Jondavid Klipp, Editor, labreporter@aol.com

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FLORIDA BILL WOULD SQUASH FALSE CLAIMS CASE AGAINST QUEST AND LABCORP

A controversial bill sponsored by Florida State Representative Jay Trumbull (R) seeks to retroactively define the term "usual and customary" for the purposes of billing Florida's Medicaid program. If passed into state law, HB 421 would effectively kill a major false claims lawsuit that Florida Attorney General Pam Bondi is aggressively pursuing against Quest Diagnostics and LabCorp. *Continued on page 2.*

SENATORS PRESSURE CMS TO ADD HOSPITAL LABS AND DELAY PAMA REPORTING

Sens. Orrin Hatch (R-Utah) and Ron Wyden (D-Oregon) on January 6 urged the Centers for Medicare and Medicaid Services (CMS) to establish a more expansive methodology for identifying laboratories that must report private payment rates and give labs more time before they have to begin reporting the payment rates. The proposed payment rule effectively excludes hospital labs, which would result in lower prices once the new payment system is finalized. *Continued on page 11.*

Special New Year's Report:

LAB EXECS SHARE OUTLOOK FOR 2016

For an inside look at what may be in store for the clinical lab and pathology business this year, *Laboratory Economics* interviewed the top executives at a diverse group of 10 lab companies. Among the anecdotal trends detected are 1) continuation of the long-term trend for double-digit volume growth in molecular genetics; 2) strong demand for clinical trials and research lab testing for targeted oncology drugs being developed; and 3) continued acquisitions of primary care groups by health systems with redirection of lab test orders to hospital-based labs. Meanwhile, some labs are hoping for the long-awaited takeoff of the direct-to-consumer testing market—a market that has been predicted for the past 20 years to be the next big thing in lab testing. *Continued on pages 5-9.*

BOSTWICK STARTS NEW LAB COMPANY

David Granger Bostwick, MD, 61, has departed Bostwick Laboratories and started a new anatomic pathology lab named Granger Diagnostics (Richmond, VA). Like Bostwick Labs, which Dr. Bostwick founded in 1999, Granger Diagnostics will focus on prostate cancer. *Continued on page 3.*

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FLORIDA BILL WOULD SQUASH FALSE CLAIMS CASE (*cont'd from p. 1*)
The false claims lawsuit (case #2007-CA-003549—see *LE* September 2015) was originally filed in 2007 by whistleblower Chris Riedel. In 2013, Attorney General Bondi intervened in the lawsuit alleging that Quest and LabCorp defrauded Florida by charging the state's Medicaid program more than their "usual and customary" charges. Bondi contends that the alleged overcharges were collected from Florida's Medicaid program over the past 15 years. The lawsuit has survived efforts to dismiss by Quest and LabCorp and is currently deep into the discovery process, which began in May 2015, according to Riedel's attorney Niall McCarthy from Cotchett, Pitre & McCarthy LLP.

On January 11, a Florida health committee held a hearing on the bill (HB 421) that would kill the above false claims lawsuit. HB 421 would define the term "usual and customary," for the purposes of Florida's Medicaid program, as the amount routinely billed by a provider to an uninsured consumer before any discount, rebate, or supplemental plan. The proposed definition would be retroactive. Furthermore, an amendment to the bill specifies that the new definition for "usual and customary" would apply only specifically to independent labs.

When asked why the bill was amended to apply only to independent labs, Rep. Trumbull bluntly told the committee, "We did narrow it down mainly because there is a lawsuit that just involves the labs, so that's why we tried to nip that in the bud."

Independent labs typically charge uninsured patients 3x or more the amount that they bill Medicaid plans for lab tests, notes *Laboratory Economics*. So the new definition of "usual and customary" under HB 421, if adopted, would mean that Quest and LabCorp had clearly never overcharged Florida Medicaid.

The Florida Medicaid lawsuit could be headed toward a large settlement and another big pay out to whistleblower Chris Riedel.

In a very unusual move, Attorney General Bondi attended the meeting and spoke fervidly against the bill.

"As your chief legal officer for the state of Florida, I have an obligation to be standing here in front of every one of you here today and tell you that we do have very active litigation pending involving massive healthcare fraud," Bondi told the state legislators. "This isn't a broad policy. You would be legislating one case pending in Florida and it's against LabCorp and Quest. And Mr. Huey, who I respect, is here representing LabCorp. And this is his legislation. [Note: J. Michael Huey is an attorney at the law firm Gray Robinson (Tallahassee, FL). He and his firm are representing LabCorp in the false claims lawsuit.]

"If this bill passes your committee, you will be an unwitting facilitator to potentially costing our taxpayers millions of dollars—millions. California, Nevada and other states have already settled for hundreds of millions of dollars. This is big. We are alleging these two companies defrauded taxpayers tens of millions of dollars here in Florida. You all know we are a bellwether state. And I'm telling you right now that the eyes of the entire country are on us. Because LabCorp and Quest, they know other states from the rest of the country are looking at them. This is active legislation. In my five years as Attorney General, I have never seen anything like this about to happen. The proper forum for this to be heard is in sworn court testimony," said Bondi.

"This is an end run desperate attempt in potentially a multi-million dollar case that impacts Florida and other states around the country. This is very serious and you need to know there is a federal component to our case. I am confident this [HB 421] is being done to kill our active litigation. It is highly inappropriate to be handled in the middle of litigation that affects all of our constituents and our taxpayers. By passing this bill, by voting yes today, you will be giving these companies an open checkbook to raid our Medicaid program," warned Bondi.

"And by the way, the amendment is just the icing on the cake. It's not even hiding anymore. They want it to be retroactive. The bill alone would be damaging enough, but to make it retroactive is basically in your face saying 'It's about the litigation,'" said Bondi.

"I do not know how it got this far, but you're the first people to vote on it. And that's why I have an obligation to you, to every single one of you in this room, to tell you what you are voting on," explained Bondi. "It needs to die right here right now."

After hearing Bondi's testimony, Doug Russell, a Florida lobbyist for Quest Diagnostics who attended the meeting, immediately waived Quest's support of the bill.

LabCorp's lawyer Mike Huey continued to support the bill saying that the term "usual and customary" was ambiguous and open to interpretation. He said that the California lawsuit (settled by Quest, LabCorp and other labs for a combined $300 million in 2011) was not comparable because California specifically requires providers to charge the lowest amount they charge third-party payers.

After hearing testimony, the Florida health committee voted to delay consideration of the bill.

BOSTWICK STARTS NEW LAB COMPANY (*cont'd from p. 1*)

Dr. Bostwick sold Bostwick Labs to Metalmark Capital LLC, a New York private equity firm, in 2011. He remained an employee for several years after the sale and worked as an independent pathologist contractor providing second opinions until November, when his four-year non-compete contract expired.

Granger Diagnostics is an affiliate of and is operating in the same building as AIBioTech (Richmond, VA). AIBiotech was acquired by Bostwick Labs in 2009. However, Dr. Bostwick retained ownership of AIBiotech after Bostwick Labs was sold to Metalmark. AIBioTech has 50 employees and is focused on molecular diagnostics and providing contract research testing services to biotech and pharmaceutical companies.

Dr. Bostwick says Granger Diagnostics will utilize the accessioning and billing departments at AIBioTech but will otherwise operate independently. Granger Diagnostics currently has six employees, including Jun Ma, MD, former associate Medical Director at Bostwick Laboratories, and Rosalyn Baskette, former Laboratory Supervisor at Hospital Corporation of America (HCA). Dr. Bostwick expects to grow to 25 employees in 2016.

Despite the draconian reimbursement cuts to pathology over the past few years, Dr. Bostwick believes independent pathology labs can flourish if they are cost-conscious, and have productive employees and efficient billing systems. "I love prostate pathology and have a lot more business experience for my second bite at the apple," he says.

In addition to providing initial diagnosis and second opinions on prostate cancer cases, Dr. Bostwick says his new company will be on the leading edge of introducing improved detection and monitoring technologies.

Settlement of False Claims Lawsuit

Separately, Dr. Bostwick has finalized a lawsuit settlement with former competitor Michael Daugherty (president of LabMD, which went out of business in 2014). Daugherty filed a qui tam lawsuit against Bostwick Labs and Dr. Bostwick in 2008 alleging that they violated the False Claims Act by offering kickback incentives to physicians in exchange for FISH bladder cancer test referrals. Bostwick Labs settled the lawsuit in August 2014 by agreeing to pay the federal government $6 million. Under a separate settlement announced this month, Dr. Bostwick agreed to pay $2.6 million plus an additional $1.1 million if certain financial contingencies occur within the next five years. "I contend we did nothing wrong. But after eight years, the case still had not made it to discovery and it was less expensive to settle," says Dr. Bostwick. As whistleblower, Daugherty will receive over $2.5 million from the settlements with Bostwick Labs and Dr. Bostwick.

LABCORP FINED $225K, TERMINATES CONTRACT WITH DIRECTLABS

LabCorp and Direct Laboratories LLC (Mandeville, LA) have settled allegations they violated New York state law by providing lab tests to consumers without proper physician authorization. DirectLabs, which markets lab tests directly to consumer via its website, will pay a $24,500 fine and cease operating in New York, according to New York Attorney General Eric Schneiderman. LabCorp, which was contracted to provide lab testing services for DirectLabs, will pay a $225,000 penalty.

The settlements follow an investigation by the New York AG that found that DirectLabs sold requisitions for a wide range of lab tests, and that these requisitions were automatically generated with a licensed chiropractor's name—who had never seen or spoken with the patients. Consumers would then take these requisitions to a LabCorp patient service center for specimen collection and lab testing.

New York State law requires that lab tests be performed only at a licensed practitioner's request. However, the chiropractor whose name appeared on DirectLabs' requisitions not only never met or spoke with any of the approximately 1,100 consumers whose tests he authorized, and he did not follow up with any of the consumers about test results. LabCorp provided testing services to DirectLabs based on the automatically generated requisitions, without ever checking to see whether the chiropractor was acting within the scope of his license, according to the New York AG. The violations occurred from September 2012 until March 2015.

As a result of the settlement, DirectLabs is barred from operating in New York and LabCorp's PSCs in New York can no longer accept requisitions generated by DirectLabs or any similar company. "This was a case involving one third-party contractor who apparently fell short of its obligations in New York. We no longer do business with that contractor," according to LabCorp's Chief Legal Counsel Samuel Eberts.

2016 OUTLOOK FOR LABS: 10 EXECUTIVE PERSPECTIVES (*cont'd from p. 1*)

Douglas VanOort, Chairman and CEO of **NeoGenomics** (Fort Myers, FL), says Medicare rate changes will lead to roughly $4 million of added net revenue for NeoGenomics in 2016. He says that following six years of declines, NeoGenomics should see its average revenue per patient case (currently approximately $652 per case) rise in 2016.

NeoGenomics completed its $310 million acquisition of Clarient Inc. (Aliso Viejo, CA) on December 30. The combined company will have approximately 850 employees and revenue of between $240-$250 million in 2016. VanOort says that NeoGenomics' lab in Irvine, California will be consolidated into Clarient's 78,000-square-foot lab in nearby Aliso Viejo. The acquisition will double NeoGenomics' salesforce to 50 sales reps and managers. VanOort says NeoGenomics' sales reps have a goal of adding $700,000 in new business per year per rep.

Among Clarient executives staying on is Mark Machulcz, who will be Vice President of Operations at the combined company. Clarient's Lawrence Weiss, MD, and Kenneth Bloom, MD, will also stay on as strategic advisors, according to VanOort.

VanOort says that the pathology lab insourcing trend has gone both ways for NeoGenomics. For example, the company's largest single client, Florida Cancer Services (180 physicians at 80 locations throughout Florida) brought histology and flow cytometry in-house in 2011. However, NeoGenomics continues to provide courier services as well as cytogenetics and molecular testing on cancer specimens from FCS. Meanwhile, he says declining reimbursement is leading some hospitals to outsource pathology services and NeoGenomics recently won a contract to provide flow cytometry services to a hospital that is closing its flow cytometry lab down.

Ben Davis, MD, Chairman and Chief Executive of **PathGroup** (Nashville, TN), says PathGroup's revenue grew by approximately 15% to reach $225 million in 2015. PathGroup's fastest growth is occurring at its molecular oncology laboratory, which has 30 employees, including seven full-time molecular scientists. PathGroup introduced five new genomic profiling panels targeting cancers of lung, colon, brain, thyroid and melanoma under the brand name SmartGenomics in mid-2015. In addition, Davis says PathGroup continues to grow its women's health laboratory, which now performs more than 500,000 Pap tests per year.

Davis says the diversification into molecular oncology and women's health helped PathGroup maintain growth over the past three years despite severe Medicare rate cuts to 88305-TC and immunohistochemistry.

PathGroup's growth strategy is weighted toward organic growth, according to Davis. However, the company has made a few small acquisitions over the past two years, including in 2014, Southern Pathology Associates (Chattanooga, TN), a hospital-based group with four pathologists.

Among the top challenges has been the bevy of pathology coding changes by CMS, notes Davis. For example, dozens of new codes for molecular pathology and changes to prostate biopsy, FISH and IHC coding require a major effort on the part of labs to get payers (Blues, Medicare carriers, hospital, et al.) to recognize and reimburse for new and changed codes. Meanwhile, Davis says that talk of a shift from fee schedules toward value-based reimbursement remains just talk. "No one is really clear on how to think about a value-based payment model and we're not even experiencing it on the margin."

PathGroup has more than 1,000 employees, including 80 pathologists, and operates a major central lab in Nashville. The company provides anatomic pathology and clinical lab services to more than 1,600 physician office clients and 70 hospital contracts in seven states: Tennessee, Kentucky, Virginia, Georgia, Indiana, Illinois and California. The company is owned by its pathologists, management and the private equity firm Primus Capital.

Colin Goldschmidt, MD, Worldwide CEO of Australia-based **Sonic Healthcare Ltd.,** says that since Sonic entered the United States lab market about 10 years ago through the acquisition of Clinical Pathology Laboratories (Austin, TX), he has been most surprised by the extreme pressure on reimbursement over the past few years. "The ongoing commoditization of the laboratory industry is somewhat at odds with Sonic's medical leadership model, which calls for greater involvement of medical personnel into management decisions," according to Goldschmidt, who practiced pathology for five years in Australia before becoming Sonic's CEO in 1993.

Goldschmidt says that laboratory operations are essentially the same in Australia and the United States. Pressure on fees is also a feature common to both countries. "However, billing in the U.S. lab market is far more complex than in Australia, mainly a function of the large number of payers in the U.S. and the many different fee levels applicable to the same test. In Australia, out-patient lab services are funded on a fee-for-service basis by only the federal government [Australian Medicare] and to a small extent by patients," notes Goldschmidt.

He says there is little difference between U.S. and Australian anatomic pathologists. However, in Australia, as in most European countries, there is a much higher percentage of dedicated, subspecialized pathologists, according to Goldschmidt.

It has been nearly four years since Sonic last completed an acquisition in the U.S. (Bridger Pathology Labs-February 2012), but Goldschmidt says Sonic continues to seek acquisition of "synergistic, sensibly-valued labs."

Sonic's U.S. anatomic pathology services business, CBLPath, was hurt by Medicare rate cuts and in-sourcing. Over the past year, Goldschmidt says CBLPath underwent a meticulous revision of its entire operation, which included changes at management, staffing and customer levels. He says the restructuring has been a success, resulting in a turnaround in revenue and morale. On a national basis, Sonic recently promoted Steve Shumpert, long-standing president of Sonic's Clinical Pathology Laboratories, to acting CEO of Sonic Healthcare USA. He succeeds Tom Lohmann, MD, who resigned from Sonic in late 2015

Sonic Healthcare recorded approximately USD $650 million of revenue from the United States in the fiscal year ended June 30, 2015, up 2% from the previous year.

Dean Li, MD, President and CEO of **ARUP Laboratories** (Salt Lake City, UT) says ARUP's revenue and testing volumes increased in the range of 7% to 12% in 2015, with molecular oncology and genetics growing fastest. Dr. Li expects that growth in 2016 will be about the same.

Among the top concerns for ARUP in the coming year is the potential regulation of lab-developed tests by the Food and Drug Administration, as well as the PAMA requirement that payment for lab tests be tied to private payer rates.

"I have mixed feelings about the Medicare reimbursement proposal," he tells *Laboratory Economics*. "The general consensus is that some tests may fare well while others may take a significant hit.

It's important to have expansive methodology, but right now the current rule doesn't give enough time to develop a good system. Anytime you try to do something too fast, there are going to be problems."

Going forward, Dr. Li sees opportunities for ARUP to partner with companies that offer direct-to-consumer (DTC) testing, although DTC testing is currently limited in Utah.

ARUP Labs is a not-for-profit national reference lab owned by the University of Utah. ARUP contracts with the Department of Pathology at the University of Utah School of Medicine to provide pathology consulting services and to serve as medical directors for each ARUP lab department. ARUP has more than 3,000 employees and annual revenue of approximately $475 million.

Krista Crews, Executive Director at **ProPath** (Dallas, TX), says ProPath has increased its profitability despite seeing revenue dip slightly to approximately $70 million in 2015 from its 2012 high. Medicare and other major payer rate cuts led ProPath to reexamine its cost structure. Over the past three years, ProPath reduced courier expenses by 30% and supply costs by 20%.

In addition, Crews says that growth in ProPath's molecular lab (~15% annually over the past three years) has boosted profitability. Last month, ProPath acquired its first next-generation sequencer (from Illumina) and is in the process of introducing several nextgen sequencing assays. Another area of fast growth has been contract research testing for universities, pharma and IVD companies, which is not contingent on Medicare rates and has no bad debt, notes Crews.

ProPath has also grown its women's health lab testing—now at roughly 270,000 Pap tests annually—by more than 10% per year. Crews says that although Pap testing intervals have increased, associated sexually-transmitted-infection (STI) testing has grown, driving up overall volume. Other areas of growth include vaginitis, prenatal and genetic carrier testing.

Goals for 2016 include gaining more in-network contracts, especially with larger out-of-state plans, allowing more business from existing clients, according to Crews. About half of ProPath's clients are in Texas with the remaining in 40 states, primarily in the southwest and northeast.

ProPath has 295 employees and 38 pathologists and is still 100% owned by pathologists. Over the years, Crews says that ProPath has occasionally met with potential investors and other lab suitors but plans to remain independent for the foreseeable future.

Francisco R. Velázquez, MD, SM, President and CEO of **Pathology Associates Medical Laboratories** (PAML-Spokane, WA), says PAML's patient volume grew 8.8% in 2015 and he expects similar growth in 2016.

He says PAML is seeing its strongest growth in molecular diagnostics, genetics, pain management, cardiovascular testing, women's health and wellness. Through Symbiodx, a national molecular oncology reference laboratory formed in partnership with CellNetix, PAML is increasing its focus on personalized medicine and companion diagnostics.

PAML's direct-to-consumer testing service, called Cinch, is also showing steady growth, reports Velázquez. Among men ages 45 to 65, men's wellness and cardiovascular testing is the most ordered while women ages 18 to 54 are most interested in women's health and thyroid panels.

In addition to reimbursement pressure, Velázquez tells *Laboratory Economics*, "We're seeing more acquisition of physician practices in some of our markets where about 65% of physicians are already employed by a hospital or health system."

Over the next five years, Velázquez believes consolidation will continue in the industry as labs join forces to achieve a critical mass required for leverage in a more competitive marketplace. He also believes that direct-access testing will grow, driven by millennials, and that consumers will force even greater transparency when it comes to health care costs.

PAML is a full-service reference laboratory owned by Providence Health & Services and Catholic Health Initiatives. PAML, which has approximately 1,800 employees, also manages nine joint ventures with hospitals and labs around the country.

Ran Whitehead, President of **PeaceHealth Laboratories** (Springfield, OR), says his lab grew by about 1% in 2015, down from more than 5% in 2014, which was boosted by newly insured patients under the Affordable Care Act.

For 2016, Whitehead anticipates growth of 1% to 2%. "Inpatient volumes are flattening, and outpatient volumes are rising, and the balance between the two keeps growth somewhat flat," he explains. The segments where PeaceHealth is seeing the greatest growth are molecular testing for infectious diseases (MRSA, the flu and tuberculosis) and pain management testing.

PeaceHealth is in the midst of installing the Epic electronic medical record system and Beaker laboratory information system, which Whitehead believes will increase standardization across the system and help streamline operations and lower costs.

Whitehead says he is "cautiously optimistic" that there will be a delay in Medicare's new payment system, which had been scheduled to start in January 2017, as well as an expansion in the types of labs that will be required to report their private payer payment rates.

Shrinking reimbursement and an increased focus on population health will force labs to become more efficient if they want to stay in business, believes Whitehead. "It will be a combination of many things that labs will have to do to respond to lower payment," he says.

PeaceHealth Laboratories, owned by the PeaceHealth Health System, is a not-for-profit laboratory with more than 800 employees at locations in Oregon, Washington and Alaska.

David Goldberg, Senior Executive at **Enzo Biochem** and General Manager of **Enzo Clinical Labs** (Farmingdale, NY), says clinical lab revenue (currently about $65 million per year) is growing by 8% annually, driven by molecular testing.

He says that molecular testing technologies developed by Enzo's life sciences division give its clinical lab a supply cost advantage over competing labs. New tests developed by Enzo and introduced at its clinical lab include its AmpiProbe HCV test for the measurement of Hepatitis C viral load and its FlowScript HPV test for detecting overexpression of HPV oncogenes that lead to cervical cancer. Goldberg says that Enzo Clinical labs is using its cost advantage to obtain preferred provider status with insurance companies for molecular testing.

Meanwhile, Goldberg notes that large health systems in the New York City area continue to acquire primary care practices (Ob/Gyns, internal medicine, cardiology, gastroenterology, et al.) and redirect associated lab testing to their hospital labs. Active acquirers include Barnabas Health, Mount Sinai and Northwell Health (formerly North Shore-LIJ Health System).

Enzo Clinical Labs is a regional full-service clinical and anatomic pathology lab serving the New York City area and New Jersey, with a central lab in Farmingdale, Long Island, a stat lab in New York City, and approximately 35 PCSs in the New York City area.

Khosrow Shotorbani, Chief Executive at **TriCore Reference Laboratories** (Albuquerque, NM), is expecting double-digit test volume growth in 2016. While the commercial lab testing brings in the most revenue, clinical trials and research testing has become an important focus for TriCore, according to Shotorbani. In early 2015, TriCore remodeled an area of its headquarters in Albuquerque and opened the TriCore Research Institute, which is focused on clinical validation of new assays. Recent IVD partners include Roche, Life Technologies (now part of Thermo Fischer Scientific), BD, Biomerieux and DNA Electronics.

In addition, TriCore acquired Rhodes Group, an IT consulting company that provides software and data integration services, in April 2015. Over the past nine months, TriCore has expanded the Rhodes Group team from 12 employees to 30 employees. The Rhodes Group, which is based in Connecticut, will be kept as a wholly owned subsidiary of TriCore, says Shotorbani, who notes that having an in-house IT shop will support TriCore's analytics expansion.

Quest's acquisition of SED Labs in 2012 has not had a significant impact on TriCore, says Shotorbani, noting that the acquisition resulted in a majority of testing for that site being sent out of state. "TriCore believes testing should be done near the patients in the most cost-effective manner," he explains. "We do 98% of our testing close to the patient."

In addition to shrinking reimbursement, Shotorbani predicts a significant impact on lab-developed tests depending on what happens with FDA oversight, as well as continued mergers and consolidations in the industry. Due to continued expansion of the physician-employment model, he expects fee-based commercial business will decline over the next five years. Finally, he predicts an increase in lab business models focused on population health and targeted intervention.

TriCore Reference Laboratories is an independent not-for-profit lab company owned by University of New Mexico Hospital System and Presbyterian Healthcare Services.

Panna Sharma, President and CEO of **Cancer Genetics Inc.** (Rutherford, NJ), says CGI has made substantial changes since acquiring Response Genetics (Los Angeles) out of bankruptcy in October for approximately $13.4 million. Sharma says Response Genetics' staffing was immediately cut by 25%, or 18 employees.

Sharma says that a cash shortage had caused Response Genetics to limit the marketing budget for its Tissue of Origin (TOO) test, an FDA-cleared test for identifying the primary site of otherwise unclassifiable malignant tumors. He sees great potential to reinvigorate sales of the TOO test, which is reimbursed by Medicare and other payers in the range of $2,700 to $3,000 per test. In addition, he says CGI will also explore partnerships and distribution arrangements for the TOO test.

CGI's fastest-growing business is contracted lab testing for biopharma clients (e.g., Gilhead Sciences, Roche, Merck, GlaxoSmithKline, Astra Zeneca, et al.). CGI's biopharma services division reported revenue of $8.6 million in the nine months ended Sept. 30, 2015, up 204% from $2.8 million during the same period in 2014. Sharma says contract lab testing has become a growth market because some 70% to 80% of all oncology drugs currently under development are using biomarkers to help identify subsets of patients who are most likely to respond to a given therapy.

Overall, Sharma expects the acquisition of Response Genetics to bring $10 million to $12 million of revenue to CGI in 2016. Combined company revenue will exceed $30 million. Sharma expects CGI to turn profitable in the first half of 2017.

THERANOS LOBBIED CONGRESS AT SAME TIME AS FDA INSPECTION

Theranos (Palo Alto, CA) spent a total of $120,000 to lobby Congress between July 1, 2015 and September 30, 2015, according to reports from the Center for Responsive Politics (Washington, DC), a nonprofit watchdog organization that monitors lobbying and political donations and their effect on elections and public policy. The reports show that Theranos paid $60,000 each to two lobbying firms: The Nickles Group LLC and Nueva Vista Group LLC. These firms lobbied on Theranos' behalf on two issues: 1) the support for FDA oversight of laboratory developed tests (LDTs); and 2) support for lowering reimbursement rates for clinical lab tests.

Coincidence or not, Theranos' lobbying activity came during the same time period that the FDA was conducting an inspection of the company's labs. The FDA's inspection occurred from the period of August 25 to September 16, 2015. The resulting FDA inspection reports, dated September 16, 2015, found that Theranos kept poor records, mishandled complaints, failed to conduct quality audits, and was "unable to produce documented supplier qualifications," among other observations.

The FDA also said that the company's tiny blood collection tube ("nanotainer") was a medical device that had not been cleared by the agency but was being shipped in interstate commerce.

In a statement, Theranos said, "We believe that we addressed and corrected all the observations at the time of, or within a week of, the inspection and have submitted documents to the FDA that say so." Theranos has also stopped using its nanotainer and is now collecting patient blood samples using traditional venous needle draws. Theranos did not comment on its lobbying activity.

FDA INDICATES LESS ONEROUS REGULATORY PATH FOR DIGITAL PATHOLOGY

The FDA, which had previously stated it considered digital pathology systems for primary diagnosis a Class III medical device, has softened its regulatory stance. Following nearly two years of discussion with the Digital Pathology Association (Indianapolis, IN) and manufacturers, the FDA now says digital pathology systems for primary diagnosis are a candidate for de novo applications as a Class II device. After one de novo application receives marketing clearance from the FDA, other vendors will then be able to submit 510(k) applications for their systems rather than go through the more lengthy and complex Class III premarket approval process.

FDA De Novo Criteria:

- There is no identifiable predicate device.
- The device is of low to moderate risk, and general controls or general and special controls would provide reasonable assurance of the device's safety and effectiveness.
- The known risks and benefits of the device can be explained, the known risks can be effectively mitigated, and the device's effectiveness can be assured through application of general controls or general and special controls.

According to FDA guidance, a de novo request must include a description of the device and detailed information and reasons for any recommended classification. FDA must make a classification determination for the device by written order within 120 days of the request. If the submitter demonstrates that the criteria are met, FDA will grant the de novo, in which case the specific device and device type is classified in Class I or Class II. The device may then be marketed immediately and serve as a predicate device. If the de novo is declined, the device remains in Class III and may not be marketed without premarket approval.

The bottom line is that digital pathology systems for primary diagnosis of cancer could be on the U.S. market as soon as within the next six to twelve months, observes *Laboratory Economics*.

SENATORS PRESSURE CMS TO ADD HOSPITAL LABS (*cont'd from p. 1*)

"We urge that CMS establish an alternative, more expansive methodology for identifying laboratories that must report private payment rates in the final rule," Sens. Hatch and Wyden told acting CMS Administrator Andrew Slavitt.

Hatch and Wyden are the latest to join a growing bipartisan group of lawmakers who are leaning on the agency to change its proposal for establishing the new Clinical Laboratory Fee Schedule. Bipartisan groups of senators and House representatives separately sent similar letters to CMS last month.

Private plans pay hospital labs more on average than independent labs, so excluding hospitals would lower the average payment rates calculated by CMS.

AHA Wants Hospitals To Report Their Lab Test Data

After some initial concern about the burden of collecting and reporting data, the American Hospital Association is now on the same page as independent labs. "We are concerned that the new CLFS rates would not be representative of overall market rates," the American Hospital Association stated in comments to CMS. "This would cause hospitals to see precipitous declines in Medicare payments for laboratory services, which could harm patient access to laboratory testing in many communities."

Extending the Time Schedule for Implementation?

Hatch and Wyden also say the proposal wouldn't give labs enough time to report private sector price data. CMS proposed giving labs until March 31, 2016 to report data from July through December of last year.

"The March 31 deadline is particularly unrealistic given that the final rule containing the information that laboratories will need to report has yet to be published," they write, adding that even if CMS were to publish the final rule today, labs would need more time. Furthermore, after the final rule is published, CMS would still also need to issue guidance detailing the mechanics on exactly how labs should report their pricing data.

CMS was supposed to publish the final rule this summer to give sufficient time to get the new pay system running for its scheduled effective date of January 1, 2017 for new Medicare payment rates. However, this time schedule now looks completely unworkable and is likely to be delayed by one year, observes *Laboratory Economics*.

SCHRYVER BUYS METROSTAT LAB IN TEXAS

Schryver Medical Sales and Marketing, LLC (Denver, CO) has acquired MetroStat Clinical Laboratory, Inc./MetroStat Diagnostic Services, Inc. (Garland, TX) marking Schryver's entrance into the Texas lab market. MetroStat is a provider of clinical laboratory services, mobile X-ray, and other mobile imaging services.

Based in Denver, Colorado, and employing over 1,000 professionals, Schryver markets mobile imaging and lab test services to 3,500 nursing homes and hospitals in 16 states. Schryver is owned by the private equity firm Revelstoke Capital Partners (Denver, CO).

The purchase of MetroStat follows Schryver's acquisitions of Main Street Clinical Laboratories (Southaven, MS) in July 2015, and B.O.N. Clinical Laboratories (Las Vegas, NV, and Burbank, CA) in September 2015.

LAB STOCKS DOWN AN AVERAGE 11% IN 2015

Sixteen lab stocks declined by an unweighted average of 11% last year. In comparison, the S&P 500 Index was down 1%. The top-performing lab stocks in 2015 were NeoGenomics, up 89%, and Myriad Genetics, up 27%. Meanwhile, LabCorp was up 15% and Quest Diagnostics was up 6%.

Company (ticker)	Stock Price 12/31/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	Latest 12 mos. Revenue ($ millions)	Quarterly Revenue Growth (YOY)
Cancer Genetics Inc. (CGIX)	$3.30	$6.68	-51%	$45	$16.6	24.2%
CombiMatrix (CBMX)	0.73	1.29	-43%	9	9.6	22.5%
Enzo Biochem (ENZ)	4.50	4.44	1%	207	98.0	1.4%
Exact Sciences (EXAS)	9.23	27.44	-66%	889	26.5	NA
Foundation Medicine (FMI)	21.06	22.22	-5%	726	85.8	54.4%
Genomic Health (GHDX)	35.20	31.97	10%	1,145	281.5	6.4%
Invitae (NVTA)	8.21	16.00	-49%	262	6.1	605.5%
LabCorp (LH)	123.64	107.90	15%	12,512	7,770.0	46.3%
Myriad Genetics (MYGN)	43.16	34.06	27%	3,011	737.8	8.7%
NeoGenomics (NEO)	7.87	4.17	89%	477	97.5	8.2%
Opko Health (OPK)	10.05	9.99	1%	5,477	241.1	623.4%
Psychemedics (PMD)	10.14	15.15	-33%	55	27.6	-8.0%
Quest Diagnostics (DGX)	71.14	67.06	6%	10,198	7,530.0	-1.3%
Rosetta Genomics (ROSG)	1.23	2.26	-46%	22	5.2	790.5%
Sonic Healthcare (SHL.AX)	17.87	18.50	-3%	7,387	4,200.0	8.5%
Veracyte (VCYT)	7.20	9.66	-25%	199	47.7	25.4%
Unweighted Averages			-11%			147.7%

Source: Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor