Volume XXI, Number 17 Monday, December 15, 2014

In this issue!
See page 3.

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Preparing the Next Generation of Lab Leaders

ACROSS THE LAB TESTING INDUSTRY, individual labs are caught in a serious conundrum. On one one hand, the ongoing transformation of healthcare and the erosion of lab test revenues are putting the financial squeeze on a large number of clinical labs and pathology groups.

On the other hand, at the very moment this is happening, the baby boomers who lead a large proportion of the nation's labs are preparing to retire. Just when capable leadership is most needed, the senior generation of lab leaders is on their way out and, due to a lack of effective succession planning, there is often no capable "up and comer" within the lab who has the sophisticated leadership skills necessary to guide the lab organization through these financially-challenging times.

This fact is confirmed from the many conversations we have with executives from billion-dollar *in vitro* diagnostic companies and lab informatics firms. In their dealings with their lab customers, they frequently observe both the absence of a succession plan and the lack of mature managers who are ready to step into key leadership roles.

If this rings true at your lab, I have good news. The team at THE DARK REPORT is preparing to put executive leadership development front and center at its 20th Anniversary edition of the *Executive War College on Lab and Pathology Management*. The conference will take place on May 5-6, 2015, in New Orleans.

One big highlight will be a session where the "U.S. Army War College meets the Executive War College." Keynote speaker Colonel Jeffrey D. McCausland (retired) is a former Dean of Academics at the Army War College and has spent his career developing leaders in both the military and in business. His presentation will describe the top 10 leadership lessons essential to boost your lab to peak performance (while also helping your professional career).

Another event of interest to pathologists and lab managers motivated to develop their leadership skills will be a one-day executive leadership workshop conducted on May 7, by Col. McCausland and his team. Attendees will learn the four dimensions of leaders, how to change the organization and its culture, and how to lead in crisis or times of high stress. This is an exceptional learning opportunity and lab administrators would do well to send their best and brightest managers to this year's *Executive War College* to attend these sessions. TDR

PAMA, LDTs and Theranos Top 2014's Biggest News

Lab industry's Top Ten Stories for this year reflect broader transformation of healthcare system

CEO SUMMARY: Not in recent memory has a single calendar year brought such a cascade of news stories that have the potential to affect nearly every clinical lab and pathology group in the United States. Blame it on the lack of money to fund healthcare and how it is motivating government and private payers to find effective ways to reduce what is spent on lab tests through price cuts and constraints on utilization. The biggest lab stories of 2014 will cause financial pain for labs for several years to come.

FROM SEVERAL DIRECTIONS, the status quo laboratory in medicine is threatened by this year's events. THE DARK REPORT'S Top Ten Lab Stories of 2014 reflect major developments that will directly touch every clinical lab and pathology group practice in the nation.

The prime example is passage of the "Protecting Access to Medicare Act" (PAMA) on April 1. Enactment of this new law tops our list of 2014's most important news stories.

Congress not only used the law to extend the SGR fix for 12 more months, but it included language in the bill that revises or reforms six different elements of the lab testing marketplace and how Medicare officials are to address these matters. *(See story 1 on page 5.)*

What quickly caught the attention of pathologists and lab administrators who looked at the language of the new law is the section that requires "applicable laboratories" to report the prices paid by each health insurer and the test volumes for each type of laboratory test. This reporting requirement will commence in 2016.

PAMA's language requires the **Centers for Medicare & Medicaid Services** to use this market data to determine the weighted median prices for tests on the Medicare Part B Clinical Laboratory Fee Schedule. These weighted medians will be the Medicare rates that are effective beginning January 1, 2017.

Critics of this section of the new law point out that there is probably not one laboratory organization in the United

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

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

States today that could assemble that information from its existing laboratory information systems. Yet, the law specifies heavy fines for any laboratory that fails to meet this requirement.

FDA to Regulate LDTs

Another major story with equal potential to engage nearly every lab operating in the United States today involves the plans by the **Food and Drug Administration** to regulate laboratory-developed tests (LDTs). The federal agency has issued draft guidance for LDT regulation and the public comment period is open until February 2, 2015.

Several national lab associations have expressed strong objections to the FDA's move to regulate LDTs. In particular, some experts believe that the FDA does not have the statutory authority to regulate LDTs in the manner it proposes. There are signs that at least one lab industry group may be ready to file a lawsuit in federal court to challenge the FDA's actions. *(See story 2 on page 5.)*

Theranos, the lab testing company based in Palo Alto, California, is the number three story on our top ten list for 2014. It claims to be have developed unique diagnostic technology which allows it to perform most common lab tests on small specimens (collected with a fingertip needlestick) and report the results in just four hours at a price to patients that is 50% of Medicare Part B lab test fees.

Theranos Is Secretive Firm

The highly-secretive lab company has an agreement with Walgreens, the national pharmacy chain, to use its stores as specimen collection sites. Currently one Walgreens store in Palo Alto and about 30 stores in Phoenix, Arizona, offer Theranos testing. Although it has just entered the clinical testing market, the company has said it is worth $9 billion, based on the $400 million of private equity money put into the company through last June. *(See story 3 on page 6.)*

Several of the other stories on our top ten lab industry stories for 2014 center on actions by health insurers and government health plans to reduce the money they pay for lab testing services. Most labs felt the pinch during 2014, as they got less money per accession and it took longer to receive payment from health insurers. *(See story 4 on page 6 and story 7 on page 8.)*

It has not gone unnoticed during 2014 that the nation's largest lab companies have become more effective at working with major health insurance companies to craft managed care contracts that favor them and disadvantage the labs that compete with them.

One tactic bigger labs used more frequently during 2014 was to encourage health insurers to exclude competing labs from their networks in exchange for better pricing terms on lab testing services by the labs that win the contract. *(See stories 5 and 6 on page 7.)*

Cost-Cutting Is Big Story

Given the financial pressure from declining lab test reimbursement and restricted access to patients due to narrow networks that exclude many local labs, it should not be a surprise that one of the big stories of 2014 is the priority labs are making of controlling their costs and developing new ways to deliver more value. *(See story 7 on page 8.)*

Similarly, the larger number of private pathology group practices that lost their independence in 2014 (through acquisition, merger, or conversion to employees of hospitals) is one of the year's big stories. This is the overdue consolidation of pathology groups in the 2010s that did not happen in the 1990s, when HMO contracting practices motivated most medical specialties to undergo regional consolidation. *(See story 8 on page 8.)*

Collectively, this year's top ten lab industry stories demonstrate the powerful market forces that are transforming healthcare, while also exerting strong pressure on the lab industry. TDR

TOP TEN OF 2014 >>STORY no. 1

SGR Fix by Congress Spawns PAMA; Lab Industry Wary of Law's Impact

ON APRIL 1, PRESIDENT BARACK OBAMA signed into law the Protecting Access to Medicare Act of 2014 (PAMA). As written, it has the potential to be the most impactful federal legislation on the clinical lab industry since passage of the CLIA 1988 bill.

Congress used the law not only to extend the Medicare Sustainable Growth Rate funding for an additional 12 months, but also to address a number of healthcare issues. Included in the bill were at least six specific items that directly affect the clinical laboratory industry. *(See TDR, April 7, 2014.)*

Several of these lab industry fixes are viewed as positive. They define how the **Centers for Medicare & Medicaid Services** is to establish coverage guidelines and reimbursement for certain types of new lab tests, for example. This is expected to benefit labs that perform complex or esoteric single-source tests.

What concerns the lab industry are sections of the new law that direct CMS to gather market data on lab test prices starting in 2016 from "applicable labs." CMS is to use this market data to establish lab test prices starting in 2017. The language of PAMA allows CMS to cut the price of a single lab test by no more than 10% in 2017, 2018, and 2019 and by no more than 15% in 2020, 2021, and 2022 (a potential cumulative price reduction of as much as 75% during those six years).

CMS is expected to use this authority to cut the prices of high volume clinical laboratory tests aggressively during those years.

TOP TEN OF 2014 >>STORY no. 2

FDA Issues Proposed LDT Regulations, Creating Plenty of Lab Industry Angst

IT'S BEEN YEARS IN THE MAKING and now regulation of laboratory-developed tests (LDTs) by the **Food and Drug Administration** is imminent.

After notifying Congress of its intent to regulate on July 31, the FDA issued draft guidance for LDTs on October 30. This started a 120-day public comment period which ends on February 2, 2015. *(See TDR, November 3, 2014.)*

The FDA says that it will stratify LDTs into the categories of Class III-highest risk; Class II-medium risk; and, Class I-lowest risk. All laboratories will need to self-report their LDTs to the FDA, then report adverse events associated with clinical use of these LDTs.

This development is meeting with widespread resistance by the clinical lab industry. For example, the **Association for Molecular Pathology** has stated that it considers FDA regulation of LDTs to be potentially "overly burdensome" and it points out that labs in the United States are already regulated by CLIA, as well as the "rigorous state, federal, and professional standards." *(See TDR, August 11, 2014.)*

One sign of the coming fight over this issue emerged on November 14. That is when the **American Clinical Lab Association** announced its retention of noted attorneys Paul D. Clement (a former Solicitor General) and Laurence H. Tribe (Professor of Constitutional Law at **Harvard University**) to advise it in its opposition to the FDA's proposed LDT guidance.

TOP TEN OF 2014 ➤➤STORY no.3

Theranos Ramps Up Clinical Testing, Has Many Skeptics in Lab Industry

MANY PATHOLOGISTS and clinical lab executives consider **Theranos**—the clinical lab testing company based in Palo Alto, California—to be the proverbial "riddle wrapped in an enigma."

Little is known about the diagnostic technology the company claims to have developed. Yet Theranos says it can deliver accurate lab test results in four hours, using a finger stick collection, just 3,000 to 5,000 microliters of specimen, and do all of this at a price that is 50% of Medicare Part B clinical lab test fees.

During the fall of 2013 and the winter of 2014, Theranos has worked with **Walgreens**, the national pharmacy chain, to put collection centers into Walgreens stores in Palo Alto, California and Phoenix, Arizona. *(See TDR, August 11, 2014.)*

In a carefully orchestrated public relations campaign, Theranos has achieved a high profile in the business press and captured the attention of pathologists and laboratory professionals everywhere. However, to date, it is believed that no individual formally trained in pathology and laboratory science and employed by Theranos has spoken publicly about the technology the company uses to perform its testing in support of clinical care.

At the end of 2014, it can be said that Theranos is viewed skeptically by a large number of experienced lab professionals. Thus, one challenge facing Theranos is to win over these skeptics.

TOP TEN OF 2014 ➤➤STORY no.4

Health Insurers Take Big Bites From Clinical Lab & Pathology Revenue

CHALK UP 2014 AS THE YEAR that both government and private payers stepped up their efforts to reduce the amount of money they pay for clinical lab testing and anatomic pathology services.

Across the nation, labs are experiencing both a decline in the amount of money they are paid for lab tests, as well as increased delays in these payments. Companies that provide coding, billing, and collection services to labs tell THE DARK REPORT that reductions in the prices paid for lab tests are a primary reason why labs are seeing a reduction in their average revenue per requisition. *(See TDR, September 2, 2014.)*

Within the Medicare program, the Medicare Administrative Contractors (MACs) remain stingy in the amounts they will pay for many molecular tests, particularly those coded with the 114 new molecular CPT codes that took effect in 2013. Another source of reduced revenue is attributed to the new bundling rules under the hospital outpatient prospective payment system.

Private payers are showing much more creativity in the approaches they use to reduce the amount of money they pay for lab tests. In some cases, they arbitrarily cut the fees for lab tests. In other cases, payers are crafting health insurance policies that require patients to pay hefty deductibles (or even the entire cost of the test) if the test is performed by an out-of-network laboratory.

TOP TEN OF 2014 >>STORY no.5

Big Labs Exclude Competing Labs From Managed Care Contracts

IN THEIR RESPECTIVE STRUGGLES TO GAIN bigger market share of the office-based physicians market for clinical laboratory testing, the nation's two biggest lab companies increasingly seek to exclude competing labs from health insurers' provider networks.

What is significant about this development is that, compared to recent years, 2014 saw more examples of the national labs not just working to exclude each other from a managed care contract, but also insisting that the health insurer exclude other local labs from the network as one term in the contract.

Across the nation, a number of independent labs and hospital lab outreach programs report that they are being excluded from payer contracts. With growing frequency, these network exclusions are coming at the time when one of the national lab companies is renewing its contract with the health insurer. *(See TDR, September 2, 2014.)*

One example involves the changes made in recent years to the Blue Card policies of the **Blue Cross Blue Shield Association** that exclude nearly all smaller labs as providers. This is widely considered to be due to the contracting strategies of the national labs.

This year, in Florida, a national health insurer implemented a program that effectively excludes one of the two national labs and nearly all clinical labs and pathology groups that provide testing services in the Sunshine State. *(See next Top Ten Story Six.)*

TOP TEN OF 2014 >>STORY no.6

UnitedHealth Launches BeaconLBS Florida Doctors and Labs Unhappy

LAUNCHED IN FLORIDA THIS FALL, the laboratory benefit management program of **UnitedHealthcare** is stirring up a hornet's nest of unhappiness among physicians in the Sunshine State.

Under the rather benign name of the UnitedHealthcare laboratory benefit management program, the national insurer has directed Florida physicians to use a lab test ordering system created and managed by **BeaconLBS**, a business division of **Laboratory Corporation of America**.

Physicians must use the BeaconLBS system to obtain pre-notification or pre-approval for a list of 82 laboratory tests. As of January 1, 2015, failure to comply with these requirements means that the physician or the clinical laboratory that performs the lab tests will not be paid by UnitedHealthcare. *(See TDRs, July 21, September 2, October 13, and November 3, 2014.)*

UnitedHealthcare and its partner in this effort—LabCorp—are playing a high stakes game with this scheme. If they can successfully engage physicians to participate in the use of BeaconLBS for lab test ordering, they intend to introduce this program in other regions of the United States.

For LabCorp, the goal is even bigger. If it can get Florida physicians to use the BeaconLBS system for their UnitedHealthcare patients, they hope to persuade other major health insurers to use the BeaconLBS system as a way to control how physicians order lab tests.

TOP TEN OF 2014 ➤➤STORY no. 7

Clinical Labs Scramble to Cut Costs, Control Utilization, Deliver Value

DURING 2014, THE HEALTHCARE SYSTEM'S TRANSITION away from reactive care and toward integrated, proactive care motivated a larger number of labs to incorporate three common elements into their business strategies.

These three elements involve cutting costs within the lab, working with clinicians to improve the utilization of lab tests, and developing ways to deliver more value. Of these three strategies, the one most visible in the greatest number of labs is aggressive management of costs. Without exception, clinical labs and pathology groups are under sustained pressure to reduce costs in order to offset declines in revenue.

It is a similar story with efforts to manage lab test utilization, particularly for labs serving accountable care organizations and patient-centered medical homes. Administrators of these provider organizations need both the cost savings that come from reducing unnecessary test orders along with the benefits of improved patient outcomes that result from physicians doing a better job of ordering the right test at the right time. *(See TDR, March 17, 2014.)*

Meanwhile, these same providers are being evaluated on the patient outcomes they deliver. Thus, ACOs and PCMHs are motivated to engage their lab providers in ways that deliver more value from lab testing and help improve patient outcomes while reducing the cost per healthcare encounter.

TOP TEN OF 2014 ➤➤STORY no. 8

Tougher Market Translates Into Fewer Anatomic Pathology Groups

ARE SMALL PRIVATE PATHOLOGY GROUP PRACTICES an endangered species in the United States? Over the course of 2014, it is believed that more private practice groups quietly ceased to exist as independent practices than in any year in the past two decades.

This is a response to changes in healthcare and the lab testing marketplace. First, payers are cutting the prices they pay for many anatomic pathology testing services. Second, payers are excluding community hospital-based pathology groups from managed care contracts. *(See TDR, March 17, 2014.)*

Third, rapid improvements in diagnostic technology and informatics mean that pathology groups must invest capital to acquire and deploy these essential tools in their laboratories. These capital demands often outstrip the funding capabilities of smaller groups.

Fourth, smaller pathology groups are caught in the generational wedge. Baby boomer partners are retiring while younger Gen X and Gen Y pathologists are reluctant to accept positions in smaller communities or where they may need to work long hours compared to pathology labs that are located in major cities, offer fixed hours, and access to ample cases in their subspecialty.

As a consequence of these trends, acquisitions, mergers, and even the dissolution of pathology groups as the pathologists are converted to employee contracts with hospitals continued into 2014.

TOP TEN OF 2014 >>STORY no.9

Lab Whistleblowers Re-Emerge In Several High-Profile Lab Cases

EVENTS INVOLVING LAB WHISTLEBLOWERS during 2014 indicate that another wave of such *qui tam* actions may be working their way through the courts.

For example, this fall, **Bostwick Laboratories** agreed to pay $6.05 million to resolve a federal whistleblower lawsuit originally filed by the CEO of a competing anatomic pathology lab company.

Similarly, on September 8, *The Wall Street Journal* published a front page story about a federal investigation into the alleged illegal marketing practices of **Health Diagnostic Laboratory**, **Atherotech Diagnostics Inc.**, **Berkeley HeartLab Inc.**, **Boston Heart Diagnostics Corp.**, and **Singulex Inc.** that is believed to have originated by a whistleblower action. *(See TDR, September 22, 2014.)* Such publications as *Forbes* gave wide coverage to the news of the federal investigation. It published a series of stories describing in detail the alleged methods used by the labs under federal investigation to induce lab test referrals.

Such investigations are ominous portents for the nation's largest lab companies. That is because employees on the inside of these labs are first to spot violations of the law and they have access to the documents needed to prove their cases in court. Motivated by the sizeable dollars to be recovered, they will file these *qui tam* cases under seal and it often takes years before these cases are unsealed and become public knowledge.

TOP TEN OF 2014 >>STORY no.10

CMS Grants CLIA Deeming Authority To A2LA, the First in Several Decades

USING A NOTICE PUBLISHED in the *Federal Register* on March 25, the **Centers for Medicare & Medicaid Services** announced that it had granted deeming authority to the **American Association for Laboratory Accreditation** (A2LA) to accredit labs to the requirements of CLIA.

This is the first organization in several decades to get deeming authority under CLIA for medical laboratories. At the time of the announcement, THE DARK REPORT noted that, along with providing CLIA accreditation services, A2LA will also offer labs the option of obtaining accreditation to ISO 15189: Medical Laboratories at the same time for a single price. *(See TDR, April 7, 2014.)*

With this action, CMS officials are recognizing the value that the ISO 9001 and ISO 15189 quality management systems can bring to hospitals and medical labs in the United States. CMS took a similar step in 2008 when it granted deeming authority to **Det Norske Veritas** (DNV) to provide accreditation services to hospitals to help them meet Medicare's Conditions of Participation. DNV offers a hospital the option of certifying to ISO 9001 at the same time it earns its Medicare accreditation.

This development is another sign that ISO 15189 accreditation is a useful step for innovative labs and pathology groups seeking recognition as leaders in lab test quality and service. TDR

Lab Market Update

The Curious Case of Dr. Cockerill, Mayo Clinic and Quest Diagnostics

Judge says former Mayo Med Lab CEO 'engaged in deception in order to hide his relationship with Quest'

MOST PEOPLE WOULD CONSIDER the job of Chairman of the Department of Laboratory Medicine and Pathology (DLMP) at **Mayo Clinic** and CEO of **Mayo Medical Laboratories** (MML) to be at the pinnacle of the pathology profession.

This makes it all the more curious as to why pathologist Franklin R. Cockerill, III, M.D., decided to announce his early retirement from these two positions, effective on September 30, 2014, only to surface a day later, on October 1, working as the Chief Laboratory Officer for **Quest Diagnostics Incorporated**, a major competitor of Mayo Medical Laboratories.

News reports say that, earlier in September, when Cockerill announced his early retirement from both Mayo positions, he told colleagues he planned to help his mother run the family fertilizer business in Nebraska. Thus, it came as a big surprise to Mayo officials to learn of his employment at Quest Diagnostics.

Praising Cockerill, Quest President and CEO Steve H. Rusckowski said, "Few individuals in health care possess Frank's impressive record of successful leadership in business, clinical, and academic roles."

Within two weeks, the Mayo Clinic filed a lawsuit against Cockerill, claiming he misled the company in order to acquire sensitive information to benefit his new employer, the *Rochester Post-Bulletin* reported.

Court documents show that, on October 15, a judge in the case issued a temporary restraining order, prohibiting Cockerill from working at Quest, having any contact with Quest, or soliciting any employees or customers of Mayo or MML for the benefit of Quest. The order also required Cockerill to return to Mayo all confidential, proprietary, or trade secret information.

The evidence presented at court "demonstrates, at this stage, a pattern of deceptive behavior by Dr. Cockerill. Plaintiffs alleged Dr. Cockerill repeatedly lied to Mayo, MML, and Dr. Cockerill's long-time colleagues about his activities, including the reasons for his retirement and separation from MML," Judge Robert Birnbaum wrote.

Birnbaum ordered the parties to confer and return to the court to modify the order.

Allegations In Mayo's Lawsuit

In the suit Mayo filed against Cockerill, the company claimed Cockerill accepted the job at Quest in June but did not inform Mayo and instead continued to work and attend meetings at Mayo, and provided advice to Quest officials before he was hired on October 1, *Fierce Healthcare* reported. Also, Cockerill took from Mayo at least seven USB drives and downloaded data from his Mayo computer to four of the drives before joining Quest, noted *Fierce Healthcare*.

On December 4, Cockerill resigned from Quest, and Mayo determined that Quest was no longer a factor in the case, the *Post-Bulletin* reported. Mayo's lawsuit against Cockerill continues, however, and a hearing is scheduled for December 22 in Olmsted County Court, the newspaper added. TDR

—Joseph Burns

More Genetic Counseling Leads to Fewer Lab Tests

Cigna may expand the program to require counseling for larger number of genetic tests

CEO SUMMARY: Cigna was the first national health insurer to require independent board-certified genetic counseling before approving coverage for certain genetic tests. Since launching this program in September 2013, the insurer has seen a 450% increase in genetic counseling for Cigna members. Such counseling has helped to reduce utilization of genetic testing because informed patients understand that a genetic test might not be appropriate for them.

WITH MORE GENETIC COUNSELING comes reduced levels of genetic testing, according to **Cigna**, a national health insurance company in Bloomfield, Connecticut.

In September 2013, Cigna became the first national health insurer to require genetic counseling before approving coverage for some genetic tests. The company required counseling from an independent board-certified genetics specialist for any member seeking coverage for certain genetic testing and who was at heightened risk for certain hereditary conditions, such as breast cancer, colorectal cancer, or long QT syndrome. *(See TDR, August 19, 2013.)*

"Since implementing the program, the number of members getting counseling from a board-certified genetics specialist has increased 4.5 times," stated David Finley, M.D., Cigna's National Medical Officer for Enterprise Affordability and Policy. "Such counseling has also helped to reduce genetic testing because more-informed patients saw that genetic testing is appropriate only for a subset of patients and conditions."

The reduction in genetic testing is a significant result even though the counseling was not designed to reduce testing, noted Finley. "Since 2012, we have seen an 88% increase in requests for genetic tests each year," he said. "That's an enormous increase in costs per year and it is not a stable situation." Cigna has also seen sharp increases in drug testing, he added.

Reduced Genetic Testing

"After seeing the results of its genetic counseling program, Cigna is evaluating whether to expand this program to other types of genetic tests—in part because it has helped to reduce genetic testing and because members are making better, more informed choices about potentially life-altering medical decisions," said Finley.

Empowering patients was the primary goal when Cigna implemented the genetic counseling program in 2013. "We saw this as a way to ensure that Cigna members got the proper genetic tests at the right time," explained Finley. "It was equally important to ensure that members under-

stood what genetic testing would reveal about their health."

One outcome from genetic counseling was that a higher percentage of Cigna members who were considering getting genetic tests chose not to get tested. "Once these members learned about the genetic test, they found either they didn't want it or they didn't meet the criteria," Finley said. "We also saw members who met the criteria but didn't want the genetic test because it was not going to change anything for them, whether it was for treatment or follow up.

Fact-Based Decisions

"One major outcome from genetic counseling is that Cigna members can make fact-based decisions rather than decisions based on incorrect information and assumptions," he continued. "That was the focus of the genetic counseling program and it is working well.

"There is so much misunderstanding and misinformation about genetic testing, particularly about who should be tested and what the test results mean," he added.

In its evaluation of genetic counseling, Cigna has been assessing its return on investment. "Yes, there may be a return that would save money and cover the cost of genetic counseling," he said. "That leads to the question of whether Cigna will expand the genetic counseling requirement to other tests. That's something we're considering even though the reason Cigna adopted this policy was not financial.

"If the cost of genetic counseling is compared to the cost of a test not being done—in the short term, the money savings are just about break-even," stated Finley. "Long term, we don't know if we'll see significant financial benefits.

"Take the example of a woman who has a BRCA test and the result shows a variation of unknown significance," Finley stated. "Assume, after genetic counseling, that the woman elects not to have surgery.

"In this case, that woman will be followed closely and have a series of MRIs over the next several years because MRIs are a sensitive way of picking up early changes in the breast," he continued. "But MRIs done every year over the many years cost tens of thousands of dollars.

"This woman also could have a double mastectomy, and that costs thousands of dollars," observed Finley. "Therefore, if Cigna can ensure that the genetic tests done for the patient are the ones that need to be done, then it may be able to reduce the downstream costs while helping patients get the best outcomes."

Cigna's focus on genetic and molecular testing is significant because all insurers are spending more as test utilization has risen. Before last year, Cigna and other insurers struggled to manage the cost of these tests but coding changes implemented last year have helped Cigna make better decisions about which tests to cover, Finley said.

"Prior to 2013, all the codes for these tests were unspecific," he noted. "Therefore, we had no way to know the purpose of each genetic or molecular test. The test request would say it was for DNA extraction, or DNA amplification, or DNA sequencing. Those descriptions told us nothing.

Confusion Over Coding

"It could be any type of molecular or genetic test—yet labs would use the same codes," he stated. "We could not identify the specific test that was being done for the patient and so we were unable to manage what was being done. All we could do was pay the claims.

"Now, the molecular and genetic test codes are more specific, allowing us to identify the tests as the orders come in and we put them into one of three categories: Tests we pay for, tests we never pay for, and the tests that require more information on whether or not the patient meets criteria," Finley said.

"This change in lab test coding occurred at the same that we saw the 88%

Last Summer's 'Angelina Jolie' Effect Increased Demand for Genetic Breast Cancer Tests, Cigna Says

IN MAY 2013, WHEN ANGELINA JOLIE REVEALED her double mastectomy, many other woman who were similarly at risk for breast cancer decided to have the same surgery. Jolie opted for the procedure after learning she has the BRCA1 gene and thus had an increased risk of breast cancer.

"Since that news came out, we saw an increase of 60% to 70% in requests from patients for the BRCA1 and BRCA2 tests, and that has continued," stated David Finley, M.D., Cigna's National Medical Officer for Enterprise Affordability and Policy. "That surprised us.

"In our counseling program for genetic testing, about 80% to 90% of the test requests are for the BRCA tests," he explained.

"At the same, we have also seen a rise in the use of genetic counseling and that our members want this counseling," he noted. "Of course, more genetic tests are being introduced all the time and that leads to more counseling.

"Each laboratory company developing genetic tests believes in its product," he said. "But Cigna must assess each new genetic test to see if it may be the right thing to do medically or not. We want to know if a test will change the patient's clinical outcome. When this standard is applied, there is a decrease in the number of genetic tests that are ordered.

"Genetic counselors are trained to address that question: will this test affect the patient's clinical outcome," Finley explained. "That's one reason genetic counseling is good for patients. However, the patient benefits in another way from this counseling because it helps decrease the number of diagnostic odysseys and fishing expeditions that some patients experience when treating physicians are unsure about a diagnosis.

"Genetic counselors know that, as individuals have genetic testing done, there will be mutations and variations of unknown significance," he said. "That's a problem because that leads to more testing and that testing is not free. There is the dollar cost of the test, but there is also the cost in terms of the increased anxiety for the patient. Genetic counselors can help prevent both of these unnecessary costs.

"When it comes to cancer, for example, there are many misunderstandings about what genetic testing can do," continued Finley. "Many women believe that—just because they have a certain gene— they are at risk for breast cancer. Others believe that, if they don't have this gene, then they don't have to worry about breast cancer. This is dangerous thinking in both cases.

Benefits Of Counseling

"The incidence of the BRCA gene in the American population is about 2% and the chance of a woman getting breast cancer in America is about 1 in 8 in her lifetime," observed Finley. "Genetic counselors help our members understand how such numbers relate to their personal situations. This is one benefit to the genetic counseling program.

"For our counseling, we use board-certified genetic counselors, clinical geneticists, and nurse practitioners with advanced degrees in cancer risk assessment and genetics," he stated. "We predict the demand for genetic counseling will increase steadily.

"That's because new genetic tests continue to be introduced," concluded Finley. "Lately, multigene testing panels have entered the market and physicians don't have the expertise to answer all the questions patients have about such genetic tests. Referring their patients to genetic counselors is the right way to help the patients evaluate whether or not they would benefit from such genetic tests."

increase in test utilization," he added. "So the extent to which the change came as a result of the new coding or increased utilization is hard to tell. My belief is that a large part of this is due to increased utilization.

"The change in genetic test coding was done in conjunction with what Medicare was doing with genetic and molecular testing and with what the AMA did to improve CPT coding," Finley explained.

"For Cigna, the problem was how to handle the thousands of genetic tests that exist and develop reimbursement guidelines for each test," he observed. "The AMA came up with 10 tiers for the different tests. Tier one codes would be the most common tests and that left thousands of other tests to be grouped into nine other tiers.

"It's still a challenge because each tier has hundreds or thousands of tests, but at least we now have a system for the most common tests," stated Finley. "It's not completely under control because of the nonspecific nature of the codes beyond tier one.

More Precision Analysis

"When Cigna evaluates a molecular or genetic test for payment, it looks at whether the test is effective and whether it improves patient outcomes," he added. "Because we can't manage everything, this approach helps us choose which tests make the most sense for our customers.

"To prioritize this process, we put genetic tests into categories," said Finley. "Common tests go in one category and the commonly misunderstood tests make up another category.

"A third category has the very expensive tests," he noted. "We manage the tests that are misunderstood and the ones that are expensive. Thus, we pay for certain tests that meet medical criteria and we do not pay for tests that do not meet medical criteria.

"Of course, there remain many genetic tests that we have not evaluated under this system," stated Finley. "If Cigna has no comment on these tests, it means they are payable.

"We also do the best we can to focus on the tests we can manage," concluded Finley. "We have a genetic counseling company, **InformedDNA**, that advises us. It helps us determine which genetic tests are likely to be beneficial in terms of improving patient outcomes." TDR

—Joseph Burns

Contact Rogelio DeLaMar at 215-761-1184 or rogelio.delamar@cigna.com.

Health Insurer Sees Jump in Drug Tests, Tox Screens

Like many health insurers, not only is Cigna handling a larger volume of genetic tests, but it is also seeing big increases in the utilization of drug tests.

"Outside of the significant increase we have seen in genetic testing, we have not seen large increases in clinical lab test utilization, except in one area," stated David Finley, M.D., Cigna's National Medical Officer for Enterprise Affordability and Policy. "We have seen large increases in testing for drugs, meaning toxicology screens.

"In the past year, Cigna put in a process to manage that testing," he continued. "This gives us some guardrails on how much testing can be done for substance abuse. "Medicare developed a process for toxicology screens that it uses to reduce some of the abuse for this category of tests. We've adopted that approach here at Cigna.

"Specifically, there were CPT codes for toxicology screens for blood or urine that would allow a lab to screen for 30 to 35 toxic substances, and the lab would charge for that screen 35 times," he explained. "However, this was not the intent of these CPT codes.

"Thus, Medicare said it wouldn't pay for the same screen done 35 times and now uses a G code or HCPCS code," noted Finley. "Under the G codes, the lab can still do a toxicology screen for multiple substances. However, Medicare will pay only for a maximum of 10 substances.

"Cigna adopted that same protocol and it has saved a lot of money," said Finley. "Cigna's policy is to have labs do a qualitative assay to see what's there before they do a quantitative assay. This is consistent with Medicare's policy."

Is PAML To Be Sold? 'No Comment!' Say Execs

Rumors persist that Spokane-based lab firm is having talks with at least one potential buyer

CEO SUMMARY: It is one of the 10 largest lab companies in the United States. Thus, if Pathology Associates Medical Laboratories in Spokane, Washington, were to be sold, it would trigger a major shift in the competitive market for lab testing services—both in the Pacific Northwest and nationally. Owners and executives at PAML have neither confirmed nor denied the ongoing rumors that the lab company's two health system owners are exploring a sale of PAML.

WHEN THE SUBJECT is whether or not the owners of **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington, are open to sell the lab company, plenty of people are talking, while those "in the know" are not talking.

The owners of PAML did not respond to inquiries by THE DARK REPORT about this matter. One executive at PAML did provide the following statement:

Thank you for your recent inquiry regarding PAML, LLC. As an organization we regularly explore opportunities that would help us improve quality, reduce the cost of care, and enhance patient experience. However, we don't discuss details publicly until all parties involved agree to do so.

Readers can judge for themselves what this statement means. As written, it does leave open the possibility that the lab company might be holding conversations with interested buyers.

So why write a story about the possible sale of PAML if company officials decline to declare that they want sell the lab company? The answer is that many lab professionals throughout the Northwest believe that PAML's owners have been considering a sale of the company.

Such rumors started more than one year ago and persist today. One consistent theme is that lab's owners have been in conversations with at least one prospective buyer. Veteran lab executives know that, if a consistent rumor pops up over many months, there is high probability that some elements of these rumors are connected to real events.

PAML's Sale Would Be News

Another reason to comment on this situation is that PAML is one of the 10 largest lab companies in the United States. Thus, if it were sold, it would shift the competitive balance in the lab testing market, both nationally as well as in the Pacific Northwest. That is why many lab executives are interested in this story.

PAML is owned by **Providence Health Associates** of Seattle, Washington, and **Catholic Health Initiatives** of Denver, Colorado. *(See TDR, November 2,*

2009.) It is a sizeable lab company. Counting its different joint ventures, including the **PACLAB** regional network, estimates are that PAML's annual revenue exceeds $300 million. Its lab testing facilities and joint ventures operate in at least eight states.

Because PAML is one of the largest employers in Spokane and in several other cities where it operates, were it to be sold, its fate would be of significant interest to government officials and business leaders in those cities. Equally concerned would be the lab employees in these communities, along with the physicians and other healthcare providers PAML serves.

What Would New Buyer Do?

Setting aside, for the moment, the reason why PAML's owners might want to sell the lab company, who are the most likely candidates to buy PAML? And, were PAML to be sold, how might different buyers manage this lab company after the sale closed?

Of course, the first potential buyers to come to mind are the nation's two largest public lab companies. They regularly state they are interested in lab acquisitions and each has ample cash to close most any lab deal. Both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** would be expected to have strong interest in acquiring PAML.

Post-acquisition, with their existing regional lab facilities in Seattle, LabCorp and Quest Diagnostics would gain major economic benefits were they to shut down PAML's large central laboratory in Spokane and move the bulk of that testing to Seattle. Moreover, since a generous portion of PAML's specimen volume originates in the Seattle/Tacoma metropolitan area, there would be savings in transportation to divert those specimens away from Spokane and do the testing in Seattle.

Such a step would leave several hundred medical technologists and other lab professionals living in Spokane with few employment options in their career field.

Another prospective buyer would be **Sonic Healthcare Limited**, based in Sydney, Australia. With about $900 million of lab testing business in the United States, it has experience successfully acquiring and managing labs in this country.

Sonic Would Need Facilities

Sonic has the financial capability to purchase PAML. Post-acquisition, what would distinguish it as a buyer from LabCorp and Quest is that it would need all the existing lab facilities and staff currently operated by PAML. Sonic has no lab facilities in Washington State and its closest existing lab facilities are in California.

Also, Sonic Healthcare regularly tells investors that it operates a "federal model" with the labs that it purchases. Sonic has a history of keeping the existing management team and lab staff in place.

Thus, Sonic would probably continue to operate PAML with few lab closures. The Spokane lab would maintain its operations and its existing employees without the layoffs and multi-year downsizing typically seen after the two blood brothers acquire a lab.

Another potential buyer mentioned in the rumors about PAML's possible sale is **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey. This public company has annual revenues of about $800 million. It has the resources to finance the purchase of PAML.

BRLI Has Not Done Big Deals

What makes BRLI different than the three labs mentioned earlier is that BRLI does not regularly acquire sizable regional lab companies the way LabCorp, Quest Diagnostics, and Sonic have done over the past decade. This acquisition would be out of character for Bio-Reference Labs.

Notwithstanding that fact, there are sound business reasons why Bio-Reference could benefit from acquiring PAML were that opportunity to become available. It would give BRLI a major cen-

Why Outsiders Think LabCorp Has an Inside Track To Possibly Acquire Spokane-based PAML

PERSISTENT RUMORS about the possible sale of Pathology Associates Medical Laboratories of Spokane, Washington, exist because outsiders are connecting multiple dots in ways they think lead to an obvious conclusion.

As these knowledgeable observers interpret recent events, they believe there are reasons why PAML's owners would consider a sale and why one national laboratory company—LabCorp—would have the inside track to buy PAML.

PAML is owned by Providence Health & Services of Seattle, Washington, and Catholic Health Initiatives (CHI) of Denver, Colorado. *(See TDR, November 2, 2009.)*

First, why would PAML's owners consider selling the company? The speculation centers on two ideas. First, revenue growth and profits at PAML are believed to be flat or slightly declining in recent years.

Second, PAML has substantial needs for capital to grow and sustain its lab testing operations. However, as a division of Providence and CHI, PAML must compete for capital with the hospitals and other clinical services the two owners control.

Competition For Capital

This could be a significant factor, because the hospitals and certain other clinical services generate the overwhelming majority of revenue and operating margin for both health systems. That is why Providence and CHI would want to give priority to capital requests from those services over the capital needs of PAML.

This is one reason why informed observers speculate that PAML's owners would be open to selling the lab company. Another reason that supports this conclusion is the fact that, if sold, PAML's purchase price would likely generate several hundreds of millions of dollars of cash to Providence and CHI—cash they can put to work developing their core clinical services.

So why would LabCorp have an inside shot at purchasing PAML, were a sale to be considered? On this point, outside observers in the Northwest connect an interesting series of dots.

They point out that LabCorp's **Dynacare** has a long-running laboratory joint venture with **Swedish Health Services** in downtown Seattle. Starting in 2007, the President and CEO of Swedish was Rod Hochman, M.D.

System Operations Merged

In February 2012, Providence and Swedish merged their operations in the Puget Sound Region. Then, five months later, on July 1, 2012, Hochman became President and CEO of Providence Health & Services.

Rumor mongers in the Northwest point out that Hochman has much personal experience with LabCorp and Dynacare, because the lab joint venture provides all the inpatient testing to Swedish Hospital. They point out that it would be natural for Hochman—now CEO at one of PAML's owners—to take phone calls from LabCorp CEO Dave King relating to LabCorp's interest in buying PAML.

LabCorp's potential to have the inside track gets reinforcement from another fact. Outsiders speculate that because PAML's current CEO, Francisco R. Velázquez, M.D., SM, was recruited directly from **Quest Diagnostics Incorporated** in 2012, there may be some residue of ill will that would make a deal with this national lab company a bit more difficult, but not impossible.

It must be noted that all of this is speculation. At the same time, these facts and interesting connections demonstrate why rumors of a possible sale continue to float throughout the Pacific Northwest. They are valid business reasons why PAML's two owners would consider a sale of the lab company to be a reasonable strategic option.

tral laboratory facility on the west coast and the ability to sell its speciality and esoteric testing services into the different communities where the PAML-hospital joint ventures are located.

Private Equity Buyers

One other class of buyer could always be in the mix: private equity companies. They have ample funds available to support a purchase of a large lab company such as PAML. However, in recent years, private equity companies have been regularly outbid by lab companies for the deals that have come to market.

All of this shows the complexity that would be involved were the two health system owners to consider the sale of PAML. That includes the engagement of the various laboratory joint venture partners as discussed in the sidebar at right.

One fascinating aspect to these ongoing rumors is that they also include speculation that such buyers as Quest Diagnostics, Sonic, and Bio-Reference Labs have approached PAML's owners to express interest and been told that the lab company is not for sale. That raises the question as to why Providence and CHI would not want to allow a competitive bidding arrangement among all qualified and interested buyers—assuming that their goal was to consummate a sale?

Speculating About Future

Because PAML is among the 10 largest lab companies in the United States today, any actions its owners take in its ongoing operation or future sale will have major implications, not just in Spokane and other communities where it has labs and employs people, but on the national scene as well.

Pathologists and lab administrators should remember that the information presented above is speculation. THE DARK REPORT has provided a statement from a PAML executive that represents the lab company's position relative to rumors of a possible sale. TDR

How to Smoke Out Rumors Of Possible Sale of PAML

SEPARATING FACT FROM RUMOR is always a challenge. That is true about persistent rumors that the two health systems who own Pathology Associates Medical Laboratories are considering the sale of Spokane, Washington-based PAML.

Interested parties in the Northwest—particularly lab executives who compete against PAML—say that one way to determine whether sales negotiations are actually taking place is to watch what happens at the different laboratory joint ventures operated by PAML.

These lab professionals believe that any operating agreement between PAML and hospitals or health systems participating in these laboratory joint ventures includes a clause that addresses what must happen if PAML were to be sold to a new owner. This is a common element in such joint venture agreements.

Thus, it is speculated that, if executives from such potential buyers as LabCorp, Quest Diagnostics, Sonic Healthcare, and Bio-Reference Laboratories, among others, were seen visiting the administrative offices of the hospitals and health systems that were PAML's joint venture partners, that would be a sure sign of a pending sale of PAML.

After all, the new buyer would need to determine if each lab joint venture would continue after a sale of PAML or whether those JV partners would want to dissolve the lab JV because of PAML's sale—and per their rights under the JV operating agreement.

From the buyer's perspective, this would be essential knowledge. It would have a role in determining the final sales price any buyer would be willing to pay for PAML.

Not surprisingly, this is why many lab professionals are keeping a close eye on which lab companies are seen visiting the hospitals and health systems that are in laboratory joint ventures with PAML.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In certain respects, the noted physician and healthcare strategist Eric Topol, M.D., of **Scripps Healthcare** in La Jolla, California, can be considered a gadfly to pathology and the laboratory medicine profession. In his latest pronouncements on patient-centered healthcare, he warned clinical labs about the need to stay ahead of the technology wave that is transforming clinical diagnostics. At the recent 2014 Digital Health Conference in New York, Topol called attention to how smartphones, apps, and other inventions are poised to transform lab testing. In offering the example of **Theranos** as disruptive technology, he is reported as saying "This is a game-changer for lab medicine and if the national labs don't keep up, they will have to change."

MORE ON: *Topol*

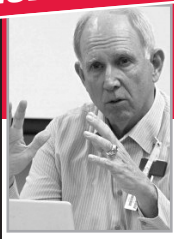
It was back in 2013 when our sister publication *Dark Daily* reported on Eric Topol's comments about the need for anatomic pathologists to change long-standing practices in tissue processing and storage. In a column published by the *Journal of the American Medical Association* (JAMA), Topol and several colleagues took pathologists to task, noting that formalin-fixed, paraffin-embedded tissue can cause the DNA to degrade. That is increasingly a problem, given the growing role of gene sequencing and genetic analysis in cancer diagnosis and treatment. Topol and his co-writers suggested that it was time for pathologists to adopt methods, such as fresh-freezing tumor specimens, that would preserve the DNA for later testing.

NEW LABS UNDER CONSTRUCTION

Despite the tough financial challenges in the lab testing market, a number of new lab facilities are under construction. For example, in New York City, **Shiel Medical Laboratories** is building a new 240,000 square foot lab facility at the Brooklyn Navy Yard. In Roanoke, Virginia, three colleges are collaborating to build a common anatomic pathology laboratory to serve patients and teach students. The lab will be built by the **Virginia Tech Carilion School of Medicine**, **Radford University**, and **Jefferson College**. The pathology lab will be located in the **Carilion Roanoke Community Hospital**, in the same building that houses the **Jefferson College of Health Sciences**. In Grand Rapids, Michigan, **Michigan State University** will build a new laboratory for its medical school. Target date for opening the MSU lab is the second half of 2014.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 5, 2015.

SPECIAL EVENT!



Executive Leadership Development *at the Executive War College!*

Colonel Jeffrey D. McCausland (retired)
former Dean of Academics at the Army War College

Learn advanced skills! Master potent leadership methods!

Now, more than ever, your lab or pathology group needs strong leaders. To take your skills to the next level, we've arranged two superb learning opportunities at this year's *Executive War College*. We've engaged **Colonel Jeffrey D. McCausland** (retired), former Dean of Academics at the U.S. Army War College. He's developed leaders in the military and business for more than four decades.

You'll hear Col. McCausland address the full *Executive War College* on Wednesday, May 6, on the how to use the military's top ten leadership lessons to advance your lab (and help your career)!

The following day, on May 7, he and his team will lead a special six-hour **Executive Leadership Workshop** for those who pre-register. Three modules will address the priority issues facing lab executives today: Leadership in four directions; Organization change and culture; and, Leading in Crisis. Plan to send your brightest managers who have key roles in your lab's succession plan.

www.executivewarcollege.com

20 YEARS

It's our 20th Anniversary!

Executive War College

Conference On Laboratory & Pathology Management

May 5-6, 2015 • Sheraton Hotel • New Orleans

UPCOMING...

- ***Three Big Threats to Patient Access Challenge Pathology Groups during 2015.***
- ***How One Hospital Lab Outreach Program Is Winning Back Managed Care Contract Status.***
- ***In Reponse to Federal Probe and Cigna Lawsuit, Health Diagnostic Laboratory Fights Back***