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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

Why Theranos Is a Big Test for CMS and CLIA

OFFICIALS AT THE FEDERAL CENTERS FOR MEDICARE & MEDICAID SERVICES are at what may be the most important crossroads in the history of clinical laboratory regulation since Congress passed the CLIA 1988 legislation. Will CMS pursue the severe sanctions it disclosed to **Theranos, Inc.**, and force the lab to close? Or will it soften its position as a result of negotiations underway with the clinical lab company in Palo Alto, Calif.?

Some clinical pathologists say, "Given the findings of 'serious deficiencies that could 'cause immediate patient harm,' CMS must revoke the CLIA license and close the lab." Others believe CMS won't act decisively, saying, "CMS will never close Theranos due to bureaucratic indecision and politics."

CMS put itself in this position as a result of how it interprets and implements the language of CLIA 88. At the inception of CLIA, CMS officials argued that if all lab deficiencies—major and minor—were made public, they could not run an effective inspection and compliance program. Thus, CMS has kept hidden from Congress, the American public, and the press all the regular inspection reports of the nation's medical laboratories.

Of equal significance, CMS has also hidden the less-than-stellar performance of the private organizations granted deeming status to inspect and accredit labs for compliance with CLIA 88. Last year, Ellen Gabler, an investigative reporter for the *Milwaukee Journal Sentinel,* explained the problem in an article, "Weak oversight allows lab failures to put patients at risk." Published May 17, 2015, the article explains the little-known weaknesses in the nation's anemic clinical laboratory oversight system.

Why is it, in recent years, that CMS has pulled the licenses of well-run, highly respected clinical labs for the inadvertent referral of proficiency testing (PT) specimens? Yet, for any other CLIA violation, it has imposed minor slaps to the wrists of offending lab organizations. It is a fact that respected labs do go off the rails and their problems will often go undiscovered for years by their accrediting bodies and CLIA assessors. The lab problems in 2004 at **Maryland General Hospital** are a prime example.

Theranos asserts it has complied with CLIA and not exposed patients to harm. The CMS inspection report is persuasive evidence to the contrary. Now, the question is: Will CMS do what's right on behalf of the American public? TDR

Walgreens Tells Theranos: 'Lab Deal Is Terminated'

Yesterday, Walgreens issued a press release announcing 'immediate end' to Theranos contract

***BREAKING NEWS:** As this issue of THE DARK REPORT went to press, it was learned that, last night, Walgreens had announced the termination of its lab testing agreement with Theranos, effective immediately. Theranos loses access to about 40 Walgreens pharmacies in Phoenix and is left with about five patient collection centers. The following story summarizes developments involving Theranos through Friday, June, 10. It was prepared before Walgreens disclosed its decision to end its agreement with Theranos*

EVENTS OF THE PAST THREE WEEKS have brought more bad news to **Theranos, Inc.**, the lab testing company based in Palo Alto, California.

Of greatest interest to the laboratory medicine profession was the disclosure by Theranos that it had voided two years of lab test results. On May 18, reporter John Carreyrou of *The Wall Street Journal* wrote, "Theranos Inc. has told federal health regulators that the company voided two years of results from its Edison blood-testing devices, according to a person familiar with the matter."

Two weeks later, on June 1, *Forbes* published a story declaring that it had revised its estimate of the net worth of Elizabeth Holmes, the Founder and CEO of Theranos. It said, "Last year, Elizabeth Holmes topped the *Forbes* list of America's Richest Self-Made Women with a net worth of $4.5 billion. Today, *Forbes* is lowering our estimate of her net worth to nothing. Theranos had no comment."

Even as these events were hitting the national news, several media outlets reported that Theranos is now the defendant in at least three class action lawsuits. One of these suits also names **Walgreens** as a defendant because the pharmacy company had allowed Theranos to use its retail pharmacies in California and Arizona to collect lab specimens from patients and consumers.

These new developments come on top of the media stories reported in April and May about how the federal **Centers for Medicare & Medicaid Services** had sent a letter to Theranos announcing its intent

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to impose the most severe sanctions for violations of CLIA, that the **Department of Justice** was investigating Theranos, and that the **Securities and Exchange Commission** had launched its own probe of the lab testing company.

Voiding Two Years Of Results

The disclosure that Theranos was voiding two years of lab test results, some of which were performed on its proprietary Edison analyzer, was a major blow to the company's representations to the public in recent years that its lab testing services were of the highest quality.

In its reporting on this story, *Bloomberg* spoke with Theranos Vice President of Communications, Brooke Buchanan. *Bloomberg* said, "Less than 1% of the blood test results Theranos Inc. has provided have either been voided or corrected, according to the company, which last month said it was canceling or altering tens of thousands of results, including two years of results on some of the company's proprietary machines."

Bloomberg also wrote, "The revisions were made out of what spokeswoman Brooke Buchanan said was an abundance of caution. In response to questions from *Bloomberg*, the Silicon Valley startup said it has informed all patients who were affected. ...The decision to void some results was made because previous tests weren't up to the standards of Theranos's current lab managers, Buchanan said. ...Theranos doesn't plan to send more corrections, and stands behind the other 99% of results, said Buchanan."

Three Class Action Lawsuits

About the class action lawsuits against Theranos, *Bloomberg* quoted Theranos, "'The lawsuits filed against Theranos are without merit and the company will vigorously defend itself against these claims,' Buchanan said in a statement."

As has been true since last October, it was *The Wall Street Journal* which first broke the story about Theranos notifying patients and physicians about problems with their lab test results.

How big is the notification effort? The journal said, "The company has told the Centers for Medicare and Medicaid Services that it has issued tens of thousands of corrected blood-test reports to doctors and patients, voiding some results and revising others, according to the person familiar with the matter."

Notably, the inaccurate tests may not be limited to tests run on the Edison analyzer, but may include assays run on conventional lab test equipment. The journal wrote, "The corrected reports include the voided Edison results and many tests run on traditional laboratory machines, the person said."

The journal also reported that the CMS inspection report of Theranos had noted that the Theranos lab in Newark performed 890,000 tests per year. Another news account reported that Theranos has performed about 6 million lab tests in total.

How Many Tests Voided?

A ballpark guess for the number of patients receiving a notice of an inaccurate lab test report can be developed along these lines. Assume an average of two tests per patient and the two-year period of 2014 and 2015. That would indicate 1.78 million tests, divided by two, or 890,000 patients. If 1% of that number were sent notices, that would be 8,900 patients.

Taking the larger number of six million tests, 1% of half that number would be 30,000 patients getting notices. In either case, this is a significant number of patients affected by inaccurate lab test reports issued by Theranos.

Of significance for lab professionals, media stories indicate that Theranos produced inaccurate lab test results even on conventional lab analyzers. In its reporting of this issue, *Bloomberg* wrote that "the corrected reports include the

Director Adam McKay to Make Movie about Theranos With Jennifer Lawrence to Play Elizabeth Holmes

IT WAS A BIG STORY LAST WEEK WHEN NEWS BROKE THAT A MOVIE ABOUT THERANOS WAS IN THE WORKS. *People Magazine* and *Time* were among the media outlets that reported the story. The director will be Adam McKay, recognized for such movies as "The Big Short" and "Anchorman."

And who will play Elizabeth Holmes, the Founder and CEO of Theranos? It is expected to be Jennifer Lawrence. She is known to the American public for her roles in the "Hunger Games" series, as well as "American Hustle" and "X-Men." No information was provided as to a date when production of the movie would commence.

What Do You Think?

Can Jennifer Lawrence pull off a portrayal of Theranos CEO Elizabeth Holmes? You be the Judge!

Elizabeth Holmes
(photo copyright TedTalks)

Jennifer Lawrence
(photo copyright Vanity Fair)

voided Edison results and many tests run on traditional laboratory machines, the person said."

At this time, it is believed that only the Theranos lab facility in Scottsdale, Arizona, is doing patient testing. News reports say that the Scottsdale lab uses conventional lab analyzers for its testing.

Probably the next major development in the Theranos story will happen on August 1. That's when Theranos CEO Holmes is scheduled to present scientific data and answer questions from the audience at a session during the **American Association of Clinical Chemistry's** annual meeting in Philadelphia. **TDR**

Quest to Manage Six Labs at HCA HealthONE Hospitals

In Denver, Quest has agreement to manage inpatient labs for HealthONE, a division of HCA

CEO SUMMARY: For decades, hospitals were reluctant to allow any outside lab company to run their inpatient lab operations because they preferred to maintain control over quality results and turnaround times. That attitude may be changing as health systems face increasing margin compression by moving to value-based reimbursement models and taking on more risk-based contracts. Hospitals usually don't make much of a margin on inpatient testing. That makes partnering with an outside manager more attractive.

FOR ALMOST THREE DECADES, the one segment of clinical lab testing that the public lab companies could not crack was managing hospital inpatient testing. Now comes news from Denver of an inpatient lab testing deal that may presage more such agreements between hospitals and public lab companies.

Earlier this month, **Quest Diagnostics Incorporated** announced that it had an agreement with the **HealthONE System**, a division of **HCA Healthcare**, to manage the inpatient laboratory operations of six of HealthONE's eight Denver-area hospitals. In a joint statement, Quest and HealthONE said that the agreement was designed to enhance the quality and value of diagnostic services and to improve efficiency of laboratory operations.

Historically, hospitals and health systems have been reluctant to turn over control and management of their inpatient laboratories to an outside entity, particularly such lab companies as Quest Diagnostics and **Laboratory Corporation of America**. The fact that Quest and LabCorp were strong competitors for the same outreach business that hospitals coveted for themselves was also a factor in why these types of deals rarely happened.

However, healthcare's ongoing transformation may be causing hospital and health system administrators to rethink the role of their clinical laboratories in the strategies of their institutions. If this is true, then the laboratory industry may see more hospitals willing to agree to have a public lab company manage their inpatient laboratories.

Hospital Lab Joint Ventures

One lab executive who has extensive experience in developing joint ventures involving hospitals and commercial lab companies is Noel Maring, who, since 2012, has been Vice President of Hospital Affiliations at **Sonic Healthcare USA**, based in Austin, Texas.

Previously, during his 17 years working for **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington, as Senior Vice President and Chief Marketing Officer for PAML, Maring developed a growth strategy that emphasized joint ventures with hospitals and lab companies across the West.

That included starting a lab outreach joint venture in Denver involving PAML and 12 hospital labs owned by **Centura Health**. Known as **Colorado Laboratory Services**, it was launched in 2010 and operates today. *(See TDR, September 13, 2010.)*

"It is too early to say that the Quest-HealthONE agreement in Denver is an early sign of a new trend," said Maring. "These types of deals have been done for a number of years, but only on a sporadic basis.

Start Of A Trend?

"On the other hand, even if it is too early to say we are on the start of a trend, this deal is evidence that some hospital CEOs are exploring ways to get more leverage from their clinical laboratory assets," affirmed Maring. "It is consistent with what we see in the marketplace. Over the past 12 months, a number of hospitals have approached Sonic to explore different options with their outreach lab business and their inpatient lab business.

"This is a definite change because, in the past, hospitals were always sensitive about allowing an outside lab company to run their inpatient lab operations for them," observed Maring.

"Hospital CEOs wanted to maintain control of inpatient lab operations to ensure that they were delivering timely, high-quality results and good customer service to their physicians on staff at the hospital," he added. "It was outside their comfort zone to think about giving a lab company management control over a key service line such as their laboratory.

"But that is changing as healthcare's transformation creates new care delivery models and new payment methodologies," stated Maring. "Now hospitals are willing to discuss every aspect of laboratory testing. That includes whether to bring in a partner to run the inpatient lab operations and whether they should consolidate all lab operations into one core lab that runs the inpatient and outreach testing activities.

Quest to Manage Six Labs At HealthONE Hospitals

EARLIER THIS MONTH, Denver's largest healthcare system, HealthONE, selected Quest Diagnostics Incorporated to manage the inpatient lab testing operations at six of its eight hospitals.

HealthONE is a division of HCA Healthcare. It has more than 10,000 staff in the metropolitan Denver area. Quest Diagnostics will operate the labs in these six facilities:

- **The Medical Center of Aurora**
- **North Suburban Medical Center**
- **Presbyterian/St. Luke's Medical Center**
- **Rose Medical Center**
- **Sky Ridge Medical Center**
- **Swedish Medical Center**

The other two facilities do not have inpatient labs, a HealthONE spokeswoman said. Financial terms were not disclosed.

Some employees in the HealthONE labs will transfer to Quest Diagnostics. The remaining HealthONE lab employees will continue to be employed at HealthONE, said Stephanie Sullivan, a HealthONE spokeswoman.

"Hospital administrators also recognize that they are being asked to take on greater financial risk with patients," explained Maring. "It is why they've built or acquired other hospitals, ambulatory surgery centers, imaging companies, and other facilities in an effort to create integrated delivery networks and better manage a patient's total health needs.

"Now that they've spent six years or more developing this network, they have the time to look at lab operations and develop a strategic direction for their labs," he said.

"All this time, clinical laboratories were almost entirely left out of the mix," observed Maring. "But today, hospitals and health systems are looking hard at their laboratory operations in order to make strategic decisions in two or three areas.

"First, hospitals are trying to decide whether to be in the lab outreach business at all," he said. "Second, they want to have their labs benchmarked and then have those labs become as efficient as they can be.

"Third, as health systems have bought more hospitals in certain regions, they've tried to centralize their lab operations for more efficiency," added Maring. "This consolidation of lab testing across multiple hospitals creates opportunities to add to the lab test menu and realize further economies of scale for their lab operations.

Two New Market Forces

"While hospitals and health systems were getting bigger through acquisitions, they were also experiencing two market forces that now drive their business decisions," he stated. "Both factors affect hospital lab revenue and those factors are compelling hospitals to take additional steps to succeed in their growth strategies.

"The first market factor is a change in reimbursement for lab tests," continued Maring.

"For several years, reimbursement for outreach lab testing has been quite lucrative for hospitals. As long as tests were paid for under the hospital fee schedule, the lab generated strong revenues," he said. "But now there is plenty of evidence to indicate that the days of exceptionally high outreach laboratory reimbursement are numbered for hospitals. As we move to value-based reimbursement, with bundled payments or risk sharing arrangements, lower lab reimbursements will affect health system margins.

"Even if a hospital lab still operates on fee-for-schedule reimbursement for some contracts, the revenue hospitals will receive in the future will be lower than it was compared with what the lab generated for its parent hospital just a few years ago," he said.

"From their lab outreach business alone, some hospitals have enjoyed payment that has been in the range of 150% to 200% of Medicare. That's great, of course, but those days are ending," added Maring. "There is plenty of evidence that, in the future, payment for lab outreach testing will be, at best, equal to what Medicare pays and will probably be significantly less than Medicare fees.

"The second market factor is the risk that hospitals must assume as they operate under new models of care delivery such as accountable care organizations," emphasized Maring. "In these arrangements, labs in hospitals become cost centers.

"When a hospital gets paid under a risk model such as capitation, labs and every other department are no longer generating revenue. They all become cost centers, which means they all have to operate at peak efficiency.

"Some larger health systems have their own insurance plans," he said. "When that happens, every department becomes a cost center because, as an insurance company, the hospital is paying itself.

"As more hospitals take on risk contracts to deliver patient care, we see them responding in two ways," Maring noted. "First, hospitals are looking closely at the value of their outreach lab operations. That value may be at its peak right about now.

Forecast: Lower Revenue

"Second, over the past nine months, a number of hospitals have sent out requests for proposals (RFPs)," he added. "They want to know whether Sonic Healthcare is interested in buying or partnering with them on their laboratory outreach business. There's more of this activity now than I've seen in many years.

"At the same time, as Sonic Healthcare gets these RFPs, then I must assume that Quest Diagnostics and LabCorp are getting the same requests," observed Maring.

TDR

—Joseph Burns

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Health System CEOs Now Ask Three Questions About Operating or Selling Their Laboratories

WHEN IT COMES TO LABS, "Hospital administrators have three basic questions they want answered," stated Noel Maring, Vice President of Hospital Affiliations at Sonic Healthcare. "One, is our lab cost effective?

"Two, can we use our outreach lab operations to generate operating cash in a value-based reimbursement environment?" he said. "Three, should we sell our outreach lab and use those funds to reinvest in areas that are more strategic for our health system?

"I expect that, if hospitals have not already asked those questions, they will be asking them about all aspects of the lab business, including the inpatient lab business," he predicted. "That seems to be what HCA has done with HealthONE. But HCA is not alone in looking at labs strategically.

Sell Lab Or Partner?

"The second and greater trend for hospitals right now involves their outreach business," he added. "Hospitals want to know if they should get out of that business. They also want to know if they should sell or partner with someone to run that business.

"And if they partner with a lab company such as Quest or LabCorp or Sonic, will they let that company run the inpatient lab operations too?" he asked. "We're talking with several hospitals that are currently considering these questions.

"To understand how hospital systems will approach the issue of lab management, you have to think of these health systems as falling into three categories," advised Maring. "First, there will be large systems that have made significant investments in streamlining their lab operations and will continue to operate clinical laboratories for inpatients, outpatients, and outreach. **Northwell Health** in New York (formerly **North Shore Long Island Jewish**) is a good example of a large system that will most likely retain its lab operations.

"Northwell invested heavily in its lab in recent years," he noted. "It built a core lab and moved from hospital billing fee schedules to commercial lab fee schedules to retain managed care contracts. They are big and have enough employed physicians so that it makes sense for them to stay in the lab business.

"Second are health systems that are medium-sized or small and that are considering their options for their labs," he continued. "At a minimum, they ask if they should sell their outreach business. If the answer is no, will they be able to maintain the margins they've had?

"Typically, these health systems perform inpatient testing and let's assume they do some modest lab outreach of about $10 million per year," he stated. "The contribution margins from those outreach lab programs are often in the 30% or higher range because they billed using the hospital fee schedule mentioned earlier. The margins have been high because the hospitals already need to operate their labs on a 24/7 schedule to support inpatient testing needs. Thus, for a modest lab outreach program, the marginal costs are relatively low.

"The problem for these mid-sized hospitals is that patients are complaining about the high out-of-pocket costs for lab testing," he noted. "Thus, that high cost of outreach lab testing to patients is becoming a source of concern for hospital administrators.

Lab Economies Of Scale

"The third group is comprised of hospitals that recognize that, either because of competition in their regional market or because of the difficulty of achieving the needed economies of scale in their lab, it makes sense to work with a partner," noted Maring. "That could include finding a partner to manage their inpatient lab operations, as Quest Diagnostics is doing for HealthONE in Denver."

Quest Makes Second Deal For Inpatient Lab Volume

➤Agreement in Denver comes just months after similar deal with Barnabas Health in New Jersey

➤➤CEO SUMMARY: For the second time since December, Quest Diagnostics Incorporated has landed a contract to manage inpatient clinical lab testing for a large hospital system. Late last year, Quest announced an agreement to manage inpatient clinical lab testing in seven hospitals of Barnabas Health, the largest nonprofit health system in New Jersey. Last month, Quest made a similar arrangement with HealthONE in Denver. The puzzling aspect of each deal: Why no discussion about lab outreach work?

NEWS OF A HOSPITAL INPATIENT LAB MANAGEMENT AGREEMENT between **HealthONE** of Denver and **Quest Diagnostics Incorporated** marks the second time in six months that the public lab company has earned an inpatient lab management pact with a multi-hospital health system.

There are two aspects of this development that make it newsworthy for lab administrators and pathologists throughout the United States. First, two such agreements in six months is evidence that Quest Diagnostics may now have an attractive value proposition that encourages hospital CEOs to consider allowing an outside lab company to manage their hospital inpatient testing activities.

Second, doing hospital inpatient lab management contracts is believed to be one strategy that Quest hopes to use as a way to replace specimen volume that it has lost in recent years. In fact, replacing lost specimen volume in the Denver market is one key to understanding this new pact between HealthONE and Quest. That's the belief of Noel Maring, Vice President of Hospital Affiliations at **Sonic Healthcare USA**.

Maring handles negotiations with hospitals and health systems for Sonic Healthcare. He is aware of the RFPs and expressions of interest concerning inpatient and outpatient laboratory options that hospital CEOs have issued to major lab companies. There are signs Quest is focusing on similar hospital lab management deals, indicating that the nation's second largest lab company is pursuing inpatient testing aggressively.

➤Agreement With Barnabas

The first of these two deals came in December, when Quest announced an agreement to manage inpatient clinical lab testing in seven hospitals owned by Barnabas Health, the largest nonprofit health system in New Jersey.

Under the agreement with Barnabas, Quest did not acquire the outreach lab business in those seven hospitals. Among those seven facilities are two of the largest hospitals in the state: **Newark Beth Israel** and **Saint Barnabas**. The other five hospi-

tals are **Monmouth Medical Center**, Long Branch; **Monmouth Medical Center Southern Campus**, Lakewood; **Jersey City Medical Center**, Jersey City; **Community Medical Center**, Toms River; and **Clara Maass Medical Center**, Belleville.

From Inpatient to Outreach

In Denver, Quest could use its agreement to manage the inpatient lab test volume for the HealthONE System as a stepping stone to do the outreach work as well. In either case, Maring noted that Quest will welcome the additional lab test volume from the HealthONE agreement.

"Denver has been a tough market for Quest," Maring noted. "Several events caused Quest Diagnostics to lose a considerable amount of market share from that marketplace in recent years. Both **Laboratory Corporation of America** and **Colorado Laboratory Services (CLS), PAML's** partnership with **Centura Health**, picked up key managed care contracts in Denver and those gains were Quest's loss."

Lost managed care contracts are an important element in the Denver story. "Everyone knows that in 2007, LabCorp signed an exclusive national contract with **UnitedHealthcare**, and that deal was costly to Quest in Denver and other markets," observed Maring. "But LabCorp also picked up a second managed care contract from Quest in the Denver market from **Anthem Blue Cross Blue Shield of Colorado**. The Anthem contract was not an exclusive deal because CLS also took some of that work, but, again, it was a loss of specimens and revenue for Quest.

Two Managed Care Contracts

"Those two key managed care contracts represented a lot of volume, which was a big issue for Quest because it has a sizeable regional lab facility in that market," he added. "One of the benefits of this deal with HealthONE is that it allows Quest to sustain enough specimen volume to maintain a local presence in the Denver marketplace.

"It's significant that Quest Diagnostics has a major lab facility in Denver because—to support inpatient lab operations—Quest can move less time-sensitive inpatient tests out of the hospitals into what should be a more efficient core laboratory operation," he commented. "When a local lab facility is located within 45 minutes to an hour in travel time, that lab can be used to pull testing out of the hospital laboratories.

"But that is not the full story behind this inpatient lab management agreement," continued Maring. "Even if Quest didn't have a lab there in Denver, there is still an opportunity for it to improve efficiency in HealthONE's hospital labs.

Consolidation Of Testing

"I'm sure the HealthONE labs are run relatively efficiently because HealthONE is part of HCA, which runs tight operations in all of its facilities," he stated. "On the other hand, if HealthONE has not fully consolidated lab testing into one of its larger hospital labs, then a fair amount of duplication of tests among those six hospitals would still exist. By centralizing some testing in a core laboratory Quest would have an opportunity to reduce lab testing costs.

"But increased efficiency is only part of the opportunity that this agreement represents for Quest Diagnostics," added Maring. "As mentioned earlier, once an outside lab gets a management contract for inpatient testing, it's in a strong position with that health system to get other associated business as well.

"That was PAML's experience in its many laboratory partnerships with hospitals," he stated. "There is no guarantee that the outside lab company will get additional lab testing volume, but such an agreement is an opportunity to become involved in the lab outreach business in addition to doing the inpatient testing.

"If the outreach work is coming from employed or affiliated physicians, for example, then the case can be made that the lab can produce all test results from inpatient and outreach, thus creating a full patient record," he commented. "That means all patients would have the same test methodologies, reference ranges, and the same content for patient profiles.

Reducing Inpatient Costs

"That level of consistency is becoming more and more important today," he said. This is particularly true if the health system wants to leverage lab data to reduce other inpatient or total health costs."

Having noted the advantages to an outside lab company that holds an agreement to manage a hospital's inpatient testing, Maring pointed out an odd aspect to the two inpatient testing agreements that Quest Diagnostics has announced during the past six months.

"The lack of access to the hospitals' lab outreach business is a surprising element of the deal that Quest announced with Barnabas last December," noted Maring. "At the time, Quest said only that it would manage the inpatient testing. By itself, that's a sizeable contract. However, no outreach lab business was associated with it.

"Now the same thing seems to be happening in Denver," he added. "That's puzzling because, historically, managing hospital inpatient labs produces lower profit margins than the profits generated by a hospital's lab outreach business.

Lower Lab Test Margins

"Inpatient lab margins are lower due to the need for 24/7 operations and on-demand testing that limit batching and economies of scale," Maring added. "That said, inpatient testing contracts can still be profitable for commercial lab companies, just not as profitable as the lab outreach business."

Asked to explain why outreach testing probably was not part of the two Quest inpatient lab management agreements, Maring speculated as to what might be true in each market.

"In New Jersey, it could be that Quest Diagnostics already had much of the Barnabas Health outreach work," Maring added. "After all, Quest has its huge lab facility in Teterboro, N.J., that may have allowed it to capture that outreach testing from physician offices around the Barnabas hospitals over the years.

"But Denver is different because LabCorp and Colorado Laboratory Services have significant portions of the outreach business from the HealthONE hospitals," he observed. "We can assume that Quest was unable to tie the outreach business to the contract because HealthONE did not have an active lab outreach program and could not commit outreach lab work (even from their employed physicians) that is performed by other laboratories.

Other Management Contracts

"This is probably not news to Quest Diagnostics because the word on the street is that they have more than 60 management arrangements with hospitals around the country," he added. "It is also known that Quest has about 20 people working full-time to develop agreements to manage hospital inpatient testing.

"I've seen estimates that hospital labs do about 50% to 55% of the nation's total inpatient and outreach lab volume," Maring concluded. "If that's true, then it's a significant untapped market for commercial laboratories, and it appears that Quest Diagnostics is devoting resources to gain market share in this sector."

If hospital CEOs are ready to attack costs in their labs, then proactive lab administrators and pathologists will want to proactively cut expenses so as to make it unnecessary for hospital administration to want to outsource the management of the inpatient labs. TDR

—Joseph Burns

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Lab Finds Payers Respond To Education on Test Utility

Commercial, public insurers also want information on analytical and clinical validity

CEO SUMMARY: In recent years, insurers have raised the bar and become much tougher when making coverage and reimbursement decisions for molecular assays, genomic, and genetic tests. Yet several lab testing companies are having good success at demonstrating the validity and clinical utility of their assays. Among them is Foundation Medicine, of Cambridge, Mass. In an exclusive interview, its president and COO shares several important lessons learned from winning favorable coverage decisions.

THREE YEARS AGO, after the introduction of new molecular CPT codes, genomic and genetic testing companies struggled to get paid. At the time, government and private payers saw the new codes as an opportunity to introduce tougher criteria when making coverage and payment decisions.

One consequence was that few labs got paid for their molecular test claims during the first four to five months of 2013. *(See TDRs, March 25 and April 15, 2013.)* Since then, it has been difficult for labs to get favorable pricing for new molecular and genetic tests.

Today, most clinical laboratories offering molecular genomic tests report that payment for these assays is less than ideal. A small number of lab companies say, however, that the slow, painstaking process of educating payers' medical directors about the value of such tests is working.

While labs pursue this educational process, medical directors for commercial and public payers have, in turn, required laboratories to demonstrate the clinical utility of their lab tests.

One example of a lab finding some success is **Foundation Medicine Inc.**, in Cambridge, Mass. In a first-quarter conference call with stock analysts last month, CFO Jason Ryan reported that increased test volume boosted total revenue for the quarter to $30.4 million, a 58% increase over the $19.3 million recorded in the same period last year.

Test Volume Boosts Revenue

"During the first quarter we reported 8,985 clinical tests, a 14% increase over the same period last year and an 8% increase from Q4," noted Ryan. "Reported tests included 7,957 FoundationOne tests and 1,028 FoundationOne Heme tests. The average reimbursement per clinical test recognized in revenue was approximately $3,100, down slightly from the $3,200 in Q4."

Just last fall, one published report showed Foundation was, "hampered by a lack of coverage decisions from Medicare and no contracts with most commercial payers, resulting in payment delays and tens of thousands of unpaid tests."

The question now is whether the first quarter numbers represent a turnaround. CEO Michael Pellini, MD, told financial analysts that what distinguishes Foundation Medicine (FMI) from other companies offering genomic-based testing is the clinical validation it provides to payers and providers. Demonstrating clinical utility may in fact be the key to long-term success for FMI and other genomic testing companies.

Validated Assays

FMI's assays are "highly validated," Pellini said during the earnings call. "In the first 12 weeks of 2016 alone, we published nine manuscripts in high-quality peer-reviewed journals and delivered 41 podium presentations and posters at various medical and scientific meetings," he added.

In an interview with THE DARK REPORT, FMI President and COO Steve Kafka said efforts to establish relationships with payers have produced notable successes. This year, FMI started testing members of **Horizon Blue Cross Blue Shield of New Jersey**, and recently agreed to do so for members of **UnitedHealthcare**, the nation's largest health insurer.

"Since 2012, we have worked with insurance companies and with the Medicare program to educate and provide the evidence they require to make coverage decisions," Kafka said. "One of the earliest coverage decisions was from **Priority Health** in 2014. Since then, we've had a number of other regional plans initiate contracts or coverage decisions with us."

Financial Effect Of Testing

On January 1, FMI began collecting data for Horizon with Horizon's data partner, **COTA**, to establish the financial effect of testing Horizon members with FMI's FoundationOne test. Last fall, **Palmetto GBA**, a Medicare Administrative Contractor, said it would cover the FoundationOne test.

"UnitedHealthcare will cover tests for patients newly diagnosed with stage four non-small cell lung cancer," explained Kafka.

Chief among the lessons learned in obtaining favorable coverage decisions from payers is that it takes time and data to obtain such agreements.

"We call ourselves a 'molecular information company' because we believe our work is about more than running tests and delivering results," he added. "What we do is put information into the hands of decisionmakers, meaning physicians first and including the patient's insurer."

What steps are necessary to obtain positive coverage decisions? "There is no single playbook or a set of criteria to present to health insurers, but we do know there are three critical factors that every testing provider needs to show," answered Kafka. "First is analytical validity. Does your test actually do what you say it does?

"Second is clinical validity. Is there an actual clinical implication?" he continued. "The third critical factor is clinical utility: Is there a benefit that comes to patients as a result of this test?

Patient-Centric Approach

"In addition to these three criteria, the lab needs a patient-centric approach and that means partnering with payers to serve their patients," Kafka explained. "We've learned that the medical directors at health insurers are patient-centric. Thus, they are looking for partners—including labs—who are patient-centric as well.

"These are not adversarial relationships," commented Kafka. "They are the health insurer and we are the vendor bringing new solutions to cancer patients in ways that meet payers' needs. We do that with new diagnostic technology that has evolved along with our understanding of cancer as a disease.

"Over the past 10 years, we have come to understand that cancer is a disease of the genome," explained Kafka. "It is no

Key to Reimbursement for Molecular Genomic Tests Is to Document Clinical Utility and Educate Payers

FOR FOUNDATION MEDICINE, education is the key to getting health insurers to pay for comprehensive genomic profiling (CGP).

"With payers, we know we must make a significant investment in education to help them understand two issues," stated FMI President and COO Steve Kafka. "First, payers want to know how to distinguish a comprehensive approach from other testing modalities. Second, they want to know how we define quality and clinical utility for each genomic test.

"One way to define quality and utility is to never put physicians in the position of guessing what to test," he said. "Therefore, our comprehensive genomic profiling approach looks at the totality of the relevant cancer genome. We look across the known set of cancer-related genes, and that's a large number of genes. But it's more than reviewing large numbers of genes. It involves interrogating all classes of genomic alterations.

"When we say we 'interrogate' genes, that means looking across the entire coding region of each of the genes in question," added Kafka. "This enables us to identify all classes of genomic alterations known to be altered in cancer, and we sequence them at great depth to identify the actionable alterations, insertions and deletions, base substitutions, copy number alterations, and fusions.

"That's a bit technical, but the point is that comprehensive genomic profiling is not easy to do, especially compared with most other genetic testing," he said.

"For physicians, it means they can be confident that we've left no stone unturned for their patients," commented Kafka. "If there is a genomic alteration present regardless of the class; if it's an insertion or deletion or if it's a copy number alteration, for example; regardless of the class, we'll find it. And we do so with near 100% specificity and sensitivity.

"Also, it's important to note that we've shown this validity in our peer-reviewed publications and just last month, the U.S. Patent and Trademark Office issued FMI a patent for 'Optimization of Multigene Analysis of Tumor Samples,'" announced Kafka. "The patent covers the company's methods of analyzing a cancer patient's tissue or blood specimen to detect multiple classes of genomic alterations. Foundation Medicine has similar patent applications pending with the European Patent Office and other jurisdictions outside the United States."

longer considered a disease exclusively of a particular tissue of origin.

"For example, it's not just lung cancer, it's ALK-mutated lung cancer or it's EGFR+ lung cancer," he noted. "In fact, cancer is not a single disease. Actually, it's a collection of dozens—if not hundreds—of individual diseases. There cannot be a single guidebook for cancer because cancer is not a single disease.

"At the same time, it's impractical to do several hundred prospective studies of patients for every different kind of cancer," he observed. "Such studies would require hundreds of millions of dollars and would take a long time to complete. And, during the years of such studies, patients would not be benefitting from these genomic insights.

"What we have learned is that the business model for molecular lab tests needs to catch up with our knowledge of cancer biology," Kafka commented. "Or, put another way, how we pay for these tests needs to catch up with the science. That requires innovative thinkers such as those working at UnitedHealthcare and at Palmetto.

"Recently, Horizon Blue Cross also contracted with FMI for its comprehen-

sive genomic profiling (CGP) approach," Kafka said. "This is an approach that we pioneered to understand each patient's unique cancer.

Personalized Medicine Vision

"For health insurers and providers, this personalized medicine vision is still new," he said. "And, as with anything new, our lab needs to go through an educational process with payers, providers, and regulatory agencies. While it's new for them, it is not new for us. We've done this since Foundation Medicine was founded six years ago."

The clinical and business strategies of Foundation Medicine offer important insights to pathologists, lab executives, and venture capital investors. FMI provides evidence that it is possible to succeed when launching new proprietary genetic and genomic assays, but only if the lab understands how to meet the value propositions of the various stakeholders, including physicians, patients, and payers.

Evidence of Clinical Value

Of particular importance are the resources that Foundation Medicine is investing in clinical studies to demonstrate and document the accuracy of its assays and the clinical relevance of these assays when used in patient care. The publication of these studies in credible, peer-reviewed journals, along with presentations at scientific meetings is a cornerstone in FMI's strategy to gain acceptance for its proprietary tests.

That is the evidence physicians need in order to obtain better outcomes with their patients. It is the same evidence that health insurers require to make favorable coverage decisions and establish adequate reimbursement for these genomic and genetic tests. TDR

—Joseph Burns

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Working Closely with Payers Can Improve Patient Outcomes

DELIVERING VALUE TO HEALTH INSURERS is paying dividends for Foundation Medicine. How does this work for payers?

"A great example is our work with Horizon Blue Cross, which is a three-way partnership among us, Horizon, and COTA, an analytics firm," explained FMI President and COO Steve Kafka. "COTA provides a classification system that helps Horizon to understand the clinical profile of the patients who have the FoundationOne test. Horizon can now classify patients inclusive of their genomics and in a way that can drive actionable insights for their physicians. In turn, that has beneficial effects on cost and on delivering the best care for patients.

"Horizon pays for our comprehensive genomic profile upfront, then we work with COTA to track the clinical benefits over time," he explained. "Those benefits are survival and the economic implications of using that information to guide physicians' treatment decisions at the point of diagnosis of the lung cancer patient.

"The reason we started with lung cancer is that for us at Foundation Medicine and for the oncology community as a whole, lung cancer is a prevalent and problematic disease," Kafka explained. "There are about 200,000 cases of non-small cell lung cancer diagnosed annually, and these patients represent about 20% of the annual incidence of cancer.

"Working with such a large number of patients means we have a significant amount of insight into the biology of that cancer and the progress providers make from the therapeutic perspective," noted Kafka. "Along with growth in the number of cancer genes implicated in lung cancer, the portfolio of targeted medicines is increasing. This includes immunotherapy approaches that have been shown to be effective for these cancers. It's an area where we have knowledge, where doctors have tools for treating patients, and which benefits from the use of CGP."

Precision Medicine Update

Years of Biobank Experience Pay Off for Mayo Clinic Lab

$142M NIH grant will fund biospecimen collection from 1 million Americans to establish this biobank

THANKS TO 10 YEARS OF EXPERIENCE, an existing infrastructure for banking patient specimens, and the unique capabilities of its clinical laboratory organization, **Mayo Clinic** has been awarded a five-year, $142 million grant from the **National Institutes of Health**.

Last month, NIH announced this grant to Mayo Clinic. It will establish the world's largest research-cohort biobank for the Precision Medicine Initiative (PMI) Cohort Program. To further this longitudinal research study, Mayo will enroll at least 1 million Americans. Mayo will collect and store specimens and clinical data from the participants for researchers pursuing PMI projects.

This grant is part of the Precision Medicine Initiative that President Obama announced earlier this year.

"From each participant, Mayo will collect 35 samples and then store those samples in automated freezers in Rochester, Minn., and Jacksonville, Fla.," stated Mayo's Stephen N. Thibodeau, PhD, in an interview with THE DARK REPORT. "The collection of 35 million samples of blood and urine from 1 million patients will make it the largest biobank project anywhere in the world."

Thibodeau is Co-director of the **Mayo Clinic Center for Individualized Medicine Biorepositories** Program and a professor of laboratory medicine and pathology in Mayo's College of Medicine.

What helped Mayo win the grant funding is that the facilities in both locations have already been built and are now being prepared to store the specimens. "The facility in Rochester has already been in use for five years," noted Thibodeau. "In fact, Mayo has biobanked samples in one form or another for well over 100 years.

"Our different investigators are continually involved in a variety of projects," he said. "Thus, over time we've become increasingly sophisticated with our laboratory and biobanking ability. In addition to Rochester, we have existing biobank repositories in Arizona and Florida.

Labs And Biobanking

"About five years ago, Mayo started a major effort to consolidate the labs that were involved in biobanking," stated Thibodeau. "The goal was to centralize and automate the lab involved with biobanking and processing samples. At that time, Mayo constructed this new facility.

"At the start of this project, the idea was to create a state-of-the-art laboratory for specimens that Mayo clinicians would collect and use for research," he explained. "We knew that eventually we would be able to offer these biobanking capabilities to another organization as a commercial venture.

"In fact, at about the time that work on the biobanking facility was completed and the automation work had commenced, the NIH sent out an RFP," said Thibodeau. "With the building done and the automation ready, Mayo fulfilled the requirements of this NIH grant."

This summer, NIH will announce grants for a PMI Cohort Program Coordinating Center, a Participant Technologies Center, and a Healthcare Provider Organization Enrollment Center. To reach the goal of processing 1 million samples by 2021, Mayo needs to begin collecting specimens quickly.

To collect the specimens for the PMI Biobank, Mayo Clinic will harness the resources of **Mayo Medical Laboratories** (MML), which receives 35,000 to 40,000 specimens a day and performs 23 million tests annually. MML's nationwide network covers all 50 states and includes more than 300 couriers and logistics providers.

"We expect to be processing roughly 250,000 patients per year within the next 12 months so that much of the material will be available to investigators within the first couple of years," he commented.

"In addition to collecting patient samples, the Mayo laboratory organization will analyze the biospecimens with chemical and genetic tests," continued Thibodeau. "That data will be combined with other information that patients will provide on lifestyle and health questionnaires, medication history, electronic health records, physical exams, and environmental exposures. Also, we will collect physiology data tracked through mobile health technologies.

"Mayo plans to have all the procedures in place this summer," he predicted. "By October, a pilot process will be ready for some of the collections. At that point, we expect to be fully functional. It means Mayo will be collecting samples from the first 250,000 patients, certainly by about this time next year, which is the end of the first year of the grant.

"From each patient, we will derive 35 aliquots of different components from his or her blood and urine," added Thibodeau. "That will give us a total of 35 million tubes to store. We plan to store about 75% of the specimens in Rochester and the rest in Florida. To handle this work, we'll hire 20 to 30 individuals in the next 24 months.

"Another reason NIH looked favorably on our proposal is that Mayo has an existing automated freezer process in Rochester, along with multiple layers of redundancy," he continued. "For example, one requirement of the grant is to have off-site storage. That's why we will store about 25% of the specimens in the Florida biobank facility. In case something happens at one site, back-up samples will exist at the other site." TDR

—Joseph Burns

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Pharmacogenomic Work Was a Boost for Mayo

ONE BIOBANK PROJECT AT MAYO CLINIC that is similar to the work Mayo will do for NIH involves pharmacogenomics testing for patients. In the first phase of that project, John Logan Black, III, MD, Mayo's Co-Director, Personalized Genomics Laboratory in the Department of Laboratory Medicine and Pathology, is testing 1,000 patients. In phase two, Black and colleagues plan to test 10,000 patients. *(See TDR June 22, 2015.)*

"The patient population from which Dr. Black is recruiting is in the Mayo Clinic Biobank, one of the biobanks our group manages," said Stephen Thibodeau, PhD, Co-director of the Mayo Clinic Center for Individualized Medicine Biorepositories. "In the Mayo Clinic Biobank, we have collected samples and created a repository from more than 50,000 Mayo patients.

"That Mayo patient repository of samples from 50,000 patients is analogous to the federal government's Precision Medicine Initiative," he said. "The national repository of 1 million patients is similar to what we've done for 50,000 Mayo Clinic patients, and we have those samples in hand right now."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Life insurers are adopting healthcare big data as part of their underwriting process and clinical laboratory test data has an important role. **Quest Diagnostics Incorporated** participates in this business line. *Huffington Post* recently published a story on this topic and identified companies that life insurers use to access data about prescription drug histories and lab test results. **ExamOne** is a division of Quest Diagnostics and its "QuestCheck" service queries the clinical lab database of Quest to "give insurers results from doctor-ordered tests."

MORE ON: *Life Insurers*

Consumers may be surprised to learn the majority of life insurance companies use medical information from **MIB Group**, with more than half using prescription databases, lab results, and motor vehicle records. All of this big data feeds into algorithms that life insurers use to make underwriting decisions.

18 YEARS TO ISSUE IVD LABELING RULE

It took the Canadian regulatory agency **Health Canada** only 18 years to finalize its guidance for labeling *in vitro* diagnostic (IVD) devices. It was 1998 when it released the draft version. The final guidance, issued on April 22, includes new considerations for electronic labeling, IVDs with small containers, blood glucose monitors, and information on complying with Canada's Official Languages Act (which requires product labels to be written in both French and English). There are some lab managers who would like to see the FDA take this long to produce its final guidance on laboratory-developed tests!

TRANSITIONS

• George Jabboure Netto, MD, was selected to be the next chair of the Department of Pathology at the **University of Alabama-Birmingham's** School of Medicine, beginning on October 1. He has spent the majority of his career at **Johns Hopkins University**, starting in 2005.

• Elissa Passiment, EdM., CLS, long-time Executive Vice President of the **American Society for Clinical Laboratory Science**, retired this month. She will continue to act as a consultant on regulatory affairs. Prior to joining ASCLS in 1995, she worked with **McFaul & Lyons**.

• James Flanigan is the new Executive Vice President at ASCLS. He previously held positions at the **Society of Critical Care Medicne**, and **Phi Kappa Theta International Fraternity**, among other associations.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, July 5, 2016.