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Cord Blood CEO Raises Questions About Physician Payments

The head of one of the nation’s major cord blood banks has asked his competitors to stop paying fees to physicians for referring and gathering specimens from their patients.

The request was made last month by Martin Smithmyer, chief executive officer of the New York City-based Americord Registry. Smithmyer equated the payments to physician kickbacks, which are mostly banned under federal law but are not addressed in the cord blood or tissue banking sectors specifically.

“There is a long history between some of the largest cord blood banks and hundreds of obstetricians and gynecologists,” Smithmyer said. “This results not only in millions of dollars exchanged between private banks and doctors, but situations where trusted healthcare professionals are recommending cord blood banks based on compensation rather than objective evaluation.”

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Harmonyx Releases New Tests for Gauging Painkillers

A Tennessee-based laboratory has brought to market a new assay its chief executive officer hopes will go a long way toward resolving the often thorny issues of pain medication management in the U.S.

Known as the Harmonyx Test for Pain, the assay will test genetic compatibility between the patient and 21 different painkillers, ranging from non-steroidal analgesics that are often obtained over-the-counter, to opioids such as oxycodone that require prescriptions and can sometimes lead to patient addiction and abuse issues.

“If you have a genetic makeup that allows you to take non-addictive pain medicine, then someone struggling with addiction, with a genotype favoring medicine that is non-addictive, can be moved off of an opioid,” said Harmonyx Chief Executive Officer Bob Bean. Alternatively, Bean noted that such testing can also avoid issues where patients are taking massive doses of painkillers with little result because their bodies are genetically unable to metabolize the drug.

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■ HARMONYX RELEASES NEW TESTS FOR GAUGING PAINKILLERS, from page 1

The buccal swab-based test focuses on eight genes specific to the metabolizing of painkillers. It will be available primarily through pharmacies for \$99. Results are provided in a compact one-page report that lists the drugs and plugs them into three recommendations: Try as directed, try with caution, try an alternative.

Despite Harmonyx providing a painkiller efficacy test at a relatively low price, the lab has some obstacles to overcome.

“We believe that many people are taking medicines that are ineffective, or struggling with dosing that is ineffective, or starting with medicine that is ineffective,” Bean said.

The issue of pain medication management has been inching toward a crisis for some years now. The aging population means that about one in three Americans uses some form of medication for pain management. But the use of opioids and their potential for abuse has grown into a significant public health issue. According to data from the Centers for Disease Control and Prevention, the number of prescriptions for painkillers has quadrupled since the late 1990s, and the agency estimates that about 2 million Americans are currently abusing such drugs. A total of 43,000 Americans die of drug overdoses every year, eclipsing the mortality rate from car crashes. Nearly a quarter of those die from prescription painkiller overdoses. The issue has led to huge increases in the number of lab tests performed for what is known as drug management, to determine whether patients are abusing drugs or not taking them and presumably selling them to other parties.

Some Obstacles

Despite Harmonyx providing a painkiller efficacy test at a relatively low price, the lab has some obstacles to overcome. Since it is a prognostic assay, the company has been unable to obtain clearances from the Food and Drug Administration to market the test directly to consumers, prompting it to try the pharmacist route (Harmonyx will provide a physician for interpreting the test). And while Bean noted that it is willing to work with any physician or pain management clinic to provide the tests for patients, the current reimbursement environment does not favor the assay (although Medicare, Medicaid and private payers cover drug monitoring assays).

“There is no financial incentive for physicians to do these tests. They cannot bill for them ... and doctors are choosing tests that will make them money,” he said.

There is also some question in the pain management community whether an assay such as Harmonyx’s would make a difference in prescribing habits of clinicians in the first place.

“My feeling is that, if a prescriber is appropriately conservative in prescribing and provides appropriately close follow-up, these tests may only be necessary if you see undesirable results from the medication trial,” said Robert Twillman, executive director of the American Academy of Pain Management. And while Twillman acknowledged that assays along the lines of Harmonyx’s have slowly gained traction, he observed that “given that it is a minority of patients who are not normal metabolizers, I’d expect that this testing would actually be useful in well under half of all cases.”

Takeaway: A new test for predicting the efficacy of painkillers may have a tough battle in gaining widespread acceptance. 

Could Drones Play a Role in Lab Operations?

Drones have been used by the military to fight terrorists, for hobbyists to buzz their neighborhoods and take video and photos, and may soon deliver goods from online retailers such as Amazon.

But a new study by researchers at Johns Hopkins University and Makerere University in Uganda has concluded that drones could also play a role in laboratory operations, possibly serving a crucial role in providing laboratory services to patients living in secluded and rural areas in the U.S. or in isolated regions of developing countries.

The results were surprising to the researchers: The blood tests could still be performed on the samples even after up to 40 minutes of drone travel, and there were no difference in the results when compared to the tests performed on the samples that did not leave the ground.

The researchers placed blood samples on hobby-sized drones to determine whether they would be affected by the altitude, hovering, and other elements of flying through the air, semi-exposed to the elements. Altogether, three paired samples were drawn from 56 adult volunteers, with tubes for chemistry, hematology, and coagulation testing. Half of the 336 total samples were kept stationary as a control. The other 168 samples were flown in a drone for between six to 38 minutes.

The flights were kept at an altitude below 100 meters (338 feet) and were performed in unpopulated areas within the line of sight of the remote pilot in order to conform with federal aviation regulations. At the end of the flights, 33 common chemistry, hematology, and coagulation tests were performed. Such tests comprise about 80 percent of all lab tests that are performed.

The results were surprising to the researchers: The blood tests could still be performed on the samples even after up to 40 minutes of drone travel, and there were no difference in the results when compared to the tests performed on the samples that did not leave the ground. That was despite the fact that such samples can be agitated by the gravity forces of a drone taking off, and the buffeting that occurs on landing. Most drones do not have landing gear, and therefore engage in controlled crash landings on their bellies instead.

“Such movements could have destroyed blood cells or prompted blood to coagulate, and I thought all kinds of blood tests might be affected, but our study shows they weren’t,” said Timothy Kien Amukele, M.D., a pathologist at the Johns Hopkins University School of Medicine and director of a lab collaboration between Johns Hopkins and Makerere, in an essay released by Johns Hopkins late last month.

The study’s findings were published in *PLOS One*, an open access academic journal. It was peer reviewed by a researcher at Gentofte University Hospital in Denmark.

Amukele said the next phase of testing would likely be a pilot in Africa, where many clinics are dozens of miles from the nearest laboratory. “A drone could go 100 kilometers (60 miles) in 40 minutes,” he said. “They’re less expensive than motorcycles, are not subject to traffic delays, and the technology already exists for the drone to be programmed to ‘home’ to certain GPS coordinates, like a carrier pigeon.”

Takeaway: Drones could play a role in delivery of laboratory specimens at some undetermined date in the future. 

Inside The Lab Industry

Mid-Year Earnings: LabCorp Eclipses Quest As Biggest Lab Company

It's official: LabCorp has eclipsed Quest Diagnostics as the nation's largest laboratory company—both in terms of top line revenue, and for the moment, bottom line profit.

Having folded in revenue and earnings from its acquisition earlier this year of pharmaceutical firm Covance, LabCorp reported net income for the second quarter ending June 30 of \$168.4 million on revenue of \$2.2 billion. That compares to net income of \$141.7 million on revenue of \$1.5 billion the prior year. Revenue was up a total of 46 percent.

"We are extremely pleased with our results this quarter, in which we began to see the power of our combined businesses. We delivered impressive growth, as well as record revenue, earnings and free cash flow to our shareholders. We remain focused on executing our long-term growth strategy, and delivering on our mission of improving health and improving lives."

— Dave King, CEO, LabCorp

In a call with analysts, LabCorp Chief Financial Officer Glenn Eisenberg said Covance contributed \$621 million in revenue during the quarter.

For the first six months of 2015, LabCorp reported net income of \$169.7 million on revenue of \$4 billion. During the first half of 2014, it reported net income of \$254.4 million on revenue of \$2.94 billion.

Growth from existing operations was strong. LabCorp's diagnostics division saw revenue growth of 5.4 percent, to \$1.6 billion. Total test volume rose 4.7 percent, while revenue per requisition rose 0.2 percent. The latter has been rising rarely in recent years, suggesting that some of the pressure from payers on the lab sector may be easing.

LabCorp's earnings per share of \$2.09 beat the consensus, which was \$2.03.

"We are extremely pleased with our results this quarter, in which we began to see the power of our combined businesses," said LabCorp Chief Executive Officer Dave King in a statement. "We delivered impressive growth, as well as record revenue, earnings and free cash flow to our shareholders. We remain focused on executing our long-term growth strategy, and delivering on our mission of improving health and improving lives."

However, combining Covance has been a bit of a challenge. Revenue for that business was down 2.7 percent from the year-ago quarter. LabCorp also revised its estimates for growth in Covance for 2015, forecasting a decline of 1.5 percent to 5 percent, down from the original estimate of flat to 2 percent growth. By contrast, the company has forecast that its diagnostics division's revenue would grow 3.5 percent to 5.5 percent during this calendar year, up from the original guidance of 3 percent to 5 percent growth.

Inside The Lab Industry

“The questions on Covance’s growth are likely to limit the opportunity for near-term multiple expansion and may limit upside until the next catalyst (be it a PAMA resolution, which we view as a meaningful headwind removal) or next quarter’s earnings,” said Michael Cherny, an analyst with Evercore ISI, in a report. “The earnings power opportunity for the new LabCorp remains firmly in place.”

“We are not just driving growth, we are driving profitable growth. Our strategies to restore growth and drive operational excellence are delivering both a better customer experience and earnings growth.”

— Steve Rusckowski,
CEO, Quest

Quest Earnings

By contrast, Quest Diagnostics’ growth was muted. It reported net income of \$129 million on revenue of \$1.93 billion. That compares to net income of \$142 million on revenue of \$1.9 billion for the second quarter of 2014. However, Quest took a \$52 million after-tax writeoff. Of that, \$41 million was associated with its recent debt refinancing, with the remainder connected to ongoing restructuring.

“We are not just driving growth, we are driving profitable growth,” said Quest CEO Steve Rusckowski in a statement. “Our strategies to restore growth and drive operational excellence are delivering both a better customer experience and earnings growth.”

For the first six months of 2015, Quest reported net income of \$199 million on revenue of \$3.76 billion. That compares to first half 2014 net income of \$253 million on revenue of \$3.65 billion. However, income from operations was \$529 million, compared to \$470 million a year ago, which company officials attributed to greater efficiencies due to ongoing restructuring and cost savings.

During a call with analysts, Rusckowski said that pressure from government payers on reimbursement has relented somewhat. “We don’t see any significant headwinds for 2016,” he observed. “Any changes to the clinical lab fee schedule proposed as part of the Protecting Access to Medicare Act, also known as PAMA, would go into effect in 2017.”

Like LabCorp, revenue per requisition also rose modestly for Quest, up 0.9 percent—the first time it has done so in three years, which was attributed to a shift toward pricier molecular and esoteric tests. The company has also seen rising volumes in its Medicaid business and fewer uninsured patients. However, total volume by requisitions was down 0.4 percent, although CFO Mark Guinan told analysts that total test volume was actually up.

Quest did bump up its revenue guidance for calendar 2015 to between \$7.49 billion and \$7.57 billion, up 2 percent to 3 percent from 2014. But its guidance for earnings remains unchanged.

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Amanda Murphy, an analyst with William Blair & Co., noted in a report after the earnings release that “We ... see upside to guidance driven by additional M&A activity (the company has indicated its intention to add 1 percent to 2 percent in revenue growth annually via acquisitions) and buybacks.”

Other Lab Results

Florida-based NeoGenomics reported a loss of \$176,000 on revenue of \$24.4 million for the second quarter. That compares to second quarter 2014 net income of \$274,000 on revenue of \$20.7 million.

“We expect NeoGenomics to drive meaningful earnings leverage into 2016 and 2017.”

— Amanda Murphy,
Analyst, William Blair & Co.

NeoGenomics Chief Executive Officer Douglas Van Oort said that business growth was strong, but partially masked by cuts in FISH reimbursement. Murphy noted that Medicare had cut FISH reimbursement by about 60 percent over the past couple of years, but that the 2016 Physician Fee Schedule includes a 42 percent increase in the technical component in FISH, but given the codes NeoGenomics uses, its reimbursement could be even higher.

“We expect NeoGenomics to drive meaningful earnings leverage into 2016 and 2017,” Murphy wrote.

Massachusetts-based Foundation Medicine reported a \$33.1 million net loss for the second quarter ending June 30. Although that loss was significantly higher than the \$13.8 million reported for the second quarter of 2014, revenue for this most recent quarter was \$22.5 million, up 55 percent from the \$14.5 million reported a year ago. A good part of the widening loss was attributable to spending \$14.4 million in advisor fees in connection to the recent collaboration with pharmaceutical giant Roche. Test volume was up 50 percent from the second quarter of 2014, and 13 percent from the first quarter of this year.

However, CEO Michael Pellini, M.D., noted that the company has had some issues obtaining local coverage determinations from the various regional MACs, particularly from Palmetto GBA regarding its non-small cell lung cancer test, for which it received coverage just last month. Partly as a result, the company cut revenue guidance from \$105 million to \$115 million to \$85 million to \$95 million.

“Prior guidance implied a meaningful acceleration in growth, which was difficult to rationalize given a lack of reimbursement announcements,” Murphy wrote. William Blair cut its 2016 guidance from \$186 million in revenue to \$158.5 million, although it also reduced the projected loss per share from \$2.63 to \$1.90.

Takeaway: Among national laboratories, the lead has officially changed between LabCorp and Quest Diagnostics. 

■ CORD BLOOD CEO RAISES QUESTIONS ABOUT PHYSICIAN PAYMENTS, from page 1

Cord blood banks store both blood from umbilical cords and placental tissue from newborns at the behest of their parents. Both the blood and tissue may be used for genetic and other medical therapies if the child has a serious medical issue in the future.

The banks have both close and peripheral ties to the lab sector. Virtually all perform laboratory testing on samples they receive to detect any presence of disease, with Americord performing this task at an affiliated facility in Indianapolis. And one of the largest of such banks, ViaCord, is owned by PerkinElmer, the large laboratory concern.

“Exchanging money between private companies and independent physicians creates a quid pro quo and an unprincipled system within health care.”

— Peter Francis,
President, Clinical Laboratory
Sales Training

Americord has always been fairly vocal about its refusal to pay physicians for tissue gathering and referral, but Smithmyer said in an interview that the pending \$700 million acquisition of Cord Blood Registry by pharmaceutical giant AMAG Pharmaceuticals convinced him to push the issue even further. Cord Blood Registry is the largest such bank in the U.S., managing about 600,000 samples. AMAG, which is also in the midst of becoming a publicly-traded company, said the deal would immediately be accretive to its bottom line.

Laboratory operators and pharmaceutical firms are barred by anti-kickback laws from making such payments. Virginia-based Health Diagnostic Laboratory recently settled a federal lawsuit accusing it of violating anti-kickback laws by paying physicians a \$30 fee, ostensibly to collect and forward blood samples for testing.

Smithmyer said in an interview he feared that the same sales force that is representing AMAG’s pharmaceutical lines would be used for cord blood and placental tissue.

And according to Smithmyer, the payments are anything but token. He claimed that medical practices were being paid anywhere from \$200 to \$700 in collection fees per sample. For the most part, the work of gathering samples and placing them in samples cases took just a few minutes.

“Exchanging money between private companies and independent physicians creates a quid pro quo and an unprincipled system within health care,” said Peter Francis, president of Clinical Laboratory Sales Training in Maryland. Although Francis noted that he’s not familiar with the cord blood banking sector, he observed that such payments “(engender) an air of unscrupulous business dealings.”

ViaCord confirmed that it pays physicians to gather the specimens, but denied they were kickbacks. “None of the payments that are made are provided in exchange for recommending or providing favorable status to ViaCord’s offerings—they are payments for medical services that are rendered at the time of delivery,” spokesperson Elizabeth Gray said in an email. She noted that testing occurs at a PerkinElmer laboratory in Ohio. She would not disclose how much physicians are paid for collection services.

A Cord Blood Registry spokesperson did not respond to a request seeking comment.

Takeaway: The issue of physician payments in the cord blood banking business could become more visible in the coming months. 

INDUSTRY BUZZ

CAP Helps Facilitate Cancer Data Sharing Partnership

Software developed in part by the College of American Pathologists is playing a key role in a unique cancer data partnership in California. St. Joseph Health System, a 14-hospital healthcare system in California, is submitting pathology data directly to the California Cancer Registry (CCR), which will then be used to study cancer trends and patterns among Californians. Ten of St. Joseph's hospitals are participating in the reporting, with more expected to be added shortly, officials said.

The initiative is the first in the United States where a hospital system is collecting and sending structured pathology data directly to a cancer registry. "Every second we save in sharing data gives researchers more time to spend on curing cancer," said Karen Smith, M.D., director of the California Department of Public Health (CDPH), in a statement.

The CDPH operates the CCR, which has been collecting data on every Californian who has contracted the disease since the late 1980s. It has data on about 3.4 million cases, and collects data on about 162,000 patients a year.

However, reporting and collecting data on cancer cases in close to real time is considered the gold standard for researchers to be able to understand trends in pathology and help develop treatments in response. The CCR had been months to years behind abstracting and analyzing the data they had gathered. CAP received a \$300,000 grant from CDPH earlier this year to begin facilitating the exchange of clinical cancer information electronically in California.

The linchpin of the reporting effort is CAP's electronic Forms and Reporting Module, known as eFRM. The reporting software was developed in conjunction with mTuitive, a Massachusetts-based software firm that sought a solution to the CCR's slow process of analyzing the data it had received.

Samantha Spencer, M.D., the director of CAP's structured reporting division, said the organization has outreach to expand this initiative to other states, but nothing was yet definitive. The California program is expected to involve other hospitals, and will run at least until June of next year.

Takeaway: The College of American Pathologists is playing a significant role in the direct reporting and collection of cancer data. 

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| | | |
|---|--|--|
| Americord Registry 866-503-6005 | Cord Blood Registry 888-776-3285 | Quest Diagnostics 973-520-2700 |
| Clinical Laboratory Sales Training 410-299-6562 peter@clinlabsales.com | Harmonyx 901-692-9248 | ViaCord 781-663-5800 |
| College of American Pathologists 847-832-7000 | LabCorp 336-229-1127 | William Blair & Co. 312-236-1600 amurphy@williamblair.com |
| | mTuitive 508-771-5800 | |

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