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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Rep. Burgess Pledges to Ensure LDTs Are Regulated Under CLIA, Not FDA

Rep. Michael Burgess, M.D. (R-Texas) has pledged to continue pushing for enactment of legislation that would create an expanded notification and review process for laboratory-developed tests (LDT) at the Centers for Medicare and Medicaid Services (CMS).

Speaking April 23 at the annual meeting of the American Clinical Laboratory Association (ACLA), Burgess said he firmly believes LDT oversight authority should fall under the Clinical Laboratory Improvement Amendments (CLIA) and should not fall under the Food and Drug Administration (FDA). Burgess introduced legislation in October 2011, the Modernizing Laboratory Test Standards for Patients Act (H.R. 3207), which would ensure that LDTs would be regulated under CLIA.

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Quest's New CEO Faces Challenges Ahead

Quest Diagnostics' new president and chief executive officer will have his work cut out for him when he takes over one of the largest independent diagnostic testing companies at a time when declining reimbursements, increasing industry consolidation, and uncertainty over health care reform place continued pressure on health care companies.

Quest (Madison, N.J.) said April 11 that Steve Rusckowski will succeed Surya Mohapatra, Ph.D., as president and CEO, effective May 1. Ruskoswski was formerly CEO of Philips Healthcare, the largest unit of Royal Philips Electronics, a position he had held since 2006. He also has been a member of the board of management of Royal Philips Electronics and its executive committee.

During Rusckowski's tenure as CEO of Philips Healthcare, revenues increased from approximately 6 billion euros in 2005 to about 9 billion euros in 2011, accounting for 39 percent of Philips's consolidated revenues. Philips Healthcare has 38,000 employees in more than 100 countries worldwide. Prior to his current role, Rusckowski was CEO of the imaging systems business group within the company. Before joining Philips he held numerous management positions with the health care division of Hewlett-Packard/Agilent Technologies. He joined Philips when it acquired Agilent's Healthcare Solutions Group in 2001.

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Burgess Makes Pledge on LDTs, *from page 1*

The FDA in July 2010 announced plans to regulate LDTs and is working on a final guidance that would establish review based on risk levels. FDA has long asserted that it has jurisdiction over LDTs but has exercised this jurisdiction only with respect to analyte-specific reagents, the ingredients used in LDTs, and in certain assays—in vitro diagnostic multivariate index assays—that use a proprietary algorithm to produce patient-specific results.

"The FDA already has a lot on its plate" and taking on regulation of LDTs would simply slow down its overall approval process for medical devices and tests that it already regulates, said Burgess. ACLA supports the Burgess bill, saying it "offers a modern, innovative, and flexible approach that builds on the success of CLIA."

The Burgess bill would require the secretary of Health and Human Services (HHS) to establish a single publicly accessible test registry data bank of LDTs and direct-to-consumer DNA tests, which should include information on the purpose of each test, the claimed use or uses of each test, and information regarding the analytical validity of each test. Labs would be required to notify HHS (1) before marketing such a test, (2) after any significant modification of such a test, or (3) if the evidence of clinical validity is inadequate to support one or more of the claimed uses.

"CLIA needs to be modernized, and this would allow that to happen. This bill has been structured in a way to avoid harm in innovation while the FDA approach would harm innovation."
–Rep. Michael Burgess, M.D.

The measure would also require HHS, within 90 days of receiving such notification, to determine whether the test is clinically valid and would deem the secretary to have authorized marketing of the test if no response is received within 90 days. In addition, the bill would give the secretary authority to order a laboratory or test-offering entity to cease offering or marketing a test if the information submitted in notifications does not demonstrate the clinical validity of the claimed uses and the test poses a risk of immediate harm to the public health.

H.R. 3207 would set forth requirements for (1) registration of a test-offering entity, (2) information that must be included in disseminated materials and advertising, (3) notice to the secretary if a test may have caused or contributed to a death or serious bodily injury, and (4) sanctions for violations of the law ($10,000 for each violation). It also would require the secretary to administer this program solely through CMS.

The new notification and review process would be paid for entirely through user fees paid by clinical laboratories seeking test approval.

"CLIA needs to be modernized, and this would allow that to happen," said Burgess. "This bill has been structured in a way to avoid harm in innovation while the FDA approach would harm innovation." G2

Quest, LabCorp Report Strong First-Quarter Results

The nation's two largest clinical laboratory companies reported strong first-quarter results in April, due in part to mild weather during the winter.

Quest Diagnostics (Madison, N.J.) reported revenues of $1.94 billion (6.3 percent growth), beating analysts' expectations of $1.88 billion. Total clinical testing revenue growth of 6.4 percent was entirely driven by the acquisitions of Celera, Athena, and S.E.D. Laboratories, according to Amanda Murphy, an analyst with William Blair & Co. Excluding those acquisitions, the company's revenue was flat.

Testing volume increased 3.4 percent, and revenue per acquisition was up 2.9 percent. Again, adjusted for acquisitions, both volume and revenue per acquisition were relatively flat. The company reported strong gross profit of 42.6 percent, compared with Blair's target of 41 percent.

Quest raised its guidance on 2012 diluted earnings per share (EPS) to between $4.45 and $4.60, up 5 cents from the previous guidance. Capital expenditures are expected to be between $200 million and $225 million, or $25 million less than the previous guidance. Operating margin is still expected to approach 18 percent.

As mentioned by management previously, the priorities of operating cash usage in 2012 is paying down debt (to drive leverage closer to 2.5 times), return cash via dividend, and repurchase shares. The company paid down about $100 million in debt during the quarter.

Blair continues to rate the shares market perform until it gains visibility into new CEO Steve Rusckowski's vision for the company, including the previously announced $500 million cost-cutting initiative.

Quest at a Glance ($MM)

	First Quarter 2012	First Quarter 2011	Change
Total revenues	$1,936.5	$1,821.6	6.3%
Gross profit	824.0	733.6	12.3
Net income	171.2	151.5	13.0

LabCorp Revenues Better Than Expected

LabCorp (Burlington, N.C.) reported revenues of $1.42 billion for the quarter, which exceeded analysts' expectations by about $2 billion. Revenues increased 4 percent over the first quarter of 2011. Net earnings were $161.6 million. Adjusted EPS of $1.74 were 6 cents better than Blair's estimates.

Testing volume, measured by requisitions, increased 2.8 percent, and revenue per requisition increased 1.2 percent. The quarter benefited from relatively mild weather, which increased the revenue and volume growth rate by about 1.5 percent.

Operating cash flow for the quarter was $197.1 million. The balance of cash at the end of the quarter was $129.9 million, and there was $460 million of borrowing outstanding under the company's $1 billion revolving credit facility. During the

quarter, the company repurchased approximately $122.3 million of stock, representing about 1.4 million shares. During the first quarter of 2012, the company recorded a net credit of $3.6 million in restructuring and other special charges.

LabCorp reaffirmed its 2012 guidance, expecting revenue growth of approximately 2 percent to 3.5 percent; adjusted EPS, excluding amortization, in the range of $6.75 to $7.05; and capital expenditures of about $155 million.

LabCorp at a Glance ($MM)			
	First Quarter 2012	First Quarter 2011	Change
Total revenues	$1,423.3	$1,368.4	4.0%
Gross profit	576.1	568.4	1.4
Net income	172.7	160.9	7.4

MedTox Beats Market Expectations

Medtox Scientific beat market expectations in the first quarter of 2012 helped by strong revenue in its clinical laboratory segment.

For the quarter, Medtox's revenue was up 14 percent to $28.6 million when compared to the first quarter of 2011. Net income rose to $1.5 million, or 17 cents per share, up from $0.8 million or 9 cents a share a year ago. Gross profit increased 20.8 percent to $11.9 million.

In the laboratory segment, revenues from drugs-of-abuse testing in the quarter increased 9.7 percent to $10.6 million, up from $9.6 million in the first quarter of 2011. The company's diversification efforts initiated in 2008 continue to maintain momentum with clinical laboratory revenues in the quarter increasing 25.2 percent to $9.2 million. Clinical trial service (CTS) revenues for the quarter decreased to $2.4 million, compared to $2.5 million for the prior-year period, which had been a record CTS quarter.

In the diagnostics segment, revenues were up 15.4 percent for the quarter. The increase is attributable to improved sales in the workplace drugs-of-abuse and government markets, with the company's newly introduced EZ-SCREEN cup device and increased sales of PROFILE®-V sold into the hospital market with the MedToxScan® Reader.

Gross margins improved in both the laboratory services and diagnostic products segments with overall gross margin increasing 240 basis points to 41.5 percent, compared to 39.1 percent in the first quarter of 2011.

MedTox at a Glance ($MM)			
	First Quarter 2012	First Quarter 2011	Change
Total revenues	$28.6	$25.1	14%
Gross profit	11.9	9.8	21
Net income	1.5	0.8	88

Molecular Diagnostics at a Turning Point: G2 Conference Examines Critical Issues

Molecular diagnostics, which continues to grow at a double-digit pace and is expected to top $8 billion by 2015, is at a turning point with MDx making its way into mainstream medicine. As this continues, clinical laboratories increasingly will be faced with new challenges, from figuring out whether to bring molecular testing in-house to coping with changing coding and reimbursement models to ensuring that staff members are adequately trained to handle molecular tests.

G2 Intelligence examined the evolution of this rapidly growing field, ongoing challenges, and the outlook for the future at MDx NEXT, held April 17-19 in Boston. Below are some of the highlights from the conference.

From Cost Center to Profit Source

By choosing the right tests to bring in-house, clinical laboratories can turn molecular diagnostics from a cost center into a profit source, says Jeffrey Kant, M.D., Ph.D., director of the Division of Molecular Diagnostics, Department of Pathology, at the University of Pittsburgh Medical Center.

Before bringing MDx tests in-house, labs must first determine whether they have the space, equipment, expertise, and volume to operate profitably, advises Kant. Competing with commercial providers on volume and turnaround time is difficult for "average" labs, even for "average" academic medical centers. However, by carefully selecting your test menu, you can save money spent on outsourcing or even make money on MDx testing.

Labs should focus on tests that are high volume, high interest and clinically useful, high value (in other words, they cost a lot to send out), and that provide high visibility for the lab. When determining volume, consider "batchability," says Kant, noting that testing for infectious agents (human papillomavirus, other sexually transmitted diseases, methicillin-resistant Staphylococcus aureus, and respiratory viral panels) and those for heritable conditions and oncology usually are good choices. Labs must also examine turnaround time since they will be competing with large commercial labs.

Tests that may not be wise to bring in-house are those that may not be particularly useful, such as those for MTHFR variants and pharmacogenetics, and tests requiring high capital outlays or sophisticated technical expertise (fluorescence in situ hybridization, sequence analysis, mass spectrometry).

Efficiencies to be considered include test panels, multi-institutional purchasing plans for in vitro diagnostics and other reagents, the ability to create lab-developed tests, and the ability to maximize batch sizes. If you continue to send out molecular diagnostic tests, Kant advises developing an alliance with a single reference provider and perhaps even considering a joint venture if you are big enough. Actively monitor send-out testing, which is especially important as bundled payment develops. Finally, scrutinize expensive panels for their value and shop around to compare pricing of tests. In some cases, the same assay can fluctuate by up to $3,000.

Cancer Requires New Personalized Medicine Business Models

Kenneth Buetow, Ph.D., the former associate director of the National Cancer Institute and current director of the Complex Adaptive Systems Initiative at Arizona State University, gave an engaging portrayal of the latest molecular scientific understanding of cancer and warned that the resulting conclusion that cancer acts as a complex adaptive system means that testing, studying, and treating this disease is going to become more challenging going forward.

What makes cancer a complex adaptive system?

- ❑ Cancer is a type of "organ"—it is composed of hundreds of types of different cells created in an embryonic fashion through iterative genetic mutations in three dimensions. As in other organs, there is tremendous cellular heterogeneity across the tissue;
- ❑ The types of molecular variations are multiple and complex. For example, they extend beyond genetic mutations to include allele loss and epigenetic changes;
- ❑ Each cancer selects (probably randomly) from a portfolio of different processes controlled by networks or pathways of genes. For example, the cancer may adopt the angiogenesis, evade apoptosis, or telomere maintenance pathways; and
- ❑ The genetic somatic environment surrounding the tumor impacts its behavior. This is a factor outside of the cancer that can alter its molecular dynamics and functioning.

The complex nature of cancer has a number of implications for both molecular diagnostics and personalized medicine business models, Buetow asserted. First, laboratorians will need a variety of technologies, markers, and samples to understand the molecular state of a cancer. Moreover, these tumors are dynamic, so they need to be analyzed over time. Furthermore, new clinical trial models are needed, because the patient sample sizes explode with permutations of multiple markers.

Buetow offered examples of new ways of approaching biomedicine and product development. At a high level they involve freely sharing information by networking between stakeholders (viewing biomedicine as an ecosystem), leveraging real-world clinical experience as evidence for product development, and designing trials that utilize multiple, parallel arms and adapt their designs based on results.

Barriers to Personalized Medicine

Heralded as the solution for improving patient care, reducing health care costs, and increasing pharmaceutical research and development (R&D) productivity, personalized medicine will rely on biomarkers to improve diagnosis, prognosis, and drug safety and efficacy, yet most of the hundreds of identified protein and nucleic acid biomarkers sit in limbo—unvalidated,

unapproved, and unused, according to Jeremy Bridge-Cook, Ph.D., senior vice president of assay R&D at Luminex Corp. (Austin, Texas).

Bridge-Cook began by acknowledging the handful of pharmacogenomic biomarkers that can be considered to be clinically successful, such as EGFR/KRAS, BRAF, and Her2/neu, but noted that outside of oncology, where molecular understanding of the disease is greater and reimbursement is less critical, biomarker use remains very rare. For example, the U.S. Food and Drug Administration (FDA) recommends that 60 drugs be administered based upon CYP450 biomarkers, but none of these biomarker-based tests are in widespread use.

According to Bridge-Cook, four key factors are holding back personalized medicine outside of oncology. First, few seem interested in taking on the large, expensive clinical trials needed to definitively prove that a particular biomarker will improve outcomes. Secondly, reimbursement for biomarker-based testing is spotty and not tied to FDA clearance or approval. Meanwhile, physician adoption has been slow due to lack of clear direction and lack of clinical evidence. And finally, pharmaceutical companies have not been on-board for the last full decade.

Despite the multiple barriers, there are glimmers of optimism on the horizon for biomarkers. For example, a number of initiatives are under way at the National Institutes of Health to provide funding for proof of comparative effectiveness, which Bridge-Cook singled out as the single most critical dataset to drive adoption and reimbursement.

Genetic Counselors Increasingly Important

With genetics moving out of the genetics clinics and into mainstream medicine, genetic counselors will play an increasingly important role in helping consumers decipher and understand the results of genetic testing, according to Brenda Finucane, executive director of Elwyn Genetics and president of the National Society of Genetic Counselors.

In the past, patients turned to their primary care physicians for help in understanding test results, but many physicians do not have the training or knowledge base to adequately interpret results of complex genetic tests, says Finucane. "Consumers are more savvy, but many primary care docs don't know how to respond," she notes.

Genetic counselors are specifically trained in genetics and are nationally certified and licensed in some states. Typically they provide information and support to individuals and families with genetic disorders and those who may be at risk for inherited conditions. Genetic counselors also serve as educators and resources for other health care professionals. Understanding of genetic test results is especially important when one considers the potential implications of an incorrect interpretation, explains Finucane.

"It's an exciting time, but all it takes is a couple of high-profile disasters to set the whole field of genetics back," she says. G2

■ **Quest's New CEO Faces Challenges Ahead**, *from page 1*

Rusckowski earned a bachelor of science in mechanical engineering from Worcester Polytechnic Institute and a master of science degree in management from the Massachusetts Institute of Technology's Sloan School of Management.

Investors and industry analysts have high hopes for the new CEO. While Quest's revenues grew fivefold to $7.5 billion during Mohapatra's eight-year tenure, the company's stock price and earnings have trailed those of its chief competitor, LabCorp.

New Study on Self-Referral Supports Closing Loophole

A new study by researchers at Georgetown University supports efforts by lab and pathology industry groups to close the loophole in the Stark law that permits self-referral to in-office pathology laboratories.

The long-awaited study, funded by the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP), compared Medicare billings and prostate cancer detection rates over a three-year period by practices with a financial interest in the pathology lab doing the test versus those without a direct financial interest. The study was conducted by noted health economist Jean Mitchell, Ph.D., and published in the April issue of *Health Affairs*.

Results of the study support the premise that the practice of physician self-referral for diagnostic imaging and pathology services leads to increased use and escalating health care expenditures with little or no benefit to patients. The study found that:

- ❑ On average, self-referring urologists billed Medicare for 72 percent more anatomic pathology specimens than physicians who did not benefit financially from ordering more tests; and
- ❑ The prostate cancer detection rate per biopsy episode was significantly higher for men who had the biopsy performed by non-self-referring urologists.

The study concluded that "self-referral of prostate surgical pathology leads to increased utilization and higher Medicare spending but lower cancer detection rates. The findings support eliminating the exception that permits physicians to self-refer to in-office pathology laboratories. Both government and commercial insurers could reduce health care spending substantially by adopting measures to restrict self-referral."

Ancillary Services Exception

The Stark law includes an exception related to in-office ancillary services (IOAS) that allows physicians and group practices to self-refer or insource designated health services, including diagnostic imaging, physical therapy, and anatomic pathology. Although self-referral for advanced imaging has been widely studied, the consequence of self-referral on the use of other ancillary services has received little attention. This study addresses the impact of self-referral on Medicare payment for anatomic pathology services, specifically biopsies to detect prostate cancer. Both CAP and ACLA have long supported elimination of the IOAS exception.

"The implications of Dr. Mitchell's study are clear," said Stanley Robboy, M.D., FCAP, CAP's president. "Self-referral has created an incentive to spend millions and millions of dollars without any data showing that this practice benefits patients."

"This study suggests that men are at heightened risk of unnecessary and costly prostate cancer biopsies when under the care of a physician who benefits financially through self-referral," said Alan Mertz, president of ACLA. "This is a serious unintended consequence of a legal loophole that needs to be corrected immediately by Congress.

Groups representing urologists criticized the study, saying that it "grossly misrepresents the prevailing urological standard of care and scurrilously criticizes physicians for adopting evidence-based clinical protocols." Deepak Kapoor, M.D., president of the Large Urology Group Practice Association (LUGPA), charged that the study utilized suspect methodology in small numbers or hand-selected groups, producing results inconsistent with both the scientific literature and direct clinical observations.

Mitchell, speaking at the ACLA annual meeting April 24, defended the methodology and responded to challenges one-by-one.

The full report is available online at *www.healthaffairs.org*.

Regulatory, Reimbursement Consistency Said Key to Spurring Genome-Based Test Use

Major changes in the systems for developing, regulating, and reimbursing for genomic diagnostic tests are necessary for more health care providers to adopt these tests and integrate the potential of genomics into mainstream clinical use, an Institute of Medicine report released March 20 concluded.

The report, *Genome-Based Diagnostics: Clarifying Pathways to Clinical Use*, summarizes a workshop held Nov. 15, 2011, called "Facilitating Development of and Utilization of Genome-Based Diagnostic Technologies" that sought to find solutions to bring these diagnostic tests successfully to clinical use to benefit patients. It followed up on a workshop held a year prior to determine what evidence is needed to develop genomic diagnostic tests of clinical value.

"These tests have the potential to direct therapeutic interventions, predict risk or onset of disease, or detect residual disease. As research progresses and an increasing number of associations are found, further tests will be developed that can aid in providing personalized treatment options for patients," the report stated. "However, the adoption of genomic diagnostic tests by health care providers has been limited due to a lack of evidence regarding the clinical utility of many tests."

During the latest workshop, the report stated, stakeholders presented on new models, strategies, and actions to generate evidence for genomic diagnostic test development. They specifically explored the differences in evidence required for the clinical use, regulatory oversight, guideline inclusion, coverage, and reimbursement of genomic diagnostic tests.

Two Presentations Spark Debate

According to the report, proposals by two presenters sparked much of the debate that day: changing the regulatory approval pathway for these tests and eliminating disincentives to investment in the life sciences.

First, Daniel Hayes, a professor of internal medicine and clinical director of the Breast

Oncology Program at the University of Michigan Comprehensive Cancer Center in Ann Arbor, Mich., proposed a new system for approving genomic diagnostic tests through the Food and Drug Administration (FDA) instead of the current pathway of laboratory-developed test (LDTs). Performed by specialists with advance training, LDTs typically are developed under the provisions of the Clinical Laboratory Improvement Amendments and therefore do not require clearance or approval from FDA. In the report, IOM stated that genetic tests initially focused on single genes but today are often based on "complex testing algorithms that encompass multiple genetic variants, genes, or gene expression patterns and most recently, whole-exome or whole-genome sequencing. Hayes argued that eliminating the LDT pathway in favor of FDA regulation could yield high-quality evidence regarding the analytical validity and clinical utility of these tests.

Secondly, Sue Siegel, a partner with the venture capital firm Mohr Davidow, said during the workshop that venture capital firms are backing away from investing in life sciences and health care because there is a lack of clarity in the regulatory and reimbursement structures of these fields.

"It's happening today. It's happening pretty aggressively," she stated. Siegel said a "predictable and efficient"—but not necessarily easier—pathway from regulatory approval by FDA to reimbursement from the Centers for Medicare and Medicaid Services (CMS) could help attract venture capitalists.

Finally, workshop participants recommended standards for molecular diagnostics that they said could help establish regulatory and reimbursement pathways that test developers can follow.

Test Developers, Patient Perspectives

The test developers who provided their perspectives said the regulations governing these tests can be "critical factors" in how the tests are used and the competitiveness of the company. They also identified several factors that could move the tests from the bench to the bedside including standards, quality control, regulatory guidelines, and technology assessments.

Further, they said, changes in existing coverage and reimbursement strategies should "recognize the value of advanced medical diagnostic tests, their impact on health care, and the resources needed to develop and validate them." Finally, the test developers said that to establish the value of these tests, their use should be compared to traditional health practices.

The patient group representatives that provided presentations at the workshop had varying claims about the usefulness of genomic tests and said they can be confusing to patients. They further said that the focus of developing new diagnostic tests should begin with the needs of the patient, not a discussion on how to get reimbursement. Cancer patients need ways for their questions to be answered by health care professionals at the point of clinical decisionmaking. There also was a recommendation to have different rules and guidelines based on the severity of the illnesses.

Progressive Regulatory Framework

From the payer perspective, the speakers recommended an adaptive regulatory or reimbursement framework. Under this model, initial approval would be conditional upon further study.

Sean Tunis of the Baltimore-based Center for Medical Technology Policy and former chief medical officer in the CMS Office of Clinical Standards and Quality, said no new regulatory or statutory authority would be needed to move to such a structure of approval.

"Having single yes/no decisions over time is just too crude an approach," Tunis said, according to the report. "If we're going to solve this problem with technologies generally, and certainly with diagnostics, we need to think about our regulatory decision making in a way that's more compatible with the accumulation of knowledge and the reduction of uncertainty over time."

Tunis further recommended a collaboration among all the stakeholders—regulators, payers, clinicians, patients, and others—to define what the evidentiary thresholds should be.

"Critical reasoning medicine can support coverage decisions when the data to make these decisions are incomplete," the report stated.

Muin J. Khoury, director of the Centers for Disease Control and Prevention Office of Public Health Genomics, said during the workshop that a lack of a coherent oversight system is creating a chasm between the use of diagnostic tests and improved health. The speakers during the regulation, reimbursement, and public health portion of the workshop called for better collaboration among the federal agencies, which they said could ease some of the limitations of the current regulatory system.

Major Proposals

The IOM report identified a number of major proposals, including Hayes's proposal to eliminate LDTs in favor of FDA review and approval. The other major proposals include:

- ❑ Base FDA approval on analytical validity and clinical utility, not clinical validity and intended use.
- ❑ Consolidate the review of all oncology products within a single FDA office.
- ❑ Base reimbursement on the value of a genomic diagnostic test to patients, payers, and society.
- ❑ Clarify the regulatory and reimbursement pathways for genomic test development.
- ❑ Preserve physician discretion in ordering, interpreting, and delivering diagnostics, therapies, and other forms of care.
- ❑ Ensure that agency decisionmaking is transparent, with rulemaking by notice and comment rather than through guidelines.
- ❑ Standardize the validation of protocols and enhance quality control to improve the efficiency of test development.
- ❑ Provide guidance for institutional review boards on how to review genomic tests.
- ❑ Provide opportunities and incentives for guidelines committees and regulatory bodies to harmonize their definitions of clinical utility.
- ❑ Reform reimbursement to recognize the value of diagnostic tests, their impact on health care, and the resources needed to develop and validate tests.

EDITOR'S NOTE:
Laboratory Industry Report ***will no longer track lab stocks on a monthly basis. Instead, we will publish biannual updates on publicly traded lab companies and their stock prices.***

INDUSTRY BUZZ

LDT Guidance Likely Delayed Until After Election

Final guidance on lab-developed tests being developed by the Food and Drug Administration (FDA) is likely to be delayed until after the fall elections, predicts a former FDA official. Scott Gottlieb, M.D., resident fellow at the American Enterprise Institute and deputy commissioner of the FDA from 2005 to 2007, said that while in vitro diagnostic test manufacturers are pushing FDA to get the guidance out, there is not a great deal of urgency because "there's not a lot of data that there have been problems in this space." Gottlieb gave his prediction during the annual meeting of the American Clinical Laboratory Association, held in Washington, D.C.

The FDA in 2010 proposed to regulate LDTs under what it considered its "enforcement discretion." The agency is currently working on guidance that will set up a regulatory framework for LDTs based on risk with exceptions for rare diseases, emerging biothreats, and emerging infectious diseases. The lab industry, however, is pushing for LDTs to be regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA). Legislation introduced by Rep. Michael Burgess (R-Texas) would set up a system within CLIA for LDT oversight (*see related story on page 1*).

In addition to setting up a regulatory framework, there are additional issues that FDA must grapple with in terms of LDT oversight, including staffing, possible use of a third party for inspection of LDTs, and grandfathering of existing LDTs.

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Philips Healthcare
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Quest Diagnostics
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