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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Era of Digital Pathology Steadily Approaches

IMMEDIATELY AFTER **GENERAL ELECTRIC** ANNOUNCED its partnership with the **University of Pittsburgh Medical Center** (UPMC) on June 5 to develop a fully integrated digital pathology system, we took a closer look at how some pioneering pathologists are using digital imaging systems in their daily clinical practice.

What we found is that the technology is fairly well developed and, in some other countries, pathologists already use digital pathology images for primary diagnoses on a regular basis. That won't happen in the United States until the FDA clears this type of technology for clinical applications.

To share what we learned with you, we provide an intelligence briefing on pages 12-13 about how pathologists at the **University Health Network** (UHN), in Toronto, Ontario, have used digital pathology for frozen sections with great success for several years. Using ScanScope, a digital imaging system from **Aperio Technologies, Inc.**, the UHN pathologists have improved workflow and patient care. They now regularly use the system to transmit images over the Internet from surgical sites around the corner or from a hospital 400 miles north of Toronto. By allowing pathologists to work remotely, the system supports the pathology needs of hospitals where no regular pathologist is on-site.

To be sure, companies developing fully-integrated digital pathology systems face plenty of hurdles. That's the topic of our second intelligence briefing, found on pages 15-18. We interviewed two CEOs of companies that sell pathology imaging products and systems to learn their views about how the pathology profession is likely to react to digital pathology technology which holds the potential to eventually move pathologists away from glass slides and microscopes.

Repeatedly over the past decade, THE DARK REPORT has reminded its clients and regular readers about the strategic implications of baby boomer demographics. As experienced pathologists begin retiring in significant numbers, it will be new technologies—including fully-digital pathology imaging systems—that will become useful tools for increasing the productivity of individual pathologists. These same technologies will also contribute to improvements in the clinical quality delivered by pathologists to physicians and patients. As you will read in this issue, the sustained success of Toronto's UHN pathologists in using fully-digitized, whole-slide pathology images for frozen sections offers some fascinating reasons why the era of digital pathology may be closer than we all think. TDR

NY & Calif. Act to Stop Web Gene Testing Firms

Regulators in New York and California target certain Web-based genetic testing companies

CEO SUMMARY: Events in the past month indicate that a war is developing between Internet-based companies offering genetic tests to consumers and state and federal health regulators. New York state authorities have sent letters to at least 31 such companies in recent months. Then, on June 9, the California Department of Health sent cease-and-desist letters to 13 Web firms. Just days later, the Federal Trade Commission disclosed two investigations of genetic testing companies.

BATTLE LINES ARE FORMING between companies offering genetic testing to consumers over the Internet and state regulators in California and New York. At stake in this developing war is how genetic testing will be regulated at the state and federal level.

Triggering this war is the explosion in the number of companies already on the Web offering genetic tests and genetic testing services directly to consumers, frequently without the involvement of a physician in either the ordering of the test or in its interpretation for the consumer.

THE DARK REPORT considers emerging efforts to regulate genetic testing offered directly to consumers as having the potential to be harmful to the established network of clinical laboratories that serve physicians, hospitals, and other providers—and that is not an outcome intended by legislators and regulators. As state and federal regulators attempt to constrain and control genetic testing activities they consider abusive, they run the risk of over-regulating the ability of the nation's established clinical laboratories to develop new diagnostic assays in ways that have been traditionally accepted by the scientific community.

Health regulators in New York State opened the first battle front in this new war. Since November, 2007, state authorities have sent letters to at least 31 companies that offer genetic tests directly to consumers. The letters inform these genetic testing companies that they must be licensed before they can offer genetic tests to residents of New York state.

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The second battlefront in this developing war came last month. On June 9, the **California Department of Public Health** sent cease-and-desist letters to 13 companies offering genetic tests to consumers. According to department spokeswoman Lea Brooks, companies that received a letter have 14 days to provide documentation of their laboratory's certification with requirements of California and the federal government. The companies must also provide proof that tests they sell to California residents are ordered by a physician, as required by California state law.

Strong Enforcement Action

California laboratory regulators are giving every indication that they are ready to take strong enforcement action. On its blog, *Wired* reported on a conference call conducted on June 13 by the Department of Health with members of its Clinical Laboratories Advisory Committee. *Wired* characterized unfolding events as the trigger for a major confrontation, writing that "the [California] health department actions should be viewed as a challenge to the viability of the nascent industry."

During this call, Karen L. Nickel, Ph.D., Chief of the Laboratory Field Services at the California Department of Public Health, stated that "We have worked with our legal office and have full support for this...We [are] no longer tolerating direct-to-consumer genetic testing in California.

"These businesses are apparently operating without a clinical laboratory license in California," observed Nickel. "The genetic tests have not been validated for clinical utility and accuracy... and they are scaring a lot of people to death."

Scientific validation of the genetic tests offered by the companies receiving cease-and-desist orders from California may become a focal issue in the public debate about unfettered consumer access to genetic tests. In the cease-and-desist letters sent out on June 9, after notice of: 1) state requirements for licensure; and, 2) that a physician must order the test; the letter states "In order to be granted a California clinical laboratory license, in addition to meeting all other licensure requirements, [company name] *must provide satisfactory validation documentation to verify the test performance specifications of all genetic tests*." *(Italics by THE DARK REPORT.)*

The request for satisfactory validation documentation is notable. California regulators clearly intend to begin separating genetic tests accepted by the scientific and medical community—and in clinical use—with genetic tests offered to consumers over the Internet that lack generally-accepted scientific research and clinical studies, and that may involve a combination of unproven clinical value and unethical promotion to consumers.

Even as news of California's cease-and-desist letters was rattling the Web-based genetic testing industry, a third battle front was opened, this time at the federal level. On June 12, Senator Gordon Smith (R-OR) conducted a roundtable meeting on genetic testing. A variety of stakeholders participated and discussed scientific, ethical, and regulatory issues involved with genetic testing. At this roundtable, Matthew Daynard, Senior Attorney in the **Federal Trade Commission's** (FTC) Bureau of Consumer Protection, Advertising Practices Division, disclosed that the FTC has two active and ongoing investigations of direct-to-consumer (DTC) genetic testing companies.

Three Government Actions

Until now, these three separate activities have not received much attention from the laboratory testing profession. Yet, individually and collectively, these three regulatory initiatives send a clear message. Genetic testing is now an issue at both the state and federal levels. Regulators and elected officials are ready to take steps to protect consumers by controlling perceived abuses and preventing the potential misuse of genetic science.

California Sends Cease-and-Desist Letters To 13 Internet-based Gene Testing Companies

LAST MONTH, THE CALIFORNIA DEPARMENT OF HEALTH sent "cease-and-desist" letters to 13 companies that operate Web sites and offer genetic tests directly to consumers. California is requiring these companies to hold valid state and federal laboratory licenses, to only perform testing that is ordered by a physician, and to provide documentation about the scientific validity of the genetic tests they offer. California has declared that it does not allow direct-to-consumer genetic testing to state residents.

These companies received letters from the State of California:

Company	Web Site	Types of Genetic Tests	Model
23andMe	www.23andme.com	Broad genome scans	Info only
CGC Genetics	www.cgcgenetics.com	Individual disease & gene tests	Info only
deCODEme Genetics	www.decodeme.com	Broad genome scans	Info only
DNA Traits	www.dnatraits.com	Heritable disease testing	Info only
Gene Essence	www.geneessence.com	Genome wide arrays	Info only
HairDX	www.hairdx.com	Hair loss risk assessment	Info + product
Knome	www.knome.com	Whole genome scans	Info only
Navigenics	www.navigenics.com	Broad genome scans	Info only
New Hope Medical	www.newhopemedical.com	Nutrigenetic testing	Info + product
Salugen	www.salugen.com	Nutrigenetic testing	Info + product
Sciona	www.sciona.com	Nutrigenetic testing	Info + product
Smart Genetics	www.smartgenetics.com	Alzheimer's risk testing	Info only
Suracell	www.suracell.com	Nutrigenetic testing	Info + product

Should these concerns lead to regulatory overkill, that will hamstring the efforts of established *in vitro* diagnostics (IVD) companies, academic centers, and clinical laboratories to develop, validate, and introduce new diagnostic assays to the clinical community.

Already, the silicon valley crowd is interpreting the actions of the California Department of Health as a curb on consumer rights and freedom to access the healthcare services they want. Advocates from this community are drawing battle lines based on the consumer's ability to choose their own products and services.

In contrast, both the lab medicine profession and the healthcare establishment recognize the myriad of issues that come into play as new science and diagnostic technologies surface and are evaluated for clinical effectiveness. It is often a long and frustrating road to establish agreement and consensus across healthcare as to when a newly-developed laboratory test is ready to become the standard of care. Look at the efforts, reaching back into the 1990s and 1980s, to improve the conventional Pap smear. Even 12 years after the first FDA clearances for new types of Pap tests, pathologists and clinicians are still learning about the technologies and appropriate ways to utilize these tests.

The point here is that, like with so many other diagnostic technologies, the laboratory medicine profession is again at this familiar crossroads, where the potential of genetic medicine is recognized, but not yet a reality. It is a moment when advances in genetic science have advanced to where events are outstripping the ability of existing state and federal laws and regulations to effectively guide science while protecting consumers from charlatans and frauds. **TDR**

Hospital Trends

Growth of Medical Tourism May Become Political Issue

Americans going overseas for healthcare mean fewer patients visiting hospitals in this country.

HERE'S AN UNLIKELY PARTNERSHIP that is a sign of the healthcare times. The **InterContinental Hotels Group** (IHG) and the **Medical Tourism Association** (MTA) recently announced that they will work together to facilitate medical-related travel into Latin America.

Th goal of this partnership is to promote medical tourism. IHG is one of the world's largest hotel companies while the non-profit MTA, based in West Palm Beach, Florida, represents international hospitals, insurance companies, healthcare providers, and medical tourism companies. MTA said medical-related travel into Latin America has increased exponentially over the past decade, as patients and insurers seek viable, innovative alternatives to manage healthcare costs.

Keeping Patients In U.S.A.

Growth in the number of Americans willing to travel abroad for healthcare may become a political issue. In this country, unions have noticed this trend. During the past two years, several union leaders have commented publicly that Americans should get their healthcare in America.

Obviously, more patients in the United States means more employment for union members who work in hospitals and other healthcare settings. At the same time, about half of the acute-care hospitals in the United States are insolvent and teetering on the edge of bankruptcy, according to a recent report. *(See TDR, May 26, 2008.)* These struggling hospitals would welcome access to these patients—who can afford to pay for their own care and are willing to travel great distances for quality medical care.

Many American patients in the United States travel abroad for better care, according to an article "Medical Migration," in the May 5 issue of *Modern Healthcare.* The magazine published the results of a study by the **Deloitte Center for Health Solutions** showing that U.S. healthcare providers will lose $16 billion in revenue this year as a result of patients seeking care in other countries. That study also predicted that, by 2010, U.S. patients traveling to other countries for healthcare could cost U.S. hospitals and other providers $68 billion.

The numbers are significant. According to the Deloitte study, some 750,000 U.S. residents traveled abroad for medical care last year. Predictions are for an increase to six million by 2010.

Sustained growth in medical tourism means access to fewer patients by hospitals and physicians in this country. THE DARK REPORT foresees the possibility that the hospital industry and unions might unite in calling for political action to discourage or rein in medical tourism, making it tougher for Americans to seek healthcare in other countries and to have their health benefits program reimburse for part or all of their care outside the United States. TDR

HealthPartners Promotes Same-Day Lab Test Results

In Minneapolis, walking urine collection cup educates consumers about speedy lab reports

CEO SUMMARY: Patient focus groups told HealthPartners that they had anxiety as they waited days for lab test results. That encouraged HealthPartners to redesign workflows in its pathology department. Once it could deliver same-day lab test results electronically, HealthPartners launched a unique marketing campaign to educate consumers about this benefit in early May. Already, HealthPartners reports a 28% increase in the number of patients going on-line to access their lab test results.

DELIVERING LABORATORY TEST RESULTS quickly is giving **HealthPartners** in Minneapolis, Minnesota, a competitive advantage. The large integrated delivery system is finding that patients want to get their lab test results within 24 hours or less. HealthPartners expects that it will attract new patients this year because of its ability to deliver same-day lab results.

To capitalize on its speedy lab test turnaround times to patients and their physicians, HealthPartners launched a unique advertising campaign that, among other things, includes two characters, one dressed as a urine sample container and the other as a syringe, to attend public events in the Twin Cities to alert consumers that they can get their lab results fast when they come to HealthPartners.

For lab directors and pathologists, this unique promotional effort demonstrates the steady shift in the healthcare marketplace that brings consumers front and center. HealthPartners, after studying consumer wants and behaviors, recognized that its ability to deliver speedy lab tests was something it could use to distinguish itself from other health providers in Minneapolis and attract new patients.

Moreover, speedy lab test turnaround time is just one element in how HealthPartners' laboratory division is revamping its operational focus. "Right now, pathologists are in a position to assist the healthcare system to be more efficient," explained Douglas A. Olson, M.D., Medical Director of HealthPartners' central laboratory and Assistant Medical Director for Clinical Laboratory Medicine. "The traditional focus of laboratory services has not been on the pre-test and the post-test interval.

Improving Turnaround Times

"However, at HealthPartners, we are now focusing on how lab testing affects other aspects of healthcare delivery," he noted. "This is part of the natural evolution of pathology, which encourages us to think about all the steps and processes involved from the time a physician conceives of the test to the time the test result is in the patient's hands."

HealthPartners created its unique advertising campaign, emphasizing speedy

Meet Petey P. Cup (left) and Pokey the Syringe (below): Created as part of a promotional campaign by HealthPartners, these two characters can be seen at public events in the Twin Cities, promoting speedy access to lab test results and immunization records. You can even purchase Petey and Pokey merchandise, including a Pokey baseball jersey for your kids, a $15 Petey P. Cup yard sign, and an $11 Petey P. Cup clock. Petey P. Cup even has his own YouTube video!

lab test reporting, in response to three key factors. First, Minneapolis has a highly competitive healthcare market, dominated by large multispecialty clinic systems. Thus, any competitive edge can generate increased patients and market share.

Anxiety About Lab Results

Second, in conducting focus groups, HealthPartners learned that many patients are anxious about their lab test results and do not want to wait for them. The third factor was the interest HealthPartners had in increasing patient use of online services that are part of its electronic medical record, and leveraging that feature to gain a competitive advantage. Among other benefits, patients who sign up for online services can view their test results on a secure, personalized Website, often within 24 hours or less. By contrast, those patients who do not sign up get their results through the mail, a process that takes days rather than hours.

Responding to focus group insights that patients did not want to wait for their lab test results, HealthPartners introduced a new marketing campaign in May specifically to advertise the fact that patients who use online services could get their laboratory test results within 24 hours. It created two characters. One is called Petey P. Cup, who is a cartoon character in the form of a urine specimen collection cup (with lid) who touts the message, "Get Same-Day Test Results. HealthPartners.com." The other character is Pokey, a walking syringe with the message "Verify and print immunization records anytime."

HealthPartners tells THE DARK REPORT that the campaign is producing results. "The primary goal of the campaign is to increase patient use of our Web site," explained Larrissa Rodriguez, HealthPartners' Director of Care Delivery Marketing. "When we started this campaign on May 19, about 14% of our patients were registered to use the online services on our Web site. After just a few weeks, that has increased to 18%! Our goal is to get 40% of our patients using online services by year's end. We see a steady increase in the number of patients registering to get their results online."

HealthPartners Focused on Workflow to Improve Turnaround Times for Laboratory Test Reports

HEALTHPARTNERS HAS BEEN SUCCESSFUL in attracting new patients in the past several weeks because it has a winning combination of a successful advertising campaign and fast turnaround times from its pathologists.

Joe Dangor, a spokesman for HealthPartners, said lab turnaround times (TAT) are extremely important to patients. "In recent years our health system has devoted considerable resources to re-engineering the workflows that support online services. Laboratory services is one department involved in these projects," he explained. "We believe same-day test results can be a significant differentiator for us in our market. Our competitors also have online services. We believe our workflows make us more efficient, however, and we think consumers will notice that difference.

"In focus groups with patients, we learned that wondering about lab test results causes quite a bit of anxiety," noted Dangor. "Typically, a patient visits the doctor, has a test done, then waits several days for the results.

"We learned from our focus group members that patients want to know their results right away," he added. "They don't want to wait for several days for these results.

"Our efforts to produce same-day test results is generating great benefits," he continued. "Last week, one of our doctors told us a story that demonstrates how technology is changing our lives—and how patients are using Web access to their lab test results. The doctor had a patient who needed to be re-tested. She was sent to the laboratory to provide a specimen, then returned to the doctor's office to review the results with her doctor. While waiting to go back into the

The campaign's success is partly due to the efforts of HealthPartners' pathologists to improve workflow in the laboratory. "In the past several years, we have worked diligently to improve turnaround time," stated Olson. "The last piece needed to speed up delivery of laboratory test results to patients was implementation of electronic medical records that patients could access via the Internet."

The organization of laboratory testing within the HealthPartners system is designed with an eye to speeding delivery of results to physicians and their patients. "Each of the 30 medical clinics associated with HealthPartners has a laboratory on site," noted Olson. "Our courier system picks up three times daily from these sites and delivers specimens to our central laboratory.

"If a lab test result is needed within four hours, we do a point-of-care (POC) test at the clinic site," he added. "If the test result is needed the same day, we can do it afternoon or evening at the centralized laboratory. Because of the EMR, test results are available very rapidly.

"We did two major changes in recent years to improve lab test turnaround time and improve productivity in the lab," he continued. "One change involved restructuring the courier system so that specimens get to the laboratory in a timely manner. A second change was structuring the centralized laboratory so that its operational hours meshed with those of the medical clinics. For example, all the clinics and the central laboratory open at the same time every morning. However, because laboratory work to support the clinics is largely done in the afternoon and evening, we've adjusted staff levels in the laboratory to ensure laboratory testing is done quickly throughout the day.

Unique Marketing Campaign Emphasizes Speedy Access to Lab Test Results for Consumers

FOR HEALTHPARTNERS, the positive results of its new advertising campaign to consumers is a winning outcome.

"There have been some great reactions to this marketing campaign since it launched in early May," said Larrissa Rodriguez, Director of Care Delivery Marketing for HealthPartners, an integrated delivery system in Minneapolis, Minnesota. "This is rewarding because healthcare marketing is not known for being very creative.

"In Minneapolis, we compete against several other big healthcare systems, such as Allina, Park Nicollet, and Fairview," she continued. "Each has lots of similarities in terms of size and what is offered. That is why we wanted our marketing campaign to deliver a message that makes us stand out with consumers in this community.

"Once HealthPartners had its electronic medical record (EMR) system in place last year, we saw the opportunity to educate patients about the benefits of accessing online services via the Web," she explained. "To emphasize immediate access to lab test results, we created Petey P. Cup, the pee cup who explains to consumers in a memorable way that about 90% of our lab test results are available to them online within 24 hours.

"Another character in our marketing campaign is Pokey the Syringe," said Rodriguez. "Pokey's message is that patients can go online to view and print their immunization records. Of course, patients can also go online to communicate via e-mail with physicians, make an appointment, pay bills, and access other services.

"Anyone who goes to the Web site, www.PeteyandPokey.com, can learn about each mascot and about the online services as well," she said. "It seems to get the message across and consumers are reacting favorably.

"As a result of this marketing campaign, we expect use of the Web site to rise among our patients and we suspect it will also generate new patients," commented Rodriguez. "It will take another 12 months for us to evaluate the overall effectiveness of this advertising approach.

"I should add that we also see another source of savings from this emphasis on accessing lab test results via the Web. Currently we send out more than one million letters each year telling patients their lab test results," observed Rodriquez. "When patients go online, we

"The next big gain in improving lab test TAT was availability of the electronic medical record," he said. "It allows our laboratory to electronically deliver lab tests results to the EMR patient files in real time. That has greatly reduced average lab test reporting times.

"It is common now for a patient to see a HealthPartners' doctor in the morning, then use the Web to access online services to see those results that afternoon," observed Olson. "That's a big win for patient safety. After all, it is the patient who has the greatest interest in his/her test results and when you get those test results to the patient, you've eliminated one opportunity for that information to fall between the cracks.

"At HealthPartners, our laboratory is proud of how it has reduced average turnaround time for reporting lab test results, while maintaining a high quality of laboratory testing services," added Olson. "That is why point-of-care testing is incorporated in our service mix. For specific assays, we may determine that the POC test is more

expensive than the test done in the central lab, but if it improves the quality of care received by the patient, then we will implement the POC test with appropriate utilization guidelines."

POC Testing For Hemaglobin

Olson described developing a system to do point-of-care testing of hemoglobin A1c at some clinics as an example. "Currently, we have a couple of clinic sites offering a point-of-care hemoglobin A1c test," he noted. "This creates a significant clinical and service benefit.

"Assume that it took the patient three to six weeks to get an appointment to see the diabetes specialist," continued Olson. "Both the patient and the physician want the HbA1c results during that visit so that the proper diagnosis can be made and appropriate treatment can be started. Anything less than that is a waste of time for the diabetes specialist, the patient, and the healthcare system. We believe the economics of the overall healthcare encounter support the lab's decision to offer that more expensive POC test to the clinician.

Calculating All Benefits

"For example, assume that the marginal cost to perform a hemaglobin A1c test in the central laboratory is under $5 and assume that the POC HbA1c test costs no more than $20," theorized Olson. "Certainly it is more expensive to support POC testing. But, for the difference in lab test costs of about $15, this individual patient and the attending physician get the information they need on the first visit. This saves the system the cost of a follow-up visit—when the core lab's HbA1c result is available. Those savings are significantly greater than the additional cost of the POC hemglobin A1c test."

THE DARK REPORT observes that Olson and his staff are on the cutting edge of a significant development in the lab business. First, his parent health organization, HealthPartners, has recognized how the laboratory can play a role in: 1) providing more patient-friendly clinical services; 2) boosting the quality of care; and, 3) contributing to a reduced cost per healthcare encounter. That means administration is ready to support some of the laboratory's needs for capital and projects to improve productivity and performance.

Second, the laboratory division at HealthPartners is looking externally for opportunities to deliver value-added services. One external opportunity is make laboratory test results available more quickly to patients. Another external opportunity is to contribute to a lower overall cost per healthcare encounter by enabling and supporting point-of-care hemoglobin A1c testing in clinics.

Patient-Focused Services

These are all attributes that will be common in hospital/health system laboratories as the American healthcare system continues to evolve toward patient-focused, patient-facing services. The laboratory at HealthPartners is already moving down that path.

Another unique aspect of this story is the willingness of HealthPartners to organize one primary theme of its consumer marketing campaign around faster patient access to laboratory test results. Although it is uncommon to see hospitals and health systems advertise fast access to laboratory test results today, that may soon change.

After all, consumers in the Twin Cities are proving that they will respond to an opportunity to receive improved lab testing services. As noted above, in the weeks since the mid-May launch of the HealthPartners' unique advertising campaign, it has generated a noteworthy 28% increase in patient use of its online services, including access to laboratory test results. TDR

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Toronto Pathologists Use Whole-Slide Imaging

Digital pathology and whole-slide imaging increase concordance and pathology productivity

CEO SUMMARY: It was the "frozen section problem" and productivity issues that led pathologists at the three-hospital University Health Network (UHN) in Toronto to implement a fully-digital pathology system with whole-slide imaging in 2006. Use of digital, whole-slide images makes it faster to report results to the surgeon, while making it easier to involve colleagues in difficult cases. Now UHN's pathologists use the system to support hospitals 400 miles away.

IT WAS MAJOR NEWS LAST MONTH when **General Electric** and the **University of Pittsburgh Medical Center** (UPMC) announced that they were forming a $40 million joint venture specifically to develop and bring to market an integrated digital pathology system. Given GE's prominent role in digitizing radiology and its deep pockets, this joint venture attracted widespread attention in healthcare and within the pathology profession as well *(See TDR, May 27, 2008.)*

Changing Surgical Pathology

Clearly, there are revolutionary forces gathering momentum in surgical pathology, and the GE–UPMC joint venture is just one example. For pathologists who would like to see a glimpse into the future of digitized pathology and how it will change long-standing practices in surgical pathology, then a site visit to the pathology department at the **University Health Network** (UHN) in Toronto, Ontario, would be enlightening.

Take frozen sections, for example. At the three hospitals of UHN, digital pathology and whole-slide imaging has improved the clinical quality of pathology professional services provided to referring surgeons, while increasing the productivity of individual pathologists.

At the heart of this new workflow arrangement for frozen sections and surgical pathology is the ScanScope system from **Aperio Technologies, Inc.**, in Vista, California. Using this system, UHN pathologists can scan frozen section slides and create a digitized, whole-slide image in less than two minutes.

Images of these digital slides are available to a pathologist for immediate viewing on a desktop computer. As a result of this new system, computer monitors have become like virtual microscopes that allow pathologists remote access to images to deliver consistent and accurate results for primary diagnosis.

In the United States, the FDA has not approved the use of digitized slides for diagnosis. Therefore, pathologists in the U.S. cannot use the same digital pathology system that the pathologists at UHN use for primary diagnosis.

"Implementing a fully digital pathology system provided no strategic business

advantage for us here north of the border," explained Andrew Evans, M.D., Associate Professor of Pathology at UHN in Toronto. "But there is certainly an advantage in terms of increased efficiency. Moreover, without question, our work in the digital pathology environment allows us to predict with confidence that these developments will revolutionize the way pathology is practiced.

Improving Workflow

"As a result of using whole-slide imaging, we have maximized pathologist efficiency in the institution," he said. "Previously, we had an inefficient system—in part because the University Health Network has a three-site academic medical center in downtown Toronto. All the pathologists sit at **Toronto General Hospital** (471 beds) but across the street is the **Princess Margaret Hospital** (220 beds), which is a tertiary cancer referral center. Then, about a mile to the west is the **Toronto Western Hospital** (256 beds), which is home to the **Krembil Neuroscience Centre**, one of the largest neurological facilities in North America.

"For these three facilities, our old system didn't make any sense from a pathologist workflow perspective," continued Evans. "Because all the pathologists are at the Toronto General site, we often had someone sitting in one of the other two hospitals twiddling their thumbs much of the time. The move to a fully-digital pathology arrangement has greatly improved the productivity of individual pathologists.

"More important, the whole-slide imaging system has benefited patient care," said Evans. "Now, any time we have a difficult case, it is fast and easy to have multiple pathologists look at that case all at the same time. That is a change from the past, when a pathologist was working alone at one of the other facilities and the use of glass slides limited the possibility for consultation on difficult cases.

"That's all changed with the fully-digital pathology system. Because it is so quick and simple to share cases, our pathologists have developed a low threshold for showing difficult cases around," he added. "As a result, our accuracy has been very good, meaning concordance between initial and frozen section interpretation is quite high."

UNH's move to digital pathology began more than four years ago. "We knew about the history of telepathology—particularly in Scandinavia and Norway in the late 1980s and early 1990s," recalled Evans. "We thought telepathology would be a viable alternative to our workflow at that time. We developed and implemented the technology and started using a robotic microscope in the fall of 2004.

"For about two years we used a robotic microscope, and it helped us in many ways," he continued. "But because the technology was not advanced enough, the arrangement had limited value.

"With this telepathology arrangement, when viewing the frozen section slides from the other two hospitals, the pathologist at Toronto General could adjust the focus, but the robotically-controlled system required the pathologist to review a series of compressed images," noted Evans. "These images captured only one field at a time. The pathologist was required to review the image and then move to the next field and repeat the process until he/she reviewed the whole section. This usually took about 10 minutes, sometimes longer.

High Accuracy Rates

"During the time we were using the telepathology system, our research group was using some Aperio instruments," stated Evans. "The decision was made to bring digital imaging to hematology and oncology. So, between pathology and hematology, we put the money together to get a scanner and make the switch to whole-slide imaging.

"When this first digital system was set up, all the blood films and marrow aspirates were scanned and sent to a server on the west end of the city," Evans said. "We did this because the digital files were so large.

"Once these images were scanned, any clinician could access them in the patients' electronic charts at any workstation in any hospital," Evans continued. "A pathologist could click on the digital image and review the slide. That was back in 2003, and that step paved the way for digital imaging in pathology.

"Government grants helped us purchase and implement this equipment. That's because the government is keen on digital healthcare technology to provide consultation services to underserviced areas."
—Andrew Evans, M.D.

"Given the business relationship that UHN already had with Aperio, we next considered switching to a digital system similar to what was in use in hematology," Evans explained. "When our pathology department implemented the fully-digital system, I believe we were the first site in the world to use whole-slide imaging for primary diagnosis for patient care.

"In October 2006, we started using the Aperio system for primary frozen sections. Combined with the robot and the Aperio scanner, we have used this arrangement for about 1,000 cases in less than two years," Evan said. "The system is ideal because, if the digital instrument were ever to fail, we are a 20-minute walk away from the glass slide. During this two-year period, there have been only about four times when the pathologist had to walk over to the other site because of a problem with the instruments.

"Despite those few problems, this fully-digital pathology system is performing successfully for frozen sections and we have learned how to prevent the problems we had initially," he observed. "The big difference—and benefit—is improved turnaround time. We typically deliver an answer in 15 minutes. Also, as noted earlier, our pathologists can quickly share difficult cases and that's improved our concordance.

"Workforce issues in Canada are another reason why this digital pathology system is a success," Evans added. "Adequate staffing of pathologists is a challenge. Using technology to extend pathologists and make them more productive is widely supported. Government grants helped us purchase and implement this equipment. That's because the government is keen on digital healthcare technology to provide consultation services to underserviced areas.

"Here's an example," Evans said. "We entered into a partnership with a group of hospitals in Timmins, Ontario, about 400 miles to the north. Most of the time, they have only one pathologist on site. For one week each month, no pathologist is on site for primary cases. Most of that work is sent to us to report. And, when there are frozen sections or ultra-rush biopsies that need triaging, we receive digitized, whole-slide images and report these cases by digital assessment. This system is working very well."

➤An Ideal Pathology Solution

Other hospitals in Canada, having seen the results achieved by the UHN pathology department's use of digital pathology images, are considering using whole-slide imaging systems for primary diagnosis in their pathology departments as well. THE DARK REPORT observes that the Canadian experience is one example of how digitized pathology systems are being used in the healthcare systems of other developed countries. Improvements in turnaround time and in the concordance of frozen sections at University Health Network in Toronto demonstrate two ways digitized pathology systems can contribute to better patient care and improved clinical outcomes. **TDR**

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Is Digital Path Imaging Ready for Prime Time?

FDA clearance of digital pathology imaging is one factor that will encourage wider adoption

CEO SUMMARY: Digital pathology imaging systems are finding uses in all phases of drug discovery (discovery, pre-clinical, clinical trials), as well as education, research, and clinical. One hurdle to widespread adoption of fully digitized, whole-slide pathology imaging systems is FDA clearance that allows the use of this technology for primary diagnosis. Executives at two of companies offering digital pathology systems offer their predictions about how this market will evolve.

IS DIGITAL PATHOLOGY ON THE VERGE OF BECOMING MAINSTREAM in the United States? Have advances in information technology (IT) and digital imaging reached the point where fast, detailed, and responsive systems can totally replace glass, paper, and microscopes in surgical pathology?

Several companies believe the answer will soon be yes. The newest entrant into digital pathology systems is **Omnyx, LLC**, (*www.omnyxpath.com*), the new $40 million joint venture between **GE Healthcare** and the **University of Pittsburgh Medical Center** (UPMC). Omnyx intends to develop and market digital pathology systems for primary diagnosis. It believes it can have its products cleared by the FDA and into the pathology marketplace within two years. Omnyx promises that its system will perform whole-slide scanning in 30 seconds. *(See TDR, June 16, 2008.)*

To help pathologists and their practice administrators understand how fast things are changing in the field of digital pathology, THE DARK REPORT tracked down executives from **Aperio Technologies, Inc.**, and **DMetrix Inc.**—two companies currently selling digital pathology systems in the United States and other countries around the world. Both are optimistic that digital technology is ready for day-to-day use in pathology groups and that market acceptance of digital pathology imaging is growing steadily.

GE's Entry Into Pathology

"When a big company like GE enters the market, that's good for everyone in our space, including Aperio," commented Dirk G. Soenksen, CEO of Aperio Technologies, in Vista, California (*www.aperio.com*). "Undoubtedly that means there will be a lot of new competitors coming into the market. GE won't be the last one. **Philips** is actively looking to participate in this market, and within the next two years, all the digital radiology companies will likely be focused on pathology as well.

"In fact, we encourage all those companies to learn more about digital pathology, just as GE did over the last few years," Soenksen said. "GE visited us last year and we both shared our assessments about this market. They were evaluating several strategies for entering the digital pathology market and decided to partner with UPMC."

Michael R. Descour, Ph.D., President of DMetrix Inc., in Tucson, Arizona, (*www.dmetrix.com*) agrees that GE's decision to enter the digital pathology market is a positive development. "The fact that GE is now involved in this market is stimulating interest from potential investors who want to go after companies that have innovative technology," Descour said. "Certainly there has also been a significant uptick in inquiries from potential customers who view the entry of GE as validation of this field.

"When GE puts down specific targets about the size of the market, the performance of instruments, and some real resources behind this effort," noted Descour, "then that has an immediate short-term effect that benefits companies like ours. We believe that GE's public entrance into digital pathology will directly help companies like ours over the next two years. This news gives us a significant opportunity in the coming months to grow the market for digital imaging systems in pathology."

Challenges Ahead

Both Aperio and DMetrix acknowledged that other companies, such as **Carl Zeiss Inc.**, **Olympus**, **Nikon**, and **BioImagene, Inc.,** are developing digital pathology products for pathologists.

"One technical challenge for any slide scanner involves developing a system capable of focusing down to a fraction of a micron," Soenksen explained. "By comparison, the width of a human hair is 100 microns. Once the technology for generating well-focused high-quality digital slide images is perfected, FDA clearance must be obtained to market digital pathology systems for routine diagnostic review, in the same manner that pathologists routinely use microscopes and glass slides to make diagnoses. Right now, digital pathology systems are not cleared for use in the U.S. for the primary diagnosis of H&E specimens, although Aperio has obtained FDA clearance for manually reading (i.e., primary diagnosis of) digital HER2 slides on a computer monitor.

"But the market is poised to grow rapidly, almost the way radiology adopted digital imaging," commented Soenksen. "It took radiology 10 to 15 years to get to where it is today, and digital imaging in radiology is a very large market. Modality sales that include MRIs, CT, PET, CAT scanners and so forth represent up to $9 billion per year. Sales of picture archiving and communication systems (PACS) represent another $1.5 billion per year.

Improving Workflow

"There is a fundamental difference, however, that sets radiology apart from pathology," continued Soenksen. "Radiology has fully adopted the use of digital imaging. By contrast, pathology is just beginning its evolution toward wider use of digital pathology systems and digital technologies.

"Pathology is adopting digital imaging in pieces, meaning customers use digital imaging technology for applications in specific niches," he added. "The idea that a hospital will digitize 100% of the glass slides in its system and that pathologists will read them out on a computer monitor in conjunction with an electronic medical record system is well into the future.

"It is GE's goal to develop a system for full adoption, and that highlights the difference between GE and Aperio," Soenksen explained. "Our strategy is to focus on where there is pain today by addressing the specific market needs of pathology customers. In fact, we believe there is no compelling reason today to routinely read digital slides on a computer monitor when the glass slide, the microscope, and the pathologist are all in the same room. In this case, reading glass slides will be more efficient. The value of digital pathology emerges for remote viewing applications where the glass slide is not co-located with the right pathologists, or for archival and retrieval, image analysis, or data management."

"Our customers include pathology groups of all sizes and none of them are digitizing 100% of the glass slides that they generate," Soenksen said. "They take only a subset of those slides and digitize them, such as cases diagnosed with cancer or slides for tumor boards. Some pathology groups are instituting digital pathology systems to serve a remote hospital, for instance, obviating the need to ship glass slides or pathologists between facilities. Others use this technology for FDA-cleared applications, such as image analysis for Her-2 immunohistochemistry.

"There are several reasons why full adoption of digital pathology will take some time," Soenksen added. "First, there are the technical challenges involved in simply engineering a solution to the throughput, workflow, and IT integration challenges. For example, how do you scan glass slides in a cost-effective way? How do you integrate the scanning systems into the existing workflow of surgical pathologists? And, finally, how do you integrate all of this new pathology information with an LIS or HIS? The bigger companies in healthcare informatics are not ready and waiting to solve this problem for pathologists.

"Second, there is a lack of publications and other proof sources that focus on the benefits and value of digital pathology, and draw attention to those groups successfully using digital pathology to address current challenges," noted Soenksen. "It is difficult for pathologists to get credible information about the value of this technology.

Improving Workflow

"Third, and perhaps most important in the United States, is that manufacturers of digital pathology systems cannot promote the use of digital pathology for making diagnoses from digital slide images of specimens displayed on a computer monitor," observed Soenksen. "We have to demonstrate to the FDA that, what a pathologist sees on the digital slide image on a computer monitor and what the pathologist sees on the corresponding glass slide through a microscope, yield the same diagnosis.

"This is a huge regulatory hurdle that is related to the most important performance parameter in this market, which is image quality. Image quality is critical in proving that what you see in a digital slide image is the same as what you see on a glass slide," he continued. "For that reason, image quality cannot be compromised because then you will never overcome the regulatory hurdles.

"Aperio has FDA clearance for primary diagnosis of digital Her-2 immunohistochemistry slides," stated Soenksen. "We demonstrated to the FDA that, if a pathologist reads an immunohistochemistry slide for Her-2 on a monitor, that pathologist will get an equivalent diagnosis as if he/she read the corresponding glass slide under a microscope.

"Once the FDA cleared our digital pathology system for IHC in 2007, we embarked on the process of obtaining FDA approval for reading digital H&E

Advice When Looking to Buy Digitized Pathology Systems

WHEN NEW TECHNOLOGY comes to market, it can be difficult for pathologists and lab directors to know how to invest in emerging systems. Both Dirk G. Soenksen, CEO of Aperio Technologies, Inc., in Vista, California, and Michael R. Descour, Ph.D., President of DMetrix Inc., in Tucson, Arizona, offered similar advice on this topic.

Point 1: Invest in an "open standards" system. If it turns out, a few years later, that the product is not a market leader, at least your lab will be able to use those digital images—produced by an open standards platform—in any new system.

Point 2: Invest in hardware and software that will be easy to upgrade. That makes it easier to acquire new imaging features. Leasing is a good option for maximizing upgrade opportunities.

Point 3: Test prospective digital systems before purchase to see how each performs in your laboratory environment. Vendors use the term 'throughput,' but you won't really know how it works unless you see it in your own laboratory.

slides on a computer monitor," commented Soenksen. "We hope that FDA clearance of digital pathology for selected H&E applications will come in the second half of 2009. That will be an inflection point for the market because it will alleviate the potential concerns that digital pathology cannot support the accuracy required for making primary diagnosis from a computer monitor."

Considering Full Adoption

Descour also agreed that FDA clearance is a significant challenge. He further noted that many pathologists remain skeptical about imaging. "GE estimates that digital pathology imaging systems will be used to view some 1.5 billion tissue specimens worldwide per year," Descour said. "Obviously, it will take some time before the market reaches that size.

"It's not the size of the market for digitized pathology imaging that is in doubt, but the time to reach that size that is the uncertain parameter," he added. "It's uncertain because pathology customers will be switching away from the tried-and-true method of the glass slide and light microscope and adopting something new.

"The areas of pathology where adoption of digital imaging is growing fastest are research, pre-clinical use, and education," observed Descour. "Adoption of digital pathology systems in healthcare is happening at places like UPMC, **M.D. Anderson**, the **Cleveland Clinic**, and **Massachusetts General Hospital**. These facilities are seriously studying how to deploy this technology to most effectively improve clinical performance.

"There are several reasons why wider adoption of digital imaging in pathology should increase in the coming years," Descour explained. "First, digital imaging in radiology is well established and provides a template that we can follow for digital imaging in pathology. There are substantial differences of course, but there also are similarities. We at least have a model and there are efforts, for example, to extend the DICOM standard for picture archiving and communication in medicine to digital pathology. There is also an ongoing effort to draft DICOM specifications for exchanging pathology images.

"Second, today—compared to a decade ago—most pathologists are much more familiar with computer and imaging technology and the lab and software interfaces that are needed to make digital imaging work in pathology," he noted. "Young pathologists now coming out of training do not see digital pathology as something distinct from their everyday experience. The pervasiveness of this technology in medical education means we are primed to use this technology in clinical practice."

DMetrix has some 30 patents for its systems and says it offers the world's fastest slide scanners available today. Its systems use an array-microscope technology that allowed it to break the 60-second slide scan-time barrier in 2004.

Considering Full Adoption

The Dark REPORT observes that digital imaging systems in pathology are poised to usher in a new generation of technology for pathologists and lab directors. Fortunately, pathologists have a model to follow. In the early 1990s, radiologists began adopting digital imaging systems for diagnosis. In the intervening years, the market grew significantly.

In the coming months and years, similar growth is likely to occur in pathology. Large companies will be choosing partners and developing systems for sale to pathologists in hospitals and labs of all sizes. The next step in the development of his nascent field is FDA approval. When that happens, it could mark the final days for the era of glass slides standard microscopes in pathology laboratories. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

GI Pathology, PLLC, of Memphis, Tennesseee, announced that it has contracted to be a national gastrointestinal (GI) pathology laboratory provider with **CIGNA HealthCare** of Hartford, Connecticut. It also has a five year, national provider contract with **UnitedHeathCare.**

SPENDING CUTS ADVERSELY AFFECT CANADIAN LABS

Widely-publicized errors in pathology services have caught the attention of the Canadian public. Pathologist Kenneth Pritzker, M.D., recently told an inquiry into problems with breast cancer testing in the provinces of Newfoundland and Labrador that deep spending cuts by the national health service have made it difficult for pathology labs to function properly. Pritzker is the chief pathologist at **Mount Sinai Hospital** in Toronto. Health system spending cuts made 20 years ago are still being felt, he noted, adding that these cuts came just as demand increased for more pathology services and better quality services.

CANCER-DETECTING MICROCHIP UNVEILED

Researchers at **Massachusetts General Hospital** (MGH) in Boston used a microchip-based device to detect and analyze tumor cells in the bloodstream and the genetic signature of lung tumors. The analysis allows researchers to identify the cells most appropriate for targeted treatment and to monitor genetic changes during therapy. Called the CTC-chip, the device is the subject of a research article to be published in the *New England Journal of Medicine* (JAMA) on July 24.

ADD TO: Cancer Chip

This research generated so much interest that JAMA published the results early by posting the study on-line. "The CTC-chip opens up a whole new field of studying tumors in real time," explained Daniel Haber, M.D., MGH's senior author of the study. "When the device is ready for larger clinical trials, it should give us new options for measuring treatment response, defining prognostic and predictive measures, and studying the biology of blood-borne metastasis."

TRANSITIONS

• **Exiqon Inc.**, of Vedbaik, Denmark, announced the appointment of Cynthia K. French, Ph.D., as Chief Scientific Officer. French has held positions at **Affymetrix**, **Specialty Laboratories**, and **Quest Diagnostics**. Also joining Exiquon is Erik Holmlin, Ph.D., who will be Chief Commercial Officer. Holmlin was a founder of **GeneOhm**, and comes to Exiqon from **BD Diagnostics**. French and Holmlin will work at Exiqon's **Oncotech** division, in Tustin, California.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...how **Sonic HealthCare, Ltd.**, has entered the Hawaii market by acquiring **Clinical Laboratories of Hawaii**. Announced last week, Sonic noted that the purchase price will be approximately $121 million.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 28, 2008.

It's New!

PREVIEW #1

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UPCOMING...

- ***Good-bye to Manual Histology: Why Progressive Labs Are Combining Automation and Lean.***
- ***What's Happening with Sales of Lab Outreach Businesses at Stanford and Carilion.***
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