Volume XXII, Number 11 Monday, August 3, 2015

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

Collecting Big Patient Deductibles

THERE HAS BEEN EXPLOSIVE GROWTH IN THE NUMBER OF PATIENTS enrolled in high-deductible health plans. Currently, more than 20 million people have HDHPs. This is one reason why many labs are experiencing high levels of patient bad debt never before seen by the lab industry during the past three decades.

For several years, THE DARK REPORT has helped you understand the trend of soaring enrollment of consumers into HDHPs. This trend is why we recommend that every clinical lab and pathology group work to develop the capability to collect these sizeable co-pays and deductibles at the time of service, when patients show up at patient service centers to provide specimens.

In fact, THE DARK REPORT was first to write about the capabilities of **Sonora Quest Laboratories** in Phoenix, Arizona, to collect overdue amounts of money from patients during their visits to PSCs. In the first 15 months of the program, SQL collected $3.2 million of patient bad debt. That's a hefty return on investment and should be an inspiration to other labs considering how to collect from patients at the time of service. *(See TDR, December 2, 2013 and January 13, 2014.)*

In this issue, you will read about another lab that is innovating with a program designed to help it collect more patient co-pays and deductibles. On pages 3-6, we introduce you to **Counsyl**, self-described as a "clinical laboratory and technology company" in the Silicon Valley. Counsyl has implemented a lab test cost tool that patients use to obtain an estimate of how much the cost of the genetic tests will be, given their specific insurance plan.

Not only has this innovative service helped Counsyl increase revenue from patient payments by 63% since its partial implementation several months ago, but the lab company's patient satisfaction scores have gone up as well!

I recommend that you and your lab management team study our intelligence briefing about Counsyl's program to provide cost estimates of what patients can expect to pay at the time that their physician is ready to order these genetic tests. It is a road map that can inform your own lab's efforts to be better at collecting the substantial co-pays and deductibles that ever-larger numbers of patients owe your lab. As you do, this will be one more example of how THE DARK REPORT is delivering measurable value to you and your laboratory. TDR

How Price Transparency Increased Lab's Revenue

Gene testing company finds patients want to get estimate of costs before test is ordered

CEO SUMMARY: In California, a gene testing firm is increasing satisfaction among patients and physicians with a tool that provides patients with an estimate of the anticipated cost—before the physician orders a test! By providing transparency about the cost of tests upfront, Counsyl of South San Francisco increased revenue collected from patients by 63%, while also improving its customer satisfaction scores. This innovative online cost estimator tool is an example of how labs can deliver services that complement their lab tests and help them move "from volume to value."

BY DELIVERING AN INNOVATIVE SERVICE that better meets the expectations of patients and provides more value, one genetic testing lab company in California has seen a 63% increase in revenue collected from patients while increasing its Net Promoter Score (NPS) by 4% for customer satisfaction. NPS is a measure of satisfaction or enthusiasm among customers.

Earlier this year, **Counsyl, Inc.**, a clinical laboratory and technology company in South San Francisco, implemented an online system that allows patients—even during a consult with the physician—to check the costs of genetic tests before the physician orders the test. This cost estimator was designed to be a customer-friendly method of helping patients understand how much they might pay, based on their health insurance coverage, and spare them any sticker shock months after the test is completed.

"Every lab is familiar with this problem," stated Tom Schoenherr, Counsyl's Chief Commercial Officer. "Not only are patients unaware of the exact cost of most molecular and genetic tests at the time of service, but it may then take up to six months before the typical patient learns precisely how much money he or she will be required to pay for their lab tests. This is why patients are often unprepared to pay their share of the lab test bill."

Counsyl aims to do a better job of meeting or exceeding patient and physician expectations. "Not only is our upfront lab cost estimator tool patient-friendly, but it

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

is also physician-friendly," he emphasized. "Physicians are fatigued by the myriad new genetic tests arriving on the market. Moreover, each genetic testing laboratory seems to have different billing procedures.

Meeting Patients' Needs

"Physicians are tired of talking to patients about billing because it is something over which they have no control," stated Schoenherr. "It was our belief that physicians would welcome a cost transparency program that meets the needs of patients and that was quick and easy for patients to use."

Counsyl's lab test pricing tool has been popular with both patients and physicians, as the company's data show. "Since introducing the tool this spring, Counsyl, which performs thousands of patient samples per month, has over 50% of their volume running through this transparency program," he said.

"Counsyl's online cost estimator is designed to be easy for patients to access and use," continued Schoenherr. "When a physician recommends our test, a patient can pull up the cost estimator on a mobile phone, provide basic insurance information, and get a clear sense of the anticipated cost.

"Counsyl's price transparency tool gives patients an accurate price estimate of what they might pay out-of-pocket, based on their health benefit plan and how much of their deductible has been met," Schoenherr explained. "Ideally, patients can learn their out-of-pocket costs before their sample even arrives at our lab."

Positive Patient Response

Counsyl was pleasantly surprised by the response from patients who receive an estimate of their costs upfront, he added. "Contrary to the popular assumption that patients will cancel lab tests if they know their expenses upfront, we had just a 1.4% increase in the number of patients canceling their tests after the price transparency tool was available for them to use. Since launching the program, Counsyl has found that patients welcome the transparency and use it to plan ahead," he said.

"One positive outcome from the introduction of the price transparency tool is that patients like it, and it helps strengthen our patient satisfaction scores," observed Schoenherr. "We score a 4.9 out of 5 and those scores cover all our services, ranging from genetic counseling to the patients' experience with our billing department.

"We also saw billing inquiries in our client service center drop by 11%, which we thought was significant," he commented. "Previously patients would call to ask how much a test would cost and those calls are among the highest volume of calls made to the client service centers of labs across the country.

Reducing Calls To Lab

"If we could eliminate those calls, we believed that it would take a lot of work and frustration off our team, even as we help patients at the same time," added Schoenherr.

At this time, Counsyl offers three gene screening panels:

1) Family Prep Screen, which can detect more than 100 inherited conditions passed from parent to child;
2) Informed Pregnancy Screen, a cell-free DNA screen that detects chromosomal conditions, such as Down Syndrome and Turner Syndrome; and,
3) Inherited Cancer Screen, which analyzes a patient's DNA for more than 20 genes associated with an increased risk of developing certain cancers.

"We have a clinical advantage in that we consider our genetic screens to be top notch," noted Schoenherr. "Further, because Counsyl is in-network with all the big health insurance companies nationwide, we also have a very competitive price point so that patients with insurance pay, on average, about $150 to $300 for

To Be Patient- and Payer-Friendly, Counsyl Provides Genetic Counseling, Video Tutorials

SOME HEALTH INSURERS REQUIRE that a patient receive genetic counseling before approval for certain genetic tests. But even when insurers do not require genetic counseling, patients may need genetic counseling advice to make an informed decision about testing and understand their results, stated Tom Schoenherr, Chief Commercial Officer for Counsyl in South San Francisco.

"As an example, for the genes that are part of our Inherited Cancer Screen, at least one national payer requires pre-test counseling through a third-party genetic counselor before they will authorize the test," he said. "In those cases, the counselor is usually recommended by the patient's physician. But patients also need help understanding their genetic test results.

"That is why Counsyl has a series of educational videos," noted Schoenherr. "Once the results of the genetic screen are ready, we can have patients view a tutorial or educational video that is specific to their results.

"While viewing the video, a patient can click an option to get an on-demand genetic counselor on the phone in less than five minutes," commented Schoenherr. "Patients can also set up a telephone appointment with a genetic counselor if that works better for them.

"For patients who want on-demand counseling, Counsyl makes genetic counselors available 12 hours a day five days a week by telephone," he added. "Should the patient prefer to schedule an appointment for counseling, we have genetic counselors available at different times, including weekends."

In this way, Counsyl adds value that differentiates it from competing labs. That's because it is not always simple for a patient to get access to a genetic counselor.

"Nationwide, there are currently only about 4,000 genetic counselors," said Shoenherr. "As recently as 2013, these genetic counselors could address only about 10% to 15% of the need across the country. So it can be challenging for patients to find and get an appointment with a genetic counselor. This is why we include that service for them as part of our screens.

"Currently there are 35 genetic counselors who work with us and they specialize in prenatal tests and inherited cancer tests," he concluded. "We have enough counselors to meet current demand, but as volume increases, we may need to add more genetic counselors."

our tests—depending on their benefits and coverage.

"We also provide on-demand genetic counseling to patients, a service that is unique to our lab," he commented. *(See sidebar on this page.)*

Adding Value For Physicians

"Another feature that adds value for our physicians is how we track this activity for them," he stated. "Physicians know when the patient got the cost estimate and if the patient viewed the cost estimate. We also track when results are sent to the patient and if the patient reviewed those results.

"We know if and when the patient selects a genetic counselor, when the counseling session has been done, and when the counseling report is sent back to the physician," added Schoenherr. "All of this information takes much of the workload off the physician's plate.

"We can do this because Counsyl is a health technology and software organization that has a laboratory embedded within," he stated. "Among our 400 employees, we have more than 100 engineers on staff. Over half of them are software engineers. That allows us to build sophisticated software programs—such as our cost estimator tool—that other labs typically would not invest the resources to create.

"It took a while to build this cost estimator tool and test it before we rolled it

out at the end of the first quarter and the beginning of the second quarter this year," he noted. "Currently about half of our lab volume is on this program and a about half our client clinics use it. We expect to have it in use for 100% of our volume by the end of the third quarter.

Need For Collateral Pieces

"One lesson we learned as we did pilot testing of our cost estimator tool was the need to have collateral materials that physicians could hand to their patients," recalled Schoenherr. "Counsyl took that feedback seriously and has since created a postcard for physicians to hand to patients regarding billing inquiries.

"For us, the benefit of these materials was that patients had the details of how to use the online tool and how to contact us online or by phone," he said. "In addition, our lab directly benefits in other ways.

"For example, early patient engagement on lab test costs has reduced the number of invoice inquiries and the average time to resolution," concluded Schoenherr. "In fact, patients now use their phones to pay invoices and the time to payment with these patients is two to three weeks faster than with paper invoices."

There is much that other clinical labs and pathology groups can learn from Counsyl's experience with providing patients with up-front estimates of their costs for lab tests. In many ways, this is a radical idea, as the entire lab industry has a tradition of waiting until the health insurer settles the claim before engaging patients to collect the balance of the bill.

Accurate Metrics

For its part, Counsyl is making the effort to collect accurate metrics about how patients respond to the service of obtaining an estimate of what their out-of-pocket costs are at the time that these genetic tests are suggested by their physicians. To date, it is an impressive statistic that only 1.4% more patients declined to go forward with the testing, once the cost estimates were available. This demonstrates that a significant proportion of patients want to proceed with genetic tests their physicians deem useful. Morever, it is interesting that these patients tell Counsyl that they appreciate the cost estimate because it allows them to make arrangements to pay their share of the bill."

At a time when tens of millions of Americans are enrolled in high-deductible health plans and thus responsible for annual family deductibles of as much as $10,000, it is imperative that all labs have a strategy as to how they will successfully collect these funds from their patients. TDR

—Joseph Burns

Contact Shivani Nazareth at 917-409-7051 or shivani@counsyl.com.

Managed Care Strategy Is to Be a Network Provider

BECAUSE BOTH HEALTH INSURERS AND PATIENTS with high-deductible health plans are concerned about the cost of expensive genetic tests, Counsyl has designed a pricing strategy to differentiate its genetic screens in the marketplace.

"We know that we are already about 50% to 90% less expensive than our competitors," stated Tom Schoenherr, Chief Commercial Officer at Counsyl. "We bill at least 50% less than our competitors for similar lab tests. To serve uninsured patients, we can offer a low self-pay price that is accessible at a few hundred dollars.

"When insurers receive our claims, they reimburse us according to our contract with them," he noted. "To make these genetic tests affordable, it was our goal to be in-network with the majority of the national health insurers.

"By getting into as many managed care networks as possible, we could offer a very competitive price point for our genetic screens," added Schoenherr. "At this time, Counsyl holds managed care contracts that allow it to be an in-network benefit for approximately 80% of all the commercial lives in the United States."

UnitedHealth Not Paying Lab Claims of Some Docs

One Florida medical group says it is prepared not to renew its contract with UnitedHealthcare

CEO SUMMARY: It continues to be tough going in Florida for UnitedHealthcare and its contractor, BeaconLBS. Efforts to implement the UHC laboratory benefit management program face stiff resistance from some physicians and a number of state medical associations. One primary care group in Vero Beach says payments for its clinical lab test claims have been inconsistent since April 1 because it refuses to use UnitedHealthcare's Beacon Laboratory Benefit Solutions program when ordering tests for UHC's commercial patients.

Some physicians in Florida continue to battle **UnitedHealthcare** over its requirement that they must order a designated menu of lab tests using the BeaconLBS system.

In fact, UnitedHealthcare has told one 12-physician group in Vero Beach, Florida, that its contract with the health insurer will not be renewed at the end of the year if it does not use the BeaconLBS system when ordering lab tests.

"Since April 1, payment from UnitedHealth for our practice's in-office lab test claims has been inconsistent," stated J. Michael Luton, CEO of the group, **Primary Care of the Treasure Coast** (PCTC). "On that date, United stopped paying our group for any laboratory tests it submitted from the group's physician-office laboratory."

When the group complained, UHC paid some bills but not others, reported Luton. When he learned that the group's lab test invoices were unpaid, Luton sent an email to UnitedHealthcare asking why. In its response, UHC recommended PCTC register to use the BeaconLBS system and said that if the group did not register with and use the BeaconLBS system, United would not renew its contract with the group for 2016, added Luton.

United patients represent only about 8% of PCTC's patients, Luton said. About 58% of PCTC's income is from Medicare, and about 20% is from **Florida Blue**. The remainder is from UnitedHealthcare and other sources, Luton explained.

Managing Lab Orders

BeaconLBS is a laboratory benefit management program that UnitedHealthcare introduced last year for its commercial members in Florida. The program was scheduled to start October 15, 2014, but that date was postponed until January 1, 2015, when United required physicians serving its members in the Sunshine State to use the BeaconLBS decision support system when ordering any of 79 tests on a list UHC publishes on its website. *(See TDR, July 21, 2014, and October 13, 2014.)* On April 15, UnitedHealthcare started

making claims-payment decisions based on whether physicians followed all of the rules it required for the BeaconLBS system. "But United stopped paying PCTC before April 15," noted Luton.

Many physicians in Florida have told THE DARK REPORT that using the BeaconLBS system to order any of the 79 clinical laboratory tests is difficult and requires extra time. Some physicians and their state medical associations have voiced similar concerns to UnitedHealthcare and BeaconLBS, further stating that the pre-notification or pre-authorization requirements for the designated laboratory tests infringe on physicians' professional practice of medicine and could lead to patient harm. *(See TDR, November 3, 2014, and January 26, 2015.)*

"In May we noticed that UnitedHealthcare stopped paying for our lab tests," explained Luton. "When we asked one of our billing clerks to check it out, UHC said we didn't submit all the information we were supposed to submit for our claims. We then checked with our claims processing clearinghouse, **Emdeon**, and they said all the claims were submitted correctly, just as we had been doing for years.

Pending Payment Cuts

"Next, I sent an email to UnitedHealthcare and they explained that they had not paid our lab test claims because we had not registered with the BeaconLBS system," he added. "We had already told UHC that we wouldn't use the BeaconLBS system because it didn't work with our electronic health record system, **eClinicalWorks**.

"We know from eClinicalWorks that the Beacon interface won't be ready until the fall when eClinicalWorks does a complete upgrade," continued Luton. "After we've reviewed the upgrade, we will either approve the BeaconLBS system or not. If we don't approve it, we won't use it. That was a decision the physicians made.

"But even after we see how it works, I'm not sure it will be worthwhile," he said. "The BeaconLBS system was demo'ed for us last fall. We tried to submit a request for a pregnancy test and that request required the physicians to complete a 4- to 5-page report just for one test.

"We told them, 'That's crazy. You can't expect our physicians to go outside of our system to go to the BeaconLBS website to fill out the forms just to order a routine test. That doesn't make any sense.' And they replied that they didn't know why it took so much time. To that, I said, 'You just saw for yourself how long it takes," said Luton.

"At that time, several of our physicians looked at how the system works and threw up their hands in frustration," Luton added.

"We don't have many tests on the BeaconLBS list that we perform here in our lab," he noted. "But several lab tests that our physicians order frequently are on that list. Given the difficulty and time required for physicians to order in the BeaconLBS system, we are skeptical that any benefits will result from our use of the system.

"We have asked UnitedHealthcare and Beacon to show us the evidence that the lab tests they require to be approved via a point-of-care decision instrument have been misused, but they have never been able to do so," Luton added.

"At this moment, our physicians have decided not to use the BeaconLBS system until we see how it works with eClinicalWorks, and we are not adding any new UnitedHealthcare patients," commented Luton. "In addition, we may need to notify our UnitedHealthcare patients that we may not renew the contract next year."

This is one example of physicians who continue to voice their discontent about the requirements of UnitedHealthcare's laboratory benefit management program. Rumors continue to circulate that UHC has exempted some large medical groups from the program, but no one is willing to speak on the record about such situations. TDR

—Joseph Burns

Contact J. Michael Luton at 772-567-6340 ext 108, or jmluton@primarydocs.net.

UnitedHealthcare, BeaconLBS Still Face Strong Resistance From Some Physicians

MANY PATHOLOGISTS AND CLINICAL LAB PROFESSIONALS who read comic books during the silver age (1956-1970) may recall the great conundrum often presented in issues of *Superman*: What happens when the unstoppable force (typically a villain) meets the immovable object (Superman)?

This same conundrum aptly describes the current situation in Florida involving UnitedHealthcare and its contractor, BeaconLBS (a business division of **Laboratory Corporation of America**) and physicians who care for patients enrolled in UHC's commercial plans. In this scenario which continues to play out from day to day, UnitedHealthcare is the unstoppable force. Opposing United is a significant number of Florida physicians in medical specialties who are the immovable objects.

Since UnitedHealthcare began enforcing "claims impact" on April 15, 2015, with its laboratory benefit management program that is handled by BeaconLBS, an unknown—but significant—number of Florida physicians have refused to follow the requirements for ordering the 79 lab tests designated for pre-authorization or pre-notification via use of the BeaconLBS system. *(See TDR, March 9, 2015.)*

One example of physician resistance is found at Primary Care of the Treasure Coast, in Vero Beach, Florida. Its 12 physicians have taken a tough stand against using the BeaconLBS system until they can test how it would work in their practice. In an interview with THE DARK REPORT, J. Michael Luton, CEO of PCTC, shared an email exchange he had with Todd Kamenda, Network Account Manager for UnitedHealthcare.

On June 25, Luton wrote: "Dear Mr. Kamenda, I have been forced to write this email (separate letter to follow) due to your lack of responses to the various voicemails my staff and I have left you concerning the [non-]reimbursement of UnitedHealthcare patient's laboratory payments... We have done extensive testing with our claims processing service, Emdeon, and have found no problem with the data being submitted.

"It is my opinion that these claims are being held due to our failure to participate with the Beacon lab management program," wrote Luton. "Although there are only 79 lab tests covered by the Beacon program you have elected to withhold all laboratory payments to our practice. This is an unconscionable act on the part of your company.

"...The actions taken by UnitedHealthcare in refusing to pay for laboratory services approved by contract with you forces us to react by closing our practice to all new United Healthcare patients," said Luton. "UHC has stated that physician participation with United Healthcare programs would be eliminated by refusal to participate with the Beacon program. Should that be your decision and it is immediate, we will abide by it and notify all UHC patients that we are no longer participants with UnitedHealthcare.

Formal Resignation

"After discussion by the Board of Directors of PCTC, we believe that you have violated the terms and spirit of our contract, and thus consider this our formal resignation for all Primary Care of the Treasure Coast, Inc., providers from all UnitedHealthcare programs effective January 1, 2016," concluded Luton.

In response to Luton's email, Kamenda replied on July 1 as follows: "Hi Michael, Thank you for your patience in allowing me to research this issue further. In terms of the pended claims, we do not pick and choose who we deny claims for. ... You will continue to see pends if you do not register and map the lab as well... There are 79 tests that require Advance Notification. ...Just because you are not performing a Decision Support Test does not mean you don't have to comply with the program. All of this information is listed in our Administrative Protocol... The Beacon team advised that this is the same for the PCTC lab. You will continue to see these pends if you do not register and map your lab [to the BeaconLBS system]..."

CEO SUMMARY: There's a new competitor in the digital pathology marketplace with ambitious plans to deliver a fully-integrated pathologist workflow solution. Inspirata, Inc., of Tampa, Florida, made its debut in March at an international pathology conference. In this exclusive interview, Inspirata Chairman and CEO Satish K. Sanan explains his company's strategic vision for digital pathology, along with the details of how Inspirata intends to overcome digital pathology's return-on-investment challenge.

Inspirata Working to Deliver Useful

New Company R
Slow Digital Pa

IN THE 2000S, DIGITAL PATHOLOGY WAS THE HOT NEW TECHNOLOGY that held great potential to transform anatomic pathology in myriad ways, not the least of which was an essential tool to streamline pathologist workflow while supporting greater diagnostic precision.

Yet today, approximately 10 years later, those high hopes have not come to fruition. The number of pathology laboratories using digital pathology on a regular basis remains limited.

The primary customers today are mostly biotech researchers, academic pathology groups, national pathology labs, and some large regional pathology practices. Few private practice pathology groups own and use digital pathology systems and digital images in daily practice. It is estimated that around 1,000 pathology labs worldwide own and use digital pathology systems on a regular basis.

Thus, it is noteworthy that a well-financed company in Tampa, Florida, has just launched with the goal of making digital pathology easier to use because of the integrated pathologist workflow solution it has developed.

That company is **Inspirata, Inc.**, and it unveiled its products and services in March

at the **United States Canada Association of Pathology** (USCAP) meeting in Boston. Recently, THE DARK REPORT visited Inspirata's corporate offices to learn more about the company's business strategy and to see a demonstration of its pathologist workflow solution.

The first aspect that distinguishes Inspirata from the handful of companies offering digital pathology products is that Inspirata is not manufacturing and selling its own hardware, scanners, and associated products. Instead, it is selling a cloud-based pathologist workflow solution.

"It is our view of the pathology marketplace that one big barrier to further adoption of digital pathology is the need to provide pathologists with tools that support an integrated workflow," stated Satish K. Sanan, Chairman and CEO of Inspirata. "Therefore, early on, we decided to focus our efforts on developing software that would make the pathologist more productive. As to hardware, our strategy is to partner with the manufacturers of digital pathology hardware and scanners."

Executives at Inspirata evaluated the variety of scanners and digital pathology hardware available. "We were impressed with the products that **Philips Digital Pathology Solutions** manufactures and sells," noted Sanan. "It turned out that Philips was receptive to the idea of a collaboration with us.

"What is significant about this relationship is that we are working together so that the software and applications that are part of our workflow solution for pathologists are properly interfaced and integrated with the specifications of the scanners and digital pathology hardware Philips manufactures," he explained. "Our goal is for a pathologist working in our pathology cockpit to have a seamless experience in utilizing all the tools and accessing the images and supporting data needed for diagnosis."

This is how the formal partnership between Inspirata and Phillips was created. The two companies state that they "are jointly developing, selling and supporting an end-to-end digital pathology workflow solution designed to streamline processes and expedite diagnoses in the nation's comprehensive cancer centers."

Inspirata's first stage strategy is to market its digital pathology workflow solution to academic pathology departments and researchers. These laboratories typically find value in using digital pathology images for research, subspecialist consults, tumor boards, and teaching. This is why both sectors have been the fastest to acquire and use digital pathology systems over the past decade.

Clinical and Workflow Tools

Ready to Heat Up thology Market

However, it would be a mistake to view Inspirata as simply a company that will offer an integrated, cloud-based, workflow solution for pathologists that incorporates a multi-screen pathology cockpit. Along with helping pathologists become more productive, the company has a more comprehensive vision that includes developing advanced diagnostic capabilities to allow pathologists to contribute greater value to patient care.

"What we are discussing with pathologists who look at our services is an end-to-end digital workflow solution," noted Sanan. "Think of this as made up of three capabilities. The first capability is what we have already discussed, which is improving the pathologist's workflow in ways that directly decrease the time to diagnosis.

"This integrated workflow system will address everything, including surgery—where biopsies are collected, transportation, accessioning, histology, scanning, and archiving to support the pathologist in the cockpit who is doing the diagnosis and who may need to share these images with colleagues or subspecialist pathologists," he explained.

"The second capability is to help pathologists increase diagnostic accuracy by providing novel quantifiable prognostic and predictive assays," noted Sanan. "Not only will this improve patient care and help pathologists deliver more value, but the use of these assays can bring new sources of revenue to the pathology lab.

Use of Data Analytics

"Over time, the third capability we intend to develop is data analytics that can be accessed through the use of comprehensive databases," stated Sanan. "Healthcare is moving toward big data, and the pathology profession will gain great benefit when it has the opportunity to access the clinical data of thousands of cancer patients."

To implement its first strategy—improving the workflow of pathologists—Inspirata has a clever business plan. Company officials recognize that one important reason digital pathology systems have not grabbed a larger share of the anatomic pathology marketplace is because today's return on investment (ROI) for acquiring the hardware and software does not pencil out for most pathology labs.

"This is true for several reasons," noted Sanan. "First, the speed of most scanners means that throughput is not fast enough to meet the daily workflow needs of many pathology labs. Second, the cost of the hardware and systems needed to store and retrieve whole-slide images remains relatively expensive.

"Third, integration of digital pathology images and workflow with the major pathology laboratory information systems is less than ideal," he added. "Pathologists attempting to work within both systems can be frustrated by the need to jump back and forth when working on a case.

Meeting Expectations

"We believe that most software and workflow systems that come with digital pathology hardware fall short of meeting the expectations of those surgical pathologists who must use them," emphasized Sanan. "Solving this problem is an opportunity for any digital pathology company that can provide a solution that addresses these issues, performs with an acceptable ROI, and allows pathologists to be more productive while also delivering more diagnostic value to referring physicians"

One way that Inspirata may prove disruptive to the anatomic pathology profession is its business strategy to address the ROI issue with digital pathology in the short term. "Typically, existing competitors will sell pathology labs the scanners, monitors, and associated hardware," noted Sanan. "The labs need to add storage to handle the increased data. Then the pathologists are somewhat left on their own to use their newly-acquired digital pathology capability, while generating an acceptable rate of return for all that investment.

How a Successful Software Entrepreneur Decided To Create a New Digital Pathology Company

ON OCCASION, IT IS OUTSIDERS to laboratory medicine who bring the most disruption to the status quo. In the case of Inspirata—the new company aiming to deliver a digital workflow solution to anatomic pathologists it hopes will be disruptive in the current marketplace—the moving force is its Chairman and CEO, Satish K. Sanan.

Sanan is a serial entrepreneur. He founded **IMRglobal Corp.** in 1988 and the company went public in 1996. It was sold to **CGI** for $438 million in 2001. Sanan next acquired **Zavata Inc.**, of Atlanta, Georgia. This company provided business process outsourcing and revenue cycle management services to the healthcare provider and insurance market. It was sold to **Apollo Hospitals** of India in 2008.

In 2013, at a showcase for emerging companies in Tampa, Florida, Sanan met Mark Lloyd, Ph.D., who had founded a company to develop diagnostics products. Lloyd was a scientist at the **Moffitt Cancer Center's** Analytic Microscopy Core Laboratory. He was doing advanced work in digital pathology and computational image analytics.

Meeting Pathologists' Needs

Intrigued by Lloyd's work and his vision for digital pathology, Sanan did extensive research. Working with Lloyd, the Inspirata team spent a year studying the clinical and workflow activities of pathologists at Moffitt Cancer Center. At the same time, they researched all the scanners and digital pathology systems currently offered for sale to evaluate their strengths and weaknesses at meeting pathologists' needs.

Sanan recognized one big gap in the digital pathology marketplace. Despite improvements in the function and productivity of scanners and digital pathology hardware over the past decades, pathology labs still lacked one element necessary to use scanners and digital pathology systems cost-effectively: a pathologist workflow solution that functions in a way that meets or exceeds the needs and expectations of pathologists.

However, Sanan's vision goes beyond providing the pathology profession with a pathologist workflow solution. He sees the opportunity to collect pathology case data and images and combine that with other clinical data sources to create a data warehouse that pathology labs and diagnostic companies—including Inspirata—can use to develop new lab tests and support advances in pharmacogenomics.

Three Business Initiatives

To tackle these business challenges, Sanan did three things to distinguish the company from most other digital pathology vendors. First, he invited 12 prominent pathologists and scientists to be part of an advisory board that is engaged for input.

Second, Sanan tapped his network of successful entrepreneurs to be investors in Inspirata. These individuals believe in the company's potential to develop and deliver game-changing products and services to the profession of anatomic pathology.

Third, Sanan is moving forward with a $3 million investment in a research center in Bangalore, India. It will start with about 30 scientists, engineers, and software developers. Through its partners, it has relationships with The **Rajiv Gandhi Cancer Institute and Research Centre** and the **All India Institute for Medical Sciences** (AIIMS) to access tissue specimens of cancer patients.

Sanan believes that the demand for anatomic pathology services in India will complement subspecialist pathology capabilities here in the United States. "Digital pathology will be the bridge that allows pathology labs in both countries to work collaboratively to improve the diagnostic services available to patients," he predicted.

"By contrast, Inspirata's strategy is to eliminate the ROI question," he explained. "Inspirata will place full scanning capability into a pathology laboratory. We will also put our staff in that laboratory's new scanning center to operate the systems.

"Under this sales arrangement, the pathology laboratory does not need to put up capital in order to acquire the equipment," noted Sanan. "Rather, the lab can pay back Inspirata over time. This approach allows the lab to get the scanners, monitors, servers, storage, staffing, and the pathologist cockpit necessary to support diagnostic activities.

Provide A Single Solution

"By eliminating the need for a pathology laboratory to make a substantial up-front capital investment, Inspirata can provide a single solution that covers all that is needed for a pathology lab to begin working with digital images," emphasized Sanan. "There is strong interest in this business model, and we are in discussions with a number of respected academic pathology departments that are studying this business arrangement."

Essentially, Sanan is talking about the "rent to own/lease to own" business model that has been successful in all sorts of industries. A form of this is used in clinical laboratories with agreements known as "reagent rental," where the lab agrees to perform a specific volume of tests and pays the vendor a "per click" fee for each test it runs.

Similarly, back in 2008, another pioneering digital pathology company used a another type of "pay as you go" pricing model for its equipment. **BioImagene, Inc.**, (acquired by **Roche Holdings** in 2011), offered its scanners and hardware to pathology laboratories priced at 99¢ per scan, similar to the iTunes pricing model. Pathology groups that purchased BioImagene under this arrangement also agreed to pay for a minimum number of digital pathology scans per month. *(See TDR, September 29, 2008.)*

Thus, there is established precedent in the lab industry for pay-as-you-go pricing similar to what Inspirata is willing to offer pathology laboratories. The downside for Inspirata with this business strategy is that it requires substantial amounts of capital up front to place these instruments and it may take several years for the monthly cash payments to Inspirata from these pathology labs to reach a financially-sustainable level.

If Inspirata is to succeed in distinguishing itself compared to the existing companies in the digital pathology marketplace, it will need to do two things. First, it must convince skeptical pathologists and pathology practice administrators that it is feasible to implement a digital pathology workflow solution that delivers improved pathologist productivity in a cost-effective manner.

Second, Inspirata's pathologist cockpit must deliver a seamless workflow experience that fully meets or exceeds the expectations of surgical pathologists who spend each day viewing slides and producing diagnoses. These expectations represent a high bar for performance, one that the digital pathology industry has yet to meet.

A Trump Card At Inspirata?

If Inspirata does have a trump card, it is likely to be its hard-driving, visionary Chairman and CEO, Satish K. Sanan. He has access to ample amounts of investment capital to fund the development of the workflow solution, as well as the quantifiable prognostic and predictive assays and the "big data" cancer database. As Inspirata's leader, Sanan is demonstrating that he can produce significant results in a compressed timeline. That may be what is needed to create momentum across the entire field of digital pathology. TDR

Contact Satish Sanan at 813-570-8905 or SSanan@Inspirata.com.

Digital Pathology's Pioneers: Where Are They Now? Much Has Changed Over the Past 15 Years

DURING THE 1990S, rapid advances in information technology, computer chips, and software made it feasible to develop products to support telepathology and digital imaging of glass slides.

One early entrant in the telepathology sector was **Interscope Technologies, Inc.**, founded in 1997 in Pittsburgh, Pennsylvania (it later became **Trestle Holdings, Inc.**). Its telepathology products found a market, but information technology and the Internet were not developed well enough to properly support the performance of these systems.

In 1999, **Aperio Technologies, Inc.**, of Vista, California, was founded. It developed one of the first lines of digital pathology products that gained market acceptance. During the second half of the 2000s, it was placing digital pathology systems in pathology labs worldwide. In 2012, Aperio was acquired by **Leica Biosystems** (itself a division of **Danaher Corporation**).

In 2002, **DMetrix Inc.**, of Tucson, Arizona, began offering scanners and digital pathology solutions. It has had only a small market presence in recent years.

BioImagene of Cupertino, California, was founded in 2008. It differentiated itself from Aperio by offering a "pay per digital scan" sales model. Roche Holdings purchased BioImagene in 2010 and it became part of **Ventana Medical Systems Inc.** (now renamed **Roche Tissue Diagnostics**).

GE And UMPC Form Omnyx

Also in 2008, **Omnyx, LLC**, was formed as a partnership between General Electric and the **University of Pittsburgh Medical System**. The headquarters for this digital pathology company is in Pittsburgh.

By 2010, a division of **Royal Philips Electronics** had entered the digital pathology market with a line of scanners and digital pathology hardware.

Along with these companies selling scanners and digital pathology hardware, there were several companies that developed solutions to allow pathologists working with digital pathology images to communicate with each other. These companies did not manufacture or sell scanners or digital pathology hardware.

Founded in 1993, **Apollo PACS** of Falls Church, Virginia, earned patents related to telepathology. In the mid-2000s, it developed and introduced a PACS solution for digital pathology images.

Collaborative Tool

Aurora Interactive of Montreal, Quebec, Canada, was founded in 2004. Under the brand name, mScope, it developed tools to manage digital images and enable collaboration among pathologists at different sites. Between 2006 and 2011, it had installations operating in both North America and Europe.

This is not a complete list of the pioneering companies in telepathology and digital pathology. But it is representative of the early entrants who marketed their products and systems. These companies used information technology, computer chips, and software that was state-of-the-art for those times, but performed significantly under the capabilities of today's technology.

There is another field within digital pathology that appeared late in the 1990s and was centered more upon systems designed to help pathologists analyze digital images. One example of such a company was **ChromaVision Medical Systems Inc.**, of San Juan Capistrano, California. It was founded in 1993 and marketed a digital imaging system that supported its ACIS test, that "detects, counts and classifies the HER2 protein." Chromavision was renamed **Clarient Inc.**, in 2005. In 2010, General Electric (a co-owner of Omnyx, LLC), acquired Clarient.

Investment Bank Bullish On Clinical Labs, Pathology

➤Multiple trends in healthcare opening doors for laboratories to deliver value in new ways

➤➤CEO SUMMARY: For clinical laboratories and anatomic pathology groups willing to adapt to the evolving needs of the American healthcare system, there are many positive opportunities. That's the view of a Wall Street investment bank that just published a report on the lab testing sector. The report on healthcare trends includes commentary about developments in cancer care, acceptance of personalized medicine, and the growing activity in direct-to-consumer lab testing.

DESPITE THE FACT that the clinical laboratory industry and the anatomic pathology profession have experienced tough financial times recently, at least one New York investment bank sees opportunity in the coming years.

This is welcome news for many pathologists and lab administrators who have felt financially-beleaguered in recent years because of severe budget cuts and falling lab test prices. There was optimism in a report released in July by **Cain Brothers**—an investment bank in New York City solely focused on healthcare services. This optimism is based on labs responding appropriately to meet the changing needs of the American healthcare system.

The report titled, "Medical Labs and Diagnostic Testing: A Growing Value Proposition," was written by Tom Gallucci, Managing Director, and Dan Gofman, Vice President, both of Cain Brothers. Gallucci, who has covered the lab testing sector since the late 1990s and thus has deep experience and a long-term perspective on the lab testing industry, said he was responsible for most of the contents.

In its introduction, the report said, "the medical lab and diagnostic testing industry are being presented with significant opportunities as the healthcare system moves away from fee-for-service reimbursement and toward a model that is based on value while pushing risk onto the provider."

➤Efficiency, Quality, Outcomes

After calling attention to the major transformation of the American healthcare system, Gallucci identified the opportunity for labs, saying, "Looking ahead, as the overall reimbursement paradigm shifts, the healthcare system will be increasingly focused on efficiency, quality and outcomes. This dynamic plays into the hands of the lab industry given that testing is vital to driving optimal care patterns at the lowest cost."

Within the clinical laboratory testing sector, the report noted the tension between hospital and health system labs with outreach programs and how they compete with independent lab companies. Going forward, hospitals will see reimbursement evolve away from fee-for-service in favor of value-based and bud-

Cain Brothers See Opportunities for Laboratories To Provide Direct-Access Testing to Consumers

IN A NEW REPORT ABOUT THE LABORATORY TESTING industry, author Thomas Gallucci, Managing Director of Cain Brothers, discussed the emerging business opportunities in direct-access testing (DAT).

Personalized medicine is driven by a new focus on consumerism, and this development leads to another trend that can favor the lab sector, which is direct-access testing, he said. "Advancing... technology is bringing lab testing logistically closer to the patient, while making it more economical as well," wrote Gallucci. "At the same time, rising consumerism in healthcare is being driven by a growing focus on transparency, wellness and prevention, as well as patient demands for greater control over their own healthcare. As a result, even regulators are loosening lab-related policies, helping to open the door of opportunity in the direct-access or direct-to-consumer testing market."

The shift in the design of health insurance plans is another driver of the DAT trend. "The introduction of high-deductible health plans and growing opportunities for individuals to purchase health insurance via exchanges are fostering a new element of consumerism throughout healthcare," he wrote. "As patients more closely consider their healthcare choices, many kinds of improvements in transparency are developing.

"With lab data driving the majority of healthcare decisions, it is natural that demand for greater patient control over testing and test results is on the rise," stated Gallucci. "This dynamic, combined with a more favorable regulatory environment, should foster solid growth of the direct-to-consumer (DTC) laboratory testing business over time."

"Consumers are drawn to direct-access testing for another reason: It lets them have a bit more privacy while also monitoring their health over time without having to go to a doctor frequently," Gallucci added. "Many direct-access labs let consumers order tests without a doctor's order and they can get results online, again bypassing the doctor... Direct-access or direct-to-consumer testing is a positive trend."

geted payment. Thus, hospital administrators may start to view lab testing as a cost and look for new ways to reduce those costs and improve efficiency, including potentially partnering with labs or outsourcing lab work, Gallucci said. This scenario would favor the national labs or other labs and related companies because of their expertise and economies of scale, he added.

Improving Patient Outcomes

For some hospitals and health systems, partnering and outsourcing are two solutions. But Gallucci added that other strategies may be appropriate for some hospitals as well. Within an integrated delivery network, such as an accountable care organization, the hospital lab on the medical campus within a community is positioned to provide fast turnaround times that contribute to improved patient outcomes in physicians' offices, while also maintaining a full longitudinal record for patients that is based on the same test methodologies and reference ranges across all care settings: inpatient, outpatient, and outreach.

The difference between the somewhat higher marginal cost per test of these labs versus the lab test prices offered, say, by a national lab, is not enough for many health systems to opt for outsourcing their lab testing needs. This is certainly the experience of such integrated healthcare providers as **Kaiser Permanente**, **Geisinger Health**, and **North Shore Long Island Jewish Health System**.

The report has much to say about anatomic pathology and the molecular

diagnostic and genetic testing that is associated with pathologists. Gallucci is optimistic, he said, that reimbursement will improve, for example.

"It looks like anatomic pathologists may have put the worst behind them," he said. "Reimbursement cuts have hit this sector very hard in recent years, particularly from Medicare. But while government-related reimbursement can be difficult to predict, it appears to have hit bottom."

Several trends will continue to increase the demand for more sophisticated diagnostic services in the field of pathology. For example, "the rapid growth of cancer underpins utilization trends and the potential for related data to generate value in research and development circles is strong, making anatomic pathology a potentially attractive area for investment," the report said.

"Testing in support of cancer will be a major opportunity for anatomic pathology labs," it continued. The incidence of cancer is increasing and the report noted that, "cancer is one of the four diseases that account for more than half of the global healthcare spend" and is growing at the rate of 10% per year.

Personalized Medicine

The report also addressed the personalized medicine trend and how it will fuel the demand for lab tests. "Simply put, lab drives the 'precision' in precision medicine," the report noted. "The growth of companion diagnostics offers a lab the opportunity to reinvigorate its value proposition across not only the provider/payer landscape (at a time when payment systems will increasingly reward efficiency), but within the pharma/R&D world as well.

"This trend is particularly important given that payment systems will increasingly reward efficiency," the report continued. "Certainly personalized medicine is not a new concept but it's in a position to take off now. This trend is particularly significant given that payment systems will increasingly reward efficiency."

Lab data will become a source of value for both clinical labs and anatomic pathology groups. As the report stated, "technology is also fostering the ability to gather new information about the individual, with genomics enabling consumers to better predict future health risks, then allowing them to take a proactive stance toward maintaining their health. Finally, beyond specific tests, information technology is enabling the massive amounts of data generated by labs to be turned into actionable information across a number of platforms, i.e. product manufacturers, healthcare providers, and research organizations."

Lab Industry Segmentation

For older pathologists and lab executives, one of the insights from this report is how Gallucci views segmentation within the laboratory medicine profession. In the 1990s, it was generally recognized that three segments dominated the industry: independent labs, hospital labs, and anatomic pathology labs. Gallucci, however, provided this list of sectors in the lab industry today, noting that there is some overlap among them:

- Full-service and/or major publicly traded
- Not-for-profit and hospital-affiliated
- Esoteric, genomic and personalized medicine, including cardiology, oncology, chronic disease management, pharmacogenomics and genetic testing companies
- Anatomic pathology
- Toxicology
- Niche laboratory and related companies, including regional and dialysis-oriented labs, breath testing, laboratory management and benefit management, information technology and distribution companies. TDR

—Joseph Burns

Contact Tom Gallucci at 212-981-6890.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Cerner Corporation is celebrating a big summer of contract awards from the **Department of Defense**. First up was a project to support further standardization of anatomic pathology within the laboratories operated worldwide by the DoD. Early in July, it was announced that the DoD had awarded a global software contract to Cerner. The company will provide its CoPathPlus pathology LIS and associated hardware to DoD pathology laboratories throughout the United States and abroad. In language from the 2014 DoD contract announcement, it was noted that Cerner "was the only contractor" that can provide proprietary services and equipment for the CoPath Plus system.

MORE ON: *Cerner*

Of greater significance is the announcement last week by DoD officials that it would award a huge contract to provide electronic health records to DoD medical facilities to the joint venture made up of Cerner, **Leidos** and **Accenture Federal**. The first two-year phase of the contract is worth $4.3 billion. There are additional multi-year option periods and DoD officials stated that the collective value of the contract and these options will be at least $9 billion.

QUEST ACQUIRES MEMORIALCARE'S LAB OUTREACH BUSINESS

By the end of August, one of California's longest-running hospital laboratory outreach programs will be acquired by **Quest Diagnostics Incorporated**. On June 30, **MemorialCare Health System** of Fountain Valley, California, and Quest Diagnostics announced an agreement that calls for Quest to purchase MemorialCare's lab outreach business. MemorialCare is a six-hospital health system. One of its anchor hospitals, 420-bed **Long Beach Memorial**, has operated a competitive laboratory outreach program for several decades.

TRANSITIONS

• Pathologist Bruce Quinn, M.D., Ph.D., was appointed as Senior Director at **FaegreBD Consulting**, a consulting company that is part of **Faegre Baker Daniels LLP**, a law firm with 12 offices nationally. He has previously worked at **Foley Hoag LLP**, **Accenture**, **Northwestern University School of Medicine, the New York University School of Medicine**, and the **UCLA Center for Health Sciences**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 24, 2015.

Back by Demand

Lab Quality Confab

and Process Improvement Institute

November 3-4, 2015 • Sheraton Hotel • New Orleans, LA

Lucia Berte of Labs Made Better!
Tania Motschman of Laboratory Corp. of America

Our Popular Quality Managers Roundtable Is Back and Even Better than Last Year!

This two-hour session was the surprise hit of last year's conference! You'll interact with other quality managers to explore best practices, share innovations, and expand your personal network. This is the only time and place in the nation where lab leaders doing what you do in managing quality initiatives come together for a candid sharing of what works and what doesn't.

Berte

Motschman

Plan to be with us and guarantee your place by registering today.

For updates and program details, visit www.labqualityconfab.com

UPCOMING...

- ***What to Watch this Fall as Medicare Officials Publish Proposed New Lab Test Rules for 2016.***
- ***Theranos Enters Pennsylvania Market with Capital Blue Cross Contract: What Comes Next?***
- ***More Bad News for Toxicology Labs as Major Health Insurer Asks to See Proof that Patients Paid their Co-Pays and Deductibles to Labs.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends