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HIGHLIGHTS

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Survey Says Many Hospitals Are Reluctant to Adopt Precision

A new survey by the organization Healthcare Catalyst suggests that many hospital executives are on the fence regarding using precision medicine within their walls.

The findings come on the one-year anniversary of an Obama administration initiative that provided more than $200 million in funding to push precision medicine. At that time, the White House had declared that "translating initial successes to a larger scale will require a coordinated and sustained national effort."

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Theranos Encounters More Regulatory Obstacles in Its National Buildout

Theranos founder Elizabeth Holmes has declared she would change the future of laboratory testing, but her startup's own future is looking increasingly thornier.

Late last month, the Centers for Medicare & Medicaid Services said Theranos' Newark, Calif. laboratory was posing an immediate danger to patients in the area of hematology. That's the same kind of ding hospitals get when they leave medical instruments inside patients.

The response was immediate: Walgreens, the Fortune 100 pharmacy retailer that just months ago was poised to make Theranos as much as a fixture in its stores as greeting cards or antacid tablets, has suspended operations at the company's retail lab at its Palo Alto store.

"No patient samples will be sent to the Newark lab until all issues raised by CMS have been fully resolved," Walgreens said in a statement. "Walgreens informed Theranos that tests collected at 40 Theranos wellness centers located at stores in Arizona must be sent only to Theranos' certified lab in the Phoenix area or to an accredited third-party lab for analysis."

Walgreens had previously put a hold on introducing Theranos testing centers at its other stores nationwide.

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Theranos Encounters More Regulatory Obstacles in Its National Buildout, *from page 1*

CMS gave Theranos 10 days to issue a plan of correction, a typical requirement of an immediate jeopardy letter. If Theranos does not satisfy CMS, it could have its CLIA certification revoked or suspended.

Regulatory experts were unable to say how common such immediate jeopardy letters are in the laboratory realm—they are fairly commonplace among hospitals, where patients are exposed to potentially dangerous medical errors on a daily basis. The agency suspended or revoked 35 CLIA certifications in 2014 and 37 in 2013, the most recent years for which records are available. Most of the revocations include smaller standalone or community hospital labs. The number of actual warning letters sent to labs by the CMS was not available.

Theranos issued a statement that simultaneously suggested that the problems were all but corrected while it was among the few labs that invited such scrutiny.

The Palo Alto, Calif.-based Theranos has had its testing platform come under fire from both the CMS and the FDA for a variety of issues, including the accuracy of its tests and its testing platform, which includes the ability to test tiny amounts of blood that can be drawn from patients without needles.

"Theranos remains the sole company to call for—and voluntarily submit itself to—stronger regulatory oversight," it said, in reference to the fact that it had decided to submit all of its tests to the U.S. Food and Drug Administration for approval—a practice that most other labs are actively resisting.

"It's important to note this particular survey was conducted months ago and is not a reflection of the current state of our lab in Newark," the statement continued. "As the survey took place we were simultaneously conducting a comprehensive review of our laboratory's systems, processes and procedures to ensure that we have best-in-class quality systems. CMS' findings included standard and condition-level deficiencies, and one finding at the 'immediate jeopardy' level...to be clear, that finding does not apply to the whole lab, and none of these findings relate to our Arizona lab, where we currently process over 90 percent of our tests."

To correct some personnel deficiencies, Theranos said it has hired two new key employees: Kingshuk Das, M.D., a board-certified pathologist and associate medical director of UCLA Health's Clinical Laboratories; and Waldo Concepcion, M.D., chief of clinical transplantation and professor of surgery at Stanford University Medical Center.

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There are a variety of reasons Theranos is drawing such scrutiny from regulators. Laboratories are not glamorous or even high-visibility businesses. Holmes, a Stanford University dropout with a penchant for wearing black turtlenecks, has been a regular on the media circuit, talking up her company to national print and electronic news outlets. The company is also taking the risk of selling tests directly to consumers—a relatively new business model that often makes regulators uneasy if done so on a large scale, according to the publication *Business Insider*.

A former high-ranking lab executive who asked not to be named suggested that Theranos has also drawn the ire of would-be competitors, which in turn may be bringing more heat on the company.

"This sometimes happens when a lab is talking up a technology that may not be ready for prime time," the person said.

Theranos has more than 200 tests on its menu, but only one assay for herpes has received FDA approval for deployment through its own platform.

Takeaway: Theranos has more obstacles in its path toward becoming a lab giant, and they seem to be growing more formidable by the day. G2

Magellan Lends Lead Testing Platforms to Flint

One of Magellan Diagnostics' testing platforms is playing a small role in addressing the contaminated water crisis in Flint, Mich.

The Massachusetts-based lab has been shipping its LeadCare II testing platform to county health officials in Flint in order to test the levels of lead contamination in the population.

Flint has made national headlines since its governor-appointed city manager switched water supplies. The change caused lead and other contaminants to leach into the water for months. Health officials believe a large majority of the city's children have been exposed to lead. The Magellan system, which received U.S. Food and Drug Administration approval last year, can obtain test results from a blood sample within three minutes.

"It is critical to identify and monitor kids who have been exposed to lead. Our system is the fastest and easiest way to do this—it's simple to run, and in three minutes the doctor has an answer. People with potential exposure in Flint should have access to testing," said Magellan Chief Executive Officer Amy Winslow. "We are proud to partner with Genesee County and other community groups who want to implement screening programs. Too many people think lead exposure is a thing of the past. As Flint has shown, it still lurks in our environment and can cause major, lasting health issues."

Magellan spokesperson Matt Burke said that more than two dozen testing platforms have been shipped to Flint officials in recent weeks. The company was unable to say how many tests have been performed so far.

Takeaway: Magellan Diagnostics is using a significant health crisis to spread the word on its latest testing platform. G2

Inside The Lab Industry

Bostwick Labs Founder Starts Anew in Pathology Testing

Although there is no clinical pathologist considered a household name, David G. Bostwick, M.D., may be the closest found in the laboratory sector.

Bostwick founded Bostwick Laboratories in 1999. Within a decade, the company operated testing facilities in Virginia, New York, Texas and Florida and had about 750 employees and revenue topping $100 million a year in 2007—more than triple its 2005 numbers.

The lab announced in 2008 that it was going public, although it never did so. Three years later, a majority share in the company was purchased by private equity firm Metalmark Capital LLC for an undisclosed amount. Five years later, Bostwick's non-compete clause that was part of the Metalmark deal has expired. He has just settled federal civil charges of improper testing that dogged him for nearly a decade. And, at age 61, he does not have plans to retire.

"I'm a pathologist, and this is what I do."
— David G. Bostwick, M.D.

In other words, it's the perfect time to try another lab business. Bostwick announced late last year that he had started up another eponymous business venture, Granger Laboratories (that's his middle name; the business rights to his last name went with the sale of his former lab).

Based in North Chesterfield, Va., just 25 miles south of Bostwick Laboratory's headquarters, Granger consists of himself and one other doctor—former Bostwick pathologist Jun Ma, M.D., and a total of six employees. Granger is focusing specifically on urological and gynecological pathology, niches where Bostwick believes some success may be found.

Indeed, Bostwick is optimistic Granger will grow to a half-dozen pathologists and 25 employees by the end of the year. He is even planning on adding a second lab space near his home in Orlando.

Known to be closed-mouthed on his business numbers, Bostwick said he had financial backers, but aside from calling them "qualified investors" would say nothing specific about who they are. But he was clear as to why he was starting up another company.

"I'm a pathologist, and this is what I do," he said.

Bostwick's skills as a pathologist are unquestioned. He has written more than a dozen texts in the field, including the renowned "Urologic Surgical Pathology." Even after leaving Bostwick he has had a thriving practice rendering second opinions for pathology cases.

"He was always seen as a really good pathologist," said Dennis Weissman, a Washington, D.C.-based laboratory consultant and co-founder of G2 Intelligence.

Inside The Lab Industry

But whether this is the right time to start up a pathology practice or lab is another question altogether. Bostwick said that Granger would focus on quick turnaround times and customer service and developing novel assays.

"The combination of excellence and state of-the-art for anatomical pathology and reimbursable and medically necessary genetic tests should be a winning combination."

— David G. Bostwick, M.D.

Bostwick has some traction in that last area. Another company he founded, American International Biotechnology (AIB), has developed several molecular tests that will fit into Granger's service line.

They include a recently developed next-generation sequencing (NGS) assay for vaginosis. That test, known as GynecoloGene, is far more effective at picking up infections than urine culturing, according to Bostwick. Granger also plans NGS tests for urology patients as well, although Bostwick declined to provide specific details.

"The combination of excellence and state of-the-art for anatomical pathology and reimbursable and medically necessary genetic tests should be a winning combination," he said.

Genetic tests tend to command far higher prices than older assays, and Bostwick sees that as a way his lab can overcome the recent deep reimbursement cuts for pathology services. A decision by the Centers for Medicare & Medicaid Services to reduce reimbursement on the technical component of CPT code 88305 for tissue pathology work drove some practices out of business and devalued others to the point that prices fell by a third or more, industry observers say. And while Bostwick agrees that the reimbursement environment for pathology is rough, he has seen what he claims are far worse blows to the sector.

"The government allowing insourcing of lab tests by urologists consumed more than 30 percent of the market," he said. "And by my reckoning, that was patently illegal." Another development that hurt the space was allowing donations by labs of electronic medical record systems to physician practices, another instance of government intervention—Congress passed a law allowing the practice—that Bostwick considered illegal.

To say that Bostwick's relationship with the federal government is freighted would be a judicious understatement. Just 10 days after he officially announced the Granger startup, the U.S. Justice Department issued a statement saying he had settled a *qui tam* lawsuit connected to his tenure at Bostwick Labs.

The suit, which had been filed in 2008 by former Bostwick Labs employee Michael Daugherty, had accused both Bostwick and his lab of ordering FISH tests that were neither medically necessary nor ordered by physicians between 2006 and 2011. FISH reimbursement under Medicare during that period ranged from

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$456 to $966. Bostwick Laboratory was also accused of improperly inducing physicians to enroll patients into a prostate cancer study, a separate whistleblower action brought by a New York City urologist.

Although the U.S. Attorney General's office declined to intervene in the FISH suit, Bostwick Labs attorneys could not get the case dismissed. It settled the matter with the feds in 2014 for $6 million. It also settled the prostate cancer whistleblower action—in which the feds did intervene—for little more than $500,000.

"I am proud of being affiliated with it as a physician and a pathologist by putting my name on it. I have a personal commitment to doing the best job I can."

— David G. Bostwick, M.D.

Bostwick himself settled the FISH whistleblower case for $3.75 million. That included a $2.6 million upfront payment and another $1.13 million over the next five years if certain undisclosed financial contingencies are reached. Daugherty will receive more than $2.5 million of the total settlement, the Justice Department said—somewhat higher than the standard 15 percent contingency most *qui tam* relators receive.

"This case shows that the Justice Department will not hesitate to hold accountable both the companies and the individuals who order or perform excessive, non-patient specific tests and provide inducements to physicians that lead to unnecessary costs being imposed upon our nation's health care programs," said Benjamin C. Mizer, head of the Justice Department's Civil Division, in a statement.

Weissman remembers the case well. "There is no doubt that the company got involved in some shady practices," he said, although he could not say if Bostwick himself was directly involved.

Bostwick sees it a little differently. He noted that in over eight years of litigation, his case never even reached the discovery phase—which his attorneys said would have cost as much as $2 million to slog through. "The relator decided to proceed hoping that Bostwick Labs and I would concede and capitulate," he said. Some of his settlement was paid by his insurance company. Bostwick would not say how much, but observed that he was "very grateful" for its contribution.

Bostwick did not completely deny wrongdoing. "I am not saying we didn't do anything wrong," he said, but was upset that he was never given an opportunity to put on a viable defense that would not have been financially ruinous. Having put those legal issues behind him, Bostwick is now focused on making Granger Laboratories a success.

"I am proud of being affiliated with it as a physician and a pathologist by putting my name on it. I have a personal commitment to doing the best job I can," he said.

Takeaway: David G. Bostwick is attempting his own style of pathology practice management in the laboratory space. G2

Survey Says Many Hospitals Are Reluctant to Adopt Precision, *from page 1*

The results of the Healthcare Catalyst survey tend to bear that out. Of the 61 hospital executives surveyed—mostly chief information officers with a smattering of clinical leaders and no lab managers—only 25 said precision medicine would play a significant role at their institutions in the next five years. That's just 41 percent. Factor out academic medical centers—which tend to embrace research and technological initiatives much more earnestly than community hospitals—and the numbers drop to 32 percent.

> *"I think it is a combined pressure of both the dollar amount that would need to be invested and the financial return on (precision medicine), while avoiding penalties for readmission and other clinical benchmarks"*
>
> — David Crockett, Health Catalyst

Those surveyed at academic medical centers have a vastly different view. Seventy-one percent said precision medicine would play a significant role in the near term, while 64 percent said they planned to fold genomic data into the electronic health records of their patients.

"The disconnect between the recognition that genomics holds great promise and yet the lack of preparation for precision medicine may reflect the fact that technology adoption is often driven by research efforts at major academic medical centers, with others following in their footsteps," said David Crockett, Health Catalyst's senior director of research and predictive analytics. Crockett did note that the survey confined its focus to next generation sequencing, gene panels and exome genetic work, and not specifically molecular testing.

That lag could spell trouble for some esoteric laboratories, which have been developing tests intended specifically for use in the hospital setting and to more quickly respond to serious issues such as hospital-acquired infections like sepsis. The mortality rate of such infections can be cut dramatically with a quick diagnosis, which molecular testing can deliver.

Crockett, who was formerly a senior manager at ARUP Laboratories and was a professor of pathology at the University of Utah, believes that hospital managers may have other issues on their minds.

"I think it is a combined pressure of both the dollar amount that would need to be invested and the financial return on (precision medicine), while avoiding penalties for readmission and other clinical benchmarks," he said. "I think genomics just gets pushed to the back burner. It is not ready to be prime time."

Relevance of DNA Sequencing To Treating Your Patients

	Academic Medical Centers	Non-Academic Hospitals
Very Relevant	36.00%	4.00%
Relevant	50.00%	35.00%
Slightly Irrelevant	14.00%	39.00%
Completely Irrelevant	0.00%	22.00%

Source: Health Catalyst

Crockett suggested that the mindset might be changed as the current government reimbursement system moves away from fee-for-service and more toward bundled payments. However, even private payers do not focus on the long-term. "They are typically focused on near-term risks across all plans," he said.

Takeaway: Despite a push for precision medicine, many hospitals are not expected to wholly embrace its use for many more years. G2

INDUSTRY BUZZ

PerkinElmer Acquires Swedish Lab for Prenatal Testing Technology

PerkinElmer has acquired a Swedish laboratory in a bid to significantly expand its portfolio of prenatal testing products.

The Massachusetts-based PerkinElmer announced the acquisition of the Sollentuna, Sweden-based Vanadis Diagnostics. Terms of the transaction were not disclosed.

Vanadis NIPT testing platform remains under development, but the company said it can zero in on cell-free DNA to perform prenatal diagnostics without sequencing or PCR amplification, cutting down the time to render test results and the amount of training for lab staff to operate its platform.

"We founded Vanadis with the mission to make NIPT available to all women, and we developed this technology to fundamentally change the cost structure and workflow for NIPT," said Vanadis Chief Executive Officer Olle Ericsson in a statement. "We are confident that with its leading position in prenatal screening, PerkinElmer is best situated to bring this system to market and address the under-served segment of average-risk pregnancies."

PerkinElmer officials suggested that the transaction would allow it to expand its prenatal testing capabilities without investing an enormous amount of money.

"High capital investment, advanced molecular skills, and complex data handling for lab staff, along with the difficulty of integrating these systems into the existing screening infrastructure, have been barriers to more widespread adoption of NIPT," said Prahlad Singh, head of PerkinElmer's diagnostics division. "Vanadis' simplified NIPT platform, once available, should help overcome these obstacles, giving labs a wider range of prenatal testing capabilities and providing important information to physicians and patients."

PerkinElmer has not provided a timeline as to when the development of the testing platform would be completed and it would be brought to the U.S. market.

The deal is part of a continuation of global transactions involving U.S. laboratories, the most notable one of recent years involving Eurofins' acquisition of Boston Heart Diagnostics for $200 million. However, most of the deals as of late have involved overseas operations acquiring U.S.-based labs.

Takeaway: PerkinElmer has targeted a small overseas lab as an inexpensive way of rapidly expanding its portfolio of prenatal assays. G2

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