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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CMS Gets 1-Week Delay to File Response To ACLA Lawsuit

U.S. District Judge Emmet Sullivan has granted a request by the U.S. Department of Health & Human Services (HHS) for a 1-week delay to file its response to ACLA's lawsuit. HHS says the delay is necessary because its primary counsel, Michael Drezner, trial attorney for the U.S. Department of Justice, had an unexpected family medical emergency. HHS is now scheduled to file its response by March 23.

The lawsuit by ACLA asserts that CMS, operating under the purview of HHS, ignored congressional intent when it omitted hospital outreach lab pricing data to devise private-payer-based rates for Medicare's Clinical Laboratory Fee Schedule for 2018-2020.

Meanwhile, three more laboratory organizations—AAB, CAP and AdvaMed—have filed briefs supporting ACLA's lawsuit. They join the National Assn. for the Support of Long Term Care (see *LE*, February 2018), bringing the total to four. However, a noticeable absence is the American Hospital Association. For the latest news and analysis on ACLA's lawsuit, *see page 4*.

Nasty Noncompete Fight At Bako Diagnostics

Litigation over a noncompete agreement between Bradley Bakotic, DPM, DO, and the dermatopathology lab company he helped found, Bako Diagnostics (Alpharetta, GA), has revealed lurid allegations of extramarital affairs, cocaine use and violence.

The story begins in January 2016 when the private equity firm Consonance Capital Partners (New York City) acquired a majority stake (67.5%) in Bako Diagnostics (formerly named Bako Integrated Physician Solutions). As part of that transaction, Dr. Bakotic, age 52, was paid $30.4 million in cash and equity, while another co-founder Joseph Hackel, MD, age 48, received $14.4 million. Dr. Bakotic remained with the company as President and CEO and Dr. Hackel continued as Vice President and Medical Director. They each signed noncompete agreements that forbid them from competing with Bako Diagnostics or soliciting the company's employees or clients.

Then in July 2017, the company's Board of Directors received a letter from an attorney representing a female regional sales manager ("Jane Doe") that included several disturbing allegations against Dr. Bakotic.
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Nasty Noncompete Fight At Bako Diagnostics (*cont'd from page 1*)

"You have pursued Jane Doe for sex despite the fact that you were married, and her supervisor. In the early morning hours of Sunday, July 23 around 3:30 a.m., you were at her apartment and brutally struck Jane Doe in the face," according to the letter from Jane Doe's law firm Parks Chesin Walbert (Atlanta). "Your conduct has now created a hostile work environment fraught with violence, and the sexual harassment of workers."

The letter demanded that Bako Diagnostics conduct a full investigation into Dr. Bakotic's alleged behavior, "both with respect to the attack and the long term sexual relationship you made an unspoken, but very clear condition of [her] employment."

Jane Doe reached separate nondisclosed settlements with both Bako Diagnostics and Dr. Bakotic in late 2017. She was briefly on paid leave under the Family Medical Leave Act after the alleged attack occurred and ultimately resigned from the company.

Meanwhile, soon after receiving the letter, the Board of Directors at Bako Diagnostics hired a law firm, Latham & Watkins LLP (L&W-New York City), to investigate Jane Doe's allegations. The company says that the investigation found evidence of misconduct on the part of Dr. Bakotic, including battery and inappropriate sexual relationships with subordinates. As a result, Bako Diagnostics fired Dr. Bakotic in early September 2017.

Shortly after Dr. Bakotic was forced out of Bako Diagnostics, Dr. Hackel resigned.

In early October 2017, Drs. Bakotic and Hackel formed the not-for-profit Rhett Foundation for Podiatric Medical Education (Alpharetta, GA) to provide educational activities and a residency program specializing in podiatric dermatology.

On December 27, 2017, Drs. Bakotic and Hackel filed a lawsuit asking a judge in Delaware, where Bako Diagnostics is registered, to invalidate their agreements not to compete against their former company for two years after departing. Drs. Bakotic and Hackel filed the lawsuit to clear the way for a new dermatopathology lab company, named Rhett Diagnostics, that they are forming.

Their lawsuit cites a portion of Delaware law (6 Del. C § 2707), which states that any noncompete agreement "between and/or among physicians which restricts the right of a physician to practice medicine in a particular locale and/or for a defined period of time…shall be void."

"No additional facts are needed to resolve this controversy, which is purely one of law," according to their complaint for declaratory judgment.

In early February, Bako Diagnostics filed its answer to the lawsuit as well as counterclaims. The company said that Drs. Bakotic and Hackel are more than just two regular doctors who simply want to practice pathology. The company noted that they are co-founders and former senior members of the management team who still hold significant equity interests in Bako Diagnostics—Dr. Bakotic still has an 11.6% stake and Dr. Hackel has a 4.5% stake. The sale of Bako Diagnostics to Consonance Capital Partners never would have occurred without the noncompete agreements, wrote the company's lawyers in their response.

Bako Diagnostics' 66-page response then offered pages of details of alleged "gross misconduct" to support their counterclaims for breach of duty of loyalty, unjust enrichment and defamation.

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Among other things, Bako Diagnostics claims that Dr. Bakotic has begun soliciting Bako's clients and employees for his new laboratory company, obtaining investors for it, and boasting that other individuals will operate it for him to circumvent his noncompete agreement.

Bako Diagnostics is seeking a court determination that upholds the company's noncompete agreements with Drs. Bakotic and Hackel. The company is also seeking to recover the millions of dollars of consideration that was paid to Drs. Bakotic and Hackel when Consonance Capital Partners acquired a majority stake in the company.

In a March 5 reply to the counterclaims, Drs. Bakotic and Hackel said that none of Bako Diagnostics' allegations are relevant to the noncompete dispute, "but are illustrative of this sad truth: Defendants are willing to use this Court and its compulsory powers in a campaign of character assassination because the Delaware legislature declared the public's right to medical choice outweighs the interests of private equity."

The lawsuit (case no. N17C-12-337 WCC) is currently in the discovery phase.

Brief History of Bako Diagnostics

Bako Diagnostics was founded in early 2008 when Bradley Bakotic, DPM, DO, and Joseph Hackel, MD left Quest's AmeriPath to join Bakotic's brother, Wayne Bakotic, DO, in forming a new dermatopathology lab primarily focused on serving the nation's 18,000 podiatric physicians.

The new lab company grew rapidly and in 2011, Ampersand Capital Partners (Boston, MA) made an equity investment in Bako Diagnostics. Bako then acquired a physician-dispensed product line of antifungal creams, gels and tablets. Bako has integrated therapeutic suggestions into its pathology reporting and now also distributes antifungal products to its podiatrist clients.

In January 2016, Consonance Capital Partners (New York City) acquired a 67.5% stake in Bako Diagnostics. The company's ownership also currently includes Dr. B. Bakotic, 11.6%; Ampersand Capital, 10.9%; Dr. Hackel, 4.5%; and Dr. W. Bakotic, 3.4%.

Following the departure of Dr. B. Bakotic in September 2017, Bako Diagnostics hired Laurence McCarthy, PhD as Chairman and CEO. McCarthy was formerly Chairman and CEO of Focus Diagnostics, which was sold to Quest Diagnostics in 2006. Following this he joined Ampersand Capital Partners as an Operating Partner.

Fast Facts on Bako Diagnostics

Chairman & CEO	Laurence McCarthy, PhD
President & COO	Dan Spragle
Director ENFD Services	Wayne Bakotic, DO
Chief Financial Officer	Scott Bakotic
Number of employees	230
Annual revenue	$50+ million
Annual patient cases	250,000+

Source: Bako Diagnostics and *LE* estimates

Bako Diagnostics currently has 230 employees, including seven dermatopathologists who diagnose more than 250,000 patient cases per year for 7,500 ordering physicians. *Laboratory Economics* estimates that the company's annual revenue is more than $50 million.

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CMS Gets 1-Week Delay to File Response To ACLA Lawsuit (*cont'd from p. 1*)

The American Association of Bioanalysts (AAB) and its special interest group, the National Independent Laboratory Association (NILA), represent nearly 100 laboratories across the United States. NILA Administrator Mark Birenbaum, PhD, tells *Laboratory Economics* that CMS's exclusion of hospital outreach lab data and the resulting drastic cuts to the Medicare CLFS is already forcing NILA members to scale back their lab testing services to nursing homes and homebound patients. He notes that one of NILA's members, a laboratory that serviced skilled nursing facilities in New Jersey, has already closed its clinical lab serving nursing homes and instead will focus on its anatomic pathology division.

Revised Briefing Schedule for ACLA Lawsuit

February 14, 2018:	ACLA filed its motion for summary judgment.
March 23, 2018:	HHS to file its opposition to ACLA's motion for summary judgment, along with any dispositive motion seeking court order entirely disposing all or part of ACLA's claims.
April 6, 2018:	ACLA to file its reply and opposition to any dispositive motion filed by HHS.
April 20, 2018:	HHS to file its reply in support of any dispositive motion.
April 27, 2018:	The parties will submit their E-briefs and paper submissions to Judge Sullivan.

Another NILA member, an independent nursing home lab based in Pennsylvania, said it has decided that it can no longer afford to continue sending phlebotomists to homebound patients. This laboratory said that approximately 85% of its revenue is tied to the Medicare CLFS and that it will be forced out of business within the next few years if Medicare rates are not revised and corrected.

AAB's brief included a declaration from Thomas Kennedy, President and Owner of Interpath Laboratory (Pendleton, OR). Interpath has 747 employees, operates a main lab in northern Oregon and has 60 PSCs in Washington, Oregon, Idaho, Nevada and Alaska.

"Thirty-eight percent of our business is reimbursed directly from Medicare or state Medicaid plans, with the remaining reimbursed by third-party commercial payers. The majority of those third-party commercial payer rates are set by the insurers at a percentage of Medicare. Basically 82% of our reimbursement is tied to the Clinical Laboratory Fee Schedule. If Medicare rates go down, these commercial rates will go down," according to Kennedy.

Ultimately, Birenbaum says that ACLA's lawsuit could be resolved in one of several different ways.

1) In the best case scenario, Judge Sullivan would grant ACLA's summary judgment motion and force CMS to (a) establish new parameters for data collection that include data from hospital outreach laboratories services, (b) calculate new rates based upon such data, and (c) reinstate 2017 rates pending determination and publication of such new rates.
2) Judge Sullivan could rule to leave the current Medicare CLFS intact, but require CMS to include hospital outreach lab data in the next data-collection and rate-setting cycle.
3) The case could be referred to a trial jury.
4) Judge Sullivan could deny ACLA's motion for summary judgment thereby ending the case.

Of course, another possible solution would be an out-of-court settlement agreement between ACLA and HHS/CMS. *Laboratory Economics* believes that any potential settlement deal would most likely keep the current Medicare CLFS intact, but require CMS to include hospital outreach lab data in the next data-collection and rate-setting cycle.

OIG Investigating Billing At Myriad Genetics

Myriad Genetics (Salt Lake City, UT) says it has received a subpoena from the Department of Health and Human Services, Office of Inspector General (OIG), in connection with an investigation into possible false or otherwise improper claims submitted for payment under Medicare and Medicaid. The subpoena has requested documents relating primarily to Myriad's billing to government-funded healthcare programs for its hereditary cancer tests.

The subpoena covers the time period starting January 1, 2014 through the date of issuance of the subpoena.

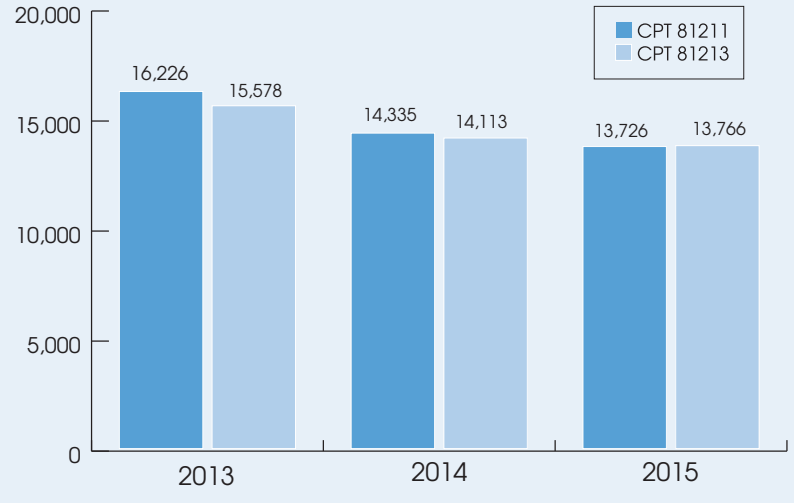
Myriad says that it is cooperating with the government's request and is in the process of responding to the subpoena. At this time, no claims have been made against Myriad.

Laboratory Economics notes that the time period under investigation came shortly after Myriad lost its monopoly over BRCA testing for hereditary breast cancer. In June 2013, the U.S. Supreme Court unanimously ruled that "A naturally occurring DNA segment is a product of nature and not patent-eligible merely because it has been isolated," thereby invalidating Myriad's patents on the BRCA1 and BRCA2 genes. The decision opened the door for competing labs, including Ambry Genetics, BioReference Labs/GeneDx, LabCorp and Quest Diagnostics, to begin marketing their own BRCA tests at lower prices.

Laboratory Economics further notes that the time period under investigation follows a Correct Coding Edit issued by CMS in April 2013 that was intended to stop labs from stacking CPT 81211 (BRCA1&2 full sequence analysis and common duplication/deletion variants in BRCA1) and CPT 81213 (BRCA1&2 uncommon duplication/deletion variants) together when billing for BRCA testing.

The latest available Medicare utilization data from CMS shows that Myriad Genetic Laboratories received a total of $29.1 million in Part B payments for 13,726 claims for CPT 81211 in calendar-year 2015. That same year, Myriad also received a total of $7.8 million in Part B payments for 13,766 claims for CPT 81213.

Myriad Genetic Laboratories Paid Part B Claims for CPT 81211 & 81213



Source: CMS 2013-2015 Medicare Fee-for-Service Provider Utilization & Payment Data

CPT 81211 is currently reimbursed by Medicare at a rate of $2,396; adding CPT 81213 boosts reimbursement by another $553.

Other labs that appear to have stacked CPT 81211 and CPT 81213 when billing Medicare in 2015 include GeneDx (Gaithersburg, MD) and Advanced Molecular Diagnostics (Ramsey, NJ).

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OPKO's BioReference Labs In Midst of Turnaround

OPKO Health (Miami, FL) reports that its BioReference Laboratories (Elmwood Park, NJ) posted an operating loss of $136.5 million in full-year 2017 versus an operating loss of $3.4 million in full-year 2016; revenue decreased by 12% to $889.1 million. OPKO says that the decrease in BioReference's revenue was attributable to both decreased volume and reimbursement. BioReference's revenue was also hurt by a $73 million loss related to accounts receivable writeoffs on claims from commercial and federal payers that were processed throughout 2017 and earlier.

On March 1, BioReference held a conference call with analysts and investors. Below we highlight comments on a few key topics from OPKO's Chairman Philip Frost and its CFO Adam Logal.

Billing System Conversion

BioReference recently transitioned to a new billing system at its clinical lab business. "The early days of that implementation did not go as smoothly as we had anticipated. We worked aggressively on claims in the billing process. We were not as successful as we anticipated in cash collections. As we completed our review of the year, it became clear that we would not realize the cash collections on those early claims and as a result changed our estimates, which negatively affected our fourth quarter revenues," according to Logal. He said that the transition is complete and that BioReference's speed of payment and cash collections have been greatly improved.

GeneDx

BioReference's GeneDx division (Gaithersburg, MD) suffered reimbursement pressure last year, but volume growth was strong. In particular, its whole exome sequencing test volumes grew by more than 40% in 2017.

4Kscore Prostate Cancer Test

Frost said that Medicare reimbursement for the company's proprietary 4Kscore test (CPT 81539) was raised to $760 per test in 2018, up from $602 per test previously. The 4Kscore test is a laboratory-developed blood test that uses an algorithm to calculate a patient's risk of aggressive prostate cancer for making decisions about whether a prostate biopsy is needed. OPKO began selling the 4Kscore test in the U.S. in March 2014.

OPKO acquired BioReference for $950 million in 2015, in part so that it could better market the 4Kscore test. BioReference recently launched a modest TV ad campaign (<$1 million) for the 4Kscore test in New York and Florida. During fourth quarter 2017, BioReference performed 20,600 4Kscore tests, up 15% compared with the same period in 2017. "4Kscore still has the potential for being one of the most important tests in the history of the diagnostics industry. I think eventually the market will begin to understand this," according to Frost.

Investigation

BioReference Laboratories remains under investigation for allegedly improperly billing Medicare and TRICARE for lab tests provided to hospital inpatient beneficiaries at certain hospitals. OPKO says that BioReference is still reviewing and assessing the allegations made by the U.S. Attorney's Office for the Southern District of New York.

Outlook

For the first quarter of 2018, Logan said that OPKO is anticipating volume growth at GeneDx, but a volume decline of approximately 3% at BioReference's core clinical laboratory business. BioReference gets roughly 16% of its revenue from Medicare and Medicaid. The PAMA rate cuts are expected to depress its overall revenue by 1% to 2% in 2018. Finally, Frost said that OPKO is in the midst of an active search for a new President for BioReference (see *LE*, February 2018).

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Comparing Productivity At Quest, LabCorp And BioReference For 2017

On a weighted basis, three publicly-traded lab companies collected average revenue of $48.27 per requisition in 2017. Average collected revenue per test was an estimated $16.09.

The three companies—Quest Diagnostics, LabCorp and OPKO's BioReference Labs—generated a weighted average of $177,175 in revenue per employee in 2017. The average number of requisitions processed was 3,671 per employee, while employees processed an average of 11,012 tests. These figures are based on the total number of employees at the three companies, including all administrative, courier, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is 4.6% with an average days in accounts receivables of 49 days. The combined revenue mix at the three publicly-traded labs is approximately 46% from fee-for-service healthcare insurance, 26% client bill, 14% Medicare, 4% managed care capitation, 4% paid directly from patients, and 2% Medicaid.

Productivity Stats at Quest, LabCorp and BioReference for 2017

2017 Financials	*Quest Diagnostics*	*LabCorp Diagnostics**	*BioReference Laboratories*	*Total*
Annual Revenue 2017	$7,709,000,000	$7,170,500,000	$889,076,000	$15,768,576,000
Operating Income 2017	$1,165,000,000	$1,298,600,000	-$136,540,000	$2,327,060,000
# Employees	45,000	39,000	5,000	89,000
EMPLOYEE EFFICIENCY				
Avg. Annual Revenue per Employee	$171,311	$183,859	$177,815	$177,175
Avg. Annual Oper. Income per Employee	$25,889	$33,297	-$27,308	$26,147
REQUISITION STATS				
Est'd Annual Requisitions 2017	163,800,000	152,000,000	10,900,000	326,700,000
Est'd Avg. Revenue per Requisition	$43.58	$47.17	$81.57	$48.27
Est'd Avg. Oper. Income per Requisition	$7.11	$8.54	-$12.53	$7.12
Est'd Avg. Reqs Processed per Employee	3,640	3,897	2,180	3,671
TEST STATS**				
Est'd Annual Test Volume 2017	491,400,000	456,000,000	32,700,000	980,100,000
Est'd Avg. Revenue per Test	$14.53	$15.72	$27.19	$16.09
Est'd Avg. Operating Income per Test	$2.37	$2.85	-$4.18	$2.37
Est'd Avg. Tests Processed per Employee	10,920	11,692	6,540	11,012
BILLING STATS				
Bad-Debt %	4.1%	4.4%	10-11%	4.6%
Days in AR	46	45-50	75-100	49
REVENUE MIX BY PAYER				
Healthcare Insurers (fee for service)	44.7%	44.3%	68.0%	45.7%
Client Payers (physicians, hospitals, et al.)	22.4%	32.0%	12.0%	26.2%
Medicare	14.3%	13.0%	15.0%	13.7%
Managed Care Capitation	4.0%	3.6%	0.0%	3.6%
Private Patients	2.3%	5.0%	3.0%	3.6%
Employer	5.7%	NA	NA	2.9%
Medicaid	2.3%	2.1%	2.0%	2.2%
Other	4.4%	NA	NA	2.2%

*Data is for LabCorp's lab testing business only. **Test volume stats assume an average of 3 tests per requisition.
Source: Company reports and *Laboratory Economics'* estimates

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A Closer Look At *LE's* Private-Payer Rate Outlook Survey

Last Month, *Laboratory Economics* published a summary of results from our survey of 150+ labs and their expectations for private-payer rate changes. In response to reader requests, we are providing more detailed survey results below.

Survey results were fairly uniform with respect to the question, "Will private insurance companies lower their clinical lab test reimbursement rates as a result of reductions to Medicare's 2018 Clinical Lab Fee Schedule (CLFS)?" The overwhelming answer from all segments was "it's already happening" or "I anticipate it will happen."

Will private insurance companies lower their clinical lab test reimbursement as a result of reductions to Medicare's 2018 CLFS?

	All Surveyed Labs	Hospital Labs	Independent Labs	National Labs	AP Labs	POLs & Other labs
Yes, it's already happening	15%	17%	18%	18%	18%	0%
I anticipate it will happen	61%	58%	60%	73%	73%	80%
No, I anticipate stable rates	5%	0%	6%	9%	0%	0%
I can't make a good prediction	19%	25%	16%	0%	9%	20%

Source: *Laboratory Economics'* survey February 2018 (n=163)

In terms of how various labs plan to cope with lower reimbursement rates, *LE's* survey revealed that no hospital labs are planning on cutting wages or benefits, and only 14% anticipate reducing staff. Hospital labs are most likely to seek lower reagent prices from vendors (69%).

Independent labs are most likely to seek a sale (17%).

The top strategies among the national labs include improving billing and collections (73%), seeking lower reagent prices (64%) and increasing lab automation (64%).

What adjustments will your lab make as a result of lower Medicare rates?

	All Surveyed Labs	Hospital Labs	Independent Labs	National Labs	AP Labs	POLs & Other labs
Seek lower reagent prices	60%	69%	54%	64%	45%	80%
Improve billing & collection	51%	42%	64%	73%	27%	75%
Seek lower send-out test prices	48%	64%	46%	55%	27%	25%
Delay new instruments	32%	22%	44%	27%	9%	20%
Increase lab automation	29%	33%	24%	64%	0%	40%
We will expand into molecular/genetic testing	24%	14%	36%	27%	27%	0%
Reduce staff	22%	14%	24%	27%	36%	20%
Consolidate labs	21%	36%	14%	18%	9%	20%
Cut wages/benefits	14%	0%	20%	27%	45%	20%
May be forced to sell lab	10%	4%	17%	0%	0%	0%

Note: The 163 lab executives responding to the survey represented 74 independent labs, 47 hospital labs, 11 anatomic pathology labs or groups, 11 national labs, and 20 physician office labs (POLs) and other labs.

Source: *Laboratory Economics'* survey February 2018 (n=163)

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FDA Taking Steps to Ease Premarket Approval for Lab-Developed Tests

While the head of the Food and Drug Administration (FDA) believes that comprehensive legislation ultimately is the best way to address regulation of laboratory-developed tests (LDTs), the agency is already taking steps to make it easier for laboratories to receive premarket approval (PMA) for their assays.

FDA Commissioner Scott Gottlieb, MD, says that the agency recently launched a pre-certification pilot program for LDTs that would allow labs that are pre-certified to bypass the analytical validation process. The pilot is modeled after FDA's Digital Health Software Pre-Certification Program announced in July 2017. In fact, he noted, pre-certification was first used to review direct-to-consumer (DTC) genetic health risk tests.

"In the setting of these DTC tests, we realized that if we had enough confidence in the quality of a lab's underlying system, we could exempt from premarket review many individual tests that met pre-specified standards," said Gottlieb during the annual meeting of the American Clinical Laboratory Association (ACLA) on March 6.

This is a different approach than the one advocated by the FDA during the previous administration. In October 2014, the agency issued draft guidance outlining a framework for phasing in oversight of LDTs but failed to finalize the guidance while President Obama was still in office. However, the FDA has long maintained that it has enforcement discretion over LDTs.

The pre-cert approach is just one way that the FDA is working to improve the regulatory experience for test developers, explained Gottlieb. "We're seeing increased interaction and inquiries about the path to FDA approval, and our staff is working hard to address the unique concerns of the lab community as they pursue FDA review of their tests," he said. "In the current fiscal year, several more LDT developers have come forward with premarket submissions to the agency, and we've also received more than a dozen pre-submission requests."

The agency also has qualified the New York State Department of Health as third-party reviewer, which means that labs whose tests have been approved by the NY Health Department – including labs with advanced next-generation-sequencing (NGS) tumor profiling tests – do not need to submit separate applications to the FDA. Instead, they can choose to request that their NY State application, and the state's review memorandum and recommendation be shared with the FDA for possible 510(k) clearance.

Three-Tiered Approach to NGS Tests

On the NGS front, the FDA has developed several policies designed specifically to improve the development and review of advanced NGS technologies, including implementing a three-tiered approach to review of NGS oncopanel tests in order to minimize the burden on developers.

Gottlieb said the FDA will be providing information soon to help NGS developers, including final guidance on FDA's more flexible regulatory approach to all NGS tests. Not only is the agency developing policies that will permit more tests to be exempt from the burden of premarket review, but it is also looking into new, innovative approaches to demonstrating analytical and clinical validity. For example, a developer may be able to demonstrate analytical validity by showing that its test conforms to FDA-recognized standards, perhaps including standards established by the scientific community.

To help implement this approach, the FDA plans to qualify third-party databases that could be used to help establish clinical validity. For NGS, in particular, this could include adoption of ClinGen as a reference database, said Gottlieb. This is a database maintained by the National Institutes

of Health that aggregates information about genomic variation and its relationship to human health. Under this approach, a new NGS test can rely on a reference database to help demonstrate clinical validity.

"We're already starting to see tangible benefits from these changes," Gottlieb told ACLA attendees. "Last November, we authorized the marketing of two NGS-based LDTs for which developers came forward and requested FDA review. These tests are capable of detecting hundreds of genetic mutations by testing a single solid tumor, and thus differ from many other cancer diagnostics, which are designed to detect just one cancer biomarker for use with a single drug."

Gottlied said the FDA is also making sure their approach does not duplicate the work done by CMS under the Clinical Laboratory Improvement Amendments. "Whereas CMS is focused on setting laboratory standards and overseeing laboratory accreditation, inspection and certification, FDA regulates and reviews the tests themselves. It's key we understand and continue to act upon that distinction to avoid recreating the wheel and imposing unnecessary burdens."

Theranos Story Was Make Believe (And So Is The DTC Testing Market)

Theranos CEO Elizabeth Holmes, age 34, has settled allegations that she lied about nearly every aspect of the company's business model and finances in a massive fraud that raised more than $700 million from naive private equity investors and wealthy individuals, according to an announcement from the U.S. Securities & Exchange Commission (SEC).

Theranos told investors it generated revenue of more than $100 million in 2014 and that it was on track to make $1 billion of revenue in 2015, but this information had no basis, according to the SEC lawsuit. In fact, the SEC says that Theranos generated only a little over $100,000 in 2014 and was reckless in projecting $1 billion for 2015.

According to the SEC lawsuit, Theranos' key product—a desktop point-of-care testing system that supposedly required only fingerstick samples—did not work as advertised and the company actually used standard commercial analyzers made by other vendors for most of the small number of patients it actually tested.

As part of her SEC settlement, Holmes will pay a $500,000 fine, give up her majority voting control of the company, and will not be eligible to serve as a director or officer of a publicly traded company for a period of 10 years. However, she was not forced to admit any wrongdoing.

Theranos says it is now focused on developing its "miniLab," which is basically a desktop point-of-care testing system. However, *LE* notes that competing desktop analyzers have already been approved by the FDA and on the market for decades, such as Abbott's i-Stat, the Abaxis Piccolo Xpress and Cholestech's LDX Analyzer.

From *Laboratory Economics* viewpoint, the Theranos saga clearly illustrates that there is no significant market for direct-to-consumer lab testing. Theranos marketed fingerstick testing at prices that were 50% of Medicare at 40 Walgreens stores in the Phoenix area between 2013 and 2016. The company successfully lobbied Arizona to pass a law allowing consumers to order any lab test themselves without a doctor's order in 2015. Theranos then spent millions advertising its services, but was never able to attract more than a few thousand patients per year.

In fact, there are only two tests that consumers are really interested in buying for themselves. At-home pregnancy tests have always been popular. And, more recently, consumers have been spending a lot on genetic tests to determine their ethnic backgrounds—a fad market that may be cooling down.

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Spotlight Interview with NMS Laboratories' CEO Pierre Cassigneul

NMS Laboratories (Willow Grove, PA) provides clinical, forensic and new product development laboratory services to clinicians, forensic scientists, law enforcement agencies and corporations. With 350 employees and eight locations in four states, NMS offers more than 2,500 tests, as well as custom analysis for use in clinical medicine, industrial and environmental chemical exposure, forensic investigations, and new product development services. *Laboratory Economics* recently spoke with Pierre Cassigneul, President and CEO.

Pierre Cassigneul

Where are your laboratories located?
Our two main facilities are located in Willow Grove—one is largely dedicated to our clinical markets and the other central facility is dedicated to our forensic criminal investigation services. We have six additional laboratories in Texas, North Carolina, Florida and Pennsylvania. These six laboratories are dedicated to our Integrated Forensic Services customers, serving law enforcement agencies and district attorneys through public-private partnerships.

What is your annual revenue?
We are in the $65 million range. We have grown about 10% a year for the past four years.

What is driving that growth?
We have developed a unique expertise on so-called "novel psychoactive substances" (NPS) or "designer drugs," which includes synthetic opioids and cannabinoids. We are one of the few laboratories that have developed the surveillance and rapid method development required to keep pace with the evolving drugs-of-abuse landscape.

We recently expanded our services in abuse deterrent formulations (ADF) and new product development services for both pharmaceutical companies and clinical research organizations (CRO)—where we work with companies developing new pain management drugs. The FDA now requires pharmaceutical companies to demonstrate that the galenic form of these new compounds is harder to break down by clandestine labs to extract the active compounds to make street drugs. We can actually work as if we are a clandestine lab to show that the galenic form is more difficult to extract for abuse purposes. The report we generate is then included with the new drug application that's given to the FDA. It's a fast-growing business.

How fast is your traditional drug testing growing?
It's growing in the 3% to 4% range per year.

Do you do drug testing for employers?
Yes, although that is a relatively small part of what we do.

Are you pursuing new areas of testing?
I mentioned that ADF and CRO are expanding. We also test for compounds seeping into water, such as PFOA, which are compounds found in foam that Navy and Air Force bases use to extinguish fires. There are a number of tests for water, but we believe we are the only CLIA-certified laboratory that can detect PFOA in human blood.

How did the bundling of drug screening codes by Medicare a few years ago affect NMS?
We don't bill Medicare or other third-party payers, so it did not affect us.

What do you see as NMS's greatest challenges? Greatest opportunities?
The greatest challenge is to keep up with the pace of novel psychoactive substances being developed. We see opportunities to grow through public-private partnerships in support of forensic customers, particularly in the area of criminal investigation services.

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Lab Stocks Down 3% Year To Date

Prices for 16 publicly-traded lab stocks were down 3% on an unweighted average basis through March 16. In comparison, the S&P 500 Index is up 2% year to date. The top-performing lab stocks so far this year are Foundation Medicine, up 17%, and Genomic Health, up 13%. At the two largest public labs, LabCorp is up 9% and Quest Diagnostics is up 6%.

Company (ticker)	Stock Price 3/16/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.75	$1.85	-5%	$42	NA	1.5	1.4
CareDx (CDNA)	5.79	7.34	-21%	166	NA	3.6	NA
Enzo Biochem (ENZ)	6.48	8.15	-20%	304	NA	2.8	3.5
Exact Sciences (EXAS)	52.57	52.54	0%	6,360	NA	23.9	12.2
Foundation Medicine (FMI)	79.85	68.20	17%	2,920	NA	19.1	92.1
Genomic Health (GHDX)	33.07	29.39	13%	1,150	NA	3.4	6.2
Interpace Diagnostics (IDXG)	1.05	1.02	3%	28	NA	1.9	0.7
Invitae (NVTA)	7.56	9.08	-17%	400	NA	5.9	3.3
LabCorp (LH)	173.83	159.51	9%	17,710	14.2	1.7	2.6
Myriad Genetics (MYGN)	30.17	34.35	-12%	2,110	17.6	2.7	2.3
NeoGenomics (NEO)	8.30	8.57	-3%	667	NA	2.6	3.9
Opko Health (OPK)	3.60	4.90	-27%	2,010	NA	1.9	1.1
Psychemedics (PMD)	20.04	20.56	-3%	110	18.2	2.8	5.9
Quest Diagnostics (DGX)	104.35	98.49	6%	14,150	19.0	1.8	2.9
Sonic Healthcare (SHL.AX)	23.87	21.40	12%	10,090	21.9	1.9	2.6
Veracyte (VCYT)	6.19	6.53	-5%	212	NA	3.0	5.7
Unweighted Averages			-3%	$58,429	18.2	5.0	9.8

Source: Capital IQ

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