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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Prosecutors Ready to Target Pain Management

OVER THE PAST DECADE, many lab executives and pathologists have become aware of the abusive activities in the field of drugs of abuse testing and pain management testing. The frustration for those who understood the true scale of the fraud and abuse in this sector of healthcare was that no federal or state prosecutor seemed to be willing to tackle these problems and take enforcement actions against the guilty.

That is, with the exception of Martha Coakley, Attorney General for the state of Massachusetts. Clients of THE DARK REPORT have regularly read about her successful prosecutions of numerous drugs of abuse and pain management testing lab companies over the past six years. The question is this: If Coakley could bring these actions and win guilty pleas and sizeable settlements, what prevents other state attorneys general and the Department of Justice from doing the same with other labs—and physicians—doing pain management testing and engaged in illegal inducement or kickback arrangements?

Yes, there was the $16 million settlement of the federal whistleblower lawsuit against **AmeriTox**, one of the earliest labs to move from drugs of abuse testing into pain management services. Back in 2010, AmeriTox agreed to settle the case for $16 million. But the buzz on the street is that, following this settlement, multiple labs in this sector continue to offer illegal inducements and kickbacks. Florida even passed a law to more objectively define illegal behavior. *(See TDR, June 4, 2012.)* However, THE DARK REPORT is unaware that Florida authorities have used this law to initiate enforcement actions against any lab organizations operating in the state.

Thus, events in California may mark a turning point in how regulators view the drugs of abuse and pain management sectors. Earlier this month, California officials singled out at least 29 rehab clinics for fraudulent activities. It was an exposé by **CNN** that triggered this action. Further, both the *New York Times* and *The Wall Street Journal* are reporting that the drug screening market is now $2 billion per year in the United States. *(See pages 17-18.)*

Evidently, public and private payers can no longer ignore the multi-billion-dollar cost of drug screening and its rapid growth. We can only hope that those fly-by-night lab operators who entered the drug screening business in recent years are about to face enforcement action because of their illegal activities. TDR

Labs Push To Cut Costs As Budgets, Prices Shrink

Repeated budget cuts and lower test prices are now forcing labs to aggressively cut costs

CEO SUMMARY: Cost-cutting is now the prime directive at progressive labs because nearly every laboratory organization in the United States is under sustained financial pressure. This is due to shrinking budgets for hospital labs and more aggressive price-cutting by private payers. Even Obamacare is a factor, because of the Medicare Part B price cuts it mandates for five consecutive years. For this reason, proven ways laboratories can use to cut costs will be the main theme at the* Lab Quality Confab *that takes place on October 1-2, 2013.

By Robert L. Michel

CUTTING COSTS IS NOW A PRIMARY TREND in the clinical lab industry these days. Not only is there is less money for hospital lab budgets, but both government and private payers are regularly decreasing the prices they pay for lab testing services.

Labs thus find themselves in a financial squeeze. They have less money available to pay for lab operations. At the same time they must perform more lab tests as specimen volume increases.

This financial squeeze has created new urgency for every lab to identify and eliminate unnecessary costs throughout its organization. Failure to do so subjects the lab to financial risk.

Unless that financial risk is addressed, the poorly-performing lab typically must do one of two things: a) be acquired by a financially-stronger lab, thus losing its independence; or, b) it must radically downsize staff and operations to align costs with shrinking budgets and declining net revenue.

Evidence that these things are already happening can be seen in any number of deals that occurred over the past year. For example, **Quest Diagnostics Incorporated** acquired the assets of the **University of Massachusetts-Worcester's** laboratory outreach program in October, 2012. That outreach lab was experiencing revenue erosion as private payers cut the prices they paid the UMass lab for lab testing services.

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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).

More recently, Quest Diagnostics purchased the laboratory outreach business of **Dignity Health** of Stockton, California. Following that sale, newspapers reported that layoffs involving as many as 148 lab employees were planned.

For its part, **Laboratory Corporation of America** recently purchased **Genesis Clinical Laboratories**, the lab outreach program of **McNeal Hospital** that was based in Berwyn, Illinois. LabCorp is expected to downsize operations at the Genesis core lab facility. *(See TDR, July 29, 2013.)*

New Reality: Less Money

The new reality for the clinical lab industry is this: labs will be paid less for the same volume of testing. Anyway you want to cut it, government and private payers—as well as employers—are becoming bolder at cutting prices for lab tests.

Clear evidence of this are the actions taken by **Aetna, Inc.**, to reduce the prices it pays labs. This spring, Aetna sent letters to labs stating that it would pay much lower prices for many important and high volume CPT codes, effective July 1, 2013.

We reported that Aetna's letter included such prices as:

- $6.54 for CPT 80053-Comprehensive Metabolic Panel
- $4.00 for CPT 85027-Complete CBC Automated
- $35.05 for CPT 88305-Level IV Surgical Pathology, Gross and Microscopic

There is another disturbing dimension to this price-cutting crusade. At the same time that lab test prices are being cut, almost all payers are aggressively denying coverage for many new molecular and genetic tests.

Any pathologist or lab manager who doubts the truth of this statement need look no further than how both government and private payers have dealt with the introduction of the 114 new molecular test CPT codes since January 1, 2013.

Even today—eight months into the calendar year—many laboratories will tell you that they do not have satisfactory and reasonable decisions on coverage and pricing for the molecular CPT codes that are most important to them.

In my view, this is not an accident. There is plenty of evidence to argue that both the Medicare program and private payers were willing to let a train wreck happen on January 1 in order to use the disruption in claims adjudication to reconfigure how the entire system handles molecular tests and genetic assays.

As a result of this situation, the financial damage to any number of lab organizations has been extensive. For example, **Pathwork Diagnostics** and **Predictive Biosciences** both shut down their labs and closed their doors in April and May, respectively. *(See TDRs, May 28, 2013, and July 8, 2013.)*

THE DARK REPORT's coverage of this situation only scratches the surface of the financial turmoil caused by the molecular CPT code fiasco. After all, a very large number of lab companies in this country saw their cash flow stop or drop precipitously after January 1 because government and private health programs were not fully prepared to process and settle claims submitted under the new molecular CPT codes.

Expect More Lab Price Cuts

Collectively, these actions by government and private payers make a persuasive argument that further price cuts and restricted coverage guidelines will continue next year and into the future. That means lab executives and pathologists who are business leaders of their pathology groups must have strategies for cutting costs in their lab organizations.

In today's financially-strapped lab testing marketplace, no lab is exempt from the need to control costs, reduce waste, and boost labor productivity. That is the reason for the heightened interest in process improvement programs that

incorporate Lean, Six Sigma, and ISO 15189 accreditation, for example.

This interest in more effective strategies to cut lab costs was front and center at last May's *Executive War College on Laboratory and Pathology Management* that took place in New Orleans. Sessions with the highest attendance were those that dealt with cutting costs and achieving much higher levels of productivity within the lab.

To further support this interest by lab managers to learn and use proven strategies for cutting costs while maintaining their lab's high quality of lab testing services, the upcoming seventh annual *Lab Quality Confab* meeting has put effective cost-cutting front and center in its sessions. It will take place on October 1-2, 2013, at the Astor Crowne Plaza Hotel in New Orleans.

For seven years, *Lab Quality Confab* is the place where serious cost-cutters and quality management practitioners come together to share case studies and teach the secrets of using Lean, Six Sigma, and continuous process improvement techniques.

Every lab administrator, pathology practice administrator, or pathologist wanting to achieve substantial cost reductions in a controlled manner that protects and improves quality and service would be well-served to send their team to *Lab Quality Confab* this year. They will learn from first-rank lab organizations, ranging from **ARUP Laboratories** and **Mayo Medical Laboratories** to **Massachusetts General Hospital** and **Baylor Health System**.

These are cost-cutting ideas and programs that bear immediate fruit. Each year, attendees report they were able go back home and apply what they learned to save tens of thousands of dollars for their labs by the end of the year.

Lab leaders have a responsibility to do more than just lay off staff to meet shrinking budgets. The knowledge and techniques shared at *Lab Quality Confab* can help every lab perform more work with less money, even while motivating staff to successfully meet these challenges. TDR

Reducing Lab Costs Is Theme Of October Lab Conference

FOR THE PAST DECADE, innovative laboratories have used proven management techniques to drive down costs in all sectors. These methods also boost the productivity of equipment and staff while improving the quality of lab testing and lab services.

The toolset includes Lean approaches, Six Sigma methods, process improvement and workflow redesign strategies, and the growing adoption of quality management systems (QMS). However, although most lab executives and pathologists are aware of these cost-cutting tools, it is likely that their respective laboratory organizations do not employ them to their full potential.

That means that a large proportion of lab organizations across the nation are missing the opportunity to greatly reduce existing costs, *without sacrificing quality*!

This is why the upcoming seventh annual **Lab Quality Confab** conference is putting laboratory cost reduction front and center. It will take place on October 1-2, 2013, at the Astor Crowne Plaza Hotel in New Orleans, Louisiana.

More than 50 top-performing lab leaders will lead sessions and lab case studies designed to give attendees a blueprint that they can use in their own lab to eliminate unnecessary costs, save substantial amounts of money, and improve quality—all at the same time.

Keynote speakers include James Westgard, Ph.D., on finding the hidden weaknesses in QA/QC and how to fix them; Denise Geiger, Ph.D., on how her lab saved her hospital $3 million in recent years by reducing hospital-acquired infections; and Richard Zarbo, M.D., Ph.D., on how CAP 15189 accreditation across multiple sites at **Henry Ford Health** has significantly lowered costs while boosting patient satisfaction.

www.LabQualityConfab.com
for full agenda and registration details

Cigna Program Addresses Genetic Test Utilization

➤Patients referred for molecular tests for cancer and cardiac abnormalities to have genetic counseling

➤➤CEO SUMMARY: Cigna launched a program that requires genetic counseling for patients and pre-authorization of genetic tests. Its partner is InformedDNA, a firm that provides genetic counseling services. The goals include better patient engagement, improved test utilization, and a process to evaluate the clinical effectiveness of new genetic tests. Cigna customers getting genetic tests for breast cancer, colon cancer, and the long QT syndrome will be provided with genetic counseling.

IN RESPONSE TO THE RAPID YEAR-OVER-YEAR INCREASE in the utilization of genetic tests, **Cigna** is the latest health insurer to implement a program to require patients to undergo genetic counseling. Pre-authorization of genetic tests will be part of this program.

Cigna will administer the Genetic Testing and Counseling Program. It is working with **InformedDNA** of St. Petersburg, Florida, which will provide genetic counseling services to Cigna customers by telephone. Also, InformedDNA will provide technical advice about emerging tests and other technical assistance.

Cigna announced the new program and its agreement with InformedDNA on July 23, 2013. Cigna wants to get ahead of what is becoming a major clinical, administrative, and financial challenge for health insurers: the rapid uptake of genetic testing by physicians.

Spending on genetic tests totaled about $5 billion in 2010. It is projected to increase to as much as $25 billion by 2020, according to a 2010 study published by **UnitedHealthcare**.

Recognizing the value of genetic testing, health insurers want to ensure that spending on these tests is appropriate. In its 2010 report, UHC noted that insurers had no way to assess the clinical value of each of the 2,000 genetic tests available at that time.

➤Assessing Clinical Utility

Cigna wants to use its genetic counseling and genetic test pre-authorization program to ensure the appropriate utilization of these genetic tests. When the program begins next month, customers will be required to undergo genetic counseling when getting genetic tests for breast cancer, colon cancer, and for long QT (LQTS) syndrome, a rare inherited heart condition.

In an interview with THE DARK REPORT, David Finley, M.D., Cigna's National Medical Officer for Enterprise Affordability and Policy, said, "The growth trend in genetic testing is considerably higher than the actual growth trend in medical services." He would not disclose the rate of genetic test volume that Cigna has seen in recent years.

"InformedDNA, our partner in this initiative, recommended that we begin with these three tests because they are relatively high volume and there is confusion about them," said Finley. "Genetic counselors from InformedDNA will consult with Cigna customers by phone as part of this program.

"We plan to add other tests to this program for which genetic counseling would be appropriate," he added. "That list of tests is much longer."

Improving Transparency

In addition to the need to alleviate confusion among physicians and their patients about the appropriate use of these genetic tests, Cigna has also found a lack of transparency in how much time, effort, and resources labs put into genetic testing. "One source of this lack of transparency was the use of stacking codes by labs when submitting claims," observed Finley. "This was common before January 1 of this year, the implementation date for the new molecular and genetic test CPT codes.

"When a lab submitted a claim that used stacked codes, we couldn't tell which tests were done," he explained. "That is because, for each genetic test, the lab would report different codes for DNA extraction, for DNA amplification, for DNA sequencing, and so on.

"Unless a molecular or genetic test had a specific CPT or HCPCs code, we could not tell which specific test the lab had performed," he stated.

"But the stacking codes were deleted as of January 1," said Finley. "Because the **American Medical Association** has assigned CPT codes to the 114 new tier 1 and tier 2 codes, we have an idea about the level of resource intensity that labs put into each genetic test.

"It's not ideal because there are 10 levels of resource intensity," he added. "But it's better than it was. There is much more specificity now. As a payer, when processing these claims from laboratories, Cigna now has a higher comfort level about what genetic test it is paying for.

"Currently, if a physician requests a genetic test, we will use the criteria now in place to either: 1) pay for that test or not; or 2) to require genetic counseling or medical review," noted Finley. "Our primary goal is to help ensure that individuals get appropriate genetic testing and quality care.

"In this first phase of our genetic counseling program, we will rely on the genetic counselors for the three tests mentioned earlier, " he continued. "For other genetic tests, we will rely on our own policy department to make coverage determinations."

Going forward, Cigna understands the need to evaluate new genetic tests. "Cigna has a rigorous process in place for making coverage determinations," Finley stated. "If we get a request for a certain test and have a coverage policy for that test, we will apply it.

"But if we don't have a policy for that genetic test, we will research it, meaning we will review what's published in the peer-reviewed medical literature, and consult with the experts at InformedDNA," he said. "If this test is requested once every year or so, we may leave it at that.

Technology Assessment

"In cases where a genetic test is requested several times a year, we will bring that published information to our medical technology assessment committee," continued Finley. "About 15 doctors of different specialties make up the committee.

"This committee will make a determination about whether to cover that genetic test or not," he noted. "Cigna does this for all new technology, including molecular tests, other lab tests, and new technology.

"Contrary to what some people believe, Cigna does not always follow what Medicare does with regard to covering genetic tests or other coverage decisions," emphasized Finley. "We notice what Medicare does, but we make our own decisions by following the evi-

dence. Cigna covers genetic tests only if they are associated with beneficial clinical outcomes."

Coverage Decisions

Cigna is making progress on establishing guidelines for the new molecular test CPT codes. "We are in the process of submitting a number of the tier 1 and tier 2 tests for coverage decisions," stated Finley. "We currently have coverage decisions in place for about 50 of those tests.

"In addition, this is an ongoing process," he said. "That is because, every month, many new genetic tests come out and the labs that developed these tests ask us to make coverage determinations. It is important that these genetic tests be properly reviewed."

There is ample evidence that physicians themselves are struggling to stay current with all the genetic tests that are available. Studies show that physician ordering of genetic tests based on a prior indication of cancer in a patient's family history was inappropriate about 60% of the time. That statistic was mentioned by Trisha Brown, MS, LGC, a genetic counselor and founder of **Shama Consulting**, during her presentation at last May's *Executive War College on Laboratory and Pathology Management*, which took place in New Orleans.

Managing Patients' Fears

Finley agreed that a certain number of genetic tests are indeed inappropriate. "The rate of inappropriate ordering may be in the 20% to 30% range," he said. "While it's not 60%, there is a problem with unmanaged requests for genetic tests and there is a problem if patients do not get counseling for these tests.

"It's understandable, for example, when female patients worry that they might get breast cancer—particularly if there is a history of breast cancer in their family," observed Finley. "But even women with no known history of breast cancer worry. They think they should have the BRCA test to make sure they are not at risk. We know there are a lot of faulty assumptions in that logic.

"First, at most, the BRCA mutation accounts for only about 5% of breast cancer in the United States," he stated. "Thus, 95% of the cases of breast cancer have nothing to do with the BRCA mutation.

"Second, the fact that a patient tests negative for the BRCA mutation doesn't mean she is not at risk for having breast cancer," explained Finley. "In fact, that woman's risk is still about the same as the risk for every other woman in the United States. The risk that a woman in the United States will get breast cancer at some point in her life is somewhere between 1-in-8 and 1-in-7.

Patients Want Screening Test

"These are the facts," he continued. "Yet patients still want to get the screening test because they have heard about it and believe the results will help put them at ease.

"The second problem genetic counselors can address is the percentage of patients who have indeterminate test results," noted Finley. "That means there is some kind of mutation in the gene but no one knows if that mutation is associated with an increased risk of cancer or not.

"This indeterminate result can make the patient uncomfortable and provoke anxiety," he commented. "A genetic counselor is adept at addressing this issue and has more time to spend with the patient than a physician does.

"The third problem addressed by genetic counseling is that physicians may not be the ideal sources of information about these tests," he noted. "Oncologists know the genetics of the tests they order. But many physicians have trouble keeping up with the latest information on many of the genetic tests available today.

"For these reasons, making genetic counselors available helps Cigna improve patient care and manage the growing volume of these genetic tests," stated Finley.

Here's Why Genetic Counseling Is Needed: 50% of Genetic Test Orders Are Inappropriate

ABOUT HALF OF ALL GENETIC TESTS that physicians order are inappropriate for the patients involved, according to a genetic counselor. This is one reason why genetic counseling can be useful to both patients and physicians.

"With certain complex tests, we have found that up to 52% of genetic tests ordered may be inappropriate before a health insurer implements any type of prior authorization procedure," observed Amber Trivedi, a genetic counselor and Senior Vice President of Provider and Client Services for InformedDNA, a company that provides genetic counseling services. "Further, even with a prior authorization process in place, it may be that the health insurer continues to see that 25% to 33% of genetic tests are ordered inappropriately. That's why health insurers are interested in genetic counseling.

"There is a good reason why this happens," continued Trivedi. "Typically most doctors are unable to get a detailed family history in the 15 minutes they have for each patient's office visit. Contrast that with the one hour that a genetic counselor would spend with each patient. This session would review the patient's history and the family history for three generations.

"Many insurers have policies in place to manage genetic testing, such as requiring pre-authorization," she noted. "Cigna is the only major insurer to require genetic counseling prior to testing and for now that is limited to just three different genetic tests. Cigna has indicated that if this part of the program proves successful, it may require genetic counseling for additional genetic tests.

"We recommended that Cigna begin with these three genetic tests for the following reasons: 1) they are complex tests; 2) they are commonly ordered inappropriately; and, 3) these are three high-dollar tests, priced at $3,000 to $5,000 per test," Trivedi concluded.

"But I want to emphasize that Cigna didn't come to this decision on its own.

"Several of the specialty societies—including the **National Cancer Institute**—have made very definitive recommendations that genetic counseling should be done before certain tests," he emphasized. "That includes the first three tests that we have identified.

"It's important to note two factors about this program. First, the requirement for genetic counseling is the high profile element of Cigna's efforts," he said. "However, these three tests account for only about 20% of all the genetic tests that we will be assessing.

"The other 80% are mostly among the tier 2 codes," said Finley. "We will make coverage decisions on those tests to ensure that they are associated with beneficial clinical outcomes.

Better Educated Patients

"The second factor I want to emphasize is that this requirement of genetic counseling will result in patients being better educated and better informed about the genetic tests done on their behalf," continued Finley. "That means they will be able to play a larger part in their own healthcare decision making, which is an important part of providing good patient care."

—Joseph Burns

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CEO SUMMARY: Described by its CEO as "an information company that happens to do laboratory testing," PeaceHealth Laboratories of Springfield, Oregon, is moving swiftly to develop and deliver value-added services to its client physicians. The lab's goal is to help referring doctors achieve improved patient outcomes.

Tapping the data warehouse to deliver value to client physicians

PeaceHealth Lab Helps Docs With Info to Improve Outcomes

HEALTHCARE IS CHANGING RAPIDLY, and perceptive pathologists and laboratory directors recognize that clinical labs must do more than simply deliver lab test results quickly and accurately. Today, all laboratories need to offer useful, actionable information to their client physicians.

Two distinct forces are driving this marketplace change. One is the transition from fee-for-service reimbursement to value-based reimbursement. This factor alone has major implications for how labs are organized and deliver clinical services in the coming years.

The second force is equally significant and the subject of this intelligence briefing. It is the transition to integrated clinical care and is best illustrated by the formation of accountable care organizations (ACOs) and patient-centered medical homes (PCMHs).

Physicians practicing in these settings not only need timely and accurate clinical laboratory test results, but they also need something that labs are perfectly positioned to provide: consultations and actionable information that helps physicians to improve patient outcomes and control the cost of care. Without this information, physicians could be penalized for going over budget or could be unable to share in any savings that represent a considerable proportion of reimbursement.

Clinical laboratories that recognize this changing environment are moving to deliver useful and actionable information to physicians. Among them is **PeaceHealth Laboratories**, in Springfield, Oregon.

"Early on, PeaceHealth Laboratories began developing several strategies to help clinicians in ways that add value," stated Ran Whitehead, the lab's CEO and Chief Mission Officer. "One strategy involves building a data warehouse. This is both an internal and external strategy because it helps us within the lab. It also creates new ways for us to support physicians, patients, and providers in our service area."

Whitehead made these remarks during his presentation at THE DARK REPORT'S 18th Annual *Executive War College* last spring in New Orleans, Louisiana. In his presentation, Whitehead explained the specific ways that **PeaceHealth Laboratories** is positioning itself to deliver useful information as physicians join PCMHs and ACOs.

PeaceHealth Laboratories already has innovative service offerings, such as physician scorecards that support improved patient outcomes and identify the physician's use of obsolete tests. It now offers a patented and proprietary pain management assay that delivers improved detection for a wider range of drugs. It is also developing different physician and patient portals that can be accessed by mobile applications.

In fact, PeaceHealth Laboratories is building the foundation needed to be a player as "big data" assumes a larger role in the healthcare system. "We've already spent hundreds of thousands of dollars developing a data warehouse," noted Whitehead. "We are using it to mine information in new and creative ways for our customers.

"This data warehouse launched with a valuable asset," he said. "Our laboratory information system (LIS) has 16 years worth of data on patients throughout the Pacific Northwest. That's a lot of laboratory information that our providers are anxious to use to improve patient care.

"In addition, we added a business intelligence (BI) capability on top of that data warehouse," stated Whitehead. "Business intelligence allows more people on our lab's front line—in real time—to get detailed answers to the questions they have and improve our service to physicians."

The laboratory is part of a large health system. "Our parent is PeaceHealth," he noted. "This is a $2.5 billion organization with a network of hospitals, physician groups, clinics, and laboratories in Oregon, Washington, and Alaska.

"In the health system, there are about 16,000 employees, whom we call caregivers," he continued. "In that number are more than 800 physicians. The number of physicians has risen sharply in the past few years from 250 or so to the current total.

Serving A Wide Area

"Our central laboratory facility is in Springfield, Oregon, and we have 11 other laboratories interspersed around the Pacific Northwest, particularly around the hospitals that we serve, some of which are in very rural areas," explained Whitehead. "We operate 27 patient service centers in and around all those locations. About 1,000 caregivers work in our clinical labs.

"There are 45 pathologists in four pathology groups that work with our labora-

tory," he added. "Three are contracted groups: **Lower Columbia Pathologists**, **NW Pathology**, and **Pathology Consultants, PC**. The fourth group is called **PeaceHealth Southwest Medical Center Laboratory and Pathology**. Pathologists in this group are employees.

"This year, our laboratories will do about seven million billed procedures and generate about $120 million worth of net revenue," said Whitehead. "About half of this revenue is from our lab outreach program that serves physician offices outside of the PeaceHealth system."

In recent years, the lab team recognized the shifts taking place in healthcare. "At that time, the laboratory administrators had a strategic retreat in which we talked about how to prepare for the future," recalled Whitehead. "We tried to answer a series of questions, including these: Should we aim to be the highest-volume and lowest-cost provider lab? Should we try to do every test known to man, as is done by **Mayo Medical Laboratories** and **ARUP Laboratories**?

"Our answer to these questions was, no," he said. "We concluded that the asset our lab has is information and we should leverage that as a way to add value.

Adopting a New Mission

"That became our tagline and mission: As a laboratory, we are an information company that just happens to do lab tests," noted Whitehead. "Plus, who is in a better position to be an aggregator of laboratory information than laboratorians?

"In order to provide information that makes a difference, every lab must first do other things well," commented Whitehead. "One element is a strong menu of the best diagnostic tests that can be processed at a low cost and with excellent turnaround time (TAT).

"Regarding TAT, we aim to produce results for our outpatient clients in less than two hours," he said. "That is measured from the time the sample arrives at our laboratories until the results leave. We have consistently been above 99% for five years. In 2009, we were at 99.4%, and this year, we are at 99.7%. One part of our strategy to achieve this goal included hiring a full time process improvement individual," stated Whitehead. "He taught our lab teams how to improve using Lean technologies. It is one of the best investments we've made.

"Another success factor is for a lab to maintain a low cost per test," he added. "Our fully-loaded average cost has been under $19 for the past five years and is about $18.37 this year.

Lab Delivers Actionable Information To Physicians Involved in Pain Management

One fast-growing sector in clinical care is pain management. The executive team at PeaceHealth Laboratories recognized an opportunity to provide actionable information to physicians treating these patients.

"In tandem with Lean efforts and similar improvement projects, we considered how to deliver greater value to physicians," said CEO Ran Whitehead. "For example, we wanted to respond to the changes unfolding in pain management services. We decided there was an opportunity to help physicians who treat these patients.

"This segment of clinical care is growing due to the aging population," he noted. "Physicians are putting more patients on significant narcotics. The problem with these medications is that—if the patients are not appropriately monitored—they can die. In fact, each year, more Americans die from medication overdoses than by automobile accidents.

"To deliver more value to the pain management clinicians, our team here at PeaceHealth Laboratories used mass spectrometry to develop a test we call PT Protect," he recalled. "The algorithms in our report are simplified so physicians can understand the results easily. That contrasts directly with the typical reports that toxicologists produce, which can be like trying to read hieroglyphics.

"We filed a patent application for this test and received a U.S. patent in November 2011," noted Whitehead. "The patent covers the technical analysis that goes into the test and the algorithms in the report we send to the physicians.

"Consistent with our strategy to add value, the patent allows us to license the PT Protect test to other laboratories," he emphasized. "We held discussions with select labs across the country to explore their interest in licensing this test. We are optimistic that licensing this test will generate a new source of revenue for us."

Once the new assay was introduced, Peacehealth Laboratories produced a study that showed the improved performance of this proprietary assay. "When matched against the offerings of competing pain management companies, our PT Protect test detected positive results 37% more often than our leading competitor has," explained Whitehead.

"This data changes the conversation our sales professionals have with physicians," he noted. "When discussing the patient safety issues involved in pain management and the accompanying legal liabilities, physicians will often counter that they know all their patients well and their patients wouldn't do anything untoward.

"But we can show that, on average, at least 37% of the time we found other things in the patient's urine sample that the physician might want to know about," stated Whitehead. "Upon learning this, physicians see the value that our lab offers to them, compared with competing pain management companies. Our pain management expertise is an excellent example of how we use information to empower our client physicians."

PtProtect

US008067243B2

(12) **United States Patent**
Erfurth et al.

(10) **Patent No.: US 8,067,243 B2**
(45) **Date of Patent: Nov. 29, 2011**

PtProtect® Opiates/Opioids Sensitivity Tool

Medication/Drug	Total Results	Total Positive Results	Positive %	PtProtect Detection Threshold	Enter Alternate Threshold (ng/mL)	Impact of Alternate Threshold: PtProtect Positive Results Below Threshold	Impact of Alternate Threshold: PtProtect Positive % Below Threshold
6-Monoacetylmorphine	16,938	123	0.7%	5 ng/mL	50	33	27%
Codeine	17,073	586	3%	5 ng/mL	50	253	43%
Fentanyl	16,938	575	3%	2 ng/mL	50	347	60%
Hydrocodone	17,082	6,272	37%	5 ng/mL	50	1,414	23%
Hydromorphone	17,073	5,256	31%	5 ng/mL	50	3,673	70%
Meperidine	16,938	45	0.3%	5 ng/mL	50	8	18%
Morphine	17,073	2,361	14%	5 ng/mL	50	425	18%
Norfentanyl	16,938	682	4%	2 ng/mL	50	162	24%
Oxycodone	17,073	5,501	32%	5 ng/mL	50	608	11%
Oxymorphone	17,073	3,862	23%	5 ng/mL	50	2,403	62%
Minimum Thresholds from a leading lab competitor					AVG	9,326	37%

Here is the reporting format for PeaceHealth Laboratories' proprietary, patent-protected test used by pain management physicians. In this example, the lab says its "PT Protect" assay's threshold levels would have detected positive opioid use in an average of 37% more patients then the competing laboratory, reducing the risk factors for both the patient and the physician.

"For many labs, this number would be high," he stated. "But within these numbers are the costs for us to operate laboratories across a large service area that includes rural communities.

"For example, our lab in Ketchikan, Alaska, operates 24/7 and is in an expensive market," observed Whitehead. "What is important is that our laboratory organization has continously driven down our unit costs over a multi-year period.

"At the same time, our staff productivity has risen continuously since 2007," noted Whitehead. "For example, in that year, we did 3.52 billable tests per tech hour. It is now at 4.26 billable tests per tech hour.

"These are strong metrics, but keep in mind that our over-arching strategy is to convert lab data into actionable information for clinicians," he continued. "That allows us to use the patient data we generate in ways that make a difference to our physician customers.

"For example, we empower physicians by giving each referring physician a scorecard that shows different metrics on how the physician uses our lab," said Whitehead. "This includes the lab test results that the physician gets in key clinical areas of his or her practice. (*See sidebar on page 15.*)

"For an individual physician, this scorecard shows the overall test volume and which tests are ordered," he continued. "A second component is a report on test turnaround times. This is included to show not only the physician's performance but our performance as well.

"If the physician has patients on pain management medications, we can show his or her discrepancy rates," he said. "These numbers give us an opportunity to talk about patient safety and legal liability.

"Our physician scorecard includes a section on obsolete tests," Whitehead stated. "This information allows us to talk about which tests the physicians may not be using correctly. We can also offer other recommendations about better tests to order in these situations."

As payers begin reimbursing physicians on the patient outcomes they deliver, Peacehealth Laboratories has created information-rich reports that physicians can use to manage individual patients effectively. "The scorecard we provide to physicians is perhaps best at showing the physicians their patients' key health indicators," observed Whitehead.

"In our region, accountable care organizations are forming and physicians are being asked to do population health management," he said. "Two of the biggest challenges they face is managing patients with diabetes and cardiovascular disease.

"Therefore, the scorecard lists hemoglobin A1c, LDL, and HDL scores," stated Whitehead. "Those scores are compared with what we have in our data warehouse.

"This is one way we can convert data into actionable information for physicians," he said. "In step one, the data in our warehouse allows us to look for any abnormal hemoglobin A1c results among a doctor's patients for the past three years.

"In step two, we fast forward and review the past five months to see if there's been any follow up on those patients," noted Whitehead. "Step three is where we show the physician the percentage of patients who had follow up based on the results of their hemoglobin A1c test.

"These results are significant because they help physicians identify gaps in care, which is very important to health plans, ACOs, and PCMHs," he added. "As an example, we can show how, for one particular physician, maybe there was follow up only 58% of the time.

Comparing Physician Scores

"Step four in this use of actionable information is to show an individual physician how he or she compares with other physicians in the community," Whitehead stated. "Most doctors are data driven and very competitive. Not one of them wants to be an outlier. They have keen interest in our scorecard and how it can help them.

Physician Scorecard Helps Improve Test Utilization

PeaceHealth Laboratories

Physician Scorecard
Richard M. Hones MD / 99999
Evaluation Period: Jul 2012 – June 2013

Test Volume	This Period:	9,785
	Last Period:	10,160
	VAR %:	-3.7%

Rank	Test #	Test Description	Volume
1	20000	CBC WITH AUTO DIFF	1,246
2	30000	COMPREHENSIVE METABOLIC	1,092
3	30901	GLUCOSE,BEDSIDE (LAB)	974
4	20150	CBC NO DIFFERENTIAL	833
5	40250	TSH, THIRD GENERATION	688
6	31300	BASIC METABOLIC PANEL	451
7	43370	VITAMIN D,25-HYDROXY	445
8	25000	PROTHROMBIN TIME	346
9	42550	GLYCOHEMOGLOBIN (A1C)	277
10	43560	LIPID PANEL	272

TAT Score: Target: >90% — 93%

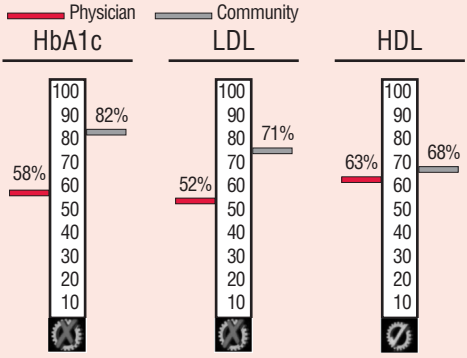
Variances: Target: <.05% — 7 — .04%

Pain Mgmt (Discrepancies): 44 — 23%

Key Health Indicators

% of Patients with an abnormal HbA1c within the last 3 years that have had a follow-up visit within the past 5 months

>5% VAR
<5% VAR



Obsolete Tests:

Currently Ordering:	*Recommended Best Practice:*
25350 / Bleeding Time	→ 17102 / Cardiovascular Coag.
41955 / Down/NTD Screen, Quad Marker	→ 41990 / Seq. Screen, 1st trim → 41968 / Seq. Screen, 2nd trim.

CLIENT PHYSICIANS AT PEACEHEALTH LABORATORIES ARE PROVIDED WITH A UNIQUE SCORECARD. This scorecard shows each physician lab test results and utilization information specific to his or her practice. Included are lab results, number of patients who were followed up, and even information about a physicians' use of obsolete tests. Local physicians appreciate getting this level of detail from their laboratory because it helps them achieve better patient outcomes.

"Armed with this scorecard, our sales team is having much different conversations than they do without it," Whitehead commented. "Rather than telling a physician, 'We've got this great serum cholesterol test you should use,' they can talk about how the physician can manage patients more effectively. It makes our lab a team player in the physician's effort to improve patient outcomes.

"Physicians know that, in the near future, they will participate in population health management strategies in which physicians will be on the hook for financial losses, but can also share in any savings," he noted. "Physicians will be paid or penalized based in how effectively they manage their patients. Laboratory information like this will be extremely useful to them.

"Internally, we are converting data into actionable information that our team can use to deliver more value to clients," continued Whitehead. "We recently invested in a customer-relationship management (CRM) system to support this effort.

PeaceHealth Laboratories Has Lab Test Solution to Help Physicians Manage Readmissions

WANTING TO DELIVER MORE VALUE to physicians and patients, lab scientists at PeaceHealth Laboratories decided to tackle the problem of "polypharmacy." This is when physicians prescribe many medications for a single patient.

"In particular, older patients are at risk for this condition," said Ran Whitehead, CEO and Chief Mission Officer of PeaceHealth Laboratories, in Springfield, Oregon. "With different specialists issuing prescriptions, it is not uncommon for the patient's primary care physician to be unaware of all the drugs that have been prescribed for his or her patient.

"Our lab can help with this problem," he noted. "We adapted our experience from pain management to see if we could use mass spectrometry to develop a screen to identify the multiple therapeutic drugs that a patient is taking.

"This approached worked," stated Whitehead. "We can tell a physician at any point in time what's onboard with a specific patient. We started with the most-prescribed medications. Now we are about halfway to our goal of having the capability to accurately identify 400 prescribed drugs.

"We believe this type of testing will have significance for hospitals treating patients with conditions such congestive heart failure and pneumonia who are discharged but readmitted in 30 days," he continued. "Currently the federal Centers for Medicare & Medicaid Services fines those hospitals for each readmission within 30 days.

"The main reason most patients get readmitted they don't take the medications that physicians prescribe, which can cause a relapse and that leads to a readmission," added Whitehead. "By using this new diagnostic technology, we are getting closer to the day when we can give physicians a timely report on the specific medications these patients are taking. That would give physicians the opportunity to intervene before that 30-day window is reached. Further, we have a patent pending on this diagnostic test."

"Today, our CRM system—along with the scorecard data—can be viewed on iPads," he stated. "Our sales and our service reps—before they meet with the physicians or staff at a particular account—can look up any of this client's current problems or needs.

"Having that information in real time before a call empowers our reps to suggest ways that our laboratory can provide better service to clients in the form of actionable information."

Whitehead was careful to point out that his laboratory continues to pursue excellence in all the routine, daily functions that physicians expect of their lab providers. "It is essential that our laboratory delivers the lab testing services that complement the needs of client physicians," he said. "That has always been true and it won't change moving forward.

"What is different today is that our lab also provides useful and actionable information to physicians," Whitehead explained. "That's a value-added service as opposed to what we used to do, which was deliver test results quickly and accurately.

"We still do that, of course," he concluded. "But now we put those results in context in a way that empowers physicians in this new healthcare environment. If we do it correctly, the physicians will succeed and we will succeed as well." TDR

—Joseph Burns

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Dark Index

Reporters & Investigators Target Fraud in Pain Management Market

In California, state investigators take action against rehab clinics for several types of crimes

PAIN MANAGEMENT IS COMING under increased scrutiny by law enforcement officials and government regulators. Even the national media have begun to notice the fraud and abuse that is rampant in this rapidly-expanding sector of healthcare.

Many pathologists and clinical laboratory managers will welcome increased enforcement by state and federal officials. Over the past decade, lab professionals have become uncomfortable with the sales and marketing schemes of some lab testing companies formed specifically to serve physicians in pain management. Questions have also been raised about the scientific usefulness of the algorithms offered by these labs in conjunction with their urine drug tests.

Urine Drug Testing Business

Recent events in California may be a sign that the lid is about to come off many of the illegal practices that seem to be common in the pain management industry. Reporting on the urine-drug testing business earlier this month, *The New York Times* said the increased number of urine drug tests performed follows a similar increase in the number of prescriptions for painkilling opioids. *(See sidebar on page 18.)* With the increased volume of testing has come questions about whether labs and doctors are exploiting the testing boom financially, the *Times* said.

To demonstrate the problem, the *Times* article described a brochure from **Liberty Diagnostics,** a lab testing company in Pasadena, California. The brochure said physicians could earn an "average of $400 profit per screen" with "No Additional Overhead."

A chart in the Liberty Diagnostics' brochure showed the potential profit a physician could earn by ordering just 10 urine screens each week. The Liberty Diagnostics' brochure said a physician would generate income of $155,000 annually from the tests and additional fees of $133,000 per year for reviewing the test results and discussing them with patients, the *Times* reported.

Ordering 10 urine screens each week for 52 weeks would total 520 urine screens annually. If those 520 tests generate income totaling $288,000, that would mean the physician would earn $746.15 for ordering each test and discussing the results with patients. The laboratory company declined to discuss the brochure and would not confirm the facts as reported by *The New York Times*.

Last month, CNN broadcast the results of an investigation it conducted with the **Center for Investigative Journalism** into drug rehab companies in California. One patient quoted in the investigation was given drug tests and yet said she did not have a drug abuse problem.

CNN said **Medi-Cal**, California's Medicaid program, paid $94 million in the past two fiscal years to 56 clinics in Southern California that have shown signs of deception or questionable billing practices. This

amount represents half of all public funding for the program, CNN reported.

After the CNN broadcast, officials with the California Department of Health Care Services suspended clinics suspected of using deceptive practices. One official pledged to review every rehab facility in California.

Earlier this year, Massachusetts Attorney General Martha Coakley cited two lab companies in New England as part of a case involving kickbacks related to: a) drugs of abuse testing; b) the collection of illegal fees from patients; and c) illegally prescribing medication to patients diagnosed with opiate addiction.

Coakley has been consistently aggressive in her investigations and prosecutions of drug-testing companies. Last year, **Calloway Laboratories, Inc.**, a drug-testing company in Woburn, Massachusetts, paid $20 million in restitution to resolve allegations of an elaborate kickback scheme that cost **MassHealth** millions of dollars for unnecessary urine drug screens, Coakley announced.

Since 2004, Coakley has brought enforcement actions and won settlements against the following laboratories offering pain management and drugs of abuse testing: **Diagnostic Laboratory Medicine, Inc.**, Bedford; **Clinical Science Laboratory, Inc.**, Mansfield; **Life Laboratories**, Springfield; and **Willow Street Medical Laboratory, LLC**, Lynn.

Lab Settles Federal Charges

National labs also have drawn scrutiny. In November 2010, **Ameritox, LLC**, a diagnostic blood testing laboratory, paid $16.4 million to resolve Medicare and Medicaid claims that Ameritox paid cash kickbacks to physicians to induce them to refer Medicare reimbursable drug tests to the lab, the U.S. attorney said.

Also last year, *Reuters* reported a federal grand jury in Boston was investigating another urine drug testing company for allegations of health care fraud.

Legitimate Need to Know If Patients Are Complying

ONE FACTOR DRIVING INCREASED DRUG TESTING is physician concern that patients are not abusing prescription painkilling drugs. Therefore, more doctors are ordering urine-screening tests to learn which drugs patients are taking and not taking.

"The result has been a boom in profits for diagnostic testing laboratories that offer the tests," wrote the *New York Times*, citing a report by **Frost & Sullivan**, a market research and consulting company in Mountain View, California.

As reported by Frost & Sullivan, the drug screening market totals approximately $2 billion in the United States. This is up from about $800 million in 2000. Approximately 75% of this spending is for drugs of abuse testing in medical settings. The remainder takes place in workplaces and in sports. The tests include screens for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates, phencyclidine, propoxyphene, THC, trycyclic antidepressants, and acetaminophen.

In its coverage of this market sector, *The Wall Street Journal* reported that, in 2011, drug-test volume totaled 486 million tests, an increase of 28% from the 380 million tests done in 2006. It cited reports from **Venture Planning Group** in New York, adding that, by 2016, volume could total 592 million tests. This is a projected increase of 21% in the drug screening market in just five years.

Collectively, events in California along with news coverage by CNN, *The New York Times*, and *The Wall Street Journal* demonstrate how the explosive growth in pain management services—along with evidence of seedy and illegal business practices—has finally become a problem that public and private payers can no longer ignore. TDR

—By Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is a billion-dollar laboratory acquisition underway in Ontario, Canada. **LifeLabs Medical Services** is moving ahead with its planned purchase of **CML HealthCare** for US$917 million. The deal was made public on June 25 and, because it represents a major consolidation of the province's two largest clinical laboratory organizations, there have been some critics. However, both companies expect regulatory approval of the merger.

MORE ON: *LifeLabs*

LifeLabs is the current name for the former laboratory services business of **MDS, Inc.** It was 2006 when this lab business was acquired by the **Ontario Municipal Employees Retirement System** (OMERS) for a price of US$1.18 billion. Earlier this year, LifeLabs purchased **BC Biomedical Laboratories** of Surrey, British Columbia. This purchase represented further lab consolidation in that province, since LifeLabs operates a sizeable regional laboratory facility in Burnaby, a suburb of Vancouver.

LOINC & SNOWMED TO BE LINKED

Here is another sign of the ongoing integration of healthcare informatics. Last month, the **Regenstrief Institute** and the **International Health Terminology Standards Development Organization** (IHTSDO) announced a 10-year agreement that calls for the two organizations to more tightly link their respective technologies. The Regenstrief Institute manages the Logical Observation Identifiers Names and Codes (LOINC) and IHTSDO manages SNOWMED. The two organizations intend to more tightly link the clinical semantics of the two code sets.

TRANSITIONS

• **Boyce and Bynum Pathology Laboratories** of Columbia, Missouri, announced the retirement of General Manager Michael Gray. Gray will finish his duties by year end. Gray has served as General Manager since 1968.

• Richard Cotten will be the new Chief Operating Officer and General Manager of Boyce and Bynum. He has held executive positions at **Laboratory Corporation of America, Quest Diagnostics Incorporated**, and **SmithKline Beecham Clinical Laboratories.**

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...the acquisition of **Hunter Laboratories, Inc.**, of Campbell, California, by **Bio-Reference Laboratories, Inc.**, (BRLI) of Elmwood Park, New Jersey, last week. The acquisition gives BRLI its first lab facility on the West Coast of the United States.

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

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 9, 2013.