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TOP TEN LAB STORIES 2018

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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

Expect Significant Disruption during 2019

EACH TIME A NEW YEAR APPROACHES, IT IS NATURAL TO LOOK AHEAD and think about what the next 12 months will bring. My bet is that certain sectors of the clinical laboratory industry are soon to experience substantial disruption.

This disruption will come in two forms. First, federal regulators will be tougher on labs that violate the Anti-Kickback Statute and other fraud and abuse regulations. Passage of the Support for Patients and Communities Act (H.R. 6) in October, for example, now makes it against federal law for providers (including labs) to pay commissions to sales reps for generating referrals from physicians. The law covers referrals for both governement and private health plans. Lab industry attorneys and associations are scrambling to get Congress and the federal government to address the conflicts in this law versus the long-standing safe harbors in the Anti-Kickback Statute. However, until that happens, labs that pay sales commissions are at risk of enforcement action by the government and whistleblowers. *(See TDR, Dec. 3, 2018.)*

Second, in the final Medicare Rule for 2019 PAMA reporting of private payer lab prices, the federal **Centers for Medicare and Medicaid Services** (CMS) defines hospitals that use the CMS-1450 14x claim form as "applicable labs" that must report their private payer lab test price data to CMS. Many hospitals with billing for Medicare Part B lab tests lack the capability to easily and accurately assemble, assess, and report their private payer lab prices and test volumes.

Yet, failure to report, or to report inaccurate and/or incomplete data, puts every applicable lab at risk of federal fines of as much as $10,000 per day. Thus, a substantial number of hospitals and health systems will find themselves either unable or unwilling to devote the manpower and financial resources needed to collect and report this data. Assuming this is true, then this will be disruptive.

The lab industry knows, from the first data reporting cycle in 2017, that many labs required to report failed to submit any data to CMS. Other labs submitted data that were obviously inaccurate or incomplete. That experience is likely to be equally true for hospitals during this reporting cycle. This raises the possibility of many hospitals choosing to sell their lab outreach programs during 2019 to avoid the need to report this PAMA data (and avoid the possibility of federal fines). If that happens, it will be disruptive to the clinical laboratory industry. TDR

Several Big Surprises in 2018's Top 10 Lab Stories

Actions by federal government, judges, payers require attention from every lab to stay compliant

CEO SUMMARY: This year's list of the Top 10 Lab Industry Stories for 2018 is dominated by new directives from Medicare and private health insurers, as well as significant decisions by federal courts. Collectively, these developments create new compliance risks for all clinical laboratories and anatomic pathology groups. What is more notable about these top 10 lab industry stories is that, during 2018, several long-standing lab business practices may now be illegal, based on one new federal law and several federal court decisions.

IN MORE THAN TWO DECADES of preparing THE DARK REPORT's list of the Top 10 Lab Industry Stories for the year, there has never been a list that was overwhelmingly dominated by government and private payer actions.

That changed in 2018. Of the 10 stories selected for this year's list, six stories involved one of three things:

1) Actions of the federal government;
2) Decisions in federal courts; and,
3) Tougher audits by private payers.

There is another major difference in the stories that make up this year's Top 10 list. To a greater degree than ever before, multiple stories on this list will directly create new audit, compliance, and legal risks—and a need to respond—for every clinical laboratory and anatomic pathology practice in the United States.

Two factors are among those used to identify the stories selected to make each year's list of the Top 10 lab industry stories. One factor is whether the story affects the larger proportion of clinical labs and anatomic pathology groups in this country.

A second factor is if the immediate the consequences of a story will require a response by a majority of labs. For example, in this year's story number one, CMS now defines hospitals using the CMS-1450 14x claim form for outreach lab test billing as applicable labs. These hospitals will be required to submit private payer price data as of Jan. 1, 2020. That is one way that story number one requires an immediate response by hospitals meeting this criteria.

By contrast, story number three, which describes how pharma and private equity companies want to acquire and hold pro-

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pietary diagnostic biomarkers that will be companion diagnostics for specific therapeutic drugs, is a development that will take a number of years to play out.

Lab executives and pathologists should assess each of these developments and craft an appropriate strategy and compliance policy to protect their lab from enforcement actions by the federal government and tougher audits by private health insurers.

One issue of concern to all clinical laboratories in the United States is how the **Centers for Medicare and Medicaid Services** uses the coming reporting period for private payer lab test prices to set the Medicare Part B Clinical Laboratory Fee Schedule for 2021, 2022, and 2023. This is why the **American Clinical Laboratory Association's** (ACLA) lawsuit against the **Department of Health and Human Services** is on this year's list at number five. However, it is unlikely that this lawsuit will produce a timely judgement in ACLA's favor, which addresses the critical flaws in how CMS is defining and implementing the requirements of the PAMA law.

Ramifications of Fraud

One interesting theme that emerged from compiling the 2018 list of the lab industry's Top 10 stories was the ramifications of fraud and abuse among certain sectors of the clinical lab industry. At least four stories are related in some way to the efforts of government and private payers to curb fraud and abuse.

The quick overview is tougher compliance requirements (Support Act and federal court rulings: stories one and eight); rigorous audits that use extrapolation and statistical sampling (story four), and more private payer lawsuits filed against hospitals and labs using pass-through billing schemes (story 9).

Most pathologists and lab administrators in hospital and health network labs are unaware of the extent of fraud and abuse, particularly in lab testing sectors, such as toxicology, pain management, and specialty testing, like cardiology. Both government and private payers have found themselves paying substantial amounts of money for medically-unnecessary testing, often billed at prices that are 10 times or more greater than the competitive price of any lab company that is an in-network provider for most major health plans.

Limited Tools, Resources

To stamp out this fraud, payers have limited tools and limited resources. Thus, it is much easier to implement restrictive coverage guidelines and slash reimbursement for the lab tests that are most often involved in fraud and abuse schemes. However, that punishes those long-established lab organizations that are diligent with compliance and truly deliver value to the physicians and patients they serve.

A comparison of the 2018 list of the lab industry's Top 10 stories to the 2017 list shows that the issues of compliance and fraud are not new developments. Several stories relating to payers' efforts to control fraud and excessive utilization of lab tests made the 2017 list.

In 2017, the FDA's decision to approve the first digital pathology system for use in primary diagnosis was number three on the list. *(See TDR, Dec. 11, 2017.)* However, 2018's list has no comparable example of new diagnostic technology. The closest example to a new technology advance is story number 6, how several pioneering health networks are first to use genetic tests in primary care settings.

Unfolding Industry Trends

When viewed collectively, THE DARK REPORT's list of the Top 10 Lab Industry Stories for 2018 reflects the current state of the profession. It is under stress. Some stress is from declining reimbursement for lab tests. Other stress comes from tough compliance requirements and audits. These are signs that the times will remain challenging for labs going forward. TDR

TOP TEN 2018 1

Labs, Pathology Groups Face More Challenges with Federal Compliance

As 2018 comes to an end, three serious new compliance threats confront the nation's clinical labs and anatomic pathology groups. All three emerged in the last quarter of the year.

The first threat is a federal judge's ruling on Sept. 21 that claims involving a lab's payment to physicians for packaging specimens, and the lab's waiver of patient co-pays and deductible, are violations of the federal Anti-Kickback Statute and could go forward to trial. *(See TDR, Oct. 1, 2018.)*

The second threat emerged on Oct. 24, when the President signed the "Support for Patients and Communities Act." This new law makes it illegal for providers—including labs—to pay commissions to sales reps for generating referrals from physicians. Lab industry lawyers were quick to point out that this law conflicts with the safe harbors in the federal anti-kickback law. It is uncertain whether any federal agency will issue guidance about conflicts between the two federal laws. *(See TDR, Dec. 3, 2018.)*

The third threat is the final rule for PAMA lab test reporting. Issued by Medicare officials on Nov. 2, the rule includes a requirement that hospitals using the CMS-1450 14x claim form to bill Medicare must submit their private payer lab test data to Medicare officials. Few hospitals have the information systems required to gather this data and may have to do it manually. Federal penalties are $10,000 per day for failure to submit data, or to submit inaccurate or incomplete data. *(See TDR, Nov.13, 2018.)*

TOP TEN 2018 2

UHC, Aetna, Horizon Sign Deals to Have Both Quest, LabCorp in Network

This year marked the end of a decade-long strategy by three of the nation's major health insurers to only include one national lab company in their respective networks.

For **UnitedHealthcare**, **Aetna**, and **Horizon BCBS of New Jersey**, it means that both **Laboratory Corporation of America** and **Quest Diagnostics** will be network providers for all three insurers, effective Jan. 1, 2019. *(See TDR, July 20, 2018.)*

For the past 10 years these three health insurers liked the strategy of including one national lab in their network and excluding the other. It is a significant development that all three, within a period of weeks, announced that they were ending that strategy so as to contract with both national lab firms.

Certainly competitive forces were one factor in this development. But regional labs and hospital lab outreach programs will be watching closely to see if the three health insurers decide to exclude more labs from their networks. In recent weeks, UnitedHealthcare began sending notices to regional labs that their network status with the insurer will not be renewed. *(See pages 11-13.)*

Another reason why these three health insurers restored both national lab companies to network status is likely to be access to lower prices for lab testing (compared to existing regional lab network providers) and the ability to get more complete and uniform sets of their benefiaries' lab test data from the two national lab companies.

TOP TEN 2018 3

Pharma, Private Equity Want Control of Diagnostic Technologies, Lab Tests

FOR DECADES, PATHOLOGISTS AND THEIR ALLIES generally controlled the development and ownership of new diagnostic technologies and laboratory tests. After all, they were closely involved in much of the research that identified and validated new biomarkers and assays.

That is no longer true. THE DARK REPORT was first to analyze and describe the emerging trend of pharmaceutical companies and private equity investors taking ownership of new diagnostic technologies and lab tests. *(See TDR, Mar. 26, 2018.)*

This is a development that has serious long-term strategic consequences for the entire clinical laboratory industry. For example, if a pharma company has the patents for the diagnostic biomarkers that go with its therapeutic drug, might be that pharma company license only one lab to perform those companion diagnostic tests? Or would that pharma company be willing to allow a larger number of labs to perform that companion diagnostic test?

Seen from this perspective, if pharma and private equity were to end up controlling most of the intellectual property and patients for valuable diagnostic markers, it may be that they choose to only license these technologies to the very largest lab organizations in the United States. Were that to happen, it would be another negative factor for regional and independent clinical laboratories. This trend involves a strategic shift in the market that will take years to gather momentum. That gives regional labs time to develop an effective response.

TOP TEN 2018 4

CMS, Private Insurers Expand Use of Audits with Extrapolation, Sampling

GOVERNMENT AND PRIVATE PAYERS INCREASED their use of extrapolation and statistical sampling as tools during audits of the nation's clinical labs and pathology groups. This is a major problem, for several reasons.

First, in recent years, at least three genetic testing companies went out of business following federal audits that used extrapolation and then hit each of these labs with substantial recoupment amounts of tens of millions of dollars. This shows the dangers to a lab when auditors sample a small number of lab test claims, then extrapolate those audit findings across a large proportion of the audited lab's total claims.

Second, attorneys with experience representing labs that challenged audits that used extrapolation and statistical sampling say these methods are frequently not done correctly by the payers' auditors. They recommend that clinical lab executives and pathologists retain experts who understand extrapolation and statistical sampling. These experts can help ensure that the auditors sent by payers correctly understand and apply these methods. *(See TDR, Sept. 10, 2018.)*

Attorneys also advise that use of extrapolation and statistical sampling is established for the Medicare and Medicaid programs. But that is not yet true when private payers use these methods.

TOP TEN 2018 5

Federal Judge Rules Against ACLA, ACLA Files Appeal in PAMA Case

ON DEC. 11 OF LAST YEAR, a lawsuit against the federal **Department of Health and Human Services** (HHS) was filed by the **American Clinical Laboratory Association** (ACLA).

The primary claim by ACLA was that HHS, and its **Centers for Medicare and Medicaid Services** (CMS), failed to comply with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA). In particular, ACLA claimed that CMS disregarded the requirement that CMS have all applicable laboratories report relevant market-rate data.

The clinical lab industry has much riding on this lawsuit. It has repeatedly pointed out to CMS and to members of Congress the many flaws in how CMS is interpreting and implementing PAMA requirements.

One criticism is how CMS defined "applicable laboratories," the term used in the PAMA statute. Less then 2,000 of the nation's tens of thousands of labs provided data in the first collection period.

However, on Sept. 21, the judge issued a ruling against ACLA. Judge Amy Berman Jackson wrote that ACLA's claims lacked "subject matter jurisdiction." But she also noted that the "plaintiff's arguments on the merits raise important questions." *(See TDRs, Jan. 22, and Oct. 1, 2018.)*

The next chapter in this unfolding story came on Dec. 4, when ACLA filed an appeal in its case against HHS. Attorneys representing ACLA believe that the federal court needs to review the merits of the plaintiff's arguments that were not addressed by Judge Jackson in her earlier ruling.

TOP TEN 2018 6

Important Steps for Genetic Testing to Be Used in Primary Care Settings

THIS IS THE FIRST YEAR that at least two nationally-respected health network officially made genetic testing part of their primary care offerings. It is a sentinel event in the acceptance and use of genetic testing by family practice physicians.

Of course, two health networks does not represent a broad trend. But it is an important development for every clinical lab and anatomic pathology group that wants to be an added-value contributor—and be paid for that added value.

This spring, **Geisinger Health** of Danville, Pa., announced it would begin offering DNA sequencing to patients as part of routine preventive care. Such genetic testing services would commence during the summer.

Also in the spring, **Sanford Health** of Sioux Falls, S.D., stated that its primary care clinics would offer patients a $49 genetic test panel. *(See TDR, July 9, 2018.)*

Geisinger's program is a pilot and will target 1,000 patients in this first phase. Exomes will be tested at a cost of about $500, but patients will not be charged. Funding will come from grants and Geisinger. Sanford's genetic test panel will include markers for 60 diseases and 30 prescription drugs. It is designed to be a practical test that generates clinically-actionable results.

TOP TEN 2018 7

New Examples of Laboratory Errors That Caused Significant Patient Harm

DURING 2018, systemic diagnostic errors were discovered at three locations. Two sites involved anatomic pathology errors and one site involved cytology errors.

In February, officials from the federal **Centers for Medicare and Medicaid Services** (CMS) inspected 885-bed **Wake Forest Bapitist Medical Center**. The inspectors identified serious deficiencies in histopathology and put the hospital on notice that its Medicare license was about to be revoked. Errors in breast cancer diagnoses by a former chair of pathology had cased severe harm to several patients. *(See TDR, Apr. 16, 2018.)*

In Ireland, starting in March, there were news stories about multiple women whose cervical cancer screening results were inaccurate or never reported to their physicians. Each of these women had learned that they had cervical cancer that was untreatable, even though they had undergone cervical cancer screening in earlier years. Named in the news coverage were **Quest Diagnostics** and **Sonic Healthcare**, the two labs contracted by the **Irish Health Service** to perform all cervical cancer screening tests for the nation. Source of the errors has not yet been reported publicly. *(See TDR, July 9, 2018.)*

Then, in early summer, a series of news stories reported on the discovery that the head of pathology at **Veterans Health Care System of the Ozarks** in Fayetteville, Ark., was believed to have misdiagnosed patients for several years. At least three patients died and 11 had serious consequences. The VA was reviewing 33,000 cases that this pathologist had handled. *(See TDR, Oct. 1, 2018.)*

TOP TEN 2018 8

HDL's Mallory, BlueWave, Lose Federal Case of Lab Fraud, Abuse

IF IT WAS JUSTICE LONG OVERDUE, it was justice, nonetheless. On Jan. 31, 2018, a jury in federal court found several principals of the once-high-flying **Health Diagnostic Laboratories, Inc.** (HDL), of Richmond, Va., to be guilty of violating the federal False Claims Act (FCA).

The jury found Tanya Mallory, the founder and former CEO of HDL, guilty of violating the FCA. Also found guilty of violating the FCA were Floyd Calhoun Dent III and Robert Bradford Johnson. Dent and Johnson had served as sales representatives for HDL while working for their company, **BlueWave Healthcare Consultants**, which was HDL's former marketing partner.

In the sentencing phase, the judge ordered the three individuals to pay a total of about $54 million. This included restitution and treble damages, as allowed under the FCA. A portion of this amount was associated with BlueWave's marketing of lab test services for **Singulex**, another specialty heart testing lab. *(See TDR, Feb. 12, 2018.)*

The outcome of this trial was welcomed by many clinical lab executives, pathologists, and their attorneys. It was evidence that when federal prosecutors press charges against those individuals who operate lab testing companies in violation of federal law, they can recover substantial recoupment and penalties.

TOP TEN 2018 9

Private Payers File More Lawsuits Against Tox Labs, Rural Hospitals

PASS-THROUGH BILLING SCHEMES were a common theme of the many lawsuits filed this year by different private health insurers against small hospitals and the lab testing companies that used the hospitals to bill for the toxicology and pharmacogenomic tests they performed.

During 2018, a growing number of health insurers filed lawsuits generally alleging fraud and overbilling in contractual arrangements where lab companies offering tox and PGx testing used agreements with community hospitals as a way to access the hospital's in-network contract status for submitting laboratory test claims to the payers.

THE DARK REPORT investigated one such scheme, based on the lawsuit that **UnitedHealthcare** (UHC) filed against **Next Health, LLC**, of Dallas. UHC claimed it had paid Next Health $100 million for what it said were fraudulent clinical laboratory test claims. *(See TDR, Jan. 22, 2018.)*

During the year, TDR reported on similar lawsuits claiming fraud from pass-through billing arrangements involving lab companies and community hospitals. The toxicology and PGx sector of clinical lab testing has seen widespread fraud and abuse in recent years. It seems that 2018 was finally the year when a number of health insurers were ready to take legal action against these entities. *(See TDRs, Mar. 5, May 7, and Aug. 30, 2018.)*

This widespread fraud has consequences. Payers often enact onerous coverage requirements to stamp out fraud, or enact deep cuts in reimbursement for CPT codes involved in these scams. That makes it tough on compliant labs.

TOP TEN 2018 10

Theranos Goes Out of Business, Former CEO Faces Criminal Charges

THIS WAS THE YEAR that federal officials piled on to the now-defunct **Theranos**, a lab testing company that was once the darling of Wall Street and the media.

On March 14, the federal **Securities and Exchange Commission** charged Theranos, ex-CEO Elizabeth Holmes, and ex-COO Ramesh "Sunny" Balwani with "massive fraud."

Next, on June 14, prosecutors from the federal **Department of Justice** announced criminal charges against Holmes and Balwani. Each faces two counts of conspiracy to commit wire fraud and nine counts of wire fraud.

In what was the final curtain for the company itself, on Sept. 5, David Taylor, the firm's CEO and General Counsel, announced that Theranos would be dissolved later that week and its remaining cash on hand of $5 million would be distributed to unsecured creditors. *(See TDRs, Mar. 26, Jun. 18, and Sept. 10, 2018.)*

All that remains is for federal regulators and prosecutors to pursue their respective cases against Holmes and Balwani. Meanwhile, there are two last acts for Theranos yet to come. First will be a documentary of Theranos that will be shown at the Aspen Film Festival in January. The second is a movie about Theranos and Holmes, titled "Bad Blood." The screen play is being written and production of the film will start when the script is ready. TDR

Pathology Update

UK's NHS to Build Five New Digital Path and Imaging Centers

Facing a shortage of histopathologists, NHS may want to use digital systems and AI to speed diagnoses

To shorten the time for cancer diagnoses, the United Kingdom's **National Health Service** (NHS) will open five new digital pathology and imaging centers that will use artificial intelligence. The digital pathology and imaging centers will open in Coventry, Glasgow, Leeds, London, and Oxford.

Last month, the UK government announced that it will invest £50 million ($68.9 million) in the five centers. The money comes from a fund that aims to bring together representatives from academia, the charitable sector, and industry. Those involved in the project say the goal is to transform digital diagnostics in healthcare to benefit patients by streamlining and modernizing these processes.

The UK is suffering through a severe shortage of anatomic pathologists (which in the UK are called histopathologists). The shortage delays cancer diagnoses. *iNews* reported that in July, the National Health Service recorded its worst cancer treatment waiting times when more than 3,000 people had been waiting more than two months to start treatment for cancer. NHS has set a target for 85% of patients to begin such treatment within 62 days of getting a referral from a general practitioner.

Few patients in the United States would tolerate such long wait times to learn their cancer diagnosis and start treatment.

It could be that the announcement last week to open five new digital pathology and imaging centers is one way to make the current number of pathologists more productive at diagnosing cancer cases. If so, then the government is betting that combining digital pathology technology with artificial intelligence can help reduce the backlog of cancer cases awaiting diagnoses.

For pathologists in the United States, this experiment in the use of technology is worth watching to see if the use of such technology does in fact improve the speed of diagnosis and increase pathologists' productivity without compromising accuracy.

Investing in Digital Pathology

In the U.S., *HealthITNews* reported that companies working with the **Northern Pathology Imaging Cooperative** in Leeds said that, in addition to the £50 million investment from the UK government, the cooperative would invest £7 million ($9.08 million) in the program. Dr. Darren Treanor, a pathologist with the **Leeds Teaching Hospitals NHS Trust**, is leading the initiative.

"This new northern cooperative will allow us to use digital pathology to help patients across the region, and provide a platform on which we will develop artificial intelligence tools for pathology diagnosis to be used around the world," Treanor said.

The UK investment in these five centers could be an example of government efforts to show UK citizens that the government is doing something to solve the problem of long delays for cancer diagnoses, even if these centers will not begin producing diagnoses for at least a year or more. TDR

—Joseph Burns

UHC Reportedly Cutting Ties with Regional Labs

In past month, UnitedHealthcare sent notices to exclude independent labs from its networks

CEO SUMMARY: By cutting out smaller, regional labs, UnitedHealthcare appears to want to shift an unknown percentage of its lab test volume to Quest Diagnostics Inc., which it recently restored to its national provider network. Clinical lab directors should be concerned about this development because UHC is the nation's largest health insurer and because other health insurers are likely to follow its lead. Another factor may be UHC's goal of getting more accurate and complete lab test data from national labs.

One of the nation's largest health insurers is taking steps to jettison smaller and regional laboratories from its network as it prepares to hand over a big part of its business to **Quest Diagnostics**, according to laboratory consultants.

In the past few months, **UnitedHealthcare** (UHC) has been putting its new partnership with Quest into place. On Jan. 1, 2019, Quest will become a preferred, in-network provider for approximately 49 million UHC members nationwide. **Laboratory Corporation of America** is already a national provider for UHC.

"We're fielding some concerned calls from regional, non-national laboratories indicating that their UnitedHealthcare contracts are being terminated," said Andrew Stimmler, Managing Partner of the **Shipwright Healthcare Group, LLC**, a lab consulting company in Greensboro, N.C.

"Some labs getting these termination letters have been in-network UHC providers for a decade or longer," added Shipwright Managing Partner Steve Stonecypher.

Asked to comment, UnitedHealthcare said it was preparing a response to questions The Dark Report sent. As of press time, the health insurer had not yet responded.

Labs should be concerned about this development for two reasons, Stimmler and Stonecypher commented. First, with almost 49 million members, UHC is the largest health insurer in the United States, and second, other health insurers could follow suit.

Aetna Culled Labs in Past Years

Years ago, **Aetna** underwent a similar culling of in-network labs and may do so again given that it has a new contract it signed with LabCorp earlier this year. Both new lab contracts (Quest with UnitedHealthcare and LabCorp with Aetna) will be effective Jan. 1.

In 2007, both Quest and LabCorp locked up exclusive deals with the health insurers when LabCorp partnered with UHC and Quest joined forces with Aetna.

Since then, smaller, regional laboratories and some hospital lab outreach programs have filled the gaps in UHC's network, particularly in geographic areas where LabCorp and Quest were not present. But now UHC appears to be moving its business toward the two largest lab companies, Stimmler and Stonecypher said.

"These moves potentially signal the first fallout of the pending addition of Quest Diagnostics to the UHC's network," Stimmler explained. "For labs that are losing these contracts—some of which have been in place for longer than 10 years—UHC is citing the need 'to adapt to the ever-changing healthcare environment' as the reason for terminations."

Changes at Aetna, UHC

In May, Quest announced that it will lose its exclusive contract with Aetna but will become a preferred provider for UHC. At the time, LabCorp also announced that its 10-year-old exclusive lab testing agreement with UHC was ending and that it would be an in-network provider for Aetna.

When it announced the new deals, UHC said its lab services contracts "will include a broad range of value-based programs" and that it will use lab test data "to drive more personalized care support."

"One obstacle for smaller and regional labs is that many cannot provide the data health insurers may soon demand in their efforts to succeed under value-based contracts," explained Stimmler. "But LabCorp and Quest can deliver consistent volumes of data to payers.

"UnitedHealthcare has an increasing appetite for lab test data in part because it has a subsidiary—**Optum Healthcare**," he added. "Optum is a health information technology company that specializes in using data to manage costs and quality associated with certain disease states. This need for data is one reason UnitedHealthcare wants accurate and complete sets of lab test results on all of its beneficiaries."

Stonecypher agreed, saying another reason UHC may be cutting labs from its network is the need to contain costs and promote quality initiatives. "These decisions are not about any one lab's capabilities as much as they are about the volume that these two large lab companies bring to the table," he explained.

"Consider the New York City area, for example," he added. "If you're UnitedHealthcare, do you want data from 30 different labs in 30 different formats? Or do you want most, if not all, of that data coming from larger labs, who can deliver everything you need in the correct format?"

The decisions to cut certain labs could be an early signal that more changes will result from UnitedHealthcare contracting with both national labs for the first time in 11 years. "This may be the first round under the new contracts," he commented. "And it shows that all—or at least most—of the lab work is being promoted to the bigger labs.

Standardized, Complete Data

"From LabCorp and Quest, payers get large quantities of data in single files," Stonecypher added. "Typically, smaller labs have trouble providing the data payers need in the normalized way that large health plans want.

"The smaller labs have trouble matching what LabCorp and Quest provide because labs and other healthcare providers are big data companies," he commented. "That's essentially what labs are, data companies that do lab testing."

"Quest and LabCorp will have massive amounts of useful lab test utilization data that will be of great value to UHC versus the somewhat limited and disparate information that regional labs might offer," observed Stimmler. "That data proposition makes Quest and LabCorp far more attractive as network labs to larger health insurers than most regional labs, regard-

less of how long they've been in business or how many years they have worked with UHC."

Earlier this year, Quest Diagnostics and LabCorp characterized the new deals with UHC and Aetna as being about delivering value-based care, which for insurers means low costs, high customer service, and reams of data to help the insurers fill gaps in care.

Horizon Includes National Labs

Not only did UnitedHealthcare and Aetna announce that they had entered into agreements with both LabCorp and Quest to be providers in their respective networks, but just weeks later, **Horizon Blue Cross Blue Shield of New Jersey** issued a press release stating that its network would now include LabCorp and Quest Diagnostics. *(See TDR, July 20, 2018.)*

The fact that all three major health insurers—after excluding one of the national labs from their respective networks for more than a decade—took steps to restore that lab as a network provider is significant. As Stimmler and Stonecypher noted, two obvious reasons may have motivated these actions.

One is the benefit from the lower test prices that the restored national lab offers, compared to regional labs. Second is the benefit of getting regular feeds of utilization data and lab test results that are more complete and more uniform than what these health insurers get from regional labs.

But another reason behind these decisions to include both national lab companies to their provider panels may be the growing use of value-based payments to other providers. Payers may see that the national labs are better positioned to support physicians that have value-based payment arrangements **TDR**

—Joseph Burns

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Do Non-Network Labs Have Alternatives?

WHEN A HEALTH PLAN CUTS LABS FROM ITS NETWORK, there are steps the labs can take. "But it is best that labs prepare before a payer makes such a move," said Steve Stonecypher of the lab consulting firm Shipwright Health Group.

"It is a smart strategy to identify the advantages your lab brings to a health plan," he advised. "Your lab needs some significant factor in its favor—something besides geography.

"Does your lab do something different to control costs, for example? If so, then highlight that," he continued. "Does your lab have a big specialty group or a large health system under contract? If so, that would be important to mention to payers.

"Does your lab have key clinical opinion leaders on your side?" he asked. "If so, bring them into the discussion or have them at least write letters to the health insurer on your behalf.

"It is essential to have already prepared an analysis of the strengths and weaknesses in your market," noted Stonecypher. "This should be updated on an ongoing basis because UnitedHealthcare is not the only health plan that will look to eliminate high-cost labs, even if they do good work."

Shipwright's Andrew Stimmler agreed. "It's a good idea to be pre-emptive with all of your lab customers. What are your pathologists doing to help reduce costs, for example, both within the lab and with referring physicians? What is your lab doing to support value-based care contracts? How does the role you play in your community or geography make you distinct or unrivaled?

"Your lab should consider your singular or unusual value proposition because LabCorp and Quest have largely complete service footprints nationwide and are more cost competitive than most smaller regional labs," concluded Stimmler.

Boyce & Bynum Sells to Quest Diagnostics

Reasons for the sale include Medicare fee cuts, less private payer reimbursement, more competition

CEO SUMMARY: With the year end approaching, lab buyers and sellers are working to finalize deals that may have been in discussion for months. The first big lab acquisition for this season came on Nov. 27, when Quest Diagnostics announced it was acquiring Boyce and Bynum Pathology Laboratories of Columbia, Mo. The pathologists will keep their private group practice and separately sold the Boyce and Bynum long-term care business to Gamma Healthcare of Poplar Bluff, Mo.

ONCE AGAIN, THE END OF THE CALENDAR YEAR is a time when acquisitions become common. The first big acquisition announced this season was Quest Diagnostics' purchase of **Boyce and Bynum Pathology Laboratories** (BBPL) in Columbia, Mo.

Announced on Nov. 27, specific terms of the sale were not disclosed. Founded in 1965, BBPL has been the major independent clinical laboratory company in central Missouri. Quest has a large regional laboratory facility in St. Louis, about two hours away from Boyce and Bynum in Columbia, Mo. Thus, it is probable that much of BBPL's lab testing will be shifted to that and other Quest lab sites and the facilities in Columbia will be downsized.

Core Lab in Columbia, Mo.

BBPL employs 20 board-certified pathologists and more than 350 medical, technical, and support staff. The clinical lab company does 95% of its testing in its core lab facility in Columbia and has 21 patient service centers in Missouri, Arkansas, and Oklahoma.

In the press release describing the transaction, it was stated that Quest was not purchasing Boyce and Bynum's anatomic pathology division (**Boyce and Bynum Pathology Professional Services**), nor its long-term care (LTC) division, which serves hundreds of nursing homes and similar facilities.

Pathologists Keep the Group

It is common for the pathologists who own an independent clinical laboratory company to keep their professional group practice when selling the lab. Also, the fact that Quest did not want the long-term care business is consistent with the actions of the two national lab companies since the mid-1990s.

The two billion-dollar lab companies do not want long-term care clients because of two factors: the costs of serving nursing homes are substantial, and many nursing homes are located in smaller communities or rural areas, which further adds to the expense for a lab to service them.

Thus, the interesting side note to the sale of Boyce and Bynum to Quest is the fact that, about one week prior to this sales agreement, BBPL sold its long-term care business to **Gamma Healthcare**. At

the time of this sale, BBPL was serving about 500 nursing homes and other long-term care facilities. Gamma Healthcare, in Poplar Bluff, Mo., says it is a provider of laboratory and radiology services for long-term care facilities in the Midwest.

BBPL has pathologists on staff at 26 hospitals and clinics, although that part of the business will not go to Quest. Instead, those pathologists will remain in their positions, according to sources familiar with the deal Quest made.

Why a successful independent lab company would sell out to a large lab company after having annual growth rates of 10% to 20% in recent years is a cautionary tale for all clinical laboratories. Sources told THE DARK REPORT that the lab lost approximately $1 million in profit in its long-term care division this year due to changes Congress and the federal **Department of Health and Human Services** (HHS) made to Medicare Part B clinical laboratory fees under the Protecting Access to Medicare Act (PAMA).

PAMA Fee Cuts a Factor

Under PAMA, HHS cut what it pays labs for clinical lab testing by 10% from what it paid for those same tests in 2016. Further, BBPL anticipated similar reductions from Medicare lab price cuts in 2019, given the lack of interest at the federal legislative level to address the flawed implementation of PAMA data collection and pricing analysis.

In addition to the financial impact of PAMA to its LTC division, BBPL saw several larger commercial payers seek similar reimbursement reductions as often happens when private health insurers tie their reimbursement to Medicare reimbursement schedules. The state of Missouri further sought a 30% reduction in Medicaid lab reimbursement without input from the laboratory community.

THE DARK REPORT has been told that one factor in the decision to sell to Quest was that Quest was interested in bolstering its pathology resources in this region. One source said she believed that Boyce and Bynum Pathology will be the exclusive providers for Quest in the Missouri area and in the surrounding states.

She added that Quest's **AmeriPath** pathology group in Greater Kansas City recently "imploded." THE DARK REPORT has not yet verified that statement.

UnitedHealth Contract

Also mentioned was the opportunity that Quest may have because it is again a network provider for **UnitedHealthcare**.

"In Missouri, the fact that Quest will be in-network with UnitedHealthcare could benefit BBPL's clinical lab business directly, especially if Quest takes business away from LabCorp," sources said. "If Quest scoops up much of the UnitedHealthcare business that has been going to **Laboratory Corporation of America**, the pathologists at Boyce and Bynum Pathology Professional Services (BBPPL) would get a substantial increase in tissue volume.

"Plus, in Missouri, Quest has 45 sales people where BBPL has a limited sales force. Quest will be able to saturate the market a bit better than BBPL has done simply because Quest has a much larger sales force," sources added. For all these reasons, the pathologist-owners of BBPL decided to focus their efforts on professional services, which means that in some ways they are returning to their roots, sources concluded.

Clinical Trials Business

"In addition, BBPPL has built a relatively strong clinical trials book of business that it can continue to use to boost its revenue," said one source.

"And now the pathologists at BBPPL will no longer need to worry about all the day-to-day problems associated with running a clinical laboratory in these challenging times." TDR

—Joseph Burns

Sonic to Pay $540 Million to Buy Aurora Diagnostics

➤Australian lab company plans to integrate anatomic pathology with clinical pathology

➤➤CEO SUMMARY: Sonic Healthcare, Ltd., announced that it would pay $540 million—a multiple of 9.2 times EBITDA—to acquire Aurora Diagnostics, the anatomic pathology company based in Palm Beach Gardens, Fla. Sonic will gain 32 pathology practice sites and add 220 pathologists to its network of regional clinical and pathology laboratories. The transaction marks the end of a pathology company that struggled to achieve sustained financial success.

In yet another year-end transaction this month, Australia's **Sonic Healthcare Ltd.** of Sydney, Australia, agreed to buy all of **Aurora Diagnostics LLC**, of Palm Beach Gardens, Fla., for $540 million.

In an announcement Dec. 12, Sonic said it expects to complete the deal next year, pending antitrust and other reviews. It will mark the end of the independent life of Aurora Diagnostics, a company founded in 2006 to acquire and manage anatomic pathology group practices. Aurora says it has 220 pathologists in 32 practices located nationwide.

➤Struggling Pathology Firm

Since its inception, Aurora Diagnostics has struggled to find an effective, profitable business model. Observers noted that it often paid premium prices to acquire private practice pathology groups. Because many of these groups were serving community hospitals, it was difficult to generate the successive year-over-year increases in specimen volume and revenue that would satisfy investors.

For this reason, each time Aurora's private equity owners attempted to sell the company over the past 10 years, there was little interest among potential buyers.

Despite this history, the soon-to-be-new owners of Aurora Diagnostics are excited about this transaction. Sonic Healthcare considers this an opportunity to combine anatomic pathology services with its existing clinical laboratory capabilities in ways that will benefit its clients.

"We see a convergence of anatomic pathology (AP) and clinical pathology (CP)—including molecular and genetics—here in the United States," stated Jerry Hussong, MD, Sonic's Chief Medical Officer, who as of Jan. 1 will become the CEO of **Sonic Healthcare USA**.

"We think pathologists have great value as members of the healthcare delivery team," Hussong said in a written response to questions from The Dark Report. "Within Australia, Sonic Healthcare holds the number one market position in both AP and CP. It operates with anatomic and clinical pathologists residing in the same laboratories and practicing together.

"In a similar way, we believe the acquisition of Aurora Diagnostics will allow us to integrate the AP and CP markets and build upon these synergies within the United States," he said. "Sonic does not plan to close any of the practices Aurora operates."

If this synergy is successful, then the two companies might be a better fit than if another lab, or an investment company, acquired Aurora. That's because any other acquiring company might struggle to get a return on its investment given Aurora's recent financial problems.

Losses in Recent Years

Last year, for example, Aurora reported that in 2016 it had a net loss of $29 million on revenue of $284 million. When added to the losses the company incurred since 2012, Aurora lost a total of $401 million over five years. This included net losses of $83 million in 2015, $55 million in 2014, $73 million in 2013, and $161 million in 2012. *(See, "Aurora Diagnostics Acquires Pathology Groups, Posts Loss," TDR, April 17, 2017).* These amounts were impacted by significant interest expense on debt and intangible asset impairments related to years of extensive acquisition activity, Sonic said in its written response.

Acquisitions Last Year

Despite these losses, Aurora continued to acquire pathology groups. Last year it acquired five pathology practices:

- **University Pathologists** in Warwick, R.I.;
- **Pathology Associates of Princeton** in Plainsboro Township, N.J.;
- **Cleveland Skin Pathology Laboratory, Inc.**, in Cleveland;
- **CytoPath** in Alabaster, Ala.; and,
- **CBM Pathology** in Gaithersburg, Md.

Earlier this year, Aurora acquired **Cascade Pathology Services** in Portland, Ore.

From 2014 to 2016 Aurora's acquisitions helped the company increase its net revenue from $242.6 million to $284.0 million, an increase of 17%, according to Randy Durig who wrote about Aurora for for the stock site, *Seeking Alpha*.

For pathologists and lab executives watching the valuation of clinical and pathology laboratories, the Sonic–Aurora Diagnostics transaction provides an interesting insight about the current state of the laboratory marketplace. In its announcement about the deal, Sonic said

Sonic's CMO Lays Out Benefits of Acquisition

IN AN EMAIL TO THE DARK REPORT, Sonic Healthcare USA's Chief Medical Officer Jerry W. Hussong, MD, explained that Sonic's acquisition of Aurora Diagnostics will allow Sonic to add some 200 pathologists to its current team of pathologists. Sonic Healthcare USA has pathologists operating at CBLPath in Rye Brook, N.Y., at Sunrise Medical Laboratories on Long Island, and at Clinical Laboratories of Hawaii, in Honolulu, Hussong said.

"We see pathologists as natural leaders in the laboratory space—as laboratory directors and team builders—in addition to their professional roles in AP and CP," he said. "They will become integrally involved with our lab operations and businesses. This will enable us to 'keep our business medical,' as has been done so successfully by Sonic Healthcare in Australia, Germany, Switzerland, and the United Kingdom.

"As one part of our overall strategy, Sonic will continue to partner, as appropriate, with hospitals and health systems," Hussong added. "These partnerships will be enhanced by our pathologists and strengthen us as a laboratory company. We do not have any plans to consolidate or close practices; this is not the reason for our acquisition of Aurora."

that Aurora had revenue of about $310 million for the fiscal year that ended on Sept. 30, and of that amount, $59 million was earnings before interest, taxes, depreciation, and amortization (EBITDA).

It also said that the $540 million that it would spend on Aurora represented a multiple of 9.2 times EBITDA. After one year, Sonic said it expects its return on invested capital (ROIC) in Aurora would be in the range of 9% to 10%. Any return in this range would exceed that of Sonic's fiscal 2018 group ROIC, the company said.

More Lab Acquisitions?

Also, Sonic expects to retain capacity for other acquisitions, in part by raising $600 million in Australian dollars (or $427.3 million in U.S. dollars) in what it called a fully underwritten institutional placement and by raising $100 million Australian ($71.2 million in U.S. dollars) through a non-underwritten share purchase plan to retail shareholders in Australia and New Zealand.

So why would Sonic, a company that operates clinical laboratories in the United States, be willing to invest in a large anatomic pathology company? Hussong explained that Sonic recognizes the value of comprehensive care delivery that spans a range of diagnostic services including AP, CP, and molecular genetics in the era of precision medicine and value-based care.

"As a medically-led company, Sonic Healthcare is excited about the signing of a binding agreement to acquire Aurora Diagnostics," he wrote in the e-mail. "This acquisition will allow us to build upon our medical leadership model. By medical leadership, we mean leadership that keenly has a deep understanding of physicians and the healthcare profession."

Hussong is referring to the fact that Sonic Healthcare's CEO is Colin Goldschmidt, MD, a pathologist. It is the only billion-dollar lab company operating in the United States that has a board-certified pathologist as CEO.

Some may speculate that Sonic was willing to pay a strong price to acquire one of the nation's largest independent antomic pathology companies because it believes that the location and hospital affiliations of Aurora's pathology practices complement the regions and scope where Sonic has coverage with its existing clinical laboratory facilities.

Economies of scale also have a role in Sonic's strategic planning. Toward that end, Sonic said it expects to use Aurora Diagnostics to transform its operations in the United States, saying, Aurora "adds significant scale" to the company's existing AP practices, which operate as **CBLPath** in Rye Brook, N.Y., **Sunrise Medical Laboratories** on Long Island, and **Clinical Laboratories of Hawaii** in Honolulu.

The price Sonic Healthcare will pay to acquire Aurora Diagnostics does bring it a substantial volume of anatomic pathology work. Sonic Healthcare USA said that Aurora's pathologists process about 2.5 million accessions each year.

Those specimens come from more about 23,000 referring physicians. These pathology groups hold contracts with more than 100 hospitals and health networks nationwide.

Molecular Testing Center

One asset that may have been attractive to Sonic is the molecular testing center that Aurora Diagnostics developed and operates in Jacksonville, Fla.

Another aspect of this acquisition also is notable. Aurora Diagnostics is a sizeable lab company that *was not* acquired by either **Quest Diagnostics** or **Laboratory Corporation of America**. That may be evidence that Sonic believes there are substantial synergies it can harvest from buying Aurora Diagnostics. **TDR**

—Joseph Burns

Contact Jerry Hussong, MD, at jhussong@sonichealthcareusa.com or 512-439-1600.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathologists at the **Houston Methodist health system** created a website that tracks confirmed flu cases in real time. It is located at: *https://flu.houstonmethodist.org* and uses epidemiology data from the eight hospitals in the health system. The system updates every morning by polling the previous day's data in the laboratory information system. Wesley Long, MD, an Assistant Professor of Pathology and Genomic Medicine at the **Houston Methodist Research Institute**, told *Health Data Management* that one primary goal of the system during a flu epidemic was to provide physicians with access to accurate regional laboratory observation data to help them develop a diagnostic and therapeutic strategy for their patients.

MORE ON: *Flu Tracking Website*

The Houston Methodist pathologists used an open-source library called Chart.is framework to plot the data into HTML5-based JavaScript charts for web applications. They initiated the project during the 2017 flu season, at a time when the Houston Metro was experiencing a steep rise in flu cases. This flu-tracking website demonstrates how it is feasible for clinical laboratories to extract information from their laboratory information systems and present it to clinicans and others in different and useful forms.

MOMENTUM TO FIX DIAGNOSTIC ERRORS

Earlier this fall, **ACT for Better Diagnosis** was formed as a coalition of 41 major health systems. It is participating with the **Society to Improve Diagnosis in Medicine**. The shared goal is twofold. First is to identify the main sources of diagnostic errors. Second is to develop solutions to reduce and eliminate those diagnostic errors. Paul Epner, formerly of **Abbott Laboratories**, is the CEO of the Society. Epner points out that research indicates that errors in diagnosis are involved in about 10% of patient deaths and between 6% and 17% of adverse events in hospitals.

TRANSITIONS

• **Glympse Bio** of Cambridge, Mass., appointed Stanley Lapidus as its Chairman. Lapidus was the founding CEO of **Exact Sciences**, **Helicos**, and **SynapDx Neogenomics, Inc.**,

• **PerkinElmer** named Prahlad Singh, PhD, as President and COO. He had been President of Diagnostics at PerkinElmer and previously held positions at **GE Healthcare**, **Philips Healthcare**, **Bristol-Meyers Squibb**, and **DuPont Pharmaceuticals**.

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