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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

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Government Joins Lawsuit Against Mayo Clinic Over Allegations of Billing Fraud

The U.S. Department of Justice has joined a lawsuit against Mayo Clinic (Rochester, Minn.) that accuses the clinic of submitting fraudulent claims to Medicare and Medicaid for thousands of pathology tests.

According to the *Pittsburgh Tribune-Review*, the complaint states that over the last 10 years, Mayo billed federal health care programs for certain pathology services that were not performed.

The lawsuit was originally filed in November 2007 by attorney and neurologist David Ketroser. U.S. District Judge Richard Kyle unsealed the allegations in late September after the Department of Justice joined the case.

"Over the course of the last 10 years, Mayo has routinely billed Medicare, Medicaid, and other federally sponsored health care programs for surgical pathology services that have not been performed," the complaint alleges.

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MedPAC Takes 'Go-Slow' Approach on Self-Referral Issues

The Medicare Payment Advisory Commission (MedPAC) continues to voice concern over the growth in volume and increased Part B spending associated with physician investment in ancillary services under the Stark self-referral exception. But it is not yet ready to make recommendations on the issues in its next report to Congress.

Instead, at its Sept. 13-14 meeting in Washington, D.C., the panel continued its discussion of a range of policy options to address overutilization of in-office ancillary services (IOAS), including anatomic pathology and clinical laboratory tests and to curb medically unnecessary testing. The options for diagnostic imaging and lab tests, outlined in the recent College of American Pathologists' *Statline*, included:

- ❑ Exclude services from the in-office exception unless provided on the same day as the visit;

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GOVERNMENT JOINS LAWSUIT, *from page 1*

The Department of Justice declined to litigate allegations that Mayo improperly obtained laboratory accreditation and didn't retain slides for a decade as required, but those claims have not been dropped from the lawsuit.

> ***"Mayo has fully complied with the law, and we believe our response to the billing error and our approach to surgical pathology represents 'a best practice.'"***
> ***– Mayo Clinic***

The Mayo Clinic has denied the allegations through a statement issued by spokesman Bryan Anderson.

"Upon discovering a billing error in 2007, Mayo corrected it and voluntarily refunded $242,711 to the federal government. The error was identified and corrected long before Mayo became aware that a sealed complaint had been filed and well before Mayo was notified that the Department of Justice was evaluating whether to become involved in the complaint. Mayo has fully complied with the law, and we believe our response to the billing error and our approach to surgical pathology represents 'a best practice.' Mayo's strong culture of compliance allowed us to identify the error, correct, and refund the money," the statement said.

LabCorp Acquisition of Genzyme Offers Long-Term Potential

Laboratory Corporation of America's (Burlington, N.C.) decision to acquire Genzyme Genetics (Cambridge, Mass.) has potential to boost LabCorp's long-term earnings although the deal will initially dilute earnings per share, say equity analysts.

LabCorp announced in September that it had agreed to pay $925 million for Genzyme Genetics, a business unit of Genzyme that performs reproductive and oncology testing in the United States. The transaction is expected to close by the end of 2010.

Specializing in esoteric testing, Genzyme Genetics performs approximately 1.5 million tests per year in its nine clinical laboratories. Its offerings range from maternal serum screening and prenatal diagnostics to carrier screening and postnatal testing services. Approximately 70 percent of the business consists of prenatal genetic testing, with the remainder focused on hematology and oncology.

The 20-year-old business, which also fields the nation's largest network of board-certified genetic counselors, reported revenue of $371 million in 2009. This puts the purchase price of the proposed transaction at approximately 2.5 times revenue, similar to the multiple paid by Quest Diagnostics in its 2007 acquisition of AmeriPath.

Kemp Dolliver, managing director of AvondalePartners LLC, sees other similarities with the AmeriPath acquisition, which he says has been disappointing for a

variety of reasons (additional information technology investment, disappointing cross-selling results, and in-sourcing by oncology practices).

"The Genzyme Genetics deal possesses many of the same risks, but with some differences," writes Dolliver in a research note. "First, we think the long-term (two to three year) cost synergies are more significant than advertised (relocating labs, removing duplicate infrastructure, etc.). Second, leukemia testing business is more complex and less susceptible to insourcing than AmeriPath's derm and GI tests."

The all-cash deal would bolster LabCorp's growing esoteric testing business, which in 2009 accounted for just over a third (36 percent) of revenue. The addition of Genzyme Genetics would bring LabCorp's esoteric testing revenue to more than 40 percent.

The announcement of the LabCorp deal comes four months after Genzyme announced its intention to explore "strategic alternatives" for the genetics business unit as well as its diagnostic products and pharmaceutical intermediates businesses.

Under terms of the agreement, LabCorp will purchase Genzyme Genetics in its entirety, including all testing services, technology, intellectual property rights, and its nine laboratories. LabCorp has also indicated that it will offer to retain the unit's approximately 1,900 employees, including senior management, when the deal closes.

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"The acquisition will substantially expand our capabilities in the reproductive, genetic hematology-oncology, and clinical trials central laboratory testing," said David King, chairman and CEO of LabCorp, on a conference call with investors and analysts. "The acquisition of Genzyme Genetics provides us with an unprecedented opportunity for revenue growth in our key strategic focus areas of esoteric testing and personalized medicine."

King went on to emphasize the revenue opportunity that the deal represents rather than the cost reductions that may be realized in combining the companies. "First of all, from selling the full LabCorp test menu of approximately 4,400 tests into the existing Genzyme Genetics accounts [and] secondly, offering the Genzyme Genetics brand and capabilities to existing LabCorp accounts," he noted.

Additionally, Genzyme accounts would gain access to LabCorp's network of patient services centers, while LabCorp stands to substantially boost its use of genetic counseling services, which it now offers on a limited basis. On the cost side, specimen collection and logistics are two areas believed to be significantly hindering the profitability of Genzyme Genetics and which LabCorp is expected to focus on immediately following the transaction close.

Genoptix Lowers Revenue Expectations for Third Quarter

Shares of Genoptix Inc. (Carlsbad, Calif.) fell in late September after the company said it expects revenue and case volume to decrease in the third quarter. The stock dropped 10.6 percent after the Sept. 21 announcement. During the session, it fell to a low of $13.93, its lowest share price since the stock began trading in October 2007.

In a presentation to investors, Genoptix said it expects third-quarter revenue and volumes to be 5 percent to 10 percent less than in the second quarter. Management cited continued macro challenges (including physician insourcing of lab tests, the high number of uninsured patients, and acquisition of physician practices by hospitals) as well as increased pressure from managed care given the labs' out-of-network status with most managed care providers.

Management also referenced a maturing market, with a stable hematology-oncology ordering base of between 1,300 and 1,350 ordering physicians, driven by an intensifying competitive environment.

The company reported $50.9 million in revenue in the second quarter. A decrease of 5 percent to 10 percent implies third-quarter revenues of $45.8 million to $48.4 million. Analysts were expecting $54 million on average, according to Thompson Reuters.

As a result of the announcement, equity research firm William Blair & Co. (Chicago) has lowered its revenue and earnings per share (EPS) expectation for 2010 and 2011. Blair now expects revenue of $190 million for 2010 (versus its previous estimate of $206 million) and $183 million for 2011 (versus its prior target of $232 million). EPS has been revised downward to $1.10 in 2010 (versus prior $1.18) and $1 in 2011 (versus prior $1.30).

Blair projects that Genoptix will continue to face volume pressure throughout 2010 and pricing pressure in 2011 as it goes in-network. The company maintains its market perform rating on the stock.

PAML Teams Up With Centura Health in Colorado

Spokane, Wash.-based Pathology Associates Medical Laboratories (PAML) has entered into an agreement with Centura Health, Colorado's largest health care network, to develop a lab outreach program named Colorado Laboratory Services.

Centura is Colorado's largest hospital and health care network, with 13 hospitals and more than 6,000 physician partners. Approximately 90 percent of the testing completed by Colorado Laboratory Services will be performed in Colorado, although PAML will serve as the reference lab for the remaining tests.

The agreement follows formation of a joint-venture lab in California. PAML and Providence Health & Services announced over the summer that they are forming a new clinical laboratory services company serving the San Fernando and neighboring communities (*LIR*, September 2010, p. 9). The newly formed California Laboratory Associates is scheduled to begin business early next year.

Anatomic Pathology and Cytology Market Growth May Be Slowing

The anatomic pathology and cytology markets are continuing to grow, although the pace appears to have slowed slightly when compared to that in recent years.

Washington G-2 Reports' estimates the combined anatomic pathology and cytology market totaled approximately $11.8 billion in 2008 and about $12.7 billion in 2009. The cytology market was estimated at $2.12 billion in 2008, rising approximately 3 percent, to $2.18 billion in 2009. The anatomic pathology market was estimated to be $9.67 billion in 2008, rising by 9.1 percent, to be worth $10.55 billion in 2009. That increase appears to be moderating in 2010.

Quest Diagnostics and LabCorp continue to dominate the anatomic pathology and cytology market. Quest Diagnostics reported an estimated 2008 anatomic pathology and cytology revenue of $1.16 billion, approximately 9.8 percent of the overall AP-cytology market, rising to approximately $1.254 billion in 2009, or about 9.9 percent of the total market. In 2008 LabCorp reported approximately $1.018 billion in AP-cytology revenue, or about 8.6 percent of the market. In 2009, LabCorp was projected to report $1.144 billion, or about 9 percent of the total anatomic pathology and cytology market.

Although Quest and LabCorp are responsible for almost 19 percent of the anatomic pathology and cytology market, 81 percent of the market is dominated by smaller independent laboratories, hospital labs, and pathology groups.

While the anatomic pathology market is expected to grow by at least 5 percent to 6 percent over the coming year, growth in cytology appears to be slowing even more (2 percent to 4 percent) as Pap smear testing decreases slightly because of the development of human papilloma virus (HPV) vaccines and molecular-based HPV testing.

The anatomic pathology market is showing its largest areas of growth in molecular-based testing and personalized laboratory testing on tumor tissues. Companies such as Aureon Laboratories and Genoptix are developing novel ways to diagnose and analyze tumor specimens for therapeutic guidance and, partly due to the high cost of the tests, are reporting significant revenue growth. Quest Diagnostics and LabCorp are aware of this trend as well and are placing considerable focus on dominating the market space for esoteric and molecular-based anatomic pathology tests.

Although Quest and LabCorp are responsible for almost 19 percent of the anatomic pathology and cytology market, 81 percent of the market is dominated by smaller independent laboratories, hospital labs, and pathology groups. Although there has been some consolidation of the industry, most notably by Quest Diagnostics' 2007 acquisition of AmeriPath, the overall AP and cytology market remains very fragmented. According to a Washington G-2 Reports' anatomic pathology market survey conducted in late 2007, 52 percent of the AP market comes from hospital inpatient and outpatient sources, while 48 percent comes from non-hospital outpatient sources.

Reimbursement

Reimbursement for anatomic pathology procedures continues to grow more and more complicated as the technical components (TC) rise and the professional components (PC) decrease. Although this places unusual competitive stress on pathology groups and hospitals, it gives laboratories a boost and has created an incentive for pathologists to open laboratories.

For example, in 1992 the professional component Medicare reimbursement for the most common anatomic pathology procedure, CPT 88305 (gross and microscopic exam, Level IV), was $63. This dropped to $44 in 1999 and remained stable for about three years before it dropped to around $41 or $42 from 2002 to 2006. It then dropped again in 2007, to about $38, then again in 2008, to $36, where it remained at approximately $37 in 2009.

The top seven anatomic pathology procedures are:

88305.....Level IV, Surgical Pathology

88342.....Immunohistochemistry

88185.....Flow cytometry

88312.....Special Stains; Group I for org.

88304.....Level III, Surgical Pathology

88313.....Special Stains; Group II, all other

88307.....Level V, Surgical Pathology

CPT 88305

The most frequently billed anatomic pathology procedure is CPT 88305, gross and microscopic exam, Level IV. CPT 88305 provides an overview of anatomic pathology services reimbursement trends. From 1992 to 2008 there had been a consistent overall decrease in the professional component reimbursement for CPT 88305, from a high of $63 in 1992 to a low of $36 in 2008. Although 2009 has shown a slight increase to $37, this is un-

Medicare Reimbursement for CPT 88305*, 2000-2009

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	10-yr CAGR**
Global	$76.15	$88.38	$93.39	$94.54	$95.21	$103.46	$103.46	$102.82	$102.85	$103.87	3.15%
Technical	31.12	44.00	52.85	53.77	53.77	61.39	61.39	64.77	66.65	$66.72	7.92%
Professional	45.03	44.38	40.54	40.83	41.44	42.07	42.07	38.05	36.20	$37.15	-1.91%

**Unadjusted for geographic practice cost differences **Compound annual growth rate*

Source: Medicare physician fee schedules, 2000 to 2009. CPT codes ©American Medical Association

likely to be a trend given the overall downward pressure on professional component reimbursements. From 1992 to 2009, professional component reimbursement for CPT 88305 has dropped by nearly 40 percent.

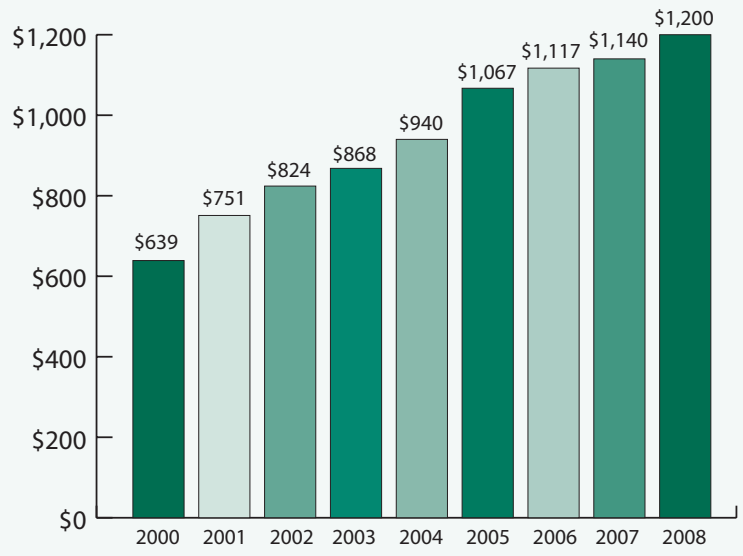
The chart below indicates how dramatically different the trends are for the technical and professional components of anatomic pathology services reimbursements as profiled for CPT 88305. From 2000 to 2009, the global reimbursement for CPT 88305 rose from $76.14 to $103.87, a 10-year compound annual growth rate (CAGR) of 3.15 percent. This has been driven by the technical component reimbursement, which in 2000 was $31.12 and rose in 2009 to $66.72, a 7.92 percent CAGR. However, the professional component reimbursement, which in 2000 was $45.04, dropped in 2009 to $37.15, a CAGR of -1.91 percent.

Between 2000 and 2008, national Medicare payments in total for CPT 88305, after denials, increased 87.8 percent, or a compound annual growth rate of 7.25 percent.

Between 2000 and 2008, the number of Medicare claims for CPT 88305 rose from 12,819,000 to 18,833,000, with a high in 2006 of 20,861,000. This constitutes a 46.9 percent increase in claims overall with a CAGR of 4.37 percent.

Editor's note: This article is excerpted from Washington G-2 Reports' latest research report. Lab Industry Strategic Outlook: Niche/Specialty Markets *is available for purchase for $995 for G-2 Reports subscribers. To order, go to* www.g2reports.com *and click on "Books and Reports."*

Medicare Expenditures for CPT 88305 for 2000-2008 ($ Millions)



Source: Washington G-2 Reports, CMS, and CodeMap LLC

SELF-REFERRAL ISSUES, *from page 1*

- Exclude from the exception unless the practice is clinically integrated;
- Reduce payments for tests performed by self-referring physicians where abusive utilization patterns are identified;
- Require prior authorization for advanced imaging services; and
- Package or bundle payment for testing services. "Bundling" refers to a per-episode-of-care payment for multiple procedures by several providers. "Packaging" refers to a single payment for multiple services by a single provider.

MedPAC members favored reducing payments where abusive utilization patterns are found but split on prior authorization from Medicare, which some warned created a new administrative burden that could impede access by patients to timely magnetic resonance imaging testing.

Lab, Pathology Groups Seek More Input On FDA Oversight of Lab-Developed Tests

As the U.S. Food and Drug Administration (FDA) prepares to tighten its regulatory grip on laboratory-developed tests (LDTs), 13 organizations across a broad spectrum of pathology and laboratory medicine providers in clinical and public health lab settings have called for a formal role in crafting a framework for expanded oversight.

In a recent letter to Jeffrey E. Shuren, M.D., J.D., director of the FDA Center for Devices and Radiological Health, the groups asked that the agency "host interactive meetings with stakeholders to discuss specific issues about the framework before [it] moves ahead with any proposal."

Expanded LDT oversight is a complex new initiative, the groups noted, and because of the operational challenges involved for those they represent, they want to be engaged in devising "solutions that will not disrupt innovation, and the value that LDTs bring to patient care and public health needs."

The 13 signatories, which included the American Clinical Laboratory Association and the College of American Pathologists, questioned whether the FDA had the additional resources required to do the job, with thousands of multiple similar, if not identical, LDTs submitted by many clinical labs for review. Oversight should be "clearly defined and balanced, because [it] is already in place by federal, state, and accreditation authorities."

LDTs and test kits requiring premarket review are also operationally different, the groups noted. Clinical labs offering LDTs provide a service, not a test kit that is sold nationwide for use in clinical settings. Another big challenge the groups cited is whether the FDA can implement its plan to increase oversight without disrupting patient access to cutting-edge technology.

HHS Shuts Down Secretary's Advisory Committee on Genetics

Eight years after being established to provide a forum for expert discussion and deliberation on issues related to developments in human genetics, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is no more.

The Department of Health and Human Services (HHS) recently announced that the Oct. 5-6 meeting of the SACGHS would be its last one, saying that the committee has addressed all of the major topics delineated in its charter, including the integration of genetic and genomic technologies into health care and public health; the clinical, public health, ethical, economic, legal, and societal implications of these technologies; and the impact of patent policy and licensing practices on their accessibility and availability.

Vorhaus notes that the decision to disband SACGHS is "curious" given that issues the committee investigated in detail have not been resolved with any meaningful degree of finality.

Over the past eight years, the SACGHS has tackled all of these issues, along with many others, notes Dan Vorhaus, an attorney with Robinson Bradshaw & Hinson and the lead blogger for *Genomics Law Report*. Some of the committee's most significant undertaking included (1) repeated efforts to encourage passage of the Genetic Information Nondiscrimination Act (GINA), (2) a 2008 report on the *U.S. System of Oversight of Genetic Testing*, (3) a 2010 report on *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, and (4) a 2010 report on *Direct-to-Consumer Genetic Testing* (links to all the reports are available at *http://oba.od.nih.gov/SACGHS/sacghs_home.html*).

Vorhaus notes that the decision to disband SACGHS is "curious" given that issues the committee investigated in detail have not been resolved with any meaningful degree of finality. GINA, while finally law, is still being implemented by regulatory agencies, and significant enforcement has yet to occur. Regulatory agencies have only recently begun to implement new policies designed to close the gaps in genetic testing oversight identified by SACGHS more than two years ago, says Vorhaus.

In addition, the issues identified in the committee's two most recent reports—on gene patents and DTC genetic testing—have yet to be meaningfully addressed by federal agencies and represent some of the most contentious issues in genetics law and policy today, he adds.

"As we head into a second decade of increasingly personal genomic science and services, there is every reason to expect that as our technological capabilities expand, so too will the number and complexity of issues we are forced to address," writes Vorhaus on his blog. "Our challenge is to continue to develop legal and policy strategies that are reflective and not reactionary—strategies that ensure the safety of individuals while encouraging the innovation necessary to realize the promise of personalized medicine. We hope that the announced disbanding of this experienced and distinguished committee does not signal a declining commitment on the part of [HHS] Secretary Sebelius or [National Institutes of Health] Director Collins to this challenge."

Eye ON IMAGING

New California Law Requires Reports Of Radiation Dose Levels, Excessive Exposure

California radiologists will be required to incorporate radiation dose levels in their reports under a measure signed into law in late September by Gov. Arnold Schwarzenegger. The measure requires that radiologists include in their reports the dose length product or the computed tomography dose index if the machine is able to calculate it.

The new law also requires health facilities to notify the state Department of Public Health any time a patient receives a radiation dose in an imaging scan that exceeds 20 percent of what was intended.

Effective July 1, 2012, the law requires that CT scanners receive accreditation by an organization approved by the Centers for Medicare and Medicaid Services (CMS) by Jan. 1, 2013.

The legislation comes in the wake of several incidents in California hospitals in which patients received dangerous overdoses of CT radiation. A year ago, officials at Cedars-Sinai disclosed that 260 patients who underwent CT brain perfusion scans to detect a stroke between February 2008 and September 2009 had developed rashes and hair loss and were at increased risk of developing cataracts. The radiation dosages were estimated at as much as eight times what the patients should have received, according to hospital statements.

In 2008, at Mad River Community Hospital in Humboldt County, a 2-year-old boy who had fallen out of bed received 151 scans during a 65-minute imaging test and an excessive overdose of radiation.

Under the new law, hospitals and clinics that use CT X-ray systems for human use will be required to record, if the CT systems are capable, the dose of radiation on every CT study produced during the administration of a CT examination, according to the California Legislative Counsel's digest.

The dose is required to be verified annually by a medical physicist unless the facility is accredited. The law also requires the facility administering the scan to report certain information about the scan to the department, the affected patient, and the patient's treating physician. Technical factors and dose must also be sent to the electronic picture archiving and communication systems.

The California incidents, as well as CT overdoses elsewhere in the nation, have prompted the U.S. Food and Drug Administration to issue new rules for how manufacturers of imaging devices set dosage controls on their machines.

Lab Index Falls a Little More in September

The G-2 Reports' Laboratory Stock Index fell another 3 percent in September. For the year, the index is down an unweighted average of 10 percent. In comparison, the Nasdaq composite is up about 4 percent, and the S&P 500 is up almost 3 percent.

Eleven of the 13 publicly traded lab companies tracked by the index posted gains during the period, while two experienced declines in their share prices.

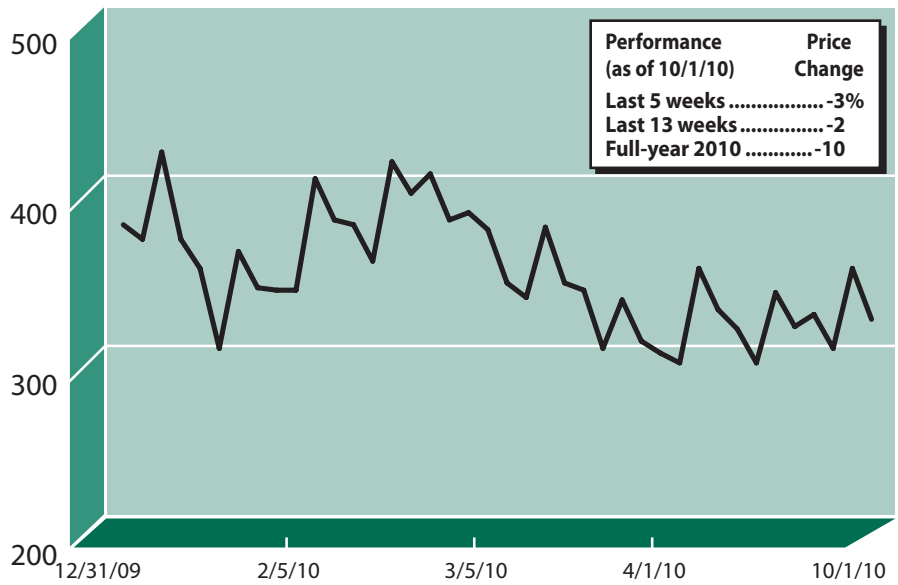
Shares of **Enzo Biochem** (New York) rose 6 percent to $3.89, giving it a market cap of $148 million. The company on Sept. 20 announced that it has streamlined its operations, which is anticipated to result in a reduction in annualized operating expenses of more than $4 million beginning in the first quarter of fiscal 2011. At Enzo Clinical Labs, the company expects gross margin improvements and expense reductions, primarily through selective workforce rationalization and process improvements, say officials.

Genzyme (Cambridge, Mass.) shares climbed 5 percent to $70.88. The company in September announced that it was selling its genetics division to LabCorp (*see related article on pg. 2*). In addition, French drug giant Sanoti-Aventis is continuing to pursue the parent company.

For up-to-the-minute laboratory and diagnostic firm data and financial news—go to **www.g2reports.com**

Shares of **Clarient** (Aliso Viejo, Calif.) rose 3 percent to $3.43 for a market cap of $300.9 million. The company recently announced that the U.S. Patent and Trademark Office and the European Patent Office have allowed patents covering the technology behind Clarient Insight Dx Mammostrat, a test designed to aid in the classification of the risk of recurrence of breast cancer following surgery and initial treatment.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 13 laboratory testing service stocks.*

Percent Price Change, Five weeks ended 10/1/10

	Price	Percent Change
UP		
Bio-Reference	$20.41	+4%
Clarient	3.43	+3
Enzo Biochem	3.89	+6
LabCorp	78.03	+4
Medtox	11.42	+2
Myriad	16.49	+5
Quest	50.13	+12
Psychemedics	9.41	+7
Orchid Cellmark	1.52	+10
Genzyme	70.88	+5
Neogenomics	1.10	+8
DOWN		
Genomic Health	13.46	-7
Genoptix	14.53	-18

INDUSTRY buzz

Quest: Prescription Opiate Use Up

More American workers and job applicants are testing positive for prescription opiates, according to U.S. general workforce data in the 2009 annual Drug Testing Index (DTI) released recently by Quest Diagnostics (Madison, N.J.). Results from more than 5.5 million urine drug tests reveal an 18 percent jump in opiate positives in the general U.S. workforce in a single year (2008 to 2009) and a more than 40 percent climb from 2005 to 2009.

In addition, 2009 post-accident drug tests found opiates up to four times more often than pre-employment tests (3.7 percent in post-accident as compared to 0.78 percent in pre-employment tests in the case of hydrocodone), suggesting that these drugs may be playing a role in workplace accidents.

The new DTI findings are consistent with a June report from the Drug Abuse Warning Network (DAWN), part of the U.S. Department of Health and Human Services. The DAWN study reported a 111 percent increase in the estimated number of emergency department visits for nonmedical use of opioid analgesics from 2004 to 2008 (from 144,600 to 305,900), and a 29 percent jump from 2007 to 2008.

References

American Clinical Laboratory Association 202-637-9466

Avondale Partners 615-467-3500

Centura Health 303-290-6500

Clarient 888-443-3310

Enzo Biochem 212-583-0100

Genoptix 760-268-6200

Genzyme 617-252-7500

LabCorp 800-334-5161

Mayo Clinic 507-284-2511

MedPAC 202-220-3700

PAML 800-541-7891

Quest Diagnostics 800-222-0446

William Blair & Co. 312-364-8951

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