

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PAYERS TARGET \$300 LAB TESTS; BIG PHARMA PRICES NEW CANCER DRUGS AT \$100K

The Medicare program has issued 101 additional molecular pathology procedure test codes established by the American Medical Association. The goal is to eliminate code stacking and set new reimbursement rates for molecular diagnostic tests starting in 2013.

The change will have the greatest effect on pharmacogenomic tests (e.g., KRAS, EGFR, BCR/ABL, etc.) used to make treatment decisions for expensive cancer drugs that don't cure anyone but just extend life for a few months.

Reference labs are being scrutinized for charging \$300 to \$500 to perform these tests. Meanwhile, the pharmaceutical companies have carte blanche to set their own prices. For example, Pfizer's new lung cancer drug Xalkori

(crizotinib) costs about \$115,000 per course of treatment, and Roche has priced its new melanoma drug Zelboraf (vemurafenib) at \$56,400. For more details, see *The Value of Pharmacogenomics*, pages 5-9.

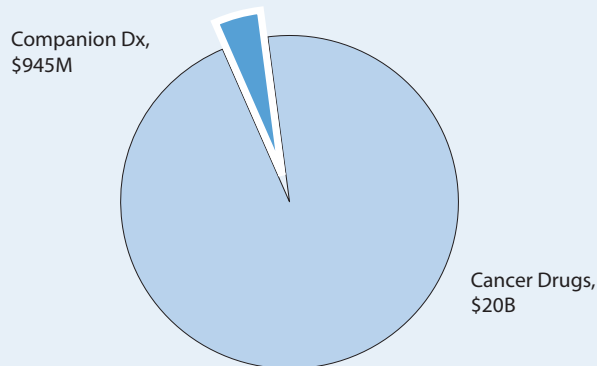
TAMPA PATHOLOGY LAB SETTLES ALLEGED TC/PC MEDICARE FRAUD CASE

Tampa Pathology Laboratory (TPL) and its owner, Jose SuarezHoyos, MD, have signed a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is part of a settlement that resolves allegations that the lab and a dermatologist client collaborated in a technical component/professional component (TC/PC) kickback scheme to defraud Medicare.

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U.S. Cancer Spending Comparison, 2011

An estimated \$20 billion was spent on cancer drugs in the United States last year versus \$945 million for related companion diagnostics.



Source: *Laboratory Economics*

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TPL SETTLES ALLEGED TC/PC MEDICARE FRAUD CASE (*cont'd from p. 1*)

The lawsuit (United States v. Jose SuarezHoyos, et al., case number 8:04-cv-933-T-24 EAJ) was originally filed in April 2004 as a whistleblower action by Alan Freedman, MD, who worked at Tampa Pathology Laboratory (TPL) from 2000 to 2003. The U.S. Attorney's Office intervened and filed an amended complaint in October 2010.

Federal prosecutors had alleged that the defendants had a TC/PC arrangement that allowed the dermatologist, Steven Wasserman, MD, to bill Medicare for professional slide interpretations, even though he did not do the work.

TPL said that it prepared slides for Wasserman and provided a diagnostic opinion. Wasserman would review the slide and either agree or disagree with the lab's professional interpretation. TPL billed for the technical component (CPT 88305-TC) and Wasserman billed for the professional component (CPT 88305-26).

TPL's medical director SuarezHoyos sought advice from Medicare on this type of arrangement in 1996. Medicare Provider Education responded to SuarezHoyos on behalf of Medicare and did not object, according to the defendants. TPL noted that while it disclosed in detail its proposed course of conduct in 1996, the U.S. Attorney's Office did not file any claim until nearly 15 years later.

Furthermore, the defendants noted that the Medicare program suffered no actual damages since it paid for a slide read interpretation and received a slide read interpretation. The defendants argued that provision of courtesy read pathology reports by a laboratory to a physician do not constitute remuneration under the Anti-Kickback Act.

The federal prosecutors said that Wasserman never actually reviewed the slides. From 2000-2005, Wasserman submitted more than 35,700 claims for CPT code 88305-26 and received more than \$3.5 million in reimbursement from Medicare, while TPL submitted the same number of claims for 88305-TC and received \$3.9 million from Medicare, according to the complaint.

In addition, the government said that Wasserman increased the number of biopsies he performed as a result of financial incentives. In 1997, the year in which Wasserman and TPL entered into the kickback agreement, the number of biopsies Wasserman performed nearly doubled from what he had performed annually in each of the previous six years, according to the lawsuit.

Federal prosecutors claimed that TPL hid the fraud from Medicare by preparing pathology reports with a signature block for Wasserman, suggesting that he had interpreted the slide and drafted the report.

In addition, prosecutors said there simply was not enough time in the day for Wasserman to physically perform all the procedures he billed. For example, the lawsuit cited November 2, 2004, when Wasserman billed Medicare for 77 office visits, four time-consuming tissue transfers, more than 100 biopsies and reading 58 slide specimens.

On December 15, 2011, TPL and SuarezHoyos agreed to a settlement and the case was dismissed. The corporate integrity agreement was made public on February 1. Under the 39-page agreement, TPL said it would appoint a compliance officer and a compliance committee to ensure it does not violate the anti-kickback statute and/or the Stark Law. The lab must also set up a whistleblower program.

Finally, the settlement requires TPL and SuarezHoyos to pay their own attorney's fees and court costs for the seven-year legal battle.

No whistleblower bounty for Freedman was mentioned in the settlement.

Wasserman, who continues to practice dermatology in Florida, was not part of the settlement and federal prosecutors are still pursuing their claims against him.

Laboratory Economics asked Jane Pine Wood, member at the law firm McDonald Hopkins, for her opinion on courtesy read TC/PC arrangements. Wood believes these types of arrangements violate both the anti-kickback law and the Stark law. She advises pathologists to avoid TC/PC arrangements that involve courtesy reads.

PATHGROUP BUYS ATLANTA DERMATOPATHOLOGY

PathGroup (Nashville, TN) has purchased Atlanta Dermatopathology (AD)—both the lab and the professional group—for an undisclosed price effective March 1. PathGroup chairman Ben Davis, MD, says the AD laboratory will be maintained as a standalone operation in its current location. AD's previous owners, Drs. Petra Milde, Michael Lee and Quyn Rahman, will continue to provide professional services.

Davis says PathGroup will expand AD's breadth of service to the dermatology market in Georgia. Likewise, he says AD's three pathologists will bring additional expertise to PathGroup's existing dermatopathology services in Nashville.

This marks the third acquisition by PathGroup in the past 12 months. PathGroup purchased Associates in Laboratory Medicine (Dalton, GA), with two pathologists, in August 2011, and Pathology & Forensic Consultants (Fort Wayne, IN), with four pathologists, in December 2011.

LABORATORY INDUSTRY MOVERS & SHAKERS

Bostwick Laboratories (Richmond, VA) has hired **Martin Stefanelli** as chief executive. Former CEO **David Bostwick, MD**, will continue as chief medical officer. Stefanelli was formerly chief operating officer at **Aurora Diagnostics**.

Nate Headley, former chief executive at Spectrum Laboratory, is now managing director for **Quest Diagnostics** in Chicago.

Geoffrey Gottlieb, MD, has been named co-director for dermatopathology at **StrataDx** (Lexington, MA). Gottlieb was formerly medical director at **AmeriPath's Ackerman Academy of Dermatopathology**.

Bradly Clark, MD, has been named medical director of the new Women's Health Laboratories division at **Poplar Healthcare** (formerly named GI Pathology). Clark was previously vice-chair for anatomic pathology at **Maimonides Medical Center** (Brooklyn, NY).

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COMPENSATION TRENDS FOR PATHOLOGISTS AND THEIR CLIENTS

Median compensation for pathologists grew by 5.3% per year between 2005 and 2010 to \$354,917, according to The American Medical Group Association's 2011 Compensation and Financial Survey.

The table below presents median gross charges for four key referral sources for pathologists (dermatology, Ob/Gyn, gastroenterology and urology). Compensation grew fastest for dermatologists, 4.7% per year to \$386,068, and grew slowest for Ob/Gyns, 2.2% per year to \$302,638.

Many factors influence physician compensation, including market demand for certain specialists and new technology or procedures that impact physician productivity.

Median Physician Compensation 2005-2010

Specialty	2010	2009	2008	2007	2006	2005	5-Year CAGR
Pathology (M.D. only)	\$354,917	\$354,750	\$344,195	\$310,025	\$288,731	\$274,792	5.3%
Dermatology	386,068	375,176	350,627	344,847	316,473	306,935	4.7%
Gastroenterology	415,872	405,000	389,385	374,674	356,388	344,200	3.9%
Urology	413,746	413,941	389,198	383,029	365,999	349,811	3.4%
Ob/Gyn-General	302,638	295,761	294,190	283,110	270,793	271,273	2.2%

Source: AMGA

Annual gross charges for dermatologists grew by 6% per year between 2005 and 2010 to a median of \$1.586 million per dermatologist, according to the AMGA survey. Over this time frame, median gross charges per pathologist increased by 0.5% per year to \$1.145 million.

Median Gross Charges 2005-2010

Specialty	2010	2009	2008	2007	2006	2005	5-Year CAGR
Dermatology	\$1,586,069	\$1,451,081	\$1,375,405	\$1,278,430	\$1,226,808	\$1,184,430	6.0%
Ob/Gyn-General	1,196,029	1,154,407	1,151,148	1,102,417	1,071,669	1,023,106	3.2%
Gastroenterology	1,911,359	1,913,137	1,862,452	1,739,170	1,739,414	1,630,932	3.2%
Urology	1,751,208	1,876,901	1,850,882	1,793,582	1,724,219	1,610,700	1.7%
Pathology (M.D. only)	1,145,417	1,350,017	1,298,110	1,263,743	1,151,442	1,120,187	0.5%

Source: AMGA

Median net collections were highest for dermatologists (\$915,812), followed by gastroenterologists (\$831,646), urologists (\$768,289) and Ob/Gyns (671,783). Net collections were lowest for pathologists (\$495,456).

The AMGA survey is based on data from 239 medical groups (207 multispecialty and 32 single-specialty groups) representing 51,700 physicians. Forty-percent of the surveyed groups are physician-owned, 34% health system, 17% hospital, 2% university/academic and 7% other.

THE VALUE OF PHARMACOGENOMICS *(continued from page 1)*

New drugs get patent protection for 20 years starting from the date they are filed with the U.S. Patent and Trademark Office. Because pharmaceutical companies file even before clinical trials, by the time a new drug hits the market, it might have only 10 years of patent protection left.

However, pharmaceutical companies can set their own prices once a new drug is cleared by the FDA. The FDA does not regulate prices, and Medicare is banned from considering price when deciding whether to cover treatments. Private healthcare insurers can negotiate prices, but they have limited leeway to exclude drugs from coverage based on price.

As a result, the price of cancer drugs is soaring and has little relation to their effectiveness.

Pfizer's Inlyta for Kidney Cancer

For example, on January 27, 2012, the FDA cleared Inlyta (axitinib), made by Pfizer, for the treatment of advanced kidney cancer.

Big Cost: Inlyta costs \$8,900 per month and the average duration of treatment is five to six months. The total cost for a course of treatment is approximately \$50,000 per patient.

Trial and Error: There is no PGx test linked with Inlyta; prescriptions are based on trial and error. The starting oral dose of Inlyta is 5 mg twice daily. Patients who tolerate Inlyta for at least two consecutive weeks with no adverse reactions can have their dose increased. Patients that do suffer an adverse reaction will have their dosage reduced. More than 20% of patients that are prescribed Inlyta suffer an adverse reaction, which can include diarrhea, hypertension and fatigue.

Small Benefit: Clinical trials showed that Inlyta slowed down the progression of cancer by two months (median progression-free survival of 6.7 months vs. 4.7 months) compared with the standard existing treatment (Nexavar/sorafenib).

FDA-Approved Cancer Drugs in 2011-2012

Brand Drug	Generic Name	Pharma Manufacturer	FDA Clearance	Cancer Type	Treatment Price	Survival Benefit*
Erivedge	vismodegib	Roche/Curis	Jan-12	skin	\$75,000	Not avail.
Inlyta	axitinib	Pfizer	Jan-12	kidney	\$50,000	2.0 mos.
Erwinaze	asparaginase	EUSA Pharma	Nov-11	leukemia	\$150,000	Not avail.
Xalkori	crizotinib	Pfizer	Aug-11	lung	\$115,000	Not avail.
Zelboraf	vemurafenib	Roche/Genentech	Aug-11	melanoma	\$56,000	3.7 mos.
Adcetris	brentuximab	Seattle Genetics	Aug-11	lymphoma	\$108,000	Not avail.
Sutent	sunitinib	Pfizer	May-11	pancreatic	\$46,000	4.8 mos.
Afinitor	everolimus	Novartis	May-11	pancreatic	\$68,000	6.4 mos.
Zytiga	abiraterone	J&J	Apr-11	prostate	\$40,000	3.9 mos.
Sylatron	peginterferon	Merck	Apr-11	melanoma	\$60,000	Not avail.
Caprelsa	vandetanib	AstraZeneca	Apr-11	thyroid	\$100,000	6.2 mos.
Yervoy	ipilimumab	Bristol-Myers	Mar-11	melanoma	\$120,000	3.6 mos.

*Survival benefit compares additional months of survival gained by taking each cancer drug versus a placebo or current standard of treatment.

Source: *Laboratory Economics*

Over the past three years, the FDA has approved 30 cancer drugs, but only two (or 6%) have had pharmacogenomic test information included in their labels. Both drugs—Xalkori and Zelboraf—were approved in August 2011.

Pfizer's Xalkori for Lung Cancer

Xalkori (crizotinib), made by Pfizer, was cleared by the FDA for the treatment of non-small cell lung cancer (NSCLC) on August 26, 2011.

Cost: Xalkori costs \$9,600 per month and the average duration of treatment is 12 months. The total cost for a course of treatment is approximately \$115,000 per patient.

PGx test: The FDA approved Xalkori in parallel with Abbott Molecular's Vysis ALK FISH Test. The test identifies the 5% of NSCLC patients with the ALK gene mutation. These patients can benefit from Xalkori. Abbott sells the Vysis ALK FISH Test kit to labs for about \$250. Reference labs charge \$300 to \$600 to perform the test.

Benefit: Clinical studies showed that in ALK-positive patients treated with Xalkori, overall survival was 77% after one year and 64% after 2 years. ALK-positive patients who were not treated with Xalkori had an overall survival of 73% after one year and 33% after two years. PGx testing for Xalkori helps identify those patients that can be helped by this expensive drug and avoid adverse reactions for those patients that can not benefit. The most common side effects include vision disorders, nausea and diarrhea.

Cost vs. Benefit: It takes 20 PGx tests to discover one of the 5% of NSCLC patients who is ALK-positive. So spending \$10,000 for 20 tests (~\$500 each) leads to a \$115,000 drug treatment decision.

Roche's Zelboraf for Melanoma

Zelboraf (vemurafenib), made by Roche's subsidiary Genentech, was cleared by the FDA for the treatment of late-stage melanoma on August 17, 2011.

Cost: Zelboraf costs approximately \$56,400 for a six-month course of treatment.

PGx test: In conjunction with its approval of Zelboraf, the FDA approved a PGx test made by Roche that determines whether a patient has the BRAF V600E mutation. It was the first-ever joint FDA approval of a drug and a PGx test. Approximately 50% of melanoma patients have the BRAF V600E mutation and can be helped by Zelboraf. Reference labs charge an average of about \$250 to perform BRAF mutation analysis.

Benefit: In the phase III clinical trial, progression-free survival was 5.3 months for patients on Zelboraf versus 1.6 months for patients on standard chemotherapy.

Cost vs. Benefit: It takes two PGx tests to discover one melanoma patient that has the BRAF V600E mutation. So spending \$500 for two tests (~\$250 each) leads to a \$56,400 drug treatment decision.

Outlook for 2012

The FDA is expected to approve about 10 new cancer drugs this year. But only one or two will be accompanied by PGx tests. These include Roche's pertuzumab for HER2-positive breast cancer patients, which has been given priority review by the FDA.

PHARMACOGENOMIC TEST SUMMARY

Cancer drugs typically cost between \$5,000 and \$10,000 per patient per month. Reference labs charge an average of roughly \$300 to \$500 for PGx tests that help guide cancer treatment decisions.

There are currently 19 cancer drugs on the market with companion PGx tests. However, the PGx testing market for cancer is dominated by a handful of drugs and tests. These include Herceptin (HER2), Gleevec (BCR/ABL and c-Kit), Erbitux (KRAS), Tarceva (EGFR), Camptosar (UGT1A1) and tamoxifen (ER/PR).

The real growth in pharmacogenomics is likely to occur in the next 3-5 years.

Brand Drug	Generic Name	Pharma Manufacturer	Cancer Type	Treatment Cost per Month	Biomarker/ PGx Test	Reference Laboratory Test Cost
Aromasin	exemestane	Pfizer	breast	\$500	ER/PR	\$200-\$400
Camptosar	irinotecan	Pfizer	colorectal	\$7,500	UGT1A1	\$150-\$300
cisplatin	cisplatin	generic	bladder/ testicular/ ovarian	\$300	TPMT	\$75-\$150
Eribitux	cetuximab	Eli Lilly/ Bristol-Myers	colorectal	\$7,500	KRAS	\$300-\$600
Femara	letrozole	Novartis	breast	\$500	ER/PR	\$200-\$400
Gleevec (1)	imatinib	Novartis	leukemia	\$4,500	BCR/ABL	\$150-\$400
Gleevec (2)	imatinib	Novartis	gastro	\$4,500	c-Kit	\$100-\$300
Herceptin	trastuzumab	Roche/ Genentech	breast	\$4,000	HER2	\$200-\$400
Iressa	gefitinib	AstraZeneca	lung	\$2,500	EGFR	\$300- \$1,000
Purinethol	mercaptopu- rine	Teva Pharma	leukemia	\$150	TPMT	\$75-\$150
Sprycel	dasatinib	Bristol-Myers	leukemia	\$7,000	BCR/ABL	\$150-\$400
tamoxifen	tamoxifen	generic	breast	\$100	ER/PR	\$200-\$400
Tarceva	erlotinib	Roche/ Genentech	lung	\$2,500	EGFR	\$300- \$1,000
Tasigna	nilotinib	Novartis	leukemia	\$7,500	BCR/ABL	\$150-\$400
Trisenox	arsenic trioxide	Cephalon	leukemia	\$8,000	PML/RAR	\$100-\$300
Tykerb	lapatinib	GlaxoSmithKline	Breast	\$5,500	HER2	\$200-\$400
Vectibix	panitumumab	Amgen	colorectal	\$7,500	KRAS	\$300-\$600
Xalkori	crizotinib	Pfizer	lung	\$9,600	ALK	\$300-\$600
Zelboraf	vemurafenib	Roche/ Genentech	melanoma	\$9,400	BRAF	\$150-\$300

Source: *Laboratory Economics*

DRUG-DIAGNOSTIC PARTNERSHIPS ON THE RISE

Drug companies were initially reluctant to abandon their blockbuster approach (*see page 7*) and switch to targeted therapies aimed at smaller patient populations. But the FDA is increasingly requiring validated PGx tests prior to giving market clearance to new cancer drugs. As a result, drug companies are actively seeking to form partnerships with diagnostic test makers. Over the past year, more than 20 partnerships have been announced.

Selected Pharmacogenomic Partnerships

Diagnostics Partner	Pharma. Partner	Partnership Goal	Cancer Type	Deal Date
Abbott Molecular	Merck	Develop FISH-based companion diagnostic test for investigational cancer therapy.	Unspecified	Mar-12
Foundation Medicine	Array BioPharma	Will use FM's gene sequencing test to help develop Array's targeted therapies.	Unspecified	Mar-12
Dako	Amgen	Develop PGx test for an unnamed cancer drug in clinical development.	Unspecified	Feb-12
Siemens	Tocagen	Develop PGx test for clinical trials for viral gene therapy (Toca 511 & Toca FC).	Brain	Feb-12
Qiagen	Pfizer	Develop PGx test for CDX-110, a vaccine being developed by Pfizer for brain cancer.	Brain	Feb-12
Roche/Ventana	Pfizer	Develop an automated test for ALK gene rearrangements for Pfizer's Xalkori (crizotinib).	Lung	Jan-12
Roche/Ventana	Syndax	Develop a PGx test for Syndax's lead developmental product entinostat.	Lung	Jan-12
Roche/Ventana	Aeterna Zentaris	Develop a PGx test for Aeterna's targeted compound AEZS-108.	Multiple	Jan-12
Foundation Medicine	Sanofi	Develop PGx tests for select Sanofi oncology drug candidates.	Unspecified	Jan-12
Siemens	Tocagen	Develop PGx test for clinical trials for viral gene therapy (Toca 511 & Toca FC).	Brain	Feb-12
Dako	Roche/Genentech	Collaborate on FDA submissions for HER2 tests to identify cancer patients eligible for Roche's breast cancer drug pertuzumab.	Breast	Dec-11
Abbott Molecular	GlaxoSmithKline	Develop a PCR test to screen NSCLC tumors for the PRAME antigen.	Lung	Nov-11
Life Technologies	GlaxoSmithKline	Develop a PGx test to be used with GSK's candidate cancer immunotherapy MAGE-A3	Lung	Nov-11
Dako	Bristol-Myers	Develop PGx tests for drug candidates under development by Bristol-Myers Squibb.	Unspecified	Nov-11
Qiagen	Eli Lilly	Develop a PGx test for Eli Lilly's investigational compound for leukemia.	Leukemia	Sep-11
Qiagen	Pfizer	Develop a PGx test for Pfizer's investigational compound dacomitinib for NSCLC.	Lung	Aug-11
Roche	Clovis Oncology	Develop an EGFR test for CO-1686, which is in clinical investigation for NSCLC.	Lung	Jun-11
Roche	Merck	Expand use of AmpliChip p53 assay to select patients for Merck's cancer clinical trials.	Unspecified	Jun-11
Foundation Medicine	Celgene	Will use FM's gene sequencing test to recruit patients for Celgene drug candidate trials.	Unspecified	May-11
Agendia	AstraZeneca	Assist AZ in identifying specific colorectal cancer subtypes in order to develop targeted therapies.	Colorectal	May-11
MolecularMD	Ariad Pharma.	Develop a PGx test for Ariad's candidate drug ponatinib for chronic myeloid leukemia.	Leukemia	Mar-11
Invivoscribe	Novartis	Develop a PGx test for Novartis' investigational acute myeloid leukemia drug midostaurin.	Leukemia	Feb-11
bioMerieux	Ipsen	Identify PGx opportunities for hormone-dependent cancers, such as prostate cancer.	Prostate and others	Feb-11
Beckman Coulter	Transgene	Develop a PGx test to select clinical trial patients to be treated with TG4010 for NSCLC.	Lung	Jan-11

Source: *Laboratory Economics*

A NEW MODEL FOR MARKETING DRUGS

It's understood that PGx testing holds the potential to save billions of dollars per year by helping doctors select the patients that can be helped by a drug, while avoiding prescriptions to patients that won't benefit.

Less understood is the potential that PGx testing has to trim the marketing budgets at pharmaceutical companies. Drugs targeted at specific patient populations don't need to be marketed because the associated PGx testing gives doctors a straightforward "yes" or "no" for prescription decisions.

Under the still-prevalent blockbuster model, pharmaceutical companies spend an estimated \$25+ billion dollars per year on marketing in the United States. Billions are spent on sales reps, sample giveaways, advertising and political lobbying, all intended to influence the decisions made by doctors, patients and politicians.

Sales Reps and Free Samples

Drug companies employ approximately 75,000 sales reps in the United States, according to the consulting firm ZS Associates (Evanston, IL). That's about one sales rep for every 10 physicians. Pharmaceutical companies pay these reps an estimated \$10 billion per year to make sales visits to doctors. In addition, sales reps hand out \$10+ billion worth of free samples to doctors each year, according to the market research company CAM. The combined \$20+ billion for sales reps and free samples is equal to a whopping \$15,000 per doctor.

Pharmaceutical Marketing Expenditures

Samples	\$10 billion
Sales reps/detailing	\$10 billion
DTC advertising	\$4 billion
Journal advertising	\$500 million
Political lobbying.....	\$200 million
Total.....	~\$25 billion

Source: *Laboratory Economics'* estimates based on data from CAM, CRP, IMS and Kantar Media

Direct-to-Consumer Advertising

Pharmaceutical firms spend about \$4 billion per year on direct-to-consumer TV, Internet and magazine advertising, according to Kantar Media.

Advertisements in Medical Journals

Pharmaceutical companies spend about \$500 million per year on advertisements in U.S. medical journals, such as *The New England Journal of Medicine* and *JAMA*, according to IMS Health. A full-page advertisement in *JAMA* currently costs about \$13,000, while *NEJM* charges \$12,000.

Political Lobbying

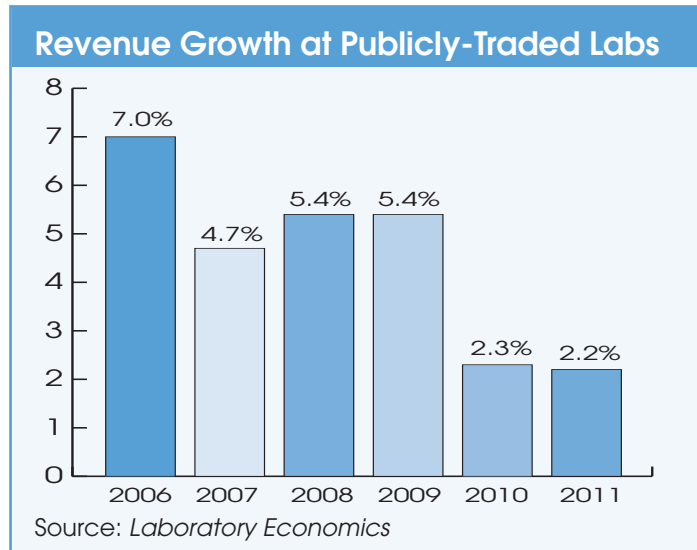
The pharmaceutical industry employs more than 1,500 lobbyists—that's an average of three lobbyists for each of the 535 members of the House and Senate. Lobby spending by the pharmaceutical industry averages more than \$200 million per year. It peaked at \$272 million in 2009, according to the Center for Responsive Politics (Washington, DC). This was the year leading up to the Patient Protection and Affordable Care Act, which was signed into law by President Obama on March 23, 2010.

Conclusion

Under the emerging "nichebuster" drug model, the added cost of PGx testing should be more than offset by fewer but more precise prescriptions, less adverse drug reactions and smaller pharmaceutical advertising budgets.

PUBLICLY-TRADED LABS GREW 2.2% IN 2011

Twelve publicly-traded labs grew their revenue by 2.2% to \$15.3 billion in 2011 (after adjustments for acquisitions), according to financial reports collected by *Laboratory Economics*. Over the past five years, growth has ranged between 2.2% and 7%. Excluding Quest Diagnostics and LabCorp, 10 publicly-traded labs grew by 12% last year. Revenue growth was fastest at three cancer-testing lab companies—CombiMatrix (up 28%), Transgenomic Inc. (up 60%), NeoGenomics (up 27%) and Bio-Reference Labs (up 22%).



Revenue Growth at 12 Publicly-Traded Lab Companies (\$000)

Company	Revenue 2011	Revenue 2010	Reported Change	Pro Forma Change*
Quest Diagnostics	\$7,511,000	\$7,368,925	1.9%	-0.3%
LabCorp	5,542,000	5,003,900	10.8%	2.0%
Sonic Healthcare USA ¹	863,500	738,590	16.9%	3.0%
Bio-Reference ²	558,642	458,024	22.0%	21.5%
Myriad Genetics ³	402,084	362,648	10.9%	10.9%
Genomic Health	206,111	178,101	15.7%	15.7%
Medtox Scientific	108,149	97,101	11.4%	11.4%
Enzo Clinical Labs ⁴	52,762	44,178	19.4%	19.4%
NeoGenomics	43,484	34,371	26.5%	26.5%
Transgenomic Inc.	31,971	20,048	59.5%	59.5%
Psychemedics	24,090	20,109	19.8%	19.8%
Combimatrix	4,558	3,554	28.2%	28.2%
Total, 12 companies	\$15,348,351	\$14,329,549	7.1%	2.2%
Total, 10 companies (excluding Quest and LabCorp)	\$2,295,351	\$1,956,724	17.3%	12.0%

*Pro forma change is estimated by Laboratory Economics after adjustments for acquisitions.

¹Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2011; ²Bio-Reference's revenue is for fiscal year ended October 31, 2011; ³Myriad Genetics' revenue is for fiscal year ended June 30, 2011;

⁴Enzo's revenue is for lab services only for fiscal year ended July 30, 2011.

Source: *Laboratory Economics* from company reports

COMMERCIAL LABS AVERAGE \$216K REVENUE PER EMPLOYEE

Commercial lab companies averaged \$216,246 in revenue per employee in 2011, according to an *LE* analysis of financial data from 14 commercial lab companies. On an unweighted-average-basis, revenue per employee was \$183,521.

Average annual revenue per employee at four commercial clinical labs was \$178,236. Bio-Reference was highest at \$199,729 per employee. Enzo Clinical Labs was lowest at \$158,444.

Revenue per employee at eight esoteric/pathology lab companies averaged \$242,091. Genomic Health was highest at \$403,348 per employee. Combimatrix was lowest at \$101,289.

At two drugs-of-abuse testing companies, revenue per employee averaged \$188,888. Psychemedics averaged \$215,634 and Medtox was \$162,142.

Revenue per Employee at 14 Commercial Labs

<i>Lab Companies</i>	<i>Full-Year 2011 Revenue (\$000)</i>	<i>Number of Employees</i>	<i>Revenue per Employee</i>
Quest Diagnostics	\$7,511,000	42,000	\$178,833
LabCorp	5,542,000	31,500	175,937
Bio-Reference	558,642	2,797	199,729
Enzo Clinical Labs	52,762	333	158,444
Average			\$178,236
<i>Esoteric/Pathology Labs</i>			
Myriad Genetics	\$402,084	1,057	\$380,401
Aurora Diagnostics*	283,500	1,125	252,000
Genomic Health	206,111	511	403,348
PathGroup	125,000	700	178,571
ProPath	75,000	300	250,000
NeoGenomics	43,484	239	181,941
Combimatrix	4,558	45	101,289
Transgenomic Inc.	31,971	169	189,178
Average			\$242,091
<i>Drugs-of-Abuse Testing Labs</i>			
Medtox Scientific	\$108,149	667	\$162,142
Psychemedics	24,090	119	215,634
Average			\$188,888
Overall Unweighted Average			\$216,246
Overall Weighted Average	\$14,968,351	\$81,562	\$183,521

*Revenue for Aurora Diagnostics is annualized from the six months ended June 30, 2011.

Note: Calculations were based on total number of employees at each company, including all technical, administrative and sales and marketing staff. Source: *Laboratory Economics* from company reports

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LAB STOCKS UP 14% YEAR TO DATE

Ten lab stocks have risen by an unweighted average of 14% so far this year. The combined market capitalization for the group is up 1% to \$22.3 billion. Shares of Bio-Reference Labs have performed best (up 40%). In comparison, the S&P 500 Index is up 12% and the Nasdaq is up 17% year to date through March 16. In terms of valuation, Quest Diagnostics is currently trading at 1.3x its annual revenue and 10.5x its trailing EBITDA (earnings before taxes, interest, depreciation and amortization). LabCorp trades at 1.6x annual revenue and 8.6x trailing EBITDA.

Company (ticker)	Stock Price 3/16/12	Stock Price 12/30/11	2011 Price Change	Market Capitalization (\$ millions)	Enterprise Value/ EBITDA	Price/ Sales
Bio-Reference (BRLI)	\$22.75	\$16.27	40%	\$632	8.1	1.1
CombiMatrix (CBMX)	1.75	2.00	-13%	19	NA	3.8
Enzo Biochem (ENZ)	2.71	2.24	21%	105	NA	1.0
Genomic Health (GHDX)	31.48	25.39	24%	930	53.3	4.5
LabCorp (LH)	90.33	85.97	5%	8,780	8.6	1.6
Medtox Scientific (MTOX)	15.09	14.05	7%	135	9.7	1.2
Myriad Genetics (MYGN)	25.37	20.94	21%	2,138	9.6	4.9
Neogenomics (NGNM)	1.68	1.40	20%	75	48.5	1.7
Psychemedics (PMD)	9.87	9.10	8%	52	7.5	2.1
Quest Diagnostics (DGX)	59.81	58.06	3%	9,470	10.5	1.3
Unweighted Averages			14%	\$22,336	19.5	2.3

Source: Bloomberg

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The U.S. Anatomic Pathology Market Forecast & Trends 2012

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- Medicare claims data for 30 key pathology codes
- Liquid Pap and HPV test trends and pricing data
- In-office histology lab trends
- Detailed analysis of the pharmacogenomic market
- Digital pathology market size and trends
- Medicare and managed care reimbursement stats
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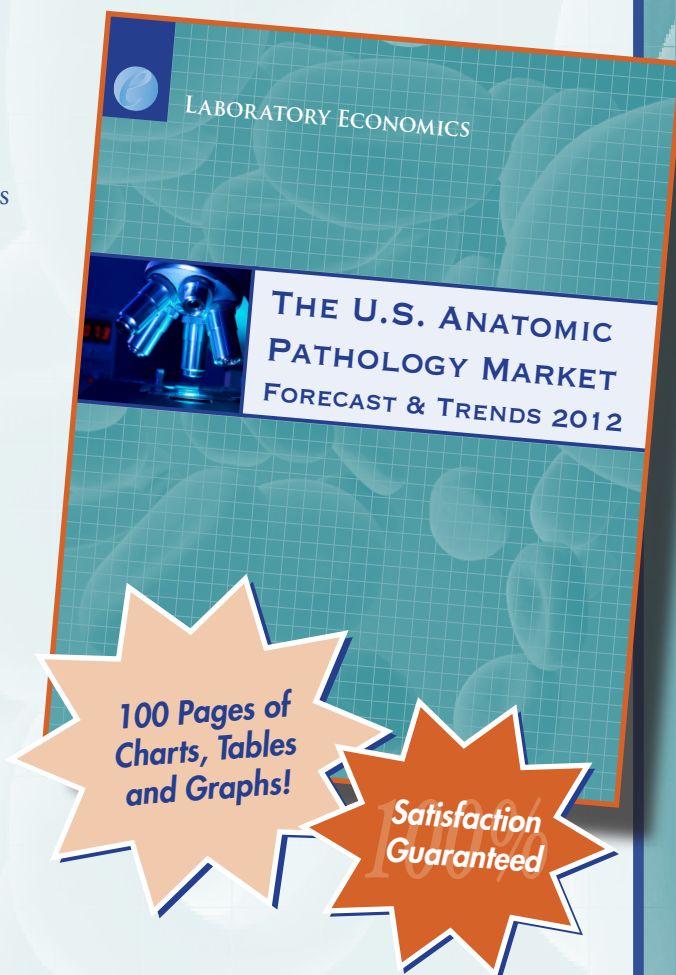
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