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HIGHLIGHTS

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Troubled Calloway Laboratories Shut Its Doors

Calloway has gone away. The troubled Calloway Laboratories abruptly shut its doors on Oct. 16. The closure of the Woburn, Mass.-based lab put about 240 employees out of work.

Calloway Chief Executive Officer Gail Marcus did not respond to e-mail and telephone queries to confirm the closure, but it was reported by several publications.

The lab also issued a statement through Ball Consulting Group, a well-known crisis PR firm in New England, that Calloway was closing "due to unforeseen circumstances beyond the company's control." Employees were paid through Oct. 16, would continue to receive benefits through the end of October, and apparently would maintain control of any accrued retirement funds, according to the statement.

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Boston Heart Diagnostics CEO Pushes for More Holistic Role for Labs

Susan Hertzberg, the chief executive officer of Boston Heart Diagnostics, opened her presentation at this year's G2 Intelligence Laboratory Institute with a statistic that is often cited by sector leaders: Testing drives about 70 percent of the clinical decision-making process but consumes only about 2 percent of the health care dollars.

But Hertzberg—a blunt-talker in a sector where mild politesse tends to be the rule—all but rolled her eyes when she cited those stats in a weary, singsong manner. She noted that it's so-often repeated that many seem to miss the point: Labs should be getting paid more for their work, and they should probably secure a bigger role in how they serve patients.

"We're cheap. And that's the wrong message," she said. "The right message is that we do drive clinical decisionmaking, and we could drive better clinical decision making if you would pay for the tests that we want to bring to market that would do better than the tests we introduced 40 years ago."

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Boston Heart Diagnostics CEO Pushes for More Holistic Role for Labs, *from page 1*

However, Hertzberg noted that the sector's biggest players have been overly reliant on trading volume for advances, a quandary that could take a long time to exit.

> *"This is the case for doing more earlier. This is the case for using diagnostic insights to drive better treatment and intervention in patient management."*
>
> — Susan Hertzberg, CEO, Boston Heart Diagnostics

In the meantime, she suggested that labs push more aggressively into personalized medicine (she noted that population medicine has not yet worked, and this could be a new approach). The demand is enormous: Most Americans lead sedentary lives with little exercise, and often eat processed foodstuffs to the exclusion of all else. At the same time, food scientists are creating more products that are addictive to eat. Those are among the reasons heart disease is the leading cause of death.

While drugs can be effective, they only show demonstrable changes about 30 percent of the time—and nearly a quarter of those patients prescribed statins never obtain their medicine to begin with, and 60 percent stop taking the drug after the first year a prescription has been ordered. And if a patient has a heart attack, each year of their life moving forward can cost about $50,000 a year due to the far more intensive case management and monitoring that is involved.

"This is the case for doing more earlier. This is the case for using diagnostic insights to drive better treatment and intervention in patient management," Hertzberg said.

Boston Heart focuses on identifying at-risk patients and using the diagnostic data to better individualize treatment. The lab focuses on four factors: Their lipid levels, metabolic issues, the presence of inflammation and any genetic factors.

Last year, Boston Heart introduced a test that focuses on levels of myeloperoxidase (MPO), an enzyme generated in conjunction with cardiac inflammation. Elevated levels of MPO in conjunction with a patient complaining of chest pain is considered a reliable predictor of a heart attack or stroke within one to six months.

Earlier this year, the lab introduced a graphically intensive, 25-page report for each patient who undergoes testing. It provides specific information as to whether they are at risk for a heart attack or another cardiac event. Hertzberg believes that it cuts through the jumble of data that many patients have to navigate when they receive their test results from the doctor.

"We have now contextualized for them the treatment the doctor wants them to provide," said Hertzberg, who noted that improving patient healthcare literacy is a key to improving their health.

After the exam and test results, patients can visit the Boston Heart portal and answer a survey regarding their diet, exercise habits and other information about their background. That and their lab data help create another report regarding how they should tweak their diet. No foods are prohibited, although cutbacks may be recommended. Boston Heart also provides thousands of recipes keyed to each specific diet recommendation.

"It is a very deep and rich support system that supports how the patients live their lives," she said, quipping that "if you're a lactose intolerant vegan, we have a diet for you."

The lab also encourages patients to keep a food journal, because academic studies indicate those who do lose twice as much weight as those who do not. And Boston Heart also has nutritionists on staff to provide coaching to patients to help improve their eating habits and health.

"We want to get patients on the right path and keep them there," Hertzberg said.

Takeaway: The lab sector could probably fare better in the marketplace with new genomic tests if it focused more on improving the health of individual patients. G2

FDA Approves Quest Influenza Test

The U.S. Food and Drug Administration (FDA) has granted approval to a Quest Diagnostics affiliate for a significantly expanded test for influenza and respiratory syncytial (RSV) virus.

"With the influenza virus constantly evolving year after year and the potential to infect large populations, it's critical that physicians have access to tests to aid the detection of newly circulating and geographically diverse strains."

— Michelle Tabb, VP R&D, Focus Diagnostics

The FDA granted clearance to Focus Diagnostics' Simplexa molecular assay for an additional 46 strains of the influenza A and the influenza B virus, including 20 avian and two swine flu strains. The real-time test can now detect 92 strains in total. The clearance also adds seven additional RSV strains. Nasal swabs are tested on a portable platform developed by 3M.

The FDA originally approved the assay in 2012, and approved some expansions last year.

The need for accurate testing has grown over the years in the U.S., particularly as the population has continued to age and is therefore more susceptible to influenza. Epidemiologists have also been concerned about the viruses mutating into a strain that causes a global pandemic such as the Spanish strain that killed some 50 million people in 1918. Influenza affects up to 10 percent of all adults and 30 percent of all children annually.

"With the influenza virus constantly evolving year after year and the potential to infect large populations, it's critical that physicians have access to tests to aid the detection of newly circulating and geographically diverse strains," said Michelle Tabb, vice president of research and development for Focus Diagnostics, in a statement. "We are particularly gratified that we have validated recently circulating influenza viruses—including the Switzerland, California, Phuket and Brisbane strains—before this year's flu season takes off."

The timing of the FDA approval—just as the flu season begins in the United States—is particularly helpful for Quest. The approval did not lead to any significant fluctuations in Quest's stock.

Takeaway: Quest's Focus Diagnostics division appears to have the market lead on comprehensive influenza testing. G2

Inside The Lab Industry

At Lab Institute, Thorny Reimbursement Dilemmas Weigh Heavily On Heads

If there is an unwritten code about industry gatherings, it is that civility rules the day. But a verbal scrap at G2 Intelligence's Laboratory Institute in Washington earlier this month highlighted anxiety the sector is experiencing over the seismic shifts in how they will be paid for their work in the coming years, as the painfully written CPT codes dictating how they are reimbursed are upended by federal regulators and fiscal intermediaries.

Not only did the conference explore the concerns regarding PAMA, but dramatic cuts being faced by the toxicology labs and the proposed crosswalking for several molecular codes were also topics that had been extensively—and sometimes emotionally—explored.

The sharp exchange between Julie Scott Allen, government relations director with the Washington law/lobbying firm of Drinker Biddle & Reath LLP, and Alan Mertz, president of the American Clinical Laboratory Association (ACLA), occurred during a session discussing how the Clinical Laboratory Fee Schedule was being overhauled, and was related to the shaping of the lab reporting requirements codified in last year's Protecting Access to Medicare Act (PAMA).

PAMA has prompted deep concern throughout the entire sector. Under that law, labs will be required to report their reimbursement levels from private payers to the Centers for Medicare & Medicaid Services (CMS), ostensibly to give the Medicare program a floor at which new rates could be set. Hospital laboratories, which tend to receive higher payment rates, would mostly be excluded from this process but would be subjected to the new rates nonetheless. Mertz noted that there has been little success in reaching out to the hospital labs through the American Hospital Association—most are more concerned about the reporting rather than the financial burden.

Not only did the conference explore the concerns regarding PAMA, but dramatic cuts being faced by the toxicology labs and the proposed crosswalking for several molecular codes were also topics that had been extensively—and sometimes emotionally—explored. Mertz had said that the reporting requirement under PAMA was negotiated in lieu of immediate deep technical component cuts and across-the-board cuts proposed by Congress. But Allen, who sat on a panel with Mertz and Vince Stine, director of government affairs for the American Association for Clinical Chemistry (AACC), didn't buy it.

"Alan, you led them down that path," she retorted, claiming that the reporting rule was contrary to the wishes of the National Independent Laboratory Association. Allen also asserted that the delays negotiated under PAMA will not stop CMS from making its planned cuts anyway.

Inside The Lab Industry

"CMS' objective is absolutely to drive prices down," Allen said, noting that despite performing only 12 percent of Medicare's volume, industry giants LabCorp and Quest Diagnostics account for half of the volume among private payers, often at rates smaller laboratories cannot hope to match. Allen indicated the rates they offered to providers in lieu of higher volumes are likely to serve as the predominant template for the anticipated changes under PAMA.

"What led us here is you used Medicare (rates) to subsidize low-priced contracts for years."

— Susan Hertzberg, CEO, Boston Heart Diagnostics

Mertz—and by extension, much of the general laboratory arena—was also taken to task from the audience by Susan Hertzberg, chief executive officer of Boston Heart Diagnostics, one of the fastest growing specialty laboratories.

Hertzberg said that the call from the ACLA and laboratories—including Quest Chief Executive Officer Steve Rusckowski during a keynote address—to collaborate on raising rates was coming too late. "What led us here is you used Medicare (rates) to subsidize low-priced contracts for years," she told Mertz, criticizing the two nationals for moving to narrow lab networks and trading price for volume among private sectors over the past decade. As a result, they won't face extinction while other labs will get "pushed to the brink"—a statement that drew brief applause from the attendees. Mertz reiterated that the lab sector's choices in shaping PAMA were limited, and paraphrasing Benjamin Franklin, said it needed to hang together by being more vocal about proposed cuts, or hang separately by squabbling over the issue.

Unhappiness Elsewhere

But the anxiety radiating through that session was repeated elsewhere. In a session about the Food and Drug Administration's attempt to better regulate laboratory-developed tests, Rina Wolf, vice president of commercialization strategies, consulting and industry affairs at XIFIN, referred to the pending reimbursement cuts for toxicology services as "demonic."

Interviewed after her presentation, Wolf noted that the payment structure CMS had proposed on Sept. 25 was far below what had been discussed by the agency in the past, and even below that of proposals floated at the recent PAMA advisory meeting.

CMS proposed three tiered codes for presumptive testing, based on increments of the $19.79 currently paid for code G0434, and would range from $9.89 to $59.37. There would also be four codes for definitive testing, crosswalked to code 82542, which currently pays $24.58. The reimbursement would range from $61.46 to $167.24, depending on the complexity of the test being performed. According to Wolf, some labs could see a drop in revenue of more than 60 percent if these changes are implemented. And while she did acknowledge that there has been some overtesting in the toxicology realm, the vast majority of labs are good corporate citizens that will pay for the misdeeds of a few rogues.

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Fears were also high regarding the proposed crosswalking of various molecular codes, specifically for advanced molecular tests. According to Mertz, CMS disregarded recommendations to gapfill the new codes, and instead crosswalked them to codes many in the industry do not consider to be technical equals. As a result, Medicare payments for these tests are expected to be cut between 30 percent and 90 percent starting in January.

"We believe the agency went against precedent by setting rates using a 'crosswalk' pricing approach. As a result, prices for an entire group of precision medicine diagnostic tests ... are based on other, lower-priced tests that differ significantly—both in technical performance and intended use."

— Bonnie Anderson, CEO, Veracyte

Wolf noted that Genomic Health's Oncotype DX test for the BRCA gene would be cut from $3,416 to $2,900—although that is likely to be reversed due to the omission of some data from fiscal intermediary Noridian. Meanwhile, Agendia's Mammaprint pricing was unchanged. She suggested that CMS may have not had the time to complete the gapfill process as recommended by CMS Advisory Panel on Clinical Diagnostic Laboratory Tests and instead chose crosswalking for the sake of expediency.

Diana Voorhees, a coding expert based in Salt Lake City, noted that some of the crosswalking appeared to be appropriate, but that in other instances, prices were cut well below what they had been before.

Some big commercial tests, such as Veracyte's Afirma GEC, would be cut from $3,200 to about $2,152, which raised strong objections from the company.

"We believe the agency went against precedent by setting rates using a 'crosswalk' pricing approach. As a result, prices for an entire group of precision medicine diagnostic tests ... are based on other, lower-priced tests that differ significantly—both in technical performance and intended use," said Veracyte Chief Executive Officer Bonnie Anderson in a statement.

CareDx's AlloMap assay would be cut even further, the result of being crosswalked to the gene sequence analysis of hereditary non-polyposis colorectal cancer. The result would be a 77 percent reimbursement reduction, from $2,821 to $644.62.

"CMS is proposing drastic changes in reimbursement for a number of established molecular diagnostic tests," CareDx said in a statement.

The AACC's Stine, in attempting to calm the audience during the sometimes tense exchanges in the PAMA-focused panel discussion, tried to unify the sector under the reality every lab faces. "We all agree up here we don't like what's out there, we want to make changes. So let's focus on that part."

Takeaway: One of the most intense themes of Lab Institute was the high anxiety laboratory leaders are feeling over impending reimbursement cuts, and whether they will be able to unify over the issue or become fragmented and fractious. G2

Troubled Calloway Laboratories Shut Its Doors, *from page 1*

Calloway, which focused on toxicology and substance abuse testing and was founded in 2003, has been in a crisis PR mode for much of the past three years.

In 2012, the company paid $20 million to the state of Massachusetts and agreed to enter a corporate integrity program to settle allegations that straw companies were used to funnel payments to managers of sober living homes where involuntary drug testing takes place. Those venues then allegedly proceeded to overtest their residents and those excess tests were billed to the state's Medicaid program.

The exposure of Calloway's illicit billing practices under its prior regime apparently not only halted the company's growth in its tracks but also dimmed its prospect for long-term survival.

Former Calloway CEO Arthur Levitan and former Chief Operating Officer Patrick Cavanaugh pleaded guilty to state charges connected to the scheme, as did the owner of the sober homes. Levitan and Cavanaugh received probation and are barred from being involved in any health care program in Massachusetts until 2016.

Not long after the bribery scheme surfaced, Calloway was acquired by equity firm Ampersand Capital Partners, which installed Marcus and a whole new management regime. But Ampersand still could not completely steer the company out of trouble.

Last year, Calloway agreed to pay $4.7 million to the federal and West Virginia governments that it allegedly defrauded by billing Medicare and the West Virginia Medicaid program for pathology services bundled into urine tests. The venues that ordered the urine tests never requested the pathology services and they were never performed. Instead, Calloway undertook a medical review for each test, but such reviews are not a covered service under the Medicaid program. The alleged false billing took place between March 2009 and April 2013, prior to Ampersand taking ownership, officials said. The settlement was the largest ever for health care fraud in West Virginia history.

The exposure of Calloway's illicit billing practices under its prior regime apparently not only halted the company's growth in its tracks but also dimmed its prospect for long-term survival. Its workforce was about 500 employees prior to the settlements; it was less than half of that at the time it closed.

Additionally, the laboratory sector may be entering what is best described as peak toxicology. That kind of testing has been one of the few areas of the laboratory business that has experienced brisk growth in recent years. However, it is facing potentially steep cuts under the recently released Clinical Laboratory Fee Schedule (CLFS). Under the new schedule, some industry observers say toxicology could be facing reimbursement reductions of 50 percent or more from Medicare in the coming years, cuts that will no doubt be replicated by private payers.

Calloway may have become one of the first victims of the hard new facts facing the toxicology niche. The changes to the CLFS "were probably its *coup de grace*," remarked one lab executive familiar with the pending payment cuts.

Takeaway: Calloway could not recover from its prior wrongdoing and pending deep cuts in reimbursement for toxicology testing. G2

INDUSTRY BUZZ

OHSU Collaborates With Swedish Firm to Develop Pancreatic Cancer Assay

The Oregon Health and Science University has collaborated with a Swedish biotech firm to bring a molecular test to market that could detect pancreatic cancer in its earliest stages.

The test, ostensibly called IMMray PanCan-d, would analyze a patient's immune system to detect signs of the cancer. It is being developed by Immunovia and OHSU's Knight Cancer Institute. Pancreatic cancer can be treated successfully if detected in its earliest stages, but that rarely happens, as it is asymptomatic until it is in its most advanced form. As a result, the five-year survival rate is below 10 percent in most cases.

Despite its relative rarity compared to other cancers—fewer than 50,000 cases are diagnosed annually in the U.S., less than a quarter the number of breast cancers—the pancreatic form of the disease kills 41,000 Americans every year. Under the terms of the arrangement, OHSU will provide confirmation services for the test by collecting and analyzing blood samples from patients with pancreatic ductal adenocarcinomas and running clinical tests with control groups.

"If we're going to make a significant impact on patients' lives and improve their chances of survival, we need to detect cancer earlier when it's most treatable. The immune system provides an early warning system that is invaluable in that effort," said Brian Druker, M.D., director of the OHSU Knight Cancer Institute, in a statement. "We expect that our collaboration with Immunovia will not only improve the kind of screening tests available, but it will also allow us to intervene earlier in the course of the disease."

The completed test would be run through Immunovia's IMMray platform, which analyzes serum proteins for changes that signify the onset of disease.

"Our goal is to establish IMMray PanCan-d as a standard amongst pancreatologists and diabetes physicians worldwide for detecting pancreatic cancer in high-risk groups," said Immunovia Chief Executive Officer Mats Grahn in a statement.

Neither Immunovia or OHSU provided a timeline for the release of a test.

Takeaway: An overseas collaboration may eventually bring a vital tool to diagnosing pancreatic cancer to market. G2

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202-637-9466

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508-877-8711

Drinker Biddle & Reath LLP
202-842-8800

Food and Drug Administration
888-463-6332

Immunovia
46-46-275-60-00

LabCorp
336-229-1127

OHSU Knight Cancer Institute
503-203-1000

Quest Diagnostics
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