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HIGHLIGHTS

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FDA to Begin Regulating Laboratory-Developed Tests

The Food and Drug Administration (FDA) has come under fire in recent years from the pharmaceutical and medical device lobbies for regulatory overreach. But that has not stopped the agency from inserting itself into the laboratory sector and the scores, if not hundreds, of unique tests it develops each year.

On July 31, the FDA notified Congress that it would take steps to regulate some forms of laboratory-developed tests (LTDs). Its primary focus for now will be on companion diagnostics, which typically focus on determining whether or not specific drugs will benefit or hurt a patient's treatment. Such tests have become more prominent in the field of oncology in recent years, although they have also been used to determine the efficacy of more commonly used drugs such as statins and blood thinners.

While the FDA has had some discretionary authority over LDT kits since the mid-1970s, the agency has expressed concern that more of the assays contain components not legally marketed for clinical use

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Palmetto Backtracks on Gastric Staining Guidelines

The College of American Pathologists (CAP) and the Centers for Medicare and Medicaid Services (CMS) have chimed in on the great gastric staining debate—and Medicare administrative contractor Palmetto GBA has blinked.

Palmetto recently removed from its Web site an education article stating that pathologists should refrain from using special stains for some gastrointestinal (GI) diagnoses a large majority of the time or potentially face action from Palmetto.

"We removed it under consideration that a better approach for this and other [immunohistochemical] utilization issues may be to consider publishing a [local coverage determination] but that next step is under review at this time," Palmetto Vice President of Operations Mike Barlow said in an e-mail.

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FDA to Begin Regulating Laboratory-Developed Tests, *from page 1*

while playing an expanding role in medical decisionmaking—all without any scrutiny as to their clinical utility.

Cognizant of the sensitivity to the issue, the agency said it would take the better part of a decade to phase in the regulations. Moreover, it would also focus its scrutiny primarily on tests that have a high risk of affecting patient care. It would place tests into three classes, with only class III tests undergoing the highest level of scrutiny, including premarket review and a requirement that labs report any adverse events within 30 days of receiving notice they have occurred. Tests for rare diseases or with no other approved alternative would be exempt.

"The agency's oversight would be based on a test's level of risk to patients . . . while still providing flexibility to encourage innovation that addresses unmet medical needs," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health.

The reaction to the FDA's move has been mixed.

The American Clinical Laboratory Association (ACLA) asked the FDA to exercise caution in how it regulated lab tests, noting that more regulation could stifle innovation.

"Laboratories have been regulated for decades by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA) and by state law," said ACLA President Alan Mertz. "Under the CLIA framework, a thorough and detailed regulatory process, we've seen an explosion of innovation in laboratory diagnostics that has allowed labs to diagnose and measure disease with an accuracy and precision never before possible."

Amanda Murphy and Brian Weinstein, analysts with William Blair & Co., observed that "increased regulation is never a good thing" because it delays product introductions and stifles innovation. But they added that the FDA "appears to be taking a reasonable approach."

Heather Creran, an Atlanta-based health care consultant with a focus on laboratories, observed that "better standards need to be applied to testing so that patients receive consistently accurate results, regardless of where the test is performed. In addition, patients are demanding and probably soon will and should be allowed to order many diagnostic tests on their own, without having to go through a doctor, and to that end, the results they receive need to be reliable."

However, Creran added that "it is a mistake to layer another level of bureaucracy on top of the existing CMS and CLIA regulations. [The Department of Health and Human Services] needs to take a step back and consider how to reform the entire process from diagnostic test clearance, to laboratory oversight and reimbursement. If diagnostic tests are going to require an approval process, like pharmaceuticals and devices, then the reimbursement model must change as well. Currently, FDA-cleared tests cost multiple times more than that of the same non-FDA cleared test, but the reimbursement from Medicare and other third-party payers is the same."

Foundation Medicine, a Massachusetts-based laboratory that has developed a number of molecular tests related to oncology, expressed confidence that the FDA's regulation would not impede ongoing product development.

"Foundation Medicine developed [its FoundationOne assays] on the basis that tests for patients with advanced cancer should be fully comprehensive, thoroughly validated and backed by peer-reviewed publications," the company said in a statement. "The stakes are extremely high for this patient population, and testing options must meet high quality standards. We will continue our work with FDA and ensure our approach meets its standards of excellence in this field."

The FDA said it would release draft regulations later this year. They will be subject to a public comment period.

Takeaway: The decision by the Food and Drug Administration to regulate laboratory-developed tests could have a far-ranging impact on personalized medicine and the development of new assays. G2

Sequenom Enters Into Licensing Deal With Mayo Medical Laboratories

Sequenom, the San Diego-based laboratory, has entered into a license deal with Mayo Medical Laboratories for patents on its prenatal tests and applications.

The Minnesota-based Mayo Medical Laboratories is part of the Mayo Clinic. It performs about 20 million assays a year for more than 4,000 hospitals worldwide.

Sequenom's primary product is the MaterniT21 PLUS assay, a blood test that combs cell-free fetal DNA for potential abnormalities. It is typically used for pregnant women over the age of 35 who are at risk for giving birth to children with chromosomal abnormalities and is considered a safer alternative to amniocentesis. The test is covered by most major commercial insurers, as well as Medicaid programs in 15 states. Quest Diagnostics also recently came to terms with Sequenom on a distribution agreement, suggesting the company will use such deals to drive revenue growth beyond its own capacity to market the test. Sequenom also has finished developing another test, VisibiliT, which would replace conventional prenatal serum screen testing. It is expected to be commercially available later this month.

"We have great appreciation for Mayo Clinic's commitment to research, innovation, and patient care, and we welcome the opportunity to partner with the organization's leading clinical research laboratory to expand patient access to this revolutionary technology," said William Welch, chief executive officer of Sequenom Inc.

Financial terms of the deal were not disclosed.

Takeaway: Sequenom may enjoy more revenue growth in the future by licensing its testing technology. G2

Inside The Lab Industry

Second Quarter Is Decent Showing for National Labs, Big Gain for Smaller Players

As the laboratory sector moves into the second half of 2014, is the flat growth that has defined the two large national players in recent years being left behind?

New Jersey-based Quest Diagnostics, which had reported shrinking revenue for seven consecutive quarters, finally ended that dubious streak with its second-quarter earnings report. And North Carolina-based LabCorp, which has reported modest growth in recent years, also reported an uptick, although overall profitability at both were lower. Meanwhile, several smaller labs reported strong earnings.

For the second quarter, ending June 30, Quest reported revenue of $1.9 billion, up 4.8 percent.

In a conference call with analysts, Quest Chief Executive Officer Steve Rusckowski observed that "our top priority is restoring growth and we made solid progress in the quarter. . . . [W]e are seeing continued improvement in sequential trends and revenues, organic volume, and organic price. We are seeing continued improvement in sales productivity. We saw a strong revenue growth in several product categories driven by clinical franchises, including prescription drug monitoring, health and wellness, and infectious disease."

> ***"[W]e are seeing continued improvement in sequential trends and revenues, organic volume, and organic price. We are seeing continued improvement in sales productivity. We saw a strong revenue growth in several product categories driven by clinical franchises."***
> ***—Steve Rusckowski, Chief Executive Officer, Quest Diagnostics***

Rusckowski said the Sustainable Growth Rate "doc fix" legislation passed by Congress earlier this year added some stability to the company, along with a likely favorable 2015 Physician Fee Schedule from the Centers for Medicare and Medicaid Services, and mildly favorable numbers as a result of the implementation of the Affordable Care Act, which added about 10 million Americans to the insurance rolls since last autumn.

Rusckowski was also enthusiastic about Quest's recent affiliation with Sloan-Kettering Cancer Center to use molecular testing in next-generation sequencing to improve treatment of patients with solid tumor cancers, and with Sequenom to distribute its MaterniT21 PLUS noninvasive prenatal test. "The clinical franchises are positioning us for future growth," he said.

Not all was rosy with Quest: Net income for the quarter was $133 million, down 19 percent from the $165 million reported for the second quarter of

2013. The company took a $24 million hit associated with restructuring and costs associated with integrating recent acquisitions. And while the company upwardly revised its forecast for revenue for the remainder of the year, it was a mild bump at best: 2.5 percent to 3.5 percent, compared to the prior 2 percent to 4 percent.

"Despite the added level of reimbursement clarity highlighted by the company this morning, lingering questions on the visibility of organic volume reacceleration remain an overhang," said Michael Cherny, an analyst with the ISI Group. Although Cherny increased Quest's stock price target from $62 to $62.50 a share, his organization did not budge on its neutral rating.

Modest Growth for LabCorp

Meanwhile, LabCorp reported that second-quarter revenue grew 3.3 percent from a year ago to $1.52 billion. Although it was a modest increase, it beat Wall Street's expectation of $1.5 billion.

First-Half Earnings Numbers for National, Esoteric Labs

Company	First Half 2014 Revenue	First Half 2013 Revenue	First Half 2014 Net Income	First Half 2013 Net Income
Quest Diagnostics	$3.65 billion	$3.6 billion	$253.0 million	$318.0 million
LabCorp	$2.95 billion	$2.9 billion	$255.2 million	$300.0 million
Sequenom	$76.80 million	$53.6 billion	$-11.2 million	-$60.3 million
Illumina	$868.30 million	$677.0 million	$106.6 million	$13.3 million

Source: Company Reports

LabCorp attributed the growth to an increase in test volume, along with recent acquisitions. Total test volume increased 5.3 percent, but revenue per requisition dipped by 2 percent.

"We are pleased with the strong volume growth in the quarter and the sequential stability of revenue per requisition, which has been under pressure due to mix," said LabCorp Chief Executive Officer Dave King.

Net income for the quarter was $141.7 million, down 7 percent from the $152.3 million that was reported for the second quarter of 2013. LabCorp attributed the dip to cost increases in performing tests, bad-debt expense, and the mix of tests themselves.

David Clair and William Quirk, analysts with Piper Jaffray, said the recent decision by TRICARE, which provides health care services to military dependents, to cover 40 molecular tests could be an upside for LabCorp moving forward. However, they also noted that "CMS' molecular pathology changes continue to negatively impact LabCorp's business with state Medicaid reimbursement delays remaining a headwind."

LabCorp did not change its guidance of a 2 percent increase in revenue for the calendar year. Piper Jaffray maintained a neutral rating on its stock.

Quest's stock price rose slightly after Quest released its earnings but has since dropped back to about $61 a share. LabCorp's stock is up about 5 percent since LabCorp released its earnings numbers and is trading at around $106 per share.

Smaller Labs Saw Bigger Growth

Smaller publicly traded players in the lab sector reported significantly stronger revenue growth for the quarter.

Massachusetts-based Thermo Fisher Scientific reported a 33 percent growth in revenue for the second quarter, ending June 28, reaching $4.32 billion, up from $3.24 billion a year ago, while net income rose 6.4 percent to $278.5 million. Thermo Fisher's laboratory and specialty diagnostics divisions grew, but not at the same pace as the rest of the company: 7 percent and 8 percent, respectively, representing $2.6 billion of the firm's overall revenue. Both divisions reported adjusted operating income increases in the high single digits.

The company revised its low-end calendar-year revenue forecast up slightly, to $16.86 billion from $16.84 billion.

San Diego-based Sequenom reported revenue of $39.8 million for the quarter, up 62 percent from the $24.5 million reported during the first quarter of 2013. Accessions of its MaterniT21 increased by 7 percent, including a robust uptake of testing by state Medicaid programs.

> ***"The progress we've made in the clinical market validates our strategy and the utility of sequencing in health care."***
> ***—Jay Flatley, Chief Executive Officer, Illumina***

The company also entered into the black, reporting net income of $4.5 million, compared to a loss of $31 million a year ago, although all of that was attributed to the sale of its biosciences division. Its operating loss was $13.2 million, significantly lower than the year-ago quarter's $29.2 million.

Illumina, also based in San Diego, reported a 29 percent increase in revenue for the fiscal second quarter, ended on June 29, reaching $447.6 million, compared to $346.1 million for the fiscal 2013 second quarter. Its service revenue—which includes sequencing tests—rose 75 percent, to $57 million.

"The progress we've made in the clinical market validates our strategy and the utility of sequencing in health care," Illumina CEO Jay Flatley said in a conference call with analysts. "We're confident in our technology leadership and believe we will continue to deliver significant growth as we unlock the power of the genome."

Takeaway: Revenue growth for the large national labs appears to have resumed, though it remains sluggish, while smaller labs are growing at a more dramatic pace.

■ Palmetto Backtracks on Gastric Staining Guidelines, *from page 1*

Palmetto was recently contacted by CMS regarding the matter, according to correspondence between the agency and CAP.

CAP sent a formal letter of complaint in late June to the CMS regarding Palmetto's issuance of new guidelines regarding the use of immunohistochemical stains for some gastric patients. It claimed the guidelines were arbitrary and did not take into consideration the individual circumstances involving each case.

Palmetto, which called the advisory it issued last spring an "education article," directly discouraged the use of ancillary special stains such as alcian blue and periodic acid schiff for stomach biopsies, noting that "there is potential for either overutilization or under-utilization of these ancillary special stains" for both intestinal metaplasia and H. pylori.

Palmetto concluded that the use of such stains is justifiable in 20 percent or fewer GI cases and that it might take action against pathologists who exceed that threshold.

Medicare is billed for such stains at the rate of $12.12 to $97.67 apiece. While some pathologists may order two or three such stains, some industry observers say it is not unheard-of for some to order a dozen or more of the stains—a likely sign of abuse.

But CAP, in a five-page letter sent to CMS Administrator Marilyn Tavenner on June 25, asserted that Palmetto was acting in an arbitrary manner.

"CAP believes that Palmetto has overreached its authority by imposing an arbitrary numerical utilization threshold on providers utilizing special stains in gastric biopsies and then threatening to use unspecified enforcement actions against providers," said the letter, which was under the signature of Jonathan L. Myles, M.D., who chairs CAP's economic affairs committee.

The letter urged CMS to have Palmetto remove the article from its Web site or modify it significantly, noting that the letter cannot be educational if it includes threats of further actions.

"Providers can only assume that Palmetto's threat of 'additional action' against providers who exceed its arbitrary utilization threshold is a reference to the use of some component of the government's broad arsenal of compliance and fraud and abuse investigative and enforcement mechanisms."

The letter also stated that if Palmetto wants a blanket policy regarding gastric stains, it can resort to the local coverage determination process—which includes feedback from providers—in order to do so.

In a letter Tavenner sent to Myles sent in late July, she said that Palmetto was contacted and it decided to remove the educational article.

Palmetto told *Laboratory Industry Report* back in June that it detected overutilization of special gastric staining and that it took the appropriate action to rein it in. At the same time, it also issued an educational letter discouraging the use of Ki-67, PI3K, and gene expression assays for breast cancer diagnoses. That letter remains on Palmetto's Web site.

Takeaway: Pushback from the College of American Pathologists appears to have caused Palmetto GBA to yield on the GI special stains utilization issue. G2

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INDUSTRY BUZZ

bioTheranostics Makes Economic Case for Oncology Test

Another study has been released regarding the cost-effectiveness of an esoteric molecular test, slowly bolstering the economic case for using such assays.

The latest study, published in the *Journal of Medical Economics*, focused on the San Diego-based firm bioTheranostics and its CancerTYPE ID assay for metastatic cancer.

The study, which was conducted by researchers with the Los Angeles-area Partnership for Health Analytic Research, focused not only on whether the test improved cancer diagnosis, but also on a variety of economic issues related to oncology care, including annual costs and quality of life for a patient undergoing treatment. The study took into account patients with eight common cancers: breast, colon and rectum, kidney and renal pelvis, liver and intrahepatic bile duct, lung and bronchus, ovarian, pancreatic, and prostate.

The study concluded that the bioTheranostics' test increased the proportion of patients with metastatic cancer of unknown origin who were treated correctly to 81 percent from 58 percent, decreased the proportion of patients treated incorrectly to 15 percent from 29 percent, and increased survival time adjusted for quality of life by 1.15 months.

But perhaps more significant, using the test appeared to keep the costs of care in line. According to the study, using the test helps keep the cost-effectiveness of treating a cancer patient at $50,273 for a year, adjusted for quality of life. According to a statement issued by bioTheranostics, society as a whole accepts up to $100,000 a year per patient for oncology care, when adjusted for quality of life.

The costs do go up if the test is used prior to using a common set of six immunohistochemical stains. However, the proportion of patients correctly diagnosed rises to 83 percent.

"This study reinforces that CancerTYPE ID is associated with improved diagnosis and outcomes for metastatic cancer patients and that it is cost-effective—providing clinical benefit at a reasonable cost," said bioTheranostics Chief Executive Officer Richard Ding.

Takeaway: bioTheranostics is the latest esoteric laboratory to release a study claiming an economic benefit to using its test.

References

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