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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Will 2016 Bring Opportunity or Tribulations for Labs?

WE ARE JUST ABOUT EIGHT WEEKS FROM THE ADVENT OF 2016. Given the rapid transformation of healthcare that continues to unfold, it is timely to assess how clinical labs and pathology groups are likely to fare during the coming year.

On the plus side, the ongoing evolution toward integration of clinical care will benefit hospital-based laboratories. The number of ACOs continues to increase and these are usually anchored by a hospital or health system. Because of that fact, the hospital's lab is positioned to be the preferred provider of inpatient, outpatient, and outreach lab testing. This is particularly true when the managed care contracting team at the hospital or ACO negotiates contracts that include outreach lab testing services.

Another positive opportunity is the steady progress toward population management, informed by big data. Because clinical labs originate the largest proportion of useful clinical data, they have an opportunity to combine lab test data with other clinical data sets in ways that physicians can use to improve patient outcomes while reducing the overall cost of care.

The challenges facing labs in 2016 are well-known. During the year, the Medicare program will collect market price data and use that to set Medicare Part B clinical laboratory fees for 2017. Another emerging issue is whether CMS will follow the intent of the Protecting Access to Medicare Act (PAMA). Following release of the proposed rule to implement market reporting and proposed fees for advanced diagnostic laboratory tests (ADLTs) this fall, the entire lab industry has concerns that CMS is poised to enact significant fee cuts that will be painful to all labs. We report on one specialty lab company that says it will have to close if the proposed pricing for its ADLT assay is not increased. *(See pages 11-16.)*

Similarly, expect private payers insurers to be tougher on lab test coverage and pricing. As well, THE DARK REPORT has been first to alert lab administrators and pathologists to new targets in payer audits of labs, including whether labs are collecting amounts due from patients. Expect tougher payer audits during 2016.

For those lab executives tracking events at **Theranos**, 2016 may prove to be a challenging year for the lab company that says its diagnostic technology will disrupt the clinical laboratory testing industry. Stories published this month by *The Wall Street Journal* have put the high-profile start-up in an unwelcome spotlight. You'll be fascinated by our coverage, found on pages 3-8. TDR

WSJ 'Sticks' Theranos, Raises Serious Questions

Two front-page stories describe problems with lab test technology and issues with the FDA

CEO SUMMARY: Following months of investigation, reporter John Carreyrou of The Wall Street Journal published back-to-back reports about aspects of Theranos that the secretive company has kept from public view. Based on interviews with several employees and others with knowledge of events at Theranos, the WSJ disclosed that Theranos runs only a handful of tests using its proprietary technology. Theranos said the information in both stories was "factually and scientifically erroneous."

FOR THE FIRST TIME, one of the nation's most respected news organizations has raised serious questions about the accuracy of the diagnostic-testing technology used by **Theranos** and its compliance with federal and state regulations governing clinical laboratories.

The Wall Street Journal published back-to-back front page exposés about the lab company on October 15 and 16. The articles were based on a detailed investigation that reporter John Carreyrou and other staff members conducted over several months.

Publication of these stories launched a firestorm of additional news coverage. Stories published by other media outlets included the revelations by some well-known scientists and respected business leaders that they had personally raised questions when undergoing clinical laboratory tests Theranos performed or investigating the company for a possible investment.

Overnight, Theranos CEO Elizabeth Holmes ceased to be a media darling. Instead, she found herself confronted with serious questions from major news organizations. Holmes and her lab company immediately launched a public communications blitz. Theranos emphatically challenged the accuracy of the information presented in the *The Wall Street Journal*.

Many clinical lab executives and pathologists are following these developments closely because Theranos has consistently stated that its corporate goal is to disrupt their business, the clinical laboratory industry. Also, medical laboratory

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professionals know how challenging it is to run lab tests quickly, consistently, and accurately using today's complex technologies. Thus, they want to understand more about how and why the innovative diagnostic technology Theranos claims to have is capable of delivering safe, accurate, and reliable results for clinical care.

Investigation Of Theranos

Based on its investigation into Theranos, the WSJ identified a number of lab operations and regulatory issues at Theranos. In its front-page story on October 15, the journal reported the following:

- As of December 2014, Theranos was using its proprietary lab analyzer (which Theranos calls Edison) for only 15 of the lab company's 240 tests for consumers and patients.
- Some current and ex-employees were concerned about the accuracy of lab tests run on the Edison analyzer.
- Information, documents, emails, and comments from individuals the journal interviewed described questions they had about how Theranos conducted proficiency testing, including splitting PT samples.
- An employee or other individual filed a complaint with the **New York State Department of Health** alleging that Theranos was "manipulating" proficiency testing. According to the journal, the NYDOH referred this matter to the federal **Centers for Medicare & Medicare Services**, which declined to comment. The NYDOH confirmed it received a complaint in April 2014.
- Employees or other individuals described how, for 60 of the 240 lab tests Theranos offered, nanotainer-sized specimens collected via a finger stick were diluted to run those specimens on conventional lab analyzers Theranos operated.
- About the dilution issue, the journal wrote "some of the potassium results at Theranos were so high that patients would have to be dead for the results to be correct, according to one former employee."

Within hours of the journal's publication of the article on October 15, Theranos issued a public statement challenging the information in the story. In one comment, Theranos said, "Today's *Wall Street Journal* story about Theranos is factually and scientifically erroneous and grounded in baseless assertions by inexperienced and disgruntled former employees and industry incumbents."

The complete press statements Theranos issued in response to articles in the journal are available on the Theranos website at *theranos.com/news/press-releases.*

A Second Front-page Story

The following day, on October 16, the WSJ published a second front-page story about Theranos. This story described issues involving Theranos and the FDA, including the following:

- "Under pressure from regulators, lab firm Theranos Inc. has stopped collecting tiny vials of blood drawn from finger pricks for all but one of its tests, according to a person familiar with the matter, backing away from a method the company has touted as it rose to become one of Silicon Valley's hottest startups."
- A source said FDA inspectors "recently showed up unannounced at Theranos," based on concerns about the data Theranos had voluntarily submitted to the FDA in an effort to win approval for its proprietary testing methods.
- During that inspection, the FDA said it considered Theranos' Nanotainers to be unregulated medical devices.
- Also, following the FDA inspection, Theranos would need to resubmit data for a number of its proprietary blood tests currently under FDA review.
- Following the FDA inspection, Theranos was audited by CMS. A

Holmes Says It's Lab Industry Who 'Are Seeding the Press With Negative Stories about Theranos'

IN THE DAYS FOLLOWING PUBLICATION of these stories about Theranos by *The Wall Street Journal*, many business publications and media organizations have published their own stories about this situation. There is a healthy scepticism in this news coverage that has been absent in many of the stories that profiled Theranos and Elizabeth Holmes in recent years.

An example is a commentary posted on October 15 by Matthew Herper, Senior Editor for Pharma & Healthcare at *Forbes*. He interviewed Holmes during her appearance at a conference in Philadelphia the previous week.

Herper reported that, when he asked Holmes about those criticizing Theranos, she replied that it was laboratory companies "which she says are seeding the press with negative stories about her." She stated, "To be clear, the commentary in the press is 100% instigated by the lab industry and it showed up in the press about us last year and it's just been repeated. What I would say is that we're the only lab company that is really focused on transparency."

In his commentary at *Forbes.com*, Herper wrote, "...Holmes and Theranos need to stop blaming every question that's asked them on a conspiracy. Of course their competitors say bad things about them. That's what competitors do. But how many Theranos tests are conducted using Edison? How does accuracy compare to other tests? What, praytell, is factually inaccurate and erroneous in the Journal story? These are fair questions, and deserve a better answer than simply that Theranos has submitted 130 tests to the FDA (reminder: only one is approved) and that it is under attack from the laboratory industry."

He continued, "Great companies aren't paranoid about their competitors. They're paranoid about their products, and they know that if they did everything right, their competitors can't touch them. It's time for Theranos to provide some answers. Holmes is scheduled to be interviewed at the Forbes Healthcare Summit on December 3, but I, for one, would like some factual responses sooner than that."

CMS spokeswoman declined to comment to the *WSJ*.

- A **Walgreens** official declined comment on these issues, referring the reporter to Theranos.
- The journal called a Walgreens store in Phoenix and "a blood-drawing technician at a Walgreens in the Phoenix area, reached by phone late Thursday, said Theranos had 'temporarily suspended' finger-prick draws and was only drawing blood from patients' arms with needles at that store."

The same day as publication of this second WSJ story, Theranos released another public statement. It said: "As we continue with our transition to all FDA-cleared or approved tests, we are now operating only under full FDA quality standards and systems. It's the right choice and the highest standard. And as of this exact moment, that means temporarily using a different tube—tubes for venous blood—so we can maintain the quality standards we have in our labs as we complete the clearance process on the Nanotainer. Still smaller tubes, smaller samples, lower costs. So right now we are taking samples, transporting them, and running the tests. That is an FDA-cleared process. That is our process."

Interview At WSJ Conference

Five days later, on October 21, Elizabeth Holmes answered questions from a senior editor at the journal during the **WSJD Live** global technology conference in

Laguna Beach, California. The next day, the journal published a third article, based on the interview, highlighting these key points:

- Holmes stated Theranos is now in a "pause period" while it works for clearance from the FDA for its proprietary diagnostic technology.
- Holmes confirmed the "unannounced" inspection by the FDA in August, as reported by the journal.
- Holmes confirmed Theranos is using the finger stick collection and Nanotainer device only for the single FDA-cleared HSV-1 test. Theranos took this step following the FDA inspection in August. It is using venipuncture to collect specimens for all other lab tests.
- Holmes acknowledged Theranos currently uses an alternative process for proficiency testing, as allowed per federal regulations.
- Holmes asserted Theranos never diluted the Nanotainer-sized specimens to allow testing on its conventional lab analyzers.

Theranos Statement

On the day following this conference, Theranos issued another public statement. In part, it said, "We are confident in the reliability of our tests, because we comprehensively validate the accuracy of every test we run. In addition, we are the only laboratory that has committed to submitting all of our laboratory-developed tests, including our technology, procedures, and methods, to FDA for review and clearance. FDA has already cleared one of those tests, including our underlying test systems and Nanotainer tubes, for use in detecting the herpes simplex virus (HSV-1). The decision summary, which describes the rigorous science behind the clearance, is available online."

The most recent development in the story involving Theranos and *The Wall Street Journal* came on October 23. On that day, the WSJ published information about the **Walgreens Boots Alliance Inc.** relationship with Theranos. The key points described in this story were:

- The previous day, executives from Walgreens Boots Alliance Inc. met with senior Theranos staff in Palo Alto, California.
- A Walgreens official said the company would open no additional Theranos Wellness Centers in its stores until questions about the company's diagnostic technology are "resolved." Also, there are "no concrete plans at this stage" to expand the partnership with Theranos.
- Walgreens executives were unaware—until publication of the WSJ stories—that Theranos had not been using finger stick collections and nanotainer-sized specimens for 239 of its lab tests and that only the FDA-cleared HSV-1 lab test involved this collection method and specimen.
- The Walgreens' board of directors created a team to examine the "scientific and legal questions raised by the two journal articles."
- A person familiar with the matter told the journal that Walgreens has an equity stake in Theranos.

The following day, Theranos General Counsel Heather King responded to the journal's coverage of Theranos and Walgreens. She stated, "Walgreens is our business partner and we meet with them regularly. We would not comment on ongoing discussions with any business partner, of course. Our partnership with Walgreens has been a positive one, realized through our program in Arizona, and we are continuing to work with them on future opportunities and arrangements."

More News Coverage

Using recent news coverage as a gauge, it appears that, going forward, Theranos will probably get more scrutiny from journalists and investors alike. TDR

Lab Professionals Knew Of Challenges at Theranos

THE DARK REPORT was first to report news of issues with Therano's diagnostic technology

CEO SUMMARY: For most of the past year, pathologists and medical laboratory professionals in the San Francisco and Phoenix markets were aware that Theranos was not delivering to patients and consumers the specific lab testing services it regularly touted in news stories and at conferences. Another sign was that, as of July 2014, it was known that Blue Cross Blue Shield of Arizona was including Theranos as a network lab provider, but not for lab tests using a capillary specimen collected by finger stick.

THERE ARE FEW SECRETS in the clinical laboratory testing industry. For that reason, much information unavailable to Wall Street analysts and venture capitalists about how **Theranos** was performing in the clinical marketplace has been known to a surprisingly large number of pathologists, lab executives, and medical lab professionals.

This is true both in the San Francisco Bay Area and the Phoenix metro. In each region, Theranos has operated Theranos Wellness Centers in **Walgreens** pharmacies. At the same time, it is hiring phlebotomists and medical technologists who have spent decades working in labs in these communities and continue to have friends in these labs.

Add to this the regular flow of secret shoppers sent by labs into the Theranos Wellness Centers in Walgreens. These individuals often undergo parallel lab testing. That is, they have blood drawn at Theranos and at their clinical lab during the same window of time. Thus, when the lab test results from Theranos are received, they can be compared to the results produced by that secret shopper's clinical laboratory.

Another reason why this source of market research into Theranos is significant is that the clinical pathologists, clinical chemists and medical technologists at these other labs understand the different causes of failures to produce an accurate lab test result. They know how specific types of failures in specimen collection, specimen transport, specimen preparation and specimen analysis might cause the lab test results to be inaccurate.

Assessing The Evidence

Thus, it was no mystery to lab professionals, particularly in Phoenix, that Theranos was struggling with its proprietary lab test technology. The results of parallel lab testing on the labs' secret shoppers were evidence of that.

Further, labs were being told by client physicians who had referred patients to Theranos that they were seeing instances where the lab test results produced by Theranos raised questions, given the patient's history and/or repeat of the same lab tests by a CLIA-certified medical lab in the community.

Essentially, Theranos was, and is, being "tested" and watched daily by a highly-efficient intelligence network. Labs in the same community have a regular source of information that, in important ways, cannot be matched by journalists and financial analysts who may also be researching Theranos.

It was this intelligence network of labs and physicians that was tapped by THE DARK REPORT earlier this year. In April, we were first to report that patients visiting the Theranos Wellness Centers in Walgreens in Phoenix were not getting finger stick draws. Instead, nearly all patients were being drawn by venipuncture, using conventional Vacutainer blood collection tubes. THE DARK REPORT submitted a list of questions about these issues to Theranos in advance of publishing this story, but Theranos did not respond. *(See TDR, April 20, 2015 and Dark Daily, May 4, 2015.)*

Health Insurer's Decision

Another confirmation of this situation was made public this summer. On July 8, Angela Gonzales, Senior Reporter at the *Phoenix Business Journal*, wrote a story titled, "Will insurers cover the new FDA-approved Theranos blood test?" This was a follow-up to the announcement by Theranos of FDA clearance for its Herpes Simplex 1 test.

In her story, Gonzales wrote, "**Blue Cross and Blue Shield of Arizona Inc.** already includes Theranos in its network, but does not cover the single-drop blood test because there isn't enough research to support it, said Andrea Parsons, spokeswoman for BCBS. 'We review our medical guidelines on a regular basis to accommodate new evidence and practices,' she said. 'There are a number of considerations we take into account, in addition to the FDA's approval, such as clinical effectiveness and impact on health outcomes.'"

THE DARK REPORT has asked BCBS of Arizona to make a medical director available to discuss the insurer's decision not to cover any clinical laboratory tests Theranos performs using a finger stick and capillary blood specimen, but the health insurer has not responded to these requests.

The fact that the BCBS of Arizona spokeswoman specifically indicated that the insurer would not reimburse Theranos for any of its lab tests that are capillary blood specimens collected by finger stick needs to be given credibility. It is reasonable to assume that medical expertise at the health insurer had concerns with the data that Theranos provided about these proprietary lab tests.

The point here is that Theranos is being evaluated in a myriad of ways and by a variety of individuals and healthcare organizations. This is happening every day that Theranos serves a patient or a consumer and interacts with physicians and other providers.

Thus, the series of stories about Theranos published by *The Wall Street Journal* this month could turn out to be a defining moment for the lab testing company. If Theranos was to pursue greater transparency about the progress it is making to generate accurate, reliable, and reproducible clinical lab test results with its proprietary diagnostic technology, and if it was to engage in a more open exchange with pathologists and clinical chemists at other labs, at lab scientific meetings, and in peer-reviewed journals, then it might find it much easier to gain acceptance across the clinical lab testing industry.

Benefits Of Transparency

Certainly it is true that **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** are considered competitors by most lab organizations. At the same, their pathologists and lab professionals are accepted and continue to have productive scientific collaborations with their peers at competing labs. The same could be true for Theranos. If this happened, then the winners would be patients who would benefit much sooner from all the advantages Theranos says it can deliver. TDR

New DAT Law, Competition Heat Up Phoenix Market

One lab serving price-sensitive patients says Theranos' ultra-low test prices are tough to match

CEO SUMMARY: In Arizona, Theranos supported a new state law this year that allows patients to order lab tests without a doctor's order. Since the law took effect, that law and the ultra-low prices offered by Theranos are drawing away some cash-paying customers from one lab company that has operated in Phoenix for 26 years. It is still too early to gauge whether Theranos is grabbing market share from other labs in the Phoenix area and whether it can to build market share by promoting extremely low pricing.

TWO FACTORS ARE HEATING UP the clinical laboratory market in Arizona. One factor is the new law allowing consumers to order any clinical laboratory test and the other is **Theranos**, the new lab company.

Last year, Theranos launched operations in Arizona. It now has phlebotomists in 41 locations, mostly in Phoenix **Walgreens** stores. *(See TDR, April 20, 2015.)*

On July 3, the new state law, "Laboratory Testing Without Order," became effective. This law allows consumers to order any clinical lab test without a physician's order. Before the new direct-access testing law went into effect, Arizona had a law allowing patients to order only 25 basic screening lab tests without a physician's order.

Theranos advocated the new law's introduction. When Gov. Doug Ducey signed the bill into law, he did so at the new Theranos laboratory in Scottsdale. During the signing ceremony, Ducey stood with the bill's sponsor, state Rep. Heather Carter (R-Cave Creek), other lawmakers, and Theranos CEO Elizabeth Holmes.

The law's supporters say it empowers consumers by letting them order their own tests without having to wait for a physician visit. It also protects physicians and other health care providers from legal liability because physicians do not need to interpret results of tests they do not order.

One disadvantage of the new law is that if any specimen has to be sent to a reference lab in any other state, the laws in that state may prevent these tests from being processed because there is no physician authorization with the referral.

Both the arrival of Theranos and the new DAT laws have stirred up the lab testing marketplace. For example, since the law went into effect, **LabXpress**, a company that caters to walk-in customers and thus now competes directly with Theranos, has lost more than 50% of its cash business volume, stated LabXpress President Scott Farrell.

Farrell had hoped to see an increase in volume when more patients sought lab tests because of the new DAT law.

"However," he noted, "we have not seen any increase in test volume as a result of this law. In fact, we've actually seen a decrease of more than 50%.

Price-Sensitive Patients

"After the Affordable Care Act became effective in 2014, LabXpress had an increase in lab test orders," stated Farrell. "This was because, in part, we serve patients who are price sensitive and the ACA health plans have high deductibles that patients must pay.

"That did not happen with the new Arizona DAT law," he continued. "Since it took effect in July, our lab test orders dropped off sharply."

For LabXpress, the entry of Theranos has made it difficult to compete on price. Theranos says its prices are 50% lower than those of Medicare and it posts those prices online. LabXpress also posts its prices online but they are not as low as those of Theranos.

"It is impossible for any lab that operates patient service centers, pays for couriers, operates a modern lab facility, and maintains an information system to recover the cost of testing by charging just half of Medicare," noted Farrell.

Getting Lawmakers' Support

The drop in lab test orders came from walk-in customers and from orders from physicians' offices, said Farrell. "Many patients are sensitive to price today," he stated. "Walk-in patients and those who come to LabXpress from doctors' offices are particularly concerned about the price of tests.

"Since our founding in 1989, we've had not only walk-in customers, but also patients referred to us by our physician clients," explained Farrell. "We have sales people calling on the doctors' offices and those doctors have been sending us lab test orders for years.

"Our sales reps tell us the doctors say, 'We're sending our lab test orders to Theranos now because they are much lower in price than you are,'" noted Farrell. "These are patients who pay cash and may also have high deductibles.

"In the past, doctors didn't care about the price of lab tests, but they do now because their patients care about price," he added. "If patients can't pay, then they can't get tested and doctors care about that. For years, our doctors sent lab tests to us because we were the low-cost provider, competing almost exclusively against **LabCorp** and **Quest Diagnostics**.

"In fact, we introduced the concept of discount laboratory testing in 1989 and we introduced direct access testing in Arizona which was eventually copied nationally," said Farrell.

Quality Is a Tough Sell

"For all those years, we dominated in this market for cash-paying patients," Farrell added. "But we're no longer the lowest-priced lab and so now we will compete on quality and personal service of lab testing such as providing same-day results on the majority of lab tests.

"The problem with trying to promote quality lab testing is that cash-paying patients assume testing is a commodity product and all quality is the same," he said. "They expect the results are accurate and equivalent regardless of price.

"But now we're hearing from some doctors that patients, when using some low-price labs, are getting results that are out of line," Farrell said. "That's why we are emphasizing to doctors that patients need to know the quality of their lab testing."

LabXpress has about 50 employees, most of whom work in the clinical lab in downtown Phoenix. LabXpress also has six patient service centers in the Phoenix area, one in Tucson, and one in Prescott Valley. The company does several million lab tests per year. **TDR**

—Joseph Burns

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Labs React with Criticism To Proposed ADLT Rule

Medicare officials seem prepared to interpret and implement PAMA in an unexpected manner

CEO SUMMARY: Some in the lab industry had high hopes that passage of the Protecting Access to Medicare Act (PAMA) last year would favorably resolve a number of important issues. However, those hopes were dashed following the September 25 release by CMS of a proposed rule setting out how it will collect market test prices and how it will price a certain class of new lab tests that it now calls Advanced Diagnostic Laboratory Tests (ADLTs). Lab experts were quick to point out serious concerns.

When CMS released its proposed rule for market reporting of lab test prices last month, it contained unwelcome language to describe how it would define certain new tests that CMS calls advanced diagnostic laboratory tests (ADLTs).

In general, lab industry associations and lab test companies found much to criticize about how CMS is proposing to define what it calls multianalyte assays with algorithmic analyses (MAAA) codes or ADLTs, establish coverage guidelines, and set prices for such tests.

The federal **Centers for Medicare & Medicare Services** issued the proposed rule on September 25 in order to implement two sections of the Protecting Access to Medicare Act (PAMA).

One section is the requirement that labs submit market price data during early 2016, which CMS will use to set prices for the Part B Clinical Laboratory Fee Schedule in 2017. The lab industry reaction to this part of the proposed rule was presented in the last issue of The Dark Report. *(See TDR, October 5, 2015.)*

The other section of PAMA directed CMS to establish a procedure for handling certain types of new lab tests that companies are ready to introduce into the clinical market. The intent of Congress was to establish a defined process that CMS would use to evaluate these new lab tests and set prices.

ADLT Definitions

In its announcement about the proposed rule, CMS said, "An ADLT is a laboratory test that is covered under Medicare Part B and that is offered and furnished only by a single laboratory, not sold for use by a laboratory other than the original developing laboratory (or a successor owner), and that meets at least one of the following criteria:

- "the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
- "the test is cleared or approved by the **Food and Drug Administration** (FDA);
- "the test meets other similar criteria established by the secretary."

These criteria were defined by Congress in the PAMA legislation. What concerns the clinical lab industry is that CMS is creating additional criteria that seem to go beyond the intent of the PAMA language.

In addition, CMS proposes that an ADLT must be a molecular pathology analysis of multiple biomarkers of DNA or RNA; that it must yield a result when combined with an empirically derived algorithm that predicts the probability a patient will develop a certain condition or respond to a particular therapy; that it must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests and it may include other assays.

ADLT Definition Questioned

CMS also proposed that the test must be novel. "For clinical laboratories, this definition raises a lot of questions and deep concerns," stated Rina Wolf, Vice President of Commercialization Strategies, Consulting and Industry Affairs for **Xifin**, a health economics optimization company for labs in San Diego.

"The definition also requires that the test provides results that are not available from any other test. What if one lab has a test it developed and then another lab develops a similar test?" she asked. "Which of those tests would then be granted (or keep) ADLT status? Is it the one that was the first to be commercialized, the second one, or neither? The language of the proposed rule is not clear about this issue.

"Also, what does it mean to say 'as defined by the secretary?' she asked. "That could mean anything."

In addition to concerns about this definition of ADLTs, clinical lab directors questioned a recommendation in the proposed Clinical Laboratory Fee Schedule (CLFS) for 2016 to slash what it will pay for ADLTs. CMS released its proposed CLFS on the same day it issued the proposal to implement the regulations under PAMA.

The **American Clinical Laboratory Association** said that, if CMS implements its proposed deep cuts to the prices of the nine codes for ADLTs that CMS currently covers, this would hamstring physicians' ability to determine the best course of treatment for patients.

ACLA said that if these proposed cuts of 33% to 91% were approved in the final CLFS rule, it would conflict with CMS' precedent for letting its Medicare Administrative Contractors set rates for these tests. *(See related story about **CareDx** and its ADLT on pages 14-16.)*

"This proposed rate-setting methodology is inconsistent with the vast majority of stakeholder input and the recommendations of CMS' own Advisory Panel on Clinical Diagnostic Laboratory Tests," ACLA wrote.

ACLA President Alan Mertz stated, "Slashing payment of these tests—of as much as 90%—will have a profound impact on the success we've achieved thus far, thanks to life-saving diagnostic discoveries. These highly-advanced diagnostics tests are on the cutting edge of science and guide physicians as they treat several conditions afflicting hundreds of thousands of Americans, including heart disease, cancer, and rheumatoid arthritis."

Watch Out for Crosswalks

"CMS has made a preliminary pricing decision to use a crosswalk system to set payment rates for these tests," explained Mertz, "while clinical labs prefer the gapfill method that the MACs use to set rates."

"Congress had reasons to require CMS to assemble a PAMA Advisory Panel. Yet CMS officials seem determined to go their own way," observed Wolf. "When the advisory panel first met in August, CMS began the meeting by stating that the panel was only to advise and that its recommendations would have no more weight than comments from anyone else." TDR

—Joseph Burns

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CMS Creates 'Advanced Diagnostic Lab Tests,' Then Slashes 2016 Prices for ADLTs by Up to 91%

ON THE DAY CMS ISSUED ITS PROPOSED RULE to implement PAMA, the agency also released a proposed Clinical Laboratory Fee Schedule (CLFS) for 2016.

In this proposal, CMS recommends slashing what it pays for a set of nine ADLT codes by 33% to 91% off what Medicare Administrative Contractors currently pay for these assays. Labs have special concerns about this ADLT policy because the PAMA statute defined these tests and provided specific price concessions for when they entered the market.

Each ADLT is basically a multianalyte assay with algorithmic analyses or MAAAs, commented Bruce Quinn, MD, PhD, an expert in Medicare policy and health care reimbursement with **FaegreBD Consulting**. He noted that, in its proposed rule, CMS inserted a novel requirement for ADLTs that was not in PAMA itself, requiring labs to provide new clinical information for such tests that cannot be provided by other tests or test combinations on the market.

"The statute defines ADLTs basically as sole source MAAA tests, and there is no platform for CMS to create novel sides of the definition," wrote Quinn in a blog post. "Further, I would argue that, from a policy perspective, it is counterproductive. No one would ever be incentivized to bring out an ADLT in the same general field (Mammaprint versus Oncotype) because the second test would be so disadvantaged nobody would ever create it and invest in it, while the privileges for the first test go on forever.

"Even bringing out an improved test version by the same lab might meet the general ADLT definition but not the special CMS novelty test. Bad idea," continued Quinn. "I think that CMS was concerned about longstanding algorithms of common use not being ADLTs, but this is the wrong way to do it."

Quinn pointed out additional problems with CMS' definition of ADLTs. "PAMA says that an ADLT is a test of DNA, RNA, or protein biomarkers combined with an algorithm into a single patient-specific result," he wrote. "CMS says that this means that the MAAA (ADLT) must contain DNA or RNA. What? If you state, 'Measurement of A, B, or C' is required, it doesn't mean that, if you measure A or B it is OK, and if you measure C instead it is wrong. It means you can measure A, or B, or C, or any two, or all three. CMS completely lost me in this bit of rulemaking as it interpreted the statute into regulation."

Julie Khani, Senior Vice President for the American Clinical Laboratory Association, agreed. "When you look at the definition of an ADLT, the PAMA legislation is quite clear. It sets out specific criteria that an ADLT must be an analysis of multiple biomarkers for DNA, RNA, or protein biomarkers or it must be cleared or approved by the FDA or specified by the secretary of Health and Human Services," she said. "But in the proposal, CMS left off the part of the definition referring to protein biomarkers. This is a very serious oversight and given the specificity of the PAMA statute, there is no rational explanation for this exclusion."

Attorney Charles C. Dunham IV of **Epstein Becker Green** explained in a client alert that PAMA defines an ADLT as a test offered and furnished only by a single laboratory and the proposed rule defines that as not sold for use by a lab entity other than the original developing lab entity (or a successor). But CMS proposes that an entity with multiple CLIA certificates associated with multiple testing locations would not satisfy the definition of a single laboratory, he added. Therefore, as proposed, if the applicant cannot meet the single laboratory definition, the test would not be eligible for ADLT status, even if the test met all other ADLT criteria, he wrote.

"Moreover, under this proposed definition of a single laboratory, the test would not be eligible for ADLT status if a referring lab billed for a test performed by the original developing lab entity as a reference lab. In this case, [CMS proposes] more than one lab entity would be engaged in the testing activities and [would thus be] required to report applicable information related to the test," noted Dunham.

New ADLT Payment Rate May Force Lab to Close

➤California lab company has clinical trial results, yet faces steep Medicare price cut of almost 80%

➤➤CEO SUMMARY: Four Medicare Administrative Contractors currently pay $2,821 for CareDx's AlloMap test. But under the proposal that CMS issued last month to overhaul the clinical lab fee schedule, CareDx would get only $644. Such a steep price cut would put the lab out of business because the payment would be lower than the cost of doing the test, the lab's CEO explained. Heart transplant patients on Medicare would be denied a non-invasive blood test and instead would be treated with an invasive surgical procedure. Also, closing the lab would put 100 employees out of work.

HEART TRANSPLANT PROGRAMS are at risk of losing access to a clinical laboratory test used in about half of the nation's 2,500 heart transplants each year if CMS moves forward with a preliminary pricing determination for the 2016 Clinical Lab Fee Schedule (CLFS).

CareDx, Inc., of Brisbane, California, said the federal **Centers for Medicare & Medicaid Services** recommends cutting what it pays for its FDA-cleared AlloMap test by 77% under the proposal CMS issued September 25. If the rule is implemented as written, the fee schedule will go into effect January 1, 2016. CareDx said it will be forced to close if CMS approves the proposed price next month.

In an interview with THE DARK REPORT, CareDx CEO Peter Maag, PhD, said the company has annual revenue of $27 million to $28 million, but is not yet profitable. Until last year, the company was supported by venture capital. In July 2014, CareDx had an initial public offering that raised $40 million at $10 per share. On October 22, the stock was trading at $4.50 per share, down from $6.80 on September 24.

"AlloMap is used to determine the risk that a transplant patient will reject a new organ," stated Maag. "Transplant centers use our test about 12,000 times each year.

"Among the 130 heart transplant centers in the United States, 110 use the AlloMap test," he added. "That's because it's noninvasive, less stressful, and more affordable than the alternative, which requires an invasive surgical biopsy."

➤Deep Lab Test Price Cuts

The 130-page proposal CMS issued last month describe Medicare's plan to overhaul the CLFS as PAMA requires. CMS intends to establish a market-based system to set clinical lab fees. This new approach will cut what CMS pays labs by $360 million in 2017 and $5 billion over 10 years. CMS's annual budget for Part B CLFS payments is $8 billion. *(See TDR, October 5, 2015.)*

There are many contentious issues in CMS's proposal rule. One section of the rule would make severe cuts of 33% to

91% to nine codes for advanced diagnostic laboratory tests (ADLTs), including AlloMap. *(See pages 11-13.)*

"Currently, four Medicare Administrative Contractors pay $2,821 for the test," noted Maag. "However, under CMS' proposal, CareDx would get only $644.

"That amount would put us out of business because the payment would be lower than the cost of performing the test," he explained. "Should CareDx cease operations, transplant patients would be forced to use the more invasive and stressful biopsy procedure. Using a biopsy to test these patients could cost Medicare significantly more than it pays for AlloMap."

At issue is how Medicare officials priced the test. CMS used the crosswalk method, which involves analyzing what CMS charges for tests that have similar steps and for which a lab uses similar resources. Some lab directors have criticized the crosswalk method, saying it does not reflect the actual steps and resources a lab must use to run tests. What's more, CMS crosswalked AlloMap to a colorectal cancer screening test that looks at a single gene. AlloMap is a complete test that analyzes 20 genes to determine risk of heart transplant rejection.

Labs Favor Gapfill

The other way to set lab test prices is to use the gapfill method. This method is to be used when, as is the case with AlloMap, there is no comparable test existing on the CLFS. With gapfill, officials evaluate charges, payments, and discounts for the test in question; the resources required to perform the test; what other payers pay for the test; and what resources labs use for comparable tests.

CMS recently convened the Advisory Panel on Clinical Diagnostic Laboratory Tests. This panel represents clinical labs and makes recommendations to CMS on pricing and other PAMA implementation issues.

After the panel's first meeting in August, CMS did not follow the panel's recommendations to gapfill the ADLTs, Maag said. On October 19, the panel held its second meeting, and Maag presented data showing the flaws in the crosswalk method.

The panel voted unanimously to reject the CMS proposal to use the crosswalk method for AlloMap and the other eight ADLTs because there are no comparable tests available on the CLFS, Maag said. CMS is not expected to announce a decision until it issues the final Medicare clinical lab fee schedule in late November.

Rejected Recommendation

"The October 19 meeting was the second one in which the panel recommended CMS use the gapfill method," noted Maag. "The first time, CMS rejected the recommendation."

Analyst Amanda Murphy of **William Blair & Co.**, agreed with Maag, writing in an advisory to clients, "For most of the [lab test] codes being priced in 2016, the panel [again] unanimously recommended against CMS' recent preliminary determination to crosswalk new multianalyte assays with algorithmic analyses (MAAA) codes being priced for 2016 (including **Veracyte's** Afirma assay and **Genomic Health's** Oncotype DX test for colon cancer).

"In many cases, CMS did not appear to incorporate the panel's recommendations when it published preliminary determinations for how codes proposed for 2016 should be priced; therefore, it continues to be unclear how much authority the panel has," added Murphy. "Some panel members suggested that crosswalking to existing CPT codes that represent different technical tests shows that CMS' crosswalk proposals do not make sense."

In addition to hearing Maag's comments, the panel also heard from representatives of **Genomic Health** and **Veracyte,** and discussed the definition of ADLTs under PAMA.

"For the past 10 years, this test has made an important contribution to patient care," commented Maag. "There is no substitute. Plus, AlloMap is a precision

Lab Company's CEO Explains Reasons to Use Gapfill Over Crosswalk to Establish ADLT Prices

FOR ONE LAB CEO, a plan to slash prices for Advanced Diagnostic Laboratory Tests (ADLTs) by as much as 77% defies logic.

Peter Maag, PhD, is the President and CEO of CareDx, a molecular testing laboratory in Brisbane, California, that markets AlloMap, a gene-expression profiling test. Physicians use AlloMap to stratify patients for organ-rejection risk following transplantation. The FDA-cleared test has been shown in a randomized controlled trial to be as effective as the conventional biopsy method of risk assessment, said Maag.

Results of the trial were published in 2010 in the *New England Journal of Medicine* (Gene-Expression Profiling for Rejection Surveillance after Cardiac Transplantation, N Engl J Med 2010; 362:1890-1900).

AlloMap looks for the presence of donor derived cell-free DNA in the bloodstream for patients who have had solid organ transplants. CareDx also is developing a test that will be useful for all transplant patients.

On September 25, the federal Centers for Medicare & Medicaid Services proposed to pay CareDx $644 for the test instead of the current $2,821. Since then, Maag has said the company will need to close, putting 100 employees out of work and depriving half of the 2,500 patients who get heart transplants every year the opportunity to have a non-invasive test rather than an invasive biopsy test.

About 40% of transplant patients are on Medicare. Thus, CareDx bills Medicare's administrative contractors directly.

AlloMap is one of nine advanced diagnostic laboratory tests (ADLTs) that CMS designated for deep price cuts of 33% to 91% when it proposed overhauling the clinical laboratory fee schedule last month. Currently, four MACs pay CareDx the full $2,821. Yet, CMS used the crosswalk method to set a price of $644.

"When setting the new, proposed prices for the nine ADLTs, CMS used the crosswalk method," noted Maag. "CMS officials chose a test that they said was closest to AlloMap. But they overlooked the fact that there is no test comparable to AlloMap on the clinical laboratory fee schedule. Comparing AlloMap to the other test is incorrect because the other test is not as complex or as useful as AlloMap."

The gapfill method would have been a more accurate way to price AlloMap, he added. "Gapfill uses the existing price that the four contractors pay. CMS would simply need to survey the MACs, identify which ones are paying for the test and what prices each is using. Once that was done, CMS would see that four MACs cover AlloMap at $2,821."

When Maag presented to the Advisory Panel on Clinical Diagnostic Laboratory Tests, which advises CMS on pricing issues under PAMA, he observed how, when CMS officials fail to understand the complexity and clinical value of these assays, the price-setting process CMS uses can go awry.

"On the staff level at CMS, there appears to be a lack of understanding about ADLTs," he said. "They seem to think that a lab test is simply a number of analytes plus an algorithm," he observed. "But the advisory panel points out that these assays are highly-studied, evidence-based, outcomes-changing diagnostics. They are not simply analytes plus an algorithm. These are highly-sophisticated diagnostic tools that inform precision care and help physicians achieve significantly better patient outcomes while reducing the overall cost of care."

medicine tool that gives data to physicians that improves decisions on how to treat heart transplant patients.

"Precision medicine is the future of healthcare," he continued. "Yet, our lab company, with ample clinical data to support this lab test, is at risk of going out of business if CMS implements this proposed rule as written." **TDR**

—Joseph Burns

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NeoGenomics to Acquire Clarient for $275 Million

Annual revenue at NeoGenomics will more than double once this transaction is closed

CEO SUMMARY: In a surprise move that further consolidates national anatomic pathology services, NeoGenomics will acquire Clarient, Inc., from General Electric Healthcare. General Electric is getting cash, and preferred and common stock. The two companies announced plans to pursue integrated diagnostic services that would combine lab testing and diagnostic imaging data. The deal is subject to antitrust review and approval from NeoGenomics' shareholders and is expected to close by the end of the year.

LAST WEEK, **NeoGenomics, Inc.,** announced that it would acquire **Clarient, Inc.,** a unit of **GE Healthcare's Life Sciences** business, for $275.2 million. Included in the sale is Clarient's subsidiary, **Clarient Diagnostic Services, Inc.**, which provides cancer diagnostic tests to hospitals, physicians, and pharmaceutical companies.

This is an unexpected consolidation among molecular diagnostic testing companies. To pay for the acquisition, NeoGenomics will use a mix of $80 million of cash, 14.7 million shares of preferred stock at $7.50 per share, and 15 million shares of common stock. In addition to common stock representing 19.8% of NeoGenomics, GE also has preferred stock that, if fully converted, would give it 32.9% ownership of NeoGenomics, the companies said.

The pending acquisition is subject to regulators' and shareholders' approval. The transaction is expected to close by year-end. Clarient has 415 employees working in Aliso Viejo, California, and Houston, Texas.

The acquisition will more than double NeoGenomics' revenue. Last year, Clarient had revenue of $127 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of about $13 million. In 2014, NeoGenomics reported revenue of $87 million and adjusted EBITDA of $9.2 million.

Five Years and $312 Million

Five years ago this month, GE Healthcare, a division of **General Electric Co.**, paid $587 million to acquire Clarient. At that time, it said that it intended to combine molecular diagnostic technologies in anatomic pathology with its molecular imaging technologies in radiology.

Five years after the acquisition, GE now is, in essence, recognizing that the value of Clarient is lower by $312 million. In an email to clients, Amanda Murphy, an analyst with **William Blair & Co.,** estimated that the price NeoGenomics will pay suggests a multiple of 2.1 times revenue, "which is quite reasonable for a lab in this space."

Yet in 2010, GE paid about 5.3 times revenue to acquire Clarient. "By historic measures, this is a premium price for a pathology testing laboratory," wrote *Dark Daily* on October 22, 2010. At the time, GE Healthcare President and CEO John Dineen said GE could, "build a $1 billion plus business by developing integrated diagnostic solutions for cancer and other diseases." Clearly, GE was unable to generate such revenue from its vision of integrated diagnostics.

Acquisition Seen as Good Fit

Yet NeoGeonomics CEO Douglas VanOort is bullish on the deal, viewing the acquisition as a good fit involving two companies with complementary assets. Annual revenue at NeoGenomics will more than double to about $240 million to $250 million and adjusted EBITDA will more than triple to $33 million to $38 million, next year, he said in a press release.

"Of all the possible acquisition candidates we have reviewed, Clarient is by far the best fit for NeoGenomics," noted VanOort. "NeoGenomics has been talking with GE about acquiring Clarient for more than one year."

Acquiring Clarient will allow NeoGenomics to offer more cancer diagnostic tests to hospitals and physicians across the country. It will also accelerate its movement into pharmaceutical trials and research. Additionally, the two companies will collaborate on new bioinformatics that take advantage of each company's interest in precision oncology with the goal of developing new products that combine genomic and imaging data, the companies said.

Integrated Diagnostics

Murphy agreed, writing, "Clarient and NeoGenomics are highly complementary businesses, bringing together strengths in tech-only hematopathology and molecular assays as well solid tumor/IHC testing and digital pathology. Thus, we view this as a good deal with a number of areas to drive synergies. The combination provides robust East and West Coast presences, a low-cost testing position in all testing paradigms, a combined clinical trials business of $25 million, and GE as a significant long-term investor," she added.

"We're expecting the prices overall for our collective mix of business to increase slightly in part because of changes CMS is proposing for the physician fee schedule for 2016," VanOort said. "CMS increased the proposed FISH reimbursement rates to correct an error in the rates for 2015 and that will have a positive impact on the mix of business that we each have. There is a slight offset to that because the proposed rates for flow cytometry are expected to decline significantly."

In addition, the acquisition gives NeoGenomics broader coverage of markets nationwide. "Both Clarient and NeoGenomics are national companies and have significant footprints across the country," he said. "In geographic areas where we currently don't provide as much access, the combined companies will provide a greater coverage across all of the United States.

Managed Care Opportunities

"That expanded geographic coverage has benefits for managed care organizations, particularly the national ones that want to make sure that a single lab will cover all of their clinicians and hospital providers," emphasized VanOort. "Additionally, hospitals and pathology groups also want one-stop diagnostic services.

"With the complexity increasing for many types of cancers, it's a benefit for a pathology group or a hospital to have a single lab that can handle these diagnostic services, rather than sending specimans to multiple labs and having to manage that administrative burden," he concluded. "Sole-source lab testing services continues to be a core part of our strategy." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Describing "nutritional chemistry and food safety as an exciting growth opportunity," CEO David King of **Laboratory Corporation of America** announced his company's recent acquisition of **International Food Network and The National Food Laboratory**. Terms of the deal were not announced. Some analysts considered this to be a small diversification play by LabCorp as a response to tougher times in the clinical lab testing marketplace.

CALLOWAY LABS CEASES OPERATIONS

One of the first lab casualties in the coming decline of the toxicology and pain management sector is **Calloway Labs** of Woburn, Massachusetts. On October 16, it ceased testing and went out of business. In early 2012, the toxicology lab had entered into a $20 million agreement to settle state charges that it defrauded Medicaid with a kickback scheme that included sham companies, fake doctor signatures, and excessive urine tests for drug addicts. Later in 2012, Calloway Labs was acquired by **Ampersand Capital Partners**. Ampersand then hired Gail Marcus, formerly CEO of **Caris Diagnostics** to be the new CEO of Calloway Labs and turn the business around. Executives at Calloway would only tell reporters that the lab company closed due to "unforeseen circumstances beyond the company's control."

MORE ON: *Calloway*

Calloway was caught in a sweep of toxicology lab companies in Massachusetts that was initiated by then-Attorney General Martha Ann Coakley. Between 2007 and 2012, she prosecuted at least seven toxicology lab companies for Medicaid fraud, including Calloway Labs. It was in October 2012 that CEO Arthur Levitan and COO Patrick Cavanaugh of Calloway Labs pled guilty to criminal charges of Medicaid fraud and were sentenced to four years of probation.

TRANSITIONS

Empire Genomics of Buffalo, New York, named John J. Rushton, PhD, as its new Chief Operating Officer. He has held management positions at **PAML**, **Signature Genetics**, and **University of New Mexico Health Sciences Center**.

- Effective January 1, 2015, Eyas Hattab, MD, will become the new Chair of the Department of Pathology and Laboratory Medicine at the **Louisville School of Medicine** in Louisville, Kentucky. Hattab formerly held the position of Vice Chair of Pathology at **Indiana University School of Medicine**.

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DARK DAILY UPDATE

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...how, after years of EHR adoption, interoperability has not been achieved. To that end, Congress is passing laws to require EHR vendors to reduce the barriers to interoperability. That would make it easier, cheaper, and faster for labs to create LIS-to-EHR interfaces with their client physicians.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 16, 2015.