



More Consolidation in Anatomic Pathology!

- Sonic Healthcare Acquires ProPath
- PathGroup Buys Pathology Consultants

(See page 14)

From the Desk of R. Lewis Dark...

THE R. LEWIS 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



Witness the Land Grab to Control Healthcare Data

LIKE MOST OF YOU, IT CERTAINLY CAUGHT MY ATTENTION WHEN I LEARNED in December that **Oracle** will pay \$28 billion—with a B!—to buy **Cerner Corporation**.

I don't question the value of Cerner's products; the company has an EHR product that holds significant market share. It also has an impressive list of hospital and health system customers that use its full menu of health-care information systems—including LIS products for clinical laboratories and anatomic pathology groups. However, lab executives and pathologists should understand the primary reason Oracle is willing to pay \$28 billion to purchase Cerner: it gains access to huge quantities of patient and healthcare data that is handled daily by Cerner's information systems.

Healthcare in the United States is transforming and the foundation for this transformation will be how providers and other players access data, analyze data, and use that data to identify patients who are at risk, then guide physicians and other providers to deliver proactive and preventive care to those patients.

One key technology that will enable this transformation is artificial intelligence. A growing number of AI-powered healthcare solutions are now entering the healthcare marketplace and demonstrating that they can add value. But it requires access to large quantities of data for AI to be used in ways that can deliver value in the delivery of clinical care. The executive team at Oracle knows this. By acquiring Cerner, Oracle positions itself to have access to the multiple types of clinical, operational, and claims/reimbursement data that flow daily through all the Cerner information systems.

Seen from this perspective, Oracle isn't really investing \$28 billion to purchase a company (Cerner) that provides basic information technology services to hospitals, health systems, clinical labs, pathology groups, physicians, and other providers. Rather, it's spending that money as a way to access the vast amount of healthcare data and information that flows into these systems.

Oracle will then develop AI tools to analyze that data and create actionable intelligence to guide clinical care and generate new insights about population health and the effectiveness of precision medicine services delivered to patients. In this regard, one can say that Oracle is spending \$28 billion as its ticket to gain entry into the Brave New World of Healthcare Big Data.

LIS Market Will Change After Oracle, CliniSys Deals

➤ Two acquisitions in recent weeks may trigger significant shifts in the LIS products labs can buy

➤➤ **CEO SUMMARY:** *With its purchase of Cerner Corporation, Oracle becomes the owner of Cerner's Millennium laboratory information system (LIS) and CoPathPlus, Cerner's anatomic pathology LIS. Only three weeks later, CliniSys, a division of Roper Technologies, announced it was acquiring Horizon Lab Systems and would combine the Horizon LIS with its Sunquest Information Systems' LIS.*

IN JUST THREE WEEKS, TWO MAJOR LIS VENDORS announced significant deals, raising important questions about what these moves mean for clinical laboratory directors and pathologists.

In an acquisition worth \$28 billion, cloud database giant **Oracle** in Austin, Texas, said on Dec. 21, 2021, that it had agreed to buy **Cerner Corporation**, the healthcare information technology company in Kansas City, Mo., that is best known for its cloud-based electronic health record (EHR) products. Oracle will now also own Cerner's other software products, including the Cerner Millennium laboratory information system (LIS) and CoPathPlus, Cerner's anatomic pathology LIS.

Then, on Jan. 18, 2022, U.K.-based **CliniSys**, a division of **Roper Technologies**, reported that it had acquired **Horizon Lab Systems** in Raleigh,

N.C., along with the disclosure that it planned to combine the Horizon LIS with the LIS of its **Sunquest Information Systems** division, located in Tucson, Ariz. The expanded firm will be known by the CliniSys name, although it's possible that Sunquest will keep its branded product line.

Horizon develops lab tests outside of healthcare in areas such as environmental management and agriculture. Financial terms of the deal weren't disclosed.

"These are clearly major events and will change the LIS market landscape," said Dennis Winsten, President at **Dennis Winsten and Associates**, an LIS consulting firm in Tucson, Ariz.

Clinical lab administrators and pathologists should note that the CliniSys and Oracle deals are quite different from each other. In Oracle's case, it hopes to use Cerner to gain a larger presence in health-

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care, hospitals, and clinical laboratories. (See sidebar on pg. 6 for more details.)

“For years, Oracle had pockets of horizontal solutions skinned at the edges for healthcare, but this acquisition signifies the company’s entry into the industry as a major contender—inheriting one of the two largest electronic health records vendors (the other one being **Epic**),” Daniel Hong, Vice President and Research Director at **Forrester**, wrote in a Jan. 3 blog entry.

Cerner already uses Oracle’s database technology, so there is compatibility with the software and integration concerns are low, Winsten said.

CliniSys, on the other hand, is bringing in Horizon to stretch beyond the clinical lab market, such as environmental laboratory testing. (See sidebar on pg. 8 for more details.) Integration of technologies between CliniSys, Horizon, and Sunquest may be challenging, Winsten predicted.

“I don’t see any software synergies,” he noted. “They have different operating systems, different programming languages, and different databases.”

► LIS Acquisitions Often Fail

Winsten said time has shown that non-healthcare firms buying healthcare companies in the clinical laboratory field doesn’t always turn out well for the acquired parties.

“Historically, whenever a company that doesn’t have healthcare as its core business thinks it wants to get into this industry, it acquires a company that in many cases is doing quite well,” Winsten observed. “Frequently, that acquisition can turn out to be the kiss of death for the acquired healthcare company. Many of these types of arrangements have not always gone well, particularly when it involved an LIS company.

“Several historical examples make this point,” he continued. “**3M** acquired **MedLab**, which is now gone. **General Electric** acquired an up-and-coming

company, **Triple G Systems**, which is gone. **McKesson** acquired **Advanced Laboratory Systems**, also now gone.”

Because a significant number of hospital and health system labs use the Cerner Millennium LIS and CoPathPlus, those lab clients will want to closely follow how Oracle plans to handle those products, along with Cerner’s other hospital LIS systems.

► Sunquest Part of CliniSys

What has unfolded at Roper Industries is that CliniSys, based in the United Kingdom, is now the operating division that includes Sunquest, which has its flagship LIS, along with Sunquest CoPathPlus and Sunquest PowerPath, used by pathology laboratories.

Winsten thinks that the LIS market may tip in favor of younger and more nimble LIS companies. “The folks who are making it in the LIS business are the smaller, more focused LIS companies,” Winsten noted. “One reason is that the scale of the big LIS companies means they must generate significant numbers of new—and sizeable—lab clients to meet the revenue goals of their parent firms.

“By contrast, the newer and smaller LIS companies can be competitive working with smaller labs and pathology group practices,” he explained. “These young LIS providers don’t need a whole lot to survive and grow.”

► ‘Big Data’ Plays?

What may be a success factor in Oracle’s ownership of Cerner and the CliniSys/Sunquest/Horizon combination is that the LIS systems generate and store huge amounts of valuable patient lab test data.

Oracle and CliniSys may learn to sell that de-identified data in ways that produce a substantial stream of new revenue. This may be particularly true because of the growing interest in pooling genetic data from lab tests with other types of patient data.

TDR

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Oracle's \$28b Cerner Deal Shows Value of Health Data

➤ One of Epic's major EHR competitors will soon be owned by a major Silicon Valley IT corporation

➤➤ **CEO SUMMARY:** *For three decades, pathologists and clinical lab executives regularly pointed out that clinical laboratory data was extremely valuable. But it seemed nothing changed, no one listened, and labs could not monetize their lab data. Now, one of Silicon Valley's bigger players in information technology is investing \$28 billion to acquire one of the nation's major healthcare IT companies. Will Oracle find ways to use the Cerner Millennium LIS to gather and package lab data in valuable ways?*

ONE IMPORTANT WAY TO UNDERSTAND ORACLE'S INTEREST in paying \$28 billion to acquire **Cerner Corporation** is the general recognition that control of healthcare data will be a guaranteed path to revenue growth and profits.

While many industry observers have focused on Cerner's cloud-based electronic health record (EHR) business as Oracle scoops up the company, Cerner is also a long-time player in the laboratory information systems (LIS) market. This is important because clinical laboratories are producing ever-growing volumes of genetic data and lab test results.

➤ **Footprint in Healthcare**

Research firm **Forrester** pegged business segments that support clinical laboratory operations as a significant trend in the healthcare industry for the 2020s, and the Cerner deal fits nicely into that prediction. Beyond that, two advantages for Oracle stem from its acquisition of Cerner Corporation: a greater footprint in healthcare and a bigger market for its cloud-based products.

"Oracle currently lags behind **Amazon**, **Microsoft**, and **Google** in cloud market penetration overall—healthcare presents a sizable opportunity, as healthcare organizations are in the earlier phases in their migration to the cloud," wrote Daniel Hong, Vice President and Research Director at Forrester.

➤ **Seat at Table for Oracle?**

"According to Forrester, 40% of U.S. healthcare life sciences infrastructure pros say that their primary cloud strategy is to move existing workloads to the public cloud. The [Cerner] acquisition also gives Oracle a seat at the table alongside tech titans **Amazon**, **Google**, **Apple**, and **Microsoft**, which have entered healthcare with varying degrees of success.

"There will be ripple effects in the market from the Oracle-Cerner acquisition," Hong continued. "The likelihood of an acquisition of **Epic** or another EHR vendor is a strong possibility over the next year, with tech companies looking to add more capabilities and data as they further verticalize their enterprise health clouds." Epic is the market leader in EHRs.

However, Oracle's acquisition of Cerner may come with an unwelcome consequence. Healthcare companies—including hospital information systems and laboratory information system companies—that use Oracle's databases or cloud software may find themselves in an awkward position if they compete against the software systems sold by Cerner (and now owned by Oracle), said Dennis Winsten, President at **Dennis Winsten and Associates**, an LIS consulting firm in Tucson, Ariz.

"This aspect of the merger of the two companies will be worth watching," Winsten explained. "There's probably not much competing companies can do if they find themselves in this situation."

► **Cerner's LIS Sales**

In the 1990s and 2000s, Cerner gained a solid share of the LIS marketplace. However, beginning in 2011, as U.S. government incentives rolled out to encourage hospitals and doctors to implement EHR systems, Cerner naturally devoted more resources towards its health record products. As a result, investment in its LIS dropped over the years.

"When you look at the greater value of an EHR system compared to the lab information system, it's significant," Winsten said. "Cerner's competitiveness in the lab world was diminished, and where it got benefit was the fact that a provider using both the Cerner EHR and LIS gained a more complete electronic health record for patients."

► **Product Investments**

According to a news release, Oracle intends to continue investing in Cerner's products. Oracle also wants to push its voice-assisted technology into Cerner's services, which could benefit LIS users.

"Oracle's focus on usability and voice-enabled user interfaces will dramatically reduce the amount of time that medical providers spend dealing with systems and increase the time they spend directly caring for patients," Oracle said.

At-a-Glance: Oracle, Cerner Corp.

THIS OVERVIEW provides a brief look at Oracle and Cerner.

ORACLE



CEO: Safra Catz

Founded: 1977

Industry: Technology

Revenue: \$40 billion in FY 2021

Core products: Cloud-based software and infrastructure

Market reach: Sells to 430,000 customers in 175 countries

CERNER CORPORATION



CEO: David Feinberg, MD

Founded: 1979

Industry: Health IT

Revenue: \$5.5 billion in FY 2020

Core products: Electronic health records (EHR) system, laboratory information system

Market reach: Has 25% of the hospital EHR market

Sources: Cerner, Oracle, Health Leaders Media.

During the next few years, clinical laboratories using the Cerner Millennium LIS, and anatomic pathology groups using the Cerner CoPathPlus pathology LIS, may not see major changes in the service and sales teams representing these products.

One reason for this is that these will be new product categories for the Oracle executives. It will take time for the Oracle acquisition teams to better understand all the different IT products in the Cerner portfolio. It is logical to believe that Oracle considers ownership of Cerner to be a big data play in healthcare because a hospital or health system that is "all-Cerner" can deliver a large volume of valuable patient health data.

TDR

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More LIS Consolidation as CliniSys Buys Horizon Lab

➤ **CliniSys' acquisition of Horizon Lab Systems gives it a presence in U.S. and European Union**

➤➤ **CEO SUMMARY:** *By acquiring Horizon Lab Systems, CliniSys has committed to moving some of its services beyond the clinical laboratory as Horizon sells into other lab markets, such as environmental management. Also, CliniSys will combine with Sunquest Information Systems, bringing two LIS vendors under one corporate brand. It remains to be seen what effect that move will have on both companies' LIS products.*

RECENT MOVES BY CLINISYS, A BUSINESS DIVISION OF **ROPER TECHNOLOGIES**, might be positioning this provider of laboratory information systems (LIS) to have a substantial market presence in both the United States and the European Union (EU).

The most recent move was CliniSys' purchase of Raleigh, N.C.-based **Horizon Lab Systems** on Jan. 18. Horizon has lab customers in several different industry sectors using its LIMS (laboratory information management system).

The second move happened earlier. Roper made its **Sunquest Information Systems** a part of its U.K.-based CliniSys Solutions Group. It appointed Michael Simpson, then Chairman and CEO of CliniSys, as the leader of this business group.

These business moves have interesting implications for clinical lab administrators and pathologists here in the United States who use the Sunquest LIS and its anatomic pathology LIS solutions—Sunquest CoPathPlus and SunQuest PowerPath. It means executive leadership and strategic direction for the Sunquest product line will come from the CliniSys headquarters in Surrey, U.K.

Further, the addition of the Horizon Lab Systems product line positions CliniSys to serve many different types of laboratories. In its website, Horizon says it is “one of the only commercially available LIMS that may operate as both sample-centric and batch-centric, making it ideal for use in the public health laboratory sector where it can be used across the entire laboratory. Horizon is sold into environmental, agricultural, cannabis, clinical, pain management, forensic toxicology, and public health laboratories both domestically and abroad.”

➤ **Environmental Testing**

“CliniSys can now provide organizations and governments at all levels, and across different sectors of the public health ecosystem, solutions to improve health at population scale,” CEO Michael Simpson said in a news release.

“Horizon may be the hidden jewel in these new developments at CliniSys,” explained Dennis Winsten, President at **Dennis Winsten and Associates** in Tucson, Ariz., noting further that “those non-hospital areas are expanding quicker than hospital-based laboratory services.” “In the environmental, public health, and

agriculture fields, the lab market is expanding because there is a growing need for more sophisticated testing,” Winsten noted. “That makes Horizon and its LIMS a strategic growth asset for CliniSys.”

Winsten outlined several positive and negative aspects to the overall CliniSys announcement.

“First, CliniSys and Sunquest each get access to a broader, worldwide market as a combined organization,” Winsten observed. “Second, they both have good corporate reputations.

“Third, there may be the opportunity to reduce the sales and marketing overhead, and they are not competing with each other,” he added. “And, of course, Horizon gives them entrée into a growing market.

► Different Operating Systems

“One possible negative to these developments is that the various products use different operating systems, programming languages, and databases,” Winsten noted. “That could offset the benefits of software synergies.”

In addition, having two LIS brands under one company may be confusing to customers. “With these three brands, there is uncertainty as to what they’re going to do and which LIS may emerge as the flagship system. Deciding which products will address what market segments or geographies is a question that CliniSys management will need to answer,” Winsten said.

Another interesting factor that CliniSys will need to address is that clinical laboratories in the United States and the United Kingdom serve very different healthcare systems and lab tests are reimbursed via two radically different payment methodologies. This is one reason why few LIS companies are able to sell the same LIS to clinical labs in both countries at the same time. **TDR**

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Companies At a Glance

HERE’S A BRIEF LOOK at CliniSys, Horizon Lab Systems, and Sunquest Information Systems.

CLINISYS SOLUTIONS GROUP



- CEO: Michael Simpson
- Founded: 1988
- Industry: Health IT
- Revenue: Not broken out (owned by Roper)
- Core products: Laboratory information system (LIS) and result consultation software
- Market reach: LIS used by 70% of National Health Service trusts in England

HORIZON LAB SYSTEMS



- General manager: Eric Dingfelder
- Founded: 1987
- Industry: Health IT
- Revenue: Not reported, private company
- Core products: LIS
- Market reach: Sells to environmental, agricultural, cannabis, clinical, toxicology, and public health labs

SUNQUEST INFORMATION SYSTEMS



- CEO: Michael Simpson
- Founded: 1979
- Industry: Health IT
- Revenue: Not broken out (owned by Roper)
- Core products: LIS and lab analytics tools for pathology
- Market reach: Counts 1,700 laboratories as customers and has over 300,000 end users

Sources: CliniSys, Horizon Lab Systems, Sunquest Information Systems


Regulatory Update

Non-COVID Part B Lab Spend Declined by 15.9% in 2020

OIG says 2020 Medicare Part B CLFS spending for non-COVID tests was \$6.5 billion, lowest since 2016

MEDICARE PART B CLINICAL LABORATORY FEE SCHEDULE CUTS mandated by PAMA continue to bite deeply. A new government report shows that during fiscal 2020, the Medicare program spent 15.9% less for lab tests, when COVID-19 test payments are excluded.

The federal **Department of Health and Human Services Office of Inspector General** (OIG) recently released a report examining test spending for Medicare Part B patients in 2020. “Aside from COVID-19 tests, spending for all other tests as a group decreased by 15.9% from 2019, to \$6.5 billion,” the OIG wrote in its report. “The decline in spending was driven by a decline in overall healthcare utilization during the pandemic, as well as a further reduction in payment rates for some tests, as required by PAMA.”

Medicare shelled out \$1.5 billion for COVID-19 tests in 2020. That helped overall spending for Part B clinical lab testing rise in 2020 to \$8 billion, up 4.2% from 2019.

The reductions in non-COVID test spending reflect a wider pandemic theme: Americans avoided routine healthcare tests while providers triaged their services to better respond to urgent COVID-19 cases, particularly in spring 2020.

“The monthly volume of non-COVID-19 tests did not ... increase during the second half of 2020, suggesting that many Medicare beneficiaries did not make up the tests they may have missed in the spring during the rest of 2020,”

the OIG noted. “Research suggests that delays in diagnostic testing, such as cancer screening, could have long-term effects on beneficiary health and well-being.”

► **Wide Range of Payments**

The OIG report had one interesting insight into the extent of COVID-19 testing for the Medicare population. The OIG determined that more than 8.4 million unique Medicare Part B beneficiaries received at least one COVID-19 test in 2020. Federal payment rates for these tests ranged from \$18.09 to \$100 for high-throughput assessments.

For the time being, demand will remain healthy for COVID-19 tests as Americans manage virus variants.

If SARS-CoV-2 becomes endemic, similar to seasonal flu, it's possible that related testing reimbursement will help clinical laboratories endure upcoming PAMA reductions.

Taking the pandemic out of the equation, however, the reduction in test spending is alarming—but not unexpected—news for clinical laboratories and pathology groups. The Protecting Access to Medicare Act of 2014 (PAMA) has hit labs hard since 2018 by requiring Medicare to reduce test payments under the Clinical Laboratory Fee Schedule to reflect private payer rates.

Clinical laboratories avoided PAMA cuts in 2021 and 2022 due to COVID-19 concerns, but these lab test price cuts are scheduled to resume in 2023. (See *TDR*, Dec. 20, 2021.)

NEWSMAKER

INTERVIEW



John King
President
OmniSYS Division



Lâle White
CEO, XIFIN

Labs, Pharmacies Learn from Each Other as Barriers Drop

“Some services that have transitioned to retail pharmacies may essentially bring clinical labs closer to the consumer, which I don’t think labs truly appreciated since they traditionally have not had much direct access to the consumer.” —*Lâle White, CEO, XIFIN*

►► **CEO SUMMARY:** *When XIFIN purchased OmniSYS, it put an exclamation point on the growing trend of retail pharmacies offering consumers point-of-care testing and an expanding menu of primary care services. More than 30,000 retail pharmacies use an OmniSYS informatics product. XIFIN hopes that its expertise in lab testing and diagnostics—combined with OmniSYS’ existing pharmacy relationships—will open the door to relationships with retail pharmacies.*

EDITOR’S NOTE: XIFIN’s recent acquisition of OmniSYS is a strategic response to the emerging trend of retail pharmacies offering primary care services to consumers. Also, several of the national retail pharmacy chains are preparing to expand lab testing options to patients as a convenient alternative to physician offices. XIFIN’s strategy is to leverage OmniSYS’ existing relationships with retail pharmacies. (See *TDR*, Jan. 10, 2022.)

In this follow-up Q&A, Lâle White, CEO at XIFIN, and John King, the new president of the OmniSYS division at XIFIN, explain why retail pharmacies face new challenges with clinical laboratory test reimbursement claims, what lessons clinical laboratories and pharmacies can learn from each other, and how clinical data from medical laboratories can bolster electronic health record (EHR) systems used by pharmacies.

EDITOR: Retail pharmacy chains are making major investments to support their plans to become big players in primary care going forward. Logically, this will make pharmacies major buyers of clinical lab tests. It seems what XIFIN and OmniSYS are doing is a market example of how new players are lining up to serve this emerging class of buyers for clinical lab tests. Is that basic analysis correct?

WHITE: Yes. Along with telehealth, retail pharmacies are the new front door of healthcare. Clearly there’s a huge convenience factor of pharmacies, as they are located close to where patients live and work. Some statistics show that 95% of Americans live within five miles of a retail pharmacy. So, it’s a convenient setting for care. Many people today don’t need to travel to a big hospital campus for much of their healthcare. It makes sense that we see a huge increase in clinical services being offered at retail pharmacy settings.

EDITOR: What market trends made the OmniSYS–XIFIN combination appealing?

KING: The traditional “dispense-and-fill business model” within the pharmacy is evolving. Profit margins are getting compressed and it’s becoming harder and harder to compete because of the growth

of mail order pharmacies, and services like Amazon’s PillPack.

EDITOR: What is different in how consumers and patients want to access care?

KING: That’s easy. Consumer demand is shifting towards convenient, accessible care. Pharmacies themselves are increasingly moving towards a clinical services business model. For example, because of the pandemic, we saw a further tipping point as demand for care outstripped the supply of traditional access points. As a result, legislation was passed that improved access to healthcare by expanding the scope of practice for pharmacists as providers of clinical services.

EDITOR: Did these laws help retail pharmacies?

KING: Their clinical services business model has grown to include not only immunizations and medication reviews, but also clinical encounters such as point-of-care testing, point-of-care screenings, birth control prescribing, and patient counseling. It is this expansion of scope of practice that brings us back to the laboratory. Over the past year and a half, our team at OmniSYS has been hard at work helping our retail pharmacy customers expand their business into new

services—specifically point-of-care testing and point-of-care screening.

EDITOR: With the pharmacies doing so much COVID-19 testing, is the ability to file a correct lab test claim just as essential now to a pharmacy as it is to a lab?

WHITE: Yes, gathering all the necessary information for a test claim to be successfully submitted is just as critical to pharmacies as it is to labs. That's why OmniSYS was such a great fit for XIFIN; together, they can submit clean medical claims on behalf of pharmacies to ensure they get reimbursed for the clinical services, including COVID-19 testing, that they provide to patients.

EDITOR: Will this acquisition create opportunities for a whole host of clinical labs that might otherwise struggle to get access to pharmacies?

WHITE: We believe we can democratize this arrangement through technology and open it up to multiple lab providers, as well as providers with continuous monitoring devices who specialize in disease states—without restricting access through exclusive agreements. We think there are a number of labs strategizing how they could support pharmacies. There's a number of synergies here and the ability to offer phlebotomy services or reference lab services across the board—and not through an exclusive contract—might be something that we would explore with all of these pharmacy outlets.

EDITOR: Given all the talk about forging new relationships between retail pharmacies and clinical labs, what do you think pharmacies could learn from laboratories as this partnership grows? And what might labs learn from pharmacies about serving consumers and patients in innovative new ways?

WHITE: Pharmacies do provide a good strategic road map for clinical labs. Once pharmacies started losing their share of prescription drug orders to mail order systems and online disrupters like Amazon, they didn't just sit idly by and accept

their declining business. They knew their marketplace and understood consumer demand for convenience. This guided their rapid pivot into offering clinical services.

EDITOR: Did labs respond to these same market signals?

WHITE: By comparison, labs were slow to support the increases in the health-care services provided by pharmacists, including their ability to draw blood and become providers of clinical services. And, during these same years, **Theranos** was going state by state to encourage passage of direct-to-consumer testing laws. Yet the clinical lab industry did not support that effort. However, once this was accomplished, forward-thinking labs became the beneficiaries of these new laws. Additionally, some of the services that have transitioned to retail pharmacies serve to essentially bring labs closer to the consumer, which I don't think labs truly appreciated since they traditionally have not had much direct access to the consumer.

EDITOR: You are describing a significant change in consumers access care.

WHITE: Yes. This ongoing shift completely changes the environment for how clinical labs should operate to meet consumer demand. Labs should be much more cognizant about the fact that coordination of care amongst providers is going to be essential to their growth, especially as state and federal legislation looks at areas where healthcare is delivered the most efficiently and effectively to reduce costs.

EDITOR: How should labs respond?

WHITE: If clinical labs understand that the consumer is now a direct customer, I think they'll see that this gives them a huge opportunity for better testing access for the average individual. People are much more inclined to participate in their healthcare than they used to be. They know a lot more about lab testing and they understand a lot more about genetic testing and its impact on their daily life choices. And so, consumers will drive

their own healthcare much more than has been true. This is the landscape that clinical labs must understand.

KING: One big thing that pharmacies can learn through this process is the value of clinical data interoperability and the use of clinical decision support tools in the delivery of care. Pharmacies today are highly optimized around e-prescribing, order management, and inventory management. But clinical decision support is something that's going to become important to pharmacies, as they increasingly will rely on data and tools that help pharmacists proactively identify intervention opportunities for at-risk patients.

WHITE: That's an excellent point that data and access to data makes a big difference in the quality of care. I think most people talk to their pharmacists about drug interactions and side effects at a much more detailed level than they do with their prescribing physician. There's a lot of data that pharmacists can use to assist with daily disease management tips or what type of vaccines a patient might need.

EDITOR: Does this acquisition help boost data quality between the lab and pharmacy?

WHITE: Most of the EHRs just don't contain usable data when it comes to laboratory data. XIFIN developed a solution for oncology that provides analysis using biomarker level clinical data that they can't get out of their own EHR. That's made all the difference in the world in the way oncologists analyze that data and the way they use it to improve standards of care, including identifying with precision the most appropriate clinical trials provided by pharmaceutical companies. We have the same type of opportunity in pharmacies to populate the pharmacy-level EHR with the type of laboratory detail that they can now get in an automated fashion. This data sharing and integration process that we talk about—and the sophisticated technology it takes to do

that—is not available in the major enterprise systems used by health systems. Our systems have been developed to facilitate data sharing between disparate entities and are designed to preserve data integrity in a manner that enables useful analysis and summaries of clinical information, including lab data, which comprises 80% of what's in the EHR.

EDITOR: This is a significant advancement in data sharing.

WHITE: Yes, the entire process of data exchange is going to look much different. Most of the major technology companies that have tried to do data integrations for clinical laboratories have not been successful, certainly not at the biomarker level. That level of data is needed to do the right analytical job and to interface with apps that provide a tremendous amount of feedback to the consumer on how to manage their health.

EDITOR: To pick up on your earlier mention of oncology, when XIFIN handles a claim from a pathology group or a lab that involves a tissue-based biopsy, are you getting the test result report itself? And can you set up a system that provides to the referring oncologist a complete patient summary that the pathology lab itself is incapable of doing?

WHITE: Yes, we can, particularly in genetic and molecular testing. There is an important reason for this capability. For a long time, this level of data has been required to file successful appeals. Reimbursement in molecular and genomic testing is challenging; you need to know diagnostic results for a lot of those claims. But even beyond that, we have our lab information system and our clinical data aggregation system, VisualStrata, which consolidates all types of clinical data for analysis purposes. So, we do integrate with labs for their clinical data on the basis of those product lines and also for claims processing. **TDR**

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Pathology Update

Sonic Healthcare Acquires ProPath, PathGroup Buys Path Consultants

Two large private practice pathology groups decide to sell to larger pathology superlabs

CONSOLIDATION AMONG PRIVATE PRACTICE ANATOMIC PATHOLOGY GROUPS continues with news that two large regional pathology groups decided to sell to larger pathology companies.

The first transaction announced was on Dec. 16, 2021, when **Sonic Healthcare** of Sydney, Australia, disclosed that it had acquired Dallas-based **ProPath**. Sales price and other terms were not announced.

The second transaction happened last week. On Jan. 24, Nashville-based **PathGroup** announced it had acquired **Pathology Consultants** of Greenville, S.C. Price and terms of this transaction were not disclosed.

► Pathology Consolidation

The decision by two of the nation's leading regional pathology groups to sell themselves to larger pathology entities confirms that the trend of consolidation is continuing within the pathology profession. It is also a sign that smaller pathology groups will find it increasingly difficult to compete and stay profitable as new technologies transform the surgical pathology profession.

ProPath was considered a financially strong regional super-group. Headquartered in Dallas, it operates facilities in three states and has 50 pathologists and 500 employees. In the press release announcing the acquisition, Sonic noted that ProPath's annual revenue was about \$110 million.

Sonic Healthcare has been a major acquirer of anatomic pathology practices

in the United States. In 2010 it acquired **CBL Path** for a purchase price of \$123.5 million. (See *TDR*, Nov. 15, 2010.)

Sonic Healthcare also purchased **Aurora Diagnostics** in 2018 for \$540 million. That deal brought it 32 pathology practice sites and added 220 pathologists to its roster. (See *TDR*, Dec. 24, 2018.)

► PathGroup's Growth

With its acquisition of Pathology Consultants, PathGroup adds 30 pathologists and 100 employees currently working with the group headquartered in Greenville, S.C. Prior to this acquisition, PathGroup said it had 225 pathologists.

Anatomic pathologists will want to understand why two major regional pathology groups have decided to give up their independence and sell to a larger company. The reasons are several and include:

- Need for cash to purchase the equity of retiring baby boomer pathologist partners in the group.
- Challenges in recruiting new pathologists to the group.
- Need for capital to acquire digital pathology capabilities and other needed advanced diagnostic technologies.
- Access to managed care contracts as private health plans continue to narrow their provider networks.

It should be noted that graduating pathology residents and fellows are tech-savvy and want to work in practices that have all the latest technologies in histology, scanning, and digital pathology. **TDR**


Lab Market Trends

Microbiome Startups Pushing into the Clinical Lab Space

Startup companies testing patients' gut bacteria attracted approximately \$1 billion in venture capital

REPUTABLE CLINICAL LABORATORY COMPANIES HAVE A NEW COMPETITOR in what has been called the Wild West of microbiome startups.

Some of the companies in this nascent industry have been hailed for developing health breakthroughs while others have been indicted for fraud, according to *Kaiser Health News*. Either way, these companies are serving up a cautionary tale for consumers, *KHN* noted.

Among the companies in this space are those that provide individualized diet regimens based on analyzing consumers' microbiome, or gut bacteria. Consumers pay hundreds of dollars for tests not covered by insurance, hoping to get answers to health problems ranging from irritable bowel syndrome to obesity, the health news service added.

A financial database for investors called *Pitchbook Data* has identified more than a dozen direct-to-consumer providers offering gut-health tests, *KHN* noted.

➤ A Worrying Trend

Early reporting on this industry shows a worrying trend of new lab entrants seeking to sell consumers tests that analyze the human microbiome, which is an inexact area of science and medical care.

Perhaps most concerning for clinical laboratories is that these companies not only advertise to consumers, but they also send sales representatives to physicians' offices, perhaps crowding out the time doctors might reserve for sales calls from

highly-reputable clinical laboratories that have long histories of serving physicians and their patients.

Companies peddling human microbiome tests also are sending sales professionals to chiropractors, homeopaths, naturopaths, and other providers treating patients seeking more information on their health.

➤ Consumer Interest

As these companies proliferate, established clinical lab companies can expect to get questions from many consumers, and perhaps physicians, about whether long-standing clinical labs can offer these same tests of individuals' gut specimens.

Clinical labs also may get questions about the reliability, accuracy, and utility of microbiome tests.

Another concern for reputable clinical labs is that startup companies testing patients' gut bacteria attracted approximately \$1 billion in venture capital between 2015 and 2020, *KHN* reported, citing data from **Crunchbase**, a tech company that collects and publishes information on public and private companies.

Note that venture capitalists have been attracted by what they consider to be promising research and consumers' embrace of at-home testing.

"Not all companies in this relatively new industry are equal. While some are developing peer-reviewed studies to promote their offerings, others are peddling murky science, *KHN* reported.

“A lot of companies are interested in the space, but they don’t have the research to show that it’s actually working,” Christopher Lynch, Acting Director of the Office of Nutrition Research at the **National Institutes of Health** (NIH), told *KHN*. “And the research is really expensive.”

To examine the value of studying the human microbiome, the NIH is planning to spend \$160 million to launch a nutrition for precision health research effort early in 2022. In this effort, the NIH plans to enroll one million Americans to study how diet, genes, metabolism, and other factors affect the microbiome, *KHN* reported.

► Microbiome Testing Firms

Other companies seeking to run tests for individuals who want to know more about their gut microbes include **Viome**, a company that says its advisory board includes holistic medicine advocate Deepak Chopra, and George Church, PhD, the Robert Winthrop Professor of Genetics at **Harvard Medical School** who developed the first direct genomic sequencing method, which resulted in the first genome sequence. Church also helped to start the Human Genome Project in 1984 and the Personal Genome Project in 2005.

Another company in this arena is **ZOE**, which says it is backed by cutting edge science and researchers who work in collaboration with scientists from **Massachusetts General Hospital**, **King’s College London**, **Stanford Medicine**, and the **Harvard T.H. Chan School of Public Health**.

Microbiologists and clinical pathologists understand that the human microbiome is one of the exciting new fields in laboratory medicine. Microbiome testing has great potential for use as a diagnostic tool. At the same time, it can be expected that a number of “quick buck” operators will seize the opportunity to sell microbiome tests of questionable value to consumers. For these consumers, *caveat emptor* is good advice! **TDR**

Feds Charge uBiome with \$60 Million Fraud

FURTHER RESEARCH MAY HELP SEPARATE THOSE COMPANIES with clinically useful human microbiome laboratory tests from those companies that are not reputable.

In the latter group is the microbiome testing company **uBiome**, a biotechnology developer in San Francisco that was among the first to offer fecal sample testing to consumers. Founded in 2012, uBiome offered at-home, direct-to-consumer tests for health-conscious individuals seeking to learn more about the bacteria in their gut.

However, in April 2019, the **Federal Bureau of Investigation** (FBI) raided uBiome’s headquarters on allegations of insurance fraud and questionable billing practices, *CNBC* reported. The company was alleged to have billed patients for tests multiple times without consent, the network added.

Kaiser Health News reported that uBiome filed for bankruptcy after the FBI raid. In addition, *Kaiser Health News* noted that uBiome had marketed its tests as being clinical in nature and sought reimbursement from insurers for almost \$3,000 per test.

That’s when uBiome’s business tactics came under scrutiny. (See, “*Medical Laboratory Testing Company uBiome Raided by FBI for Alleged Insurance Fraud and Questionable Business Practices*,” *Dark Daily*, Aug. 9, 2019.)

Finally, in March 2021, the **U.S. Securities and Exchange Commission** charged uBiome’s cofounders, Jessica Richman and Zachary Apte, of defrauding investors of \$60 million. According to *The Wall Street Journal’s* podcast, *The Journal*, investigators considered the pair to be fugitives when they relocated to Germany after the charges were announced.

 **Managed Care Update**

Labs Can Team with Employers to Improve Worker Productivity

HEALTHCARE'S ONGOING TRANSFORMATION AND THE EMPHASIS ON VALUE-BASED REIMBURSEMENT are creating a new opportunity for savvy clinical laboratory executives and pathologists. This opportunity is centered around the need of self-insured employers to address the problem of employee presenteeism.

"Helping employers with presenteeism can create a value stream for clinical laboratories," says Kristine Bordenave, MD, FACP, a consultant in precision medicine with **KKBordenave Consulting Group** in Chicago. "I see an opening for laboratories and laboratory benefit managers to work directly with employers, as the pharmacy benefit managers have done for the last 20 to 30 years."

➤ Not Productive on the Job

Specifically, clinical labs can help solve a major problem for companies: "presenteeism," a term used to describe those times when employees are on the job but not working their best due to a chronic condition, acute illness, or an injury. According to Bordenave, presenteeism is four to five times more costly for employers than acute injuries, resulting in loss of over \$150 billion per year in productivity. That amount is more than losses from absenteeism.

Bordenave spoke on the topic during a general session at the *Executive War College* in November 2021 and later provided further details to THE DARK REPORT.

The phenomenon of presenteeism isn't new, as *Harvard Business Review* wrote back in 2004. According to that article, many of the health problems that result in presenteeism are common, such

as seasonal allergies, asthma, headaches, depression, back pain, arthritis, and gastrointestinal disorders. People who don't feel good simply don't perform at their best, noted the article.

For example, people with uncontrolled diabetes generally are less productive than those whose diabetes is controlled. As a result, "It is important to provide early intervention and continuous support as a preventive measure against not only diabetes and diabetes-related complications but also presenteeism," according to research published in the journal *BMC Public Health* in October 2021.

Presenteeism-related declines in productivity sometimes can be offset by relatively small investments in screening, treatment, and education. This is where clinical laboratories can step in.

Bordenave suggested that lab directors approach health benefits administrators at self-insured companies and demonstrate how a well-designed program utilizing clinical data could help reduce the costs associated with presenteeism. Using the lab's test results in proprietary algorithms as actionable indicators of employee health, the data can be the basis for community-based wellness initiatives focused on early detection, early intervention, and better disease management.

This type of program is best suited for self-insured employers because those businesses can set their own requirements for testing coverage, Bordenave said. Most self-insured plans work with outside contractors in addition to managed care providers who administer the plan. Health plan administrators typically have a med-

ical director with a background in population health who determines the best approach to improve the overall health of workers and reduce presenteeism.

Efforts to ward off COVID-19 offer a good example of how repeated lab testing may benefit the employer, she noted.

“Many employers want to make sure their workers are negative and require more frequent testing than would be covered under their health plan,” she said. “Clinical laboratories are already playing a role in keeping workplaces safe and employees healthy.”

➤ Take a Hint from Lab 2.0

Clinical laboratories that are not already involved in community health or population health initiatives can learn a thing or two from labs such as **TriCore Reference Laboratories** in Albuquerque, N.M., Bordenave suggested.

TriCore is a leader in Clinical Lab 2.0, an initiative established to help develop the evidence base for the valuation of laboratory services in the upcoming era of global healthcare. Those involved in Clinical Lab 2.0 focus on using data and insights generated by labs to support the evolving needs of health systems, hospitals, physicians, and health insurers. Under this model, clinical labs play a key role in personalized medicine and are reimbursed not just for the testing they perform, but also for the value they provide.

TriCore is believed to be one of the earliest clinical labs to collaborate with health insurers in ways that meet the Clinical Lab 2.0 business model, making its experience useful to other labs seeking to develop new sources of revenue while pursuing value-based care. TriCore has arrangements with some payers under which the lab receives compensation on a per-member per-month (PMPM) fee in exchange for providing data and insights that can improve health outcomes of the members.

Bordenave said that clinical labs that are interested in developing their own

Health Company Meets Community Need

CORIELL LIFE SCIENCES (CLS), A PRECISION MEDICINE COMPANY based in Philadelphia, is one example of an organization that saw an unmet need in the community and developed a program to address it.

In 2018, CLS initiated a personalized medicine pilot program in conjunction with the **Teachers’ Retirement System** of Kentucky, which is self-insured.

CLS used pharmacogenomic testing to determine members’ response to medications based on how their genes metabolized drugs. One key aim of the pilot was to advance patients’ health and to reduce costs using pharmacogenomics and expert pharmacy review.

During the initial phase of the pilot, more than 4,000 retirees enrolled and 2,800 submitted DNA samples, according to CLS. About 83% of retirees received recommendations for an alternative medication or dosage adjustment based on the results of their DNA tests. In addition, 94% of these suggestions were approved by prescribers. The project pilot received a national award for healthcare innovation from the **State and Local Governments Benefits Association**.

programs to assist employers might start by joining a local business group on health and engaging with participants about what their needs are. A program can then be developed to help meet those needs.

“It goes way beyond just performing tests,” Bordenave said. “Some labs are even offering blood pressure measurements. Labs can fill the gaps in services because they touch people so frequently.”

Many employers need help to properly manager their workers’ health conditions, and if clinical laboratories don’t step up to meet this need, someone else will, Bordenave cautioned. **TDR**

Contact Kristine Bordenave at 312-520-6657 or kkbordenave@gmail.com.

INTELLIGENCE

LATE & LATENT
 Items too late to print,
 too early to report



DNA-based breast cancer testing is taking a step forward. **Illumina** in San Diego, which sells next-generation sequencing (NGS) technology, announced a partnership with **Agendia** in Irvine, Calif., to develop *in vitro* diagnostic tests for oncology. Agendia offers proprietary breast cancer tests. The companies expect Agendia's MammaPrint test to become the first decentralized, NGS-based breast cancer risk test cleared by the FDA. A decentralized screening program refers to an approach for which the testing and interpretation are left to the testing company, but follow-up and treatment decisions fall to the referring oncologist.

➤➤➤ MORE ON: **Agendia**

On Oct. 28, 2021, Agendia filed with the U.S. **Security and Exchange Commission** to become a traded company through an initial public offer-

ing (IPO). The company hopes to raise \$75 million in its IPO but did not list a date for the offering, according to its filing. Agendia was founded in 2003 and operates facilities in Amsterdam, the Netherlands, and Irvine, Calif.

➤➤➤ **ACLA: LAB STAFFING WOES AFFECTING LAB TEST CAPACITY**

The **American Clinical Laboratory Association (ACLA)** noted that staffing issues related to the SARS-CoV-2 pandemic are affecting the industry's capacity to turn around tests. It's not just lab employee illness with COVID-19 that is straining rosters; additionally, the time it takes to bring on temporary staff and train them is reducing capacity limits, according to a statement from the ACLA. Competition from other healthcare sectors for those temporary workers is also a factor.

➤➤➤ **OLD WINDOWS IOS MAY BE IOT RISK**

Old versions of the **Microsoft** Windows operating system may be putting laboratory internet-of-things (IoT) systems at risk, according to a new report from **Cynerio**, a healthcare IoT security platform vendor. More than 50% of devices in oncology, pharmacology, and medical laboratory departments run on versions older than Windows 10. Some of those software versions may no longer be updated, putting the equipment and data in them at risk of cyber attacks, the company said.

➤➤➤ **TRANSITIONS**

- Robin Divine was named President and CEO of **TriCore Reference Laboratories** in Albuquerque, N.M. Divine has been with TriCore as Chief Strategy Officer and a Director since 2019, and before that held various executive roles during a 17-year run at **Presbyterian Health Services**.

*That's all the insider intelligence for this report.
 Look for the next briefing on Tuesday, February 22, 2022.*

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UPCOMING...

- Maintaining adequate staff throughout the lab, despite 'Great Retirement,' employee resignations.**
- Converting lab test orders to collected specimens: how labs use new real-time digital tools.**
- Early assessments in how payers now handle out-of-network test claims under 'No Surprises Act.'**