Volume XVII, Number 7 Monday, May 10, 2010

Specialized Information Publishers Foundation
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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

Irish Labs Are at an Important Crossroads

GLOBAL OUTSOURCING OF CLINICAL LABORATORY TESTING IN IRELAND has entered its second phase. The **Irish Health Service Executive** (HSE) granted **Quest Diagnostics Incorporated** a contract for an additional two-years of cervical cancer screening tests while awarding 25% of the nation's annual Pap testing to **Sonic Healthcare Ltd.** in a similar two-year contract.

These developments are significant, because as long as the Irish outsourcing experience is favorable, it makes it easier for other nations to outsource laboratory testing to lab testing companies located in other countries.

But there is another dimension to the lab testing story in Ireland which fascinates me even more. As clients and regular readers of THE DARK REPORT know, the Irish HSE has announced a complete restructuring of laboratory services throughout the country. *(See pages 6-8 and TDR, January 25, 2009.)*

I'd like to make two observations about this ambitious project, which is a typical government health official approach to saving money. First, veteran pathologists and lab managers know all too well that, over the past 25 years, there are more disasters than successes when a government health system decides that it can take out costs by consolidating pathology testing, laying off medical technologists, and reducing the number of labs and blood collection centers serving a community.

Certainly the cost of lab testing did go down in the short term in these cases. But it was physicians and patients in these communities who often endured service deficiencies, glitches in the process of consolidating lab testing, and even serious problems in the accuracy and trustworthiness of lab test results.

Second, I'll guess that the Irish Health Service Executive, in developing its "total laboratory consolidation" plan with a consulting company from England back in the years 2004-2007, did not spend much money sending a team of experienced pathologists, laboratory scientists, and healthcare policy makers on a tour to several countries to do first-hand investigations of successful, innovative regional laboratories, along with an on-the-ground visit to some of the larger—and often not-so-successful—laboratory consolidation projects.

If this assumption is true, it is an interesting comment on the due diligence of Ireland's healthcare leaders that they would embark on a major makeover of the nation's pathology service without having invested a rather modest amount of time and money to send their laboratory profession's best and brightest out on a fact-finding tour of the world's best examples of lab testing. To the contrary, might it be true that the HSE, for the cost of a consulting fee to an English company, has gotten the answer it wanted and is proceeding with a laboratory restructuring and consolidation plan that was likely pre-ordained as early as 2004? TDR

Optimism & Opportunity at Executive War College

This year's gathering was high-energy and marked by a positive outlook for lab testing

CEO SUMMARY: Instead of our annual review of key speakers as a source of emerging trends and common themes, this year we assess the attitudes, opinions, and activities of the pathologists, laboratory administrators, managers, and industry executives in attendance at the 15th Annual* Executive War College*. These people are the grass roots of laboratory medicine and they are ready to tackle all the coming challenges in healthcare and the laboratory testing marketplace.

By Robert L. Michel

EVERY SPRING, IN ONE LITTLE CORNER of the laboratory testing industry, an interesting group of pathologists, laboratory administrators, consultants, and executives from a wide range of laboratory vendors come together. It makes for an interesting mix of opinion, insight, and networking.

Of course, I am describing the *Executive War College on Laboratory and Pathology Management*, which took place in New Orleans two weeks ago. It is our custom that, in the first issue of THE DARK REPORT which follows the *Executive War College*, to provide you with an intelligence briefing of the key strategic themes that emerged over the course of the event. Typically, I'll present the core points of several speakers to illustrate emerging new trends in laboratory management and operations.

Our objective is to help clients and regular readers understand how forward-looking clinical laboratories and anatomic pathology groups are adapting to new opportunities and threats in the diagnostics marketplace.

But this year, I am throwing that tradition out the window! There is a good reason to do this. Sharing the comments and insights from several speakers means that you would miss an equally interesting story that unfolded during the *Executive War College* two weeks ago—a story that bears directly on the current state of the laboratory testing marketplace.

In my view, the tone, tenor, and theme that predominated the more than 80 speakers and sessions was one of optimism and opportunity. This was mirrored by the enthusiasm of all the participants on site at the conference. There was energy

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

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

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

and exhilaration in every corner and at almost every session.

That is a remarkable fact, given that this nation is still in the throes of the deepest economic recession since 1981-82. After all, unemployment in the nation still hovers at almost 10%. The stock market is stumbling. Economic activity has stirred in recent quarters, but to my knowledge, no economist has declared that the recession has ended.

Why Are Labs Bullish?

Thus, this important question: why is this cross section of lab industry leaders and innovators so bullish on their collective future? As a strategist with a 15-year track record of publishing analyses and predictions—in advance of events—I'd like to use these pages to explain why I think the activities connected with this year's *Executive War College* signal an important shift in the attitudes and mind sets of pathologists and lab administrators leading many of the nation's top-rank lab organizations.

First, it is significant that these folks spent time and treasure to travel to New Orleans specifically to hear the featured speakers, to attend sessions of interest on innovations in lab management and operations, and to network with the truly disparate group of characters who populate the *Executive War College* every year.

Start with the numbers. Attendance was up more than 20% from 2009. Almost 600 people were registered. There were laboratory leaders from 12 different countries, a number equal to last year.

This attendance, engagement, and yes—enthusiasm—is important. There is a message here. These busy individuals are willing to invest time and money to gain the knowledge they will take back and use to push their lab's performance to the next higher level of achievement.

That is a sign that these accomplished laboratory professionals see a bright future ahead for their laboratory organizations. They want to pro-actively gather useful information, poll their peers for opinions, and get a better sense of the primary drivers actively reshaping healthcare and the laboratory testing industry.

Next, special interest communities have popped up within the crowd that attends the *Executive War College* each year. Want to sell your laboratory or pathology group? All the merger/acquisition professionals are in attendance to provide advice. Want to interact with other laboratory executives in your area? Discussion roundtables for laboratory Chief Financial Officers (CFOs) and for Chief Information Officers (CIOs) have been organized by attendees. They are now a regular feature each year.

Similarly, this year, the **Diagnostic Marketing Association** (DxMA) and THE DARK REPORT organized a special breakfast session for IVD sales and marketing managers. Not only was this well-attended, but lab managers even sneaked in to catch the conversation.

Ambitious Growth Plans

This activity is itself a sign of the optimism to which I earlier referred. By sitting in and monitoring these various roundtables, it was clear that pathologists and lab administrators have ambitious plans for growing specimen volume and revenue.

This is a powerful source of business intelligence about the lab testing marketplace. There are few places where you can hear lots of peers exchange candid opinions about developments in their local market.

Multiply these conversations across the three days of programs presented at the *Executive War College* and the collective sense of successful pathologists and lab executives is unmistakable. They see opportunities for their laboratories to grow, to acquire and offer new diagnostic technologies, and to improve the financial performance of their laboratories.

I assert that this representative cross section of relatively more innovative and pro-active laboratory directors, patholo-

Executive War College: What It Is, What It's Not

WE ARE OFTEN ASKED to describe the *Executive War College on Laboratory and Pathology Management*. It is many things, most of them unorthodox when compared to the more traditional and long-established meetings across the range of laboratory medicine specialties.

By no means does this annual conference—now in its 15th year—claim to represent the wider laboratory testing industry in some form or fashion.

After all, the laboratory industry has other much larger, more established meetings that speak to the science and the clinical role of lab testing in medicine. Similarly, there are regular gatherings of pathologists, lab scientists, and *in vitro* diagnostics (IVD) manufacturers specifically to exercise leadership and political action on behalf of lab medicine and the interests of what is an extremely diverse profession.

But there is a knowledge vacuum in the collective industry associated with clinical laboratory and anatomic pathology testing services that has come to be filled by the *Executive War College*. That knowledge vacuum centers around the intersection of several essential elements in diagnostics.

First, the *Executive War College* has a razor-sharp focus on the management and operations of clinical laboratories and anatomic pathology practices. No other gathering matches the 60 to 80 speakers and sessions presented each year at one time and in one place on this topic.

Second, the *Executive War College* presents innovators in lab management and operations who share the specifics of how their labs are solving problems common to all labs. It's an effort to help other labs learn and avoid having to "reinvent the wheel."

Third, the *Executive War College* always includes a sophisticated look at the immediate future of healthcare and laboratory medicine—delivered by capable strategic thinkers from pre-eminent companies and organizations. Attendees are often informed about major tends and developments months and years before their colleagues.

Fourth, the *Executive War College* devotes considerable time and resources to guarantee a powerful networking experience. Often, the best ideas come from casual conversations with peers at lunch or in the halls between sessions.

gists, and managers provides relevant evidence that optimism about the future of laboratory medicine prevails today.

Speakers See It Same Way

This is congruent with the attitudes, messages, and recommendations offered by the 80 speakers at this year's *Executive War College*. There was little or no "hang dog" carping from the podium. To the contrary, speakers generally painted a positive picture of the opportunities available to laboratories today and in the near future.

However, these speakers were also clear about the threats that lie ahead. Declining reimbursement, onerous coverage guidelines for tests, surging demand versus shrinking lab budgets, baby boomer retirements which will diminish both staff levels and experience in the lab: all these were mentioned.

But these admonitions took nothing away from the broader message heard from the podium. There is plenty of opportunity for any laboratory that will study its local market, then deliver services that add value to physicians, payers, and physicians.

These are the reasons why I consider the relevant theme at this year's *Executive War College* to be opportunity and optimism, validated by the grass roots of lab industry managers who were in attendance. TDR

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Sonic Health Wins Irish Contract for Pap Testing

First nation in the world to outsource 100% of its Pap testing also renews contract with Quest

CEO SUMMARY: Evidently the Irish Health Service is satisfied with its decision to outsource all the nation's cervical cancer screening tests. In recent weeks, it announced that two international laboratory companies would handle Pap testing for the next two years. Sonic Healthcare, Ltd., won a contract to perform 25% of Ireland's 300,000 Pap tests annually. Quest Diagnostics renewed its contract and will perform the balance. Both lab companies indicate they will build laboratory facilities in Ireland.

IRELAND CONTINUES TO PROVIDE a pioneering case study that involves outsourcing 100% of the nation's cervical cancer screening tests to overseas laboratories. In recent months it has announced the latest contract awards for Pap testing.

For the contract cycle that runs from August 1, 2010 through July 31, 2012, Ireland's health service has awarded 25% of the approximately 300,000 Irish cervical cancer screening tests performed per year to Texas-based **Clinical Pathology Laboratories** (CPL), a division of **Sonic Healthcare, Ltd**. The other 75% will stay with **Quest Diagnostics Incorporated**, the commercial laboratory company that was awarded an exclusive contract by the Irish health service two years ago.

For pathologists and cytology professionals in Ireland, the addition of Sonic Healthcare/CPL may be welcome news. That's because Sonic has announced that it will build a new laboratory in Ireland. Until that laboratory is ready to open, Sonic will perform its share of Irish Pap tests at CPL's main laboratory in Austin, Texas.

Colin Goldschmidt, M.D., CEO of Sonic, stated that his company's Irish laboratory would be open and processing Pap tests "within months." News reports say that Eamon Madden is heading up Sonic's business interests in Ireland.

Madden was a co-founder of **Claymon Laboratories**, one of the few private clinical lab companies that operates today in Ireland. Founded in 1991, it was sold to **Biomnis**, a French company, in 1999.

Quest Diagnostics has established an office in Dublin, Ireland. Robert Quinn is its country director. Quest has indicated that it will build laboratory facilities in Ireland.

Prediction Is Fulfilled

By adding a second laboratory to the global Pap testing outsourcing contract, Irish health officials have fulfilled a prediction made earlier by THE DARK REPORT. This editor believed that, in future tenders, appropriately licensed and accredited clinical laboratories from other countries would surface and bid for the Irish cervical cancer screening test contract. *(See TDR, August 31, 2009.)*

At that time, THE DARK REPORT speculated that very low cost cytology laboratories in such countries as India and Malaysia might offer lower prices that would be attractive to Irish health officials. It is not known whether such lab companies did enter bids in the latest tender. But what is clear is that the Irish health service decided that putting all its cervical cancer screening eggs in one basket was not the ideal solution. It rectified that situation by awarding Sonic Healthcare a portion of the contract for Pap testing.

Outsourcing Pap Tests

There is an interesting story behind the decision of the **Irish Health Service Executive** (HSE), which manages all public health programs, to contract with Quest Diagnostics to process all Irish Pap smears—about 300,000 annually—outside the country. HSE cited extremely long turnaround-times as its major reason for doing so. Irish women and their doctors were waiting on average six months for Pap smear results. In some cases, the wait was as long as a year.

Though six Irish labs bid, none of them were awarded any portion of the Pap testing contract. At the time, Irish health officials stated that none of the Irish labs were accredited, nor did any of these labs meet other requirements specified in the tender.

Some months later, however, a telling comment was printed in the *Irish Times*. Minister of Health Mary Harney defended the decision to exclude the Irish labs by noting that Quest Diagnostics would guarantee a turnround time of 10 days. She then added that the Quest bid was one-third lower than the lowest bid offered by the six Irish labs!

Makeover Of Nation's Labs

The next shock soon to come to the pathology testing profession in Ireland is a planned total makeover of both hospital inpatient testing and outpatient testing throughout the nation. THE DARK REPORT was first to inform American lab executives and pathologists about the details of this plan. *(See TDR, January 25, 2010.)*

A year ago HSE formally announced its plan to regionalize all lab services in Ireland, based on recommendations from a study done in 2007 by **Teamwork Management Services Limited**. At present, Ireland's 46 hospital laboratories process 58 million tests each year, costing €328 million. There are 16 small, 21 medium, and nine large laboratories, employing about 3,000 full time workers. About 32% of the total work comes from outpatient settings.

HSE proposed consolidating the inpatient and acute care work at a handful of large laboratories, most likely the current nine largest hospital laboratories. These would be the "hot" labs—providing rapid TATs, usually less than four hours. In addition, three free-standing "cold" labs would be built to do the 32% of the work that comes from general practice clinics and physician offices.

More Lab Tenders Expected

Since announcement of the reorganization plan, Irish pathologists have been concerned that HSE would extend the international outsourcing of lab work to the routine tests slated for the "cold" labs.

In December of last year, the *Irish Medical News* reported that Minister Harney told the Dáil (the lower house of the Irish Parliament) that HSE intends to put the work out to bid internationally as part of the reconfiguration of laboratory services proposed in the Teamwork report. She said stakeholders had been consulted on the issue.

"One would hope that the public service [existing Irish labs] would be successful in that tender, but clearly it must compete on the basis of quality, turnaround time, and cost," said Harney. "That must be the future because if we waste €200 million on this [pathology testing] service that could be used in areas where

we have deficiencies, be that in the child protection area or the many other areas where there are deficiencies, no one could defend that."

Those comments launched some interesting rebuttals. Fine Gael (**United Ireland Party**) health spokesperson Dr. James Reilly responded to Harney's statement with concern that the plan would cost thousands of Irish jobs and result in the loss of indigenous expertise.

Another physician concerned about the consequences of the HSE's major restructuring of the nation's pathology laboratory services is Dr. Bill Tormey. He is Chairman of the HSE **Dublin North-East Regional Health Forum**. In January, he responded even more strongly than Dr. Reilly.

Tormey called the idea a massive mistake. "This is a catastrophically stupid thing to do because they [HSE] are separating out the investigation of treatment of patients in primary care from those in secondary care and tertiary care," warned Dr. Tormey. "I think that the …Committee on Health should bring in the people responsible, including the Minister, and question them as to their motivation, their competence, and what they intend to achieve."

Appropriate Lab Structure

The *Irish Medical Times* (IMT) reported that an official of the HSE countered back by noting that the external review upon which the laboratory restructuring plan was based had the objective of "recommending the most appropriate structure and arrangements for the delivery of laboratory medicine services across the full spectrum of care, including primary, community, secondary, and tertiary care."

The HSE spokesman noted in the IMT that the "hot lab" (hospital laboratory) element of the national lab restructuring plan recognizes the need to process tests "from patients in regional hospitals receiving acute 'round-the-clock' care through dedicated 'hot' labs which will provide more access to clinical laboratory medicine advice and more direct care of the patient."

Dr. Tormey's response, as published, was to criticize the separation of outpatient and inpatient laboratory testing services (currently both provided almost exclusively by the hospitals in each community). He claimed that this plan "flies in the face of the amalgamation of the NHO and the PCCC at the Health Service Executive level and is reflective of the chaos of the HSE."

Dr. Tormey's Proposal

Dr. Tormey, who is a pathologist and specialist in general internal medicine at **Beaumont and Connolly Memorial Hospitals** in Dublin, has his own proposal for improving lab testing services in Ireland. He advocates establishing a core laboratory service in each hospital. This would be available to all patients and general practitioners on an equal basis in their local community, with the exception of some specialist clinics.

Across the globe, all pathologists and laboratory administrators recognize that decisionmakers in Ireland are debating the two fundamental models of clinical laboratory testing. One is the consolidated model, where economies of scale are achieved by aggregating as much test volume as possible into large testing centers.

The second is the integrated care delivery model, where the objective is for the local laboratory to support local care—whether inpatient or outpatient—by doing the work as close to the patient as possible. One benefit is that the same laboratory performs the tests and maintains a cumulative record of the patient's test results, even as the local lab's pathologists and laboratory scientists contribute their knowledge and expertise in support of clinicians and patients.

Irish health policy makers face the classic conundrum in clinical laboratory management. Centralized lab testing does generate a lower cost per test. But it misses the opportunity to do pathology testing in near-patient and point-of-care settings, where a faster answer can improve patient outcomes and contribute to a much lower overall cost per episode of care—and those savings can often far outweigh the added cost of doing pathology tests in a high-volume central laboratory. TDR

Pathologists Can Still Earn Medicare PQRI Incentives

Federal program offers pathologists a 2% bonus during 2010 for reporting required quality measures

CEO SUMMARY: During 2010, the Medicare Physician Quality Reporting Initiative (PQRI) will pay a 2% bonus to pathologists who register and report data on 80% of their cases for the specified CPT codes. However, independent pathology laboratories still cannot participate in the PQRI program. Also, PSA, LLC, reports it can be challenging to audit the Medicare PQRI bonus amount paid at year's end against the actual amount that was billed to Medicare by individual pathologists for the CPT codes included in the PQRI program.

IT'S OFTEN SAID THAT WHAT THE GOVERNMENT GIVES WITH ONE HAND, it takes away with the other. That statement might accurately describe Medicare's Physician Quality Reporting Initiative (PQRI), at least as it pertains to pathologists.

Now entering its third year, the PQRI program does offer pathologists a way to get paid more for selected types of cases. But upon receipt of the bonus checks at year end, it is not easy to determine whether Medicare accurately paid the correct bonus amount to participating pathologists.

"When the program was initially made available to pathologists in 2008, Medicare paid a 1.5% bonus to pathologists who met PQRI criteria for 80% of their cases involving target CPT codes," stated John Outlaw, CHC, the Chief Compliance Officer of PSA, LLC, of Florence, South Carolina. "In 2010, pathologists can earn 2% bonuses through Medicare's PQRI program.

"When PQRI was introduced two years ago, we told our pathology billing clients that we believed CMS would require participation in PQRI at some point in the future," recalled Outlaw. "That has proved to be right. Passage of the new healthcare reform law in March mandates that PQRI reporting bonuses will be scaled back to 1% beginning in 2011; then reduced further to 0.5% from 2012 through 2014. Beginning in 2015, physicians who do not participate and do not report their data will have their payments reduced by 1.5%. In 2006, the penalty for not reporting increases to 2.0%."

Can Still Earn Bonus In 2010

Having explained the future mandatory reporting requirement, Outlaw pointed out that any pathologist wanting to earn the 2% Medicare PQRI bonus for 2010 can still register and start reporting quality measures for breast cancer and colon cancer resection, beginning July 1. This is due to a new six-month reporting option for the PQRI program.

"If pathologists report on 80% of these measures from July 1 through December 31, 2010, they will be eligible for a bonus from CMS at year end," explained Outlaw. "In prior years, if a pathologist had not begun reporting the PQRI measures by mid-March, it was unlikely that he or she

would be able to satisfy the requirement to report the measures for at least 80% of the cases. Thus, he or she would miss PQRI incentives for the entire year," he noted. "In 2010, physicians who start participation by July 1 and meet the 80% goal for the last half of the year will still be eligible for the bonus payment based on the six-month reporting period."

Pathology PQRI Measures

At present there are only two pathology measures approved for the 2010 PQRI program. Participating pathologists will earn a 2% Medicare bonus of the amount billed to Medicare, upon reporting data on 80% of the cases involving:

• Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade;

• Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.

One challenge of the PQRI program is how it restricts certain types of pathology groups from participating. "At PSA, almost all our billing clients began reporting when we recommended that they do so back in 2008," observed Outlaw. "But under Medicare's rules, independent labs aren't eligible to participate in the PQRI program.

Independent Pathology Labs

"Medicare classifies independent laboratories as facilities—not as individual physicians nor even as physician group practices. They are considered a facility like a hospital," he said. "Because the Medicare claims system doesn't permit independent laboratories to report services by individual physicians, they can't quality for the PQRI bonus. This is frustrating for independent labs." *(See TDR, August 18, 2008.)*

Another challenge to participation in the PQRI program is determining the accuracy of the bonus payment sent by Medicare. "When the **Centers for Medicare and Medicaid Services** (CMS) distributed reimbursement checks in the fall of 2009 to pathologists who participated in PQRI in 2008, it was a lump sum total for a single pathology practice," said Stephanie Denham, CPA, PSA's audit supervisor.

"That made it difficult to precisely map the 1.5% bonus paid against the total amount billed to Medicare that year," she explained. "After all, the correct bonus payment amount must be verified for each individual pathologist in that group, since some qualified for the PQRI bonus that year and some did not."

PSA President Al Sirmon, CPA, explained, "For example, if one of our client pathologists collected $1 million in 2008 from Medicare, this pathologist should expect a 1.5% bonus from Medicare last year, or $15,000. However, if the practice received a $12,000 bonus, the verification process is so cumbersome the client may choose not to try to verify how Medicare calculated the bonus for their practice.

Tracking PQRI Data

"Because of the time-consuming procedures required to go back to Medicare officials to get a more detailed accounting of the PQRI bonus payment, we've built edits and features into our software to make it easy to record the data on how pathologists are complying with these PQRI measures," he said. "Going forward, our clients have a detailed audit trail that will help us verify the accuracy of future PQRI payments."

Pathologists and practice administrators interested in participating in PQRI still have time to register and begin reporting by the July 1 deadline. In the meantime, independent pathology laboratories are excluded from participation in the PQRI bonus program and tracking the accuracy of the Medicare incentive payments remains difficult. TDR

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French Company Buys Pittsburgh-Based RedPath

ExonHit Therapeutics acquires Redpath's proprietary molecular test and its CLIA laboratory

CEO SUMMARY: Here's a deal that is all about proprietary molecular assays and access to new markets. With its purchase of RedPath Integrated Pathology, ExonHit Therapeutics, S.A., of Paris, France, gains a CLIA laboratory and access to the U.S. market, even as the new owner opens the door to the European market for RedPath. As announced by the two companies, ExonHit will spend $22.5 million to acquire RedPath Innovative Pathology and will pay an additional $9.5 million if RedPath achieves certain sales targets.

INVESTOR INTEREST IN PROPRIETARY MOLECULAR ASSAYS remains strong. The latest evidence is the acquisition of **RedPath Integrated Pathology** of Pittsburgh, Pennsylvania, by **ExonHit Therapeutics, S.A.**, of Paris, France.

ExonHit is a publicly-traded diagnostics and therapeutics company that also has operations in Gaithersberg, Maryland. On April 26, ExonHit entered into a binding agreement to acquire RedPath for $12.5 million in cash and $10 million in ExonHit stock. If the combined companies reach specific sales targets, ExonHit will pay $9.5 million more starting in 2012, the companies said.

Sale To Close In July

The transaction is subject to approval by ExonHit's shareholders and is expected to close before the middle of July. Privately-held RedPath has investors that include **NewSpring Health Capital**, **CID Capital**, **Seneca Health Partners**, and **Inflexion Fund, L.P.**

RedPath offers proprietary molecular assays for evaluating pancreatic cancer. These assays were developed by pathologist Sydney D. Finkelstein, M.D., who founded the company in 2004 and is Chief Scientific Officer at RedPath.

"Our primary focus is in pancreatic cancer and differentiating metastatic cancer versus a new primary cancer through the use of our proprietary molecular assay, the PathFinderTG," stated Mark D. Myslinski, President and CEO of RedPath Innovative Pathology in an interview with THE DARK REPORT. "In the case of a patient with two pancreatic tumors, clinicians want to know if these tumors are metastasizing

"If the tumors are metastasizing, it puts them into Stage 4 cancer," explained Myslinski. "But if each tumor is a primary, it puts them into Stage 1, which is generally curable by surgery. The PathFinderTG assay helps the clinician make a material diagnosis.

"Currently, there are no other products for diagnosing pancreatic cancer in this way," added Mylinski. "There are traditional fluid chemistries but they are not nearly as specific or sensitive to allow the clinician to make a determination of Stage

1 versus Stage 4 cancer. Because our assay can provide that answer with a high degree of clinical confidence, it has filled an unmet need and has been successful in the marketplace."

Products in Development

Another asset that RedPath brings to ExonHit is its CLIA-certified and CAP-accredited laboratory in Pittsburgh. ExonHit is developing proprietary technology based on the analysis of alternative RNA splicing. It wants to develop molecular diagnostic tests and therapeutics for neurodegenerative diseases and cancer indications.

One interesting element in the combination of the two companies is that RedPath's technology is based on DNA analysis and ExonHit's technology is based on RNA analysis. "We have some products in development but nothing specific that I can talk about right now and they have products in development," noted Myslinski.

"RedPath will commercialize both ExonHit's products and our new products," he continued. "With our commercial capabilities and our DNA platform, we expect to help ExonHit move new products to market faster. Our sales force provides the conduit to introduce new molecular assays."

Opens Door To Europe

Myslinski also pointed out that its new relationship with ExonHit opens the door for RedPath to offer its molecular tests in the European Union. "This transaction gives us access to capital and more resources to, among other things, begin offering our molecular assays in Europe. We think the clinical utility of our assays will be recognized by clinicians and patients in Europe."

RedPath Innovative Pathology has a staff of 35, including two pathologists, along with a sales staff that operates nationwide. All employees will remain in Pittsburgh, Myslinski said.

RedPath Pathology Offers DNA-Based Molecular Tests

AT REDPATH INTEGRATED PATHOLOGY of Pittsburgh, Pennsylvania, the primary product is its DNA-based PathFinderTG. The company describes the test as follows:

RedPath's primary product is PathFinderTG, a molecular analysis of mutations in genomic DNA for cases in which traditional pathology produces an "indeterminate" diagnosis. The results of the PathFinderTG test can help resolve diagnostic dilemmas and help physicians develop a personalized treatment plan.

The patented test uses a broad panel of microsatellite markers to perform mutational analysis on many types of pathology specimens. Unlike tests for inherited genetic predisposition to cancer, it is an analysis of acquired genomic damage in an individual patient's tumor.

PathFinderTG can differentiate metastatic, synchronous, and recurrent tumors in various organs such as the breast, lung, liver, endometrium, and ovary. Also, it works with a wide variety of standard pathology specimens, even minute solid samples and small fluid volumes from specimens such as histology slides, cytology slides, fluid aspirates, and brush samples.

ExonHit is applying proprietary technology based on the analysis of alternative RNA splicing to develop molecular diagnostic tests and therapeutics for neurodegenerative and cancer indications.

The deal between RedPath Innovative Pathology and ExonHit not only affirms continuing investor interest in proprietary or patent-protected molecular assays, but it also shows the steady globalization of laboratory testing. It is also an further example of the ongoing consolidation taking place in the *in vitro* diagnostics (IVD) industry. These trends are continuing to shape the laboratory testing market, both here in the United States and abroad. TDR

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Letter to Editor

Letter to Editor on EMR Donations, Deeply-Discounted Client Prices

Dear Editor:

Because THE DARK REPORT is willing to tackle tough issues regarding the business end of the pathology profession, I am writing to call attention to a serious situation. What follows is presented as mostly factual and minimally perceptive. While I have no fear of transparency regarding our lab organization, I prefer anonymity to ensure there are no reprisals to our lab's clients because of what I am about to reveal.

First, an introduction to our laboratory enterprise. It is a private pathology practice. It has managed to survive because: 1) of the service mix we provide to the community we serve; 2) how we provide it; 3) the frugality of our operation; and, last but not least, 4) the quality and value of the service we provide to referring physicians. Best of all, we deliver this improved quality at a decreased cost!

As a small pathology laboratory, we survive only by providing a niche product, by maintaining a high level of quality, and by delivering top service. But that is only true if the Goliath-sized pathology companies play a fair game.

Compliance Policies

The modest size of our business operation means we must never take a chance of being on the wrong side of federal and state compliance laws (despite the widespread recognition that too many of the larger lab companies will push compliance to capture new customers).

That brings us to the purpose of my letter. Going back several years, my colleagues and I have confirmed on multiple occasions that certain commercial lab companies are willing to stretch the intent of compliance rules to either snag a big new client or keep a competitor from winning an existing customer.

In our experience, it is pathology companies funded by venture capital which most frequently bend compliance rules. What is most frustrating is that they act like they have no fear of any government enforcement action. If they were to be caught, they consider the risk like a driver stopped and ticketed for speeding: while it hurts to pay the fine, the pain is less than the gain.

Inducements To Physicians

But the continued practice of offering client physicians a range of inducements—many types of such inducements that common sense would recognize as crossing the compliance line—has an insidious effect: these large pathology companies kill the small entrepreneurial pathology groups. Government regulators seem to always be tolerant of the big lab corporations and invariably react after the fact. Let me cite some real life examples.

A physician client with a large volume of biopsies distributed his specimens for a long time between a local hospital, Lab X (large commercial lab) and our pathology group. He indicated that he was giving us all his case referrals with the exception of biopsies from hospital employees (which went to that hospital's lab) and biopsies from managed care patients for which Lab X was the exclusive contract laboratory.

Suddenly, our referral volume from this physician plummeted. We visited him. He told us that Lab X was paying a large amount of money for his EMR and asked if our pathology laboratory could pitch in $25,000.

Next, he told us that Lab X had told him that such "lab donations" to fund his EMR system are allowed by federal regulations. Lab X had given his office an official document explaining this. We obtained a copy of this document from his staff.

It was on Lab X letterhead but lacked any signature. This letter explained the CMS EMR Safe Harbor policy. Having not heard of this

before, I indicated that I don't believe this is possible and—even if it is—we couldn't possibly afford to contribute $25,000 to his practice for an EMR. The volume of specimen referrals from this physician dropped off quite rapidly!

EMR Donations To Doctors

Another client physician in a different specialty, asked me one day if it was OK for labs to pay for EMRs. When questioned, this doctor indicated that it came from the same Lab X mentioned earlier. This time, I explained the Safe Harbor rules and he still uses us exclusively.

We belong to a state organization, whose leader brought the subject of EMR donations up to the CEO of Lab X. The president acknowledged that one of his lab's subsidiaries was venturing into providing EMRs but that it is not company policy!

Another long-time client of our pathology lab disclosed to us that the management company of his endoscopy center would be getting Lab Y to pay 85% of the cost of his EMR. For that reason, this physician would be sending some biopsies to Lab Y. At the same, the staff in this doctor's office openly volunteered that Lab Y provided poor service and cumbersome processes in shipping. They indicated that Lab Y would be used by other clients of this management company.

We continue to show this client our lab's service and our electronic interface capabilities with the hope of retaining this business. But we realize that it is only matter of time before our lab will lose all the specimen referrals to Lab Y. I am told Lab Y paid a considerable amount of money to the EMR company for programming, and this EMR company then sells its software at a deep discount to the physician accounts of Lab Y!

Another example comes from a different specialty. We have a long-time client who now only uses for us for specific cases. He shifted the bulk of his specimen referrals to the hospital and Lab Z because they paid for the EMR he uses in his practice. His staff gave us this information.

The above incidents occurred during the past 24 months. Recently, a prospective client asked if we would do discounted client billing on his specimens. This physician shared with us the CPT codes and the prices offered by Lab X; the same lab company mentioned earlier! The prices were well below Medicare and below what we offer clients like Planned Parenthood!

This prospective client indicated that he would switch to our lab if we could come close to these low prices because of the poor service provided by Lab X. We indicated that the CPT codes were incorrect for the services he wanted. He has not yet gotten back to us. Stay tuned!

Another long-term client suddenly stopped using us. His staff indicated that he was sending his specimens to Lab X because of the deeply discounted prices offered as part of a client billing arrangement. As it turned out, Lab X's service was so poor, this physician switched back to our laboratory within couple of months.

No Compliance Enforcement

Mr. Editor, our government has never voluntarily been for the small guys. I reported my anger over this situation to the ***Centers for Medicare and Medicaid Services*** *(CMS) through our carrier. The medical director had lunch with me and said that there is nothing our lab can do in response to these situations.*

Do you have advice on how to cope with these situations? How can these investor-funded pathology companies can spend tens of thousands of dollars to provide EMR systems to hundreds of their clients and still earn enough margin to stay in business? Why do clear examples of certain labs stretching Medicare compliance laws fail to get attention and enforcement action from Medicare officials?

These issues strike to the ability of smaller pathology laboratories to survive. We provide important services to the community and employ close to 40 people. Thank you in advance. Respectfully,

Anonymous Pathologist

Editor's Note: On the pages which follow, attorney Jane Pine Wood of McDonald Hopkins speaks to the issues described by this pathologist.

EMR Donations, Client Bill Issues in Anatomic Path

Federal law has lots to say on EHR donations and discounted client bill pricing to referring docs

CEO SUMMARY: In today's market for anatomic pathology services, local pathology practices are facing tough competition from national pathology companies that are quite aggressive at using EHR donations and discounted client bill arrangements to win new clients. Attorney Jane Pine Wood of McDonald Hopkins identifies federal safe harbor requirements governing EHR donations involving laboratories and referring physicians, then discusses compliance issues triggered by discounted client billing arrangements.

IT CONTINUES TO BE A TOUGH MARKET for local pathology groups. Larger pathology companies often use deeply-discounted client bill pricing to win business. Now EHR donations are being used for competitive advantage.

In recent years, federal rules on EHR (electronic health record) donations have created another way for the bigger pathology laboratories to win business away from community hospital-based pathologists.

Use of these competitive strategies in the anatomic pathology marketplace recently motivated one pathologist to write the letter to the editor published on the preceding pages. *(See pages 13-14.)* This pathologist described several examples of why his local pathology laboratory is at a disadvantage when attempting to retain the business of long-standing clients in his community because of how larger pathology companies use these two strategies.

THE DARK REPORT sent the letter from this pathologist to attorney Jane Pine Wood of **McDonald Hopkins**, for her review and comment. Wood and her colleagues maintain a sizeable legal practice with pathology groups and clinical laboratories throughout the United States.

Wood responded that the pathologist who wrote that letter writer faces a common occurrence in the lab business. "I wish the issue involving your anonymous letter writer was unique, but it is not," she said. "This pathologist describes two competitive strategies often used by larger pathology companies to win new client accounts.

EHR Donations

"First is the use of EHR donations," explained Wood. "The second is when a laboratory offers discounted client bill prices to a physician who refers laboratory specimens. It is important for all pathologists to understand what the compliance requirements are for each activity.

"In order to donate an EHR to an office-based physician practice, a laboratory must follow the safe harbor and Stark requirements spelled out in federal regulations," stated Wood. "It was in 2006 when various federal agencies published these requirements.

"In 2006, the **Department of Health and Human Services** Office of Inspector General (OIG) and the **Centers for Medicare & Medicaid Services** (CMS) issued a safe harbor under the federal anti-kickback law and an exception under the federal Stark physician self-referral law," she said, "that permits certain donations of EHR software and/or information technology, along with associated training services."

Encourage EHR Adoption

Wood noted that, "The OIG's stated purpose for the safe harbor and Stark exception was to 'lower the perceived barriers to the adoption of health information technology' by promoting 'the adoption of open, interconnected, inter-operable EHR systems.' The goal is to encourage office-based physicians throughout the United States to implement and use EHR systems. The safe harbor and exception are scheduled to end in 2013.

"Under the EHR safe harbor and exception," continued Wood, "laboratories and other permitted donors can subsidize the cost of compliant EHR technology to physicians at 85% of the cost of such technology.

"However, the Office of the Inspector General (OIG) has informally acknowledged concerns about the potential for abuse by ancillary service providers and suppliers, including laboratories," added Wood. "The OIG says it will be alert to patterns of increased utilization correlated with transfers of non-monetary remuneration in the form of EHR technology."

Specific Requirements

Under the safe harbor and Stark guidelines published by CMS and the OIG in 2006, both the donor and recipient must meet specific requirements. "These final rules offer protection only if the recipient pays 15% of the donor's cost of the technology," explained Wood. "This payment is required to be made before the recipient's receipt of the items and services being donated.

"Further, the cost-sharing agreement must include all donated software and health information technology, along with the cost of training services," she stated. "Any updates, upgrades, or modifications to the donated EHR system that are not covered under the initial purchase price for the donated technology are subject to separate cost sharing obligations by the recipient (to the extent that the donor incurs additional costs).

"Laboratories should note that donors (and their affiliated individuals and entities) are prohibited from providing, financing, or making loans to recipients to fund the recipient's payment for the technology," added Wood. "The donation should be documented in a written agreement that specifies the items and services being provided; the donor's cost of those items and services; and the amount of the recipient's contribution. The agreement must also cover all of the EHR items and services to be provided by the donor (or any affiliate).

Other Safe Harbor Criteria

"To meet all the safe harbor and Stark criteria, there are several other requirements for the donor laboratory and the recipient," noted Wood. "These requirements address predominance, interoperability, certification, and electronic prescribing.

"This is why there is plenty of attention and publicity surrounding federal guidance relating to certification of EHRs and the definitions of interoperability as they relate to these EHR donation safe harbor and Stark requirements," she said.

"In response to the pathologist who wrote the letter to the editor, the main point is that the federal health establishment has created the EHR donation safe harbor and Stark exception as a way to encourage hospitals, ancillary providers, and laboratories to provide funds that encourage and allow office-based physicians to acquire and use an electronic health record system," noted Wood. "So long as the donor and recipient meet all the safe harbor and Stark require-

Deep Discounts for Client Bill Arrangements Have a Chequered History over Two Decades

DEEPLY-DISCOUNTED CLIENT BILLING ARRANGEMENTS have dogged the laboratory testing industry for almost 25 years. The frustration of the pathologist who wrote the letter to the editor published on pages 13-14 is representative of other individuals in the laboratory profession.

Many in the lab industry would argue that federal guidelines and federal enforcement of anti-kickback statutes have failed to provide a clearly-demarcated line to help laboratories comply with this law. There is no simple, objective test which can be used to determine situations where the discount offered to a physician in a client bill arrangement would represent an inducement to the referring physician—and thus a violation of the Medicare anti-kickback law.

Long-time readers of **THE DARK REPORT** are familiar with specific published guidance by federal officials during the past two decades. During this same time, there have been few successful civil settlements and criminal convictions when the federal government challenged certain laboratories alleged to have used deeply-discounted client bill prices as an inducement to physicians in violation of Medicare anti-kickback laws.

In its ongoing coverage of discounted client billing, **THE DARK REPORT** has recognized that, as a general characteristic of the laboratory marketplace, it is the larger pathology laboratory companies which seem to be more aggressive at offering physicians client bill prices which are deeply discounted. Sometimes these prices are significantly below the level of reimbursement paid by the Medicare Part B laboratory test fee schedule.

Local pathology groups and hospital laboratory outreach groups have long complained about this situation. They note that when a lab company offers such deeply-discounted prices, in many instances, it can only sustain service to that client's account because of the Medicare case referrals.

In the view of these competing laboratories, such deeply-discounted client bill prices represent remuneration to the physician (who can bill third-party payers and patients for the full value of the tests). If discounting client bill prices to this level was considered remuneration to the referring physician, these lab competitors argue that such laboratories would be offering inducements for Medicare case referrals and that would violate Medicare anti-kickback statutes.

ments, this is an activity that complies with current federal law."

In considering the second issue raised in the pathologist's letter to the editor on discounted client bill arrangements, Wood observed that client billing for clinical laboratory and anatomic pathology testing is a practice that reaches back decades. "In and of itself, offering a physician discounted prices via a client bill arrangement is an activity that is permitted, so long as the arrangement does not violate Medicare and Medicaid anti-kickback statutes and Stark law," commented Wood. "The issue of client billing is difficult to assess without knowing more about the specifics of the case to which the letter writer alluded. However, the Medicare and Medicaid anti-kickback law is clear.

"It prohibits the payment, receipt, offering, or solicitation of remuneration in exchange for the referral of services or items covered by Medicare or Medicaid," she emphasized. "Thus, because a physician who contracts with a pathology provider is a source of Medicare and Medicaid referrals to the pathology provider, the Medicare and Medicaid anti-kickback law must be considered when negotiating the compensation arrangement between the physician and the pathology provider.

Dianon Offers Urologists EHR Donations Per Policy

ONE PATHOLOGY COMPANY that has an EHR donation policy posted on its web site is **DIANON Systems, Inc.**, a subsidiary of **Laboratory Corporation of America**. The policy is designed to meet the safe harbor requirements for EHR donations. Here are highlights from the document:

...Under the EHR safe harbor and exception, laboratories can donate to physicians up to 85% of the eligible costs of compliant EHR technology.

DIANON Systems, Inc. ("DIANON") is offering an EHR donation program for urology physicians and practices utilizing EHR vendors, including meridianEMR, who have obtained Certification Commission for Healthcare Information Technology (CCHIT) approval and are deemed inter-operable.

DIANON will donate $7,500 per provider or 85% of the eligible costs for the EHR technology, whichever is less, consistent with the requirements of the anti-kickback safe harbor and Stark exception. DIANON will not be responsible for any future upgrades or ongoing maintenance of the donated technology.

This donation is nonmonetary remuneration that consists of items and services in the form of software or information technology and training services used predominantly to create, maintain, transmit, or receive electronic health records. Examples of protected technology include interface software, licenses, and intellectual property related to such software. Donors are not permitted to provide unrestricted hardware under these rules. Additionally, the urology physician or practice must contribute at least 15% of the cost of the donated technology before receiving it.

The attached Eligibility Certification document establishes the participation eligibility of the urology physician or practice that requests an EHR donation and outlines the initial understanding between DIANON and the recipient regarding the terms of the donation, consistent with applicable law.

"As a general matter, if the prices paid by the physician for the pathology services are less than fair market value, an allegation could be made that the physician has received a kickback from the pathology provider (in the form of below-market prices) in exchange for the physician's continued referrals to the pathology provider.

"Therefore, it is critical that pathology providers charge—and physicians pay—reasonable amounts for the pathology services," commented Wood. "It is significant that fair market pricing is an important theme throughout the Office of the Inspector General's (OIG) model compliance guidance for both physician practices and pathology providers.

➤ OIG Advisory Opinion 99-13

"Pathologists and their business advisors may want to review OIG Advisory Opinion 99-13, which provides parameters for discounted billing for pathology services," she said. "This Advisory Opinion explains that pathology providers and the physicians who purchase pathology services risk violating the Medicare and Medicaid anti-kickback law if they have deeply-discounted pricing arrangements.

"The OIG wrote that suspect discounts include—but are not limited to—discounted prices that are below the pathology provider's cost," said Wood. "In determining whether a discount is below cost, the OIG explained that it will consider the total of all costs (including labor, overhead, equipment, etc.) divided by the total number of tests."

In response the pathologist who wrote the letter to the editor printed on pages 13-14, this legal expert has provided the requirements for an EHR donation policy and client bill arrangements to meet appropriate federal laws. These are competitive business practices which are not likely to disappear anytime soon. **TDR**

Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Just four years since its founding in June, 2006, **Aurora Diagnostics, Inc.**, of Palm Beach Gardens, Florida, is preparing to go public. On April 30, the company filed stock registration documents with the **Securities and Exchange Commission** (SEC) for an IPO (initial public offering). Aurora Diagnostics says it wants to raise as much as $150 million. It plans to be listed on the NASDAQ exchange under the symbol "ARDX." The company says its net revenues grew from $63.4 million during its first full year in 2007 to $171.6 million for its year ending December 31, 2009.

MORE ON: *Aurora*

Aurora Diagnostics has been acquiring and operating anatomic pathology practices, with a particular focus on dermatopathology groups. It also operates several clinical laboratories. It says it has acquired "17 existing diagnostic services businesses" over the past four years. Aurora Diagnostic employs 73 pathologists and has contractual arrangements with 16 pathologists. The company is led by James C. New, who is Chairman, President, and CEO; and Martin J. Stefanelli, who is Vice President and COO. Both executives held leadership positions at **AmeriPath, Inc.**, prior to and during its sale to **Welsh, Carson, Anderson and Stowe** in 2003.

PERKIN ELMER PAYS $90 MILLION TO BUY SIGNATURE GENOMICS

Here's a deal which shows the premium prices buyers will pay for companies with high-value molecular assays. PerkinElmer announced on April 14 that it would pay $90 million to acquire **Signature Genomic Laboratories, LLC**, of Spokane, Washington. Signature was founded in 2003 by Lisa G. Shaffer, Ph.D., and Bassem A. Bejjani, M.D. It performs "diagnostic cytogenetic testing of chromosome abnormalities in individuals with unexplained physical and developmental disabilities," using a microarray diagnostic technology. Signature also recently began to offer services for diagnosing patients with leukemia. Privately-held Signature did not disclose its revenues. Some financial experts estimate that the company does between $15 and $20 million per year in sales. That would mean the $90 million purchase price paid by PerkinElmer represents a strong premium for Signature Genetics Laboratories.

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DARK DAILY UPDATE

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

...the new bachelor's degree program in molecular diagnostics at **Ferris State University** in Big Rapids, Michigan. It launches this fall and will accommodate 128 students when it reaches full capacity in four years.

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 Tuesday, June 1, 2010.