Volume XXIII, Number 11 Monday, August 15, 2016

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Medicare Poised to Hit Pathologists' Income... Again!

IN JANUARY, THE MEDICARE PROGRAM WILL INTRODUCE a new reimbursement scheme for physicians that will alter the income for every pathologist who treats Medicare patients.

Just the fact that the federal **Centers for Medicare & Medicaid Services** wants to tinker in a substantial way with how it pays physicians should catch the full attention of pathologists and their practice administrators. After all, when is the last time that Medicare introduced a different way to pay physicians that increased their overall income?

The new program will become effective on January 1, 2017, as part of the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA). The final rule for implementing changes in one Medicare payment stream to physicians was published on May 9, 2016. Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) are the cornerstones of MACRA and pathologists who don't pay attention to these sections of the law have the highest probability of paying Medicare penalties for non-participation.

Pathologists have fair warning that their group practices must be prepared to participate in a way that is most advantageous. Otherwise they will see an unwelcome bite taken from their Medicare payments. And the size of that bite will increase from one year to the next.

No less than **Deloitte** has declared that, "MACRA is expected to drive care delivery and payment reform across the US health care system for the foreseeable future. Congress intended MACRA to be a transformative law that constructs a new, fast-speed highway to transport the healthcare system from its traditional fee-for-service payment model to new risk-bearing, coordinated care models. *It has the potential to be a game-changer at all levels of our health care system." (Italics by THE DARK REPORT.)*

Do I have your attention now? MACRA is the foundation for a major shift in how Medicare pays physicians. Of course, if Medicare figures out how to pay physicians less, then private payers will quickly incorporate the same elements into their own reimbursement schemes. Recognizing the importance of helping pathologists and their practice administrators come up to speed on MACRA, MIPS, and APM, our sister publication is producing a webinar on this topic on August 25. You can get full information and register at *www.darkdaily.com*. TDR

Holmes Speaks at AACC To Skeptical PhDs, Press

Press reaction to the Theranos CEO's speech shows that the company hasn't much credibility

CEO SUMMARY: Elizabeth Holmes, Founder and CEO of Theranos, Inc., was given the ideal platform by AACC to show the science behind her lab company's much-touted diagnostic technologies. But in a surprise to the assembled audience, Holmes, accompanied by three PhDs on her team, chose to discuss: a) her company's new business strategy; b) an unimpressive lab testing instrument; and, 3) correlation data for assays that used conventional methods and venous blood.

When Elizabeth Holmes stepped up to the podium at the **American Association of Clinical Chemistry's** annual meeting in Philadelphia on August 1, she had the perfect opportunity to present scientific data and make her case that the diagnostic technology claimed by **Theranos, Inc.**, in recent years was indeed both disruptive and revolutionary.

Instead, Holmes delivered a presentation that many in the audience considered to be crassly commercial. She did not present scientific data, as was promised in press releases Theranos and AACC issued. Rather, Holmes, the founder and CEO of Theranos, introduced a new corporate strategy.

She opened her presentation by unveiling what she described as her company's newest-generation lab analyzer, which she called the "miniLab." Following a series of short videos which showed how this lab instrument operated, Holmes then put up slides showing data generated from the correlation of lab assays run on the miniLab.

It was obvious to the audience—and the very large contingent of journalists present in the hall—that Holmes was refusing to show any of the data associated with the lab testing technologies that she has touted during the past three years.

The consequences of her decision not to deliver the information promised in advance of the presentation were immediate. During the next 24 hours, most major news outlets in the United States published stories about her speech, along with the reaction of the AACC's membership to the information she provided.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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Taken collectively, news coverage of Holmes' speech showed that the company no longer has much credibility with news reporters. Most of these news stories carried quotes by clinical chemists and pathologists who listened to Holmes and expressed skepticism about the new analyzer and testing model that Holmes introduced.

New Business Strategy

Press coverage of Holmes' remarks centered around two elements. First, reporters specifically mentioned that Theranos failed to deliver the scientific data that was promised. Journalists described how Holmes used the opportunity to launch a new public relations campaign advertising her company's newest diagnostic testing system.

The second common element in the press coverage was that the clinical chemists and lab scientists interviewed for these stories were disappointed that Holmes did not show the data on the technology she and her company had touted over the past three years.

As to the scientific community, there was a consensus of sorts. Clinical chemists and lab scientists who were in the conference hall had plenty to say after Holmes finished her presentation. The reaction of these clinical lab professionals in the audience was generally negative on three points. First they reacted negatively to Holmes' decision not to present scientific data on her lab company's self-described disruptive technologies. Second, many clinical chemists objected to how she delivered a commercial speech at a scientific meeting.

Third, lab scientists reacted to the lab instrument and assay correlation data that Holmes did present. The general sense of the scientific community was that the instrument—a desktop device of about 95 pounds with miniaturized internal components—appeared to use conventional technologies not much different than these clinical labs use daily. Also, during the question and answer session, it was pointed out to Holmes that the assays and correlation data generated by her miniLab analyzer used conventional methodologies and venous blood.

Stated another way, Holmes did not show an analyzer capable of doing "up to 70 tests on a single drop of blood." Nor did she present data that demonstrated that capability. Those facts did not escape the notice of the clinical laboratory scientists in the audience.

"Every piece of technology they presented has been known for many years, and exists in other platforms largely in the same configuration, or in some cases in much more compact form in competitor's platforms," stated Geoffrey Baird, an associate professor in the department of laboratory medicine at the **University of Washington**, in a story published by *The Wall Street Journal*.

In fact, what nearly all the news reporters missed, but what did not escape the notice of the clinical chemists and pathologists in the room, is that Holmes had described a business model for clinical laboratory testing that represented a huge shift from what it has been doing in recent years: specimens collected in retail pharmacies, like **Walgreens**, are then tested in its CLIA lab facilities in Newark, Calif., and Scottsdale, Ariz.

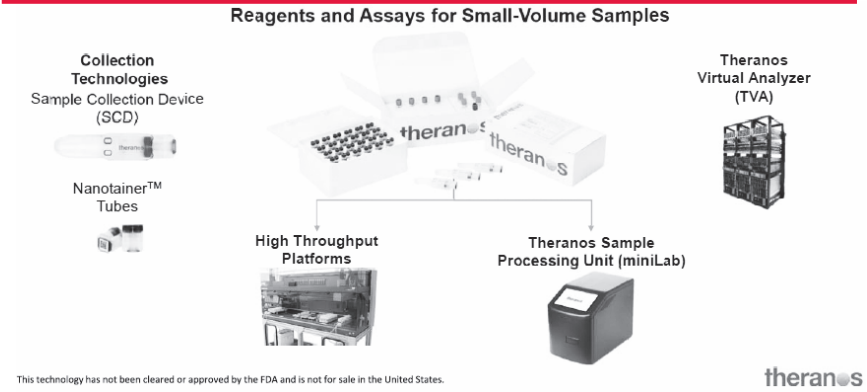
'Decentralize And Automate'

During the question and answer portion, Holmes stated, "Part of the vision we have for this is we want to decentralize and automate the pre-analytical processing steps while maintaining the connectivity to the certified lab and the ability to do analysis by certified laboratory personnel, as well as maintain oversight of control and replica data and calibrators."

When asked if this vision meant that a Theranos Virtual Analyzer (TVA) in, say Dallas, would manage data produced by a Theranos miniLab in Mexico City,

At AACC, Holmes Discusses New Business Plan, Shows New Lab Analyzer, called 'miniLab'

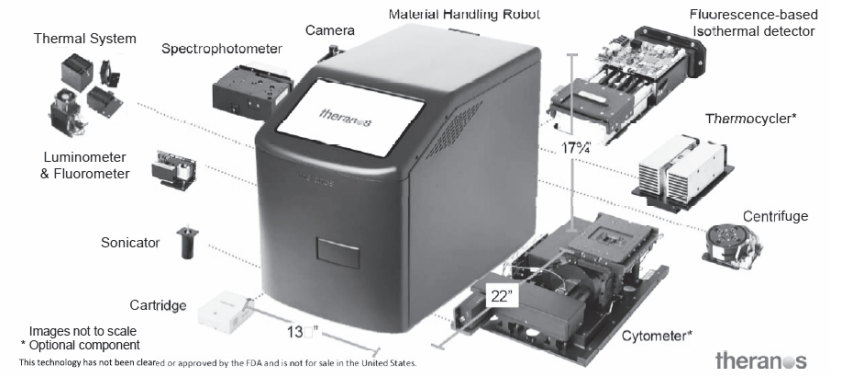
Theranos Technologies



INSTEAD OF SHOWING SCIENTIFIC DATA DURING HER PRESENTATION at the AACC's annual meeting in Philadelphia, as had been announced, Founder and CEO of Theranos, Elizabeth Holmes, used her speech to launch a new corporate strategy. The slide above summarizes her vision for the company moving forward. She described these components: collection devices for small quantities of specimens, a "sample processing unit" called miniLab, and the Theranos Virtual Analyzer (TVA). Holmes said that the miniLab was intended to do pre-analytical and analytical functions using cartridges manufactured specifically for the tests to be performed. The Theranos Virtual Analyzer handles "remote interpretation of digital images and results, reviewed and released through the clinical lab."

The slide below shows the components of the minLab sample processing unit. It has multiple instrument systems for analysis. On a single specimen in a cartridge manufactured to support multiple assays, Holmes stated that the minLab can perform chemistry, immunoassay, hematology, and molecular tests. The miniLab is a benchtop analyzer weighing about 95 pounds.

Theranos Sample Processing Unit (miniLab)



Holmes Did Not Directly Answer Questions About the Ability to Do Many Tests on Blood Drop

DURING THE QUESTION AND ANSWER PORTION of Elizabeth Holmes' presentation at the AACC annual meeting, she was asked why she had not presented data on the diagnostic technologies her company had claimed over the past three years. This exchange took place between Holmes and Stephen Master, PhD, Associate Professor at **Weill Cornell Medical College**:

MASTER: I want to start out with a question about scope. What I am surprised about—and you look at the [many] people in this room and there is clearly a lot of interest in your company. I would argue that a lot of that comes from the claims that were made very early on that were very broad: 70 tests, a whole panoply of lab tests on a couple of drops of blood. The evidence that you presented fell far short of that. So how should we think about that?

HOLMES: There's been a lot of news about our company and we chose this meeting today to begin engaging in a scientific exchange about our inventions and our technology. This technology that we introduced today is the latest version of our miniLab technology. What we wanted to do was to introduce the invention and the capability to run a broad range of assay methods on a single platform or across a single consumable. That's what this data was intended to do. We fully understand in picking this place to come and introduce it that we have a lot of work to do to engage with this community...

MASTER: But it's fair for us to say that the jury is still out on a lot of the central claims. For example, I can buy a point-of-care instrument today that does a finger stick lipid panel. That's not the interest. The interest is in the larger piece. So are you saying, "That is to come at some future point?"

HOLMES: What we've shown today is the architecture, the invention of a platform that is capable of running multiple assay methods simultaneously. That's what this presentation is for. We now have to engage in peer-review publications, engage in third party studies... piece by piece we are working to put that information out.

Holmes answered, "Yes. That's the goal with the connectivity. In different certified laboratories, you have the expertise of laboratorians who are specialized in different areas, and our objective... is to pursue certain models in which we can decentralize certain tests while maintaining the connectivity to expert pathologists or laboratory technicians at the best centers of excellence for those tests."

It was then noted by a Theranos PhD who was part of the panel discussion that, in cases in which automated algorithms were not adequate for specific types of tests, the model of performing the test in the field with results going to the TVA would allow review by a clinical lab scientist before results are released.

Holmes then added, "that is a core part of how we see the future of point-of-care testing. Not that it is waived—where you have no controls and calibrators and oversight. But where you maintain this connectivity to distribute the processing [and testing in the field] while maintaining the laboratory control and oversight of the test [via the Theranos Virtual Analyzer]."

These statements illustrate the different direction that Holmes appears to want to take her company, compared to the public statements of the past three years. However, before it can bring this business model to the clinical marketplace, Theranos will have to meet stringent FDA and CLIA requirements. TDR

Ohio State Univ. Inks Pact To Adopt Digital Pathology

New pathology system expected to improve care for current patients and support oncology research

CEO SUMMARY: For years, the adoption of digital pathology has lagged behind the predictions of its advocates. That has encouraged one digital pathology company—Inspirata, Inc., of Tampa—to come up with a different business strategy designed to help anatomic pathology labs address the barriers and capital costs involved with establishing a digital pathology system. The Ohio State University Comprehensive Cancer Center is working with Inspirata on this pioneering approach.

THIS SUMMER, an ambitious project to convert the entire department to a digital pathology system is launching at the Department of Pathology at the **Ohio State University Comprehensive Cancer Center**. The goal is to digitize all current pathology images, along with thousands of archived glass slides going back at least five years.

What adds interest to this large-scale effort to implement digital pathology is that it involves an unusual long-term partnership. The agreement was announced last month and calls for pathologists at the academic center to work with **Inspirata Inc.**, a company in Tampa that aims to transform cancer diagnostics and provide turnkey digital pathology workflow systems. *(See TDR, August 3, 2015.)*

Under the agreement, Inspirata will install all necessary hardware and software, and implement services required to run a fully-automated, end-to-end digital pathology system. One unusual aspect of the deal is that Inspirata also will provide the staff to manage the project and operate the digital imaging equipment at the **Arthur G. James Cancer Hospital** and **Richard J. Solove Research Institute** (OSUCCC-James) at **The Ohio State University Wexner Medical Center** in Columbus.

This digital pathology project will be a sizable undertaking. The pathology department has 35 pathologists and 45 other staff who together handle about 70,000 cases annually.

Improving Workflow

"The initial plan is to digitize 10 years' worth of glass slides in our archives. Those are the slides that we use the most, because we have the most need for them clinically," stated Anil Parwani, MD, PhD, a Professor of Pathology and Vice Chair of OSU's Anatomic Pathology Department.

"There are two aspects to our desire to move to digital pathology," he continued. "First, we see it as an opportunity to improve workflow. Second, we can use digital images to improve patient care and enhance the education of our trainees.

"We have slides that go back several decades," said Parwani. "But obviously, we will not digitize everything. Instead, we will digitize select groups of cancer cases that reach back more than 10 years.

"We also want a workflow that allows our pathologists to do a look-back on certain cases and to use those images as an archive for cancer research," he explained. In addition to his work for the Pathology Department, Parwani also is the Director of Pathology Informatics and Director of the Digital Pathology Shared Resource at OSUCCC-James.

Digitizing Archived Slides

Along with the workflow benefits from adopting digital pathology at OSUCCC-James, another goal of the project is to digitize, analyze, and archive millions of retrospective and prospective pathology slides, specifically to advance patient care.

"This system will make it easier for us to catalog how each patient's cancer progressed or regressed over time while looking at the treatment protocols their OSUCCC-James oncologists followed," noted Parwani. "For research purposes, we will be able to match those diagnoses and treatments with their associated patient outcomes.

"We envision that using the digital pathology system and images will enable us to perform analyses that we cannot do now, given the limitations we have with glass slides," he said. "Inspirata's digital pathology system will digitize the glass slides we have in our archives and create digital images from slides of our current patients.

"Another problem we expect to solve with this new system is improved integration with the lab information system (LIS),"added Parwani. "Lacking integration with the LIS adds 10% to 15% of the time it takes to prepare a glass slide and present it to the pathologist.

"With the Inspirata system, we expect integration that leverages all the various information systems in the OSUCCC-James Pathology Department while at the same time reducing the time it takes to create a slide and an image.

"In essence, we are creating a new workflow to fix that problem that pathologists face with most glass slides: the lack of associated information," he emphasized. "That's why we say this new system is all about what I call information management. It is a prerequisite for managing all the data in the lab: the slides, the assets, the blocks, the paper requisitions; all of which are useful and needed information for both current cases and for research.

"Once our current slides are digitized and we digitize our archive of pathology cases, we will have created a rich, highly annotated image database," noted Parwani. "Our researchers can then tap into that database to create very powerful and predictive algorithms.

"As an example, say I am looking for 600 cases of breast cancer with a specific histological subtype, a specific demographic, or some other feature of the tumor or patient type," he stated. "I now have access to that data and the corresponding digital images. As a next step, I can train the algorithms to create an image dataset that supports multiple diagnostic and research purposes.

Matching Data With Images

"This type of work is already being done on a small scale in other countries and in other clinical settings," explained Parwani. "Here at OSUCCC-James, we expect to create a large dataset—of cancer cases mostly—and link that data to other vital information about cancer and patient type, tumor type, and treatment protocols, and any other information that may be useful. That's what's referred to as the Cancer Data Trust.

"Our goal is to be able to share these images easily," he emphasized. "We have several network or affiliate hospitals, and with this platform we will be able to move these digital images among pathologists for consultation.

"Like any database, the larger the pool of images you have, the more value it will have in terms of its ability to be predictive," continued Parwani. "We are leveraging the predictive power of numbers. To boost that

Inspirata's Digital Pathology Contract with OSU Means Vendor Must Hit Specific Milestones

OVER THE PAST DECADE, adoption of digital pathology systems has not been as fast as predicted by its proponents. Cost has been a major reason for the slow adoption.

First is the capital cost of acquiring the digital scanners, hardware, and software needed to produce whole slide images, store them, and work with them. Second is the ongoing cost of labor and related expenses to scan the hundreds of glass slides generated daily by a large anatomic pathology lab.

"Generally speaking, if a hospital wants to implement a digital pathology system, it must first answer several important questions," stated Satish K. Sanan, Chairman and CEO of Inspirata, Inc., of Tampa. "If it wants to do it on its own, it must determine if it could afford the software, along with whether it should buy digital pathology software or write its own. It can require several million dollars of scarce capital to assemble the right digital pathology solution.

"Then comes the hardware and staffing that is required," he continued. "What scanners should it buy? Who will scan the glass slides? Is there space in the lab to accommodate digital pathology equipment? And what about the need to store the digital data produced by the scanners?

Barriers to Faster Adoption

"Each question involves a specific barrier to faster adoption of digital pathology systems," said Sanan. "To overcome these barriers and help labs adopt digital pathology solutions, Inspirata is pursuing a business strategy we believe better meets the needs of pathology labs interested in acquiring digital pathology systems.

"Inspirata offers a solution-as-a-service (SaaS) model that includes aspects of a managed service agreement with payments that are tied to client-approved milestones," he added. "In addition, our SaaS model provides implementation services as well as the onsite resources to manage operations, including project management, staffing for the scan lab, and overall program management. With our model, the institution essentially gets everything needed for an end-to-end digital pathology solution except the pathologists."

Inspirata's strategy in the OSUCCC-James project has three components. "The first component involves the digital pathology hardware, software, and workflow systems that a pathologist requires," noted Sanan. "Inspirata has its own workflow solution, and, instead of manufacturing our own scanners, we have partnerships with slide scanner manufacturers, including **Philips**, **Motic**, **Sakura**, **Mikroscan**, **Huron**, and **Objective Imaging**.

Milestone-based Payments

"The second component is our milestone-based payment arrangement so that labs and health systems do not have to come up with the full price of the digital pathology systems at purchase," he said. "This enables the lab to conserve cash. Instead, Inspirata offers the lab up to a 10-year pay-as-you-go plan.

"The third component is that Inspirata will hire the staff needed to scan and archive the glass slides and to manage that process," stated Sanan. "This is important because existing histology workflow is preserved.

"Inspirata develops the financial plan and the plan to integrate the new digital system with the existing workflow, including all of the delivery, adoption, training, and change management," he said. "Full implementation takes about 18 months."

Another twist in Inspirata's strategy is to reduce payments at the start of the multiyear agreement. "In this early period, payments are much less and don't increase until the lab gets new revenue increases from the use of digital pathology," Sanan stated. "This helps the lab achieve its desired return on investment and enjoy some positive cash flow."

power, we can potentially invite other institutions to participate as well.

"If we have 10 cases here at OSUCCC-James of a certain type of cancer and **Memorial Sloan Kettering** has 20 cases of that same type, and **Johns Hopkins** has 30 cases, we can share these images and allow our scientists to work on these datasets collectively," he noted.

Use Of Algorithms

"What is important is that, by having such a large dataset of a particular cancer type, we can use algorithms to quantitate the information in ways that were not possible before," said Parwani. "Typically when a pathologist looks at a slide, he or she would apply special biomarkers to the tissue and then would manually quantitate the results.

"But with this system, a pathologist can apply algorithms to quantitate that case more accurately and more objectively," he explained. "Moreover, these algorithms can separate certain features in the images that a human cannot separate easily and thus would be unable to quantitate.

"Algorithms also can find features that might not be obvious to the pathologist because those features actually are a combination of features and not just one feature," added Parwani. "Taken together, this particular combination of features can be predictive and quantitative. These features act almost like an image signature to help us make a prediction. We can say that, based on these particular features, this patient will have a good outcome or this patient will have a bad outcome.

"We can also use algorithms to do risk assessment. We can build algorithms based on these different features," he stated. "For example, there's an algorithm today that can do image-based risk assessment for breast cancer. To build such algorithms, pathologists need a large image dataset, and now we will be able to create that type of a system."

To build such a system, the Pathology Department will need to create a new workflow. "What Inspirata offers is the ability to become a digital pathology lab that eliminates all the problems we have with glass slides today," observed Parwani. "To do that, we will need a new way to work.

"We believe that digitizing glass slides will improve turnaround time significantly," he said. "This will be particularly true for difficult cases that the pathologists want to show to colleagues, even someone who is not in the vicinity or is in a remote location. That digital image can be sent and an answer returned within minutes!

"This can't be done if the lab is using only glass slides and doesn't have digitized images," he added. "Once installed, the Inspirata system will digitize slides rapidly. But it cannot cut down the time required to produce a glass slide. That's beyond their control.

Long-Distance Collaboration

"Another reason this system will be useful for us is that it will allow the pathologists in the existing James Cancer Network to collaborate more effectively," added Parwani. "The James Cancer Network is a group of community hospitals that have partnered with the OSUCCC–James to bring subspecializing oncology care to outlying communities. It will allow us to share cases more readily, to do tumor boards when needed, and to have ongoing collaborations with pathologists in different facilities.

"Another long-term goal of great importance for us is to create additional revenue opportunities for Ohio State and for the James Hospital CCC," he concluded. "We expect to achieve this by linking our capabilities to other facilities, not only here in Ohio, but to other places in the United States or anywhere in the world." TDR

—Joseph Burns

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Digital Pathology Update

GE, UPMC Ending Omnyx, Their Digital Pathology JV

Decision by the partners to dissolve the joint venture catches new pathology lab customers by surprise

IN RECENT WEEKS, pathology laboratory clients of the **Omnyx** digital pathology system learned that the joint venture is ending. Company officials tell these customers that their digital pathology systems will continue to receive service.

Omnyx was formed in 2008 as a joint venture between **GE Healthcare** and the **University of Pittsburgh Medical Center** (UPMC). Its goal was to develop a digital pathology system and the two partners contributed $20 million each to launch the new business. *(See TDR, June 16, 2008.)*

The action to end the joint venture was confirmed by a posting on *TissuePathology.com*. According to pathologist Keith Kaplan, MD, who manages the website, after contacting **GE Healthcare Digital Global Communications**, the company issued the following statement:

"UPMC and GE Healthcare can confirm plans to exit their joint Omnyx venture, primarily driven by variable global demand. GE will focus its investment strategy in other areas of its digital portfolio, for example the GE Health Cloud. GE Healthcare will support existing customers through this transition and honor contractual commitments. GE Healthcare and UPMC will continue their partnership in other areas of health innovation."

Kaplan continued, writing, "As I understand it to date, GE Healthcare will support current Omnyx customers. Many of the senior executives within Omnyx have moved on and GE Healthcare will provide resources for necessary support of day-to-day operations."

Uncertainty About Future

THE DARK REPORT has heard from several pathology labs that recently entered into agreements to purchase and install Omnyx digital pathology systems. It's unclear to pathologists at these labs how Omnyx will keep its contractual commitments.

One pathology lab shared a letter it sent to GE. It said, in part, "We are told that GE will honor existing commitments in terms of product service and support but there is no surety around future product development and availability. Potentially, therefore, we may be entering into a long term commitment that effectively 'has no future'."

The dissolution of the Omnyx joint venture is a surprise for two reasons. First, in February, following a change in how the FDA said it would review applications for digital pathology devices, Omnyx officials had stated publicly that they were optimistic that their digital pathology application, submitted in 2014, would benefit from the FDA's decision.

Second, the decision to end the JV involving GE Healthcare and UPMC is unexpected and might be an inauspicious development for the field of digital pathology. TDR

Path Profession Faces Challenges, Opportunities

After 10 years of significant change, groups must prepare for new clinical, financial models

CEO SUMMARY: For 10 years, three primary trends have reshaped the anatomic pathology profession. They are declining reimbursement, competition from physicians establishing in-office pathology labs, and a host of new government laws and regulations. More changes are coming, predicts one business expert in pathology. Those changes involve new Medicare payment models, along with opportunities for pathologists to contribute more value by helping to reduce cost, add revenue, and improve patient care.

Most pathologist business leaders and pathology group practice administrators agree that the past 10 years have been tough on the profession. Like other healthcare providers, anatomic pathologists have struggled as reimbursement shrank, competition increased from in-office laboratories, and the government introduced new regulations.

One expert in the business side of anatomic pathology said that this past decade is prologue to the future. However, he added the caveat that—despite the coming end to fee-for-service as the dominant form of payment to pathologists and other physicians—those pathology groups that learn how to add value to their basic diagnostic services have a bright future.

"To understand what is coming in the future, it is necessary to recognize how these three trends have changed the pathology profession over the past decade," commented Al Sirmon, CPA, Co-Founder and former President of **Pathology Service Associates**, better known as **PSAPath** (now part of **McKesson Business Performance Services**), in Florence, S.C. "The first source of major change over the past 10 years has been cost control by both private payers and the Medicare program.

"There are many examples of how anatomic pathologists have lost revenue," he noted. "There are two significant sources of lost pathologist revenue. One came in July 2012 when CMS changed how it paid for the technical component involved in preparing and reviewing slides, often called the 'grandfather TC clause.' *(See TDR, April 23, 2012.)*

Grandfather TC Rule

"With that rule change, pathologists could no longer bill Medicare for the technical component for their hospital's Medicare inpatients or outpatients," explained Sirmon. "Instead, pathologists had to bill the hospitals to get paid for the TC on those cases. But many hospitals—including small rural facilities—had cash flow problems and were slow to pay. Pathologists lost a lot of money as a result of that change.

"Just six months later, in January 2013, Medicare cut payment for CPT code 88305,"

Sirmon explained. "For nearly all pathology practices, that code is the most frequently used. When Medicare said it would change how it paid for 88305 TC, most observers believed it would result in a cut of 10% to 20% in revenue, but in fact it was a cut of 50%! With that one change, many anatomic pathologists took a tremendous hit, especially independent pathology labs.

"The second trend confronting anatomic pathologists over the past 10 years is increased competition, particularly as a result of the growth of in-office labs by specialists such as urologists, gastroenterologists, and dermatologists," stated Sirmon. "Physicians in those three specialties wanted to boost revenue, just as all physicians are doing. But a substantial number of dermatologists, gastroenterologists and urologists decided to build their own in-office pathology labs. That sharply reduced the volume of case referrals coming from these subspecialists to their local pathology groups.

More Regulation Of Labs

"The third major trend involves more regulation," he continued. "Anatomic pathologists could argue that their environment became particularly challenging following the implementation of several major regulations during the past 10 years.

"One big change was the move from Form 4010 to Form 5010 to comply with new rules under the Health Insurance Portability and Accountability Act (HIPAA)," said Sirmon. "This was followed by the requirement for pathologists to use thousands of new codes when Medicare, Medicaid, and other payers switched from ICD-9 to ICD-10.

"Next, it is easy to forget that we are already in the sixth year of the federal Meaningful Use program," he continued. "Physicians and pathologists had to comply with new rules for installing electronic medical record systems. A different regulation required pathologists to ensure that each referring practice had a National Provider Identification (NPI) number in order for Medicare to approve payment.

"In addition to having to meet these new regulations, since 2006, pathologists also were busy complying with new payment-incentive rules under Medicare's Physician Quality Reporting System," stated Sirmon. "That was just for starters.

New Reporting Rules

"In 2017, pathologists and all healthcare providers may face new rules under the Medicare Access and CHIP Reauthorization Act (MACRA)," Sirmon added. "The government's goal is to have the Medicare program pay more to physicians who succeed in improving patient outcomes, while paying less to physicians who don't participate in the MACRA quality reporting program.

"Another aspect of MACRA will bring more changes to pathologists as CMS replaces the sustainable growth rate (SGR) formula with new value-based payment under MACRA," said Sirmon. "This constant change in regulations has added much cost in both time and money just to get paid for the work pathologists do. In my view, these new regulations have the potential to have greater financial impact on pathologists than any of the new regulations we've seen introduced in the past decade!"

Two Business Strategies

For these reasons, Sirmon recommends that all pathology groups should develop business strategies on two fronts. "First, every pathology group should be studying the final rule on physician incentive and disincentive payments that are part of MACRA and the Merit-Based Incentive Payment System (MIPS) that will be effective on January 1, 2017," he advised. "Medicare will pay a larger incentive each year to those physicians who report quality measures and show improvements in patient care. But the opposite is equally true. Physicians, including pathologists, who don't report quality measures or who

don't improve patient outcomes will see a larger percentage debited from their Medicare payments for the entire year.

"The second strategy every pathology group needs is even more important," continued Sirmon. "Pathologists have an opportunity to lead the transition from volume- to value-based billing in the lab because of the power of the resource that the clinical laboratory and the anatomic pathology lab represent.

Enriched Diagnostic Services

"Every pathology group that seizes these opportunities and enriches their diagnostic services in ways that add value to physicians, ACOs, payers, and their hospitals will be rewarded with payments that reflect that added value," he said. "To implement these strategies may require pathology groups to restructure their businesses.

"In the past decade, all of these changes made it more difficult for many private pathology practices to remain in business," he explained. "Their options were to sell to a national lab company, a larger practice, or to go out of business.

"But private pathology practices have advantages that the larger labs don't have," added Sirmon. "For example, it's much easier for smaller practices to respond quickly to changes in the marketplace. And when they respond, they can demonstrate how nimble they can be in serving their client physicians or hospitals." TDR

—Joseph Burns

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Attention Pathologists!

Big changes in how Medicare pays physicians commence on January 1, 2017. Join us on August 25 for a webinar about MACRA, MIPs, and new Medicare incentives and penalties for physician services! Information and registration at: *http://tinyurl.com/hhqnmoa*, or:

www.darkdaily.com

New Consulting Company Ready to Serve Pathologists

It was a short semi-retirement for Al Sirmon, CPA, the former President of PSAPath, part of McKesson Business Performance Services. He became a part-time consultant in 2014. Then last month, he announced the formation of **Pathology Practice Advisors**, in Pawley's Island, S.C.

"Having been with PSA since its founding 25 years ago, it was time for a change," stated Sirmon. "The one thing that I most enjoyed was providing strategic consulting services and advice on best practices for pathology groups. Offering boutique consulting services to pathologists is a way for me to serve the profession while gaining more personal time at this stage of my life."

Joining Sirmon in the new business is Chappy Manning, RN, CPC, who has worked with Sirmon since 2003, first at PSAPath and most recently at McKesson Business Performance Services. Manning has extensive experience in the full range of issues involving compliance, coding, and billing for pathology services.

"Our emphasis will be on offering consulting services on best practices, including revenue cycle management, cash flow, and billing operations," noted Sirmon. "In this new role, our goal at PPA is to help independent pathology groups monitor their current reimbursement, manage their costs, and identify specific areas where they can add value by cutting costs and boosting revenue.

"In addition, we will advise pathologists and help them analyze their group's business options," he said. "This includes assisting them with managed care contracting issues as well as reviewing potential merger and acquisition possibilities. Many pathology groups have baby boomers retiring or about to retire. This creates the need for strategic planning, particularly because the remaining partners in the group practice want to maintain financial stability while delivering more value to their clients."

Cigna Expands Program For Genetic Counseling

After members report increased satisfaction, insurer decides to do more such counseling

CEO SUMMARY: For three years, Cigna has required genetic counseling for members seeking genetic testing for hereditary breast, ovarian, and colorectal cancer, and for a particular heart condition. Such counseling increased member satisfaction, causing Cigna to expand the program. It now requires genetic counseling with an independent board-certified genetics specialist for members considering whole exome sequencing, additional hereditary cancers, heart disease, and pediatric microarray analysis.

IT TURNS OUT THAT PATIENT SATISFACTION INCREASES when genetic counseling is done in advance of genetic testing for certain hereditary cancers and health conditions. That is one lesson learned by **Cigna**, which was the nation's first major health insurer to require such genetic counseling three years ago. *(See TDR, August 19, 2013.)*

It was this positive patient experience that encouraged Cigna, as of June 15, to expand that program. It now requires genetic counseling with an independent board-certified genetics specialist for members considering whole exome sequencing (WES), hereditary cancers and heart disease, and pediatric microarray analysis for children with certain developmental delays or intellectual disabilities.

Three years ago, Cigna became the first national health insurer to require genetic counseling before it would approve coverage for members getting genetic tests for hereditary breast, ovarian and colorectal cancer and for long QT syndrome, a heart condition. Counseling for members with these conditions was necessary because those genetic tests were complex and frequently misunderstood, leaving patients bewildered, Cigna said at the time.

Patients Bewildered

That state of bewilderment continues today because members do not know which genetic test is appropriate for their particular condition, family medical history, and risk factors, explained Jeffrey F. Hankoff, MD, Cigna's medical officer for clinical performance and quality.

"Further confusing patients are clinical laboratories that offer multiple tests in panels," he added. "Genetic counselors, therefore, minimize confusion by helping people make decisions about testing based on their individual circumstances and clinical guidelines.

"Genetic counseling helps ensure that individuals get appropriate, high quality care," explained Hankoff, who gave several reasons why the program has been successful. For one, more than 32,000 Cigna customers have had genetic counseling since 2013, while the average number of monthly claims for genetic counseling more than doubled during this time.

Cigna's genetic counseling program has also been successful according to customer satisfaction data. Among individuals who underwent genetic counseling, 95% said they are satisfied with genetic counseling and thought they were more informed about their genetic risks; 94% said they were more informed about their hereditary risks; and 97% said the counselors answered their questions and addressed their concerns, Cigna said.

No Data Yet On Cost Impact

"Another benefit is that the initiative helped to keep genetic testing costs lower than they would have been without such counseling," noted Hankoff. "However, Cigna does not yet have data on the effects of genetic counseling on the amount spent for genetic testing.

"We started this program in 2013 because at that time there were dramatic changes in coding for genetic tests that mostly eliminated the stacked codes," he explained. "Stacked codes were replaced with individual CPT codes for some 50 or more of the most common genetic tests. That change allowed Cigna to distinguish between genetic and other testing, which means we can manage testing with more precision.

"At first, Cigna's guidelines for genetic counseling were only for those three types of tests because it had to start somewhere," continued Hankoff. "Now that we have this experience under our belt and have been successful in ensuring appropriate testing, we can add a relatively small number of tests compared to what we are already doing without putting a huge burden on our customers or providers.

"It was not necessary to add a significant number of tests because we already required genetic counseling for about 90% of the genetic tests that doctors order," commented Hankoff. "Adding this handful of new tests means that slightly over 90% of genetic test orders will involve genetic counseling."

Cigna pays for the counseling under a contract with **InformedDNA**, a company in St. Petersburg, Fla., that offers clinical genetic counseling, genetic test utilization management, and hereditary risk assessment for individuals.

"We limit the counseling to certified genetic counselors, board-certified and board-eligible medical geneticists, certified nurses who have the additional genetic-testing credentials, and physicians who have added training or coursework to be knowledgeable in this area," Hankoff explained.

"As a rule, physicians don't have the 45 minutes or so that a genetic counselor will spend with a patient before the testing or the 45 minutes afterward to explain the results," he said.

"Also, counselors cannot be tied to any laboratory that has a stake in this kind of testing," added Hankoff. "For example, if a proprietary lab has a specific genetic test, Cigna will not accept a report from the genetic counselor who might work for that lab because there's an inherent conflict of interest.

"Counselors follow our posted coverage policies and we ask them to do a three-generation pedigree, meaning the individual, the parents, and the grandparents, aunts, and uncles," explained Hankoff. "We want them to look for anything that might affect the genetic disorder in question.

Pursuing Appropriate Care

"If the genetic counselor says the test should be done, then Cigna covers that test," he said. "In addition, we ask counselors to make a recommendation on which genetic test might be appropriate or no test if that's the right choice. If the counselor doesn't agree with our coverage policy, we ask why.

"In this program, Cigna is not focusing on the cost of genetic testing," noted Hankoff. "This effort was never put into place with the idea of controlling costs, even though some genetic tests cost as much as $8,000 or $12,000.

In Guidelines to Cover Whole Exome Sequencing, Cigna Has Counselors Look for Clinical Significance

BY BECOMING ONE OF THE FIRST MAJOR HEALTH INSURERS TO HAVE A COVERAGE POLICY for whole exome sequencing, Cigna is at the forefront of precision medicine. But this introduces the challenge shared with other insurers as to how to approve large panels of genetic tests in support of patient care.

Cigna is no different, stated Jeffrey F. Hankoff, MD, Cigna's medical officer for clinical performance and quality. To help ensure that members get appropriate genetic tests, it requires genetic counseling for members seeking certain tests for hereditary conditions and whole exome sequencing.

"Cigna covers these tests, including whole exome sequencing (WES), when the required criteria are met and the test result will directly affect clinical decision making in terms of patient outcomes for the individual," noted Hankoff.

"To approve WES testing, the protocol requires several conditions to be met," he continued. "The patient must have two of the following criteria: One would be an abnormality affecting a single organ system. The other would be significant intellectual disability symptoms of a complex neuro-developmental disorder.

"Should either of these criteria be met, then the next qualification is that the patient must have a family history strongly implicating a genetic etiology," he noted. "The patient must also have a period of unexplained development regression.

"The patient needs to meet two of those four criteria or the patient needs to have multiple abnormalities affecting unrelated organ systems," said Hankoff. "Further, for the patient to be a candidate for whole exome sequencing, the clinical presentation shouldn't fit a well-described scenario in which a single genetic test or a very small panel of tests would be available.

"These provisions might be confusing for most lay people, but certainly genetic counselors understand them and recognize that Cigna is looking to make a real difference in how these patients are managed clinically," he added.

Genetic Test Panel Criteria

For genetic test panels, Cigna applies similar criteria, but again, Hankoff said, the insurer wants to ensure that every test included in a panel will affect clinical decision making.

"Back in 2011 and 2012, genetic tests were ordered one at a time," he explained. "But then we started to see panels of two to three genetic tests combined together. Now, we see genetic testing panels with as many as 95 to 100 individual tests.

"Unfortunately, many of the tests included within these multi-gene test panels have unknown clinical significance," Hankoff stated. "Not only is it difficult for a clinician to explain what that means, but it could cause more worry for patients. These genetic test results also become a permanent part of that individual's medical record, which could affect a life insurance application, for example, and lead to more testing—including invasive tests without any clear benefit.

"These points illustrate how Cigna, like other insurers, struggles with how to make appropriate coverage decisions regarding genetic test panels," he concluded.

"Instead, we look at the value that genetic counseling brings. We started this program with the idea of improving quality, and we think we've accomplished that," stated Hankoff.

Pathologists and clinical laboratory directors may wonder what happens when a doctor orders a genetic test without getting the required genetic counseling first. "I understand that concern

among labs," Hankoff responded. "Very often when a doctor sends the lab order, that doctor expects the lab to run it and does not know pre-certification is required. That was a complicating factor in 2013, but we have moved past that now.

Systems In Place

"Currently, with most network laboratories, Cigna has systems in place to allow genetic counseling and pre-certification to occur before the test is run," he stated. "Because the specimen won't spoil, the lab can hold it while the counseling is done. "

Clinical labs also may ask if Cigna always covers genetic counseling. Hankoff responded, saying the insurer follows its employer-clients' medical benefit plans, and only rarely do some of those plans not include coverage for genetic testing.

"If a patient has a medical benefit plan that excludes genetic counseling, that would be the only possible exception because most people who have an exclusion on genetic counseling also have an exclusion on genetic testing," he said. "And, about 85% of our business is for employers who hire us to manage their benefit plans according to their benefit policy designs. Those contracts are called administrative services only (ASO).

Benefit Plan Language

"If an ASO client does not want to pay for genetic testing, Cigna must follow their benefit plan language," he added.

"Genetic counselors do more than give the patient the implications of the test before the testing," he observed. "They meet with patients after the testing to explain what the results mean, not only to them, but to their parents, their brothers, sisters, and children.

"Also, the genetic test a doctor might order may not be the most appropriate one for that patient," continued Hankoff. "For example, a patient's mother may have a specific genetic abnormality following her cancer diagnosis and that's the one for which we need to test.

"There are times when a doctor might recommend a whole panel, and the genetic counselor will find that a test for just one gene is best," he added. "Also, it could go the other way. The doctor may order a single genetic test and the counselor would suggest more comprehensive testing with three or four genetic tests.

"This is what I mean by saying Cigna follows what the genetic counselors recommend," Hankoff said. "In fact, a genetic counselor may say a patient doesn't need genetic testing at all. At that point, we hope that the genetic counselor will act as a consultant and explain to the ordering physicians the implications of not doing any genetic testing.

Yearly Increase In Testing

"For all these reasons, when it comes to genetic counseling and testing, Cigna does not focus on adding costs or requiring genetic counseling," noted Hankoff. "It's about improving quality in a rapidly-advancing area of medicine. We knew, starting before 2013, that the number of genetic tests ordered would increase year after year. And, that's exactly what's happening.

"Having said that, we believe that we have at least blunted the increase in costs associated with genetic testing," he added. "We can't prove that. Also, we can't compare our expenditures for genetic testing to other health insurer's genetic testing costs because the information is not available.

"Another reason why it's difficult to know exactly how much Cigna spent before 2013 is because claims were submitted that used stacking codes," noted Hankoff. "Thus, Cigna couldn't isolate out how much money spent on lab tests was for actual genetic tests." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One of the nation's largest private pathology group practices completed a successful recapitalization, thus ensuring its independence for another five to seven years. On August 1, **PathGroup, Inc.**, of Nashville, Tenn., announced an investment by **Pritzker Group Private Capital** and **Vesey Street Capital Partners**. It was in January 2010, that PathGroup had completed a $100 million investment. It is believed that the current recapitalization was needed to allow that round of investors from 2010 to cash out their equity.

MORE ON: *PathGroup*

PathGroup is one of a handful of regional pathology super-practices that continues to grow in a profitable manner. It has more than 50 pathologists and serves 70 hospitals. One of the hazards of a private laboratory company accepting capital from private equity companies is that these professional investors typically need to liquidate that investment after five to eight years to pay off the investment fund that was the source of their capital. If the private lab company is unable to find another source of capital to pay off that round of investors, it often finds that its only option is to sell the lab company to a public lab company. This has happened to a number of private lab companies over the past 20 years and has contributed to further consolidation of the lab testing industry.

LABCORP ACQUIRES SEQUENOM, INC.

On July 27, it was announced that **Laboratory Corporation of America** would pay the equivalent of $371 million to acquire **Sequenom, Inc.**, of San Diego. Sequenom is recognized as one of the early providers of non-invasive prenatal testing for reproductive health. However, as a public company, it was under financial pressure. Its CEO had resigned last fall and the company had laid off about 20% of its staff at the beginning of the year. Sequenom had revenue of $128 million during 2015.

TRANSITIONS

• Michael Mosunic was hired to be the new President and COO of **Universal Diagnostic Laboratories**, in Van Nuys, Calif. Previously, he served at **Pathology, Inc.**, **Slone Partners**, and **Laboratory Corporation of America**.

• **Provista Diagnostics, Inc.,** of New York City, named Judith K. Wolf, MD, as Chief Medical Officer. Wolf previously worked at **Vermillion, Inc.**, and **MD Anderson Cancer Center**.

• **COLA** selected Tammy Zinsmeister to be its first Chief Innovation Officer. She formerly held positions at **Transformation Systems International, LLC**, and **American Society of Internal Medicine**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the findings of the Health Care Cost Institute (HCCI) that people in certain states pay double for common medical procedures as compared to patients in other states. Clinical laboratory tests were included in this study.

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That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 6, 2016.

★ SPECIAL SESSION! ★

How Labs Can Understand, Prosper with the New Game in Healthcare

James M. Crawford, MD, PhD
Chair of Pathology, Hofstra Northwell Health

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This health system laboratory is adding value by a variety of clinical strategies. For example, you'll learn how a simple test like creatinine was the centerpiece of a lab collaboration with physicians and nurses to make faster and more accurate diagnoses of acute kidney injury (AKI) in the hospital critical care units. The gains made in patient outcomes, additional revenue and reduced cost of care are stunning!

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