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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming G2 Events

Lab Institute

October 14-16, 2015

Hyatt Regency Washington DC on Capitol Hill

www.labinstitute.com

American Registry of Pathology Chief Admits to Stealing Millions

It appears the former executive director of the American Registry of Pathology (ARP) will be transitioning from behind a desk to behind bars. Michael Parry, who had been with ARP for 17 years, admitted in federal court in Maryland to embezzling nearly $2.2 million from the organization. The sum represents roughly a third of its cash assets, according to recent tax records.

The 58-year-old Parry pled guilty to wire fraud and money laundering last month, the U.S. Justice Department announced. He faces up to 30 years in prison when he is sentenced in December. Charges had been filed against Parry only last Sept. 4. His plea agreement came less than two weeks later.

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Market Potential for Genetic Testing Large But Mixed

A new survey conducted by a California-based DNA screening company suggests that there is an audience among consumers for genetic testing, but they are uncertain about the services that are available and are sometimes fickle about using them.

That's the conclusion of the survey conducted by Counsyl, which used the services of an independent research company to sample responses from 1,020 adults nationwide. The data could be used by laboratories in the genetic testing arena to better craft and market future tests.

The survey concluded that 78 percent of those surveyed were aware that DNA can tell them if they could pass on genetic diseases to their children. Another 70 percent wanted to find out if they could pass on a genetic disease.

However, only 28 percent of those surveyed believed they should undergo genetic testing prior to starting a family, and 16 percent said only if they had learned of a history of genetic disorders in their family. Those findings concerned Counsyl officials, who noted that many genetic disorders are passed down through childbirth and often by

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Market Potential for Genetic Testing Large But Mixed, *from page 1*

parents who had no idea they were at risk for doing so. "This speaks to a lack of awareness regarding when such tests should be used," said Shivani Nazareth, Counsyl's director of women's health. But patients may lack such information, because 54 percent said they had never discussed genetic testing with their doctors.

"The information needs to be actionable, empowers the patient to do something, and reduce their risks and improve their outcomes."

— Shivani Nazareth, Director of Women's Health, Counsyl

There were also gaps in desires for testing that broke along ethnic lines. Among whites, 68 percent said they wanted to know if they had a genetic disease or were at risk of passing such a disease along to their children. But 72 percent of African-Americans and 71 percent of Latinos said they wanted such information. And among college graduates or those who attended college, 73 percent said they wanted such information, compared to 66 percent of those who had a high school degree or less.

Regarding specific reasons to obtain such data, 48 percent of all respondents said it would give them peace of mind, 20 percent said they had some family history of a specific disease, and 18 percent said they wanted the testing because they had heard it was more readily available. Only 6 percent said it was because their doctor recommended they undergo testing.

Among the groups that did not want to find out what information is contained in their DNA, 16 percent of whites said it would cost too much, while 27 percent of African-Americans thought it was too pricey. Only 9 percent of Latinos said cost was a reason for not being interested in such testing.

Whites were also significantly more likely to not be interested in finding out the results of such tests because they had heard they were often inaccurate compared to other ethnic groups, although such doubts go down dramatically in households that have higher incomes. But there was also a geographic split: 12 percent of those who lived in the South said they had heard such testing was often inaccurate, compared to 2 percent in the Midwest and 9 percent in the Northeast.

One avenue where there was little interest in DNA testing was to gain insights into one's lifespan. Only 28 percent of respondents said they were interested in testing for such a reason, although it went up slightly among groups with higher household incomes.

"The information needs to be actionable, empowers the patient to do something, and reduce their risks and improve their outcomes," Nazareth said, adding that gauging one's life span does not fit in that category.

Takeaway: The market potential for DNA-based genetic testing is significant, but can vary widely. G2

CardioDx Inks Draw Deal With Quest

CardioDx, a California-based molecular laboratory that specializes in cardiac assays, has entered into a blood draw agreement with national lab giant Quest Diagnostics.

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Under the terms of the multi-year agreement, doctors who wish to order CardioDx's Corus CAD test can order related patient blood draws through Quest's more than 2,000 patient service centers and 4,000 phlebotomists in physician offices nationwide. Samples would then be forwarded to CardioDx's lab in Redwood City, Calif. for testing.

The deal with Quest is the first major draw deal by CardioDx with a big lab, and allows it to expand access to its test without having to invest significantly in infrastructure. CardioDx previously received national coverage contracts last year with two major commercial payers, Aetna and Coventry Health, along with coverage from the Medicare program.

"The addition of this test to our offering provides a new avenue to generate value from Quest's uniquely large network of patient service centers and in-office phlebotomists in the United States."

— Patrick Plewman, General Manager, Quest Diagnostics

"This agreement with Quest represents another major milestone that will expand patient access to the test and allow CardioDx to strengthen relationships with clinicians," said David Levison, President and Chief Executive Officer of CardioDx. "Quest is the world leader in diagnostic testing, and we are thrilled that it will now be easier for patients to access the Corus CAD test."

Financial terms of the agreement with Quest were not disclosed.

CardioDx positions its test as both prognostic and prophylactic. It can predict the likelihood of coronary artery disease with a 96 percent reliability rate, higher than other traditional forms of cardiac testing, the company has claimed. It also positions Corus CAD as a far less invasive and expensive alternative to cardiac imaging procedures such as myocardial perfusion imaging and cardiac angiography, which expose the patient to radiation and potential medical complications.

A study published by CardioDx researchers last year and published in the journal *Population Health Management* concluded that use of the test also leads to a cost savings of 9.4 percent compared to those more traditional procedures. The company said that using Corus CAD in lieu of those two tests would save a health plan with 500,000 enrollees about $6.7 million per year.

"The addition of this test to our offering provides a new avenue to generate value from Quest's uniquely large network of patient service centers and in-office phlebotomists in the United States," said Patrick Plewman, General Manager of Quest Diagnostics' cardiovascular, metabolic and endocrinology clinical franchise, in a statement.

The privately held CardioDx has not disclosed any sales volumes, but has said Corus CAD has been utilized more than 100,000 times. The company recently raised $5 million in an offering to outside investors, according to documents from the U.S. Securities and Exchange Commission—on top of nearly $120 million it has raised over the past four years. The company has financial backing from venture capital firms such as GE Capital, Intel Capital, J.P. Morgan and Mohr Davidow.

Takeaway: CardioDx continues to expand the availability of its primary assay through a joint venture with a much larger laboratory. G2

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Inside The Lab Industry

Most Hospital Labs Shut Out of PAMA Reporting Requirements

Hospital laboratories will likely have to tighten their belts in 2017 regarding Medicare reimbursements as the Centers for Medicare & Medicaid Services (CMS) begins determining how much to cut payments under PAMA. But any opportunity they have to provide data on the matter is mostly being squelched for now.

According to the proposed rule CMS issued in the Federal Register this month, most hospital laboratories would be excluded from reporting the levels of reimbursement they receive from private payers, industry officials say.

> *"We believe the statute intends to limit reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold, if established by the Secretary) and not include other entities (such as hospitals, or other health care providers) that do not receive the majority of their revenues from the Physician Fee Schedule or Clinical Laboratory Fee Schedule."*
>
> — Michael Cherny, Analyst, EverCore ISI

CMS intends to collect such data in order to set new benchmark reimbursement rates that would hew closer to what private insurers pay for lab services. The Office of Management and Budget has concluded that making such an adjustment would save the Medicare program as much as $360 million for fiscal 2017 and as much as $5 billion over the next decade, although the laboratory sector has argued that Medicare is acting on less than comprehensive information.

The rule has proposed that any laboratory receiving $50,000 or more in revenue from Medicare for laboratory services or 50 percent or more of their revenues from laboratory and physician services must report private payer data and volume from July 1, 2015 through the end of this year. Qualifying labs that don't comply or misrepresent their payment data can face financial penalties as much as $10,000 per day.

CMS intends to use the data to adjust its payment rates by November 2016 for implementation at the start of 2017.

Any payment reductions would be gradual: They cannot be reduced more than 10 percent compared to the price in the previous year between 2017 and 2019, or more than 15 percent between 2020 and 2022.

However, most hospital laboratories and many physician office-based labs would be excluded from reporting their payer pricing data under the rule, observers say.

"We believe the statute intends to limit reporting primarily to independent laboratories and physician offices (other than those that meet the low expenditure or low volume threshold, if established by the Secretary) and not include other entities (such as hospitals, or other health care providers) that do not receive the majority of their revenues from the Physician Fee Schedule or Clinical Laboratory Fee Schedule," said Michael Cherny, an analyst with EverCore ISI, in a recent report.

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Inside The Lab Industry

Francisco Velázquez, M.D., chief executive officer of PAML in Spokane, Wash., was also unhappy with the apparent exclusion of hospital laboratories and affiliated parties.

"When you exempt hospital-based laboratories and physician office-based laboratories which provide a significant percentage of the testing in this country, an uneven burden is placed on independent laboratories," said Velázquez, who heads the largest independent lab in the Pacific Northwest. "For the most part independent laboratories are small to medium-sized, most often regional or extended regional facilities which provide a community focused high quality service with value added offerings such as home draws which benefit the Medicare population significantly. There seems to be a somewhat narrow focus on pricing which for the most part will not allow for value-added services, community impact and local continuity of services to be factored in as a value."

"If you take the hospitals out and they don't report their pricing, we are concerned that the pricing would not reflect the true marketplace."

— Alan Mertz, President, American Clinical Laboratory Association

Not every laboratory was concerned regarding the proposed PAMA rules. "While details on the proposed PAMA rule still need to be evaluated, we believe it provides a pathway to market-based pricing for the Afirma GEC and we continue to support PAMA's goal of bringing transparency and a market-based approach to how CMS sets Medicare rates for personalized medicine diagnostic tests," said Bonnie Anderson, chief executive officer of molecular lab Veracyte, in a statement. The South San Francisco, Calif.-based Veracyte specializes in molecular-based tests for thyroid cancer, which includes the Afirma assay.

But Alan Mertz, president of the American Clinical Laboratory Association, said he was concerned that excluding hospital labs from the reporting process would further impact the price cuts. "If you take the hospitals out and they don't report their pricing, we are concerned that the pricing would not reflect the true marketplace," Mertz said. He pointed to a 2013 study performed on behalf of ACLA by Avalere Health that concluded commercial payments for tests were significantly higher than in the hospital setting.

Avalere compared private data for 27 test CPT codes representing both low-dollar and high-dollar tests. They constituted nearly half of Medicare spending under the 2011 CLFS. ACLA claimed in a statement that the study it commissioned was far more in depth than the report issued by the U.S. Department of Health and Human Services' Office of the Inspector General in 2013 that led to the passage of PAMA the following year.

For example, a creatinine assay was paid at a commercial mean price of $14.04 in 2012, compared to $6.82 in a non-hospital setting. A comprehensive metabolic panel was priced at $57.91 in 2012, compared to $14.85 in a non-hospital setting.

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Mertz noted that under the proposed rule, hospitals are able to report their commercial pricing data if they operate a laboratory with a taxpayer identification number separate from their hospital operations. Only three ACLA members are so situated, according to Mertz. "There may be some of the larger hospitals labs with outreach (operations), but it's hard to tell," he said.

"We ... view the long-awaited release of the rule as a removal of a meaningful overhang for the space and this should serve as a clearing event for both Quest and LabCorp. Assuming that the definition of 'applicable labs' remains unchanged in the final rule, there is a clear incremental negative headwind, but we would note that this appears to be the last leg of reimbursement uncertainty for the labs"

— Michael Cherny, Analyst, EverCore ISI

Cherny also believed that the proposed rule would be an overall negative to the lab sector, and could even drag down the profitability of the two biggest publicly-traded labs, LabCorp and Quest Diagnostics. He said the development was "an incremental negative," adding "we peg the downside earnings from our current estimates at (around) 3-4 percent for Quest and 2-3 percent for LabCorp, assuming that not every single test is reduced at the maximum level."

As for PAML, Velázquez said he did expect to see some cuts under PAMA, but that he would "need to see exactly how this will be applied to better understand the long-term impact." Velázquez noted that PAML has been focused on cutting its costs over the past three-and-a-half years, even as testing volumes have decreased.

Mertz said ACLA would advocate for a change in the comments it intends to file with CMS. The agency is accepting comments until the end of November.

"We are going to strongly suggest that we fix this proposed rule that it follows the statute and the intent of the law," he said.

The news is coming at an unwelcome time, coupled with CMS' decision to set some of the molecular pricing for the 2016 preliminary CLFS under the crosswalk approach (*Laboratory Industry Report* will delve into that in depth in its next issue).

But Cherny noted that the proposed PAMA rule could signal the beginning of the end of labs getting hammered regarding future reimbursements. "We ... view the long-awaited release of the rule as a removal of a meaningful overhang for the space and this should serve as a clearing event for both Quest and LabCorp. Assuming that the definition of 'applicable labs' remains unchanged in the final rule, there is a clear incremental negative headwind, but we would note that this appears to be the last leg of reimbursement uncertainty for the labs," he wrote.

Takeaway: There is concern in the laboratory sector that the exclusion of hospital lab price reporting data could further depress the new Medicare rates as reported under PAMA. G2

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American Registry of Pathology Chief Admits to Stealing Millions, *from page 1*

Physicians, including pathologists, have been regularly prosecuted in state and federal courts for fraud in recent years, but the Parry case may involve the highest-ranking member of the laboratory/pathology community to date.

Parry, an accountant by training, was named executive director of ARP just last year, after more than two years in the role in an acting capacity. He had replaced William A. Gardner, Jr., M.D., who passed away suddenly in October 2011. Parry had joined the organization in 1998 as its director of operations. He resigned from ARP in the spring of 2014, just after being named the permanent executive director.

According to the Justice Department, Parry, who is a resident of Florida, had directed a number of wire transfers between ARP and the International Registry of Pathology (IRP), between February 2010 and April of last year.

Parry received total compensation of more than $257,000 in 2011, the most recent year for which records were available. That made him the second-highest paid executive at ARP aside from Gardner that year.

ARP is a Congressionally chartered non-profit organization that funds research for pathology in both the civilian and military world and maintains a specimen registry. It receives about $25 million a year in grants, membership fees and other revenue, tax records show. It is best known for operating the National Museum of Health and Medicine in Silver Spring, Md., and the ARP Press, which publishes a variety of pathology-related texts. It also provides staffing for the Armed Forces Medical Examiner System, which conducts autopsies among military personnel. An affiliated quasi-governmental organization, the Armed Forces Institute of Pathology (AFIP), was shut down by ARP in 2011 shortly before Gardner died, leading to the layoffs of about a third of ARP's workforce. Prior to its closure, AFIP had played a role in selecting ARP's executive director.

The ARP, which has offices in both Maryland and Delaware, keeps an extremely low profile and does not even operate its own website.

According to the Justice Department, Parry, who is a resident of Florida, had directed a number of wire transfers between ARP and the International Registry of Pathology (IRP), between February 2010 and April of last year. Parry served as treasurer of the latter organization, which provides support to pathologists working in developing countries, and had control over its bank accounts. Records show he did not receive any compensation in his role with IRP, although that organization has not filed a tax return since 2008.

The transfers were purportedly to fund medical studies, research grants and other activities that ARP normally underwrites. Parry then fabricated invoices from a legitimate vendor related to medical research studies; emails from himself to others to suggest he had funded fictional research fellowships; and wire transfer documents showing that payments were made directly from ARP's accounts to legitimate ARP vendors or educational institutions. Parry then transferred the funds from the IRP account to his own account. As part of his guilty plea, Parry has agreed to pay the ARP full restitution for the money that was taken.

Takeaway: Michael Parry's recent guilty plea is probably among the highest level convictions in the lab/pathology sector. G2

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INDUSTRY BUZZ

Seahorse Bioscience Enters Into Mitochondrial Research Initiative With University of Alabama

The Foundation for Mitochondrial Medicine (FMM) and the University of Alabama at Birmingham have collaborated with a Massachusetts-based firm to create an initiative intended to better diagnose neuromuscular diseases. FMM will create a reference laboratory focused on metabolic bioenergetics that will concentrate on developing new assays and platforms for detecting and evaluating mitochondrial neuromuscular diseases. Much of the testing platform will be provided by Seahorse Bioscience, which has developed testing platforms to measure cell metabolism and its related functions. Seahorse was acquired by Agilent Technologies Inc. just days before the deal with FMM and the University of Alabama. Financial terms of the initiative were not disclosed.

"The most serious diseases that affect developed nations, such as atherosclerosis, neurodegeneration and diabetes, are known to involve changes in bioenergetic health," said Victor Darley-Usmar, professor of mitochondrial medicine and pathology at the University of Alabama and vice-chair for research in its pathology department, in a statement. "The challenge is to translate the findings in basic research in mitochondrial function and the pathology of disease to the clinic, and this program will be a major step toward achieving that aim."

Victims of mitochondrial disease can acquire their disorders in a variety of ways, including through inherited genetics and mutations, or through aging, environmental stress or changes in their metabolism.

"By establishing the clinic and sharing this vision, we plan to address the unmet clinical, diagnostic and therapeutic needs of the mitochondrial patient community," said Laura Stanley, Executive Director of FMM, in a statement. "Clinical needs of the patient community will be coordinated under one roof, and multiple specialists will join together to serve complex patient populations whose symptoms require the collective knowledge of neurologists, geneticists, gastroenterologists and others. UAB and Seahorse Bioscience have made revolutionary advancements in the field of bioenergetics, and UAB's established research expertise and longstanding work in neuromuscular diseases make it the ideal location for the program."

Takeaway: A mitochondrial medical research initiative will include the development of new laboratory assays and test platforms. G2

References

American Clinical Laboratory Association
202-637-9466

American Registry of Pathology
301-578-1646

CardioDx
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Foundation for Mitochondrial Medicine
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LabCorp
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PAML
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Quest Diagnostics
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Seahorse Bioscience
978-671-1600

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