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LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## UNITED/BeaconLBS TO BEGIN DENYING LAB TEST CLAIMS IN FLORIDA

UnitedHealthcare (UHC) says it will begin denying claims for 80 lab and pathology tests when the ordering physician does not provide prior notification through the BeaconLBS program starting April 15, 2015. BeaconLBS is a lab benefit management program (LBMP) that is owned and administered by LabCorp.

The LBMP applies to lab services for fully-insured UHC members in Florida with employer-sponsored health plans (representing approximately 430,000 members). UHC says that if a network physician provides services to one of these members, the physician must use the BeaconLBS lab program per UnitedHealthcare's Administrative Protocol.

Florida labs and pathologists are concerned because they will not get paid by UHC for many high-volume tests when an ordering physician bypasses BeaconLBS. Thus, labs and pathologists will be penalized for actions outside of their control. *Continued on page 4.*

## FDA APPROVAL OF 23ANDME GENETIC TEST MAY BE OPENING FOR INDUSTRY

The Food and Drug Administration's (FDA) recent approval of a genetic test offered by 23andMe could be an indication that the agency is open to approving other genetic testing services offered directly to consumers. *Continued on page 7.*

## SECRET SHOPPERS DISAPPOINTED BY THERANOS

Competitors and analysts that have visited and been tested at Theranos blood draw sites at Walgreens stores in California and Phoenix have found discrepancies in their first-hand experiences versus Theranos' claims for quick fingerstick sampling and average test result turnaround time of four hours or less.

Interestingly, none of the secret shoppers interviewed by *Laboratory Economics* reported ever having to wait in line, or even seeing another patient/customer, during their visits to Theranos sites at Walgreens. *Continued on page 2.*

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**SECRET SHOPPERS DISAPPOINTED BY THERANOS** (*cont'd from page 1*)

"We can get results, on average, in less than four hours. And this can be very helpful for doctors and patients, because it means that someone could, for example, go to a Walgreens in the morning to get a routine test for something their doctor is tracking, and the physician can have the results that afternoon when they see the patient. And we're able to do all the testing using just a single microsample, rather than having to draw a dedicated tube for each type of test."

—Theranos CEO Elizabeth Holmes from *Wired Magazine*, February 18, 2014

Below, *Laboratory Economics* summarizes the experiences of four different organizations that have sent employees to Theranos draw sites to be tested.

### Piper Jaffray

The investment banking firm Piper Jaffray (Minneapolis, MN) sent an analyst to a Theranos "wellness center" in Phoenix with a doctor's prescription in hand for metabolic and lipid panel tests. "Considering recent press, we were disappointed with our sample requiring 2 more vigorous finger pricks than expected [3 total]," according to a research report from senior analyst William Quirk issued on January 15, 2015. Theranos faxed the metabolic and lipid panel results to the prescribing physician three days after the blood draw (70 hours). The following day, Theranos phoned Piper Jaffray's analyst/patient (~96 hours after the blood draw) and requested a return visit to the Walgreens wellness center for a repeat CBC test sample. Quirk's report noted that while Theranos did charge low prices (~50% of Medicare) and perform fingerstick sampling, the failed CBC test and long turnaround time for results "did not live up to media representation." Quirk concluded that Theranos posed little near-term risk to Quest Diagnostics and LabCorp, although its low prices may pressure the lab industry in the longer term.

### Arizona Lab Competitor

*Laboratory Economics* interviewed an executive at an established competing lab based in Arizona that sends several of its marketing reps to get tested at Theranos wellness centers in Phoenix every month. Each time these secret shoppers have had their blood drawn by Theranos phlebotomists by the traditional needle venipuncture method. Results are being provided in about 24 hours, according to the lab executive who wishes to remain anonymous.

### The Dark Report

Publisher Robert Michel described his visit to a Walgreens store in Palo Alto, California, that offered the Theranos testing service in the August 11, 2014 issue of *The Dark Report*. Michel had a doctor's prescription for six lab tests. Theranos collected its sample from Michel by regular venipuncture, not fingerstick, and it was five days before Theranos reported the test results to his physician. Furthermore, Michel said that Theranos was unable to perform all six lab tests, which required Michel to visit a second lab (and endure another venipuncture blood draw) in order to complete the full set of tests ordered by his physician.

### California Lab Competitor

Finally, an executive at a major commercial lab in California tells *Laboratory Economics* that he and another individual visited a Theranos draw site at Walgreens in Palo Alto, California. "It was a fingerstick draw, but I only had chemistries done, no blood counts. There was no line. I had to check in with the pharmacist and then I was taken immediately to the phlebotomist. It took about 2-3 days to get my results back," according to the executive. "The second individual had a variety of tests ordered, but nothing esoteric. Because one of the ordered tests was not run on the Theranos instrument, he had a full/traditional draw. I've always felt this was one of the significant issues. Results were even slower (3+ days) than the first. The patient service area was empty—no lines."

 

## THERANOS PUSHES FOR DIRECT ACCESS TESTING IN ARIZONA

Arizona House Bill 2645, sponsored by Rep. Heather Carter (R-Cave Creek), would expand the ability of consumers to order lab tests for themselves without a physician's written authorization. Arizona law currently allows consumers to order a limited number of lab tests (e.g., lipid profile, blood glucose, Hgb A1C, urine pregnancy, etc.) for themselves. The new legislation would allow consumers to order any test offered by a laboratory. But the state's Medicaid program and private health insurance companies would not be required to pay for direct-to-consumer tests.

The bill is being pushed by Theranos, which operates draw sites at 40 Walgreens stores in the Phoenix area. Theranos operates a CLIA-certified lab in Newark, California, and is in the process of opening a second lab in Scottsdale, Arizona. Elizabeth Holmes, CEO of Theranos, has testified in support of Bill 2645 to the Arizona Legislature. The bill has already passed the Arizona House and is now being reviewed by the Arizona Senate Health and Human Services and Rules Committee.

Holmes says the bill will allow Arizonans to take full advantage of the low prices for lab tests offered by Theranos. "I can personally speak to the people who I've had the privilege of meeting here in Arizona who have driven in buses to come to our locations in Phoenix and have flown from other states because they know what our prices are on these tests and it's the only way that they can afford to get care," she said in testimony to the Arizona Senate Health and Human Services and Rules Committee on March 4, 2015.

More than 20 states already offer direct-to-consumer testing without limitation, including Colorado, New Mexico, Ohio, Texas and Virginia. And many lab companies, including Quest Diagnostics and LabCorp, have repeatedly tried to market lab tests directly to consumers for the past 20 years. But the direct-to-consumer market has failed to materialize. Last year Quest Diagnostics obtained only 2% of its revenue from self-paying patients, including deductibles and co-insurance, while LabCorp received only 5% (see table on page 6).

Finally, *Laboratory Economics* must note that the idea of patients buying plane tickets and flying in to Phoenix to get their blood drawn at a Walgreens store seems more than a little farfetched.

## CLEVELAND CLINIC TO EVALUATE THERANOS' TESTING TECHNOLOGY

Cleveland Clinic has agreed to perform certain comparative studies on Theranos' testing technology that will compare its technique to traditional blood testing and diagnostics. The comparative studies will help Cleveland Clinic determine the feasibility of potentially utilizing Theranos' testing system, according to Kandice Marchant, MD, PhD, chair of the clinic's Robert J. Tomsich Pathology & Laboratory Medicine Institute. Marchant tells *Laboratory Economics* that the agreement is still very early in the process and the first comparative studies have not yet begun.

Marchant says that Theranos' testing system looks promising in terms of its small sample size and potential to reduce turnaround time. However, she notes that there will be multiple steps before Cleveland Clinic can determine its feasibility or make a decision to use the technology for clinical testing.

Marchant says the two organizations are also exploring the potential for Cleveland Clinic Laboratories to provide reference testing services to Theranos.

Cleveland Clinic Laboratories (CCL) is one of the largest reference labs in the nation. It has approximately 105 pathologists on staff and 1,400 other employees. CCL has a test menu with more than 1,500 tests and performs approximately 20 million tests per year.

**UNITED/BeaconLBS TO BEGIN DENYING LAB TEST CLAIMS** (*cont'd from p. 1*)

UHC has emphasized that its advanced notification process does not involve a clinical coverage review that authorizes test orders. Prenotification allows UHC through BeaconLBS to verify member benefits and share evidence-based clinical guidelines with ordering physicians, according to UHC.

But the BeaconLBS program represents a cumbersome extra step that physicians must take before ordering 80 tests. Tests requiring advance notification through BeaconLBS include high-volume clinical lab tests like Vitamin D, thyroid panels, allergy panels, as well as essentially all anatomic pathology services including biopsies, cytology and immunohistochemistry. Note: Following feedback from physicians, UHC recently removed two tests from its advance notification list: prenatal profile and gestational diabetes one-hour screen.

Numerous physician groups in Florida have complained to UHC about the interruption in workflow and extra staff time that the lab benefit management program requires, including the Florida Medical Association, Florida Association of Family Physicians, American Congress of Obstetricians and the Florida Society of Rheumatology.

For more information, we sent a list of written questions to Elizabeth Calzadilla-Fiallo, director, public relations, for Florida and the Gulf States Region for UnitedHealthcare. Below are UHC's responses:

***What can labs do to ensure they are paid for the services they provide to UHC patients if the referring docs do not go along with UHC/Beacon's advance notification requirements?***
If the laboratory receives a specimen and there is no Advanced Notification on file, the laboratory can contact the referring physician and request that they complete Advanced Notification within 10 days of the date of service.

UnitedHealthcare will also communicate with those physicians who we notice are not consistently using the notification program and offer further training or education if needed.

Additionally, the laboratory can contact their UnitedHealthcare network representative if they continue to receive specimens without the proper notification on file.

***Can labs ask patients to sign an Advance Beneficiary Notice saying they agree to be billed directly for the test if their lab test claim is denied through UHC/BeaconLBS?***
In the Laboratory Benefit Management Program, the tests that require notification are covered services, and members cannot be held responsible if there is not a notification on file. Network providers cannot bill the member for lack of notification, even if the member signed a notice.

***What is the benefit to labs that become a "Laboratory of Choice" in BeaconLBS? Do these labs get greater visibility or marketing support?***
All UnitedHealthcare network providers who perform lab services are invited, but not required, to become a Laboratory of Choice with BeaconLBS. To become a Laboratory of Choice, the provider must meet all quality and efficiency criteria and execute an agreement with BeaconLBS. Those providers that become a Laboratory of Choice are featured on the Laboratory of Choice ordering drop down list in the Physician Decision Support tool.

Note: There are currently 13 labs listed as Laboratories of Choice. These include Bako Pathology, Broward Health, Clarient Diagnostics, Dominion Diagnostics, Granite Diagnostic Laboratories, Gulf Coast Dermatopathology, Ketchum, Wood & Burgert Pathology and Millennium Laboratories. The other five are all LabCorp companies, including LabCorp itself, Dianon, Integrated Genetics, Integrated Oncology, and Medtox Laboratories.

 

## MANAGEMENT CHANGE AT AURORA DIAGNOSTICS

Peter J. Connolly has resigned from the Board of Managers at Aurora Diagnostics effective on February 24, 2015. Connolly had been a board member at Aurora since 2006. He is a principal at Summit Partners—an investment firm that owns a 53% stake in Aurora. Aurora says that Dan Crowley, the company's chief executive officer and president, will replace Connolly on the company's Board of Managers and will serve as its chairman.

In related news, med fusion (Lewisville, TX), a reference lab and clinical trials service organization, has named Jon L. Hart as chief executive officer, effective March 31. Hart was formerly president and CEO of Aurora Diagnostics.

## INVITAE RAISES $102 MILLION FROM IPO

Invitae (San Francisco, CA), which markets next-generation sequencing-based panels for a range of genetic conditions, raised $102 million from the sale of 6.35 million shares at $16 apiece in an IPO completed on February 12.

Invitae operates a CLIA-certified lab in San Francisco that performs customized panels of tests ordered by physicians for a uniform list price of $1,500. The firm sequences 216 genes, but will only interpret the genes that have been ordered by the physician. This year, the company plans to expand its panel from 216 genes to more than 500 genes, according to its IPO filing.

Invitae delivered more than 3,600 billable test reports in 2014. The majority of ordered tests were for hereditary cancers. The company posted a net loss of $47.7 million on revenue of $1.6 million in 2014. Invitae expects to deliver 14,000-17,000 billable test reports to its customers in 2015.

Invitae was founded as a spinoff from Genomic Health (Redwood City, CA). Genomic Health founder Randal Scott, who also served as CEO of that company, co-founded Invitae and took over as CEO of the startup to lead it on a mission to offer cheaper, faster genetic tests.

## COMPARING PRODUCTIVITY AT QUEST, LABCORP AND BRLI

On a weighted basis, three publicly traded lab companies collected average revenue of $45.13 per requisition in 2014. Average collected revenue per test was an estimated $15.04.

The three companies—Quest Diagnostics, LabCorp and Bio-Reference Labs Inc. (BRLI)—generated a weighted average of $167,245 in revenue per employee in 2014. The average number of requisitions processed was 3,561 per employee, while employees processed an average of 10,683 tests. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is 4.5% with an average days in accounts receivables of 52 days.

The combined revenue mix at the three publicly-traded labs is approximately 48% from managed care insurance, 28% client bill, 17% Medicare & Medicaid, and 3% from direct patient billing.

## Productivity Stats at Quest, LabCorp and BioReference Labs for 2014*

| | Quest Diagnostics | LabCorp | Bio-Reference | Totals* |
|---|---|---|---|---|
| 2014 Financials | | | | |
| Annual Revenue | $7,435,000,000 | $6,011,600,000 | $832,282,000 | $14,278,882,000 |
| Selling, General & Admin. Expenses (including bad debt) | $1,728,000,000 | $1,198,200,000 | $286,574,000 | $3,212,774,000 |
| Net Income | $556,000,000 | $511,200,000 | $46,758,000 | $1,113,958,000 |
| Employee Efficiency | | | | |
| # Employees | 45,000 | 36,500 | 3,877 | 85,377 |
| Avg. Revenue per Employee | $165,222 | $164,701 | $214,672 | $167,245 |
| Avg. Net Income per Employee | $12,356 | $14,005 | $12,060 | $13,048 |
| Requisition Stats | | | | |
| Annual Requisitions | 156,400,000 | 138,000,000 | 9,632,000 | 304,032,000 |
| Avg. Revenue per Requisition | $43.95 | $43.56 | $85.55 | $45.13 |
| Avg. Reqs processed per Employee | 3,476 | 3,781 | 2,484 | 3,561 |
| Test Stats | | | | |
| Annual Tests (assumes 3 tests per req.) | 469,200,000 | 414,000,000 | 28,896,000 | 912,096,000 |
| Avg. Revenue per Test | $14.65 | $14.52 | $28.52 | $15.04 |
| Avg. Tests processed per Employee | 10,427 | 11,342 | 7,453 | 10,683 |
| Collections | | | | |
| Bad-Debt % | 4.0% | 4.6% | 8.6% | 4.5% |
| Days in AR | 48 | 49 | 106 | 52 |
| Percent of A/R over 90 days | NA | 21.0% | 38.0% | 23.0% |
| Assets & Equity | | | | |
| Total Assets | $9,877,000,000 | $7,301,800,000 | $478,863,000 | $17,657,663,000 |
| Shareholders Equity | $4,330,000,000 | $2,820,500,000 | $318,902,000 | $7,469,402,000 |
| Efficiency | | | | |
| SG&A as % of Revenue | 23.2% | 19.9% | 34.4% | 22.5% |
| Net Profit Margin | 7.5% | 8.5% | 5.6% | 7.8% |
| Return on Assets | 5.6% | 7.0% | 9.8% | 6.3% |
| Return on Equity | 12.8% | 18.1% | 14.7% | 14.9% |
| Revenue by Payer | | | | |
| Private Patients | 2% | 5% | 2% | 3% |
| Medicare & Medicaid | 17% | 16% | 17% | 17% |
| Client Bill Hospitals, Physicians, etc. | 27% | 32% | 12% | 28% |
| Managed Care | 46% | 47% | 69% | 48% |
| Other | 8% | 0% | 0% | 4% |

*Averages are weighted based on size

Source: *Laboratory Economics* from company reports

**FDA APPROVAL OF 23ANDME GENETIC TEST** (*cont'd from page 1*)

On February 19, the FDA gave approval for 23andMe to market its Bloom Syndrome carrier test via its direct-to-consumer (DTC) genetic health kit. Bloom Syndrome, which is relatively rare, is a serious genetic disorder characterized by short stature, sun-sensitive skin changes, an increased risk of cancer, and other health problems. Along with the approval, the FDA classified carrier screening tests as Class II and said it intends to exempt these tests from FDA premarket review.

The approval marks a big step for DTC genetic testing given that in 2013 the FDA forced 23andMe to pull its DNA testing kits from the market, saying that the company has failed to obtain marketing clearance of approval to assure its tests were accurate, reliable, and clinically meaningful.

In announcing the approval, the FDA wrote:

> *The FDA believes that in many circumstances it is not necessary for consumers to go through a licensed practitioner to have direct access to their personal genetic information. Today's authorization and accompanying classification, along with FDA's intent to exempt these devices from FDA premarket review, supports innovation and will ultimately benefit consumers. These tests have the potential to provide people with information about possible mutations in their genes that could be passed on to their children.*

In a statement posted on its website, 23andMe called the approval "an important first step in fulfilling our commitment to return genetic health reports to consumers in the U.S.," adding that it's "the first time the FDA has granted authorization to market a direct-to-consumer genetic test, and it gives 23andMe a regulatory framework for future submissions."

To receive the approval, 23andMe performed two separate studies using a total of 123 samples to demonstrate that its test is accurate in detecting Bloom syndrome carrier status. The company also conducted a 295-person usability study and a study of 302 randomly-recruited participants to show that the tests were easy to follow and understand.

**Challenges and Opportunities**

Currently there are a number of companies and organizations that offer DTC genetic testing services, including Atlas Sports Genetics, Ancestry, CTLDNA, MapmyGene, GenePlanet, AthleteCode, EasyDNA, Graceful Earth Inc. and TestCountry.com. Emory University in Atlanta offers JScreen, which is designed to provide at-home genetic screening and private counseling for people with Jewish lineage to determine their risk for hereditary disease that could be passed to their children. The types of testing range from those that are clinically meaningful to those associated with the sale of a product to ancestry and recreational tests.

**Linnea Baudhuin, PhD**

Linnea Baudhuin, PhD, a clinical molecular geneticist with the Mayo Clinic (Rochester, MN), says that while the FDA's approval of 23andMe's Bloom test is a step in the right direction for genetic testing, consumers should be aware that not all tests offered by DTC genetic testing companies are approved by the FDA and not all are clinically useful.

"DTC genetic testing can be great for consumers, but they need to do their research or ask their healthcare professional about tests they are considering," she tells *Laboratory Economics*.

Companies that offer these types of tests should be transparent about the limitations of their testing and should have clear and understandable language in their reports to help consumers understand the ramifications of the test results, she adds.

In addition, DTC genetic-testing companies should be aware of the limitations of primary care providers in understanding genetic tests and should provide resources in their reports that both consumers and healthcare provides can use to obtain more information about a particular test.

Baudhuin also recommends that DTC genetic-testing companies provide consumers with a modified, shortened version of the testing report that the consumers can take to their physician. "Consumers should be able to share with their doctors just the clinically useful part of the report, not hundreds of pages of information that may not be useful."

DTC genetic testing will likely continue to increase in the marketplace, believes Baudhuin. While the regulatory landscape for DTC genetic testing is uncertain, she maintains that there are opportunities for laboratories in this area as long as labs provide responsible, clinically useful tests, are transparent about the tests and limitations, and engage with both consumers and healthcare professionals.

## AMP Modifies Position on DTC Genetic Testing

The Association for Molecular Pathology (AMP) in February updated its position statement on direct access genetic testing, concluding that clinically meaningful tests could benefit patients and consumers and should be made available directly to the public, but only if certain conditions are met.

Conversely, AMP opposes direct access to genetic tests that are performed for the purpose of selling additional health-related products or services and do not provide clinically meaningful or actionable information. For recreational or novelty genetic testing, such as ancestry testing, AMP maintains a neutral position as these reports do not include health information.

This is a change from AMP's previous position that genetic testing should be available only through appropriately qualified health professionals that order tests from laboratories that are certified by CLIA for high-complexity testing. AMP notes that in 2014 the Department of Health and Human Services finalized a new rule that gives patients access to test results, including genetic tests, directly from the laboratory. In addition, genetic tests have become increasingly available for direct purchase by consumers.

"These paradigm shifts, which are intended to give the general public a stronger role in preventive decisions and healthcare management, appear to be a permanent sector of the healthcare environment," notes the AMP. The organization supports direct access genetic testing for clinically meaningful tests under specific conditions related to clinical utility, CLIA compliance, transparency, reporting, test validation, and referrals to genetic counseling services.

The AMP direct access genetic testing position statement is available at *http://www.amp.org/publications_resources/position_statements_letters/documents/AMPpositionstatementDTCtesting-FINAL_002.pdf*.

## FDA PROPOSES GUIDANCE ON DIGITAL PATHOLOGY IMAGING DEVICES

New draft guidance from the Food and Drug Administration (FDA) on digital pathology whole-slide imaging devices has raised concern in the pathology community about potential unforeseen consequences.

The draft guidance, issued February 25, provides industry and agency staff with recommendations regarding the technical performance assessment data that should be provided for regulatory evaluation of a digital whole-slide imaging (WSI) system. The document does not cover the clinical submission data that may be necessary to support approval or clearance.

The FDA notes that recent technological advances in digital microscopy, in particular the development of whole-slide scanning systems, have accelerated the adoption of digital imaging in pathology, similar to the digital transformation that radiology departments have experienced over the last decade. The FDA regulates WSI systems manufacturers to ensure that the images produced for clinical intended uses are safe and effective for such purposes.

The draft guidance describes that technical performance assessment data that the FDA believes are necessary to allow for the regulatory evaluation of a WSI device. The components in a WSI device can be grouped into two subsystems: image acquisition and image display. Among the components discussed in the draft are slide feeders, light source, imaging optics, digital imaging sensor, image processing software, image composition, image files formats, image review manipulation software, computer environment, display, color reproducibility, whole slide tissue coverage, and test methods.

**Unintended Consequences?**

S. Joseph Sirintrapun, MD, Director of Pathology Informatics in the Department of Pathology at Memorial Sloan Kettering Cancer Center in New York and a member of the Association for Pathology Informatics (API), says that his initial take is that "this might be the recurring theme of good intentions leading to unintended consequences." The document provides a good detailed outline for tackling standardization of quality in the various components of the digital slide pipeline, he notes. However, Sirintrapun wonders whether the burden of applying these recommendations will fall more on the end user (pathologist) or on the vendor.

S. Joseph Sirintrapun, MD

While pathologists certainly would like to have the FDA's recommendations built into the WSI systems, Sirintrapun questions whether vendors have sufficient incentive to do so. "From the vendor perspective, what is the return on research and investment capital to build [the recommendations] into their devices?" he asks in a posting on the API listserve.

"My concern is that there is no seamless way to implement the recommendations at this current time, and there will be inertia on either the end user or vendor to take the initiative in taking on and working out how to seamlessly implement these recommendations," he writes. "Vendors have not built the end-user-friendly tools to enable implementation of these recommendations, or at least in my opinion, not good enough."

Sirintrapun also expresses concern about the lack of vendor competition. "I can foresee larger companies in this space losing enthusiasm or momentum for development, and smaller, disruptive

companies not even attempting to enter [the space] because the cost of such regulatory barriers is too high."

Stephen Hewitt, MD, PhD, a pathologist with the National Cancer Institute and a former consultant to the FDA, agrees that the specifications proposed by the FDA could drive up the cost of digital pathology. However, if specifications are not addressed, some WSI systems could be unusable because they are slow or hard to use.

**Stephen Hewitt, MD, PhD**

"There are a number of elements of a digital pathology system that appear to be based on assumptions and no data – color and screens being prime examples," Hewitt tells *Laboratory Economics*. "Hopefully the guidance will help clarify these."

However, the WSI instrument itself is not the most important concern, believes Hewitt. Even more critical are the server, storage and network required to make WSI functional. "We have estimated it is a 1:1 investment in IT (server, network, storage) vs. instrument, software and cockpit," he says. "This is the part no one wants to talk about."

According to the Digital Pathology Association (www.DPA.com), manufacturers may market their digital pathology technology for Research Use Only (RUO) unless the FDA has issued a clearance or approval to a specific manufacturer and for an intended use of the digital pathology hardware and software. Several manufacturers have received one or more FDA 510(k) clearances; however, no manufacturer has yet received an FDA approval of its technology for primary diagnosis.

The WSI draft guidance is available at: *www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm435355.pdf*. Comments are due by May 25.

## Guidelines for Pathologists

Since the FDA does not currently approve WSI systems for primary diagnosis, the College of American Pathologists (CAP) in 2013 developed recommendations for pathologists and laboratories to confirm the accuracy and concordance of their own whole-slide imaging systems. "Validating Whole Slide Imaging for Diagnostic Purposes in Pathology" contains 12 recommendations, including these key points:

Validation of the entire WSI system, involving pathologists trained to use the system, should be performed in a manner which emulates the laboratory's actual clinical environment.

It is recommended that such a validation study include at least 60 routine cases per application, comparing intraobserver diagnosis concordance between digitized and glass slides viewed at least two weeks apart.

It is important that the validation process confirms that all material present on a glass slide to be scanned is included in the digital image.

The full guidance document from CAP is available at: *http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2013-0093-CP*.

## CBO ESTIMATES $3.5 BILLION SAVINGS FROM CLOSING STARK LOOPHOLE

A new report issued by the Congressional Budget Office (CBO) has increased the estimated Medicare savings that would result from narrowing the In-Office Ancillary Services (IOAS) exception. According to the CBO, the 10-year savings associated with IOAS reform rose $100 million from last year's estimate to $3.5 billion, representing additional Medicare savings that could be used in legislation to permanently fix the Sustainable Growth Rate.

President Obama's budget proposal for 2016 includes provisions to close the in-office ancillary services (IOAS) exception to the Stark law. The budget for fiscal year 2016 stipulates that, starting in 2017, advanced imaging, radiation therapy, anatomic pathology and physical therapy services would be removed from the IOAS exception except for certain limited cases.

However, even though the President supports closing the self-referral loophole which CBO estimates would save $3.5 billion, Congress still must pass legislation for the provision included in the budget to become law (see *LE*, February 2015, p. 10).

## BUREAUCRACY TOP CAUSE OF PATHOLOGIST BURNOUT

Forty-six percent of physicians report being "burned out," according to *Medscape's Physician Lifestyle Report 2015*. The report defines burnout as loss of enthusiasm for work, feelings of cynicism and low sense of personal accomplishment. The Medscape survey found that pathologists, at 39%, rank among the lowest specialties reporting burnout. The two specialties with the highest rates of burnout are critical care (53%) and emergency medicine (52%).

Pathologists rated "bureaucratic tasks" and "spending too much time at work" as the most frequent causes of burnout. "Insufficient income" was also a leading cause. Unlike other physician groups, pathologists listed "difficult colleagues or staff" within the five most important causes of burnout.

The Medscape survey found that 45% of female pathologists were burned out versus only 33% of male pathologists.

### Top 10 Causes of Pathologist Burnout?*

| | |
|---|---|
| Too many bureaucratic tasks | 3.95 |
| Spending too many hours at work | 3.38 |
| Income not high enough | 3.35 |
| Difficult colleagues or staff | 3.25 |
| Impact of the Affordable Care Act | 3.20 |
| Feeling like just a cog in a wheel | 3.02 |
| Inability to keep up with current research and recommendations | 2.95 |
| Difficult employer | 2.91 |
| Lack of professional fulfillment | 2.70 |
| Increasing computerization of practice | 2.27 |

*Based on a scale of 1 ("not important at all") to 7 ("extremely important")
Source: Medscape's Physician Lifestyle Report 2015

## LAB STOCKS UP 18% YTD

Fourteen lab stocks have increased by an unweighted average of 18% year to date through March 17. In comparison, the S&P 500 Index is up 3%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 116% on news that Roche is buying a majority stake in the company. Meanwhile, LabCorp is up by 16% and Quest Diagnostics is up by 11%.

| Company (ticker) | Stock Price 3/17/15 | Stock Price 12/31/14 | 2015 Price Change | Market Capitalization ($ millions) | P/E Ratio | Price/ Sales | Price/ Book |
|---|---|---|---|---|---|---|---|
| Bio-Reference (BRLI) | $34.43 | $32.13 | 7% | $956 | 19.0 | 1.1 | 2.9 |
| Cancer Genetics Inc. (CGIX) | 7.22 | 6.68 | 8% | 71 | NA | 7.1 | 2.1 |
| CombiMatrix (CBMX) | 1.94 | 1.29 | 50% | 21 | NA | 2.8 | 2.6 |
| Enzo Biochem (ENZ) | 3.06 | 4.44 | -31% | 139 | NA | 1.4 | 4.0 |
| Foundation Medicine (FMI) | 48.09 | 22.22 | 116% | 1,400 | NA | 22.5 | 15.4 |
| Genomic Health (GHDX) | 33.82 | 31.97 | 6% | 1,090 | NA | 4.0 | 7.4 |
| LabCorp (LH) | 125.27 | 107.90 | 16% | 12,560 | 21.2 | 2.1 | 3.8 |
| Myriad Genetics (MYGN) | 36.38 | 34.06 | 7% | 2,590 | 25.1 | 3.6 | 3.8 |
| NeoGenomics (NEO) | 4.74 | 4.17 | 14% | 286 | NA | 3.2 | 4.6 |
| Psychemedics (PMD) | 16.64 | 15.15 | 10% | 89 | 27.8 | 3.0 | 6.8 |
| Quest Diagnostics (DGX) | 74.21 | 67.06 | 11% | 10,710 | 19.5 | 1.4 | 2.5 |
| Response Genetics (RGDX) | 0.48 | 0.32 | 52% | 19 | NA | 1.2 | 10.2 |
| Sonic Healthcare (SHL.AX) | 19.55 | 18.50 | 6% | 785 | 20.7 | 1.9 | 2.5 |
| Veracyte (VCYT) | 7.68 | 9.66 | -20% | 173 | NA | 5.2 | 3.6 |
| Unweighted Averages | | | 18% | | 22.2 | 4.3 | 5.1 |

Source: Bloomberg



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