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HIGHLIGHTS

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HDL CEO Tonya Mallory Steps Down

Little more than five years after building Health Diagnostic Laboratory Inc. into a $400 million-a-year powerhouse, Chief Executive Officer and co-founder Tonya Mallory has stepped down.

Mallory announced her resignation on Sept. 23. A letter she sent to her employees included a twist on the "spending more time with my family" theme often cited by departing executives.

"Many of you know that my brother lost his wife a little over two years ago. He has recently started a new business close to home to avoid what was a two-hour round trip commute each day. The new venture will permit him to keep his young kids in their supportive community. I am leaving HDL, Inc. to help him get his new company off the ground in an effort that we hope will give his family financial security in addition to allowing him more time with his children," Mallory wrote.

Mallory is being replaced by Joe McConnell, another HDL co-founder who was the company's chief laboratory officer.

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Sleep Apnea Assay Could Be Groundbreaker in Marketing and Branding

If there is any offbeat whimsy to the act of urinating in a cup, NuSomnea wants a piece of that market.

The Maryland-based startup is working with PGXL Laboratories in Louisville, Ky., to develop a test that would screen children for obstructive sleep apnea. The symptoms, which include an inability to focus on tasks and intense physical activity, can often be misdiagnosed as attention deficit hyperactivity disorder, leading to prescriptions of Ritalin and other unnecessary medications.

The test focuses on four proteins in the urine that are associated sleep apnea. Early trials indicate that the test is more than 96 percent accurate. The test could be sold at a pricepoint of $500—or far lower if it is sold over the counter in a kit form. That is a fraction of the price of monitoring and analyzing a child's breathing patterns as they try to sleep in a laboratory, according to Mike Thomas, NuSomnea's chief executive officer. "It could be a really nice disease management tool," he said.

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HDL CEO Tonya Mallory Steps Down, *from page 1*

Mallory's departure could be said to be coming at a high point for HDL, which went from virtually no sales in 2009 to $420 million just three years later. But it also came close on the heels of intensifying scrutiny of HDL's business practices, including payments to physicians that could be perceived as kickbacks.

Laboratory Industry Report reported late last year that the company may have been paying physicians as much as $30 per test remitted. It also cited sources saying the company was under investigation by either state or federal regulators, although that could not be confirmed.

Mallory denied that HDL was paying physicians directly, saying only that they were paid the $3 Medicare allows for a venipuncture, as well as other phlebotomy services "like all other labs in the country," she said. As for an investigation, Mallory said at the time that "as a policy matter, our company does not confirm or deny or comment upon any pending or threatened legal proceedings or investigations."

In July, the Richmond *Times-Dispatch* confirmed that HDL was the target of a federal investigation. And a front page story in the *Wall Street Journal* last month confirmed that physicians were getting paid by the lab as much as $20 per test, $3 for the venipuncture and an additional $17 for packaging and handling fees, which HDL believed fell under the safe harbor provision of the anti-kickback statute. Some medical practices were receiving as much as $4,000 a week as a result, according to the story. However, the newspaper also reported that HDL also decided to stop the payments last June after the U.S. Department of Health and Human Services issued an advisory saying they could violate the anti-kickback statute.

Although the story indicated HDL was not the only lab being investigated, the company issued a strong response on Sept. 8, the day the story was published, insisting that the reporting "paints a highly distorted picture of our company and our work. In particular, HDL . . . vehemently disagrees with any insinuation that payments to doctors were an inducement, or that the payments were illegal or known to violate any law."

Mallory stepped down little more than two weeks after that statement was issued.

Takeaway: Health Diagnostic Laboratory co-founder Tonya Mallory has stepped down as scrutiny on the company she swiftly built into a huge operation has intensified.

Study of bioTheranostics Assay Says It Cuts Breast Cancer Treatment Costs

bioTheranostics, the San Diego-based company focused on cancer testing, has released a new study that suggests its test can significantly cut the cost of breast cancer care.

The study, which appeared in the *American Journal of Managed Care*, concluded that breast cancer patients who underwent bioTheranostics' breast cancer index

(BCI) test had less costlier treatment regimens, reducing overall costs by about 8.5 percent on average.

The BCI assay determines whether or not the patient has an estrogen receptor-positive/lymph node-negative form of cancer.

Patients with that form of the disease tend to have better outcomes than other patients but are at a higher risk of recurrence after 10 years than patients who have other variants of breast cancer. They often require some additional treatments and follow-up care even after the cancer is considered to be in remission.

According to the study, the use of the BCI—which focuses on the H/I biomarker and the molecular grade index—was able to better target and shape long-term treatment regimens for breast cancer, particularly with the use of endocrine therapy five years after diagnosis and later.

"There is a critical need to identify which patients are likely to derive benefit from extended endocrine therapy, as consideration of adjuvant treatment beyond five years is increasing," said Catherine Schnabel, bioTheranostics' senior vice president of research and development.

As a result, those breast cancer patients who underwent the assay had median treatment costs of $41,634, compared to $45,437 among those patients whose care plan did not employ the test. That's a difference of $3,803, including the cost of the BCI assay.

Researchers pegged the cost savings not only to the ability to better target chemotherapy and endocrine therapy but also to higher rates of compliance among patients, who presumably were more likely to follow a treatment course when armed with more specific information.

"In today's cost-constrained environment, this study provides important clarity on the Breast Cancer Index's economic impact," said Gary Gustavsen, vice president for personalized medicine at Health Advances and lead author of the study. "Given its utility in both newly diagnosed and five-year post-diagnosis patients, the test fills an unmet need in helping physicians determine the long-term management of these patients. Understanding the test's economic savings will be important as third-party payors seek to establish medical policy surrounding the test."

About 230,000 women in the United States are diagnosed with breast cancer every year. Were the BCI employed as a part of every treatment regimen, it could save the health care industry as much as $876 million a year. Although such numbers are theoretical, they also comprise part of the "volume-to-value" equation many industry observers say is the key to laboratories thriving in the long term.

Takeaway: Another laboratory with a molecular-based esoteric test is attempting to place an economic value on its assay in relation to health care delivery

Direct Release of Patient Tests: It's Now Legal, But Is It Consumer Friendly?

The first week in October is filled with significance. The U.S. Supreme Court began a new session, and the baseball playoffs kicked off, among other things.

This year, a major change in health care delivery is joining those significant events. For the first time in decades, patients in the United States can receive their laboratory tests directly from a provider on demand. The change to the CLIA and HIPAA regulations by the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services superseded state laws or federal exemptions in 39 states that previously required such tests be vetted by a physician first before they're turned over to a patient. Now, labs either have to mail or provide them online in a secure form within 30 days of a patient requesting any test results. Although the rule went into effect on April 7, labs were not compelled to fully comply until Oct. 6.

How the change will affect the laboratory sector remains unclear, but not only are labs moving to comply with the rule change, some ancillary operators are trying to attempt to capitalize on the change as well.

The sector "is moving in the direction of being more consumer friendly," said Robert Gregory, chief business officer for Atlas Medical, a Calabasas, Calif.-based company that creates software applications for laboratories and other diagnostic testing facilities. Among its newest products is a patient portal that allows patients to access their records directly. It launched in the days running up to the rule change.

> ***"[The laboratory sector] is moving in the direction of being more consumer friendly."***
> ***— Robert Gregory, Chief Business Officer, Atlas Medical***

Cinch, the new consumer-oriented laboratory service recently launched by Spokane, Wash.-based PAML, had to make some changes to its Web site and interface in order to accommodate the new rule.

"It was very coincidental," said Shawn Whitcomb, PAML's chief information officer, adding that the original plan was to launch the Cinch service well prior to the rollout of the new regulation. In response, PAML is making modifications to the Cinch service in order to accommodate the new regulation.

Nonetheless, Whitcomb said that the change will in some ways complement Cinch's approach, which focuses on personal testing, with several related services occurring at the patient's home if they wish.

Yet despite the nimbleness being displayed by companies such as Atlas to respond to a changing market, it appears many laboratories and affiliated organizations are still trying to catch up with the demands of patients, who not only want access to such data, but explanations of what they mean as well.

Making Data Easier to Comprehend

One of the biggest challenges facing labs in getting test results to patients is the fact that many may not be able to understand what the numbers actually mean. Interpretative data is available through some providers, but not in others.

Oakland, Calif.-based Kaiser Permanente, for example, spent billions of dollars a decade ago to create an integrated electronic medical records system as well as a patient portal, and the effort shows. Since 2008, Kaiser has been offering lab results to patients in states whose laws permit them to do so. Kaiser patients are able to not only access their laboratory results, but the results are also accompanied by fairly concise explanations as to what the data mean (e.g., their blood sugar or cholesterol levels and how they correlate to their general health).

Other large laboratories, such as Quest Diagnostics and Health Diagnostic Laboratory, have also provided extensive interpretations that accompany test results, but many smaller labs do not provide such services. Atlas, which works with labs of all sizes from local outreach programs to national players, now provides a patient module for them to view their test results.

"Because your time matters." —slogan of Cinch, PAML's direct-to-consumer testing service

"Future versions will include data interpretation and trending for patients," noted Gregory, which will include comparisons of their test results to what is considered an appropriate range for such a patient. That updated version will be made available later this year.

And while Gregory noted there has been significant demand for the patient portal services, he declined to disclose how many laboratory clients are purchasing the product.

Recent research, such as a 2009 study in the *Journal of the American Medical Association*, concluded that there were already communication issues regarding labs, clinicians, and their patients, with the latter not being informed of abnormal test results more than 7 percent of the time. Another study that was just published in the *Journal of Medical Internet Research* suggested that nearly two-thirds of patients with lower health literacy and numeracy skills could not correctly determine when their A1C test results for blood sugar were within a normal range.

Meanwhile, the data provided by outside organizations can also be difficult for a consumer to interpret. Lab Tests Online, which has been operated for more than a decade by the trade organization the American Association for Clinical Chemistry (AACC) in collaboration with the American Society for Clinical Laboratory Science, the Clinical Laboratory Management Association, and other organizations, provides a wealth

of information on hundreds of assays, including what they do, why they're ordered, and how they work. The site provides a range of data for some tests but not for others. An AACC spokesperson said that as a result of the rule change, Lab Tests Online "has created several in-depth feature articles to help patients to better understand their lab report and results."

What the Future Holds

Although Cinch is an example of the direct-to-consumer testing model, it appears to be in sync with the kind of easy-to-use interfaces that will make labs more competitive in an environment where clinicians can no longer stand between them and their tests. "Because your time matters" is the service's slogan.

> ***"The consumer is becoming more of the center of universe than the provider, and we recognize it more so than anything else."***
> ***—Shawn Whitcomb, Chief Information Officer, PAML***

Cinch currently offers more than 150 assays. Most are focused on personal health, but many of them are reflective of the kinds of tests patients typically receive during a physician visit, such as blood sugar, lipid panels, albumin levels, allergies, and thyroid function. Prices are posted up front.

Patients have the option of visiting a PAML draw site, but they can also use a home kit that employs lancets similar to those used by diabetics to test their blood sugar. The sample can then be mailed in. Results are usually posted online within two to five days. PAML will soon launch a mobile phlebotomy service to have draws performed at a customer's home or office.

"The consumer is becoming more of the center of universe than the provider, and we recognize it more so than anything else," Whitcomb said.

PAML spent some significant advertising dollars to promote Cinch, including producing a television commercial that appeared on the personal screens of American Airlines travelers last July. It is also rolling out an extensive social media strategy, all aimed at patients rather than providers. Moreover, visitors to the Cinch Web site will soon be able to purchase gift cards friends and family members can redeem for tests.

And while Whitcomb noted that the changes PAML had to make to the Cinch Web site to adhere to the new rules were extensive, they were not terribly complicated.

"They're not minor, but it is really about the flow and process, and how we position it with the patient, as well as the providers," he said.

Takeaway: The implementation of a new regulation intended to make it easier for patients to access their lab tests without their being vetted by a physician is challenging labs and their IT vendors in new ways.

■ **Sleep Apnea Assay Could Be Groundbreaker in Marketing and Branding,** *from page 1*
However, NuSomnea and PGXL have decided to jump the tracks of the traditional route for a laboratory-developed test.

The first break with laboratory tradition is the decidedly unclinical name of the assay: The Easy Peezy Pee Test.

The second break from lab orthodoxy is the marketing campaign behind the test. It includes three characters known as the Peezies, which resemble jelly beans with human limbs. One Peezy runs around in circles, wearing a circle in the carpet. Another climbs drapes before ripping them down and using them as a blanket. A third sports a football helmet and merrily bangs its head against the wall.

The characters are backdropped by what is known as the "Easy Peezy Song," a folksy number composed and sung by Eve Fleishman, whose vocal style resembles a brighter version of Nora Jones.

"Why can't it be easy peezy, so easy peezy, let it be/You may say it's ADD, but that could just be leading us astray. Astray. Hey Hey/Hesitate to medicate—don't want to speed my life away . . . we can change the story by peeing in a cup!" Fleishman sings.

"The use of cartoons and a cleverly written song surpasses what most people are accustomed to," said Peter Francis, president of the Maryland-based consulting firm Clinical Laboratory Sales Training.

Thomas said the Peezies and the song took about six months to assemble, with the specific intent of reaching a consumer audience. The PGXL team was "very comfortable" with the concept and "completely wowed" by the execution, according to Thomas. PGXL executives were not available for comment.

The third break from orthodoxy is how NuSomnea is trying to fund a second validation test, which could involve 120 pediatric patients or more. The company has launched a $100,000 crowdfunding campaign on the Indiegogo Web site. It raised more than $31,500 of its goal within the first two weeks of its launch. Thomas said the campaign serves a second purpose: gauging consumer sentiment for such a product. A good response could make it easier to raise venture capital moving forward, he added.

However, Francis said that some investors could be put off by what he called the "hokeyness" of the marketing effort. He also noted that some investors might want more research data before investing in the development of such a test. "If I were an investor, I would want to feel comfortable that my thousands (or millions) of dollars are being used for something that has true medical merit," he noted.

Thomas said he expects the assay to be introduced by late 2015, pending the results of a second validation test. Whether it becomes endearing or just another test remains to be seen.

Takeaway: A startup firm is making a bold move in marketing a laboratory-developed test. G2

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INDUSTRY BUZZ

LabCorp Acquires LipoScience for $85.1 Million

LabCorp has taken a plunge into the cardiac testing realm, acquiring LipoScience Inc. in a deal valued at $85.1 million.

Under the all-cash transaction, LabCorp agreed to pay $5.25 per share for the Raleigh, N.C.-based LipoScience, a premium of about 70 percent over LipoScience's recent stock price.

"We believe LipoScience becoming part of LabCorp is a great outcome for patients, physicians, and our other stakeholders," said Howard Doran, LipoScience's chief executive officer.

LipoScience's primary assay is the NMR LipoProfile test. The test works by using nuclear magnetic resonance imaging technology to identify low-density lipoprotein in the blood, a signal of a higher risk for cardiovascular disease.

"LipoScience's NMR LipoProfile test will enhance our innovative clinical decision support programs . . . as we provide ever-broader, differentiated knowledge services to physicians and patients," said Dave King, LabCorp's chief executive officer, in a statement. "Furthermore, LipoScience's novel application of NMR technology furthers . . . our strategy by continuing our leadership in scientific innovation."

The acquisition will help solidify LabCorp's foray into personalized health testing, which has become a growing niche among patients wanting to know more about the risks to their long-term health.

LipoScience had been under financial stress as of late. Its stock began publicly trading early last year at $9 a share but rarely approached that price in the subsequent months. For the second quarter, ending on June 30, the company reported a loss of $4.1 million on revenues of $9 million. For the same quarter in 2013, its losses were $2.4 million on revenues of $13.3 million.

The deal is expected to be a marginal improvement to LabCorp's bottom line for now. Darren Lehrich, an analyst with Deutsche Bank, estimates the transaction will add about $35 million to $40 million in annual revenues to LabCorp and "not material to earnings per share given its size." Deutsche Bank continued its "buy" rating of LabCorp stock, noting that its recent initiatives should contribute to revenue and profit growth.

Takeaway: LabCorp is continuing to expand its personalized health portfolio with more acquisitions.

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877-886-6739

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804-343-2718

LabCorp
804-343-2718

LipoScience
919-212-1999

NuSomnea
410-777-5259

PAML
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