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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UNITED/LABCORP/BeaconLBS WON THE WAR IN FLORIDA; WILL THEY WIN IN TEXAS?

UnitedHealthcare (UHC) has delayed the claims rejection component of the Beacon Laboratory Benefits Solutions (BeaconLBS) program in Texas. This critical aspect, which had been scheduled to take effect on March 1, would have denied payment to labs when physicians failed to use the BeaconLBS system when ordering some 80 high-cost lab tests and pathology services for UHC's fully-insured members in Texas. UHC says it will provide 90 days notice prior to any future implementation.

"We're pleased with the delay, but that doesn't mean the threat has gone away," says Kevin Homer, MD, immediate past President of the Texas Society of Pathologists (TSP).

Meanwhile, it looks like UHC has weathered the initial firestorm of complaints it received when it first announced plans to pilot BeaconLBS in Florida. UHC has been using the full BeaconLBS program (with claims denials) in Florida since April 2015. And UHC says the program has improved quality and lowered costs. *Continued on page 3.*

SONIC FORMS LAB JOINT VENTURE IN CONNECTICUT

Sonic Healthcare USA (Austin, TX) and Western Connecticut Health Network (WCHN—Danbury, CT) have agreed to form a laboratory joint venture named Constitution Diagnostics Network. Sonic will own 51% of the joint venture which will focus on lowering inpatient lab test costs at WCHN's three community-based hospitals (Danbury Hospital, Norwalk Hospital and New Milford Hospital) and expanding lab outreach testing, according to Noel Maring, Vice President of Hospital Affiliations at Sonic. *Full details on page 6.*

QUEST SIGNS DEAL WITH MONTEFIORE HOSPITAL SYSTEM

Quest Diagnostics has agreed to manage routine testing services for Montefiore Hospital System (New York City). Quest will perform a portion of low-complexity (routine) inpatient and outpatient testing at its Teterboro, New Jersey lab, while the remainder of testing will continue to be performed at Montefiore hospitals under the direction of the Montefiore and Einstein Department of Pathology. Quest already provides some reference testing services to Montefiore. Montefiore is comprised of 10 hospitals and close to 200 outpatient sites in the New York City area. *Continued on page 2.*

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QUEST SIGNS DEAL WITH MONTEFIORE (*cont'd from page 1*)

On a January 26 conference call, Quest CEO Steve Rusckowski noted that Quest signed similar agreements with Barnabas Health (New Jersey) and HCA's HealthONE (Denver) last year. He said that these agreements are not negotiated at the lab director level, but more typically with the CEO and CFO of a health system. "This is strategic. And so many of these conversions are at the most senior level. It has been a big part of our strategy for a long time. We're gathering momentum and we have a strong pipeline."

Quest Reports Full-Year 2016 Financial Results

Meanwhile, Quest reported net income of $645 million for full-year 2016 versus $709 million in 2015. Quest's overall revenue increased by 0.3% to $7.5 billion.

The company's fastest growing sector was gene-based and esoteric testing which grew by 3.5% to $2.3 billion driven by noninvasive prenatal testing, hepatitis C, prescription-drug monitoring, and SureSwab (a women's health panel for sexually-transmitted infections).

Quest's anatomic pathology business declined by 1.1% to $624 million in 2016—tissue-based testing was up slightly and Pap testing was down slightly.

Drug Store Partnerships Expanding

On the January 26 conference call, Rusckowski said Quest had already opened patient service centers in 56 Safeway, Tom Thumb, Randalls and Vonns stores in California, Colorado, Delaware, Maryland, Montana, Oregon, Texas, Virginia and Washington. He said Quest was on track to open a total of 200 PSCs within supermarket pharmacies by the end of 2017. These PSCs serve patients with doctor-ordered lab tests and are aimed at increasing access and convenience. Rusckowski said the in-store PSCs are replacing stand-alone PSCs and helping Quest lower its real estate costs. "We're basically paying the same phlebotomist just to do those draws in a different location. Most of the volume that's being done in the Safeway stores was done previously in a [stand-alone] patient service center."

Quest Diagnostics Financial Summary ($ millions)

Revenue by product	*2016*	*2015*	*% Chg*
Gene-based and esoteric	$2,335	$2,256	3.5%
Anatomic pathology	624	631	-1.1%
Routine	4,179	4,078	2.5%
Other*	377	528	-28.6%
Total revenue	7,515	7,493	0.3%
Operating cash flow	1,069	821	30.2%
Capital expenditures	293	263	11.4%
Free cash flow	776	558	39.1%
Net income	645	709	-9.0%
Diluted EPS	$4.51	$4.87	-7.4%
Bad debt %	4.1%	4.0%	2.5%
Days sales outstanding	47	47	0.0%
Employees	43,000	44,000	-2.3%
Est'd number of requisitions	160.3M	157M	2.1%
Est'd revenue per requisition	$44.53	$44.36	0.4%

*Other revenue includes clinical trials testing, info tech services and testing for life insurance companies
Source: Quest Diagnostics and *Laboratory Economics'* estimates for number of reqs and average revenue per req

AncestryDNA Deal
Rusckowski said that Quest would soon begin performing genotyping test services for AncestryDNA at Quest's Marlborough Massachusetts lab. AncestryDNA (Salt Lake City, UT) markets a service that identifies and quantifies an individual's ethnic origins based on DNA testing. AncestryDNA sold 1.4 million DNA tests to consumers in the fourth quarter of 2016.

Potential to Regain UnitedHealthCare Contract?
LabCorp's long-term national contract with UnitedHealthcare is due to expire at the end of 2018, and Quest is jockeying to regain access. In September 2016, Quest entered into a ten-year agreement to outsource its billing and collection function to UnitedHealth Group subsidiary Optum. Quest's 2,400 revenue-cycle employees have been hired by Optum, which began managing Quest's billing operations in November. "I was asked the question when we did this [outsourcing to Optum] in the fall, does this help you with United? And my answer is, it doesn't hurt since it's very visible and we are clearly a strategic partner of UnitedHealth Group."

UNITED/LABCORP/BeaconLBS WON THE WAR IN FLORIDA (*cont'd from p. 1*)
Homer says that TSP has held several conference calls with representatives from UHC, BeaconLBS and LabCorp over the past few months. On a recent conference call, Homer says he was surprised to learn that claims for "Decision Support Tests" submitted by "Labs of Choice" will be paid by BeaconLBS from capitated funds the program receives from UHC. As a result, he says that BeaconLBS, a wholly owned subsidiary of LabCorp, will have access to claims data from Labs of Choice in Texas, including information about fees, clients, volumes and ordering patterns.


Kevin Homer, MD

"UHC claims there is a firewall preventing data flow from BeaconLBS to its parent company and asks Texas pathologists to trust that LabCorp will not receive or use this information. Obviously, this situation is unacceptable to the TSP," according to Homer.

Labs of Choice are a small network of lab and pathology groups managed by BeaconLBS. LabCorp recorded more than $50 million of revenue from claims processed through its Labs of Choice network in Florida last year.

Homer says another concern is reports from labs and pathologists in Florida who say they are not getting paid by UHC when ordering physicians do not properly use the BeaconLBS system. "UHC says it has lowered costs in Florida, but all it's really done is shift costs," contends Homer.

Homer says that the TSP is one of the strongest state pathologist associations in the nation. "If we can't stop or change BeaconLBS in Texas, there'll be nothing standing in the way for UHC to expand to other states expand to other states." TSP is currently working with CAP and the Texas Medical Association toward a potential legislative solution.

From UHC's perspective, BeaconLBS represents its first concerted effort to reign in lab costs, which it says have grown by an average of more than 10% annually for the past few years.

Meanwhile, LabCorp has invested millions in BeaconLBS since founding the company in 2010. "Implementation of innovative solutions, such as BeaconLBS, is complex and involves many stakeholders. We experienced similar delays in Florida and view the implementation delay in Texas as part of the 'normal course' of changing the way care is provided. We are pleased with the progress of the LBM program in Florida, and UnitedHealthcare and BeaconLBS continue to enhance the LBM platform by incorporating valuable feedback from the physician community," according to a statement from LabCorp.

Update on BeaconLBS in Florida

The Florida Society of Pathologists (FSP), representing 350 pathologists, was a vocal critic when UHC first announced in late 2014 that BeaconLBS would be piloted in Florida. But it looks like UHC is committed to BeaconLBS in Florida and FSP has been quiet on the controversial program lately. *Laboratory Economics* made several attempts by phone and email to FSP seeking comment and an update on their views on BeaconLBS, but got no response. FSP's current President Margaret Neal, MD, recently retired from practicing pathology at KWB Pathology Associates, which happens to be a BeaconLBS Lab of Choice.

The Florida Medical Association (FMA) had also been critical of BeaconLBS, saying that it represented an administrative burden and intrusion on clinical decision-making for ordering doctors. FMA's general counsel, Jeff Scott, authored legislation aimed at prohibiting an HMO from requiring that a health care provider use a clinical decision support system or a laboratory benefits management program in certain circumstances. This legislation (Right Medicine Right Time Act: SB 1084) was introduced to the Florida Senate by former Senator Don Gaetz (R) in late 2015. However, the bill was projected to increase medical costs and premiums for state-contracted HMOs, and died in appropriations in early 2016.

Jeff Scott, FMA General Counsel

Scott tells *Laboratory Economics* that FMA still views laboratory benefit management programs as an improper intrusion into the practice of medicine. He says the FMA might reintroduce the legislation this year.

But *Laboratory Economics* notes that the legislation, if passed into law as written, might not have very much effect on BeaconLBS anyway. That's because Florida Senate Bill 1084 is aimed at prohibiting an HMO from requiring a physician to use a clinical decision support system when ordering lab tests. But the bill has a loophole that states "this provision does not prohibit prior authorization requirements that the HMO has regarding the provision of clinical laboratory services."

Emily Volk, MD

Emily Volk, MD, Vice Chair of the CAP Council on Government and Professional Affairs and a practicing pathologist in Texas, says that while other insurance companies have implemented lab benefit management programs, the BeaconLBS program is unprecedented in terms of its attempt to interfere with physician decision making for routine lab tests and pathology services. "We want to keep the dialogue going. We're hoping to do more than just nip around the edges in terms of modifications to BeaconLBS."

In regard to BeaconLBS in Florida, a UHC spokesperson says, "We've been closely monitoring progress of the Florida pilot and are evaluating additional refinements based on data, experience and feedback from care providers, including concerns associated with the advanced notification process."

UNITEDHEALTHCARE CHARGES DALLAS LAB WITH $100M FRAUD

UnitedHealthcare (UHC) has sued Next Health LLC (Dallas, TX) and its subsidiary labs, alleging that they paid bribes to patients and kickbacks to doctors causing UHC to pay $100 million for overpriced and unnecessary drug tests. The lawsuit (case #3:17-cv-00243) was filed on January 27 in federal court in Dallas.

According to the lawsuit, the alleged fraud occurred between 2011 and mid-2016. UHC learned of the alleged fraud following a CBS News investigative report in June 2016 that prompted UHC to conduct a claims review. The claims review identified suspicious testing activity at Next Health and its four CLIA-certified lab subsidiaries: United Toxicology LLC, Medicus Laboratories LLC, US Toxicology LLC and American Laboratories Group LC. UHC alleges that Next Health and its subsidiary labs submitted more than 136,000 claims, charging more than $400 million for out-of-network drug and pharmaco-genetic tests, for which UHC paid more than $100 million.

Specifically, UHC alleges that Next Health and its subsidiary labs:

1. Paid 20% of the revenue collected from testing on each specimen as a kickback to referral sources.
2. Inappropriately utilized standing test protocols regardless of patients' medical histories or needs.
3. Performed and billed for testing services that were not ordered by physicians.
4. Improperly billed for services that they did not perform.
5. Charged several multiples of what other labs charged for the same tests (see table).
6. Routinely waived patients' payment responsibilities to avoid drawing attention to the scheme.

For example, UHC says that Next Health charged an average of $1,512 for a routine drug screen (G0431) versus an average of $202 for in-network labs and $890 for out-of-network labs. UHC says that patients never would have consented to this testing if they had been billed for coinsurance by Next Health.

Comparison of Charges for Drug Tests and Pharmaco-Genetic Tests

Procedure Code	Procedure Description	Avg. Network Lab Charge	Avg. OON Lab Charge	Next Health Lab Charge
G0431	Drug Screen Qualitative; Single Class Meth EA	$202	$890	$1,512
G0480	Drug Test Definitive DR ID Meth Per Day 1-7 Drugs	$244	$1,104	$2,398
G0483	Drug Test Definitive DR ID Meth Per Day 22/More Drugs	$801	$3,796	$6,457
G6058	Drug Confirmation Each Procedure	$144	$687	$1,623
81225	CYP2C19 Gene Analysis	$441	$684	$1,457
81226	CYP2D6 Gene Analysis	$793	$1,098	$2,255
81479	Unlisted Molecular Path Procedure	$2,289	$1,574	$5,223

Source: UnitedHealthcare lawsuit (case #3:17-cv-00243)

Two contracted sales consultants, Erik Bugen and Kirk Zajac, are also named in the lawsuit. UHC says that the pair set up a company (The ADAR Group) that posted advertisements online to give $50 gift cards to patients with private insurance who provided urine or saliva as part of a "wellness study." Sham PSCs were set up to collect specimens at locations in Austin, Killeen and San Antonio. One of them, in Austin, did not have a restroom, so patients were told to use one at a nearby Whataburger, according to UHC. Specimens were sent to Next Health with forged doctor orders for expensive and unnecessary testing. This one kickback scheme resulted in UHC paying Next Health more than $11 million in less than one year, and Next Health paid kickbacks equal to 20% of collections to Bugen and Zajac, according to the lawsuit.

With its lawsuit, UHC seeks to put a stop to the alleged illegal operations, be free from paying any more claims from Next Health, and recover payments for fraudulent claims.

Similar UHC Lawsuit in Florida

Last year, UnitedHealthcare filed a similar lawsuit in Florida federal court against five toxicology lab companies (Sky Toxicology, Frontier Toxicology, Hill Country Toxicology, Eclipse Toxicology and Axis Diagnostics). This lawsuit alleges that the five toxicology labs defrauded UHC and its members out of more than $50 million through a kickback scheme for drug tests (see *LE*, June 2016, p. 1).

The Link to UHC's Lab Benefit Management Pilots

It's no wonder that UHC chose to launch laboratory benefit management programs in Florida and Texas, notes *Laboratory Economics*. These are two states where a handful of unscrupulous toxicology labs have bilked UHC and self-funded employers out of an alleged $150 million. Unfortunately, the overwhelming majority of trustworthy labs and pathologists in Florida and Texas are now paying the price for the actions of a few crooked labs.

SONIC FORMS LAB JOINT VENTURE IN CONNECTICUT (*cont'd from p. 1*)

The joint venture agreement becomes effective in April. WCHN currently performs approximately 3.5 million lab tests per year, including about 25% from outreach. Maring says that approximately 80% of testing will remain at the three hospitals, with Danbury Hospital serving as the core laboratory. Non-time-sensitive clinical lab tests will be sent to Sonic's Sunrise Medical Labs division in Long Island, New York (about 2.5 hours' drive away) and esoteric tests will go to Sonic Reference Laboratory in Austin, Texas. Anatomic pathology technical services will remain at the hospital labs and local pathologists will continue to provide professional services.

Maring says Sonic's Sunrise Medical Labs is in the process of hiring a general manager for the joint venture.

"Clearly there's a growing trend for hospitals to evaluate their labs from a strategic perspective," notes Maring. He anticipates that Sonic will reach similar agreements with other hospitals later this year.

"Generally I can tell you we typically see a 12% to 22% cost reduction opportunity in these types of partnerships," according to Maring. He says projected reductions are based on:

1. Leveraging Sonic's lower cost structure for supplies, equipment and reagents.
2. Generating economies of scale by increasing outreach testing volumes, resulting in an overall reduction in unit costs per test.
3. Improving billing and collections for outreach testing.
4. Bringing information technology expertise for connecting to physician-client EMRs.

The agreement with WCHN follows Sonic's new partnership with Baptist Memorial Health Care (Memphis, TN) struck late last year. The partnership, known as BMHSI/AEL Microbiology Laboratory GP, is building a microbiology lab at Sonic's American Esoteric Laboratories (AEL) subsidiary in Memphis. AEL will manage the new lab which will serve Baptist's 17 hospitals in Tennessee, Mississippi and Arkansas, as well as Sonic's existing referrers in the mid-south region. AEL will continue to also serve as the principal reference lab for Baptist.

SPOTLIGHT INTERVIEW WITH MIRACA LIFE SCIENCES' TOM ZAVES

Miraca Life Sciences (Irving, Texas) is one of the largest independent anatomic pathology companies, with 1,100 employees including more than 80 fellowship-trained subspecialist pathologists. The company operates four main labs across the country (Irving, Phoenix; Union, NJ; and Newton, MA). In fiscal year 2016 (ending March 31, 2017), Miraca Life Sciences expects to serve more than 1.3 million patients. *Laboratory Economics* recently spoke with Tom Zaves, Senior Vice President, Strategic Operations, about the company's focus and growth.

Tom Zaves

Miraca's subspecialties include dermatology, gastroenterology, hematology, urology and breast pathology. How do you divide the different subspecialties?
To provide comprehensive expertise in each of its sub-specialties, Miraca has systematically assigned specific diseases within their subspecialty to each pathologist—in this way, each can monitor medical literature, vet the latest classifications, and educate their colleagues—elevating the performance of the entire team. In fact, one measure of that performance is the review of our diagnoses by outside academic institutions, and our concordance rate is consistently over 99.5%.

Apart from diagnostic services, Miraca has a separate business line through which it helps physician practices stay independent by offering fee-based consulting services. We also utilize our laboratories and our staff to offer research and development services, such as clinical trials, assay development, and even study design.

How many tests does Miraca offer?
Our business is predominantly anatomic pathology, and we offer 125 IHC stains, ISH, and other testing panels. Our hematopathology practice also provides flow cytometry, FISH, cytogenetics, and molecular tests.

What were Miraca's revenues in 2015 and 2016?
Since 2012, Miraca Life Sciences has had a 12% CAGR increase in patient volume. Revenue was $257.7 million for fiscal year 2014 (ending March 31, 2015) and $261.3 million for fiscal 2015 (ending March 31, 2016).

What kind of growth do you project going forward?
We expect to have approximately 8% CAGR through 2020. Our greatest growth will be in dermatopathology, hematopathology and therapeutic drug monitoring.

Please describe the venture you have with Baylor – is it a 50-50 joint venture?
The venture is structured with 60% ownership by Miraca Holdings Inc. and 40% by Baylor College of Medicine. As Baylor Genetics' sister company, we have a wider array of tests to offer our clients and their patients.

Last year Miraca expanded into clinical lab testing with the launch of InformTx therapeutic drug monitoring for patients with inflammatory bowel disease. Tell us more.
We are very excited about this new capability as there is a great demand in the market for patients and clinicians who struggle with administering and dosing biologics that treat these diseases. We focused the InformTx service on easy-to-interpret and timely results that provide the anti-drug and antibody levels, as well as guidance based on the current medical literature. We expect to see significant growth in this area going forward.

Miraca has also developed technology solutions for physician practices to assist them with efficiency and EHR integration. How successful has this been?
For over 10 years, Miraca has focused on integrating the pathology process with our clients and their EMRs through use of an interface. Integrating data into both our processes and our clients' practices is critical to better diagnoses and treating patients. Additionally, several years ago, we added fee-based consulting services to help physician practices better utilize their EMR systems and participate in programs such as meaningful use and now MIPS [Merit-Based Incentive Payment System].

Do you anticipate the new system for reimbursing clinical laboratory testing under Medicare (scheduled to go into effect Jan. 1, 2018) to have a material impact on your business?
This new system should not have a material impact on Miraca Life Sciences as very little of our business is reimbursed under the Clinical Laboratory Fee Schedule.

What are the greatest challenges facing the clinical and anatomic pathology testing industries?
Price compression by payors is always a great challenge in our industry. Another challenge we face is the shrinking of our addressable market due to hospital acquisition of clinical practices and pathology insourcing by practices.

Where do see the greatest opportunities for lab testing?
Companion diagnostics and precision/personalized diagnostics are two big areas of opportunity. Miraca is excited by the trend toward quality-based reimbursement. We believe that quality diagnostics will improve patient outcomes and reduce overall costs, which underscores our market position as a leader in high-quality diagnostics.

LAB GROUPS SCORE WIN ON BLOCKING APRNS FROM PERFORMING TESTING

Clinical laboratory groups are applauding a decision by the Department of Veterans Affairs (VA) not to allow advance practice registered nurses (APRNs) to perform and supervise laboratory testing.

In a rule released in May 2016, the VA had proposed expanding the scope of practice of APRNs to include "ordering, performing, supervising and interpreting laboratory studies." The American Society of Clinical Pathologists, the American Association for Clinical Chemistry and other lab groups objected to the proposed rule, arguing that APRNs lack the clinical training necessary to perform and supervise lab testing.

In comments submitted to the VA, the AACC argued that permitting APRNs "to serve in a supervisory capacity or as testing personnel, without first assuring they have the requisite experience, training and skills, could lead to unnecessary medical errors that may jeopardize patient care."

Concerns were also raised with the proposed rule's allowance that APRNs be allowed to interpret test results. In the final rule issued in December 2017, the VA said it is not its intent to have APRNs take over the role of laboratory specialists, noting that "these specialists perform a crucial role at VA medical facilities and are skillfully trained in performing the various testing techniques that allow health care professionals to properly treat a veteran's medical condition."

Instead, the VA is amending the rule so that an APRN may be granted full practice authority to "order laboratory and imaging studies and integrate the results into clinical decision making."

FDA DISCUSSION PAPER ON LDTS REFLECTS LIGHTER TOUCH

The discussion paper on lab-developed tests issued by the Food and Drug Administration on Jan. 13, 2017, describes a risk-based approach that differs significantly from the FDA's initial proposal put forth in 2014 and reflects a "lighter touch" for most LDTs, according to an attorney with the law firm of Sidley Austin LLP (Washington, D.C).

The LDT discussion paper is not enforceable and does not represent the formal position of the FDA, nor does it constitute a final version of the draft guidance, notes Nancy Stade, a partner with the firm. "Rather, issuing the paper allows FDA to publicize, gauge and build support for its proposals on a controversial topic while avoiding the requirement that FDA provide notice to Congress 60 days before issuing any final or draft guidance on LDTs," she says.

FDA's proposal for regulatory oversight for LDTs, which may be used to inform discussions about this issue on Capitol Hill, reflects a risk-based, phased-in approach but backs away from many provisions of the draft guidance. Notable differences from the proposal outlined in the 2014 draft guidance:

- Instead of being phased-in, currently marketed high- and moderate-risk LDTs would not be subject to premarket review unless necessary to protect public health.
- The phased-in review of new and significantly modified LDTs could be accomplished over a shorter period (four years rather than the nine years proposed in the draft guidance) because of the high number of grandfathered products and would begin with the tests that could pose the greatest risk to patients in the event of a false result.
- FDA would take measures to expedite the premarket review process by 1) collaborating with healthcare professionals, industry and other stakeholder groups to leverage accepted reference and review standards for analytical validity; 2) expanding its third-party premarket review program to include LDTs that are eligible under existing programs; and 3) permitting clinical validity to be established by sources, such as literature and "well-curated" databases, that meet the valid scientific evidence standard.
- The term "traditional LDTs" would be defined differently than it was in the 2014 draft guidance to mean "tests that use components that are legally marketed for clinical use and whose output is the result of manual interpretation by a qualified laboratory professional," which excludes tests that use automated instrumentation or software to interpret the results.

It remains unclear whether the Trump administration will support the FDA's efforts to regulate LDTs. Many in the industry have speculated that it will not, which means Congress might have the final say.

FLORIDA DERMATOLOGIST TO PAY $18M MEDICARE FRAUD SETTLEMENT

Palm Beach, Florida dermatologist Gary Marder, DO, has agreed to pay the government $18 million to settle a qui tam lawsuit (No. 1:13-cv-24503-KMM) alleging that he pocketed tens of millions of dollars from Medicare by ordering medically unnecessary biopsies, falsely diagnosing patients with cancer and performing unnecessary radiation treatments on patients.

The allegations were first made in a whistleblower lawsuit filed by Theodore Schiff, MD, in December 2013. Dr. Schiff is the medical director and managing partner of Water's Edge Dermatology, LLC (Palm Beach Gardens, FL). He filed the suit after patients came to him seeking a second opinion after seeing Marder. Schiff discovered that people with conditions as benign as freckles

had been told by Marder that they had skin cancer, according to his lawsuit which was ultimately pursued by the U.S. Attorney's Office.

The government's investigation led to evidence that Marder appeared to be involved in a kickback arrangement with a pathologist, Robert Kendall, MD. Marder allegedly required his physician assistants to perform up to 50 biopsies each day, and he instructed them to perform biopsies on skin disorders for which biopsies were not appropriate, such as acne, dried skin, warts and freckles. From about January 2008 to May 2014, Marder sent 35,000 Medicare biopsy specimens to Kendall for testing. Instead of billing Medicare himself, Kendall sent the bills to Marder, who would give him a cut, according to the lawsuit. Kendall has agreed to pay $250,000 for his role in the scheme.

As part of a separate agreement with the government, Marder can pay $5.2 million before February 24 to satisfy the $18 million settlement. The $5.2 million is the amount the government thinks Marder has the ability to pay. If Marder pays the $5.2 million, Schiff will get 22%, or about $1.1 million, for his role as whistleblower.

Despite the settlement, Marder and Kendall each continue to be licensed to practice medicine, according to records from the Florida Department of Health.

NEW SAFE HARBOR ALLOWS LABS TO PROVIDE PATIENT TRANSPORT

A new anti-kickback safe harbor allows health care providers, including clinical laboratories, to provide free or discounted local transportation to their patients without triggering potential exposure under the federal anti-kickback statute.

The safe harbor, which went into effect Jan. 6, 2017, was included in a final rule issued by the Department of Health and Human Services on Dec. 7, 2016. That rule established safe harbors for free or discounted local transportation, along with several other safe harbors. The final rule also revises the existing definition of "remuneration" under civil monetary policy (CMP) regulations and makes a technical correction to the safe harbor for referral services.

While patient transportation may not be a concern for larger labs that have multiple patient service centers or that can send a phlebotomist to patients for blood draws, small labs potentially could benefit from this safe harbor.

"A laboratory that does not have its own patient service centers may find that the new safe harbor for transportation services is useful," says Karen Lovitch, an attorney with Mintz Levin (Washington, D.C.), who notes that there are many requirements that must be met for a laboratory to use the safe harbor.

"Most importantly, the laboratory cannot base the availability [of transportation assistance] on volume or value of federal program business or shift the cost to the federal health care programs, other payors, or individuals," she tells *Laboratory Economics*. "In other words, the laboratory cannot raise its prices to cover the cost of the transportation or charge any fee to the patient or the physician (or anyone else)."

Further, the laboratory cannot advertise the availability of the transportation or otherwise use it as a marketing tool, adds Lovitch. The service can only be made available to an "established patient," and the patient must have selected and initiated contact with the laboratory before the transportation can be offered.

QUEST MAY BE LIKELY BUYER OF PEACEHEALTH LABS

PeaceHealth Laboratories (Springfield, OR), owned by the PeaceHealth Health System, is reportedly up for sale and Quest Diagnostics is the buyer. Both PeaceHealth and Quest have refused to comment, but *The Lund Report*, an independent Web news site focused on healthcare news in Oregon, says a formal announcement is imminent.

With only about 10 PSCs in the Portland area, Quest currently has a limited presence in Oregon.

PeaceHealth Labs has a total of 800 employees at 10 labs and 27 PSCs in Oregon, Washington and Alaska. Total annual test volume exceeds six million tests per year. Its largest facility is a central lab in Springfield, Oregon, that has about 500 employees and performs more than 4.5 million tests per year.

PeaceHealth Labs also manages the inpatient labs at four PeaceHealth hospitals in Oregon, five hospitals in Washington and one in Alaska. And PeaceHealth Labs provides testing services to the PeaceHealth Medical Group which has about 700 employed physicians.

Top 20 Laboratories in Oregon by CLIA Test Volume

LABORATORY NAME	CITY	TYPE	ANNUAL VOLUME
AMERICAN RED CROSS NATIONAL TESTING LABORATORY	PORTLAND	BLOOD BANKS	5,400,000
PEACEHEALTH LABORATORIES CENTRAL LAB	SPRINGFIELD	INDEPENDENT	4,578,330
PROVIDENCE LABORATORY SERVICES	PORTLAND	HOSPITAL	4,376,074
SALEM HOSPITAL REGIONAL LABORATORY	SALEM	HOSPITAL	3,670,000
PROVIDENCE PORTLAND MEDICAL CENTER LABORATORY	PORTLAND	HOSPITAL	2,526,104
PROVIDENCE ST. VINCENT LABORATORY SERVICES	PORTLAND	HOSPITAL	2,334,682
OHSU LABORATORY SERVICES	PORTLAND	HOSPITAL	1,973,000
PEACEHEALTH LABS SACRED HEART RIVER BEND	SPRINGFIELD	HOSPITAL	1,563,000
PORTLAND VAMC	PORTLAND	HOSPITAL	1,520,999
ST. CHARLES BEND LABORATORY	BEND	HOSPITAL	1,473,000
LEGACY LABORATORY SERVICES EMANUEL	PORTLAND	HOSPITAL	1,423,409
PROVIDENCE MEDFORD MEDICAL CENTER LABORATORY	MEDFORD	HOSPITAL	1,292,392
LEGACY LABORATORY SERVICES CENTRAL LAB	PORTLAND	HOSPITAL	1,282,505
BEND MEMORIAL CLINIC LAB	BEND	PHYSICIAN OFFICE	1,140,710
KAISER PERMANENTE NW LABORATORIES	PORTLAND	HMO	1,043,022
ASANTE ROGUE REGIONAL MEDICAL CENTER LAB	MEDFORD	HOSPITAL	1,031,000
SALEM CLINIC MAIN LABORATORY	SALEM	INDEPENDENT	1,005,676
OREGON MEDICAL GROUP LABORATORY	EUGENE	PHYSICIAN OFFICE	943,954
NORTH BEND MEDICAL CENTER INC LAB	COOS BAY	PHYSICIAN OFFICE	902,509
PORTLAND CLINIC LABORATORY	PORTLAND	PHYSICIAN OFFICE	897,496

Source: *Laboratory Economics* from CMS CLIA Provider Files, 9/16/2016

LAB STOCKS UP 12% YEAR TO DATE

Sixteen lab stocks have risen by an unweighted average of 12% year to date through February 10. In comparison, the S&P 500 Index is up 1.9% so far this year. The top-performing lab stocks are Cancer Genetics, up 74%, CombiMatrix, up 47%, and Foundation Medicine, up 42%. At the two big commercial labs, Quest Diagnostics is up 2% and LabCorp is up 5%.

Company (ticker)	Stock Price 2/10/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	2.35	1.35	74%	44	NA	1.8	1.6
CombiMatrix (CBMX)	3.90	2.65	47%	10	NA	0.8	1.4
Enzo Biochem (ENZ)	6.55	6.94	-6%	329	6.8	2.9	3.4
Exact Sciences (EXAS)	18.55	13.36	39%	2,060	NA	25.6	5.6
Foundation Medicine (FMI)	25.15	17.70	42%	882	NA	7.7	4.5
Genomic Health (GHDX)	28.08	29.39	-4%	940	NA	2.9	6.5
Invitae (NVTA)	8.87	7.94	12%	365	NA	19.2	4.1
LabCorp (LH)	135.01	128.38	5%	13,910	21.4	1.5	2.5
Myriad Genetics (MYGN)	15.99	16.67	-4%	1,090	12.4	1.5	1.5
NeoGenomics (NEO)	8.14	8.57	-5%	639	NA	3.0	8.0
Opko Health (OPK)	8.22	9.30	-12%	4,580	49.8	3.8	2.2
Psychemedics (PMD)	22.04	24.99	-12%	120	46.2	3.1	10.1
Quest Diagnostics (DGX)	93.56	91.90	2%	12,970	19.9	1.7	2.8
Rosetta Genomics (ROSG)	0.50	0.42	19%	11	NA	1.0	0.8
Sonic Healthcare (SHL.AX)	21.84	21.40	2%	9,093	19.9	1.8	2.4
Veracyte (VCYT)	7.76	7.74	0%	255	NA	4.2	7.2
Unweighted Averages			12%		25.2	5.2	4.0

Source: Capital IQ

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