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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CALIFORNIA MEDI-CAL PREPARES FOR SECOND YEAR OF RATE ADJUSTMENTS

The California Department of Health Care Services (DHCS) is in the process of analyzing private-payer payment data collected from approximately 75 labs. The information will be used to adjust Medi-Cal rates for clinical lab and pathology services provided to approximately three million Medi-Cal recipients enrolled in fee-for-service plans effective July 1, 2016.

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BANKRUPT ATHEROTECH DESPERATELY SEEKING BUYER

Madison Capital Funding LLC, which is owed $25.8 million from Atherotech Inc. (Birmingham, AL), is searching for a buyer for the lab company, which abruptly ceased operations in late February, then filed for bankruptcy in early March (see *LE*, April 2016, pp. 1-4). If a buyer for the complete Atherotech business entity cannot be found soon, then the bankruptcy court will be forced to sell the company's assets piece-by-piece—most likely at fire-sale prices.

Meanwhile, Atherotech's financial statements filed with the U.S. Bankruptcy Court for the Northern District of Alabama detail the company's precipitous decline in 2015.

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RACE IS ON FOR LDT OVERSIGHT OUTCOME

Which will come first—final guidance from the Food and Drug Administration (FDA) on lab-developed tests (LDTs) or federal legislation directing the FDA to suspend efforts to finalize the LDT guidance? It's anyone's guess.

FDA officials have said repeatedly that they are finalizing the LDT guidance and expect it to be issued this year. But on April 19, the House Appropriations Committee reported out the agriculture-FDA appropriations bill that includes report language directing the FDA not to issue the final guidance but instead work with Congress to develop a new pathway to regulate LDTs. *Continued on page 2.*

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RACE IS ON FOR LDT OVERSIGHT OUTCOME (*cont'd from page 1*)

"The FDA's draft guidance issued on Oct. 3, 2014, titled 'Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs),' puts forth a proposed regulatory framework that is a significant shift in the way LDTs are regulated," says the report accompanying the spending bill. "Such a shift deserves input from the public, and Congress has been working with stakeholders, constituencies, and the FDA to find common ground on regulating LDTs."

"The FDA's guidance circumvents the normal rulemaking process and changes expectations for patients, doctors, and laboratories for the first time since the Clinical Laboratory Improvement Amendments Act was passed in 1988. The Committee directs the FDA to suspend further efforts to finalize the LDT guidance and continue working with Congress to pass legislation that addresses a new pathway for regulation of LDTs in a transparent manner."

While the appropriations bill must still be passed by the full House and reconciled with a Senate version of the bill before being finalized, Alan Mertz, president of the American Clinical Laboratory Association (ACLA), says the report language sends a strong message to the FDA that House appropriators want the agency to hold the guidance until the House Energy and Commerce Committee finishes working on draft legislation designed to address oversight of LDTs.

The Energy and Commerce Committee has been working with the FDA and a number of industry groups on an alternative framework based on a proposal by the Diagnostic Test Working Group, a coalition of IVD companies and laboratories. This draft legislation would create a new FDA center for in vitro clinical tests, which would regulate both LDTs and in vitro diagnostic tests. The FDA would handle premarket review of LDTs while the Centers for Medicare and Medicare Services would continue oversight of lab operations under CLIA.

"We believe that a legislative solution is needed," Mertz tells *Laboratory Economics*. "We can't fix this within the existing statute. The discussion draft is a good starting point."

Allyson Mullen

Allyson Mullen, an attorney with Hyman, Phelps & McNamara, P.C., and a contributor to the FDA Law Blog (www.FDAlawblog.net), believes that if a final guidance is issued, it will happen in the next few months prior to the November election.

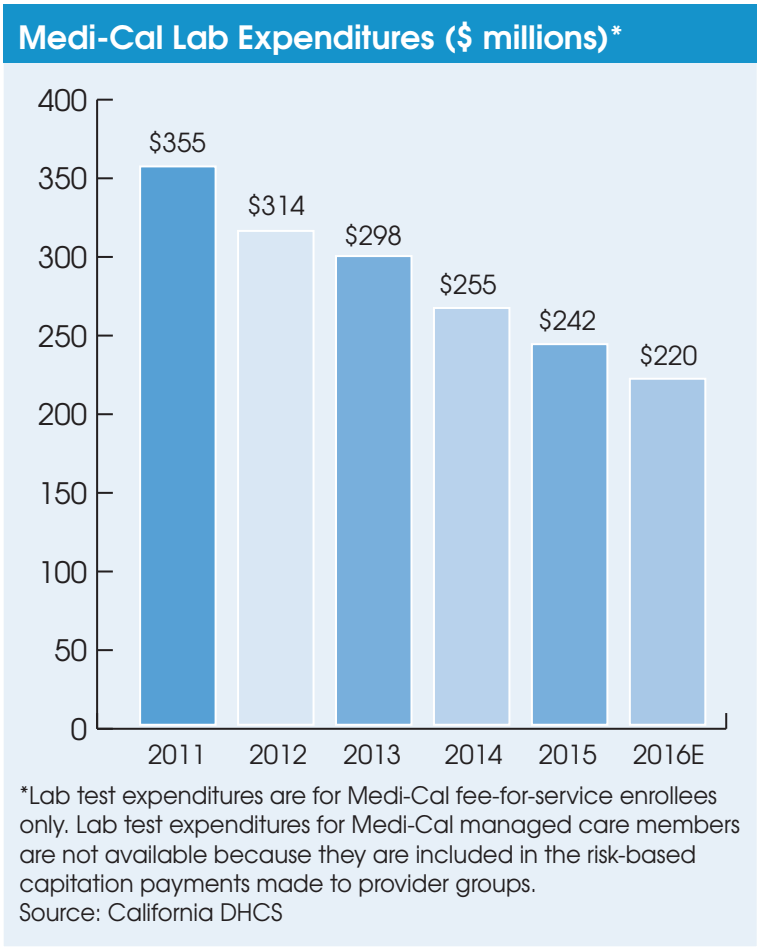
Why, then, is the FDA working with members of Energy and Commerce on the draft legislation? "FDA is covering all of its bases," says Mullen. "It appears FDA wants to be sure it has a say in whatever comes out."

The final guidance will likely go to the Office of Management and Budget for review, and the FDA is required to notify Congress 60 days before it issues the final guidance. In theory, this could give Congress time to stop the guidance through legislation, but Mullen is doubtful that will happen.

"Given that this is an election year, I am doubtful that it would stop the guidance," she says. "This is an area that FDA feels strongly it needs to regulate."

CALIFORNIA MEDI-CAL RATE ADJUSTMENTS (*cont'd from page 1*)

This will be the second year that the Medi-Cal program has used private-payer data to adjust its lab test reimbursement rates. Last year, the process resulted in cuts to 370 CPT codes, which helped the Medi-Cal program lower its lab test expenditures from $242 million in the fiscal year ended June 30, 2015, to an estimated $220 million for fiscal-year 2016. An analysis by *Laboratory Economics* showed that the average lab test is now being reimbursed by Medi-Cal at approximately 64% of national Medicare rates, including a global rate of only $46.34 for the key pathology code CPT 88305 (see *LE*, August 2015).



*Lab test expenditures are for Medi-Cal fee-for-service enrollees only. Lab test expenditures for Medi-Cal managed care members are not available because they are included in the risk-based capitation payments made to provider groups.
Source: California DHCS

The new rate-setting methodology being used by Medi-Cal has been criticized because it has been based on information supplied by a small number of labs. Under California law (AB 1494) any lab provider with annual Medi-Cal lab test claims totaling $100,000 or more, or claims volume of 5,000 or more, is required to submit its private-payer data to DHCS. However, out of a total of approximately 750 labs meeting one or both of these thresholds, only 9% actually reported their data last year, and only 10% reported this year.

Despite the low compliance rate, Anthony Cava, spokesman for DHCS, says the amount of data received has been sufficient to accurately calculate new Medi-Cal rates. "The labs that submitted the requested data represent the majority of the total fee-for-service (FFS) claims for these services," according to Cava. He says that DHCS is taking steps to increase the number of reporting labs, including direct communication with labs required to submit data and earlier notices for the upcoming 2016 data request. DHCS will be collecting data from labs and adjusting rates annually. Cava notes that the specific information provided by each lab is kept confidential and not shared with other organizations, including CMS and the Medicare program.

The move to reduce lab payments was inspired in part by the 2011 state settlements with Quest and LabCorp over charges that Medi-Cal overpaid for lab testing services.

Obviously, labs that serve a greater percentage of Medi-Cal FFS patients are being hit the hardest by the cuts. The largest Medi-Cal lab provider is Quest Diagnostics, which received $34.8 million of Medi-Cal FFS payments in 2014, according to the latest available data from DHCS. Califor-

nia's Planned Parenthood and prenatal screening programs are the next largest Medi-Cal lab payment recipients, followed by LabCorp ($11.8 million), Foundation Laboratory ($6.9 million) and BioData Medical Labs ($6.3 million).

In total, the top 10 lab organizations collected $127.2 million of Medi-Cal's lab test expenditures on FFS patients in 2014.

Top 10 Lab Companies Paid by Medi-Cal in 2014

Quest Diagnostics/Unilab Corp.	$34,863,770
Planned Parenthood	28,053,273
Genetic Disease Laboratory Branch (prenatal screening)	24,027,771
LabCorp	11,844,477
Latara Enterprise (dba Foundation Laboratory)	6,921,203
BioData Med Labs	6,306,005
American Clinical Reference	4,123,491
Alpha Clinical Lab Inc.	4,001,859
Whitefield Medical Lab	3,912,506
Physicians Immunodiagnostic Lab	3,102,833
Total top 10 labs	127,157,188
All other labs	137,351,898
Total Expenditures	$264,509,086

Source: California DHCS

BILLING TIPS FOR MOLECULAR DIAGNOSTICS

On May 5, *Laboratory Economics* hosted a teleconference featuring Rina Wolf, Vice President of Commercialization Strategies, Consulting & Industry Affairs for XIFIN Inc., and Gregory Root, ESQ., Chief Operating Officer and General Counsel of CodeMap LLC. The pair delved into a number of coding and billing issues for molecular diagnostic tests. Here are some highlights:

Pre-Pay Audits for Verifying Medical Necessity

Commercial payers are increasingly asking to review patient medical records, including progress notes, lab, pathology and radiology reports, prior to claims adjudication for molecular tests with miscellaneous codes. For example, Wolf noted that UHC is now seeking to review patient medical records prior to paying for CPT 81479 (unlisted molecular pathology procedure) and CPT 81599 (unlisted multianalyte with algorithmic analysis) and other payers are following.

Waiver of Payments

Approximately 40% of Americans under age 65 with private health insurance coverage are now enrolled in a high-deductible plan, defined as plans with deductibles of at least $1,250 for single coverage and $2,500 for family coverage, according to the National Center for Health Statistics. And this is leading to a lot of compliance issues regarding the waiver of patient payment responsibilities, noted Wolf.

"Payers are really tracking this and doing audits requiring labs to demonstrate that they actually did submit bills to patients for the amount indicated on the EOB and the only exception for any discounts or waivers must be made through a compliant financial-hardship assistance program for patients."

Some labs are still marketing their testing services by handing marketing sheets to physicians and office managers that encourage them to order their tests because patients will not be billed the full amount. "Just because you think you need to waive patient payment responsibilities for competitive reasons is not going to protect you," warned Wolf.


Rina Wolf

She noted that some commercial payers are requiring labs to submit proof, including cancelled checks and credit card receipts, that their members paid their co-pays, coinsurance and/or deductibles for claims.

Wolf highlighted a case where UHC saw a statement on a lab website that indicated that patients would only be held accountable for $100 for a $3,500 test. UHC then told the lab that it would only pay an out-of-network benefit of 60% of $100 for the test.

Direct Billing Patients

Any discount offered to self-paying patients should be justified by the savings obtained from avoiding the costs associated with submitting a similar claim to a third-party payer, according to Wolf. She said that historically, the upper limit for self-pay discounts has been 10% to 15% versus the fee schedule for third-party payers. "The greater the discount, the greater the risk you're going to expose your lab to," added Root.

Custom Panels

"If you're going to offer a customized panel make sure that your requisition is designed so that physicians have the opportunity to specifically opt in or opt out of panel components," advised Wolf.


Gregory Root

Root noted that custom drug test panels have been under the greatest scrutiny. "If your custom panels aren't specific to an individual patient's history, treatment and needs, then you've got a problem. So when everyone in the practice is ordering the same large custom panel for all patients, that spells trouble. And payer recoupment actions are usually asking for all of the reimbursement for all tests on a custom panel even if a patient really did need three or four tests on a 30-test panel."

Unbundling Panel Codes

Root noted that the new genomic sequence procedure panel Tier II codes for hereditary breast cancer and colon cancer disorders (CPT 81432, 81435, 81436, et al) are being poorly reimbursed by Medicare and private payers. So some labs are performing all the tests in these panels and submitting the individual Tier 1 test codes so they get paid better. This is a clear example of unbundling, according to Root.

In addition, Root noted that some labs are seeking to sidestep poorly reimbursed panel codes by cherry-picking a few individual tests from a panel and submitting codes for those tests individually. "I'd be very careful about doing that, both on the private side and Medicare; this could easily be identified as unbundling and you could face civil False Claims Act issues," warned Root.

MANAGEMENT SHAKEUP AT THERANOS

Theranos says that Sunny Balwani, age 50, the company's President and Chief Operating Officer, is stepping down and retiring. Balwani, who joined Theranos in 2009, also served on the company's board of directors. A replacement has not been announced. Balwani's resignation comes as the company struggles to correct 45 deficiencies found by CMS at its Newark, California laboratory during an on-site inspection last year (see *LE*, April 2016, pp. 6-7). In addition, Theranos founder and CEO Elizabeth Holmes is now under criminal investigation from the U.S. Attorney's Office, as well as an investigation from the Securities and Exchange Commission for possibly defrauding investors.

PUBLIC LAB CEOs PAID AVERAGE $4.3 MILLION IN 2015

The chief executives at 16 publicly-traded lab companies were paid an average of $4.3 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. Altogether, the 16 CEOs earned a total of $69.1 million, including $50.7 million from stock and option awards.

Myriad Genetics' Peter Meldrum, age 68, was the highest paid lab company CEO in 2015, according to an analysis of shareholder proxy statements by *Laboratory Economics*. Meldrum, who retired from Myriad effective June 30, 2015, earned total compensation of $23.4 million in his final year with the company. Meldrum received six different categories of compensation, including 1) salary of $1 million; 2) bonus of $762,814; 3) stock awards of $9.1 million; 4) stock options worth $11 million; 5) an incentive plan cash bonus of $97,953; and 6) "other" compensation totaling $1.3 million, which included a cash payment of $1,287,500 related to his resignation agreement. Finally, Meldrum accumulated 2.795 million shares of Myriad stock, valued at $95 million, during his 14-year tenure at the company.

LabCorp's David King, 59, was the second-highest paid lab CEO. He received five different categories of compensation last year that totaled $10.5 million. These included: 1) salary of $1 million; 2) stock awards of $7.9 million; 3) incentive plan cash bonus of $1.7 million; and 4) other compensation of $31,384, which included financial planning services, 401K matching contributions, long-term disability insurance and personal liability insurance.

Quest Diagnostics' Stephen Rusckowski, 58, received total compensation of $9.7 million last year, including a salary of $1.1 million, cash incentives of $1.3 million, and stock and option awards of $7 million. He also received $282,690 in perks, which included $67,186 for personal use of a company car and driver plus $83,773 for personal use of company aircraft.

Kevin Conroy, 50, Chairman and CEO at **Exact Sciences**, earned a total of $5.7 million, including salary of $575,000, bonus of $277,725, stock and options totaling $4.8 million and other compensation of $15,900. Exact Sciences recorded a net loss of $157.8 million in 2015 on revenue of $39.4 million.

At the low end, **Randall Scott, PhD**, 58, chairman and CEO at **Invitae Corp.**, earned a salary of $251,000 and nothing more. Invitae recorded a net loss of $89.8 million in 2015 on revenue of $8.4 million. The company raised net proceeds of $106 million from an IPO priced at $16 per share on February 12, 2015.

Separately, IRS Form 990s for 2014 reveal the total compensation for the top executives at the nation's laboratory and pathology trade organizations. **Charles Roussel**, chief executive at the **College of American Pathologists**, earned total compensation of $1.25 million in 2014; **Alan Mertz**, president of the **American Clinical Laboratory Association**, earned $993,891; **Blair Holladay, PhD**, chief executive at the **American Society for Clinical Pathology**, earned $562,536.

Birenbaum & Associates, the management company for the **American Association of Bioanalysts** (aka, National Independent Lab Association) received $686,114 in 2014. And the **Clinical Laboratory Management Assn. (CLMA)** paid $739,480 to **SmithBucklin Corp.** for management services.

Meanwhile, pathologists earn an average of $267,000 per year, while medical technologists make an average $64,265, according to the latest surveys by Medscape and Salary.com.

2015 Laboratory CEO Compensation

Company/Executive	Salary	Bonus and Incentives	Value of Stock and Option Awards	Other Comp*	2015 Total Comp	2015 Revenue Growth	2015 Stock Price Total Return
Aurora Diagnostics							
Daniel Crowley, 68, Chmn. & CEO	$1,250,000	$0	$0	$0	$1,250,000	9%	NA
Cancer Genetics Inc.							
Panna Sharma, 45, Pres. and CEO	473,037	50,000	0	5,788	528,825	77%	-51%
CombiMatrix							
Mark McDonough, 46, Pres. & CEO	342,577	25,000	263,925	0	631,502	25%	-43%
Enzo BioChem							
Elazar Rabbani, PhD, 72, Chmn. & CEO	555,478	375,000	57,703	187,871	1,176,052	2%	1%
Exact Sciences							
Kevin Conroy, 50, Chmn. & CEO	575,000	277,725	4,788,235	15,900	5,656,860	2093%	-66%
Foundation Medicine							
Michael Pellini, MD, 50, Pres. & CEO	479,714	166,737	3,445,764	43,582	4,135,797	53%	-5%
Genomic Health							
Kim Popovits, 58, Chmn. & CEO	686,400	297,900	0	0	984,300	4%	10%
Invitae							
Randal Scott, PhD, 58, Chmn. & CEO	251,000	0	0	0	251,000	422%	-49%
LabCorp							
David King, 59, Chmn. & CEO	1,044,481	1,672,371	7,878,178	31,384	10,626,414	42%	15%
Myriad Genetics							
Peter Meldrum, 68, Pres. & CEO	1,030,000	860,767	20,132,907	1,334,369	23,358,043	-7%	27%
NeoGenomics							
Douglas VanOort, 60, Chmn. & CEO	475,000	806,447	0	1,385	1,282,832	15%	89%
Opko Health Inc.							
Phillip Frost, MD, 79, Chmn. & CEO	525,000	200,000	3,100,000	10,600	3,835,600	440%	1%
Psychemedics							
Raymond Kubacki, Jr., 71, Chmn. & CEO	450,000	45,000	227,170	10,600	732,770	-8%	-33%
Quest Diagnostics							
Stephen Rusckowski, 58, Pres. & CEO	1,128,846	1,303,140	7,000,003	282,690	9,714,679	1%	6%
Sequenom Inc.							
Dirk van den Boom, 46, Pres. & CEO	494,231	150,000	2,589,690	825	3,234,746	-15%	-56%
Veracyte Inc.							
Bonnie Anderson, 57, Pres. & CEO	425,000	127,500	1,193,094	0	1,745,594	75%	-33%
Totals, 16 companies	10,185,764	6,357,587	50,676,669	1,924,994	69,145,014		
Averages, 16 companies	$636,610	$397,349	$3,167,292	$120,312	$4,321,563	202%	-12%

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks.

Source: *Laboratory Economics* from company proxy statements

FDA CLEARS BLOOD-BASED TEST FOR COLORECTAL CANCER

More than three years after submitting its original premarket application to the FDA, Epigenomics has finally received PMA approval for its Epi proColon blood-based colorectal cancer screening test, which detects tumor-specific DNA (aberrant methylation of Septin9) in blood. The test is intended for those patients age 50+ who are unwilling/unable to perform CRC screening using guideline methods such as colonoscopy and the traditional fecal occult blood test (FOBT).

Colorectal cancer (50,000 deaths per year) is the second most frequent cause of death from all cancer types in the United States, although it is highly treatable if detected early. There are about 23 million eligible Americans who have not been screened for CRC. The American Cancer Society has set a goal of raising the CRC screening rate from the current 65% of eligible Americans to 80% by 2018. The Epi proColon test is appealing because it requires no dietary restrictions and uses a regular veinous blood draw sample. Patients that test positive will be recommended to get a colonoscopy.

Epigenomics, which is based in Berlin and has offices in Seattle, WA, and Germantown, MD, has partnered with Polymedco Inc. (Cortlandt, NY) to distribute Epi proColon test kits in the U.S. Polymedco is a leader in traditional FOBTs—selling more than 10 million FOBTs per year to some 1,500 lab customers. Polymedco is expected to charge labs at roughly $75 - $90 per test. Testing will be performed by lab customers who are expected to charge payers approximately $140 per test, although the exact pricing will be set by each individual lab offering the test.

LabCorp has already agreed to market Epi proColon. Quest Diagnostics and ARUP Labs, both of whom have been marketing an LDT-version of Epi proColon, are expected to switch to the FDA-cleared test kit.

Nonetheless, steering doctors, patients and payers toward adoption of Epi proColon will be an expensive and long-term process, observes *Laboratory Economics*. Since being founded in 1998, Epigenomics has accumulated $56 million of losses, including a $10 million loss in 2015.

Its biggest competitor offering an alternative to traditional CRC screening methods is Exact Sciences Corp. (Madison, WI). Exact received FDA clearance for its ColoGuard stool-based DNA screening test in August 2014.

Exact operates its own laboratory and has a 260-person sales team, including approximately 210 reps directly in the field calling on physicians. The company is in the process of launching a nationwide television campaign to expand awareness of Cologuard, which has a list price of $599 to self-paying patients.

Exact anticipates completing more than 240,000 Cologuard tests during 2016, generating revenue of $90 million to $100 million. Since being founded in 1995, Exact has accumulated a total deficit of $626 million.

Options for Colorectal Cancer Screening

Test Name	*Developer*	*Sample*	*Regulatory Status*	*Price*
Epi ProColon	Epigenomics	Blood	FDA cleared 2016	~$140
ColoGuard	Exact Sciences	Stool	FDA cleared 2014	$599
ColonSentry	GeneNews Ltd.	Blood	LDT with NYS DoH approval	$795
ColoVantage	Clinical Genomics	Blood	LDT with NYS DoH approval	$355
Colonoscopy	NA	NA	FDA cleared	$1,000 - $3,000
Traditional FOBT	Beckman Coulter, Hemosure, PolyMedco, et al.	Stool	FDA cleared	$5 - $25

Source: *Laboratory Economics* and Lofton-Day, C., "Opportunities and limitations of blood-based CRC screening tests." Practical Gastroenterology 2012

ADVANCED DERMATOLOGY BUYS SKIN PATHOLOGY ASSOCIATES

Advanced Dermatology and Cosmetic Surgery (ADCS-Maitland, FL), the nation's largest dermatology practice, has acquired its first dermatopathology lab. In early May, ADCS announced it had completed the acquisition of Skin Pathology Associates Inc. (Birmingham, AL). Founded in 1995 by James Elder, MD, Skin Pathology is one of the largest independent dermatopathology labs in the nation, with 80 full-time employees, including six board-certified dermatopathologists. Skin Pathology processes more than 500 patient requisitions per day from 300 physician clients, primarily in the southeast.

The Skin Pathology lab is expected to remain in operation as part of ADCS. In addition, ADCS operates its own pathology lab in Delray Beach, Florida, that is headed by dermatopathologist Steven Glanz, MD.

ADCS was founded by dermatologist Matt Leavitt, MD, in 1989. The private investment firm Audax Group (Boston, MA) purchased a majority stake in ADCS in early 2012.

Since the investment by Audax, ADCS has acquired 31 dermatology groups in multiple states, including most recently Dermatology of Northern Colorado. ADCS currently manages a total of about 150 dermatologists at 145 office locations in 12 states with its greatest presence in Florida. In addition to its owned practices, ADCS provides billing, collections, and coding management services for about 90 independent dermatology practices across the country under the Ameriderm trade name.

PODIATRY GROUP DESCRIBES NEW IN-OFFICE PATHOLOGY LAB

Foot and Ankle Specialists of the Mid-Atlantic (FASMA) opened an in-office pathology lab at its headquarters in Rockville, MD, in late 2015. The lab was recently featured in the January/February 2016 edition of the American Podiatric Medical Association (APMA) publication *APMA News* in an article titled, "Is a Pathology Lab Right for Your Practice?" The article uses the FASMA lab as a case study to describe the details of creating an on-site pathology lab at a podiatry practice.

FASMA has 37 doctors practicing at 24 office locations in DC, Maryland, Pennsylvania, and Virginia. FASMA spent about $225,000 on equipment and infrastructure for its in-office pathology lab, which employs one full-time pathologist (Joon Yim, MD), one histotech and one lab assistant, according to the *APMA News* article.

In addition to the financial benefits, FASMA noted that it now receives pathology reports back in three days instead of seven to 14 days from an outside lab. The biggest obstacle has been getting contracts with payers. "Typically, DPMs aren't involved in the world of pathology, so that has been a roadblock. We've had trouble being paid by Cigna, for example. The learning curve has been figuring out from whom and where we can get our specimens covered," according to David Freedman, DPM, of FASMA.

PERKINELMER SELLS PRENATAL TESTING LAB TO EUROFINS SCIENTIFIC

PerkinElmer (Waltham, MA) has sold its U.S. prenatal screening laboratory PerkinElmer Labs/NTD (NTD Labs) to Eurofins Scientific (Luxembourg). NTD Labs generated approximately $20 million in revenue in 2015 and employs approximately 80 staff at its laboratory in Melville,

NY. The selling price was not disclosed. PerkinElmer had originally acquired NTD Labs in 2006 when it had annual revenue of $15 million.

Over the past two years, Eurofins has purchased several U.S. lab companies, including ViraCor-IBT Laboratories (Lee's Summit, MO) for $255 million in July 2014, Boston Heart Diagnostics (Framingham, MA) for $140 million in December 2014, and a 75% stake in Emory Genetics Labs from Emory University's School of Medicine for approximately $40 million in June 2015.

LAWMAKERS AGAIN TRY TO CLOSE STARK LOOPHOLE

Federal lawmakers are trying once again to put an end to what many see as abuses of the in-office ancillary services (IOAS) exception to the Stark Law. For the third time in as many years, Rep. Jackie Speier (D-CA) has introduced legislation to prevent physicians in certain specialties—including anatomic pathology—from referring patients to ancillary medical services in which they have an ownership interest.

The Promoting Integrity in Medicare Act (PIMA) would remove certain complex services from the IOAS exception—specifically, anatomic pathology, advanced imaging, radiation therapy and physical therapy. In terms of AP, the measure would exclude the technical or professional component of surgical pathology, cytopathology, hematology, blood banking, and pathology consultation and clinical laboratory interpretation services.

The legislation would save Medicare an estimated $3.3 billion over 10 years, according to the Congressional Budget Office (CBO). A number of reports from federal and private groups have found that the IOAS exception costs Medicare millions of dollars each year. For example, a 2014 report by the Government Accountability Office (GAO) concluded that in 2010 self-referring providers likely referred nearly one million more unnecessary AP services than non-referring providers, costing Medicare approximately $69 million.

PIMA (H.R. 5088) references a number of these reports, including a *Laboratory Economics* analysis (*LE*, October 2011, p. 10) that found there was an increase in the volume of pathology codes billed to the Medicare Part B program from 2006 through 2010, specifically for CPT code 88305, and the rate of increase billed by physician offices for this service is accelerating at a far greater pace than the rest of the provider segments.

The Obama Administration also has repeatedly recommended closing the loophole as part of its annual budget submitted to Congress.

PIMA is supported by the Alliance for Integrity in Medicare, the College of American Pathologists, the American Clinical Laboratory Association, the American Society for Clinical Pathology and a number of other industry groups.

A spokesperson for Rep. Speier tells *Laboratory Economics* that the changes to H.R. 5088 are primarily technical updates for the 114th Congress, including updates to the findings section. Additionally, the congresswoman added a few clarifying sections, such as adding language to clarify that closing the self-referral loophole will not limit access to care in rural areas.

"She also made sure to give the Secretary of Health and Human Services the authority to implement statutorily-authorized changes to health care delivery and payment systems (i.e. changes consistent with the Medicare and CHIP Reauthorization Act of 2015) to make sure that her bill wouldn't interfere with the implementation of this new law," said the spokesperson.

Asked about the chances that this bill will pass this year, the spokesperson noted that "all legislation, especially health care legislation, is difficult to pass in an election year. However, the congresswoman wanted to reintroduce this piece of legislation to keep the focus and momentum on this most important issue."

BANKRUPT ATHEROTECH DESPERATELY SEEKING BUYER (*cont'd from p. 1*)
Atherotech brought in new management in January 2015 that had promised to "increase operational efficiency" and "accelerate growth," according to a press release from the company. Among the changes made was a major increase in the amount the company billed out-of-network (OON) patients. This resulted in OON patients often being billed hundreds of dollars versus Atherotech's previous policy of capping direct bills to patients at $39 to $89 per requisition. The new policy resulted in loss of market share when doctors switched to other labs that charged patients less for advanced lipid tests or reverted back to the traditional lipid panel. At the same time, Atherotech continued an aggressive and expensive expansion into new sales territories with in-office phlebotomy deployment.

At the start of 2015, Atherotech had budgeted for a net profit of $2.5 million on revenue of $133 million. The company had anticipated processing a total of 10.3 million tests at an average collected price of $108.26 per patient requisition, according to its bankruptcy filings.

However, management's budget proved to be wildly optimistic versus Atherotech's actual results. The company wound up recording a net loss of $10.5 million on revenue of $84.1 million in 2015. Atherotech's actual revenue for 2015 was $49 million below budget and represented a 25% decline from $112.8 million recorded in 2014.

Actual total test volume for Atherotech was 6.9 million in 2015, which was more than 3.3 million tests below budget and 16% lower than the 8.2 million tests processed in 2014. Average collected price per requisition was $87.71—nearly $20 below budget and down 10% from an average $97.65 collected per req. in 2014.

Atherotech Inc. Condensed Income Statement for 2015 vs. 2014 ($000)

	2015	2014	% Chg
Revenue (before bad-debt expense)	$84,096	$112,778	-25.4%
Bad-debt expense	7,607	7,275	4.6%
Net Revenue	76,489	105,503	-27.5%
Net Loss	-10,466	-351	NA
Total Test Volume	6,947	8,247	-15.8%
Average Tests/Requisition	7.97	7.63	4.5%
Revenue per Requisition (net of bad debt)	$87.71	$97.65	-10.2%

Source: U.S. Bankruptcy Court for the Northern District of Alabama (case #16-00909-TOM)

By early 2016, the company's annualized revenue had fallen to an estimated $65 million. With unresolved government investigations into Atherotech's business practices, having missed budget so badly in 2015, and a continued decline in early 2016, it's no wonder that one of the company's key lenders, Regions Bank (owed $17.4 million in secured loans) lost faith in the company and its management and refused a deal to restructure Atherotech's loans.

Atherotech's biggest tangible assets include an accounts receivable balance of approximately $9 million. Its biggest receivable balances are with Medicare, United Healthcare, Humana and BCBS of Alabama. The company also has $10 million worth of office equipment and instruments and deferred tax loss writeoffs valued at $8.7 million.

"The Atherotech failure cannot be attributed to any one factor, individual or organization. At the end of the day, without a healthy balance sheet, continuing an aggressive growth strategy in the face of market headwinds was a risky proposition," a former Atherotech executive told *Laboratory Economics*.

LAB STOCKS DOWN 9% YTD

Sixteen lab stocks have declined by an unweighted average of 9% year to date through May 17. In comparison, the S&P 500 Index is up 1.7%. The top-performing lab stocks so far this year are Enzo Biochem, up 38%, Psychemedics, up 24%, and Sonic Healthcare, up 20%. For the two biggest lab companies: LabCorp is up 2% and Quest Diagnostics is up 7%.

Company (ticker)	Stock Price 5/18/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.19	$3.30	-34%	$30	NA	1.7	0.9
CombiMatrix (CBMX)	3.19	10.95	-71%	4	NA	0.3	0.5
Enzo Biochem (ENZ)	6.20	4.50	38%	286	17.4	2.8	5.2
Exact Sciences (EXAS)	5.52	9.23	-40%	540	NA	10.9	1.9
Foundation Medicine (FMI)	16.87	21.06	-20%	584	NA	5.7	2.4
Genomic Health (GHDX)	27.42	35.20	-22%	905	NA	3.1	6.7
Invitae (NVTA)	8.48	8.21	3%	272	NA	25.3	2.5
LabCorp (LH)	126.19	123.64	2%	12,920	27.3	1.5	2.5
Myriad Genetics (MYGN)	34.78	43.16	-19%	2,440	23.5	3.3	3.2
NeoGenomics (NEO)	8.49	7.87	8%	655	NA	4.9	3.2
Opko Health (OPK)	9.96	10.05	-1%	5,450	68.2	7.3	2.7
Psychemedics (PMD)	12.61	10.14	24%	68	56.6	2.6	6.4
Quest Diagnostics (DGX)	76.17	71.14	7%	10,770	14.8	1.5	2.3
Rosetta Genomics (ROSG)	1.17	1.23	-5%	24	NA	2.9	1.2
Sonic Healthcare (SHL.AX)	21.48	17.87	20%	8,920	24.2	1.9	2.5
Veracyte (VCYT)	5.18	7.20	-28%	144	NA	2.9	3.5
Unweighted Averages			-9%		33.1	4.9	3.0

Source: Capital IQ

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