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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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Founder & Publisher

Scrutinizing the Cost of Lab Testing

IT SEEMS LIKE THE COST OF LABORATORY TESTING continues to be a high-profile issue. On the pages that follow, you will read two different stories about how the cost of lab testing is undergoing intense scrutiny. This is not an accident. Rather, it shows how healthcare's evolution is already undermining the traditional payment methods common in the clinical lab industry.

First, on pages 7-8, is a story about a physician-operated ACO in New England. Risk-related managed care contracts already represent 70% of the organization's revenue. That has motivated the 1,000 physicians of **Atrius Health** to implement programs to improve utilization of high-cost clinical services.

No surprise was the fact that inappropriate hospital admissions and imaging studies were the first clinical services to undergo review. But you will be fascinated to learn that lab testing was quickly targeted for improved utilization. Why? Because the high volumes of lab tests ordered daily by physicians quickly add up to big numbers. Atrius Health believes that its first three programs to improve utilization of lab testing will save it more than $1 million per year. Of course, this means fewer lab test referrals (and less revenue) to its lab providers.

Second is the interesting development in the federal lawsuit involving three California lab companies that sued **Quest Diagnostics Incorporated** and several insurance companies in 2012. You will find it on pages 13-15. In response to motions and hearings, last month the judge tossed out six charges made by the plaintiff labs.

But the judge ruled that the case could move forward on the seventh charge which claims that the national lab company engaged in predatory pricing in violation of state and federal laws by charging some customers less than cost for lab tests. Of course, Quest Diagnostics is unhappy about this development and states that it has not violated laws or regulations associated with these activities. On the other hand, there are many pathologists and lab executives who would welcome having a federal court scrutinize the lab test pricing practices of any lab company that uses below-cost pricing to increase market share.

Both stories illustrate how the healthcare system is beginning to question both the price of lab testing services and whether clinicians are ordering lab tests appropriately. This is fair warning to all labs to be prepared when payers and their clients undertake similar initiatives. TDR

Labs, Path Groups Face Major Financial Issues

Early news of path group closures and lab BKs hints at coming wave of financial distress for labs

CEO SUMMARY: Are clinical labs and pathology groups ready for the end of fee-for-service reimbursement? That's just one important question that will be answered at the upcoming* Executive War College on Lab and Pathology Management *that will take place in New Orleans on April 29-30. The American healthcare system is undergoing unprecedented transformation and sessions at this year's conference will address how labs can tap new sources of revenue and deliver more value.

IT'S NO LONGER BUSINESS AS USUAL for clinical laboratories and pathology groups across the nation. Blame it on the swift evolution of the American healthcare system, in tandem with dramatic reductions in reimbursement for lab tests.

One could say that the entire profession of laboratory medicine is about to be hit full force by the "perfect storm." The list of market forces expected to be negative to most clinical labs and pathology groups is extensive. Worse, that list is growing as additional destructive market developments become visible. *(See sidebar on page 5.)*

The full consequences of these developments have yet to become obvious. But the early signs are ominous. Over the past year, THE DARK REPORT has chronicled the closures or the bankruptcies of lab companies like **Pathworks Diagnostics Inc.**, **Predictive Biosciences**, and **Laboratory Partners Inc.** and its **MedLabs** business subsidiary. Expect there to be more lab closures, bankruptcies, and acquisitions.

What THE DARK REPORT has yet to report on is the closure of several anatomic pathology group practices that have occurred in the previous 24 months. These are small pathology groups and they are quietly closing their doors and going out of business. Pathology vendors see this happening because they lose customers this way.

What makes the closure of several small pathology groups notable is that there is no precedent for this in the past 30 years. These closures are sentinel events that tell savvy pathologists that a larger wave of financial distress is about to overtake the anatomic pathology profession.

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

Given the serious market transformation that lies ahead for clinical labs and pathology group practices, this year's *Executive War College on Lab and Pathology Management* will put healthcare's market transformation front and center. It will take place in New Orleans on April 29-30, 2014. Special sessions and knowledgeable speakers will help attendees understand the changing market dynamics, along with advice and insights on how to best respond to these trends.

Hospital Lab Outreach Wins

For example, hospital laboratory administrators will find the session titled "Lessons from the Northwoods: How **NorDx Labs** is Responding to Changing Clinical and Payer Needs in the Inpatient, Outpatient, and Outreach Sectors" to be essential learning.

NorDx CEO Stan Schofield will describe how his parent healthcare system in Portland, Maine, has responded to Medicare Part A funding cutbacks while launching ACOs, establishing medical homes, and developing its ownership of physician practices in the region.

Next, Schofield will identify the steps his lab organization has taken internally and externally to absorb reduced budgets and declines in outreach reimbursement, all with the goal of maintaining financial stability and clinical value even as traditional sources of lab funding are shrinking.

Strategies for Path Groups

To address the changes underway in the anatomic pathology marketplace, a strategic case study by the **University of Miami** Department of Pathology and Laboratory Medicine will be delivered by Chair Richard J. Cote, M.D.

This session is titled "Positioning Pathology and Clinical Laboratory Services to Add Value in the Era of ACOs and Medical Homes" and addresses all the specific challenges now facing pathology groups, whether large or small; whether academic or community-based.

Florida is a hotbed of healthcare change and the University of Miami pathology department is in the midst of it all. Cote will discuss how his pathology department is developing new value-added services to retain and increase access to managed care patients. This includes providing testing to the office-based physicians that are part of the parent health system.

Cote and his colleagues recognize the importance of the pathology department supporting integrated clinical informatics. He will discuss the advanced solutions his team is developing in tandem with the ability to mine the system's EHR and provide enriched diagnostic and prognostic information to physicians and payers. Of course, digital pathology has a role in increasing the pathology group's value proposition and will be discussed.

Legislative, Regulatory News

Wonder what's happening in Washington, D.C., with CMS and Congress? Experts from the **American Clinical Laboratory Association** (ACLA), **College of American Pathologists** (CAP), **National Independent Laboratory Association** (NILA), and the **California Clinical Laboratory Association** (CCLA) will participate in a special extended panel discussion.

These individuals are in regular conversations with Medicare officials, members of Congress, and other executive branch policymakers. They will report on new developments and have invaluable insights about what can be expected in Medicare funding for lab and pathology services, as well as with implementation of new Medicare regulations to which all labs must comply.

For laboratory chief financial officers, our CFO roundtable is now in its fifth year. This special 2-hour event brings together as many as 50 CFOs, lab controllers, and other financial managers for candid conversations about the issues that directly touch their own labs. Winning solutions and effective management strategies are regularly shared.

Market Forces Putting Labs and Path Groups Under Severe Financial and Operational Stress

IN TODAY'S HEALTHCARE MARKET, change is happening at an unprecedented pace. Here is a list of individual market trends that are changing how clinical laboratories and anatomic pathology groups deliver testing services and are paid for those services:

1) Cumulative impact of multi-year fee cuts for lab tests and anatomic pathology services by the Medicare and Medicaid programs.
2) Ongoing and sustained reductions in the prices private payers pay for lab tests.
3) Impact of new Medicare bundled payment rules for the Outpatient Prospective Payment Schedule, affecting both clinical labs and pathology groups.
4) Less reimbursement and restricted coverage guidelines for molecular diagnostics and genetic tests.
5) Private health plans implementing narrow networks and excluding local labs and pathology groups as providers, limiting their access to patients.
6) Negative impact of the Blue Card policy change on local and regional labs.
7) Introduction of bundled reimbursement and capitated reimbursement arrangements that include lab tests and pathology services in the bundle.
8) Steady growth in the number of ACOs, medical homes, and other models of integrated care organizations. These care models use lab tests differently and often want to pay for lab tests using a per-member/per-month fee or a capitated rate.
9) Reduction in hospital inpatient admissions and inpatient revenue, causing hospitals to cut their labs' budgets.
10) Need for labs and pathology groups to spend money to support the Meaningful Use requirements that their physician clients must meet to qualify for federal EHR incentives.
11) Need for labs to spend money on new diagnostic technologies and the skilled lab professionals to run the tests, including next-generation gene sequencing.
12) Need for pathology groups to invest in acquiring and using digital pathology systems, as well as beefing up their informatics capabilities in support of their hospital and physician clients.
13) Shortage of newly-trained clinical laboratory professionals and subspecialist pathologists due to reduced number of training programs.
14) Staffing shortages in clinical labs and pathology groups caused by Baby Boomers choosing to cut back hours or fully retire from the profession.

Learn Effective Strategies

At the upcoming *Executive War College*, to take place in New Orleans on April 29-30, 2014, there will be 60 sessions and 90 speakers addressing these topics. *(Visit www.executivewarcollege.com to view the agenda and to register.)*

Sessions are conducted by lab executives and pathologists from lab organizations that are succeeding in building market share and are holding their own in the face of budget cuts and restrictive managed care contracting policies. Each presentation is designed to help you understand and identify these healthcare marketplace drivers, then provide you with the solutions and strategies that you can implement in your laboratory to optimize revenue, deliver more value to referring physicians, and boost productivity.

For the same reasons, there will also be a roundtable for laboratory chief information officers and a roundtable for laboratory sales and marketing VPs and managers. These are unique networking and information-sharing sessions.

New Lab Business Models

With so many changes happening across the entire spectrum of healthcare in the United States, new business models for lab testing organizations are emerging. To delve into the future of what labs will look like and how they will operate, the *Executive War College* is presenting a full-day seminar titled "Anticipating New Clinical and Business Models for Clinical Labs and Pathology Groups."

This will take place on Thursday, May 1, immediately following the conclusion of the *Executive War College* which happens on April 29-30.

Featured will be leaders from clinical laboratories and pathology companies who are posting consistent growth in specimen volume and revenue, accompanied by the needed profit margins to financially sustain the organization. They will share what they are doing differently than peer labs that works and for which payers will reimburse.

Time for Action By All Labs

Current events in healthcare and laboratory medicine make it essential that every lab manager and pathologist serving as the business leader for his or her group stay informed on the best and worst of what is to come. That makes this year's *Executive War College* a timely and smart opportunity to learn the latest developments and master new financial strategies. TDR

Lab Sales VPs & Sales Leaders: Workshop to Boost Your Sales!

NOW, MORE THAN EVER, ALL LABS need a productive sales and marketing program to offset falling revenues and tap the new sources of lab test business that healthcare's evolution is creating.

To help lab leaders boost the performance of their sales and marketing programs, a special, full-day workshop for lab sales leaders and sales managers will take place on Thursday, May 1 in New Orleans, following the *Executive War College* on April 29-30. *(Visit www.executivewarcollege.com for more details.)*

Designed specifically for sales VPs, sales managers, and lab administrators tasked with managing their labs' sales programs, this workshop fills a huge gap in the professional development of lab sales leaders. It teaches the techniques needed by effective sales managers, including:

- Accurately gauge your lab's sales program's weaknesses, with techniques to fix them.
- Do you have the right people selling? Learn and master the secrets of recruiting, training, and motivating top sales producers.
- Why your lab sales compensation program sucks! Simple changes that drive big increases in profitable new sales.
- Avoid selling on lowest price; powerful techniques to sell on value.
- Best ways to monitor sales productivity and profitability and sustain high-performance by the sales team.

Led by one of the nation's most successful sales consultants and trainers, Karl Scheible, President of **Market Sense, Inc.**, this workshop provides the executive and management principles taught by the Sandler Selling System. This is essential learning for those leading and managing lab sales programs.

ACO Trends

Physician Group ACO Targets High-Volume Tests for Savings

As one way to control costs, the ACO showed physicians how much lab tests cost at time of order

HERE'S AN EXAMPLE OF HOW an accountable care organization views cost control. **Atrius Health** sought to control excess costs by focusing on high-priced items. It started with inappropriate hospitalizations and imaging studies and moved on to laboratory testing.

Atrius Health is a non-profit alliance of six community-based medical groups and a home health and hospice agency. Its 1,000 physicians care for more than 1 million patients in 50 practice locations in Eastern and Central Massachusetts.

Currently, Atrius Health has three initiatives in place to limit the ordering of unnecessary laboratory tests. It is saving hundreds of thousands of dollars on each effort for a total savings that could be $1 million or more annually.

Different Financial Incentives

Capitated and shared savings contracts it has with health plans in Massachusetts provide incentives are designed to drive out unnecessary costs. Under these contracts, Atrius Health is responsible for the total cost of care. This includes office visits in and outside of its facilities, hospitalization, pharmacy, post-acute care and diagnostic testing.

"About 50% of our patients are on some sort of risk contract, such as a budgeted or capitated amount per month," said Richard Lopez, M.D., Chief Medical Officer. "About 70% of our revenue comes through risk-related contracts.

"These contracts create an incentive to closely manage costs," he noted. "In a completely fee-for-service medical practice, doing plenty of lab tests generates revenue. Under capitated and shared-savings arrangements, the incentives are reversed. Now we must carefully watch what we spend on care."

Meeting Quality Targets

Lopez said that the risk contracts also offer financial incentives for physicians and hospitals to meet certain quality targets. This factor thus prevents providers from skimping on care.

In November, the *Journal of General Internal Medicine* published the results of a study in which Atrius Health participated. The study evaluated the effect of real-time display of laboratory test costs on primary care physician ordering of 27 common laboratory tests for outpatients (21 low-cost and six high-cost tests).

There was a decrease in ordering rates for four of 21 (19%) of the low-cost tests and for one of six (17%) of the high-cost tests. For the low-cost lab tests used in the study, Medicare paid less than $40; for high-cost lab tests, Medicare paid above $40.

In this study, researchers showed a potential savings on lab testing of $45.45 per 1,000 visits per month. Given that Atrius Health has about 3.5 million patient visits per year, the savings could total $157,000 per year.

"This study showed that displaying more price information in the electronic health record (EHR) could result in

greater savings," observed Lopez. "That is why, in the past month, as one of three current initiatives that target use of lab tests, we've started another study.

Using EHR To Display Costs

"We are using the EHR to display lab test costs and the costs of X-ray procedures, CT scans, cardiac testing, and emergency room visits," he continued. "For lab tests, we have added the costs of another five or 10 more tests."

A second effort to control costs involved setting guidelines for pre-visit lab tests. "In the past, it was common to order many pre-visit lab tests when a patient was due for an annual physical," Lopez said. "But there was a lot of variation in how many pre-visit tests a physician would order. Some physicians would order a lot of blood tests and some would not. Even more importantly, the ordering of these tests was not always evidence-based.

"Some of the tests were unnecessary," he stated. "For example, a patient with a normal cholesterol profile typically doesn't need a lot of blood tests ordered every year. Also, there are potential risks for the patient when doing unnecessary tests.

Pre-Visit Lab Test Protocols

"The change was to intervene in the pre-visit lab process by giving the medical assistants guidelines based on the patient's age, which medications the patient was taking, and which diagnoses the patient had in the past," explained Lopez. "With that information, the guidelines identify which lab tests would be appropriate. By instituting that process, we drove down lab testing associated with routine physicals, saving about $500,000 per year.

"The cost of a typical lab test might be $15 to $40 or so, which is not a lot compared with the cost of an MRI, which can be $1,000 or more. But when we analyzed the frequency of some test ordering and recognized that we have 1 million patients, the numbers added up quickly," Lopez explained.

"In our third initiative, we reduced the number of liver function tests we do for patients on cholesterol-lowering drugs," he noted. "When statins were introduced, there was a lot of concern about their potential effect on liver function. So many physicians ordered these tests.

"Now, with more than a decade of experience with statins, we know it's not necessary to order a liver function test every year for every patient," observed Lopez. "Again, that's a low-cost lab test but we were doing a lot of them. After we promoted the most recent FDA guideline on liver function tests for these medications, we experienced a reduction in the number of tests ordered and that alone saved several hundred thousands of dollars annually."

Inappropriate Utilization

The efforts of Atrius Health show pathologists and lab executives how providers—in response to the emerging value-based reimbursement arrangements—are taking swift steps to identify inappropriate utilization of clinical services, including laboratory tests. Under capitated and shared savings contracts, providers such as Atrius Health have a powerful motivation to help their clinicians become more effective at ordering the right test at the right time for each patient.

With hundreds of ACOs and medical homes now providing care to millions of patients, labs can expect to see changes in both the volume of tests and the mix of tests referred by these care organizations. For labs that still depend on fee-for-service revenue, the resulting decline in the volume of lab testing from clients improving their utilization of lab tests may be measurable and financially painful. TDR

—Joseph Burns

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New Mass Spec Tox Test Delivers Clinical Benefits

One multiplex assay detects 112 chemicals and 500 brand-name and illicit drugs at once

CEO SUMMARY: Researchers at the University of Colorado in Aurora used mass spectrometry technology to create a paradigm-shifting toxicology test. It uses a urine specimen and can identify 112 compounds and more than 500 illicit and brand-name drugs in a single assay. For pain management testing, not only does this bend the cost curve downward, but the multiplex test gives physicians a more accurate way to screen patients for therapeutic drugs and drugs of abuse.

MULTIPLEXED MASS SPECTROMETRY IS POISED to trigger a revolution in clinical laboratory testing. Advocates of this technology point out that, for certain types of lab tests, multiplexed mass spec can produce a more precise answer and do so at considerably less cost than many existing lab test methodologies.

One innovative use of this technique for clinical purposes can be found at **CU Toxicology** of Aurora, Colorado. It has developed a multiplexed mass spectrometry test that can identify 112 compounds and more than 500 illicit and brand-name drugs at a price that can be disruptive to the existing standard of practice in pain management testing.

CU Toxicology is a nonprofit lab that is part of a public-private partnership with the **University of Colorado School of Medicine's** Department of Anesthesiology. The CLIA-licensed and CAP-accredited laboratory is on the CU Anschutz Medical Campus in Aurora, Colorado.

The use of a multiplexed mass spec approach for therapeutic and drugs-of-abuse testing is the brainchild of Jeffrey Galinkin, M.D., Chief Medical Officer of CU Toxicology. He is also a professor of anesthesiology and pediatrics at the University of Colorado School of Medicine.

"This assay tests for 112 drug compounds at once," stated Galinkin, in an interview with THE DARK REPORT. "In a urine sample, it can find virtually any substance in just about any quantity. The test is far more sensitive and specific than traditional ELISA-based urine drug testing."

Disruptive Innovation

CU Toxicology's mass spec test—capable of identifying 112 compounds and more than 500 illicit and brand-name drugs in a single assay—is a disruptive innovation. Galinkin believes that many labs may be reluctant to adopt this methodology because such a test could cut into revenue traditional testing methods generate.

CU Toxicology prices this test at $200 for a single individual. The lab negotiates lower prices for more volume.

"Most laboratories doing urine drug testing make a lot of money off the current testing methodologies because they can bill

for the initial screening up front and then separately bill for each confirmation test," observed Galinkin. "Depending on which drugs a lab or a referring physician is trying to identify, the cost of conventional testing could range from $800 or $1,600. Our proprietary multiplexed mass spec test can do the same job for a fraction of that cost by screening for 112 drugs all at once."

Primary, Secondary Uses

The assay has two primary applications in toxicology. One application is to support pain management clinics. The other use is in support of addiction treatment centers.

"Also, here in Colorado, we have emergency departments using this assay to identify the drugs an unresponsive patient suffering an overdose may have taken," commented Galinkin. "Employers and health plans can use the test to verify patient compliance with prescribed medications and to detect misuse of prescription or illicit substances.

"We have solved a difficult problem," Galinkin said. "For the 112 chemicals on our list, we can say with certainty which drugs every patient has been taking or not taking, based on the results of our multiplexed mass spectrometry test."

The typical toxicology lab will use an ELISA-based test as an initial screen. "These tests are about 60% to 70% sensitive," explained Galinkin. "Next, labs use mass spec or a radioimmunoassay—depending on the lab—to confirm the presence of the drugs identified in the initial screen. The problem with this combination testing is the traditional tests have a much higher detection limit than we do.

"The much lower detection limit of our assay allows us to identify very small quantities of a drug in a patient's system," he said. "The high sensitivity levels allow us to identify drugs that normally slip through with industry-standard drug screens.

"In addition, we can identify and confirm more than 500 prescription and over-the-counter drugs," added Galinkin. "This is important when trying to manage patients taking multiple drugs.

"This aspect of our test is significant for polypharmacy, or the use of multiple drugs at once," continued Galinkin. "Polypharmacy is an epidemic in this country. More than one in five U.S. citizens now use three or more prescription drugs, and more than one in 10 use five or more prescription drugs."

The benefits of the multiplexed mass spec assay were important to laboratory professionals at **Kaiser Permanente Colorado** in Denver, according to Michael Sheehan, Ph.D., the Technical Operations Manager for Kaiser's central laboratory.

Sheehan stated that, previously, Kaiser's central lab had sent all urine drug testing work to one of the national lab companies. However, in order to save money and reduce turnaround time, it had internalized much of that work.

Confirming Positive Results

"After we started doing our own initial drug screens, we needed a process where we could confirm a positive result that we hadn't expected to be positive," said Sheehan. "We also wanted to confirm a finding about a drug that was supposed to be there but wasn't. Further, because we're an HMO, there is a cost associated with everything our lab does and we don't get reimbursed for each test we run.

"Our drug screens were developed based on consultations with our client clinics," he noted. "Currently, for dependency clinics and pain clinics, our lab runs a screen for seven drug classes. Those seven classes are amphetamines, benzodiazepines, cocaine, methadone, opiates, THC (or delta-9-tetrahydrocannabinol), and oxycodone.

"It is important to note that, here in Colorado, Kaiser does not have any hospitals," said Sheehan. "Thus, our lab does not need to do any toxicology screens for the emergency room.

Pain Management Doctor Saw Potential in Using Mass Spectrometry for Toxicology Screens

IN 2011, RESEARCHERS at the University of Colorado were seeking to develop a mass spectrometry assay to identify athletes using performance-enhancing drugs.

At the time, Jeffrey Galinkin, M.D., was a professor of anesthesiology and pediatrics at the University of Colorado School of Medicine. In this role, he recognized that it would be relatively easy to adapt mass spec technology for toxicology screening.

"At that time, we referred our tox screens to an outside laboratory and it took weeks to get the results back," said Galinkin, who is also the Chief Medical Officer of CU Toxicology. "Moreover, the lab test results we got back never seemed to correlate with what the patients were taking.

"I saw that, by developing mass spectrometry for toxicology testing, we could do something that could literally change the industry," recalled Galinkin. "Market research showed that toxicology was a much bigger industry opportunity than sports screening for performance-enhancing drugs.

"From there, it took us two years to find the right mass spectrometry instrumentation," he continued. "We selected the QTRAP 5500 System manufactured by **AB Sciex**. We now have three of them. We also needed to develop our own proprietary software to manage the many points of data we were getting from the mass spec.

"Today, our three machines at CU Toxicology run 24/7 and our throughput is variable," stated Galinkin. "We currently do about 50 to 100 tests per day but we have the capacity to do about 1,000 tests per week."

On staff are four toxicologists and there are no pathologists. CU Toxicology's turnaround time is between 24 and 48 hours.

"We believe this is an important technology because the mass spec can weigh every compound in the sample every time," noted Galinkin. "Each time one of these compounds comes through, we know—based on the mass spec—the specific drug and the quantity of that drug.

"This high level of confidence is very different from traditional lab testing technology used in toxicology today," he concluded. "The accuracy of our multiplexed mass spec test delivers an important clinical benefit. It allows an addiction clinic or a pain management center to build trust instantly between a client and patient. Our multiplexed mass spec assay changes the whole idea about patient/physician trust because the toxicology screen can't be fooled."

"There are two benefits from the CU Toxicology testing that are extremely useful for us here at Kaiser," he continued. "The first benefit is that we can screen down to a level that is extremely low. The level is so low that it's actually below the threshold for detection with more traditional testing.

More Precise Detection

"The detection level of CU's mass spec-based toxicology screen is about 10 to 30 times lower than we can detect with our lab equipment," stated Sheehan. "To say whether a test is positive or not, CU Toxicology can go down to 5 to 10 nanograms per milliliter. By contrast, our lab can go down to only 100 to 300 nanograms per milliliter.

"The second benefit for us involves the chemical dependency clinics that are helping patients get off of opiates," he explained. "Those patients now are on suboxone, which cannot be detected by our seven drug screening panel.

"That means the chemical dependency clinics don't know if the patients are compliant or if they are diverting the drug to a family member or someone else," stated Sheehan. "However, we can send that test

for confirmation to CU Toxicology, where it can easily detect if it is present or not.

"Another advantage for us in working with CU Toxicology is that their test can detect traces of illicit drugs (such as cocaine and methamphetamine) up to one month post ingestion, whereas our screen would be negative in three to five days," he noted. "This gives our clinics a better picture of whether their patients are compliant with their non-drug regimens.

"This level of detail cannot come from traditional toxicology testing, yet that information is critically important for these clinics," Sheehan explained. "These are the clinical advantages of having a toxicology screen that is highly sensitive and specific for pretty much any drug a patient might be able to obtain."

For Sheehan, it was important to manage the cost of toxicology testing in appropriate ways. "Take the example of testing someone for amphetamine use," he said. "If I send that test to a national lab, it would cost us $45; and all I would know was whether or not the patient was taking an amphetamine-like drug. If I sent that one test to CU Toxicology, that would cost us $115, but I would get the patient's complete drug history as well.

Benefits of Multiplex Assay

"Thus, for a single test, the CU Toxicology pricing is not always the first choice," he continued. "But if our lab needs to test for two, three, or multiple drugs at once—which is more often the case—then the CU Toxicology price of $115 is very good. And it is certainly more efficient to order one test and cover any and all drugs that need confirming rather than piecemeal testing."

Multiplex testing is becoming more important in toxicology, Sheehan added. "That ability to economically screen for many drugs simultaneously is very important for addiction treatment," he said. "That is because those patients sign contracts saying they won't take anything while they're in the clinic; and we know that they are compliant out to a month rather than the three to five day period that we would get with conventional testing.

"Using CU Toxicology's multiplexed mass spec method, which is confirmatory testing, thus gives our ordering physicians a one month drug history window, rather than only a week's look, which is uniquely important with respect to managing these patients," concluded Sheehan. TDR

—Joseph Burns

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Multiplex Mass Spec Test Finds Elderly Drug Dealer

NO ONE EXPECTS TO FIND A DRUG DEALER among the residents of an assisted-living facility. But that's just what a Colorado toxicology lab uncovered recently when it used its new multiplexed mass spec urine drug test.

When the test result came back positive for cocaine, the administrator called the lab saying there must be a mistake. The patient was a little old lady, a most unlikely cocaine user, the administrator said.

So Jeffrey Galinkin, M.D., Chief Medical Officer of CU Toxicology and professor of anesthesiology and pediatrics at the University of Colorado School of Medicine, retested the patient. The retest confirmed the first result. There was no mistake, Galinkin said. The patient had tested positive for cocaine, he told the administrator.

Upon further investigation, the center learned that the woman had been dealing cocaine in the facility and using the drug herself, Galinkin reported.

The drug-dealing little old lady was nabbed because CU Toxicology uses an assay that tests for 112 drug compounds at once. In a urine sample, it can find virtually any substance in just about any quantity. The test is far more sensitive and specific than traditional ELISA-based urine drug testing, Galinkin told THE DARK REPORT.

Judge Lets Trial Proceed In Case Against Quest

Plaintiffs say Quest used predatory pricing to win market share, drive out competitors

CEO SUMMARY: Four California labs have charged that Quest Diagnostics engaged in predatory pricing in a case filed originally in November 2012. After the lawsuit was amended last summer and fall, U.S. District Judge William H. Orrick III heard various motions in the case. On February 6 he ruled that the case could proceed against Quest Diagnostics on allegations that the lab company engaged in predatory pricing. The case could go to trial at about this time next year, according to lawyers for the plaintiffs.

In California, a federal district court judge has ruled that a lawsuit claiming predatory pricing and filed by four laboratory companies against **Quest Diagnostics Incorporated** can move forward.

This is a legal case that has the potential to be disruptive to certain of the long-established business practices of the nation's largest public laboratory companies. Allegations in the lawsuit involve how the defendant lab company has used discounted pricing for laboratory testing and how it contracts with managed care companies. The plaintiff laboratories claim that these practices violate certain California and federal laws.

The original lawsuit was filed in November 2012. *(See TDR, December 10, 2012.)* The plaintiffs amended the complaint on August 9 and again on November 18, 2013, in the U.S. District Court for the Northern District of California.

Following the filing of the amended complaint, U.S. District Judge William H. Orrick III considered various motions in the case. On February 6, Orrick ruled that the case could proceed against Quest Diagnostics, based on allegations that the national lab company engaged in predatory pricing, according to an article published about the case by *Law360.com*.

"This is a significant development because now we know we can move forward with the portion of the case that deals with below-cost pricing," said Anne Marie Murphy, a Principal with the law firm of **Cotchett, Pitre & McCarthy LLP**, which represents the plaintiffs. "Usually some narrowing of the issues is to be expected and that's what happened here. But we're pleased we can now move forward with the case against Quest Diagnostics."

Four Lab Plaintiffs

The four plaintiffs in this case are all laboratories in California. They are **Rheumatology Diagnostics Laboratory, Inc.**, **Pacific Breast Pathology Medical Corporation**, **Hunter Laboratories** (when it was owned by Chris Riedel), and **Surgical Pathology Associates Partnership**. The defendants on the amended complaint were Quest Diagnostics Incorporated, **California Physicians' Services** (doing

business as **Blue Shield of California**), **Aetna Inc.**, and **Blue Cross and Blue Shield Association**.

In the amended complaint filed in August, the plaintiff labs charged that the defendants violated three California laws: the Cartwright Act, the Unfair Competition Law, and the Unfair Practices Act. They also charged that defendants committed intentional interference with prospective economic advantage, negligent interference with prospective economic advantage, monopolization or attempted monopolization; bilateral conspiracies to restrain trade and monopolize; and bilateral conspiracies to monopolize or attempt to do so.

According to *Law360.com*, during a hearing on February 5, Orrick said he was considering throwing out the claims that the defendants engaged in antitrust activity. The labs had failed to show that the insurers had agreed to go along with a conspiracy scheme, the article reported.

Conspiracy Claims Tossed

When Orrick issued his ruling on February 6, he eliminated the conspiracy claims against the health insurers but retained the plaintiffs' claims against Quest Diagnostics alleging violations of the Unfair Practices Act and the Unfair Competition Law, noted *Law360.com*.

But it was an important development that Orrick did not dismiss the case entirely, as Quest had requested for a second time, *Law360.com* reported. In fact, Orrick criticized Quest Diagnostics for raising the same arguments it had made earlier when it said the case should be dismissed entirely. The fact that Orrick decided to leave in place the plaintiff labs' arguments against Quest is significant, said Eric Buescher, a principal with Cotchett, Pitre & McCarthy.

"The judge had already determined that the plaintiffs had sufficiently alleged that Quest Diagnostics was offering services in California that are priced below costs," added Buescher. "He was very clear in stating that he had no interest in reviewing that decision or relitigating that issue. It is time for this case to move forward on that issue."

In the amended complaint, the plaintiffs contended that Quest's actions represent a threat to competition, healthcare providers, and patients. The plaintiff labs claimed that Quest Diagnostics systematically contracts with physician groups on a loss-leader, below-cost capitated basis, court documents show.

Use Of Discounted Prices

The amended complaint stated that "Quest uses the discounted capitated rates in order to lock out competition, and induce referral of Medicare and Medi-Cal pull-through business, in violation of the anti-kickback statutes. Quest provides the capitated prices as an inducement to its customers to refer all of their lab testing business to Quest, including Medi-Cal and Medicare business, which Quest charges on a lucrative, fee-for-service basis.

"Because Quest's competitors, including plaintiffs, are unwilling to violate the law by offering such loss-leader capitated rates, Quest's capitated discounts have the effect of eliminating competition from the markets at issue in this complaint," said the amended complaint. "Quest's loss-leader capitated contracts are specifically designed to injure competitors and destroy competition, and violate the Sherman Act, California's Cartwright Act, and the explicit prohibitions of California Business and Professions Code section 17043 (California's Unfair Practices Act)," it adds.

Pricing And Contracting

Clinical lab executives and pathologists across the country will recognize the business practices described in the lawsuit. The named defendants have engaged in these controversial pricing and contract-

ing practices for decades. In the amended complaint that was filed in August, the four plaintiff laboratories charged that:

1) The Blue Card Association conspired with Quest to suppress competition through exclusionary changes to the BlueCard policy;
2) There is evidence of loss-leader, below-cost contracts;
3) Aetna conspired with Quest to exclude 400 regional labs from Aetna's network in exchange for discounts;
4) That Aetna and Quest have implemented bonus pool agreements;
5) Blue Shield of California accepted a 10% discount on lab testing from Quest in exchange for the exclusion of Westcliff and Hunter Labs from in-network status;
6) Quest has illegally waived out of network co-payment or deductible obligations for competitive advantage; and
7) Defendants' conduct limits competition and increases Quest's monopoly power.

Only the charge of loss-leader, below-cost contracts is moving forward. Orrick eliminated the other six charges in his latest ruling, parts of which are redacted.

Setting Date For Jury Trial

Murphy said that the next step in the case will be a status hearing on March 4 at which time Orrick may set a date for the jury trial, which is likely to begin next year.

Following the judge's ruling on February 6, the claims against the health insurers were dismissed and only Quest Diagnostics remains as a defendant. In its statements about this case, Quest Diagnostics has said that it believes the allegations are untrue and that it will vigorously fight this lawsuit. TDR

—Joseph Burns

Contact Eric Buescher at ebuescher@cpmlegal.com; Anne Marie Murphy at amurphy@cpmlegal.com or 650-697-6000.

Can Chris Riedel Prevail Once More in Court?

IF THERE IS ONE GADFLY who regularly challenges the business practices of the nation's two largest public lab companies in state and federal courts, it has to be Chris Riedel, the former owner of Hunter Laboratories, Inc., of Campbell, California.

Riedel filed a whistleblower lawsuit in 2005 claiming that seven lab companies, including Quest Diagnostics Incorporated and **Laboratory Corporation of America**, violated California law by charging certain clients less than they charged Medi-Cal, the state's Medicaid program. *(See TDR, April 6, 2009.)*

A series of settlements resulted from this lawsuit. In 2011, Quest Diagnostics entered into an agreement with the state attorney general and paid $241 million as one part of its settlement. LabCorp entered into a similar agreement with state officials and paid $49.6 million. *(See TDRs, February 11, 2011 and June 13, 2011.)*

Hunter has also filed whistleblower lawsuits against the national labs for similar violations of state Medicaid laws in as many as seven other states. The lawsuits in Virginia and Georgia have been unsealed and are continuing. *(See TDR, September 30, 2013.)*

For more than three decades, public lab companies have used deeply-discounted, loss-leader lab test pricing and exclusive contracts with health insurance companies to capture and defend market share from competing laboratories. Few federal or state enforcement actions have successfully challenged these practices. It was unusual when Riedel filed his whistleblower lawsuit in California and, with the state attorney general as a co-plaintiff, gained settlements and several hundreds of millions of dollars in recovery for the Medi-Cal program.

The question is whether Riedel's lawsuit against Quest Diagnostics now proceeding in California will end with a favorable outcome for him and his fellow plaintiffs.

Accreditation Update

Caris Life Sciences Achieves Accreditation to ISO 15189

Company says it is the first lab to earn this accreditation in the tumor profiling industry

In deciding to pursue accreditation to ISO 15189: Medical Laboratories, **Caris Life Sciences** considered the international benefits of this designation.

It was December when Caris Life Sciences of Irving, Texas, announced that it had earned accreditation to ISO 15189 from the **American Association for Laboratory Accreditation** (A2LA). In addition to genomic testing, the company runs Caris Molecular Intelligence, a tumor profiling service that has profiled more than 50,000 cancer patients worldwide since 2006.

The ISO 15189 accreditation "demonstrates that we are in full compliance with the most stringent global regulatory requirements applicable to clinical testing laboratories," stated Randy Vader, the company's Vice President of Quality and Regulatory Affairs. "Each patient specimen, regardless of country of origin, is tested in accordance with our ISO 15189-compliant policies and procedures."

Serving Markets Worldwide

One reason to pursue accreditation to ISO 15189 is that it demonstrates quality to markets worldwide. "Caris Life Sciences performs all of its testing in its clinical testing laboratory located in Phoenix, Arizona," Vader said. "Specimens are received from patients around the world, including the U.S., Europe, Middle East, Australia, and other international regions.

"Caris Life Sciences selected A2LA as our ISO 15189 accreditation body because the ISO 15189 accreditation from A2LA is accepted worldwide," Vader added. "Additionally, A2LA can be counted on to provide the most rigorous ISO 15189 assessment and onsite inspection of all accreditation bodies."

Besides its long-standing status as a CLIA-approved laboratory and its certifications from the **New York State Department of Health**, Caris operates one of only a handful of few commercial biorepositories that are accredited by the **College of American Pathologists** (CAP).

Independent Lab Business

In October 2011, **Miraca Holdings Inc.**, of Tokyo, Japan, paid $725 million to acquire **Caris Diagnostics, Inc.**, the anatomic pathology business division of Caris Life Sciences. The transaction did not include the acquisition of Caris Target Now, the molecular profiling service, or Carisome, a circulating microvesicle technology that was under development at the time. While retaining the profiling service and the circulating microvesicle technology, Caris Life Sciences was organized to operate as an independent company.

In recent years, there has been steady growth in the number of medical laboratory organizations in the United States that have earned accreditation to the ISO 15189 quality management system. Outside the United States, ISO 15189 is used in many countries for lab accreditation. TDR

Legal Update

Federal Judge Rules Against Idaho Hospital in Antitrust Case

Hospital said it would bill at higher 'hospital-based' rates for routine services, such as lab tests and X-rays

LAST MONTH, A FEDERAL JUDGE RULED that **St. Luke's Health System** of Boise, Idaho, violated antitrust laws when, in 2012, it acquired **Saltzer Medical Group**, the largest independent medical practice in the state.

In ruling against the merger of a hospital and physician group, the judge said that the combined entity violated antitrust law and would drive up costs by having physicians charge more for routine laboratory tests and imaging scans.

This antitrust case has interesting implications for hospitals and clinical lab companies. That's because internal documents of the defendants outlined their plans to raise prices after the merger was completed, including prices for lab tests.

Essentially, the federal government's position was that St. Luke's was illegally altering competition in a way that would allow it to increase prices for medical services, particularly in Southwest Idaho.

For its part, St. Luke's and Saltzer asserted the defense that their merger was essential to institute a new payment arrangement where healthcare providers would be rewarded for high-quality work. The defendants also said that the merger would help stabilize insurance rates in Idaho while allowing more poor patients in the region to have access to care.

In his decision issued on January 24, B. Lynn Winmill, Chief Judge of the US District Court in Idaho, ruled that the St. Luke's Health System in Boise needs to unwind its acquisition of the Saltzer Medical Group, a 40-physician multispecialty practice in nearby Nampa. The merger would have an anticompetitive effect on the delivery of care, Winmill wrote. Other hospitals in Boise had sued to stop the merger, and the FTC joined the case to oppose the merger as well.

During the trial, Winmill agreed to a request from defendants to withhold much of their testimony from public view. Following his ruling, Winmill unsealed the testimony and public documents, offering an inside look at the financial factors behind the deal.

Increase Insurer Payments

"St. Luke's own analysis of the acquisition considered the possibility that it could increase commercial reimbursements by insisting that health plans pay higher 'hospital-based' rates for routine ancillary services, such as X-rays and laboratory tests, even when those services are performed in the same physical location as before the acquisition," Winmill wrote.

Before the acquisition, Saltzer performed many routine ancillary services at its own facilities, including laboratory and diagnostic testing, Winmill wrote. "After the acquisition, if St. Luke's were to bill for these ancillary services at the higher 'hospital-based' rates, **Blue Cross of Idaho** estimates that costs under its commercial contracts would increase by 30% to 35%," he added.

Internal documents produced during the trial showed that St. Luke's projected

that it could gain an extra $750,000 per year for laboratory testing from commercial payers by billing lab specimens from Saltzer through its hospital-based billing department. Using the same methods, St. Lukes estimated it could generate $900,000 per year more for diagnostic imaging.

Billing At Hospital Prices

It was revealed during trial that the physicians alone could not bill at these higher rates. "Consultant Peter LaFleur prepared an analysis at the direction of St. Luke's showing how office/outpatient visits could be billed for higher amounts if the visit was hospital-based rather than Saltzer-based. The hospital-based billings were more than 60% higher," Winmill explained. "After the acquisition, if St. Luke's were to bill for [routine services such as lab tests or X-rays] at the higher 'hospital-based' rates, [Blue Cross of Idaho] estimates that costs... would increase by 30% to 35% percent."

To acquire the Saltzer Medical Group, St. Luke's planned to spend as much as $16 million and would give the physicians a pay raise of 30% after the acquisition, Winmill wrote. To pay for this raise, St. Luke's planned to obtain "higher hospital reimbursement from the health plans," he added.

Even before the acquisition, Idaho insurance rates for a routine doctor's office visit were already higher than 95% of those paid by other insurers nationwide, Winmill wrote.

Antitrust Lawsuit

Following St. Luke's announcement of its acquisition of Saltzer, it was sued by **Saint Alphonsus Health System** and **Treasure Valley Hospital**. The **Federal Trade Commission** and Idaho Attorney General Lawrence Wasden also joined the lawsuit, saying that the Saltzer deal gave St. Luke's control of nearly 80% of the primary care market in Nampa. The plaintiffs noted the precedent of the Magic Valley region in Eastern Idaho, where prices spiked following St. Luke's acquisition of a large share of hospitals and physician groups in that market.

St. Luke's is expected to appeal this case. If it does, a final determination may take another year.

This case attracted national attention because it went beyond the antitrust issue that were the core of the lawsuit. Following conclusion of the trial phase, a variety of interests, including media outlets, sued in the Ninth U.S. Court of Appeals to unseal and make public the pricing data and similar evidence presented during the trial. Both St. Luke's and Blue Cross of Idaho opposed that request.

The defendants opposed that lawsuit because, in antitrust lawsuits, pricing information is considered to be a trade secret. That is why the 575 written exhibits, 38 witness depositions, and approximately a third of the live testimony given in the trial were initially sealed by the judge.

Repercussions From This Case

In the meantime, the disclosure of how St. Luke's planned to generate additional revenue from its acquisition of a physician group will have repercussions. As discussed by the judge, St. Luke's own analysis of the acquisition of Saltzer Medical Group showed that it could increase revenue from the Saltzer lab specimens by $750,000 per year simply by moving the billing from the medical group to the hospital billing department.

Because of the publicity of this antitrust lawsuit, many health insurers are likely to review the prices they are paying hospital laboratories for outreach specimens—those lab tests that originate in physicians' offices. For hospital lab outreach programs that do bill using hospital lab test prices, this will be an unwelcome development. It means more downward pressure on lab test prices. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Maybe the tough financial environment here in the United States is causing **Sonic Healthcare Ltd.**, one of this nation's bigger lab players, to be more interested in overseas lab testing opportunities. On February 18, its CEO, Colin Goldschmidt, M.D., told investors that "We continue to seek out synergistic [laboratory] acquisitions and we believe that Germany is probably our most suitable and fruitful market." Sonic spent €76 million (US$104 million) in December to acquire the German lab business of **Labco S.A.** Goldschmidt was speaking during a earnings conference. He also noted that Sonic was gaining market share in Germany and winning new hospital contracts for lab testing in that country.

MORE ON: *Sonic*

Based in Sydney, Australia, Sonic Healthcare has more than $800 million of laboratory business here in the United States. In reporting its latest earnings for the six months ending December 31, 2014, Sonic said statutory revenue had increased 11.9%. Revenue grew 12% in its U.S. lab operations and 24% in its German lab operations, compared to the first six months of its prior financial year.

TRANSITIONS

• **Quest Diagnostics Incorporated** announced that Lidia L. Fonseca will become the company's Senior Vice President and Chief Information Officer, effective April 2, 2014. Previously, Fonseca was the CIO at **Laboratory Corporation of America** and held an executive position at **Philips Medical Systems**.

• Kevin Watson was named as the Director, Reimbursement-Managed Care for **Rosetta Genomics** of Princeton, New Jersey. He has held positions at **bioTheranostics**, **Becton Dickinson**, **TriPath Imaging**, Laboratory Corporation of America, Quest Diagnostics Incorporated, and **Aetna**.

• Gregory Clark, Ph.D., is the new Vice President of National Esoteric Reference Laboratory Services for **PAML, LLC**, of Spokane, Washington. Prior to joining PAML, Clark served at **Baylor Healthcare System**, **Westcliff Medical Laboratories**, **Oregon Medical Laboratories**, Quest Diagnostics Incorporated, and **Unilab Corporation**.

• **OPKO Health, Inc.**, of Miami, Florida appointed Greg Stanley as Vice President of Sales and Marketing for its global diagnostics business. Stanley was previously employed by **Oncimmune USA**, **Roche Diagnostics**, **Abbott Laboratories**, **Chiron**, and **Radiometer**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 17, 2014.

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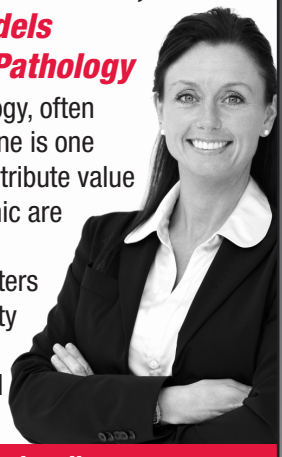

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