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Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

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HIGHLIGHTS

Labs to Pursue Amended Complaint Against Quest, Insurers

For someone who just had an antitrust lawsuit tossed out of court, Chris Riedel is remarkably upbeat.

Riedel, the chief executive officer of Hunter Laboratories in Campbell, Calif., told *Laboratory Industry Report* that his legal team is moving forward with an amended complaint in the federal lawsuit against Quest Diagnostics, Aetna, Blue Shield of California, and the Blue Cross Blue Shield Association.

Hunter and several other California labs contend that the defendants engaged in anti-competitive behavior to squeeze smaller labs out of the networks of the two health plans. The lawsuit, filed last November by Rheumatology Diagnostics Laboratory Inc., Pacific Breast Pathology Medical Corp., Surgical Pathology Associates, and Hunter Labs, alleged that the insurers conspired to allow Quest to monopolize markets for specialized testing.

The U.S. District Court for the Northern District of California dismissed the case June 25, saying the allegations were not adequately supported.

"A [dismissal] with leave to amend is very common with antitrust suits," said Riedel, who praised the rationale given by U.S. District

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Myriad Sues Competitors Over BRCA Test Offerings

Myriad Genetics is undeterred. Just weeks after losing key portions of a U.S. Supreme Court case regarding the patenting of human genetic material, Myriad has sued two other laboratories over their plans to offer competing breast cancer tests at prices far lower than what it has been charging.

The Salt Lake City-based Myriad has filed two separate suits in federal court in Utah. They allege Houston-based Gene by Gene and Aliso Viejo, Calif.-based Ambry Genetics are infringing on their still-existing patents and processes for handling and testing modified genetic material.

Along with Myriad, the co-plaintiffs are the Toronto-based Hospital for Sick Children, the University of Pennsylvania, the University of Utah, and Quebec-based Endorecherche.

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■ **Labs to Pursue Amended Complaint Against Quest, Insurers**, *from page 1*

Judge Jon S. Tigar in his decision to throw out the suit. "The judge gave us a very nice roadmap" in terms of how Hunter and the other plaintiffs should craft their amended complaint, Riedel noted.

Hunter's ability to act as a gadfly to the national labs is not to be underestimated. Riedel filed a qui tam lawsuit 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.

This most recent lawsuit alleged the health plans had agreed to accept from Quest discounts in tests in exchange for "pull-throughs"—essentially a guarantee for a bulk book of business. And the Blue Cross Blue Shield Association allegedly made changes in its billing rules for out-of-state labs that essentially rendered scores of labs as out-of-network providers.

As a result, the plaintiff labs said they were essentially cut out of Aetna's and Blue Shield's provider networks.

"Our lab has been hammered because Blue Shield took us out of their network," Riedel said, adding that the San Francisco-based health plan represents about 10 percent of the lab business in California.

However, Tigar dismissed the suit because the plaintiffs did not show that all the defendants were acting in concert, nor did they demonstrate Quest's market shares increased as a result of the offers it made to the payers.

Riedel did not give specifics about how the lawsuit might be amended, but he suggested that it would be reborn with even greater force.

"We're even having other labs call us, asking to join the suit," he said.

The attorneys for Quest, Aetna, and Blue Shield did not respond to requests for comment.

Aetna has already come under fire for keeping contracted lab rates well below Medicare and favoring laboratories with nationwide reach over regional players.

"Most labs in our network are in fact contracted nationally [by our national contracting unit] at Aetna," said spokesperson Cynthia Michener. "Only a small number of local labs might be contracted by a state team." G2

HDL Forms Joint Venture With GeneNews Ltd.

Health Diagnostic Laboratory (HDL) has entered into a joint venture to manufacture and distribute a gastroenterological test developed by a Canadian firm.

The deal, with the Toronto-based GeneNews Ltd., calls for the construction of a new 25,000-square-foot laboratory near HDL's headquarters in Richmond, Va., according to Tonya Mallory, HDL's chief executive officer.

The $1 million construction cost will be equally divided among HDL, GeneNews, and a third undisclosed entity that will focus on distribution.

The facility, which will be called Innovative Diagnostic Laboratory (IDL), is expected to be operational and CLIA-certified by this fall.

"We believe that Health Diagnostic Laboratory is an ideal partner for us in light of their experience and success in integrating high throughput laboratory operations with sales capabilities on a national scale," said GeneNews Chief Executive Officer Gailina Liew.

The IDL facility and entity will be used for development and processing of ColonSentry, a molecular-based blood test that determines a patient's genetic risk for colon cancer through the examination of seven RNA biomarkers. It can be used to detect the presence of colon cancer in a patient, the severity of the disease, or the genetic risk the patient has of developing it.

ColonSentry has been available in Canada and distributed by GeneNews since 2008. Enzo Clinical Labs, a division of Enzo Biochem, distributes ColonSentry in New York and New Jersey, according to Liew.

"Blood-based cancer testing is a natural progression for us," Mallory said. She noted that HDL already focuses on tests that assay biomarkers for heart disease and diabetes.

Case Western, University Hospitals Develop Series of HIV Assays

Case Western Reserve University has entered into a deal with the Cleveland-based University Hospitals system to distribute a suite of tests that gauge drug sensitivity in patients with the HIV virus.

The three tests, which will be marketed under the DEEPGEN™, VIRALARTS™ and VERITROP™ brands, were developed by researchers at the Case Western School of Medicine. The molecular-based assays will help determine how HIV-positive patients will react to specific doses of anti-retroviral drugs used to check the progression of the infection, as well as help predict rates of coreceptor tropism.

A fourth test, a variant of the DEEPGEN assay to help determine anti-retroviral dosages for hepatitis C, will also be covered under the agreement when it becomes commercially available.

The morphing of HIV into AIDS has been successfully controlled since the mid-1990s with the use of combinations of anti-retroviral drugs. However, determining effective dosages has often been a trial-and-error.

"This new capability will clearly benefit patients with HIV infection in a more targeted manner, thereby impacting the quality of their life," said Ronald E. Dziedzicki, chief operating officer at University Hospitals' Case Medical Center, which will spearhead distribution.

Miguel Quinones-Mateu, the Case Western assistant professor of pathology who codeveloped the assays, said they will initially be marketed in the region, but national distribution will eventually be sought. The DEEPGEN tests retail for $1,000 apiece, and volume is expected to be 1,000 monthly within the first six months, he added.

The tests were developed at and will be offered in conjunction with University Hospitals' Translational Laboratory, a 4,200-square-foot facility opened on the Case Hospital campus in 2011. Quinones-Mateu serves as its scientific director.

Under the terms of the agreement, University Hospitals will pay Case Western a royalty based on sales volume, although specific financials were not disclosed.

MAAA Pricing Dominates Medicare Lab Meeting

Algorithms dominated the discussion during the Centers for Medicare and Medicaid Services' (CMS) annual lab pricing meeting, held at the agency's headquarters in Batltimore on July 10—or more precisely, multianalyte algorithm assays, better known as MAAAs.

Algorithmic predictions are the linchpin of highly sophisticated molecular tests that can predict a patient's genetic propensity for a specific condition or how they might react to a dosage of medication. Oftentimes, a cocktail of tests with the faintest clinical relation to one another is required to make an MAAA-based assay function effectively.

And the laboratory sector, under pressure from both providers and payers to move from a volume to a value-based business model, wants MAAA testing to be made available to the largest swath of patients as soon as possible.

OVA1 and the MAAA Value Proposition

One of the tests discussed during the meeting, OVA1, is a bold example of the value proposition behind MAAA testing. It uses five different immunoassays to determine the malignancy of an ovarian tumor prior to surgery to remove it—dictating whether a gynecologic oncologist should perform the procedure in order to prevent a rupture and upstaging of the malignancy rather than a less skillful general surgeon.

> ***"Our goal is a bold one—to make regrettable first surgeries by nonexperts a thing of the past."***
>
> ***— Donald Munroe, chief scientific officer, Vermillion***

Currently, most doctors rely on CA125, a 30-year-old blood test that correctly predicts ovarian tumor malignancy only about 50 percent of the time, according to Donald Munroe, chief scientific officer for Vermillion, the Austin, Texas-based company that developed OVA1. Although CA125 is among the assay components in OVA1, the overall test's accuracy in predicting malignancies is 96 percent, Munroe claimed.

Just about one-third of ovarian cancer patients receive the appropriate standard of care for removing an ovarian tumor—due in part to the inaccuracy of CA125 and shortages of gynecologic surgeons, according to Munroe. However, the occurrence of a malignant mass is relatively rare—about 22,000 malignancies are detected among the 300,000 ovarian tumors removed from patients in the United States each year. Those that receive the standard of care had higher five-year survival rates.

"Our goal is a bold one—to make regrettable first surgeries by nonexperts a thing of the past," Munroe said. "We see this as a major breakthrough for patients, providers, and payers alike."

AMA, CMS at Odds

The American Medical Association adopted MAAA as a new Current Procedural Terminology category for 2013, and there are nine different MAAA tests included in the CPT codes. However, CMS has yet to take an official position on MAAA-based tests, primarily because the agency has not determined if the algorithmic formulas used to knit an array of assays together as in the OVA1 example provide a specific therapeutic benefit.

CMS has not yet separately priced these codes and is currently instructing providers to continue to bill for MAAA tests using existing Healthcare Common Procedure Coding System codes.

Although the agency said it requires further study before it creates a separate payment methodology for MAAA tests, it was urged by a variety of speakers to create it as soon as possible, citing the growing use of such assays.

"CMS should recognize MAAAs as a class of tests," said Eric Zimmerman, a partner with the law firm of McDermott Will & Emery, representing the Coalition for 21st Century Medicine, a lobbying group.

"The algorithm creates the value for the test," said Chandra M. Branham, vice president of payment and health care delivery policy with the Advanced Medical Technology Association (AdvaMed).

Zimmerman said if CMS eventually embraces MAAA testing, gap-filling would be the preferred methodology for pricing, with crosswalking used when it makes more sense. Such decisions could also be deferred to the Medicare administrative contractors, or MACs.

"How we set payment amounts is up to you," Zimmerman said.

Currently, Novitas is the only MAC that has set a payment rate for OVA1—$516. The Department of Defense has set its own payment rate of $650. Munroe recommended a national gap-fill rate be set for OVA1. He noted that the cost of all the tests combined is slightly less than $500 but that crosswalking for the test made no sense.

"The test aligns perfectly with the intent of gap-fill—to provide actionable information for doctors," Munroe said.

From Code Stack to Gap Fill

Ken Song, M.D., chief executive officer of Ariosa Diagnostics in San Jose, Calif., urged the use of gap-fill for his company's Harmony test, which detects fetal chromosomal abnormalities such as Down syndrome.

Although Harmony is as diagnostically accurate as amniocentesis, since it is a noninvasive assay, it is much safer. Song noted that up to 1 percent

of fetuses tested using that older method wind becoming nonviable as a result—up to 2,000 a year.

"It's a clear value proposition," Song said. He added that most commercial payers have issued positive coverage for Harmony, and that several thousand tests have been performed since it received approval two years ago.

Song recommended gap-fill to price Harmony, primarily to keep it affordable. Under code-stacking, the test costs about $1,500. But Harmony is priced at about $795 for commercial payers.

"When you look at this relative to all the other input out there, it is well within the range of other tests covered by CMS," Song said.

For Other Tests, Crosswalk Preferred

Not everyone in attendance at the meeting wanted to use gap-filling, a sometimes controversial method that is currently being used by MACs to price more than 100 new Tier 1 and Tier 2 molecular pathology codes on the Clinical Laboratory Fee Schedule (CLFS).

Paul Radensky, M.D., a partner in the law firm of McDermott Will & Emery and a physician, recommended that the Galectin-3 test for congestive heart failure be reconsidered and crosswalked to the ostecalcin test, CPT code 83937, which pays $41.03. It is currently crosswalked to the code for a non-specific immunoassay, CPT code 83520. McDermott Will & Emery is the legal counsel for BG Medicine, the Waltham, Mass.-based company that manufactures and distributes the test.

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> ***—Chandra Branham, vice president of payment and health care delivery policy, AdvaMed***

According to a survey of laboratories that perform Galectin-3, the median cost of performing the test is $43.47, while 82520 pays $17.80.

"If it's not clinically appropriate, don't cover it," Radensky said, but keeping the test at too low a price will punish laboratories, keep valuable information from clinicians, and stymie future research and development for testing.

Radensky's request was also supported by AdvaMed's Branham, who also urged CMS officials to provide greater transparency regarding the rationale behind some of their payment decisions. The agency had been heavily lobbied by the laboratory sector regarding the crosswalking of Galectin-3 to osteocalcin.

"When CMS decisions are not closely aligned with comments they should provide a more detailed response to the rationale and how it was released," Branham said.

The CMS will announce its pricing decisions on the 2014 CLFS in September and will gather further comments at that time. G2

■ **Myriad Sues Competitors Over BRCA Test Offerings**, *from page 1*

Myriad spokesperson Ronald Rogers said Gene by Gene and Ambry's planned tests infringe "on 10 patents covering synthetic primers, probes and arrays, as well as methods of testing, related to the BRCA1 and BRCA2 genes."

Both Gene by Gene and Ambry announced they would offer BRCA1 and BRCA2 tests just hours after the Supreme Court last month made a unanimous ruling that invalidated Myriad's patents on unaltered DNA. In Gene by Gene's case, it priced its test at $795, or about one-quarter of the $3,000 retail price Myriad had been charging for its BRCA testing.

The high court did rule that Myriad could retain its patents on complementary, or cDNA, that has been altered for testing purposes.

The lawsuits filed by Myriad do not contain any specific information as to how Ambry and Gene by Gene have infringed on their patents.

Ambry to Respond 'Aggressively'

Ambry said in a statement that Myriad had been overly litigious in protecting its "monopoly" on BRCA testing—an issue settled by the Supreme Court ruling. It said that it would respond aggressively to the lawsuit.

"Ambry Genetics supports the Supreme Court's decision and will vigorously defend its position," said Charles Dunlop, chief executive officer of Ambry Genetics. "We have had an overwhelming response from our clients seeking an alternative laboratory to perform BRCA testing and Ambry is fully committed to supporting our clients and patients moving forward."

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>
> ***— Charles Dunlop , CEO, Ambry***

Gene by Gene officials did not immediately wish to comment, saying they had not yet been served with Myriad's lawsuit.

Rogers said Myriad would seek a restraining order against Gene by Gene and Ambry from marketing their competing tests. The company also seeks damages and delivery to Myriad of any products and devices they have developed that infringe on their patents.

Additionally, Rogers asserted that the tests offered by rivals were not as high a quality as Myriad's and would not be turned around as rapidly, although he stressed that was not part the company's allegations of patent infringements.

Rogers would not say whether Myriad had any plans to cut its BRCA pricing in response to the Supreme Court decision and the test offerings. However, the company posted a pledge on its Web site to provide financial assistance and free tests to patients who couldn't afford its assays and that it would not interfere with other labs performing testing to confirm results provided by Myriad.

INDUSTRY BUZZ

Quest Enters Into EHR Distribution Pact With AT&T

Quest Diagnostics has entered into an agreement with AT&T to offer its electronic medical records suite through the telecommunications giant's cloud-based computing service.

The deal will make Quest's Care360 electronic health information record available via AT&T's Healthcare Community online, a cloud-based health information exchange.

The agreement includes not only Quest's electronic health records application, but also its laboratory ordering and e-prescription applications. AT&T will also sell Care360 as a standalone product.

"Our relationship with AT&T is an example of how Quest is increasingly collaborating with top companies to develop new solutions for serving the complex needs of health care providers," said Philip Present, general manager of Quest's health care information technology service line. "Quest will extend the availability of its Care360 Solution to a far larger number of large physician practices, hospitals, and integrated delivery networks, including accountable care organizations."

Offering Care360 through AT&T's cloud computing application is seen as a relatively low-cost solution for health care providers to obtain an electronic health records system without having to expend large amounts of money for extensive hardware and software applications.

"This partnership will likely provide a more secure access to health data and promote care coordination with cost efficiencies," said a recent report by Zacks Investment Research.

Quest spokesperson Wendy Bost said the deal with AT&T was nonexclusive, suggesting it may announce other partnerships in the near future. Bost declined to provide any financial information connected to the deal. She did note that it affords Quest "opportunities to extend our reach in key market segments."

Zacks said the deal was part of Quest's plan to expand its health care technology product line—a multipronged reorganization the New Jersey-based Quest announced late last year to streamline management and boost its sales.

However, the company remained unimpressed with Quest's strategy to date. "The ongoing economic challenges in the economy as well as in the company are concerns," Zacks said. It continued to rate Quest's stock as a hold, noting that the company has continued to struggle with flat revenue and earnings.

References

Aetna
800-872-3862

Ambry Genetics
949-900-5500

AdvaMed
202-783-8700

Gene by Gene
832-381-5410

Hunter Laboratories
408-341-8609

Myriad Genetics
801-584-3600

Quest Diagnostics
800-222-0446

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512-519-0400

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