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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Judge Denies ACLA's Request For Speedy Scheduling As PAMA Lawsuit Drags On

Judge Jackson

U.S. District Judge Amy Berman Jackson has denied ACLA's motion to schedule oral arguments without prejudice in its lawsuit challenging how CMS calculated market-based rates for the new Clinical Laboratory Fee Schedule. "The Court is well aware of the parties' interest in expedition and will set a hearing if and when it deems it necessary to do so," wrote Judge Jackson without further explanation in her May 30 response to the request. ACLA filed the lawsuit in mid-December and there had initially been hope that it could be resolved by the end of May. However, it now looks like a decision won't come until at least late summer, notes *Laboratory Economics*. *Continued on page 3.*

Quest Back In-Network With UnitedHealthcare; LabCorp Back In-Network With Aetna

Quest Diagnostics will become an in-network national provider with all UnitedHealthcare plans (except those with existing lab capitation agreements) effective January 1, 2019. Quest will join LabCorp and more than 1,000 other labs that have contracts with United. Terms of the contract were not disclosed, but *Laboratory Economics* believes Quest's new contract with United has base pricing that's less than 50% of the current Medicare Clinical Laboratory Fee Schedule with a contract length of approximately five years.

Quest anticipates that the increased volume it will obtain as an in-network provider will more than offset the lower rates it will receive. In addition, Quest says that it has the opportunity to earn additional revenue, if it can help United save money by driving volume away from higher priced out-of-network labs and hospital outreach labs.

Meanwhile, LabCorp says that it has extended its contract with United, which was due to expire at the end of this year. In addition, LabCorp has announced that it will join Quest as a national in-network lab provider for all Aetna plans starting in 2019. *Continued on page 2.*

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Quest Back In-Network With United (*cont'd from page 1*)
Quest had lost its contract with United back in 2007 after the company's former CEO Surya Mohapatra, PhD, had taken a hard stand against lowball pricing. But after a crushing response from investors, Mohapatra quickly switched gears and secured a low-priced exclusive contract with Aetna that shut LabCorp out of network.

Fast forward 12 years later and both national labs are back where they started, sharing national lab provider status with all five major insurers (Aetna, Anthem, Cigna, Humana and United) at rates that *Laboratory Economics* estimates are below 50% of Medicare.

Both LabCorp and Quest noted that their new United contracts include features designed to help drive patients toward the low-cost national labs.

United covers approximately 43 million members in the United States, representing an estimated $4 billion in annual lab spending. The drivers of its lab spending have included leakage to out-of-network toxicology and molecular/genetic testing labs.

In addition, on a May 24 conference call, Quest CEO Steve Rusckowski noted that hospital lab outreach pricing typically ranges from 2x to 5x more than Quest's rates. "There are certain providers that provide better value than others in the marketplace. This is a partnership that will not just be all on our shoulders. United will be shining a light to make sure that people are clear on some of those points of differentiation in value for laboratory services," explained Rusckowski.

In announcing their agreements with United, both Quest and LabCorp said they will collaborate with United to develop new benefit designs focused on incentivizing individuals to use lower-cost in-network labs. United is expected to begin introducing these new benefit designs to self-funded employer groups this fall with an effective date in 2019.

Will Reference Pricing Be Used To Drive Patients To Low-Cost Labs?

Historically, health insurers have always had difficulty steering physicians and patients toward the low-cost national labs. United has not specifically stated how it will change its health plan benefit design to encourage the use of low-cost labs. However, the language being used by Quest and LabCorp suggests a strong influence from the "reference pricing model."

The reference pricing model focuses on price transparency that gives patients specific data on lab test prices at all labs in a region. Patients selecting a lab that charges more than a predefined "reference price" for a certain test are required to pay the full difference themselves. As a result, patients have strong incentives to choose low-cost providers, but are not restricted from receiving care from other providers if they are willing to pay the difference.

The reference pricing model gained attention when the national grocery store chain Safeway reduced its average price paid per lab test by 33% over a three-year period (2010-2013) by instituting this strategy for its self-insured PPO plan. Safeway helped steer its employees by providing them with a smartphone app to compare lab prices.

Safeway's experiment with reference pricing was summarized in a study published in *JAMA Internal Medicine* in 2016 (see *LE*, August 2016). "When combined with access to price information, reference pricing was associated with patient choice of lower-cost labs and reductions in prices and payments by both employer and employees," according to lead author James C. Robinson, PhD, of the University of California, Berkeley.

Judge Denies ACLA's Request For Speedy Scheduling (*cont'd from page 1*)

Meanwhile, a new report from the National Independent Laboratory Association (St. Louis, MO) shows that the PAMA cuts will have broader implications beyond the Medicare CLFS, reaching into Medicaid and private-payer insurance contracts. In-depth telephone surveys conducted by NILA with 11 independent lab companies showed that the Medicare CLFS rate cuts will affect between 60% and 100% of their revenue, with an unweighted average of more than 80% of their business impacted.

The NILA survey found that rate cuts to the CLFS this year have resulted in:

- ❑ **Reduced or limited service offerings.** The majority of surveyed labs said they have already reduced their lab testing services in some manner. For example, by eliminating house calls to homebound patients, discontinuing 24-hour emergency STAT testing, and cutting back phlebotomy services to skilled nursing facilities.
- ❑ **Reductions in workforce.** Four labs said that they have had to reduce their workforce in order to adapt to this year's CLFS cuts.
- ❑ **Long-term viability in doubt.** Only one laboratory indicated confidence in their ability to survive past the initial three years of cuts to the CLFS. While none of the laboratories are making immediate plans to close operations, one indicated that it would reevaluate after the third quarter of 2018, while others said it would not make sense to stay in business past the second year of PAMA rate cuts in 2019.

NILA warned that as the PAMA cuts continue beyond 2018, the independent lab market will be weakened and potentially become nonexistent for some Medicare and Medicaid populations.

The NILA survey report is available at:
https://www.nila-usa.org/images/nila/PAMA%20Key%20Informant%20Summary_FINAL.pdf

Separately, *Laboratory Economics* notes that the next PAMA private-payer data reporting period will cover January 1 to June 30, 2019, which coincides with the start of new in-network contracts that Quest Diagnostics signed with UnitedHealthcare and LabCorp with Aetna. The shift from out-of-network rates to lower-priced in-network rates will put pressure on the next CLFS calculations. In addition, recent acquisitions by Quest (e.g., PeaceHealth Labs and Shiel Medical Lab) and LabCorp (e.g., PAML and Mount Sinai outreach lab) mean that pricing information from the biggest national labs will play an even larger role in the calculations.

Anthem Sues Small Hospital For Alleged Toxicology Lab Fraud Scheme

Anthem Inc. and its affiliated BCBS plans from nine states have filed a lawsuit against Sonoma West Medical Center (Sebastopol, CA), accusing the 37-bed hospital of engaging in a fraudulent "pass-through" billing scheme for toxicology testing.

Sonoma West was losing about $700,000 a month in February, March, April and May of last year and was on the verge of closing before the hospital signed a management services agreement with a personal injury lawyer from Florida named Aaron Durall.

Durall's shell company, Durall Capital Holdings, LLC, loaned the hospital $2.1 million to shore up its finances and buy new toxicology lab equipment.

According to the lawsuit, Durall then began aggressively acquiring urine specimens from a network of marketers, physicians, and rehab clinics in the Los Angeles area. These specimens were

shipped 2,300 miles to a Florida toxicology lab owned by Durall named Reliance Laboratory Testing (Sunrise, FL). Reliance would split the specimens and have one portion sent back to Sonoma West's lab in northern California for screening tests, while Reliance would perform all confirmatory testing.

A Long Trip for Toxicology Specimens in Alleged Pass-Through Billing Scheme

Source: *Laboratory Economics* and Anthem lawsuit (Case 2:18-cv-04912-AS)

All billing for both screening and confirmation tests was submitted to Anthem using the hospital's license. As a result, it appeared to Anthem that an out-of-network hospital was providing the test services, for the hospital's patients, and Anthem paid Sonoma West at a percentage of its billed charges. Furthermore, the lawsuit states that Sonoma West made no effort to hold patients accountable for their cost-sharing obligations.

In the 18 months prior to the Durall agreement, Sonoma West had submitted a total of just 50 claims for urine toxicology testing to Anthem at an average of approximately $118 per claim. But in the first nine months of the alleged scheme, June 2017-March 2018, that number ballooned to more than 15,000 claims at charges averaging $3,500 per claim.

During the course of the alleged scheme, Anthem and its BCBS plans paid more than $16 million to Sonoma West. The hospital retained approximately one-third of these payments, while the remaining two-thirds was distributed to Durall Capital, Reliance Laboratory and Medivance Billing Service.

Among other things, Anthem is seeking restitution in an amount to be determined at a jury trial, including all amounts that Sonoma West, Durall Capital, Reliance Laboratory and Medivance Billing Service received from Anthem because of their alleged pass-through billing scheme.

Anthem's BCBS of Georgia filed a similar lawsuit against the 49-bed Chestatee Regional Hospital (Dahlonega, GA) last year. Chestatee was purchased by Durall Capital in August 2016, then allegedly began a pass-through billing scheme for toxicology tests to take advantage of favorable hospital reimbursement rates. The lawsuit states that in the year following the implementation of the alleged scheme, Chestatee submitted, on average, approximately $13 million per month in fraudulent toxicology claims to BCBS Georgia.

Toxicology Labs Average $383 Per Medicare Patient

The top 50 independent toxicology lab companies received an average of $383 of revenue per Medicare patient they served in 2016, according to data analyzed by *Laboratory Economics* from the Medicare Part B program. This represents a decrease of approximately 50% from the average of $765 per Medicare patient that toxicology labs received in 2014 (see *LE*, June 2016).

The large decrease was the result of the switch by Medicare to a new coding system (effective January 1, 2016) for drug tests designed to eliminate unnecessary services and reduce costs.

Despite the new coding system, two toxicology labs still managed to get paid average revenue per Medicare patient in excess of $1,000 in 2016.

At the top end was an independent lab named Quality Sleep Specialists (Edmond, OK), which received $3.3 million of Medicare payments for 136,903 tests provided to 1,997 patients in 2016 for an average of $1,665 per patient. Quality Sleep Specialists billed an average of 68.5 CPT codes per Medicare beneficiary it served. Its three highest volume codes in 2016 were CPT 80299 (quantitation of therapeutic drug), CPT 84600 (volatile chemical measurement) and CPT 83992 (PCP drug level).

Genesis Molecular Diagnostics (Torrance, CA) had the second highest average with revenue of $1,308 per Medicare patient. The company billed an average of 14.2 CPT codes per Medicare beneficiary it served. Its three highest volume codes in 2016 were G0479 (drug tests, presumptive, any number of drug classes), CPT 87798 (detection test for organism) and CPT 87633 (detection test for multiple types of respiratory virus).

At the low range was Alere Toxicology Services (Austin, TX), which billed an average of 2.0 CPT codes per Medicare patient served in 2016 and had an average payment of $212 per patient.

Top 50 Toxicology Labs by Medicare Part B Payments, 2016

Company	Location	Number of Medicare Patients	Total Medicare Payment	Average Paid Per Patient
Millennium Health	San Diego, CA	139,021	$45,213,699	$325
Aegis Sciences Corp.	Nashville, TN	84,443	$28,177,054	$334
Ameritox	Greensboro, NC	80,841	$25,099,437	$310
Genesis Molecular Diagnostics	Torrance, CA	13,549	$17,717,715	$1,308
LabSource	Greenville, SC	14,684	$8,128,727	$554
Ethos Laboratories	Newport, KY	15,852	$7,254,568	$458
SMA Medical, Inc.	Feasterville, PA	18,629	$7,174,627	$385
Compass Laboratory Services	Memphis, TN	22,561	$7,107,448	$315
Dominion Diagnostics	North Kingston, RI	17,971	$6,543,868	$364
Acadian Diagnostic Laboratories	Baton Rouge, LA	10,134	$6,225,390	$614
B3 Diagnostic Laboratory	Troy, MI	12,052	$5,818,114	$483
MD Spine Solutions	Reno, NV	9,974	$5,506,986	$552
LifeBrite Laboratories	Brookhaven, GA	9,454	$5,496,821	$581

Company	Location	Number of Medicare Patients	Total Medicare Payment	Average Paid Per Patient
Alere Toxicology Services	Austin, TX	24,332	$5,169,680	$212
Logan Laboratories	Tampa, FL	12,293	$5,150,335	$419
American Institute of Toxicology	Denton, TX	23,100	$5,122,113	$222
Confirmatrix Laboratory	Lawrenceville, GA	12,627	$4,686,912	$371
Precision Toxicology	San Diego, CA	8,946	$4,669,837	$522
Castle Medical	Smyrna, GA	11,244	$4,492,571	$400
AvuTox, LLC	Rocky Mount, NC	12,473	$4,490,310	$360
MedComp Sciences	Zachary, LA	9,495	$4,214,428	$444
MedScan Laboratory	Williston, ND	9,846	$4,068,035	$413
DrugScan	Horsham, PA	14,616	$4,066,823	$278
Genotox Laboratories	Austin, TX	9,326	$3,789,377	$406
American Forensic Toxicology	Huntington, NY	13,593	$3,693,873	$272
Integrated Labs	Gresham, OR	5,730	$3,499,933	$611
Physicians Choice Lab Services	Rock Hill, SC	15,935	$3,469,330	$218
Infiniti Labs	Tampa, FL	8,777	$3,407,928	$388
Great Lakes Medical Laboratory	Farmington Hills, MI	6,837	$3,326,759	$487
Quality Sleep Specialists	Edmond, OK	1,997	$3,325,746	$1,665
Advanta Toxicology	Tyler, TX	7,125	$3,213,923	$451
Realtox Labs	Reisterstown, MD	4,765	$3,212,209	$674
Insource Diagnostics	Monrovia, CA	5,723	$3,150,065	$550
RAJ Enterprises of Central Florida	Ocala, FL	7,031	$2,975,959	$423
National Labs	Hayward, CA	4,346	$2,935,127	$675
Zenith Laboratory Services	Longview, TX	4,752	$2,862,191	$602
eLab Solutions Corp.	Sandy Springs, GA	7,358	$2,846,437	$387
Atlantic Diagnostic Laboratories	Bensalem, PA	8,043	$2,707,186	$337
Medicus Laboratories	Dallas, TX	11,790	$2,515,703	$213
LabCorp/Medtox Laboratories	Saint Paul, MN	7,530	$2,506,147	$333
Mako Medical Laboratories	Raleigh, NC	5,654	$2,351,228	$416
Regional Toxicology Services	Tacoma, WA	7,421	$2,222,251	$299
Synergy Laboratories	Theodore, AL	4,740	$2,175,762	$459
Helix Diagnostics (formerly ARK Lab)	Southfield, MI	3,891	$1,951,600	$502
Parkway Clinical Laboratories	Bensalem, PA	4,421	$1,938,696	$439
Genetic Technological Innovations	Irvine, CA	3,881	$1,873,954	$483
Choice Laboratory Services	Dallas, TX	6,999	$1,862,515	$266
Precision Diagnostics	Indianapolis, IN	6,342	$1,829,244	$288
Medical Tox Labs	Tampa, FL	2,426	$1,811,063	$747
Physicians Toxicology Laboratory	Tampa, FL	4,319	$1,799,430	$417
Totals & Averages		**768,889**	**$294,849,135**	**$383**

Source: *Laboratory Economics* from Medicare Part B Provider Utilization Data for 2016

Myriad Genetics To Buy Counsyl For $375 Million

Myriad Genetics (Salt Lake City, UT) has agreed to buy Counsyl Inc. (South San Francisco) for $375 million in cash, and shareholders can receive up to 25% of that consideration in Myriad common stock. The transaction, slated for completion by September 30, values Counsyl at 2.7 times its estimated revenue of $138 million for the 12 months ending June 30, 2018.

Counsyl at a Glance

Co-founder & CEO:	Ramji Srinivasan
Total employees:	~450
Sales reps:	80
Annual revenue:	$138 million
Annual requisition volume:	288,000
Avg. revenue per req:	$480

Source: Counsyl and Myriad Genetics

Counsyl operates a CLIA-certified laboratory in South San Francisco that performs two core testing services. Its "Foresight Carrier Screen" allows would-be parents to discover if they're a carrier for certain genetic diseases. And its "Prelude Prenatal Screen" tests pregnant women to determine if their baby will be born with a chromosomal disorder such as Down syndrome.

Counsyl has approximately 450 employees, including 80 sales reps that call on Ob/Gyns and reproductive endocrinologists.

The company was formed in 2007 by its CEO Ramji Srinivasan and its Chief Science Officer Eric Evans, PhD. Before Counsyl, Srinivasan was a financial associate at Morgan Stanley. Evans is a Clinical Genetic Molecular Biologist Scientist with a PhD from Stanford University.

Counsyl has raised more than $200 million in funding from firms like Founders Fund, Perceptive Advisors, Rosemont Seneca Technology Partners and Goldman Sachs Asset Management.

The acquisition of Counsyl comes as Myriad's flagship hereditary breast cancer testing business continues to struggle in the face of competition from labs like BioReference's GeneDx, Ambry Genetics, LabCorp and Quest Diagnostics. Myriad Genetics reported that its revenue from hereditary breast cancer testing declined by 11% to $377 million in the nine months ended March 31, 2019.

In addition, Myriad is under investigation by the Department of Health and Human Services, Office of Inspector General (OIG), in connection with the company's billing of Medicare and Medicaid for hereditary cancer testing from January 2014 through February 2018. *Laboratory Economics* believes that the OIG may be investigating whether or not Myriad improperly stacked CPT codes when billing for hereditary breast cancer testing (see *LE*, March 2018).

CellMax Launches U.S. Clinical Study For Colorectal Cancer Blood Test

CellMax Life (Sunnyvale, CA) has initiated a clinical study for its colorectal cancer blood test at Stanford Medicine and the U.S. Department of Veterans Affairs Palo Alto Health Care System, Johns Hopkins and University of Southern California. In this study, patients coming in

for routine colorectal cancer screening via colonoscopy or stool tests will be offered CellMax's circulating tumor cell (CTC) blood test. The trial is expected to last about two years and involve between 5,000 and 10,000 patients, according to Atul Sharan, Chief Executive of CellMax.

Sharan says that CellMax will pursue reimbursement for the test by submitting it through the Parallel Review Program for approval from the FDA and coverage determination by CMS. CellMax plans to offer a laboratory-developed-test version by year's end at a list price of between $150 and $200.

The U.S. trial comes on the heels of an Asian trial with 620 patients that demonstrated that the test can detect colorectal cancer with accuracy ranging from 84% to 88%. Sensitivity for detecting precancerous lesions was 77% (see *LE*, May 2018).

Shai Friedland, MD, Chief of Gastroenterology & Hepatology at VA Palo Alto Health Care System, as well as lead principal investigator for the new trial, says that ultimately he expects physicians will adopt the CellMax test as a first-line screening option for all patients, with colonoscopy as the confirmatory test.

Clinical Genomics Raises $26 Million for Liquid Biopsy Colorectal Cancer Test

Clinical Genomics Technologies (Bridgewater, NJ) has raised $26 million from a group of investors that includes Quest Diagnostics, Moelis Australia Asset Management, Regal Funds Management and OneVentures. The company said it will use the proceeds to commercialize Colvera, its liquid biopsy test for detection of recurrent colorectal cancer, and to further develop Colvera for use in CRC screening.

Colvera has been sold as a laboratory-developed test performed at the company's CLIA-certified lab in northern New Jersey since 2016.

Clinical Genomics recently received licensure from California authorities to offer Colvera to residents of the state. Colvera is now available in all U.S. states except New York, and the company is actively pursuing New York licensure.

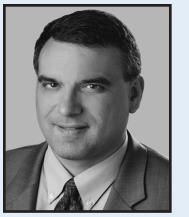
BestCare Lab Ordered To Pay $30.5 Million For Overcharging Mileage

A federal judge in South Texas has ruled that BestCare Laboratory Services (Webster, TX) must pay the United States $30.5 million for allegedly overcharging Medicare for mileage to transport patient specimens collected from nursing homes in San Antonio, Dallas, Austin, Waco and El Paso to its main laboratory near Houston.

The Medicare program compensates labs that serve nursing home patients approximately a dollar per mile for technician travel. The court found that BestCare billed Medicare for $10.1 million in claims for miles which no lab tech traveled. The False Claims Act mandates trebling of the damages, resulting in the judgment of $30.5 million.

The lawsuit was originally filed by a competing lab owner, Richard Drummond, MD, in 2008 after he hired a former BestCare employee and learned of their billing practices. For example, Drummond's lawsuit alleged that in one case BestCare had billed Medicare for $1,500 in travel expenses for a $43 blood test. The U.S. Attorney's office intervened in the lawsuit in 2011. As whistleblower, Drummond is entitled to receive 15% to 25% of any recovery.

Spotlight Interview with Chestatee Pathology Associates' John Cochran, MD



John Cochran, MD

Chestatee Pathology Associates, PC (Lawrenceville, GA) services 26 labs throughout metro-Atlanta, including two medium-sized hospitals. The practice has 17 employees, 11 of whom are pathologists, and processes 116,000 specimens annually. *Laboratory Economics* recently spoke with Dr. Cochran, the CEO and Medical Director.

Who are your clients?
We cover 26 labs, but only one is practice-owned. We operate in a number of different settings, from physician office labs (POLs) to hospital labs, to pharmaceutical, biotechnology and contract research organization (CRO) labs. We provide professional component (PC) services, but some of our contractual arrangements are for lab directorships only. The practice is not associated with a Georgia hospital of the same name.

Are you growing?
We've grown annually at a 5% to 7% rate since 2013, largely due to development of POLs and the volume that comes with that. We've also expanded into ambulatory surgery centers. We service 11 POL toxicology labs (directorships only) and eight POLs that do AP only, evenly split between GI and GU pathology.

Does your practice have a specific area of expertise?
We are one of the few predominantly outpatient pathology practices with a neuropathology subspecialty. GI cases account for about one-half to two-thirds of our clinical volume; neuropathology accounts for about 10 to 15%. The rest is general surgical pathology, ENT, GU, podiatry and dermatology.

Have you seen a decrease in your Medicare revenues in recent years?
In 2013, we suffered from cuts to technical component services in our practice-owned lab, but volume continued to grow despite the cut in revenue. We realized that we would not be as profitable as we once were on the technical component, but our professional component reimbursement has actually increased. For the "bread and butter" 88305 biopsy code, Medicare reimburses about $30 for the TC and about $40 for the PC in our geographic district. Since 2013, our revenues have increased quite a bit due to acquisition of new clients.

The Atlanta area has had an enormous growth in population in the past 20 years, from a little over 3.5 million in 1998 to the current 6.5 million. At the same time, the footprints of the major health systems in the area have remained relatively the same, although the existing systems have consolidated through buyouts and closures. The remaining hospital players are split among four different entities that compete against each other. This left the ambulatory surgical center market and the physician office markets underserved. That's where we have been able to grow our client base.

Do you still have an in-office pathology lab with Village Podiatry Group?
Yes, that was our first POL back in 2007. It's a large practice, with about 40 to 50 doctors. At the time we started with them, they had about 25 doctors. Our volume from them has grown in tandem with the growth of their practice.

You talked about pharma and biotech. What are you doing in that arena?
The pre-clinical and clinical trial markets have been underserved by private pathology practices. Many of them outsourced all of their pathology services to large reference labs. The amount of money being poured into immunotherapy for lung cancer, breast cancer, etc., is astounding. I realized about five years ago that this was an area of potential growth for the practice with high volumes, high margins, little malpractice liability risk, and relatively low stress daily work for our pathologists. We have expanded that business significantly. About 30% of our volume is related to pre-clinical and clinical trial research. There is a barrier to entry, however. If a practice wants to do clinical trial work, a lot of assay-specific training is involved, including testing of individual pathologists.

We work with a total of 12 companies in the biotech, pharma and CRO industries. We're involved in doing the research that helps bring medical devices and targeted drugs to market that improve patient well-being and increase cancer survival. It's been encouraging for us to watch some of our research give rise to FDA approval that, in turn, has led to these new therapies.

Another advantage is that there are no patient bills. We are paid directly for the work that we perform by these companies under our contracts.

What do you see as your biggest challenge?
On the clinical diagnostic side, I would say further consolidation. It is entirely possible that we could lose some of our POLs to private equity or hospital buy-outs– that's always a risk. In the contract research arena, there is not as much risk even though that arena has seen consolidation as well. The surviving companies still need pathology services.

What is your biggest opportunity?
The FDA approval about a year ago of digital pathology for primary diagnosis presents a unique opportunity for our specialty. We're about 10 to 20 years behind radiology. Large radiology groups formed as a result of the development of teleradiology. In pathology, approval for primary diagnosis is limited to just one platform – the Phillips IntelliSite– but we expect more platforms to be approved which will expand the interest among all pathology groups, whatever their practice setting. This could lead to the formation of pathology mega-groups just as has happened in radiology. Our group is not currently using it for primary diagnosis—only Quality Assurance reviews—but we do see it as an opportunity for expansion in the next five years.

Former HDL, Singulex Employees Fined $114 Million in False Claims Case

In ongoing fallout from the fraud scandal that led to the downfall of Health Diagnostic Laboratories (HDL- Richmond), a district court has entered judgment of more than $114 million against three former employees, including the former HDL CEO.

The U.S. District Court in the District of South Carolina on May 23 entered judgment of more than $111 million against defendants LaTonya Mallory, Floyd Calhoun Dent III, and Robert

Bradford Johnson, and for an additional $3 million against Johnson and Dent. Mallory was the former CEO of HDL. Johnson and Dent were co-owners of HDL's former contract sales company, BlueWave Healthcare Consultants.

The judgment follows the Jan. 31, 2018, jury verdict finding the three individuals liable for violating the False Claims Act (FCA) by paying remuneration to physicians in exchange for patient referrals and causing two laboratories to bill federal health care programs for medically unnecessary testing. During a two-week jury trial held in Charleston, SC, the government introduced evidence that the defendants paid physicians remuneration disguised as processing and handling fees of between $10 and $17 for each patient they referred to HDL and to another laboratory, Singulex Inc. (Alameda, CA). The government also introduced evidence that the kickback scheme resulted in physicians referring patients to HDL and Singulex for medically unnecessary tests, which were then billed to federal health care programs.

The jury found Mallory, Johnson and Dent liable for causing the submission of 35,074 false claims worth $16,601,591 submitted to Medicare and TRICARE by HDL. The jury also found Dent and Johnson liable for an additional 3,813 false claims worth $467,935 submitted by Singulex. As provided by the FCA, the court trebled those damage amounts, offset settlement payments received from HDL and Singulex for the same claims and awarded $63.8 million in penalties, for a total judgment of $114,148,661.86.

The verdicts against the three individuals follows a 2015 $48.5 million settlement involving HDL and Singulex. HDL paid $47 million, and Singulex paid $1.5 million to resolve FCA charges. HDL subsequently filed for bankruptcy and was purchased by True Health Diagnostics (Dallas). Singulex moved its clinical laboratory services to Round Rock, CA, and renamed the business Veridia Diagnostics.

Hope Foster, an attorney with Mintz Levin (Washington, D.C.) tells *Laboratory Economics* that this case demonstrates the government's commitment to pursuing kickback cases against individuals, as well as entities, and to taking those cases to trial. It also shows how the False Claims Act damages and penalties work when defendants lose an FCA trial.

"In this case, the jury identified the number of claims they determined were false and the amount of federal government reimbursement that stemmed from those claims ($17 million)," says Foster. "The judge then trebled that amount ($51 million) as the law dictates and later, after being briefed by the parties, applied the lowest applicable penalty ($5,500) to that trebled amount to each of these claims. Thus, the single damages of about $17 million led to a verdict of $114 million, showing the power of the False Claims Act and graphically illustrating why so many defendants settle before trial."

Top Advanced Lipid Testing Companies by Medicare Part B Revenue for 2016

Company	Location	# Medicare Beneficiaries	Total Medicare Payment, 2016	Avg. Payment Per Beneficiary
True Health Diagnostics	Frisco, TX	66,890	$41,224,413	$616
Boston Heart Diagnostics	Framingham, MA	56,246	$25,924,326	$461
Singulex Inc.	Alameda	27,611	$10,013,041	$363
Cleveland HeartLab	Cleveland, OH	47,255	$9,725,438	$206
Spectracell Laboratories	Houston, TX	11,894	$4,016,997	$338
Atherotech	Birmingham, AL	19,216	$3,176,747	$165

Source: *Laboratory Economics* from Medicare Provider Utilization File for 2016

Lab Stocks Up 21% Year To Date

Prices for 17 publicly-traded lab stocks are up 21% on an unweighted average basis through June 15. In comparison, the S&P 500 Index is up 2% year to date. The top-performing lab stocks so far this year are CareDx, up 115%, and Genomic Health, up 69%. At the two largest public labs, LabCorp is up 19% and Quest Diagnostics is up 13%.

Company (ticker)	Stock Price 5/15/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.07	$1.85	-42%	$30	NA	1.0	0.8
CareDx (CDNA)	15.79	7.34	115%	557	NA	11.0	NA
Enzo Biochem (ENZ)	5.55	8.15	-32%	261	NA	2.4	3.0
Exact Sciences (EXAS)	68.53	52.54	30%	8,354	NA	31.4	15.9
Foundation Medicine (FMI)	101.95	68.20	49%	3,780	NA	24.7	117.6
Genomic Health (GHDX)	49.59	29.39	69%	1,750	NA	5.0	9.2
Interpace Diagnostics (IDXG)	0.88	1.02	-14%	24	NA	1.5	0.6
Invitae (NVTA)	8.12	9.08	-11%	546	NA	8.0	3.6
LabCorp (LH)	189.41	159.51	19%	19,377	15.7	1.8	2.8
Myriad Genetics (MYGN)	39.42	34.35	15%	2,756	20.2	3.5	2.9
Natera (NTRA)	14.25	8.99	59%	777	NA	3.7	NA
NeoGenomics (NEO)	13.08	8.57	53%	1,054	NA	4.0	6.1
Opko Health (OPK)	4.40	4.90	-10%	2,460	NA	2.3	1.3
Psychemedics (PMD)	19.60	20.56	-5%	108	17.8	2.7	5.8
Quest Diagnostics (DGX)	111.31	98.49	13%	15,117	19.8	1.9	3.0
Sonic Healthcare (SHL.AX)	24.33	21.40	14%	10,330	22.3	1.9	2.6
Veracyte (VCYT)	8.86	6.53	36%	304	NA	4.2	8.1
Unweighted Averages			21%	$67,585	19.2	6.5	12.2

Source: Capital IQ

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