



From the Desk of R. Lewis Dark...

THE R. LEWIS DARK REPORT

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

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R. Lewis Dark
Founder & Publisher



Attention Pathologists: Change Is Coming!

IT'S BEEN A BUSY FOUR WEEKS for your editor at THE DARK REPORT. He has traveled to meetings, conducted site visits at a variety of large and small companies serving clinical labs and pathology groups, and even participated in strategic planning sessions for some labs and industry vendors.

I asked my colleague to tell me what he learned about the current state of the market for clinical lab and pathology testing services. Is the prognosis good or bad? "Too soon to tell!" he answered, explaining that his recent conversations with labs and industry vendors uncovered plenty of evidence to say that long-standing market forces are already in transition to a new competitive equilibrium. However, these changes represent as many positive opportunities for nimble lab organizations as they represent bad news.

Nearly every person he spoke with at industry meetings and in private conferences has a story to tell about some significant shift or disruption in their ongoing business activities. Vendors see lab customers becoming more cautious in the purchase of new analyzers. Lab informatics companies say that strong demand from labs for middleware solutions that provide real-time analytics to guide management decisions is fueling sales growth in this product category.

For clinical labs, a common experience is the change in the ownership of the physician groups that refer specimens to their laboratories. As doctors sell their medical practices to local hospitals and health systems, this change of ownership often leads to a decision to change lab providers; a change which often favors the laboratory of the hospital which acquired that physician practice.

In a similar fashion, local pathology groups often lose a long-time client and access to those specimens when those physicians sell their practice. This is happening at the same time that pathology groups are dealing with the reduction in reimbursement for a number of key pathology services, such as Medicare's decreased price for 88305-TC.

How are pathology groups dealing with these developments? Not easily, I am told. Our editor says that business advisors to pathologists tell about the quiet sales of some pathology groups to hospital buyers—converting those pathologists into employees. Rumors are circulating of pathology groups exploring Chapter 11 bankruptcy. If true, these are early flags to the pathology profession that major forces are at work reshaping the market for anatomic pathology services. **TDR**

Walgreens to Go National With Lab Tests in Stores

➤ Largest pharmacy chain in U.S. poised to become major player in medical lab testing

➤➤ **CEO SUMMARY:** *A disruptive innovation is one that shakes up an entire market or industry. By adding clinical lab testing to its health services offerings in more than 8,100 stores nationwide, Walgreens could disrupt the status quo in the clinical lab industry. Walgreens says its lab partner will offer testing at prices that are less than Medicare prices and it will post its prices publicly. Theranos is its partner in this effort, a firm introducing patented collection devices and test methodologies that require needlestick quantities of blood.*

STARTING THIS MONTH IN ITS STORE in downtown Palo Alto, California, Walgreens, the nation's largest pharmacy chain, starts on a path that may disrupt the clinical laboratory industry in several ways.

In partnership with **Theranos**, the new clinical laboratory company, Walgreens will make Theranos' comprehensive menu of clinical lab tests available in its Palo Alto store. This is the first step in Walgreens' plan to introduce this clinical lab testing service in more of its stores across the entire United States.

Inside these stores will be a Theranos Wellness Center, located near the pharmacy counter. Trained and certified phlebotomists will collect lab specimens from customers with a clinician order. Tests

will be processed in Theranos' CLIA-certified laboratory.

Both Walgreens and Theranos hope their pricing strategy will be disruptive enough to be a competitive advantage. Clinical laboratory tests performed on blood and other specimens will be priced to payers and consumers at 50% less than the Medicare Part B Clinical Laboratory Test Price Schedule.

The Theranos web site allows customers to see prices for medical laboratory tests. Theranos will electronically communicate results to the ordering clinician when they are available.

Another element of this agreement that Walgreens and Theranos hope will be disruptive is the use of patented diagnostic technologies that are different in two signifi-

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icant ways. First, in its press release about the partnership, the companies state that, for most lab tests, all that will be needed is a micro-sample from a finger-stick specimen, not a venipuncture. That is considered to be a patient-friendly benefit.

Another significant part of this partnership is that Theranos will use its patented technology to perform testing with a shorter turnaround time than is required by most conventional medical lab testing methodologies. (See related article, pages 6-9.)

Pathologists may be interested to learn that Walgreens has a strategic plan to become “America’s first choice for health and daily living.” It is huge, with sales in fiscal year 2012 of \$72 billion. Its 8,117 stores are located in all 50 states, the District of Columbia, and Puerto Rico.

It currently provides pharmacy, health and wellness services, and healthcare advice. It also provides respiratory services and retail, specialty, mail-order, and infusion pharmacy services. Now, its partnership with Theranos allows Walgreens to add clinical laboratory testing to the services available inside its stores.

Walgreens is a major player in the convenient care clinic business. Its subsidiary company, **Take Care Health Systems**, runs nearly 400 in-store health care clinics in 20 states and Washington, D.C., and also manages more than 370 worksite health and wellness centers.

► Six Million Customers Daily

“Every day, we have 6 million people in our stores, and many of them need laboratory testing in addition to other healthcare services,” said Richard Ashworth, Vice President, Corporate Operations, for Walgreens in Deerfield, Illinois. “Strategically, we expect to do well.”

Ashworth was willing to speak with THE DARK REPORT about the new partnership with Theranos. “The blood sample collection services that Theranos provides will give our customers access to high quality, less invasive, affordable lab testing serv-

ices,” stated Ashworth. “That’s the same level of service that our pharmacists provide in our stores and our nurse practitioners provide in our clinics. We want Walgreens to be known as a healthcare provider that offers unparalleled access to innovative, high quality affordable health services in our communities.”

► Proximity to CLIA Lab

The Walgreens store in Palo Alto is first to offer clinical laboratory testing because it is closest to the CLIA-certified lab that Theranos runs in the same town. After that, Walgreens wants to add lab testing services to its stores on a fast time frame.

“There is no definitive timetable but we both want to grow the lab test service quickly,” Ashworth explained. “At the moment, we are focused on getting the Palo Alto operation running properly in terms of patient experience and process.

“We are confident that the lab testing service will be running smoothly within a few weeks to a month or two,” observed Ashworth. “Then we will introduce it in other Walgreens locations.

“In our stores, Theranos has patient service centers and that is where the lab testing services will be located,” he added. “In this dedicated space, depending on state requirements, trained clinicians or certified phlebotomists will be completing the service.

“For example, in Palo Alto, Theranos will have state-certified trained phlebotomists,” noted Ashworth. “In other locations, as appropriate, we will staff state-certified individuals trained on Theranos’ collection methodologies.

“When it comes to medical lab testing, we believe this service will offer an improved patient experience because there will be no need for venipuncture,” he explained. “From the customer’s point of view, this part is very compelling.

“The method developed by Theranos to collect blood does not require a tourniquet nor does it need three to five vials of blood,”

said Ashworth. “It can accomplish the same clinical lab testing with just a few drops.

“This innovative technology is important for many reasons,” he said. “When you think about the patients who need laboratory testing, the list includes the frail elderly, children, or cancer patients.

“Neither patients nor providers want to do multiple draws—least of all for these patients,” Ashworth noted. “Among other reasons, it is because it can be challenging to find good veins. This technology helps us serve these populations specifically.

➤ **Benefiting Payers & Patients**

“The partnership has the potential to benefit payers and patients,” concluded Ashworth. “The advantages are significant. Theranos’ prices will be so much lower than everyone else’s and these prices will be easy to access because Theranos publishes its price list. These are all good things that help to make clinical lab testing services local and available to the masses.”

Walgreens’ partnership with Theranos is not its first foray into medical lab testing. Back in 2010, Walgreens announced that it would sell the genetic test kits manufactured by **Pathway Genomics** of San Diego, California, in its stores.

This arrangement would start with three genetic test kits: for drug response, pre-pregnancy planning, and health conditions. Walgreens was going to sell the saliva collection kit for between \$20 and \$30.

➤ **Genetic Information**

The consumer would then collect the specimen and send it to Pathway Genomics, paying from \$79 to \$179 for the individual genetic tests. These tests would provide information about the consumer’s risk of such conditions as Alzheimer’s or heart disease, and whether a parent could pass certain health problems along to children.

Following the news of this arrangement, the **U.S. Food and Drug Administration** (FDA) took swift action. It sent an enforcement letter to Pathway Genomics, giving it

Walgreens’ First Step: Assess Consumer Demand

WALGREENS RUNS 8,117 pharmacies in all 50 states. It also has a subsidiary that runs more than 770 health clinics in stores and at employer worksites. This raised the interesting question as to how many of its sites will serve as patient service centers for its clinical laboratory testing partner, Theranos Inc.

“Theranos patient service centers will certainly be located in stores that have our healthcare clinics, but I believe it also works in other Walgreens locations,” said Richard Ashworth, Walgreens’ Vice President of Operations. “With such a big demand for lab testing services, I believe there is room in the clinical laboratory testing marketplace for Walgreens.

“Since the announcement of our agreement, we are often asked how many Walgreens stores will have a Theranos presence,” noted Ashworth. “We don’t know that answer yet. We must first determine what demand there will be for clinical lab testing services. Then we will roll out this program to match that demand.”

15 days to respond with more information. The FDA asked whether Pathway Genomics believed it did not need to get FDA clearance for its genetic tests. After this news was made public, Walgreens announced that it would not stock and sell these genetic test collection kits.

Now, just three years later, Walgreens is again interested in providing a clinical lab test service in its retail stores—and with a partner, Theranos—that intends to charge prices that are half of Medicare rates. By so doing, Walgreens may be creating an entirely new competitive dynamic in the lab testing marketplace, one that could be truly disruptive to existing lab companies. **TDR**

—Joseph Burns

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Theranos Won't Discuss Disruptive Lab Technology

► Despite claims it can do clinical lab testing priced at 50% of Medicare, science is unknown

►► **CEO SUMMARY:** *In a partnership with Walgreens pharmacies, Theranos Inc. announced that it will run clinical lab tests on “micro-samples” and collect these blood samples without venipuncture. Even as Theranos touts the patient-friendly benefits of its proprietary diagnostic technology, it has provided no information about the science that supports this testing and the clinical validations it has performed that would meet the requirements of the FDA and federal and state laws governing medical laboratory testing.*

ON SEPTEMBER 9, Walgreens issued a press release with this headline: “Theranos Selects Walgreens as a Long-Term Partner Through Which to Offer Its New Clinical Laboratory Service.”

The two companies announced a long-term partnership to offer clinical laboratory testing services in all Walgreens Pharmacies nationwide. Just the fact that Walgreens wants to provide medical lab tests and specimen collection services in its thousands of pharmacies is enough to disrupt the status quo in the competitive market for laboratory testing services. This would be particularly true if the other big national retailers with thousands of pharmacies such as CVS, Walmart, and Rite Aid, followed Walgreens’ example.

► 8,117 PSCs With No Capital

On that point, national lab company executives in Madison, New Jersey, and Burlington, North Carolina, are probably giving this new clinical laboratory testing partnership their full attention. In one move, Theranos, Inc., of Palo Alto, California, gains potential access to 8,117

patient service centers in neighborhoods and communities across the United States with little investment.

But the disruptive elements of this breaking news story don’t stop there. Walgreens and Theranos are ready to bend the price curve in clinical lab testing.

To this point, the press release stated “Theranos tests are low cost—always 50% of Medicare reimbursement rates or less—and are reimbursed by major insurance carriers, Medicare, and Medicaid.”

Theranos will offer hundreds of different clinical laboratory tests at a price that will be 50% or so of the Medicare Part B Clinical Laboratory Fee Schedule. It is not just the two Blood Brothers who will need to have a competitive response to this development, but also independent lab companies and the laboratory outreach programs of hospitals and health systems.

On the surface, the use of Walgreens’ national network of stores as patient service centers and a price for clinical lab tests that is 50% of Medicare rates does create the potential for Theranos to be a disruptive

Theranos Says It Wants to “Reinvent Lab Testing,” But Has Yet to Publish or Disclose Its Science

THERANOS INC. AIMS to reinvent lab testing, the company says on its web site. How it plans to reinvent clinical laboratory testing is not well explained, although the company does say that it will draw small amounts of blood from patients without venipuncture.

“By minimizing the volume of blood required from patient draws, Theranos helps clinicians provide a new standard of care across all specialties and treatment areas,” the company said in an announcement of its partnership with Walgreens pharmacies. “Minimally invasive collection has the potential to benefit everyone, including oncology, pediatric, and geriatric patient populations that require frequent blood draws.”

A company spokesman explained the sample collection process as follows: “Blood is either taken from a tiny finger stick or a micro-sample taken from traditional methods, mitigating the need for the larger needles and numerous vials of blood required for most diagnostic lab testing. When drawn from a finger stick,

blood is collected from the finger after a small lancet is used to puncture the skin, and is transported in Theranos’ nanotainer tubes.

“Theranos’ tests can be performed on smaller samples that can be collected in a less invasive manner, and have all the associated benefits (patient experience, compliance, and so forth) that span across treatment areas,” the spokesman said.

Richard Ashworth, Vice President, Corporate Operations for Walgreens, in Deerfield, Illinois, described the blood collection process, saying, “It will be more like how a patient with diabetes takes a small sample of blood for glucose testing. It’s simple in terms of the experience but very powerful in terms of technology. Theranos will warm the finger and then use gravity and a nanotainer to wick just a few drops of blood into a unit that will be used for processing on certified lab equipment in the Theranos clinical laboratory. There’s not much more to it than that.”

player in the clinical lab testing marketplace as it is structured today.

At the same time, pathologists and lab regulators are likely to ask important questions about the new proprietary diagnostic technologies Theranos is touting. So far, Theranos has decided to keep this information out of the public eye. The statements it makes for public consumption only discuss the consumer benefits of its proprietary approach to performing a lab test—but offer no scientific details.

➤ CLIA-Licensed Lab Facility

For example, the press release noted that Theranos would use CLIA-certified laboratory services along “with the ability to run its tests on micro-samples.” It would collect blood samples without venipuncture and it

says it can deliver fast turnaround time from specimen collection to test results.

On its web site, the company says, “At Theranos, we’re working to shape the future of lab testing. Now, for the first time, our high-complexity CLIA-certified laboratory can perform your tests quickly and accurately on samples as small as a single drop.”

Left unexplained is the science and the proprietary technology Theranos will use to accomplish these goals. Because this testing is for clinical purposes, pathologists and physicians will also be interested in how Theranos demonstrated that it fully meets state and federal regulations governing new diagnostic technologies and how they are to be used in clinical settings.

In 2003, company Chairman, President, and CEO Elizabeth Holmes dropped out of

Goals at Theranos Evolved During its 10-Year Life

GIVEN ITS POTENTIAL TO BE A DISRUPTER in the clinical lab testing industry, Theranos has evolved its business goals during its 10-year life as the company sought a way to make money.

Theranos was founded in 2003 by Elizabeth Holmes, then a 19-year-old college drop-out who used her connections at Stanford University to raise tens of millions of dollars in venture capital funding.

Inc. Magazine published a profile of Holmes in 2006. It said “At the age of 20, she designed a device with the goal of saving the estimated 100,000 people who die each year from adverse drug reactions. With the Theranos 1.0, patients prick their fingers and place a small drop of blood on a disposable cartridge, which is then inserted into a reader that analyzes the medicine within the bloodstream. The device then sends the data wirelessly to a secure database, which makes it available online to the patients’ physicians.”

During an economic summit at Stanford University in 2010, Holmes discussed the evolution in thinking at her company. She said the company recognizes the ability of personalized medicine to transform healthcare. This is why Theranos was developing the technology to make information from blood tests more actionable.

“We have focused on the ability to integrate the various data sets to be able to understand how to individualize therapy or predict the onset of disease,” Holmes said in a video of the event. Moreover, Theranos can track “the dynamic progression of changes in these parameters over time,” she added.

“We can see these changes over time in the expression of proteins and other variables in the blood which—when sampled more frequently—can begin to describe the movie of disease progression rather than the snapshot,” Holmes explained.

Stanford University and founded Theranos at the age of 19. Since then, the company has raised \$100 million of venture capital and has a board of directors populated by prominent individuals. Yet, as it prepares to offer clinical lab testing to patients nationally, it has not explained its diagnostic technology in any depth.

For example, in its announcement with Walgreens, Holmes said, “For the past 10 years, Theranos has worked relentlessly to reach a point at which we could help make actionable information accessible to physicians and patients at the time it matters most.

► Test Results In Just Hours

“Clinicians can now see their patients having received lab results from fresh samples in a matter of hours,” Holmes continued in the press release. “This partnership [with Walgreens] will further our goal to bring high quality, affordable lab testing to people everywhere, with our new Wellness Centers in Walgreens retail locations closest to homes and workplaces.”

All the company says about its technology is that it uses a “proprietary laboratory infrastructure that minimizes human error through extensive automation that produces high quality results.”

Seeking more information on the technology involved in this partnership between Theranos and Walgreens, THE DARK REPORT asked questions and a Theranos spokesperson responded by email.

“This month the first Theranos Wellness Center at Walgreens will open in Palo Alto, California,” the spokesperson said, adding that Theranos plans to locate its patient service centers in Walgreens stores nationwide. “Only sample collection is performed in the Theranos Wellness Centers [within these retail stores], and then specimens are sent to the Theranos CLIA-certified laboratory. Collection is performed by Theranos’ trained, licensed phlebotomists or appropriately state-certified personnel,” the spokesperson explained.

Some medical lab testing companies have an online presence and allow patients to print out test orders and bring those orders to a lab for fulfillment. In contrast, “as a laboratory, Theranos performs physician-ordered tests and results are always communicated directly back to the ordering physician for clinical decision-making, as is done in the industry today,” the spokesperson commented.

Theranos’ lab in Palo Alto is a licensed clinical laboratory that is CLIA-certified to perform moderate and high complexity testing, the spokesperson said. In this lab, “Theranos can run multiple analytes on a single specimen, accommodating a full range of typical physician-directed test orders,” the company said.

“Theranos develops and validates laboratory-developed tests and is working to additionally have those assays FDA-cleared, as appropriate,” noted the company spokesman. “Its tests are physician-directed, and the company rigorously validates the analytical and clinical performance of its tests. The company’s current test menu is available on the web (at <http://theranos.com/test-menu>), and this menu is updated regularly.”

➤ **Validate Lab-Developed Tests**

Over the years, THE DARK REPORT has regularly predicted that technology innovations will revolutionize the methodology of clinical laboratory testing while radically reducing the cost of such testing.

Yet never before has any company burst upon the clinical laboratory marketplace with a claim that it can perform hundreds of lab assays using micro-quantities of specimens and deliver comparable accuracy, sensitivity, and specificity—all at a cost that is half of what labs typically are paid today!

For these reasons alone, Theranos is a must-watch company. Pathologists will be among those most keenly interested to learn the technical details about this new diagnostic technology.

TDR

—Joseph Burns

Contact Theranos at pr@theranos.com or 650-470-0334.

Secretive Company Has All-Star Board of Directors

IN RECENT MONTHS, the *San Francisco Business Journal* has published a series of stories about what it calls the “Secretive Theranos.” Its reporters, particularly Ron Leuty, have done their best to crack the corporate veil and report on a company that is 10 years old and has attracted \$100 million in venture capital funding.

Now that Theranos has come out of the closet—at least somewhat—with its long-term agreement to offer clinical lab testing in partnership with Walgreens, it will certainly be scrutinized by the laboratory medicine profession, along with the FDA, and state and federal medical laboratory regulators.

What pathologists and clinical lab administrators will find interesting is the make-up of the Theranos board of directors. Not only does it include a constellation of politically-influential individuals, but it seems to lack individuals with direct experience in clinical laboratory testing and anatomic pathology.

In a story published on August 2, 2013, the *San Francisco Business Journal* identified these individuals as directors on the board at Theranos:

- **Elizabeth Holmes**, Chairman & CEO
- **Ramesh “Sunny” Balwani**, President & COO
- **Henry Kissinger**, former Secretary of State
- **George Shultz**, former Secretary of State
- **William Perry**, former Secretary of Defense
- **Sam Nunn**, former U.S. Senator
- **Gary Roughead**, retired Navy Admiral
- **James “Mad Dog” Mattis**, retired four-star Marine General
- **Richard Kovacevich**, Former Wells Fargo & Co. Chairman & CEO

NEWSMAKER



INTERVIEW

Job Market for Lab Execs & Managers Favors Business Development Skills

Adam Slone, CEO | Tara Kochis, President | Slone Partners

“When it comes to hiring senior leaders, labs today are more diligent in recruiting and interviewing candidates for key executive and management positions. One reason for this change is the shrinking financial margins at most labs.”

—Adam Slone, Founder, Slone Partners

►► CEO Summary: *There is a clear shift in the hiring practices of clinical labs and pathology groups. Under financial pressure and reacting to competitive marketplace changes, labs are more diligent when interviewing candidates for C-suite positions or other top leadership jobs. Adam Slone and Tara Kochis are executives and at one of the lab industry's more active recruiting firms. They say that the high-demand candidate in today's lab marketplace is someone with demonstrated leadership skills and proven experience at business development. Today's tougher lab market means that no lab can afford to make a bad hiring decision. The following interview discusses the hottest sectors of the lab job market.*

EDITOR'S NOTE: The following interview was conducted with Adam Slone, founder and CEO of Slone Partners, and Tara Kochis, President. The company, founded in 2000, is a national recruitment firm based in Miami Beach, Florida. It specializes in identifying top executive, management, leadership, and scientific talent for diagnostic and lab testing companies.

EDITOR: With the rapid changes unfolding in healthcare and laboratory medicine,

could you tell us which types of lab management jobs are in highest demand?

SLONE: The demand for laboratory directors and top-level management has always been high for experienced clinical laboratory leaders. What has changed is that employers are putting in the extra effort when hiring top-level directors and members of the C-suite.

EDITOR: Do you associate this trend with the tougher finances for clinical labs and

pathology groups due to budget cuts and reduced reimbursement?

KOCHIS: That is part of the story. At the same time, labs are more complex organizations to manage and operate. Particularly at the leadership level, no lab can afford to make a bad hiring decision. More and more this is true.

EDITOR: Are you saying there is a smaller margin of error when hiring a new senior-level lab administrator or executive in lab organizations compared with the past?

KOCHIS: Hiring at this level is so important that the consequence of making a bad hiring decision can be significant for any lab. Whoever the lab hires at this level will have a direct effect on the company's success and its ability to be sustainable in the future marketplace. Now more than ever, clinical laboratory companies recognize that they have to hire the right leaders.

EDITOR: What trends in the lab marketplace are causing labs to be more diligent now about filling the top spots than they were 12 months ago?

SLONE: There is pressure on reimbursement. Payers' continually make threats to enact additional cuts to spending on lab testing. Molecular and genetic technologies are both expensive and add complexity to lab operations. Plus state and federal regulators are holding labs to a higher standard.

EDITOR: What are labs doing differently today when they want to recruit management talent? What should candidates expect from prospective employers?

SLONE: Labs are taking a more deliberate approach to hiring. First, they set aside more time for interviews and testing and they make committees part of the interview process. Second, labs want members of the board of directors and other top executives involved in the decision-making to mitigate the risk of hiring the wrong person. This year—more than any year in the past—we see that labs are more deliberate and careful in how they vet candidates.

EDITOR: The fact that laboratories have become more deliberate and spend more time when interviewing top-level candidates makes sense during a time when there is much uncertainty about both clinical services and financial stability. Are there different hiring trends at the manager and lower levels?

KOCHIS: This is quite an interesting issue. At some manager and lower levels, labs frequently do not go outside to hire. Rather, we see much greater emphasis on hiring from within. Anecdotally, we've seen situations where, if labs can't find the right candidate, they might not fill that spot.

EDITOR: Has “hire from within” reduced search assignments handled by Slone Partners?

KOCHIS: Despite this trend, our firm is still placing outside candidates for our lab clients at a steady pace.

EDITOR: When hiring senior positions, how do lab employers value technical skills and management skills? Has there been a change in the demand of labs for one skill over the other?

SLONE: In the past, labs frequently hired only those top level staff who have the right technical experience. Today, employers want top managers in labs to possess both technical expertise and business skills.

EDITOR: What is causing this change?

SLONE: I see three reasons why this trend is so strong. The first reason is the need for diversification in a lab's client mix and business skills. Clinical labs today see the importance of being involved in biopharmaceuticals or clinical trials.

EDITOR: That makes sense. Advances in companion diagnostics bring labs closer to development of pharmaceuticals. What is the next factor?



Adam Slone

►► "There is high demand for individuals with the skills to build the lab's revenue while, at the same time, managing operations to contain costs."

SLONE: The second reason is that labs need to serve both hospitals and office-based physicians today. Thus, a lab now working with physicians must be able to work with hospitals as well. The opposite is also true. A lab working closely with hospitals needs to develop appropriate services for physicians.

EDITOR: Your comments show how laboratory organizations are beginning to realize that they cannot have just one source of revenue.

SLONE: That's true. It is why labs want to recruit the expertise needed to serve a variety of lab customers. It includes the biopharma and clinical trial companies, along with firms involved in drug devel-

opment and biotechnology. In the past six months, we've seen a heightened focus in those areas.

EDITOR: What is the third factor?

SLONE: When hiring, labs want top level executives who have both the technical and business expertise needed to meet the challenges of declining reimbursement and organic growth. There is high demand for individuals with the skills to build the lab's revenue while, at the same time, managing operations to contain costs. The market is looking for executives and managers who are effective at work flow analysis and introducing the effective use of Lean Six Sigma methods.

EDITOR: That leads me to the issue of the economy and I want to ask two questions about that. First, what effect did the recession have on compensation for clinical lab management and staff and, second, if compensation went down, have you seen it climb back up again?

KOCHIS: The short answer is that we didn't see a sharp decrease or increase in compensation in any particular segment of healthcare over the course of the recession. Having said that, I would also say that the economy definitely affects salary.

EDITOR: Please explain.

KOCHIS: When things are great, hospitals, health systems, and clinical laboratories will pay whatever it takes to get the people they need. But the single most important factor affecting salaries is the value a hiring company sees in each candidate. It may cost a hospital or health system about \$20,000 more to hire one candidate over another. However, the candidate getting the extra \$20,000 may stay longer. That's a question of value for the hiring company.

EDITOR: It strikes me that this is not a universal approach when providers want to hire a top candidate.

KOCHIS: That's true. We have other clients, who, for whatever reason, are inflexible about adding extra dollars to the offer to help capture their candidate. They

have restraints and so our job is to work within those restraints.

EDITOR: I am curious about what factors outside the business cycle that you see affect the compensation labs will pay for management candidates.

KOCHIS: In our experience, healthcare is not immune to the economic swings that affect all businesses. However, a different set of factors drives compensation in hospitals, health systems, and clinical laboratories. Those factors are more segment driven.

EDITOR: Could you elaborate?

KOCHIS: One of these factors is that not-for-profit hospitals and health systems—including their laboratories—have equity issues to which they are bound. Thus, if a physician is slated to be hired for a particular job, that job has a salary range and the range doesn't change much. That's a limiting factor. On the other hand, commercial laboratory companies have more flexibility to react to market demand for people they want to hire for certain positions.

EDITOR: Does this put hospitals at a disadvantage when recruiting a premier candidate for a lab leadership position?

KOCHIS: Perhaps. This doesn't mean that hospitals don't find the best people. It simply means the candidate pool is not as deep and so hospitals and health systems may need to look a little harder.

EDITOR: My second question about the economy also relates to the downturn that started in 2009. Did many labs trim their mid-management ranks as a result of the downturn? After all, few labs could survive without having all authorized mid-management positions filled with competent people, wouldn't you agree?

KOCHIS: Absolutely. The mid- and upper-management levels of all labs must be staffed with people who are capable clinically. That's always been true. But, today, the management staff also needs to be capable from a business perspective.

EDITOR: This is consistent with your experience that today's hiring marketplace wants candidates with both the clinical and business skills.

KOCHIS: Labs today want to hire leaders who understand the financial consequences of their decisions. What shifted in the market to bring this on is the decline in lab test reimbursement. That change shows up in the requirement by hiring labs that their ideal candidate should bring comparable expertise in clinical or technical laboratory operations along with the business expertise needed to execute strategy.



Tara Kochis

➤ “Labs today want to hire leaders who understand the financial consequences of their decisions.”

SLONE: Allow me to chime in here. It is important that pathologists and lab administrators preparing to fill these types of positions should recognize this important development in the lab marketplace. For years, a candidate could get by on his or her skills in laboratory science. Now there is much more emphasis on the business side of clinical laboratories and the work that this new hire will do to build a firm foundation in the business management of the lab and its operations.

EDITOR: Is it tough to find qualified candidates who can fulfill both of these management requirements?

SLONE: If you look at successful labs today, nearly everyone on their management teams can deliver tangible business outcomes and possess the required scientific expertise. For years, labs could hire the clinically-skilled pathologists and scientists they needed rather inexpensively. That has changed today, because of the management skills that are needed along with the clinical skills.

EDITOR: To sum up this point, because of the ongoing changes in the lab testing mar-

ketplace, the margin for error is smaller than it was just a few years ago. That is why those labs now hiring take extra care to convince themselves that the candidate can deliver without any misfires.

SLONE: That is true.

EDITOR: What positions would you say are in the highest demand? Is it one of the C-suite positions or something specialized like a director of sales or marketing?

KOCHIS: You may be surprised to learn that it is two other positions. One is managed care reimbursement and the other is billing. That's not the answer most people would expect. Over the past two years, a number of labs have added people with those skills to their management teams.

EDITOR: That must be a response to actions by payers to narrow their networks and to negotiate tougher terms with labs when contracts need to be renewed.

KOCHIS: We think that is correct. There is a third position with a big spike in demand. Labs want more sales people on the street. They tell us that, if they are to compete effectively and bring in new revenue, they need more competent sales people who can go after that business.

EDITOR: Can you explain further about the demand for managed care specialists?

KOCHIS: There are two reasons for the focus on reimbursement. First, Medicare has a more centralized approach to making payment determinations today than it had in the past. Labs that need and want favorable payment determinations must have someone who understands this process and can work effectively with the Medicare and Medicare Authorized Contractors—as well as private payers—to achieve a successful outcome.

EDITOR: That makes sense. Because of the new molecular CPT codes which took effect on January 1 this year and all the new diagnostic tests coming to market, labs do need someone who can manage that process.

KOCHIS: Turning to the demand for candidates with billing skills, not only has

Medicare made numerous cuts in lab test reimbursement, it is threatening to make additional cuts. That is why labs must have managers on staff who understand payer issues on both a national level and a local level.

EDITOR: Given how much Medicare and all payers have cut from lab reimbursement, is that also why CFOs and revenue cycle management people are in high demand?

KOCHIS: Yes, labs are watching every penny. They are intensifying their efforts to get paid for every test they perform.

EDITOR: In the job market, you have outlined a demand for executives with strategic skills—such as the ability to develop relationships with private payers—in tandem with a demand for managers with tactical skills to run the coding, billing, and collection functions in an optimal fashion.

SLONE: That's exactly right. No business can leave money on the table. This is why we say labs are actively recruiting individuals who have these skills.

EDITOR: Would you describe which different sectors of the lab testing industry are doing the most hiring?

SLONE: We continue to see a strong demand in toxicology. We don't expect the current boom in pain management and toxicology testing to last forever. However there is a lot of pressure on physicians to demonstrate why they are providing their patients with various drugs. Experts predict that reimbursement levels will be cut for toxicology testing, but labs seem to believe there will be enough volume to make up for the decrease in revenue, so it continues to be a high growth area.

EDITOR: What other sectors of the lab industry are actively hiring executives and managers?

SLONE: Molecular testing continues to support an active job market. But we see a bit of slowing in this sector because of an interesting change.

EDITOR: Please explain.

SLONE: A number of labs active in molecular testing are looking at collaborating with academic medical centers. This allows them to tap the expertise of the medical centers. It can also create competitive advantage in the molecular testing marketplace.

EDITOR: Are laboratories in hospitals and health systems actively hiring?

SLONE: The answer is yes if that hospital or health system is creating a core laboratory to serve the physician groups they have acquired in the past few years. This is an interesting trend because these hospitals and health systems are now looking at the possibility that laboratories will create income. At a minimum, they expect the core laboratories to benefit economically from handling the specimens that originate in the physician groups they own.

EDITOR: That is an interesting development, since inpatient admissions at many hospitals have flattened or declined in recent years.

SLONE: It would be accurate to say that we see a significant number of hospitals and health systems where the volume of lab testing is growing more slowly than the volume growth at a number of independent lab companies.

EDITOR: What other notable developments in the lab testing marketplace have you seen in recent months?

KOCHIS: Along with the trend of hospitals developing their core labs, we have seen another interesting trend that is somewhat related. Certain hospitals and health systems are talking with pathology groups about acquiring those pathologists, thereby making them become employees of the hospital system.

EDITOR: How widespread is this?

KOCHIS: That is hard to tell. But we definitely know of two pathology groups that were recently acquired by hospitals. Both pathology groups are located in the Northeast.

What Laboratory Positions Are in Highest Demand?

BUSINESS DEVELOPMENT IS ONE LAB MANAGEMENT POSITION that is in particularly high demand. That is especially true in both the toxicology sector of the lab testing industry as well as the molecular testing sector.

“Every executive and manager with a demonstrated track record in business development and with experience in toxicology and pain management will be a candidate of high interest,” stated Adam Slone, founder and CEO of Slone Partners. “Over the past several years, we’ve seen those physicians with experience in business development attract much interest among labs seeking fresh management talent.

“At the moment, this is also true in the molecular test sector,” said Slone. “There’s an equally strong demand for executives who understand or have some experience in business development for molecular testing.

“Growth-oriented lab organizations are especially attracted to anyone in the lab business who has key contacts in molecular testing,” he noted. “These people are needed in a variety of settings, especially if they can form relationships to transfer technology or create meaningful partnerships. Also desirable is anyone who can assist in the commercialization of a test or product for molecular testing.”

EDITOR: Adam and Tara, this has been an enlightening interview. You’ve helped us understand what labs want today in their executive and manager positions. Thanks for the insights.

SLONE: Thank you.

TDR

—Joseph Burns

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Medicaid Suits in Two States Accuse Quest, LabCorp of Fraud

RECENTLY TWO WHISTLEBLOWER LAWSUITS, each alleging Medicaid fraud by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, have become public knowledge. One case is in Virginia and the other case is in Georgia.

Both lawsuits were filed by **Hunter Laboratories, LLC**, of Campbell, California, and its CEO Chris Riedel. Both lawsuits involve charges of alleged fraud to state Medicaid programs and are similar to the Medi-Cal fraud charges Riedel brought against these same companies in California years earlier.

In one case, a lawsuit is pending in Virginia against Quest Diagnostics Incorporated and LabCorp. It is alleged that the lab companies defrauded the state's Medicaid program in violation of Virginia law by billing Medicaid at rates much higher than what it billed other companies. Riedel filed this case in December 2007 under the Virginia Fraud Against Taxpayers Act, according to Bloomberg News. The court records were unsealed in August.

Medicaid Patients In Virginia

In the court records, the two companies are required to provide services to Medicaid patients in Virginia at the same rates that they billed other payers, according to Bloomberg News.

A news story published by *Health Care Payer News* reported that Quest Diagnostics filed a motion to dismiss the whistleblower complaint and stated that clinical laboratory companies in Virginia are “not required to give Medicaid negotiated discounts to par-

ticular customers, but rather its charge to the general public—meaning its list price to cash-paying patients.”

In the second case, Hunter Laboratories, Riedel, and the State of Georgia are listed as plaintiffs against Quest Diagnostics, **Nichols Institute**, LabCorp, and **Specialty Laboratories, Inc.** The case was filed in May and the plaintiffs assert two different theories by which the defendants' allegedly violated Georgia law. These theories are similar to those used in the California Medi-Cal cases.

Allegations Of False Claims

Under one theory, the plaintiffs allege that the laboratories knowingly made false claims to Medicaid by submitting claims for payment that reflect prices higher than the maximum reimbursement rates allowed under state Medicaid rules, court papers show. Georgia requires that Medicaid be paid the lowest price the labs charge any payer, the court papers show.

Under the second theory, the plaintiffs allege that the defendants “provided kickbacks in the form of deeply discounted private rates to draw in large volumes of ‘pull through’ Medicaid and other referrals.” These discounting practices violate the federal Anti-Kickback Statute, the plaintiffs allege, according to the court filings.

The two lab companies each deny the allegations in both whistleblower lawsuits.

The whistleblower case in California, filed in 2005 by Hunter Labs and Riedel, reached a settlement in 2011 when Quest Diagnostics paid \$241 million and LabCorp paid \$49.5 million to the state to resolve the charges. (See *TDR*, June 13, 2011.) **TDR**



Lab Briefs

➤➤ ALBERTA PROVINCE MAY SOON BID \$3 BILLION CLINICAL LAB CONTRACT

NEWS LEAKED ON SEPTEMBER 19 that **Alberta Health Services** (AHS) is preparing to issue a request for proposal (RFP) to select a company to build a state-of-the-clinical laboratory facility to serve Edmonton, Alberta, and the surrounding region.

A news report published by the *Edmonton Journal* stated that “AHS President and CEO Chris Eagle said the proposed opportunity is potentially worth \$3 billion [US\$2.9 billion] over 15 years. The contract would call for a single company to build and then run a lab facility capable of handling a greater load and variety of medical tests.”

The Province of Alberta has been among the most aggressive in Canada at attacking clinical laboratory testing costs during the past 20 years. During the mid-1990s, it pushed through a major restructuring of the entire provincial healthcare system that included a cut in lab test budgets of about 40% in one year. (See *TDR*, January 6, 1997.)

Currently, there are two regional lab operations. AHS operates a single consolidated regional laboratory operation in Calgary. The lab testing arrangements in Edmonton are different. In Calgary, **Calgary Laboratory Services** is a wholly-owned subsidiary of AHS. In Edmonton, the academic medical center handles its own testing and AHS has a contract with **DynaLife** to provide outpatient/outreach laboratory testing services.

This latest move by AHS is in anticipation of the expiration of its existing contract with DynaLife that ends in March 2015, along with the fact that DynaLife’s lease on its lab facility in downtown Edmonton will end in 2017.

DynaLife was originally created in 1996. That’s when three lab companies in Edmonton were merged into an entity then called **Dynacare Kasper Medical Laboratories**. The lab firms were **Dynacare, Inc.** (now owned by **Laboratory Corporation of America**), MDS Health Group (which sold its laboratory operations, now called **LifeLabs**), and **Kasper Medical Laboratories**, an independent lab company.

The leaked AHS memo stated that the volume of clinical lab tests in Alberta is increasing at the rate of 6% per year. There is also the need to accommodate the growth of expensive and complex molecular and genetic tests and support that testing with an enhanced information system.

What will be interesting to watch is which laboratory companies submit bids in response to the lab RFP. LifeLabs and Dynacare are the biggest private lab players in Canada, but the size of this project may attract the attention of such multi-billion-dollar lab giants like **Quest Diagnostics Incorporated** of the United States and **Sonic Healthcare Ltd.** of Australia.

➤➤ MORE DOCTORS AND A LAB SALES REP PLEAD GUILTY IN NJ LAB CASE

TWO MORE PHYSICIANS AND ANOTHER LAB sales rep entered guilty pleas on September 11 as part of the ongoing federal prosecution of **Biodiagnostic Laboratory Services LLC** (BLS), of Parsippany, New Jersey.

This case first became public on April 9 when New Jersey U.S. Attorney Paul J. Fishman announced the arrest of the owner and several executives of BLS. Fishman said the laboratory generated revenue of \$200 million between 2006 and 2013.

The scale of the fraud and kickbacks the lab paid to physicians is revealing. Fishman stated that Angelo Calabrese, M.D., a doctor with offices in North

Arlington, New Jersey, referred at least \$600,000 in lab test business to BLS between 2010 and 2013. In return, BLS paid him \$130,000 in bribes. These payments were in the form of a sham consulting agreement and a sham rental agreement that generated payments of \$4,500 per month, according to the U.S. Attorney's press release.

Paul Ostergaard, M.D., with offices in Pompton Plains, New Jersey, admitted accepting "more than \$50,000 in bribes to refer at least \$150,000 in lab business to BLS." According to the press release, this money came to Ostergaard in the form of a sham consulting agreement and a sham rental agreement.

With his guilty plea, BLS sales representative David McCann, 45, of Lyndhurst, New Jersey, admitted that he "paid thousands of dollars in cash on a monthly basis between December 2011 and April 2013 to numerous physicians on behalf of BLS in exchange for the doctors' referral of blood specimens to BLS," stated Fishman.

All three individuals face jail time and big fines. The two doctors must forfeit substantial amounts of cash. The press release said "the bribery count to which Calabrese and Ostergaard pleaded guilty is punishable by a maximum potential penalty of five years in prison and a \$250,000 fine. McCann faces a maximum potential penalty of five years in prison and a \$250,000 fine on the bribery conspiracy charge. Sentencing for all three defendants is scheduled for March 13, 2014."

As to the forfeitures, the press release went on to say that "Calabrese and Ostergaard have also agreed to forfeit \$334,000 and \$53,900, respectively. The investigation has so far recovered more than \$3 million through forfeiture."

With these new pleas on September 11, the number of people who have pleaded guilty in the BLS case now totals 17. These defendants include the owner and executives of Biodiagnostic Laboratory Services, several of the lab's sales representatives,

and physicians who have admitted to accepting bribes in exchange for referring specimens to BLS.

Laboratory administrators and pathologists may want to use the stories published by THE DARK REPORT on this case to educate physician-clients about the BLS case and how one U.S. Attorney aggressively brought charges against the doctors who willingly participated in schemes that violated federal anti-kickback laws. This information is a powerful way to make the point that there are consequences for violating Medicare and Medicaid laws.

►► **FTC FILES COMPLAINT AGAINST LABMD FOR PRIVACY VIOLATIONS**

IN ITS COMPLAINT AGAINST **LabMD, Inc.**, of Atlanta, Georgia, the **Federal Trade Commission (FTC)** accused the lab company of failing to protect the personal information—including medical data—of as many as 10,000 patients.

The action was announced on August 29. The FTC says that two separate breaches exposed patient information on the Internet. The information included "names, Social Security numbers, dates of birth, health insurance provider information, and standardized medical treatment codes," wrote the FTC in its press release.

Not only did LabMD, a cancer testing company, deny the allegations in the FTC's filing, it challenged the FTC's claim that it has the authority to require firms to adopt information practice policies. On LabMD's behalf, **Cause of Action (CoA)**, which describes itself as a government accountability organization, filed an answer to the FTC's action.

There is much Internet chatter about this case. Michael Daugherty, President and Founder of LabMD, has been outspoken in defense of his lab company. Clinical lab managers and pathologists may want to follow the progress of this case. It is an early example of how regulators want to act to enforce various laws governing protection of consumer and patient information. **TDR**

INTELLIGENCE

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



Even as the cost of genetic sequencing falls, the number of gene profiles in data repositories increases. This month, a research project in Boston, Massachusetts, that includes **Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Boston Children's Hospital** reported that it now has over 5,000 genetic profiles of tumor DNA in its database. The project is called "Profile." It is reported that 20,000 patients have already consented. Every patient at the Dana-Farber/Brigham and Women's Cancer Center in Boston can enroll and participate in Profile. Patients may also choose to have their physician notified if their test reveals genetic mutations for which treatments exist.

»» **MORE ON: DNA Profile**

Profile's research team is working with a new technology platform called OncoPanel. In their press release, it was noted that it "uses massively parallel or 'next-generation' sequencing to decode the DNA blueprint of 305 genes and find mutations—potentially millions of them, both previously

known and those being discovered for the first time. It can also detect other important genetic alterations, such as deleted or amplified pieces of DNA, or chromosomes that have been broken and incorrectly repaired." Physicians at the participating institutions are already using the information in the tumor DNA database to identify likely therapies that would benefit individual cancer patients.



WALGREENS INKS INFORMATICS PACT WITH INOVALON

Not only is **Walgreens**, the national pharmacy chain, preparing to get into clinical laboratory testing in a big way (see pages 3-9), but it is positioning itself to be a major provider of other healthcare services in its retail stores. On September 19, Walgreens announced an agreement with **Inovalon, Inc.** to use "Inovalon's data-driven encounter support platform, Electronic Patient Assessment Solution Suite (ePASS) within Healthcare Clinic at select Walgreens to support improvements in managed care quality and performance." Heather

Helle, Divisional Vice President of Walgreens' Healthcare Clinic division, described the benefits of this contract. "Through this partnership, we'll be able to utilize the power of analytics to provide a higher level of individualized care to our patients, which will ultimately improve the patient experience and outcomes," she stated.



DARK DAILY UPDATE

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...the call by the French Court of Auditors this summer to cut prices to French laboratories by 7.5%, a cut of US\$481 million in lab revenue. Experts predict medical labs in France will cut as many as 8,000 jobs due to this price reduction.

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***That's all the insider intelligence for this report.
 Look for the next briefing on Monday, October 21, 2013.***

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