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HIGHLIGHTS

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Bio-Reference Takes Steps to Publicize Dispute With New Jersey Blues

Bio-Reference Laboratories, the rapidly growing Elmwood Park, N.J.-based firm that is aiming to become a national player, is engaged in a nasty spat with the Blues plan in its home state.

Bio-Reference took the highly unusual step of describing the conflict in detail as part of its quarterly earnings report that was released late last month. It was part of an explanation as to why its days sales outstanding (DSO) had increased by three days during the reporting period.

Marc Grodman, M.D., Bio-Reference's chief executive officer, made it clear in the statement that the increase in DSO was purely the company's own choice and is "attributable to an issue with Horizon Blue Cross Blue Shield of New Jersey (Horizon) pursuant to which we have elected temporarily to suspend billing."

According to Grodman, "over the past several months, we have come to believe that we should have been paid for certain services rendered to Horizon under our agreement to service their PPO subscribers. We believe Horizon has mischaracterized these services as managed care and therefore not payable under our PPO agreement.

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Quest, LabCorp Subject of Whistleblower Suit in Virginia

A whistleblower lawsuit against the nation's two largest laboratories was unsealed in federal court in Virginia earlier this month, accusing them of practices that defrauded the state's Medicaid program while also proving anti-competitive to other labs.

The suit was originally filed in Virginia state court by Hunter Laboratories, the California-based firm that recently sold the bulk of its clinical operations to Bio-Reference Laboratories but is continuing to aggressively pursue litigation against its former competitors. The other named plaintiff is former Hunter CEO Chris Riedel. He is now CEO of HunterHeart, Inc.

Court records indicate the suit was originally filed in late 2007, although the Virginia attorney general only recently joined the litigation.

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■ **Bio-Reference Takes Steps to Publicize Dispute With New Jersey Blues**, *from page 1*

Based on Horizon's characterization of these services, we had not previously billed or recognized revenues for these services. After BioReference began to bill and was initially paid by Horizon for a fraction of these previously unbilled claims, Horizon ceased paying for these disputed services and sought to recoup those payments from monies due to us for unrelated and undisputed services rendered. As a result, we suspended billing Horizon for most services while this dispute is ongoing."

Grodman added that negotiations were continuing with Horizon through its legal counsel but that litigation was a possibility.

Bio-Reference officials declined to comment further. Horizon officials did not respond to requests seeking comment.

Observers say the dispute is unique and likely tied to Bio-Reference's way of doing business.

"I am not surprised," said Michael Snyder, president of Clinical Labs Business Solutions, a New York City-area consulting firm. "Bio has had good discipline (regarding) holding the payers to their contractual obligations, as opposed to the majority of the industry."

Dottie Miller, chief executive officer of Miller Consulting Services near Philadelphia, also believes that the dispute is unique. She added that Bio-Reference has been working hard in recent years to shed the negative publicity associated with a former vice president of sales who allegedly pocketed nearly $2 million through abuses of his expense account and that it would not be picking public fights with payers without a specific reason.

"Marc Grodman is a very up-and-up guy," Miller said.

Takeaway: Bio-Reference's public fight with a large payer is symptomatic of the tense relationship between labs and health plans these days and indicative of the company's corporate culture. G2

XIFIN Proposes Changes to Molecular Test Billing Methodologies

XIFIN, the San Diego-based revenue cycle management company, has proposed new guidelines for the billing of molecular tests.

In a recently released 28-page white paper, XIFIN noted that billing methodologies for molecular tests rarely take their ability to affect the long-term financial aspects of care under consideration (e.g., using a $3,000 test to determine whether $100,000 in treatment is required). Moreover, the tests are evolving so rapidly that they run the risk of becoming obsolete for medical purposes before commercial or government payers recognize their utility and assign a billing code.

"Today's antiquated regulatory and coverage protocols are inadequate for the rapid pace of molecular diagnostics advancements," said Lâle White, XIFIN's chief executive officer. "More importantly, the current regulatory system must recognize the economic value of these tests in order to support the rapid development and deployment of potentially life-saving diagnostics."

XIFIN proposed payments be developed along a sliding scale that shares risk between the developer of the test and the payer. Tests that have little impact on the course of treatment should be paid at a low rate. Tests that significantly alter the course of treatment should be paid at a higher rate. Tests that are more effective or more sensitive than the older assays they're replacing should be reimbursed more than the older tests. If they have an additional medical benefit, such as allowing for an earlier diagnosis, they should command a higher reimbursement.

Company officials expect any adoption of this system to be incremental at best. Rina Wolf, XIFIN's vice president of commercialization strategies, noted that these guidelines have been submitted as a trial balloon to both payers and Medicare administrative contractors.

"They've been positive as to the concept, but obviously it would be a total paradigm change, and it is not something we expect to happen overnight," she said.

Takeaway: The current reimbursement system for molecular tests needs to be revamped in light of market considerations and impact on the patient's care.

John Muir Lab Sale Appears Part of Financial Overhaul

The sale of John Muir Health's laboratory outreach operation to national giant LabCorp appears to be part of a large housecleaning operation on the part of the two-hospital system east of the San Francisco Bay Area.

Along with the sale of its outreach operations, John Muir will close its 56,000-square-foot core laboratory, part of what is known as MuirLab, which performed 2.4 million tests last year.

"[LabCorp] has the existing infrastructure and capacity locally to absorb the increase in lab work that will result from acquisition of MuirLab's outreach business," John Muir said in a statement. The terms of the transaction were not disclosed, and it is expected to be completed by the end of the year.

The transaction and closure led to the layoff of 540 workers, although John Muir officials indicated that some number of those employees would find work with LabCorp.

Days after the lab sale was announced, John Muir announced voluntary buyouts to trim its overall staff by 4 percent, as well as cut costs by $52 million by the end of 2014.

"We must take proactive steps to preserve our ability to deliver great care in the midst of growing patient concerns about health care costs and the most profound changes to health care in decades," Cal Knight, John Muir Health's chief executive officer, said in a letter recently distributed to employees. "We will make decisions, sometimes difficult ones, to maintain our short- and long-term ability to fulfill our mission and serve the community."

Takeaway: The sale of John Muir's hospital outreach laboratory businesses may be part of a larger aim to improve the bottom line.

Inside The Lab Industry

Touting New Technology, Theranos Strikes Testing Deal With Walgreens

A Silicon Valley entrepreneur has been planning since she was a teenager to remake the sometimes painful and time-consuming process for the blood draws required to perform laboratory testing.

The first phase of Elizabeth Holmes's plan was unveiled this month in conjunction with the nation's largest retail pharmacy chain.

Holmes's firm, Palo Alto, Calif.-based Theranos, has worked mostly in secret for the past decade to perfect a wide array of laboratory assays that require just a few drops of blood. For collection, the company has developed a system of minilancets, microtubes, and a draw vial so small it is shown in promotional materials on the tip of a finger. Holmes dropped out of Stanford University at age 19 a decade ago to form the company, where she serves as its chief executive officer.

> ***"This is the next step in Walgreens' efforts to transform community pharmacy."***
> ***—Kermit Crawford, Walgreens president of pharmacy***

Only 29 now, Holmes has a list of formidable accomplishments under her belt: Along with miniaturizing a collection and testing process that's remained mostly unchanged for decades, she's raised an estimated $100 million in venture capital, attracted three former U.S. cabinet members to her board, and snagged the former corporate headquarters of Facebook and Hewlett-Packard for company office space. Theranos has also been quietly acquiring additional office space and hiring dozens of employees in recent weeks. Holmes and other company officials have received five U.S. and four global patents on its draw technology and testing devices in the past year, records show.

Theranos's path appears drastically different—and more ambitious—from when Holmes initially founded the company to create a device that would provide real-time information to individuals concerned about their risks of adverse drug interactions. It's a product she described in 2006 as an "external point-of-care Blackberry."

BlackBerry has admittedly seen better days. Whether Holmes and her company can replicate that experience for the Quest Diagnostics and LabCorps of the world—or just carve out a significant niche for itself—remains a giant question mark. Observers expressed excitement at the technology advances Theranos may offer but caution that the business model it is pursuing poses numerous challenges.

The Retail Route

Rather than rely on marketing via doctors' offices, medical groups, and hospitals, Theranos will present its product in a retail setting, primarily as a personal medicine product. It announced earlier this month a deal with Walgreens to

open "wellness centers" on-site at a variety of its pharmacies. The first one opened this month in Palo Alto, not far from Theranos's headquarters.

Under the concept, patients would be able to visit Walgreens and provide blood draws for a panel of about 220 different tests, according to data on its Web site. Most of them are basic hormonal, drug, and substance assays, although Theranos's marketing materials hint at future molecular testing. All assays are priced at 50 percent below Medicare rates, with about half under $10. A basic urinalysis or glucose test is priced well under $2—less than what many drugstores charge for a pack of chewing gum.

"Most certainly, there is a space for something like this."
—Thomas Charland, chief executive officer, Merchant Medicine LLC

Tests would be processed at Theranos's lab in Palo Alto, although the company's recent patents suggest a lot of testing may be done at the draw site and also transmitted electronically. Results for most tests would be offered to patients within a few hours.

"Theranos' service offers affordable certified lab testing with quicker response times, and furthers our mission to provide a differentiated patient experience," said Kermit Crawford, Walgreens president of pharmacy, health, and wellness, in a statement. "This is the next step in Walgreens' efforts to transform community pharmacy."

Spokespeople with both Theranos and Walgreens declined to provide specifics of the business arrangement or how many sites will open in the near term. "We're right now focused on the successful launch of the first site," Walgreens spokesperson Jim Cohn said.

Separate From Retail Clinics

Theranos's services will be offered as a product distinctly separate from Take Care, Walgreens' chain of retail primary care clinics, according to Cohn. And while he added there are no plans to market the two together, he did not deny that there is a growing consumer awareness of the retail clinic concept.

Observers say that growing awareness could benefit Theranos.

"Most certainly, there is a space for something like this," said Thomas Charland, chief executive officer of Merchant Medicine LLC, a Minneaoplis-area firm that focuses on developments in the retail clinic realm—the one area where lab tests and pharmacies mostly intersect. "But to what extent it will represent significant patient volume, I can't say."

Charland added that most assays currently conducted by staff at retail pharmacies are of the kit variety and often take just seconds to process, with no referrals or outreach required. That far more tests would be available, with specimens presumably drawn far more comfortably than in a doctor's office or a laboratory draw site, might make it attractive, he said.

And while it appears that the Theranos technology is a leap ahead of traditional blood draws—anyone with a toddler undergoing testing is cognizant of nightmare encounters with a phlebotomist—the logistics of quick draws and analyses at a pharmacy site remain unproven.

Peter Francis, president of the Maryland-based Clinical Laboratory Sales Training LLC, recalled an attempt by the clinical laboratory division of SmithKline Beecham to set up draw stations in retail pharmacies in the 1990s. "It did not pan out," he said, adding that there were long lines and other logistical issues. SmithKline sold its lab business to Quest Diagnostics shortly thereafter.

Mostly Silent

While Theranos has discussed its technologies, it has been virtually silent on the specifics of its business plans to *Laboratory Industry Report* and other publications. Holmes once said in legal papers that confidentiality was critical to Theranos's success. A planning official with the Bay Area suburb of Newark, where the company rents a large space that is believed to include its laboratory, recently told the *San Francisco Business Times* it was the most secretive outfit he has ever dealt with.

"This is not the last thing [Holmes is] going to invent."
—George Schultz, Theranos board member and former U.S. secretary of state

The few names openly connected with Theranos suggest a corporate culture simultaneously seeking to leverage status while maintaining insularity.

While two of Theranos's directors are big names—former Secretary of State Henry Kissinger and George P. Schultz—both men are in their 90s and have next to no experience in the business of health care delivery. Ditto for much of the rest of Theranos's board, whose preponderance of experience is in the public service and military realms. They may have been recruited with the assistance of Elizabeth Holmes's father, Christian R. Holmes, who held high-level posts during the George H.W. Bush administration and is currently a global coordinator for the USAID relief agency. Only one director, former Wells Fargo & Co. CEO Richard Kovacevich, has extensive experience running large companies.

And data from LinkedIn suggest that Elizabeth Holmes's brother, 27-year-old Christian R. Holmes Jr., holds a key position at the company as its product development chief.

Holmes's only significant media interview in recent years has been with the *Wall Street Journal*. It was conducted by a member of its editorial board who specializes in opinion writing. His only other interview was with the 92-year-old Schultz, who suggested that Holmes could become the next Bill Gates or Steve Jobs.

"This is not the last thing [Holmes is] going to invent," he offered.

Takeaway: A potential breakthrough in the specimen collections process will be marketed in the personal medicine rather than the commercial laboratory realm as Theranos, a California-based startup, takes aim at retail clinics. G2

■ **Quest, LabCorp Subject of Whistleblower Suit in Virginia**, *from page 1*

The suit accuses Quest, LabCorp, and a variety of their corporate affiliates of offering steeply discounted test prices for some procedures to providers in order to guarantee a large volume of pull-through of commercial and Medicaid business in order to cover their losses on those tests.

The suit alleges the labs would then bill the Medicaid program directly and charge their normal commercial rates—a violation of state regulations requiring that the Medicaid program be charged no more than any provider for a procedure.

According to the litigation, this led to price inflation for Medicaid providers by more than 600 percent in some instances. Quest is alleged to have charged $1.43 for a CBC and platelet test, CPT code 85023, to non-Medicaid providers, while charging its full commercial rate, $10.53, to Medicaid providers. For LabCorp, the discounted rate for a ferritin test, CPT code 82728, would be $3.68, but it would charge Medicaid $18.83.

The suit, which was recently moved to federal court because some of the legal issues being contested cross state lines, is seeking treble damages to the state of Virginia because of the alleged antitrust violations, $11,000 per each violation, as well as legal costs.

Typically civil plaintiffs in such whistleblower actions receive 15 percent of any settlement or judgment.

Previous Settlement

Riedel won a settlement against Quest and LabCorp in 2005, claiming they overbilled California's Medicaid program. The two labs eventually settled the suit for a combined $290.5 million. Another suit against Quest in Nevada is scheduled to go to trial shortly, according to Riedel.

Quest responded to the developments in Virginia with a written statement: "The allegations have been made by Hunter Laboratories, a Quest . . . competitor. We believe these allegations lack merit, and our testing services are priced appropriately. We comply with the laws and regulations governing our business, including Medicaid pricing requirements, not only as a legal obligation, but also because it is the right thing to do. As always, Quest Diagnostics remains firmly focused on putting patients first and serving their needs."

LabCorp, which very rarely responds to media requests for comment, issued a much briefer but blunter statement: "We do not comment on pending litigation, but we intend to vigorously defend this lawsuit. LabCorp believes that the allegations are wholly without merit."

Riedel said he expected a trial in the matter to take place as early as next spring. He added that Virginia is often referred to in the legal profession as the "docket rocket" because of the relatively quick pace of civil litigation in that jurisdiction.

Takeaway: Quest Diagnostics and LabCorp could be enmeshed in qui tam litigation for years to come as Chris Riedel has made clear he intends to continue pursuing lawsuits against the companies. G2

INDUSTRY BUZZ

GeneDx Latest Firm to Jump Into BRCA Market

GeneDx, the Bio-Reference Laboratories subsidiary, has launched a full panel of inherited cancer tests that includes assays for the BRCA1/2 genes.

The Maryland-based GeneDx is the latest company to test the BRCA test market after the U.S. Supreme Court ruled earlier this summer that Myriad Genetics could not hold patents on unaltered genes.

Despite losing the case, Myriad and its affiliates have sued other labs offering BRCA assays for patent infringement, claming they are infringing on its proprietary testing methods. A GeneDx spokesperson declined to comment on whether the risk of litigation was factored into their decision.

GeneDx's BRCA products will include a panel for mutations common to Ashkenazi Jews. The other tests include a 26-gene panel for breast and ovarian cancer, an 18-gene panel for pancreatic cancer, an 18-gene panel for colorectal cancer, and an 11-gene panel for endometrial cancer. They are being marketed under the OncoGeneDX brand.

"We are excited to be launching this suite of tests, as we can now bring our extensive experience in genetic testing along with cutting-edge technologies to bear on this very important public health problem that has tremendous impact on patients and their families," said Sherri Bale, GeneDx's managing director.

The GeneDx spokesperson said the tests would be priced competitively and feature fast turnaround times but could not release exact numbers because of ongoing negotiations with insurers. Myriad had been charging about $3,000 for the BRCA test when it held a valid patent. Other firms, such as GeneByGene, are charging $795.

"We've had significant interest from both current clients and new clients" for the tests, the GeneDx spokesperson said.

The New Jersey-based Bio-Reference, which has shown rapid growth at a time when other large laboratories are struggling with flat revenues and earnings, has indicated that molecular and esoteric testing is a large driver of its current growth and plans to continue expanding offerings in that area.

Takeaway: Another lab is getting into the BRCA testing segment as a result of the Supreme Court's decision on gene patents. This area is likely to continue growing as other companies develop their own tests.

References

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410-299-6562

GeneDX
301-519-2100

LabCorp
800-222-7566

Merchant Medicine
651-483-0450

Myriad Genetics
801-584-3600

Quest Diagnostics
800-222-0446

Theranos
650-838-9292

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