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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...

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Are Labs Facing a Collapse in Test Prices?

IS IT REASONABLE, AT THIS TIME, TO ASK IF THE LAB INDUSTRY IS FACING a potential collapse in lab testing pricing? Were I to have asked that question several years ago, most of you would probably have responded with skepticism.

But how the times have changed! Take the Protecting Access to Medicare Act (PAMA) of 2014. Language in that law requires certain labs to report market prices to CMS in 2016. Then Medicare officials will use that market data to set prices for the Medicare Part B Clinical Laboratory Fee Schedule, starting in 2017. PAMA allows Medicare officials to cut the price of a single test by as much as 75% during the years 2017 through 2022.

I don't need to point out that, should the Medicare program cut Part B lab test prices like that, it won't take long before private payers take the same steps.

Let me also offer the example of 2013's introduction of the new CPT codes for molecular and genetic tests. By the time the dust cleared from that battlefield, many labs saw less revenue overall from claims they submitted with these CPT codes. THE DARK REPORT chronicled the closing of several genetic test labs in the wake of these payer actions. And that's not to mention the surprising number of "no coverage" determinations that the Medicare Administrative Contractors made for proprietary assays that were formerly paid under the old system of code stacking. This also cut lab revenue.

Next, I would call your attention to our intelligence briefing on pages 10-15. We report on the initiatives of clinical pathologist Michael L. Astion, M.D., Ph.D., and his lab team at **Seattle Children's Hospital** to improve utilization of expensive send-out molecular and genetic tests. Not only does their program involve lab scientists in helping physicians select the best test for the patient—thus improving patient care—but it also reduces the cost of send-out testing.

I was surprised to find that, overall, payers are reimbursing expensive send-out tests at an average of about 35% of the amount that Seattle Children's paid the reference lab that performed the test. If this is a common experience at other hospital labs—and Astion says that it is—this does not bode well for the budgets of hospitals labs going forward. These are a few examples of how public and private payers are actively reducing their reimbursement for lab tests. Maybe "collapse of prices" is too strong a phrase, but it is certainly not far from today's marketplace reality. TDR

What's New at Theranos? Lab Firm Expands in AZ

Theranos is preparing to make a big splash in the Grand Canyon State to build test volume

CEO SUMMARY: Over the past 18 months, Theranos has taken steps to enter the clinical lab marketplace. Across Greater Phoenix, Theranos now has specimen collection centers in about 40 Walgreens pharmacies. It is opening a CLIA lab facility in Scottsdale. Now that it is delivering clinical laboratory testing services on a regular basis, the quality of its laboratory test results and the service it provides to physicians and patients will get close scrutiny from both investors and competing labs.

IT'S BEEN 18 MONTHS since the mysterious clinical laboratory company known as **Theranos** burst into public view with a sweetheart profile published by *The Wall Street Journal*. In that story, the company's CEO promised to disrupt the clinical lab industry by serving patients in an entirely new way, using breakthrough diagnostic technology inspired by her vision.

Addressing that point, the *WSJ* reporter wrote how Theranos CEO Elizabeth Holmes and her proprietary diagnostic technology had the potential to "upend the industry of laboratory testing," while further adding that Theranos "might change the way we detect and treat disease."

In that *WSJ* story, the reporter described Holmes as a 29 year-old wunderkind who had developed a way to perform medical laboratory tests and deliver lab testing services to consumers that would revolutionize and disrupt the clinical laboratory testing market as it exists today. *(See TDR, September 30, 2013.)*

Included in *The Wall Street Journal's* story about Theranos and Elizabeth Holmes was the news that Theranos had entered into an arrangement with **Walgreens**, the national pharmacy chain with 8,200 stores. The *WSJ* stated that "the company is launching a partnership with Walgreens for in-store sample-collection centers... Ms. Holmes's long-term goal is to provide Theranos services 'within five miles of virtually every American home.'"

Moreover, it was noted that "Ms. Holmes estimates that patients and doctors will receive readouts [lab test results] in "as little as two hours."

Of course, claims such as these immediately caught the attention of pathologists, clinical lab professionals, and lab executives throughout the United States. With this announcement, they faced a new competitor; a company prepared to not just disrupt the existing business of lab tests, but to introduce an entirely new paradigm for medical laboratory testing.

Since the publication of *The Wall Street Journal* story about Theranos in the fall of 2013, the company has received fawning press coverage in such media outlets as *Wired*, *Fortune*, *USA Today*, *Smithsonian*, and *The New Yorker*, to name a few. The tone of these stories is generally to praise the company and its CEO, along with some mention of criticisms and a few quotes from outside experts who question some of the claims made by Theranos.

By the way, don't overlook the Elizabeth Holmes speaking tour. During the past year and a half, she has been carefully booked to deliver presentations at conferences ranging from TEDMED to the Clinton Global Initiative. YouTube.com is salted with video clips of the presentations delivered by Holmes.

Given these lofty aspirations and the stated mission to do nothing less than transform the way consumers and patients get their medical laboratory tests, how has Theranos progressed during the past 18 months?

Specimen Collection Centers

Its first public move was in the fall of 2013, when it opened specimen collection centers in two Walgreens stores located in Palo Alto, California. The specimens collected at these sites were transported to Theranos' CLIA lab facility, also located in Palo Alto. It apparently later closed one of the collection centers and currently offers its lab testing service in just one Palo Alto Walgreens.

Before the end of 2013, Theranos also began opening specimen collection centers in Walgreens stores throughout Phoenix, Arizona. It now offers its lab testing services in as many as 40 Walgreens stores across the Phoenix metropolitan area.

During the summer of 2014, Theranos leased 20,0000 square feet in a biotech office park. It stated its plans to build a CLIA laboratory in the facility and hire a staff of 500 people. It has been recruiting staff as it expands its operations in Arizona.

Although Holmes, in all her media interviews, discusses a business plan that is aimed at providing direct access testing to consumers through the Walgreens pharmacies, clinical labs in the Phoenix area were surprised to find sales representatives from Theranos visiting office-based physicians. These sales reps were asking physicians to refer their patients to Theranos for clinical laboratory testing.

Marketing To Physicians

Executives at competing clinical laboratories were not expecting Theranos to begin marketing directly to physicians. In its public statements, Theranos has emphasized its business strategy of having specimen collection centers located in retail stores, such as its arrangement with Walgreens, and serving customers who want to order their own lab tests.

Lab executives watching these developments observe that, if Theranos is to pursue client relationships with office-based physicians, it will need to incur the same costs as other clinical lab companies. That includes courier services, electronic interfaces with the physicians' EHR systems, along with the need to acquire managed care contracts and maintain a coding, billing, and collections department, to name a few such costs.

Could these developments be early signs that Theranos realizes it must look much more like a conventional clinical lab company if it is to gain a foothold in the lab testing marketplace? And, as it does so, will it be able to generate adequate income to sustain its business operations? In Arizona, lab competitors will be watching to learn the answers to both questions. TDR

In Arizona, New Consumer Direct Access Law Is a First Win for California-based Theranos

IN ARIZONA, A NEW LAW ALLOWS CONSUMERS to order any lab test a licensed clinical laboratory offers without a physician's order. Governor Doug Ducey signed House Bill 2645, *Laboratory Testing Without Order*, into law earlier this month.

State officials who support the law say it empowers consumers by letting them order their own tests without having to wait for a physician visit and lab test order. It also protects physicians and other healthcare providers from legal liability, said state Rep. Heather Carter (R-Cave Creek), who sponsored the bill. The law becomes effective in early July.

Pathologists and lab executives will find it interesting that Ducey signed the bill into law at the Theranos lab facility in Scottsdale. Theranos is a clinical laboratory company in Palo Alto, California, that supports the bill. During the signing ceremony, Ducey, Carter, and other lawmakers stood beside Theranos CEO Elizabeth Holmes.

The legislation eliminates "outdated regulation," Carter said, and gives consumers, "the right to order their own lab tests so they can make informed decisions and even life-changing choices about their health," according to *The Arizona Republic*.

Direct Access Testing Law

The *Tucson Sentinel* reported that the law will affect labs in several ways. First, the law eliminates the current restriction on consumers that allows them to order only those tests currently on the Direct Access Test List from the state Department of Health Services. As of early July, consumers will be able to order any lab test directly from a licensed lab without a doctor's order.

The law means healthcare providers will have no responsibility to review or act on results of a lab test done without the provider's consent and a healthcare provider is not subject to liability or disciplinary action for failure to review or act on the results of a lab test if the provider doesn't request or authorize the lab test, reported the newspaper.

Labs must send test results directly to the individuals who order the tests. Also lab tests that consumers order need not be covered by private health insurance or the state's Medicaid system noted *The Sentinel*.

In 2013, Theranos opened its first clinics inside Walgreens stores in Arizona. Today, it operates clinics in 40 Walgreens stores, most of them in and around Phoenix.

Interview With Holmes

In an interview with *The Arizona Republic* shortly after Carter introduced House Bill 2645 in February, Holmes said that patients have to pay much more for clinical lab tests before they have a diagnosis. Even if a patient's family has a history of disease and if patients could benefit from a screening test, insurance won't cover it, she said.

"Inherently, we've got a system which is by law saying you can only get these tests done at a cost that is affordable once you already have the disease," stated Holmes, according to the *Republic* newspaper. "And if they are not symptomatic, insurance won't pay for it. So people have to pay out of pocket, and paying out of pocket is insanely expensive."

During the signing ceremony, Holmes explained why Theranos supported the legislation. "My life's mission in building Theranos is to change this outdated, expensive, and disenfranchising healthcare paradigm," declared Holmes. "Our work at Theranos is about access—eliminating the need for painful needles and vials of blood, replacing that with tiny samples taken in convenient locations at convenient hours of operation, always for a fraction of the cost charged elsewhere—to build a healthcare system in which early detection and prevention become reality," concluded Holmes.

Theranos: Many Questions, But Very Few Answers

Competitors talk about a secretive company and paint a different picture than the one in the media

CEO SUMMARY: Winston Churchill famously said that "Russia is a riddle wrapped in a mystery inside an enigma." That description could apply to Theranos, the company that claims it is poised to disrupt the entire clinical laboratory testing industry. In Phoenix, where Theranos is ramping up its clinical lab marketing and operations, competing lab companies have it under the microscope. Some say not all may be going to plan and Theranos has been asked to comment on several issues.

When a company that goes public with its goals, regularly and repeatedly declaring its lofty ambitions to do good for mankind by disrupting the status quo and replacing it with something new and wonderful, it invites itself to be judged by its actions and what it actually delivers.

Since **Theranos** of Palo Alto, California, made its public debut in September 2013 with an admiring profile in *The Wall Street Journal*, it has been closely scrutinized by many pathologists and clinical laboratory professionals.

They have legitimate interests in the company's stated goals for several reasons. First, as healthcare professionals that provide patient care, most pathologists and lab scientists have a genuine interest in doing what's right for the patient. Caring for sick people and keeping well people healthy is a major reason why they chose a career in laboratory medicine.

Second, when a for-profit company makes a public declaration that its ambition is nothing short of full disruption to the existing lab testing marketplace as it exists today, it is human nature to have fears and concerns about how such developments may undermine the financial stability of the lab testing organizations where pathologists and lab professionals work today.

Put these two areas of interest together, and it becomes obvious why Theranos is a subject of importance across the lab testing industry.

Technology Is An Unknown

This is why many questions are being asked. But because Theranos operates in a highly-secretive manner, other than the enthusiastic stories it gets placed in major media outlets, the company has revealed little of substance about its proprietary diagnostic technology, the accuracy of the testing methods it has developed, and how those methodologies correlate with FDA-cleared diagnostic assays in common use by clinical laboratories throughout the United States.

Because of patient safety concerns, both the public and the clinical laboratory profession have a genuine and valid inter-

est in knowing and understanding the accuracy, reliability, and reproducibility of the innovative diagnostic technologies that the company repeatedly assures the public that it has developed.

The issue is credibility. Whether fair or not, Theranos has a credibility problem with pathologists, clinical chemists, and clinical laboratory scientists. It has itself to blame for this problem because it refuses to engage the scientific community in traditional ways. Why? Because it claims it needs to protect its proprietary technology.

Competitive Intelligence

To advance this story one step further, it is helpful for readers to understand that laboratory professionals across the United States are carefully watching its actions and sharing the tidbits of intelligence they've gathered. As is true of every industry, clinical lab professionals are observing, gathering stories, sharing anecdotes, and passing news of Theranos along to their colleagues. Some of this is competitive market intelligence and some of it happens during lab industry meetings.

This is happening now in Phoenix. Since Theranos opened its first specimen collection center there in late 2013, competing laboratories have regularly sent secret shoppers, employees, and even lab managers into Walgreens pharmacies to purchase lab tests and provide a specimen. They do this to assess the service provided to them as consumers and to see what a competitor is delivering.

Labs Compare Test Results

However, competing labs are also in a position to do something that consumers cannot do. Competing labs can draw blood from their secret shoppers at around the same time these employees visit a Theranos site at a Walgreens pharmacy. They can then perform the same lab tests as Theranos and compare the results. This form of competitive market intelligence has been in use for decades.

As noted above, competing labs have been surveying Theranos in this manner for more than one year now. So these labs are learning something about the level of service their employees received as consumers in a Walgreens pharmacy. In some cases, to compare for accuracy, competing labs have test results on the same individual that were reported by Theranos and by their own CLIA-licensed laboratories.

An additional source of market intelligence comes from physicians' offices and from consumers themselves. As consumers and physicians interact with Theranos, they are sharing the positive and negative experiences with their clinical laboratory providers.

What all of this means is that—outside of Theranos—competing laboratories in Phoenix probably have the most knowledge about how Theranos is performing in the highly-competitive lab testing marketplace in Phoenix.

Measured By Its Statements

It should be noted that these competing labs are assessing Theranos against its own statements about how it will deliver clinical lab testing services that disrupt the existing industry and provide consumers with a lab testing experience that is less painful, more pleasant, and less expensive than services offered by other clinical lab companies.

In THE DARK REPORT issue of August 11, 2104, we summarized the public statements of Theranos as follows:

- No need for a venipuncture. A simple finger stick is all that is required.
- No need for 3-4 vacutainers of specimen. A micro-sample is adequate.
- Theranos' proprietary test technology returns answers in four hours.
- Theranos says it can perform "hundreds of laboratory tests."
- Theranos is charging just 50% of the Medicare Part B lab test fees for the tests it performs.

The following is a review of what competing laboratories see Theranos doing in Phoenix, relative to these points. Theranos has been asked to comment on each of these points. No response was provided as of press time and THE DARK REPORT is prepared to provide statements by Theranos when they are received.

Finger Stick Specimen

On the specimen collection by a "less invasive" fingerstick versus a traditional venipuncture, Theranos appears to have a mixed record. This editor has visited Theranos twice in the past 12 months to have his blood tested.

In order to do just four of the six lab tests on the test requisition, Theranos on both occasions collected my specimens by venipuncture, not by finger stick. (Also, because it declined to do two of the four tests ordered by my doctor, both times I had to visit a second laboratory—and get a second venipuncture—in order to get results for all six lab tests ordered by my physician.)

It should be pointed out that, in my experience and those of others getting testing at Theranos who shared their experiences with THE DARK REPORT, that Theranos is using multiple standard vacutainers during the venipuncture to collect the patient specimen. On these occasions, it was thus not drawing a micro sample of "25 to 50 microliters collected in a tiny vial the size of an electric fuse" as described in a *Fortune* story about Theranos.

Secret Shopper Reports

Labs in Phoenix report similar experiences when their secret shoppers and employees go into Walgreens with test requests. THE DARK REPORT has asked Theranos to comment on why, for some consumers, it performs a venipuncture and draws multiple vacutainers of blood, versus using its advertised less-invasive needle stick and nanotainer-sized volume of specimen. How often this happens is unclear.

On a related point, multiple competing labs say that, over the past four to eight weeks, no Theranos collection center in a Walgreens has done a needle stick collection in the Phoenix area when the lab employees or the secret shoppers went in for lab testing. Some Theranos or Walgreens employees have reportedly indicated, during the purchase or collection process, that company policy changed about that time and they were directed not to collect specimens using the finger stick and were required to collect by venipuncture. Is such a policy in place? Were these isolated instances or something more? THE DARK REPORT has asked Theranos these questions.

Discordant Lab Results?

One issue that may be related to a policy of why Theranos is not using the finger stick procedure to collect specimens is that competing labs say they know of at least some instances where Theranos reported lab test results that some patients (and their physicians) recognized as being out of range or atypical. Some competing laboratories are sharing stories that physicians and patients have sent specimens to them for a second lab test to confirm results.

When the retesting was performed in these CLIA-licensed laboratories, it was determined that the lab test results reported by Theranos were discordant or discrepant to the range of results from earlier testing that was typical for that patient. These stories cannot be independently confirmed and, of course, all labs have atypical results from time to time. Theranos has been asked to comment on this situation.

Further, since Theranos has stated that these lab tests are performed as LDTs using its proprietary technology, THE DARK REPORT has asked Theranos to comment on how it follows CLIA requirements for resolving instances where a patient's lab test results are recognized to be out of range.

It was noted in the intelligence briefing on pages 3-5 that Theranos is sending its sales representatives into physicians' offices throughout the Phoenix area to solicit lab test referrals from these doctors. Competing labs say that they've heard stories that some sales representatives from Theranos are telling physicians in Phoenix that Theranos is "in network for all health plans in Arizona."

Payer Provider Agreements

Yet, at least in checks with selected health insurers, THE DARK REPORT has been unable to determine whether there is a record of a provider agreement with Theranos. Again, Theranos has been asked to comment on this situation and has also been asked if it would be willing to provide a list of health insurers with which it currently has provider agreements.

Now that Theranos is building out its planned business infrastructure in the Phoenix metropolitan area, it enters a new phase in its business cycle. Because it is starting to deliver clinical laboratory testing services on a much larger scale than the one Walgreens store in Palo Alto, its service performance will be visible to consumers, physicians, payers, and—of course, competing clinical laboratories.

Game On For Theranos

So in a true sense, the game commences. After 18 months of an enviable public relations campaign where Theranos founder and CEO Elizabeth Holmes was given the platform in friendly venues to explain all the benefits of its innovative diagnostic technology and customer-friendly business model for lab testing, it must now deliver in the competitive marketplace.

Probably the most skeptical audience facing Theranos are board-certified pathologists. As any long-time lab professional knows, as a group, pathologists are the lab's skeptics that want convincing evidence before accepting a new scientific premise. That's a big challenge for Theranos.

Theranos Stakes a Big Claim in the Grand Canyon State

WHY HAS THERANOS SELECTED ARIZONA as its first commercial market? "We are investing here because we see this as a model for what we do nationally," stated Theranos CEO Elizabeth Holmes in a story published in *The Arizona Republic* on February 27, 2015.

The Republic went on to write, "That means Theranos is reaching out to doctors, health insurers, and others to spread the word about its technology. It has reached an agreement to provide lab services with Tempe-based **Commonwealth Primary Care**, an accountable-care organization with more than 200 doctors and other practitioners."

In the story, Holmes stated that "Theranos also has announced an agreement with **Dignity Health**, a San Francisco-based hospital group that owns **St. Joseph's Hospital**, **Chandler Regional**, **Mercy Gilbert** and other medical facilities. A Dignity Health spokeswoman in San Francisco on Tuesday could not provide details about the type of lab testing it orders from Theranos."

Arizona may have been selected by Theranos as its first major market deployment for another interesting reason. Lab executives in California point out that the state has one of the toughest regulatory environments of all 50 states, with laws that are more rigorous than the federal CLIA statute. By contrast, Arizona is a state where laboratory testing services are basically regulated per the CLIA statute, making it simpler to meet federal compliance requirements.

As noted earlier, when this issue of THE DARK REPORT went to press, Theranos had not responded to the request that it comment on these specific issues. THE DARK REPORT is prepared to print the responses from Theranos when that information is received. TDR

Hospitals can't recover full cost of send-out tests

Increasing Costs for Genetic Tests Are Busting Lab Budgets

CEO SUMMARY: Across the nation, hospital administrators are recognizing that effective lab test utilization is a critical factor in a lab's success. At Seattle Children's Hospital, clinical pathologists, clinical chemists, and laboratory genetic counselors are using an innovative utilization management program to ensure the appropriate use of genetic and molecular tests. They also formed Pediatric Laboratory Utilization Guidance Services. In two years, PLUGS has gained 32 members, including seven hospital labs serving adults. Interest in utilization management is driven by a desire to decrease test ordering errors and to control the cost of send-out tests.

FOR MORE THAN A DECADE, the explosion of expensive esoteric and genetic tests has sent the cost of send-out testing spiraling ever higher at hospitals and health systems throughout the United States.

Another dynamic in the lab testing marketplace compounds the problem. Many lab companies providing these esoteric and genetic tests charge high prices. But when a hospital bills a health insurer, the insurer's payment is much less than the price the hospital pays to the send-out lab.

This means hospitals and health systems get hit twice. The rising number of esoteric and genetic tests that have clinical value increases the cost of send-out tests each year. At the same time, health insurers are reducing what they reimburse hospitals for these same tests, which increases the hospitals' testing costs.

To address these problems, hospital administrators support the efforts of pathology groups to introduce laboratory test utilization programs. The goal is to improve patient outcomes while controlling the cost of a hospital's send-out tests.

"Improving the utilization of lab testing is a big opportunity for pathologists, clinical chemists, and laboratory genetic counselors who want to contribute more value," noted Michael Lee Astion, M.D., Ph.D., Medical Director of Laboratories at **Seattle Children's Hospital**. "Our program is based more on the work of Ph.D. clinical chemists and masters-degree level genetic counselors than it is on the work of pathologists.

"At our institution, we focus on certain kinds of tests, such as for celiac disease, unusual infectious diseases, and especially genetic profiles," he said. "More specifically, the poor reimbursement on genetic tests is the biggest pain point. To manage these costs, we implemented an active utilization management protocol for germ line testing for heritable diseases and for cancer gene expression profiling.

"Some of these tests now cost more than an MRI," noted Astion. "Many of them cost more than $2,000 each. Just this example helps to illustrate why genetic tests are breaking laboratory budgets."

The high price for these genetic tests is only part of the story. The other factor breaking lab budgets is the meager reimbursement health insurers pay for these tests. "Assume that a lab sends a test out for $2,000 and that it marks up the bill a bit, then sends that bill to the patient for $2,500," Astion explained. "But the insurance company doesn't reimburse much, usually about only 35¢ or less on the dollar.

"Thus, for a test that costs the lab $2,000, it brings in about $700 in reimbursement from insurers," he said. "At that rate, testing costs are about three times higher than testing revenue. That's unsustainable.

"This scenario is worse if the test is for a Medicaid patient," he emphasized. "In that case, the lab gets paid little or nothing. Often, the patient can't pay and so the lab doesn't get reimbursed. Sometimes Medicaid pays something, depending on the test, the state, and the Medicaid administrator.

Losing Money on Lab Tests

"Thus, because it has a contract with the send-out lab, the hospital lab pays $2,000 to the lab that performed the send-out test," stated Astion. "But from the payer, the hospital lab is reimbursed for only about one-third of that $2,000. This is one reason why hospital labs lose money on send-out genetic testing.

"A typical, freestanding pediatric hospital might spend about $1 million per year on germline genetic testing," he explained. "At about 35¢ on the dollar, this lab is losing $650,000 every year.

"That financial gap between cost and price paid for genetic tests directly affects the entire lab budget and therefore the ability of the lab to serve its hospital," said Astion. "The fact that many genetic tests are misordered or unnecessary compounds the problem.

"We hear plenty of discussion about value-based purchasing and capitation but that's not driving the interest hospitals have in laboratory test utilization management," observed Astion. "The reasons are much more pragmatic, particularly when looking at the cost and ordering errors associated with genetic testing.

Addressing Diagnostic Delay

"At a time when hospitals are experiencing fewer inpatient admissions and budgets are declining, tighter management of every source of unnecessary or excessive cost becomes a financial priority," he added. "In addition, the diagnostic delay associated with ordering the wrong genetic test is an important, pragmatic driver."

The need for immediate and effective solutions to improve the utilization of lab tests motivated Astion's team, led by Jane Dickerson, M.D., a clinical chemist, and Jessie Conta, a laboratory genetic counselor, to develop a utilization management service that other children's hospitals and health systems could use. The team at Seattle Children's founded an entity called **Pediatric Laboratory Utilization Guidance Services**.

"PLUGS is a membership and networking organization that helps hospital laboratories decrease costs and errors associated with unnecessary laboratory testing," explained Astion, a clinical pathologist. PLUGS covers many areas of lab utilization management but the best return on investment for PLUGS members comes from focusing on high-cost tests, such as genetic tests that each cost over $700.

"Basically, our program ends up canceling 10% of these genetic tests at the ordering stage because they are wrong or duplicates or have some other issue," he continued. "Some 15% of genetic test orders are modified, usually in a way that increases the quality of the test order and decreases the cost. The remainder of genetic test orders, which is about 75% of them, go right through.

"On average our utilization management program saves us about $400 for each genetic test requisition that we subject to active utilization management." he noted. "Many of our PLUGS hospital members report similar cost savings."

The utilization management program uses the existing hospital information systems. "In our hospital we have criteria for which genetic tests to review," said Astion. "Those tests are flagged in the computer. Each time a doctor orders one of those tests, she knows the request has been submitted for a laboratory genetic counselor's review.

Assessing Medical Necessity

"If it's a genetic test, then it goes to our laboratory genetic counselors (GCs)," explained Astion. "We have three GCs on staff and they rotate. Most of the tests we flag are genetic tests, but not all.

"If it's a nongenetic test, then it goes to the doctoral-level person on call in the utilization management group," he said. "Typically, we have three doctoral level people, either pathologists, led by Bonnie Cole, M.D., or clinical chemists, who are on call and each one takes a week on call at a time."

Jessie Conta, MS, LCGC, a Laboratory Genetic Counselor and Supervisor, explained that the counselors have key questions to ask about flagged genetic tests. "We want to know if this is the right test, meaning will it make sense for this patient?" she said. "Is it medically necessary and will it affect the patient's care or is the ordering physician just curious about the result?

Most Appropriate Test

"Like many of the PLUGS members, we are a teaching institution and so the line between whether a flagged test is for clinical or research purposes is often blurred," she added. "So we delve into the medical record or discuss the case with the provider to determine why this test is necessary.

"If a genetic test is indicated, then we want the physicians and patients to have the most appropriate test," continued

Hospital Laboratories Need Processes To Limit Liability and the Cost of Send-Out Testing

WHEN SEEKING TO CONTROL LAB TEST COSTS, one area stands out for pathologists and clinical laboratory directors: send-out testing.

"We focus on improving the processes we use for send-out tests because that's where labs typically get the poorest reimbursement and where doctors make the most ordering errors," said Michael L. Astion, M.D., Ph.D., Medical Director of Laboratories at Seattle Children's Hospital.

"Here's what happens with reimbursement," he stated. "When we send a test to a specialty genetics reference lab, our hospital must pay the full amount negotiated on our contract with them. But after filing a claim with the patient's health plan, the insurance reimbursement on average is only about 35¢ on the dollar. So, if our lab pays the specialty genetics lab $1,000 for a test, we get about $350 back in insurance payment. So, the lab loses $650 on that test.

"Over time, that rate of loss is unsustainable for our lab and our hospital," he added. "This is the reason why we focus financially on send-out tests. Our goal is to not send out any test unless it is medically necessary. When we do send out a test, we refer only to certain labs that we know provide high value to patients. We know we're going to lose money but we can at least take smart steps to minimize the loss and maximize the quality of the test that the patient receives.

"Thus, one component of our test ordering protocols is to carefully manage send-out processes, and do so in a cautious manner because, in addition to financial issues, there are a number of patient safety problems related to send outs," he explained. "Not many lab directors know this, but studies of legal claims against labs reveal that three of the most significant lab service problems associated with patient harm and substantial payouts are ordering the wrong test, not retrieving the test result, and misinterpreting a test result. All three of these problems originate more from send-out testing than from other areas of the lab.

"There are many reasons why send-out tests can be problematic in this regard," observed Astion. "They are usually rare tests, for example, and the doctors who order these tests don't have great knowledge about them. That means they don't know how to order them or how to interpret the results. Also, they tend to forget they ordered these tests because it takes longer to get send-out test results.

"If they forget about the tests that were sent out, the physicians don't retrieve the results," he explained. "Moreover, when the unretrieved lab test results are abnormal, then it's easy to see why the doctor would be subject to litigation.

"For these important reasons, it is essential that the lab establish strict protocols to minimize these types of failures that lead to diagnostic errors," concluded Astion.

Conta. "Many doctors think they have identified the best genetic test.

"However, because we work in this area daily, we may know of a different genetic test that will get them a better answer, and, in some cases, it may be more expensive," she noted. "More commonly, we can identify an equivalent genetic test offered by an alternate lab that might cost less.

"We also make sure that the insurance preauthorization is in place in advance of the testing," stated Conta. "We want to protect our patients from unexpected bills."

Astion explained that, of the 1,700 tests that have required utilization management at Seattle Children's in the past three years, most are genetic tests. "About one third are not genetic tests," he explained. "These might be esoteric chemistry tests such as vitamin 1,25 D or reverse T3, or autoantibody tests like those used to diagnosis celiac disease.

"We review any lab test order that is not on the formulary or any test where a physician asks us to send to a lab that is not one of our chosen reference labs," noted Astion. "We also have a list of banned tests and we don't run any test from a direct-to-consumer kit that a patient brings in."

PLUGS members take a similar approach to utilization management and they get many of the resources they need from participating in PLUGS. "Should your hospital have nothing in terms of utilization management and it joins PLUGs, we have educational materials to help start your utilization management committee," Astion noted. "If needed, we also will attend your first committee meeting.

"Jessie, Drs. Dickerson and Cole, and the PLUGS team have developed materials on how to be effective at managing lab test utilization," added Astion. "These materials offer insights into how to talk to physicians to persuade them to change their orders in a way that is not hostile.

Access To Materials

"To join PLUGS and participate, hospital laboratories pay $4,200 per year," he continued. "This gives them access to our utilization management materials, including online webinars, written education materials, policies, procedures, and quarterly WebEx meetings that spotlight member successes, as well as access to a member discussion forum.

"Members also can call our staff if they have questions," stated Astion. "For instance, they might ask how to deal with a particular doctor, for instance. We give them ideas about how to change orders in an inoffensive way.

"The members earn their $4,200 payment back quickly because savings from careful management of high-cost lab tests is substantial," he added.

In an article published last year in the *Archives of Pathology & Laboratory Medicine,* the Seattle Children's team described the results from the first eight months of the utilization management effort. Tests that met defined criteria were subject to additional review. These were requests with multiple genetic tests included on the same requisition, requests to send to a nonpreferred or international laboratory, and requests to send out tests that are normally done in house.

Reporting On Successes

In each of these cases, the redundant test was vetted with the ordering clinician who opted to cancel the test or order a more appropriate test based on conversations with the UM consultant.

Over eight months, the researchers analyzed the costs of 251 test orders (including orders for 199 genetic tests) and found that without utilization management, the total cost would have been $610,456. They also found that UM cut spending to $491,504. The savings of $118,952, was 19% of the total without UM, or an average of $463 per test request under management.

With leadership of many hospital labs complaining about the same problems that PLUGS was addressing, the lab team at Seattle Children's developed the membership-based collaboration that PLUGS is today.

Even though PLUGS was started to serve labs in pediatric hospitals, about half of all pediatricians practice in health systems serving adults. "The **Mayo Clinic** is a good example," observed Astion. "Additionally, seven PLUGS member hospitals serve adult patients, such as **HealthPartners** in Minneapolis," commented Astion. "We also have some freestanding labs such as **TriCore Reference Laboratories** in Albuquerque, New Mexico.

"The other reason so many hospitals and health systems serving adults have joined PLUGS is that there is tremendous overlap in testing for children and testing for adults," continued Astion. "For example, the problems hospital laboratories have with celiac disease tests, other autoantibody tests, nutritional tests, and allergy tests, are the same for children

Mayo Medical Labs Seeks to Bring Utilization Management to More Hospital Laboratories

WHEN IT COMES TO MOLECULAR AND GENETIC TESTS, few hospital-based clinical laboratories have the expertise needed to effectively manage the utilization of these tests, stated Don Flott, Director of Utilization Management for **Mayo Medical Laboratories** (MML).

"The explosion in genetic-testing technology means more genetic and molecular tests are being introduced all the time," noted Flott. "The problem with such a rapid increase in the number of lab tests being offered is that doctors don't always fully understand the value of these tests. Busy physicians today may be overwhelmed by technology, and as a result, there is often a knowledge gap, which leads to testing being inappropriate or over-ordered.

"But physicians still order these tests because that's what patients want," he said. "And, often, doctors order genetic tests in a shotgun manner, meaning, they order many different tests and may not fully understand each one. That knowledge gap leads to unnecessary testing. This is a critical issue today when the spending on genetic and molecular tests is growing by 12% to 25% per year, and between 20% and 40% of these tests are unnecessary.

"When doctors don't know what to do, they need experts in molecular and genetic testing," he continued. "For example, when a physician wants to consult with a pathologist or Ph.D. knowledgeable about molecular and genetic tests, one of the first questions the expert will ask the physician is, 'What clinical question are you trying to answer?'

"Another problem is the acute shortage of genetic counselors to meet with patients, gather a patient and family history, and counsel them on appropriate genetic and molecular testing," noted Flott. "The demand for genetic counselors is so great that community hospitals just don't have access to lab-based genetic counselors.

"Across the nation, some large pediatric hospitals have genetic counselors, but small hospitals don't have them, and there are good reasons why a small hospital doesn't need full-time genetic counselors," he stated. "Instead, hospitals could benefit from having access to a genetic counselor only as needed, and these arrangements are workable because genetic counseling can be conducted by phone or email.

"That's why we joined PLUGS (Pediatric Laboratory Utilization Guidance Services) as a gold member last year," said Flott. "A gold membership allows us to supplement our Mayo Clinic genetic counselor expertise with the genetic counselors at PLUGS to better serve hospitals with large pediatric practices around the country. These hospitals may not be children's hospitals, but they still have pediatric patients and thus need utilization management.

"Meanwhile, we continue to make our in-house genetic counselors at Mayo Clinic available to our hospital clients that serve adult patients," he continued. "Because of PLUGS' expertise in pediatric laboratory medicine, it made sense for us to partner with PLUGS to serve our hospitals that have pediatric patients.

"Thus, both Mayo Medical Laboratories and the PLUGS team at Seattle Children's Hospital share a common goal: We are both helping physicians to close the knowledge gap and achieve improved patient safety and outcomes through better utilization management of molecular and genetic tests," concluded Flott.

and adults. There's a lot of overuse and over-bundling when physicians order these send-out tests." TDR

—Joseph Burns

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Legal Update

Will Federal Prosecutors Pursue HDL Lab Execs and Physicians?

Observers believe HDL and Singulex settlements are just the first and more legal actions are to come

THERE WAS MUCH TO BE LEARNED when, on April 9, federal prosecutors announced settlements of multiple whistleblower lawsuits against **Health Diagnostics Laboratory, Inc.** of Richmond, Virginia, and **Singulex Inc.** of Alameda, California.

First, the **Department of Justice** structured a settlement agreement with the two lab companies which involves money to be paid up front and additional money to be paid later, based on certain contingencies.

Second, federal prosecutors, for the first time, acknowledged that the DOJ had joined whistleblower lawsuits against several related parties. In the press release, the DOJ said, "The government also intervened in the lawsuits as to similar allegations against another laboratory, **Berkeley HeartLab Inc.**; a marketing company, **BlueWave Healthcare Consultants Inc.**, and its owners, Floyd Calhoun Dent and J. Bradley Johnson; and former CEO Latonya Mallory of HDL."

Guilty Pleas From Doctors

Third, the possibility exists that the federal attorneys prosecuting this case might follow the same pattern as the U.S. attorney in the federal case against **Bio-Diagnostic Laboratories, LLC**, of Parsippany, New Jersey. In that case, the early settlements were announced against the lab company and its owners and employees. Only then did the federal attorney pursue and win criminal guilty pleas, fines, and restitution from a substantial number of physicians who admitted to accepting inducements and kickbacks from Bio-Diagnostic Labs.

The settlements with HDL and Singulex are civil settlements and both companies deny the allegations in the lawsuit. HDL will pay $47 million plus interest, and as much as $100 million if the company is sold or HDL sells assets. Singulex will pay $1.5 million plus interest, plus additional payments over five years based on its total annual revenue.

Multiple Whistleblowers

In the DOJ press release, additional information was provided that will be of particular interest to pathologists and lab administrators. It disclosed that "the lawsuits were filed by Dr. Michael Mayes, Scarlett Lutz, Kayla Webster, and Chris Reidel under the *qui tam*, or whistleblower, provisions of the False Claims Act."

That means multiple whistleblowers with knowledge of these schemes filed separate lawsuits. The DOJ then joined the lawsuits under seal and combined them. The message here is that any lab company that is pushing its interpretation of federal and state lab compliance laws should fear employees, other insiders, and physicians. These are the individuals who have access to the documents needed to demonstrate violations of antikickback laws. TDR

COLA Questions UHC on BeaconLBS Accredit Rules

Why would health insurer exclude laboratories accredited by five CMS-approved organizations?

CEO SUMMARY: UnitedHealthcare's 'Laboratories of Choice' network in Florida accepts only labs accredited by the College of American Pathologists and The Joint Commission. In March, COLA wrote to UnitedHealth to question this policy which excludes labs accredited by the five other accrediting bodies that hold deeming status from CMS. COLA has requested that UnitedHealthcare reconsider this program requirement, but UnitedHealthcare has not yet changed this policy.

THERE IS ONE MORE CREDIBLE CRITIC to add to the list of physicians, medical associations, and other organizations expressing their objections to **UnitedHealthcare** over the design and operation of its laboratory benefit management program now underway in Florida.

On March 9, **COLA, Inc.'s** CEO, Douglas A. Beigel, sent a letter to Catherine E. Palmier, M.D., Chief Medical Officer for UHC's east region. In the letter, he questioned UHC's exclusion of five CMS-deemed laboratory accrediting bodies from the laboratory benefits management program that is managed by **BeaconLBS**, a business division of **Laboratory Corporation of America**. COLA is one of the accrediting bodies that is excluded.

Only Two Accrediting Bodies

"Of special interest to me is the fact that clinical laboratories that presently receive CLIA accreditation from COLA and four other accrediting organizations are apparently excluded from participating in the program," wrote Beigel. "Instead, in order to become a BeaconLBS 'Laboratory of Choice,' a laboratory can only be accredited by the two organizations specified on page two of the program's Administrative Protocols."

Those protocols identify the **College of American Pathologists** (CAP) and **The Joint Commission** (TJC) as the only acceptable accrediting organizations for labs that want to be in UHC's lab of choice network. The excluded accrediting organizations are:

- **AABB**
- **American Association for Laboratory Accreditation** (A2LA)
- **American Osteopathic Association** (accredits labs in AOA-accredited hospitals)
- COLA
- **National Accrediting Agency for Clinical Laboratory Sciences**.

In the letter to UHC, Beigel stated that, "With respect to the state of Florida, COLA has an especially deep relationship. In 1995, COLA received deeming status [from the state] for the purpose of helping

the state enforce its own laboratory quality law in addition to ensuring CLIA compliance. COLA presently serves 740 Florida laboratories, and has performed approximately 17,000 surveys across the state. When it comes to serving Florida laboratories, COLA has a long and proud history of success."

Stifling Competition

Beigel further noted to UHC that, "It has long been our experience that encouraging an exclusive arrangement between a healthcare provider and selected accrediting bodies stifles fair, free, and open competition. This may have the unintended outcome of fostering a sense of complacency with respect to ensuing high quality in laboratories, perhaps compromising patient care in the process.

"Therefore, I request that UnitedHealthcare reconsider its decision to exclude five CMS-deemed accreditors from participating in its Laboratory Management Program, and instead embrace the policy of open competition established by CMS," stated Biegel. "The resulting sense of competition among participating accreditors will result in better laboratory quality, ultimately benefiting patients."

Unaware of Lab Accreditors

When contacted by THE DARK REPORT for comment, Beigel stated that, "We wrote the letter basically to open up a dialogue with UnitedHealthcare. Whenever an accrediting agency has been excluded in the past, we find we need to educate the insurance companies or the delivery system because usually they are unaware that CMS grants deeming authority to accrediting agencies and that the agencies can accredit to CLIA, the state requirements, and to their own standards as well."

After UnitedHealthcare received delivery of that letter, COLA officials told THE DARK REPORT that they had been contacted by UHC staff. However, as of this date, COLA officials say that there has been no change to the status of the five lab accrediting agencies that are currently excluded from UHC's laboratory benefit management program. TDR

—Joseph Burns

Contact Douglas Beigel at dbeigel@cola.org or 800-981-9883.

Lab Accreditors Excluded from BeaconLBS Program

WHEN THE CEO OF COLA POINTED OUT that it was not unknown for a health insurer to exclude one or more medical laboratory accrediting agencies because the insurer was unaware of the existence of all seven lab accrediting bodies, that situation probably does not apply to UnitedHealthcare in this case.

It is unlikely that UnitedHealthcare was unaware of the other organizations to which CMS has granted deeming authority for accrediting labs to CLIA. That's because BeaconLBS is owned by LabCorp and LabCorp officials would be quite familiar with the seven lab accrediting bodies holding deeming authority. It would thus be reasonable to assume that it was the BeaconLBS officials who recommended that UHC's laboratory of choice protocols only include labs accredited by CAP and TJC.

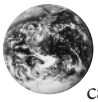
In fact, competing labs readily point out that, not only are five lab accrediting organizations excluded from UHC's laboratory of choice network, but nearly all laboratories operating in Florida that also happen to compete against LabCorp are also excluded.

Lab executives from competing labs observe that it is possible these actions by UHC and BeaconLBS/LabCorp might be construed as being in violation of antitrust or anti-business laws because of how they believe that UHC's laboratory benefit management program seems to favor LabCorp, the owner of BeaconLBS, while excluding nearly all the labs in Florida that have served patients for decades.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report



It's a lawsuit that **Quest Diagnostics Incorporated** can't seem to make go away. Last week in California, a federal judge ruled **Hunter Laboratories** and **Surgical Pathology Associates** (SPA) can continue to pursue their antitrust lawsuit against Quest Diagnostics. Plaintiffs allege that Quest conspired to monopolize lab testing in California. Hunter Laboratories claimed it was harmed because Quest Diagnostics sold lab tests below cost. SPA claimed it was harmed because Quest had below-cost capitated contracts with certain payers.

MORE ON: *Lawsuit*

In November 2012, Hunter, SPA, and three other California labs filed the original antitrust complaint against Aetna, Quest, **Blue Shield of California,** and the **Blue Cross and Blue Shield Association**. After more than two years of legal maneuvering, only the two claims of Hunter and SPA remain. One interesting legal aspect to this case is that it has claims under California's statutes that prohibit a company from selling below its cost.

UNIVERSITY OF MICHIGAN SYSTEM PLANS $160M LAB

In this age of shrinking lab budgets, the **University of Michigan Health System's** plan to spend $160 million on a new lab shows how much UMHS values lab medicine's ability to improve patient outcomes. Currently, the 450 faculty and staff work in 10 different lab locations across the campus. Following construction of the new 139,000-square-foot lab in four vacant buildings in the school's North Campus Research Complex, they will all work in the new lab facility. The lab is in the design phase and no date for the start of construction has been announced.

LABS, DX MAKERS DRAFT COMPROMISE PLAN ON LDTS

As the FDA considers regulating lab-developed tests (LDTs) as medical devices, the lab industry is presenting alternative ways to review and approve LDTs. The latest alternative comes from a working group of labs and diagnostics manufacturers who offered a compromise. Under this plan, labs would get more regulation of LDTs but they would keep the FDA away from regulating LDTs as medical devices, according to a report in the *FDA Law Blog*. The proposal could form the basis of legislation to be released soon, according to the law blog. *Genome Web* reported that participants in the working group include **ARUP Laboratories, Becton Dickinson, Laboratory Corporation of America, Mayo Clinic,** and **Roche.**

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Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

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That's all the insider intelligence for this report. Look for the next briefing on Monday, May 11, 2015.