Amplidiag and the other is Novodiag. Both are automated systems that use polymerase chain reaction (PCR) and can deliver test results in two hours or less. Mobidiag did $42 million in revenue in 2020.

Hologic is known for its Panther, Panther Fusion, and Tigris molecular diagnostic test platforms. MacMillan told analysts that the Mobidiag testing platforms will help Hologic penetrate the acute care market, which he said requires testing to be done close to patients.

Home Test Kit for Prostate Cancer Enters Trials in UK, EU, and Canada

SOON TO BEGIN IS A MULTI-NATIONAL TRIAL of a home test kit for aggressive prostate cancer. Patients in the United Kingdom, European Union, and Canada will be enrolled in the study.

A preliminary study of the test—called the Prostate Screening Box—at two UK hospital trusts indicated that the test can detect prostate cancer up to five years sooner than current methods, noted researchers who conducted the study.

In the upcoming multi-national trial, 2,000 men will collect urine samples twice a day: one specimen collected early in the day to include overnight secretions, and another collected one hour later.

"We hope that use of our Prostate Screening Box could, in the future, revolutionize how those on 'active surveillance' are monitored for disease progression, with men only having to visit the clinic after a positive urine result," Dr. Jeremy Clark, from the **University of East Anglia's Norwich Medical School**, told *News-Medical.net*. TDR

Managed Care Update

UnitedHealthCare's New Policy Further Narrows Its Lab Network

Clinical laboratories will need to apply for status as a 'Designated Diagnostic Provider' (DDP)

UNITEDHEALTHCARE'S (UHC) RECENT MOVE to designate certain clinical and anatomic pathology laboratories as Designated Diagnostic Providers appears to be yet one more way that the insurer is narrowing its network.

Effective July 1, 2021, and subject to state regulatory approval, UHC launches a new benefit design where outpatient diagnostic laboratory services will be covered for fully-insured commercial plan members only when they are covered by a "Designated Diagnostic Provider" (DDP). If services are performed by providers who are not designated, services may not be covered and patients could be responsible for payment, says UHC.

'Cost-Cutting Measure'

"My main concern is that this is another way for UHC to limit providers in their network to only those willing to accept the lowest payment," says Mick Raich, President of **Vachette Pathology**. "This is just another in a long line of cost-cutting measures by UnitedHealthcare and their shareholders."

According to UHC, non-designated diagnostic providers will remain in-network with UnitedHealthcare. However, UHC will deny—as non-covered—outpatient diagnostic lab services provided to members who have plans with Designated Diagnostic Provider benefits. This designation will not apply to lab services rendered as part of inpatient admissions, emergency room visits, or outpatient surgery pre-operation testing that is billed as part of a global surgical package. The DDP benefit design only applies to these place-of-service (POS) codes:

- POS code 19 (off-campus hospital),
- POS code 22 (on-campus hospital), and,
- POS code 81 (independent laboratory [as well as outpatient hospital labs]).

Services performed in doctors' offices and ambulatory surgery centers (ASCs) are not subject to the DDP benefit design.

To become a Designated Diagnostic Provider, clinical laboratories need to complete a quality questionnaire and meet certain quality and efficiency requirements. UHC has yet to specify exactly what those requirements are. Currently, there is no hard deadline to complete the required questionnaire. UHC has told advocacy groups that providers who complete it by May 15 have a better chance at being including in current beneficiary plan materials.

Preferred Lab vs. DDP

According to UHC, the Preferred Lab Network is different from Designated Diagnostic Providers. "The Preferred Lab Network is a subset of UHC's freestanding lab network containing labs that meet higher standards for cost, access, quality and service and will be part of the Designated Diagnostic Provider benefit designs," says the insurer in a frequently asked questions document on its website.

"Designated Diagnostic Providers must meet efficiency and quality requirements established for existing freestand-

ing labs. Freestanding and outpatient hospital laboratories that meet requirements will become Designated Diagnostic Providers," said UHC.

In other words, labs that are part of the Preferred Lab Network will automatically be considered Designated Diagnostic Providers. UHC says that, prior to July 1, a list of Designated Diagnostic Providers will be accessible to members during their open enrollment process.

Raich believes the latest move by UHC is much like the re-pricing practices insurance companies instituted several years ago and says it is likely other insurers will follow UHC's lead.

"It would be highly likely that other health insurers will follow suit, especially once the pandemic is no longer part of the narrative," he commented, while also noting that UHC may have held back on this announcement because of the imporant role clinical laboratories are playing in combating the pandemic.

Burdens Labs, Patients

Diana Richard, Director of the Anatomic Pathology Program for **XIFIN**, says UHC's DDP policy places a great deal of administrative burden on clinical and anatomic pathology laboratories, especially given that this initiative is still contingent upon regulatory approval.

"It's counter-intuitive," she notes. "Labs spent the last year knowing patients were delaying elective surgeries and critical medical care because they had rational concerns about exposure to the novel coronavirus. Providers have managed spikes in COVID-19 testing and treatments while attempting to accommodate their own policies in response to the plethora of economic impacts—such as loss of jobs and healthcare—endured by our patient populations.

"It has been a year of challenges" added Richard. "More than ever, clinical laboratories remain a critical element in patient care, as well important contributors to the ongoing success of the healthcare industry."

Ultimately, UHC's new policy governing coverage of clinical laboratory tests places the onus on patients and their ordering providers to know whether the laboratory that processes their specimen is a Designated Diagnostic Provider.

"It's inevitably going to be a challenge for patients who have UnitedHealthcare and go to an in-network provider, only to have their claims processed as out-of-network because they were unaware of the DDP status," predicted Richard. She noted that the **American Hospital Association** (AHA) opposes the designation.

The AHA said that UHC's programs "could eliminate coverage for diagnostic tests at most freestanding and hospital labs while continuing to portray these providers as in-network to health plan enrollees." *(See TDR, "AHA, Hospitals, Say UHC Policy on Lab Network Is Anticompetitive," Mar. 1, 2021.)*

This could result in more surprise medical bills for patients. Further, Richard notes that it's concerning that prior to any regulatory approval being issued on UHC's DDP initiative, UHC has already collected a tremendous amount of data from its providers.

Advice for Laboratories

Richard advised labs to apply for the DDP designation with UHC. At the same time, if they disagree with the policy, they should make their views known. "Labs need to push back and push back hard," she said. "Let your hospital system know that patients may be penalized by the consequences of this initiative. The best way to attack this is to come together as a community. Don't go at it as a single entity, but as a consortium. Reach out to your advocacy groups and state insurance commissioners. Let them know how you feel." TDR

Contact Mick Raich at 517-486-4262 or mraich@vachettepathology.com; Diana Richard at 843-319-2409 or drichard@xifin.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Superman, the superhero of **DC Comics** and movies, recently gave a positive shout-out to lab professionals during the 45th Annual Lab Week. The **American Society of Clinical Pathology** (ASCP) gave its Lab Week recognition a theme of "Avengers of the Laboratory." **XIFIN**, the revenue cycle management company in San Diego, joined in the fun by getting actor Dean Cain, who played Clark Kent/Superman in the TV series *Lois & Clark: The New Adventures of Superman,* to film a video clip recognizing the contributions of medical laboratory professionals. The short video can be viewed at: *https://www.xifin.com/info/labweek-2021*.

MORE ON: *Superman and Avengers of the Lab*

Sharp readers of THE DARK REPORT will get extra credit for recognizing that The Avengers are comic book heros in the **Marvel** universe and Superman is a superhero in DC Comics' **Justice League**.

GENE SEQUENCING BENCHMARK ANNOUNCED

Recently, the **G10K**-sponsored **Vertebrate Genomes Project** (VGP) announced completion and publication of a study representing a major step forward in gene sequencing. This study includes 16 diploid high-quality, near-error-free, and near-complete vertebrate reference genome assemblies for species across all taxa with backbones (e.g., mammals, amphibians, birds, reptiles, and fishes) developed from five years of piloting the first phase of the VGP project. Researchers focused on genome assembly quality and standardization for the field of genomics.

TRANSITIONS

• Sherrie L. Perkins, MD, will retire as CEO of **ARUP Laboratories**, effective June 30, 2021. She has been with **University of Utah School of Medicine** and ARUP Labs for 25 years.

• Andy Theurer, currently President of ARUP Laboratories, will become CEO. Tracy George, MD, will become ARUP Laboratory's President and will continue in her role as ARUP Laboratories' Chief Medical Officer.

• Kerri McWeeny is the new Vice President of Marketing at **Jumpcode Genomics** of San Diego, Calif. She held prior positions with **Illumina**, **MO BIO Laboratories**, and **GenVault Corporation**.

• **Accumen Inc.** of of Phoenix, Ariz., announced that David Levine was promoted to Vice President of its **3DR Labs** division. He previously served at **TechSolve** and **Roadway Express**.

• **LabVantage Solutions** of Somerset, N.J., appointed Mikael Hagstroem as its Chief Executive Officer. His previous positions were with **Planet Smart City**, **MetricStream**, **McKinsey and Company**, and **SAS**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 24, 2021.

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