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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

Why Capitate Genetic and Molecular Test Prices?

HOW MANY OF YOU LIVED THROUGH THE DECADE OF THE 1990s and experienced the free fall in the prices managed care plans paid for clinical laboratory testing? In California—at the peak of this insanity—some lab companies offered full risk, capitated contracts for as low as 20¢ PMPM (per member per month)!

Also during this decade, the nation's largest public lab firms found themselves in dire financial straits. I know that when **MetPath** acquired **Nichols Institute** in 1994, its executives told the Nichols staff that, at that time, MetPath's average revenue-per-requisition was about $25, its average cost-per-requisition was about $20, and its average revenue-per-managed care requisition was $10. This caused Metpath to lose $10 for each managed care requisition it handled.

MetPath execs noted that, in 1994, managed care was only about 10% of its total business. But their own strategic planning projected that continued growth in HMO enrollment would lift that number to as much as 60% of MetPath's total business within five years. Some of you know how the MetPath story unfolded. Because of serious financial losses, its parent, **Corning Corporation**, spun off that company on December 31, 1996, thus creating **Quest Diagnostics Incorporated**.

Why do I remind you of those unhappy days? It is because one of the nation's larger clinical laboratory companies has created a new business unit which is approaching the payer community and selected clinical laboratory organizations with a business plan that calls for it to offer full risk, capitated contracts for genetic tests and molecular diagnostics assays.

As you will read on pages 5-8, the new business is called **BeaconLBS**. It is an attempt by its lab testing parent to create a company that will manage the pre-authorization of expensive genetic and molecular assays. That is fine and well, as regular readers know that I support the free market as a source of innovation and added value to consumers.

On the other hand, how does any lab company have a winning financial strategy when it uses marginal cost prices to win business, with the expectation that Medicare and other fee-for-service business will offset the fully-loaded cost of performing those tests? Will BeaconLBS's willingness to write full risk, capitated contracts with major payers lead to a downward spiral in the prices paid for these important genetic and molecular tests? Were that to happen, then every clinical lab in the United States would be forced to bear the resulting financial pain. TDR

ACLA Has Its Say Regarding Molecular Dx Proposals

In a 23-page public comment letter, lab group takes issue with Palmetto GBA's draft proposals

CEO SUMMARY: It is not known how many public comments have been submitted to Palmetto GBA, the big Medicare carrier, in response to its published proposals to change how code stacked claims for genetic and molecular tests will be handled, effective February 27, 2012, for labs in Medicare region J1. After filing its comments, the American Clinical Laboratory Association (ACLA) then made its letter public. The ACLA's concerns include dissatisfaction with the draft proposals and how they were developed.

IN ITS COMMENTS ON PROPOSALS that would change how Medicare carrier **Palmetto GBA**, handles code stacks for genetic and molecular test claims, the **American Clinical Laboratory Association** (ACLA) has submitted a 23-page letter.

This letter, dated December 2, 2012, shows how the battle lines may be shaping up between the lab testing industry at large and the Medicare carrier which has published drafts of the proposed changes. In its letter, ACLA said the proposals put forth by Palmetto GBA may be unneeded because of other efforts in the industry to improve how these tests are reviewed. ACLA also noted that the Palmetto proposals leave many questions unanswered.

The nation's largest Medicare Administrative Contractor (MAC), Palmetto GBA published two proposed local coverage determinations (LCD) in September. The LCDs address how clinical labs submit claims for molecular diagnostic tests (MDTs) and laboratory- developed tests (LDTs). They are DL32288, LCD for Molecular Diagnostic Tests, and DL32286, LCD for Non-Standardized Organ or Disease-Oriented Panels.

Palmetto plans to implement the new policies for MDTs and LDTs that use code stacked claims on February 27, 2012. *(See TDRs, November 7, 2011, and November 28, 2011.)* Following these two proposed LCDs, Palmetto posted information in October about its "Molecular Diagnostic Services Program" (MolDx).

If approved as presented, these two proposed LCDs and the MolDx program will significantly change how clinical labs and pathology groups use code stacked claims and submit bills for genetic and molecular tests.

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

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Palmetto GBA's proposals will take effect first in Jurisdiction 1 (J1), meaning California, Hawaii, and Nevada. After January 1, Palmetto will introduce these two LCDs in J11 (South Carolina, North Carolina, Virginia, and West Virginia).

Seeking Improvements

In its letter, ACLA said the two proposed LCDs and the MolDx program were developed with little industry input. "ACLA agrees with Palmetto and CMS that the Medicare program should know what tests it is paying for and that those tests should be reasonable and necessary," the ACLA letter said. "However, to achieve that goal, Palmetto has established an entirely new regulatory framework that is a cause for serious concern.

"Prior to the announcement of the MolDx program in November, ACLA and other organizations had been working with Palmetto to address its concerns," the letter said. "ACLA members had offered to provide a variety of information, including test catalogs, to assist Palmetto; however we were told to wait before submitting that information.

"ACLA and Palmetto had a conference call in late August 2011 to discuss the draft coverage article that Palmetto had posted on its website," continued the ACLA letter. "Although ACLA did submit comments on the coverage article in August, many of the new features of the MolDx program, including the McKesson Z-code process, the technology assessment program, and the new coverage process, were a surprise and were developed with no notice to the industry or any opportunity to comment.

"Palmetto's MolDx program is being planned and implemented in the midst of other significant changes that will render it obsolete in a year or two," noted the letter. "The AMA CPT coding panel announced over 100 new CPT codes applicable to molecular diagnostics tests, exactly the tests that Palmetto is targeting. Most of those codes are specific to the particular genetic test being performed, so they will give Palmetto and other payers precisely the level of specificity that they seek. Therefore, once those codes are implemented, the Palmetto program will become unnecessary."

A key concern is the requirement that a lab submit proprietary information to a McKesson-managed database and enter into a licensing agreement with McKesson to obtain a "Z-Code" to be used when billing Palmetto, ACLA wrote. "The application for the Z-Code requires the laboratory to submit over 32 separate pieces of information, far more than would be necessary for the mere assignment of a code," the letter said.

"The licensing agreement, which is tilted entirely in McKesson's favor, gives McKesson significant rights with regard to the information, requires laboratories to indemnify McKesson if it is sued, allows McKesson to change the terms of use without any input from laboratories, and includes no limitations on how McKesson can use the information," the letter said.

Molecular Test Registry

"Palmetto's MolDx program would force laboratories to provide valuable commercial information to McKesson without receiving any compensation, and McKesson could use and profit from the information in its other private business arrangements," the letter said. "The Z-Code system is a part of the McKesson Diagnostic Exchange, a commercial database that McKesson has developed and that it sells to payers and other interested parties."

Comments like these from ACLA and others are expected, because the proposals would significantly change how the Medicare carrier reviews and pays for LDTs and MDTs. In turn, this would directly affect labs currently using code stacks for their test claims. TDR

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LabCorp's BeaconLBS Aims To Manage Genetic Tests

New business unit wants to create lab network, offer lab test pre-authorization services to payers

CEO SUMMARY: BeaconLBS is a new business created by Laboratory Corporation of America. It says it wants to help health insurance plans manage molecular diagnostics and genetic testing. BeaconLBS is now recruiting other clinical labs to join its network and is meeting with payers to offer its lab test pre-authorization services. What may make BeaconLBS a significant development is that it is telling health insurers that it is willing to sign capitated, full-risk contracts to manage molecular testing.

PAYERS IN THE UNITED STATES WANT to institute pre-authorization of expensive genetic tests and molecular diagnostics assays. Not surprisingly, the nation's two biggest clinical laboratory companies see pre-authorization of the most profitable menu of diagnostic lab tests as both a threat and opportunity.

In response to this situation, **Laboratory Corporation of America** earlier this year incorporated a new business it calls **BeaconLBS**. The new company's marketing material describes LBS as "Lab Benefit Solutions."

LabCorp wants to position BeaconLBS as a company that health plans can use to manage the ongoing growth in volume of genetic tests and molecular diagnostics assays and the cost of reimbursing for these expensive tests. BeaconLBS hopes to interpose itself between the payer, the physician, and a network of clinical laboratories that includes LabCorp, as well as any other laboratory organizations that BeaconLBS can recruit.

Alert lab administrators and pathologists may ask how BeaconLBS–owned by LabCorp—can be an objective pre-authorization agent and responsibly delegate to other clinical laboratories the menu of laboratory tests which tend to be most profitable. In fact, this inherent conflict of interest was quickly identified by one laboratory administrator whose lab organization was recently visited by a BeaconLBS marketing development rep. The goal of the visit was to explain the BeaconLBS business plan and recruit this laboratory to join the BeaconLBS network.

A Fox In The Henhouse?

"No farmer would think it sensible to let a fox guard his henhouse," said this lab administrator, who asked to remain anonymous. "Thus, why would a health insurer believe that BeaconLBS—a business created by and owned by LabCorp—would not have a fundamental conflict of interest in the process of reviewing a physician's lab test request and deciding which of the BeaconLBS network labs—that includes LabCorp—should perform that test?"

Her skepticism about this arrangement seems to be shared by other lab

executives. Up and down the East Coast, in recent months, reps from BeaconLBS have knocked on the doors of many clinical labs to pitch them about joining the BeaconLBS lab network.

In one letter it sent out this summer, BeaconLBS said, "We are a laboratory benefits solutions company that provides physicians with access to high quality clinical laboratory networks and physician-decision-support tools to help guide test and laboratory selection. Laboratory spending trends can be 200+% that of overall medical trends and most health plans have not yet developed tools, outside the traditional unit cost management activity, to address these developing trends."

Creation Of BeaconLBS

When contacted by THE DARK REPORT, both BeaconLBS and LabCorp declined to comment. This sensitivity to public comment may be related to how BeaconLBS came into existence, since the conception and birth of BeaconLBS demonstrates the rather incestuous nature of both the clinical laboratory industry and the health insurance industry.

The background is indeed interesting and the story begins in 2006. That's when **UnitedHealthcare (UNH)**, the managed care giant based in Minneapolis, Minnesota, issued a request for proposals (RFP) for a national laboratory testing contract. It was big news that year when **Quest Diagnostics Incorporated** lost out and LabCorp won that bid. It earned a 10-year contract to serve as the exclusive national provider of lab test services for UnitedHealth. *(See TDR, October 16, 2006.)*

At the time, Paul Conlin, the current president of BeaconLBS, was at **Oxford Health Care**, a division of UnitedHealth. After the LabCorp contract was signed, Conlin went to Minneapolis to work at UnitedHealth's headquarters. He later left to work for **Coventry Health Care**, a multi-state health plan based in Bethesda, Maryland.

By September 2010, just months after leaving Coventry, it is believed that Conlin went to work for LabCorp, in Burlington, North Carolina. Then, in February 2011, LabCorp filed the papers of incorporation for BeaconLBS.

UnitedHealth Executive

Thus, an executive of UnitedHealth who is believed to have had a significant role in negotiating LabCorp's 10-year national testing contract with UnitedHealth later became President of BeaconLBS, a division of LabCorp. From LabCorp's perspective, it was a shrewd move to hire a health insurance industry insider to run BeaconLBS. Conlin understands the needs and problems that health insurers face when it comes to managing clinical laboratory test utilization.

For BeaconLBS to be successful in its business strategy, it must develop two things. First, it will need to recruit local laboratories and other national lab companies into its network. Second, these laboratories must accept prices for lab testing which meet the needs of health insurers.

BeaconLBS must also sign contracts with as many health insurance plans as possible. That is necessary because BeaconLBS wants to dangle access to these health plans as a motivation that encourages other laboratories to join the BeaconLBS lab network.

Business Strategy Dilemma

However, this business strategy leaves executives at BeaconLBS with the "chicken and egg" dilemma. Which comes first? Can it recruit labs into its network without having an adequate number of pre-authorization contracts with different health plans?

Alternatively, can BeaconLBS succeed in signing pre-authorization contracts with numerous health plans if it doesn't first have a significant number of other local and national labs in its laboratory network?

LabCorp's BeaconLBS Business Unit Touts Four Core Competencies in Use of Lab Tests

SINCE ITS INCORPORATION EARLY THIS YEAR, BeaconLBS, a business division of Laboratory Corporation of America, has begun to get its message out in the lab testing marketplace.

In its presentations, it promotes four core competencies, as follows:

- Physician Decision Support (PDS):
- Lab Networks—Efficient and High Quality
- Pricing and Editing Support
- Risk Management

What will interest pathologists and laboratory administrators is how BeaconLBS describes its lab network. It writes that:

> *Our research has shown that there is a market segment of high quality labs that are also highly efficient. Consumers and providers alike, however, do not always have the tools to identify these labs. To address this network transparency issue, we are building a network of efficient labs that are committed to four quality attributes: CAP certification; second reads on complex pathology; electronic ordering and results capabilities; and, subspecialty credentialing. As the network grows, consumers need only remember the simple "Beacon Network" message when they are seeking high quality, cost effective lab services.*

BEACONLBS™
LAB BENEFIT SOLUTIONS

Here is the logo of the new business division incorporated by LabCorp early in 2011. The website is: *http://wwwbeaconlbs.com.*

Those unique challenges were also confirmed by a long-time health insurance executive. He noted that BeaconLBS is operating in uncharted waters.

"The problem is that BeaconLBS is neither fish nor fowl," he observed during an off-the-record briefing. "At the same time that BeaconLBS is trying to build a lab network, it simultaneously must attempt to build a provider relationship network.

"If it can get both parties to the table, then it has a business model that could work," he added. "But it takes two to tango, or in this case, three: health plans, physicians, and BeaconLBS. It has no business unless it has both health plans and physicians."

Reports from the field indicate that BeaconLBS has faced an uphill battle. Since it began sending its representatives into the field to call on health insurance plans and other clinical lab companies, it has not disclosed any major agreements.

"On one hand, the time is right for any company to step in and try to manage these expensive genetic tests and molecular assays," noted a lab CEO. "Health plans are ripe for it right now.

"On the other hand, perceptions of conflict of interest between BeaconLBS and its parent, LabCorp, would seem to be a daunting challenge for BeaconLBS to gain traction within both the payer and the lab testing communities," he continued. "However, the opportunity is there and LabCorp is demonstrating that it is willing to devote resources to develop a solution that can meet the needs of payers, of physicians, and also of the laboratories in its network."

Following Radiology Model

Several health insurance executives told THE DARK REPORT that the radiology preauthorization model may be the template that BeaconLBS wants to use in promoting its service. "To achieve the goal of managing laboratory testing utilization, the implication is that, if LabCorp wants to follow the radiology model, then BeaconLBS and health plans need to preauthorize a lot of

this testing," commented one source. "BeaconLBS becomes a management company that the physician's office calls to pre-certify any laboratory test. If the test meets the criteria, the physician can send the test to LabCorp or to another lab that is in the BeaconLBS network."

Control Of Lab Test Usage

"The critical element in such a business is that the health plans want some way to contain molecular and genetic testing costs—but they don't want to get the physicians mad," noted this individual. "Physicians know the value of these tests from a patient care perspective, just as health plans do. But the rising costs of genetic and molecular lab tests need to be managed, just like everything else.

"We think that no health plan wants to be first to say 'no' to the physicians when these tests are ordered," he added. "Therefore, many health plans are going through the preparation steps now. However, I don't know of a payer that currently requires pre-authorization of molecular tests.

"Payers are listening to **McKesson** [with its Advanced Diagnostics Management service]," continued this executive. "BeaconLBS wants these same payers to listen to its pitch as well. What these services tell payers is that innovation can be stifled if pre-authorization is handled the wrong way. That is why a health insurer needs to have a program to evaluate each genetic or molecular test on its merits. Pre-certification must be implemented in an appropriate way. Otherwise, the physicians will push back."

Assumption Of Full Risk

Another aspect of the BeaconLBS message to payers is that it is willing to assume complete risk of genetic and molecular testing. This is a significant aspect of the BeaconLBS business model that, until now, has not been publicized to the wider clinical laboratory testing profession.

In one BeaconLBS presentation seen by THE DARK REPORT, there is a description of its risk management service. It was described as follows:

Risk Management: BeaconLBS is prepared to accept full financial responsibility for all outpatient laboratory expenditures upon adoption of the BeaconLBS model. By managing laboratory economics through a capitated model, we have created a simple solution to complex laboratory trends.

Longtime clients and readers of THE DARK REPORT will recognize the implications of this lab test pricing strategy. In the 1990s, full-risk, capitated lab test pricing contracts offered to HMOs primarily by public lab companies directly caused a free-fall in the average prices paid by private payers for laboratory tests. Capitated and deeply discounted prices that are as little as 5% of Medicare Part B lab test prices can still be seen in today's marketplace.

Deeply-Discounted Prices?

Thus, it is appropriate to ask: is LabCorp, through its BeaconLBS subsidiary, prepared to deeply discount the prices it will provide to contracted payers for the expensive genetic and molecular tests covered by these pre-authorization contracts? Moreover, does this mean that labs participating in the BeaconLBS lab networks will be required to also accept these low capitated prices—along with full utilization risk—in order to gain access to lab test requisitions from physicians?

In other words, is BeaconLBS actually a Trojan horse that allows LabCorp to enter the payers' castle walls in the company of multiple labs it has recruited into the BeaconLBS lab network, then, with the payer contract in hand, LabCorp leverages its economies of scale in ways that disadvantage the network laboratories and—in some form or fashion—leaves LabCorp with access to larger volumes of tests, albeit at a deeply discounted price? TDR

—Joseph Burns

Market Update

Allina Opens State-of-the-Art Central Laboratory Facility

THIS MONTH, THE NATION'S NEWEST "designed from scratch" clinical laboratory facility began operating in Minneapolis, Minnesota. It is the central laboratory of **Allina Hospitals & Clinics** and its design is rooted in Lean and similar process improvement and workflow principles.

The $29 million new facility consolidates laboratories from 12 locations in five different Allina buildings into a single core laboratory. The project also completes the consolidation, from multiple sites, for histology and microbiology in the Allina system.

The new lab was built in a former warehouse on a single floor, using 82,000 square feet, including a 6,000-square-foot storage facility for surgical blocks, slides, and records. The project also includes the remodeling of space that remains in the main hospital, **Abbott Northwestern Hospital**, which is located one block away. This space is used for frozen sections, phlebotomy, blood product distribution, cell therapy, and outpatient reception and blood drawing.

"This is a once-in-a-lifetime opportunity," noted Rick Panning, Vice President, of Lab Services. "We set out to design a lab for today that will serve us into the future."

Panning and his team used the continuous improvement approach in the physical space design and workflow of the new facility. "Our Lean consultant, Mike Hogan from **Ortho Clinical Diagnostics**, trained eight members of our lab staff to work with the architects and laboratory technical and management staff on designing the space," he said. "They were all trained in Lean last summer and started the design in August. The design was finished in December.

"By using Lean methods and automation, we designed a work flow that will allow us to handle increased testing without having to increase our current staff," he explained. "In addition, we're implementing automation, such as a new **Abbott Diagnostics** APS line in the core lab, a new **Sysmex** HST line in hematology, and a new **Becton Dickinson** instrument to do automated plating in microbiology."

Lean And Automation

Panning expects that the combination of Lean and automation will allow Allina Medical Laboratories to improve productivity and efficiency over time. "Also, expected retirements and attrition will allow us to decrease our staff levels without the need for layoffs now, or in the future," he stated. "That is a good thing for our staff in uncertain economic climates."

Allina estimates that its system-wide test volume will soon reach 9 million tests annually. "We plan to grow our outreach business by 10% per year, and are supporting it by adding new equipment to run more tests in-house and improve turnaround times," commented Panning.

"The new laboratory facility has additional space so we can expand virology, molecular, and toxicology testing," he said. "There is also planned expansion in testing for microarray, immunology, and special chemistry."

The official opening of the laboratory will be in February. Different lines of laboratory testing are moving to the new facility now. The core lab, which includes chemistry, hematology, coagulation, urinalysis, the blood bank, specimen processing, and microbiology, will be moved by the end of February. TDR

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NEWSMAKER INTERVIEW — PART 2

Dirk G. Soenksen

Considering Full versus Partial Adoption of Digital Pathology

"Anatomic pathologists have a bright future, because they will benefit from rapidly developing technologies in gene sequencing, molecular analysis, digital pathology, and integrated informatics."
—Dirk G. Soenksen, M.S., M.B.A.,
Founder, President and Futurist,
Aperio Technologies, Inc.

➤➤ ***CEO Summary: Digital pathology is considered to be one of the more disruptive technologies now finding acceptance in anatomic pathology. Since founding Aperio Technologies, Inc., of Vista, California, in 1999, President Dirk G. Soenksen, M.S., M.B.A., has been in the forefront of this important trend. In part one of this two-part interview, Soenksen discussed the most significant forces now reshaping the profession of surgical pathology. Now, in this concluding part two, Soenksen addresses some of the barriers to the adoption of digital pathology technology. He also explains why partial adoption is the preferred course for most anatomic pathology laboratories.***

Second of Two Parts

EDITOR: Today, I would like to discuss the widespread myths and misunderstandings about digital pathology, particularly those around full adoption and partial adoption. However, as we start part two of this interview, Dirk, I'd like to remind our readers of the key points you emphasized during part one of this interview. *(See TDR, September 6, 2011.)*

SOENKSEN: Let's do that.

EDITOR: First, we discussed major trends in healthcare that you see as reshaping anatomic pathology. One such trend is the ongoing expansion in knowledge of the human genome, along with the technologies needed to speedily sequence whole genomes at a cost that shrinks steadily.

SOENKSEN: This trend creates an opportunity for pathologists to advise physicians about how to interpret genetic information and how to develop a proactive wellness and care plan for the patient.

EDITOR: One essential point you emphasized was that, even in the age of whole human genome sequencing, healthcare will still need pathologists to identify abnormal tissue.

SOENKSEN: Yes. Pathologists will continue to do everything they currently do, particularly as it relates to tissue. The new opportunity for pathologists is to become the integrator of all the diagnostic and clinical information on an individual patient—to provide a holistic view of the patient—and then advise that patient's care team.

EDITOR: You and I also discussed how the exploding number of molecular and genetic testing technologies opens new doors for pathologists. You pointed out an important fact that makes a good springboard for launching part two of our interview.

SOENKSEN: Does that fact deal with the rapid increase in molecular and genetic testing in surgical pathology, which means that pathologists now find themselves spending more time per case?

EDITOR: That's correct. It's the productivity issue. As I recall, although you noted that while this additional time per case translates directly into a more accurate diagnostic answer for the patient, it reduces the productivity of surgical pathologists.

SOENKSEN: This trend is simple to understand. Many types of cancers and diseases require the pathologist to make the primary diagnosis of positive or negative. Then, if the patient is positive, the pathologist will spend additional time in two professional activities associated with each individual case.

EDITOR: I suspect one activity is to conduct the follow-on tests that are done after the primary diagnosis. The need to identify the various types of lymphomas and leukemias would be one example.

SOENKSEN: Yes. The need to do follow-on testing is one factor that adds time to the case. The second factor is that pathologists more frequently must pull together all the diagnostic and clinical information, then participate in consultations with the referring physician and the patient's care team. That requires substantial amounts of time and reduces the productivity of pathologists—but for worthwhile reasons.

EDITOR: Tumor boards are one such activity that shows how pathologists increasingly sit at the table with other physicians to discuss patient cases.

SOENKSEN: Both of these activities show how new technologies and new clinical knowl-

edge can reduce the productivity of pathologists—even as these developments help them deliver more value to the physician and his or her patient.

EDITOR: This is a timely place to shift our conversation and discuss the adoption of digital pathology. You are on record as stating that many misconceptions exist across the pathology profession about when and how to acquire and implement a digital pathology system.

SOENKSEN: Many aspects of digital pathology are poorly understood. That is understandable, since this technology is new and its capabilities are advancing rapidly.

EDITOR: I am curious as to whether you see more acceptance of digital pathology by young pathologists coming out of their residencies and fellowships, in contrast to pathologists who may have been practicing for a decade or longer?

SOENKSEN: A majority of medical schools use digital slide images today, and so, yes, there is a sense of comfort among younger pathologists with the use of digital pathology. Having said that, there also are quite a few pathologists with 15 years of practice experience who are embracing digital pathology as well. I regularly meet pathologists who have practiced for 15 years who are ready to adopt digital pathology. They recognize that their profession is going digital and that they will have to use these new tools sometime during their career, so why not start now and be among the first? The point I'm making is that the correlation between a pathologist's age and readiness to adopt digital pathology is not as clear as you might expect.

EDITOR: Let's discuss the cost to implement digital pathology and other impediments to adoption. Cost certainly must be high on the list.

SOENKSEN: Yes, that's partly true for this reason. When many pathologists think about adopting digital pathology systems, they immediately think about full adoption. Full adoption means digitizing all cases and every glass slide, then reading all these images on a monitor. But the belief that the pathology laboratory must immediately scan 100% of their daily case flow—full adoption of digital pathology—is a false argument.

EDITOR: So your point is that there are smaller steps any pathology laboratory can take to acquire the capability to digitally scan slides, then work with those digital images.

Dirk Soenksen

➤"It is important to understand the difference between scanning speed and throughput through the digital pathology system."

SOENKSEN: Yes. We can talk about the benefits of partial adoption in a moment. But when a pathology group believes its only choice is full adoption, they have created a false impediment in making a sound clinical and financial decision.

EDITOR: What causes so many pathologists to look at digital pathology as a "full adoption" decision?

SOENKSEN: When they assume that they must digitize 100% of the glass slides they currently process in their lab, they then make another leap. They believe—falsely, I might add—that scan speed is the most important criteria. They believe that today's digital scanners aren't fast enough and so they can't adopt digital pathology.

EDITOR: I've heard that argument. Why do you consider it fallacious?

SOENKSEN: This is the argument that many vendors want pathologists to believe. These vendors tell pathologists that scan speed is the impediment for adoption. Yet, nothing could be further from the truth. Scan speed is *not* the pri-

Dispelling a Myth, Expert Says Few Laboratories Are Ready for Full Adoption of Digital Pathology

MANY PATHOLOGISTS AND LAB DIRECTORS incorrectly believe that, when adopting digital pathology, they have to start with full adoption. This would require scanning 100% of the slides, then viewing all sides on a monitor.

"The idea of having to start with full adoption is problematic because very few labs are actually ready today to support the full adoption of digital pathology," said Dirk G. Soenksen, M.S., M.B.A., the Founder and President of Vista-California based Aperio Technologies. "For full adoption of digital pathology, four requirements must be met.

Four Requirements

"First, the pathology lab must have bar code capability," he noted. "Second, the digital pathology system needs to be integrated with the laboratory information system (LIS). Third, the workflow must be as continuous as possible. Finally, the lab must be willing to validate its digital pathology implementation.

"Many pathology labs use bar codes today, and some have integrated their digital pathology systems to their LIS," he continued. "But if the pathology lab lacks small batch and continuous workflow, particularly in how it processes tissue, then full adoption of a digital pathology system will likely be cost-prohibitive.

"Overnight batch processing of tissue specimens often leaves the pathology laboratory with a small time window during which to digitize all glass slides," said Soenksen. "A batched workflow produces a large number of glass slides at one time, typically in the early morning. In the case where there may be only a four-hour window during which all glass slides would have to be digitized, the lab would require six times as many scanning instruments compared to having a 24-hour scanning window.

"The cost-per-slide for a digital pathology system decreases dramatically with a longer scanning window," noted Soenksen. "That is why continuous workflow is required to make it cost effective for a pathology lab to opt for full adoption of digital pathology.

"How tough is it to achieve full adoption?" he asked. "Currently, Aperio has more than 850 digital pathology installations worldwide. Our most fully adopted customers are in Sweden. These are the only examples of near full adoption that we have seen anywhere in the world.

"In addition to having validated their digital pathology solution, the most advanced pathology labs in Sweden have implemented continuous workflow and bar codes," continued Soenksen. "They have also integrated their LIS with our image management software.

Shortage Of Pathologists

"It was the shortage of pathologists in Sweden that motivated these laboratories to fully implement a digital pathology system," he observed. "Sweden provides an example of how external pressures and the need to optimize the productivity of individual pathologists can encourage full adoption of a digital pathology system.

"It is important to recognize that the example of full adoption in Sweden is quite unusual," he added. "Everywhere else in the world, the other 849 current installations using an Aperio system are embarked on the path of partial adoption of digital pathology to realize the benefits and productivity contribution that results from selective use of a digital pathology solution."

mary metric to tie to adoption of a digital pathology system. That's just false.

EDITOR: Can you explain why pathologists should consider other factors, and not exclusively the scan speed?

SOENKSEN: For many digital pathology vendors in the field, it is common for them to discuss the speed of digital scanners and the cost of the instruments that make up their system. But—and this is an important distinction—they rarely discuss throughput.

Dirk Soenksen

➤"Most pathology laboratories opt for phased adoption of digital pathology. This is true for both academic center pathology laboratories and community hospital-based pathology groups."

EDITOR: Would you explain why speed and throughput are not exactly the same?

SOENKSEN: It is important to understand the different concepts of "scanning speed" and "throughput" when discussing the performance of a digital pathology system. Take the example of an instrument that has a 60-second advertised scan speed—which you might think means you can scan 60 slides per hour—but whose actual throughput is only 10 slides an hour. Some instruments take only 60-seconds to capture the image, but then require up to an additional five minutes to post-process the digital slide image to get it into a viewable form.

EDITOR: That's an important distinction, because it represents the productivity of the scanner in actual clinical operation, and not just the time required to capture the digital slide image and store it in some temporary memory in the computer.

SOENKSEN: This is why it is important to understand the relationship of "scan speed" to "throughput" for any digital pathology system. If pathologists are bombarded with information about scan speed and they don't pay attention to throughput, for example, it will be more difficult to properly evaluate how the proposed digital pathology solution can benefit their pathology practice.

EDITOR: Do you have a metric that is more important than scanning speed?

SOENKSEN: In my experience with pathology clients, the metric that matters the most is the cost per slide. To calculate the cost per slide, it is necessary to include all costs associated with the instrument, the software, the labor, and image storage. Even the instrument with the highest throughput may not provide the lowest cost per slide if, for example, it has a high rescan rate that requires lots of technician time to do the rescanning; or if it uses a file format that results in larger images that will consume more storage.

EDITOR: Dirk, this brings us to the subject of phased adoption of digital pathology versus full adoption of these systems. What do you see unfolding in the pathology marketplace?

SOENKSEN: Most pathology laboratories opt for phased adoption of digital pathology. This is true for both academic center pathology laboratories and community hospital-based pathology groups.

EDITOR: When implementing digital pathology in phases, what clinical activities offer the quickest benefits?

SOENKSEN: We see pathology labs set up a digital pathology system and then use it, as appropriate, for remote frozen sections, for image analysis, for sending selected cases out for consultations and for tumor boards. They will also flag selected slides to be imaged and archived so they easily retrieve them. In academic center labs, certain pathology slides will be scanned and used in medical education.

EDITOR: In October, I was able to tour the pathology laboratory at the **University Hospital Network** (UHN) in Toronto, Ontario. They showed me how they are using their digital pathology system to do remote frozen sections.

SOENKSEN: Yes. It was as early as 2004 when UHN pathologists began to digitally scan frozen section slides at the different hospitals they cover, then read those digital slides at their main office.

EDITOR: Now the UHN pathologists have a frozen section service with a rural hospital that is located 425 miles north of Toronto. Also, they regularly use their digital pathology system to provide consults to at least two other hospitals in Ontario that are located are hundreds of miles from Toronto.

SOENKSEN: This demonstrates the power of digital pathology to bring digital images to the right pathologist

EDITOR: The remote frozen section service also shows how digital pathology can boost the productivity of pathologists, since they don't have to physically be present at the site where the specimen is harvested.

SOENKSEN: This was one major benefit from the story you published in THE DARK REPORT last summer about **Northwest Pathology**, located in Bellingham, Washington. In an example of phased adoption of digital pathology, it provides a remote frozen section service to 49-bed **Ketchikan General Hospital**, which is in a remote area of Alaska. *(See TDR, July 5, 2011.)*

EDITOR: That is an excellent example of phased adoption. Not only does this digital pathology relationship cross state lines, but it allows the hospital to schedule more surgeries. That is revenue positive for the hospital and allows more patients in Ketchikan to stay in town and be served by their local hospital.

Digital Pathology Used For UCLA-China Consults

EARLIER THIS YEAR, Aperio announced that its digital pathology system was being used to support subspecialty pathology consultations between **Ronald Reagan UCLA Medical Center** in Los Angeles, California, and the **Second Affiliated Hospital Zhejiang University**, (ZHU) in Hangzhou, China.

UCLA has more than 30 sub-specialty pathologists who provide remote consultation services to pathologists and clinicans at the 2,000-bed ZHU hospital. The natural follow-up question is: Are more international, cross-border arrangements in the offing?

"We are certainly aware of a number of projects involving academic programs to support certain countries," stated Dirk G. Soenksen, M.S., M.B.A., the Founder and President of Aperio. "We are working with a variety of institutions that want to put a scanner in Africa or the Middle East to provide pathology services to those regions.

"Also, we absolutely believe that a viable, reliable secure pathology consultation network will be a significant driver of adoption of digital pathology," he noted. "This also could foster the growth of outreach programs that use digital pathology to support diagnosis and consultations."

SOENKSEN: This shows how partial adoption of digital pathology gives a pathology laboratory the capability to develop additional clinical services as new opportunities present themselves.

EDITOR: While we are talking about adoption of digital pathology, we would be remiss to not address how digital pathology can position pathologists to benefit from the rapid advances in informatics technology and software algorithms that are capable of doing sophisticated image analysis in research settings.

SOENKSEN: It will take more time before surgical pathologists will be able to work routinely with these types of image analysis solutions.

EDITOR: Can you talk a bit about how image analysis will move in a parallel adoption curve with digital imaging and the wider use of digital pathology systems in clinical care?

SOENKSEN: You are correct that image analysis is a big driver for pathologists and scientists who want to do research. But in terms of routine usage by surgical pathologists, I believe image analysis for clinical applications—beyond the use for quantifying digital IHC for ER/PR and Her2, where we do see adoption—is far out into the future and will not be a major driver of clinical adoption.

EDITOR: Why is this true?

SOENKSEN: There are two reasons. First, routine use of image analysis requires widespread usage of digital slide images in the workflow, which is only beginning to happen now. Second, the time frame associated with clinical validation studies, FDA clearance (or approval), and reimbursement is very long.

EDITOR: As we conclude this interview, Dirk, what advice do you have for working surgical pathologists in a community hospital setting? What are the essential elements those pathologists would need to take advantage of digital pathology?

SOENKSEN: Our opinion is that pathology is going digital and it is getting there quickly. Our business is built upon this belief. Thus, unless a surgical pathologist is so close to retirement that he or she won't need this technology, embracing the use of digital images will bring significant benefits.

EDITOR: How does this tie in to pathologist productivity and the ability to deliver greater value to referring physicians and their patients?

SOENKSEN: We've discussed a few ways that digital pathology can contribute to improved productivity of pathologists. The more skills that individual pathologists have, the more efficiency they will gain.

EDITOR: At a time when the Generation X and Generation Y pathologists want more balance between work and play, how is digital pathology important to them?

SOENKSEN: Any resource that contributes to greater efficiency gives pathologists of all ages the option to devote that time to their priorities. For some, it may be to spend more time with family and to pursue hobbies like golf. Or it could be to make more money by reading slides, for example, digital slides from consultations.

EDITOR: Let's end our interview by considering the pathologist who is the physician business leader of his community-hospital-based pathology group. What recommendations or insights would you offer to this pathologist who is seeking to keep his or her group on the front edge of clinical services while also maintaining financial sustainability?

SOENKSEN: We find that just by being open-minded, digital pathology can deliver immense value. Whenever we visit a community hospital and talk about how digital pathology fits into the workflow, if the pathologist is open minded, he or she absolutely sees the value in adopting digital pathology for some specific application (not for full adoption). They see opportunities to improve their value to physicians, along with the financial benefits that would also result.

EDITOR: Thank you, Dirk.

SOENKSEN: You're welcome! TDR

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Spectra Lab in Milpitas Accredits to ISO 15189

Spectra Laboratories benefits from operating ISO 15189-accredited labs on both coasts

CEO SUMMARY: Spectra Laboratories, Inc., a renal-specific testing services company with labs in New Jersey and California, announced earlier this month that the American Association for Laboratory Accreditation awarded accreditation to ISO 1589 to its laboratory in Milpitas, California. It was in May 2010 when Spectra's laboratory in Rockleigh, New Jersey, earned ISO 15189 accreditation. Spectra is using the quality management system (QMS) of ISO 15189 to create a standardized service experience at both laboratory sites.

THERE'S A NEW CHAPTER in the ISO 15189 journey of **Spectra Laboratories Inc.** On December 6, it announced that its Milpitas, California, laboratory facility had successfully become accredited to ISO 15189:2007 Medical Laboratories.

The first chapter in this ISO story was written in May 2010. That is when Spectra's laboratory facility in Rockleigh, New Jersey, earned its accreditation to ISO 15189. *(See TDR, June 21, 2010.)* Spectra Laboratories is owned by **Fresenius Medical Care North America**, of Waltham, Massachusetts. For both laboratory locations, Spectra Labs used the **American Association for Laboratory Accreditation** (A2LA) as its accrediting body.

By achieving ISO 15189 accreditation at both laboratory sites, Spectra is realizing one of its major strategic business goals. "We want to deliver identical service for any specimen collected and tested at either laboratory facility," stated Curtis Johnson, General Manager and Vice President of Spectra's Milpitas facility.

"The quality management system (QMS) of ISO 15189 helps our laboratories at both locations to adopt common work processes and documentation," he noted. "Having standardized processes and practices across both laboratories is important as Spectra markets its lab testing services naationally and internationally.

"Our customers also recognize that ISO 15189 accreditation from A2LA supports the quality commitments that we have to our customers," added Johnson. "This is particularly true for our overseas customers."

Ensuring Consistency

"Our Milpitas lab does about 21 million tests per year and has 393 employees," observed Patricia Hui-Ng, Director of Quality and Regulatory. "The Rockleigh lab handles about 33 million tests annually. The equipment at both laboratories is nearly identical and many of the methods are the same at the two locations."

"It was in 2005 when both labs chose to go down this path," recalled Johnson. "Our goal was to raise the bar internally and achieve the most stringent standards

that we could apply to the quality of testing services that we deliver."

This desire to lift quality to higher levels was an important element in the management decision at Spectra Laboratories to pursue accreditation to ISO 15189. As Hui-Ng noted, state and federal requirements emphasize compliance and are, by design, set as a minimum to ensure public safety and basic quality.

Regulatory Standards

"In the United States, a lab can be accredited to, or compliant with, many different standards, just as we are," noted Hui-Ng. "These standards are mostly all about compliance. But after compliance, how do you lift your lab to a higher standard of quality and achievement?

"ISO 15189 accreditation from A2LA was selected because its QMS goes beyond the guidance of most federal and state requirements," she continued. "Both Spectra laboratory facilities have accreditation from **The Joint Commission** and accreditation from the **College of American Pathology**. We also are licensed in a number of states, including California, Florida, and New York.

Going Beyond Compliance

"We saw ISO 15189 and its QMS as a way to help us attain that mindset of continuous improvement and total commitment to quality," added Hui-Ng. "This gave us the tools and the structure to help our staff meet these objectives.

"This was also a team-building journey for all managers and all employees," emphasized Hui-Ng. "In one fashion or another, everyone took part in the effort of becoming accredited to ISO 15189. Now that we are accredited, we're not finished. This was simply one milestone in our ongoing journey as a quality organization."

For every clinical laboratory and pathology group that wants to perform at higher levels of performance, there is a need for a management system that can guide and support that environment. ISO 15189 has the quality management system to provide the structure and the management tools required to understand quality, to measure quality, and to improve quality.

It is for that reason that a growing number of first-adopter clinical laboratory organizations are turning to ISO 15189 accreditation as a way to realize their strategic goals of raising quality in specific ways that add value to customers and increases customer satisfaction. TDR

Contact Patricia Hui-Ng at spectra.laboratories@fmc-na.com.

Global Recognition Of ISO Accreditation

BECAUSE IT PERFORMS TESTING for specimens that originate outside the United States, it was important for Spectra Laboratories, Inc., to become accredited to an international standard that would be recognized by many other nations.

"One important factor that prompted us to look into ISO 15189 was the need to support international customers, particularly for our clinical trials work," said Curtis Johnson, General Manager & Vice President at Spectra's Milpitas Lab.

"Spectra considered both sources that offer ISO 15189 accreditation here in the United States," he explained. "We chose the American Association for Laboratory Accreditation (A2LA) because our labs' accreditation to ISO 15189 through this source would be recognized internationally by all countries that also participate in this ISO arrangement.

"The broad recognition of ISO 15189 was important to us because of the business Spectra handles that originates outside the United States," added Johnson. "In addition, our parent corporation, Fresenius Medical Care, is a German company. That gives internal value to our labs' accreditation to ISO 15189 as well."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Expanded genetic testing for cancer patients in the United Kingdom is one goal of a new effort by the Stratified Medicine Programme at **Cancer Research UK**. Officials want to ensure that the right genetic tests are available to support use of new therapeutic drugs for different types of cancer. The project will start in Wales where researchers hope to recruit as many as 9,000 patients to participate by agreeing to allow DNA analysis of their tumor tissue. The effort is being coordinated at the Cancer Research UK's **Cardiff Experimental Cancer Medicine Centre** (ECMC). Six specific tumor types will form the first stage of study. They are: breast, bowel, lung, prostate, ovary and melanoma skin cancer.

IN MINNEAPOLIS DNA TESTS USED ON DOG POOP

Here is an unexpected use for DNA testing! It's called "PooPrint." When residents of an apartment complex do not clean up after their dog, a lab will test the DNA in that dog poop sample to identify the owner. **JJS Property Management** of St. Cloud, Minnesota, manages 25 properties and now uses the PooPrint program at three dog-friendly properties. A cheek swab from each dog in the complex creates the DNA database. "We are serious about it; we do send it [the dog poo] in," stated Jennifer Ulmer, Property Supervisor. "We've sent in maybe 20 samples, and we haven't had a second offense. Messes are almost obsolete now. It's a huge deterrent."

TRANSITIONS

• On December 31, Thomas Tiffany, Ph.D., is scheduled to retire as the CEO of **Pathology Associates Medical Laboratories, Inc.** (PAML), based in Spokane, Washington. Tiffany joined PAML in 1987. A successor CEO had not been named as of press time.

• Retiring on December 31, at **Health Line Clinical Laboratories** in Allentown, Pennsylvania, is President and General Manager David G. Beckwith, M.S., Ph.D., a position he has held for the past 14 years. He worked at the parent **Lehigh Valley Health Network** for 24 years.

• Retired earlier this fall is Cheryl Vance, who was CEO of **Alverno Clinical Laboratories, LLC**, in Gary, Indiana. Vance had held administrative positions at other Chicago-area labs during her career. These included **Consolidated Medical Laboratories** (CML), **Advocate Healthcare**, and **Aurora Clinical Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 9, 2012.