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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

Anatomic Pathology's Likely Path of Transformation

RECENT DEALS INVOLVING PRIVATE EQUITY FIRMS and several of the nation's larger pathology groups hint at a major transformation soon to come to the pathology profession. No one should be surprised that pathologists of the baby boomer generation will be an important trigger in this transformation.

It is the coming wave of retirements by baby boomer pathologists that will provide the momentum for these changes to the profession. As you will read on pages 13-14, our editor observes that many pathology group practices will soon need money to cash out their retiring partner-pathologists. In response to this need, a growing number of pathology groups will either allow themselves to be acquired or will sell significant equity to outside investors. In both cases, some of the money raised by these methods will be used to purchase back the equity owned by the retiring partners.

I can see this having two direct consequences to the pathology profession. First, it is likely to signal the end of the pre-eminence of the private pathology group practice, usually anchored by one or more contracts with community hospitals. Because of either outright sale of the practice or the sale of significant equity to outside investors, private pathology practices—professional corporations (PCs)—will begin to decline in numbers and influence. That's because the buyers or new investors of these private practice groups will operate them using a different business model than the professional corporation.

Second, each time a private pathology group either sells itself to a buyer or sells a significant share of equity to outside investors, these investors will insist on one major change in the pathology group's business activity. That change will be to increase the rate of growth in specimens and revenue. To achieve this, these pathology groups will initiate their first-ever sales and marketing programs or expand and intensify existing sales efforts.

Thus, the rather collegial pathology profession we see today, dominated by private pathology group practices (often smaller groups serving community hospitals and not funding a professional sales program) is about to undergo a gradual transformation. If professional investors change anatomic pathology in a similar fashion to how the clinical laboratory was changed between 1985 and the present, then we should expect a fundamental restructuring of the anatomic pathology sector. This may take more than 10 years to accomplish, due to the pace of retirement by baby boomer pathologists. TDR

Ireland Is Restructuring National Lab Test System

Government health program plans to integrate, consolidate, and regionalize lab testing services

CEO SUMMARY: Working from a consultant's report and recommendations based on studies dating back to 2006 and 2007, Ireland's Health Service Executive is moving forward to effect a comprehensive reconfiguration of clinical laboratory testing across the nation. This may be the first time that the government health program of a developed nation has attempted to consolidate, regionalize, and integrate all the laboratory testing services within its borders.

WITHOUT MUCH NOTICE from the international laboratory medicine community, on February 25, 2009, Ireland's **Health Service Executive** (HSE) publicly announced plans to restructure, consolidate, and regionalize laboratory testing services across the entire nation.

Last week, THE DARK REPORT made its first visit to Ireland to learn more about this far-reaching effort to revamp pathology testing. Internationally, this is currently the most ambitious attempt to overhaul the entire laboratory medicine system of one nation.

The stated goal is to realign the existing laboratory testing service so that it can support current and future best practices in modern medicine while generating worthwhile savings because of consolidation and rationalization. This ambitious agenda will require many of the nation's existing hospital-based laboratories to close or downsize.

The HSE acknowledges that the restructuring will be extensive. Current plans call for the nation's 46 hospital laboratories to be reduced by an unspecified number. At the same time, up to three new, stand-alone laboratory facilities would be constructed, primarily to provide high volume, routine testing to general practice clinics. Much of this routine testing is currently performed by the same hospital laboratories slated to be closed or downsized.

In that February press release, the HSE stated it intended to proceed with a "programme to modernise its Medical Laboratory Services, as part of its ongoing transformation of services." This will involve implementation of "a unified, coordinated [lab testing] service which will dramatically improve quality and turn-

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around times in these essential diagnostic services."

Consultant Was Selected

First steps to study a nationwide scheme of laboratory test restructuring were taken mid-decade. The HSE contracted with **Teamwork Management Services Limited**, a consulting company based in England. Teamwork reported on its findings and recommendations in May 2007. Its report was titled "Implementing a New System of Service Delivery for Laboratory Medicine Services."

That same month, the HSE board endorsed the Teamwork report. However, not until February 2009, when HSE issued the press release, was the Teamwork report made available to the general public by posting it on the HSE web site.

There is one interesting criticism of Teamwork's report on laboratory restructuring. None of the members of the steering group—including Irish pathologists and laboratory scientists—who interacted with Teamwork consultants during the study period were asked to officially endorse or "sign off" on the findings presented in the document.

To Build Three "Cold" Labs

Probably the most controversial element of this laboratory restructuring plan is the decision to construct up to three "cold" laboratory facilities. "Cold" is used to describe routine testing that can be performed and reported in four or more hours.

Teamwork consultants define the "hot lab" as "a laboratory facility that processes all samples generated by patients attending the regional hospital, out patients and when admitted for emergency care or complex planned care." Hot labs must provide faster turnaround times and be located close to the point of patient care.

Many laboratory professionals in Ireland are not in agreement that the construction of free-standing "cold" laboratories is the best way to meet the needs of a rapidly-evolving healthcare system. Moreover, a study of the consultant's report reveals that this recommendation was not based on site visits to the world's best-performing laboratory facilities.

Instead, the consultants quote a range of published studies and news stories on laboratory operations. Some of these citations are as old as the mid-1990s and thus do not reflect latest-generation lab testing systems and management models.

The argument will be most familiar to pathologists and lab managers in the United States and Canada. Can a hospital laboratory serve the general practice clinics in its community better than a stand-alone commercial laboratory competitor?

Vigorous Competition

In both countries, there are cities where hospital laboratories compete vigorously and successfully against commercial laboratories. Moreover, the most innovative models of integrated diagnostics (pathology testing and radiology imaging) just now entering the marketplace demonstrate the potential for a well-run hospital laboratory to be a true force for integration of diagnostics, of clinical care, and of healthcare informatics.

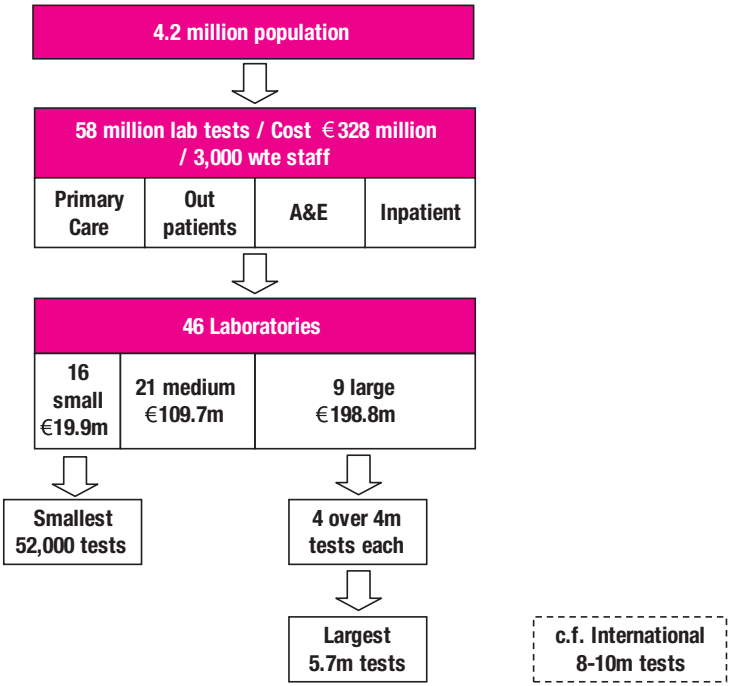
One practical concern expressed by pathologists and laboratory scientists in Ireland is about the tender process which will be used to organize the design, construction, and operation of the "cold" labs. There is a widespread perception that government health officials will create specifications for the tender that will exclude Irish laboratory organizations as successful candidates for a tender award.

Rather, a general sentiment among laboratory professionals in Ireland is that the design of the tender will favor lab companies like **Quest Diagnostics Incorporated** or **Sonic Healthcare, Ltd.** It is pointed out that the cervical cancer screening contract tender, by its design and requirements, effectively excluded any Irish lab from winning part of that testing

Restructuring Lab Testing in an Entire Nation: Is it All About the Lowest Cost Per Test?

TO EVALUATE THE EXISTING CLINICAL LABORATORY TESTING STRUCTURE IN IRELAND, consultants at Teamwork Management Services Limited developed this table. It shows how the population of Ireland is served by 46 hospital laboratories of various sizes. Laboratory tests provided to general practitioners represent about 50% of the test volume performed annually in Ireland.

Organization of Current Health Service Executive Clinical Laboratory Services



Source: Health Service Executive, "Implementing a New System of Service Delivery for Laboratory Medicine Services," February 2009.

volume. In fact, Quest Diagnostics did win that tender and has tested 100% of Ireland's Pap smears since July 1, 2008. *(See TDR, August 31, 2009.)*

Of course, the controversy about the "cold lab" proposal doesn't stop there. A number of Irish lab professionals believe that the process which generated the conclusion that cold labs were the best solution for Ireland was incomplete, flawed, and biased. The critics note the lack of transparency in the process to date as well as the lack of significant input by the Irish pathology establishment at key stages in this process.

This criticism is confirmed by a statement on page 7 of the Teamwork report. The authors wrote that "We were asked to prepare this report on an independent basis without formal engagement and consultation with the public, patients, staff and other stakeholders in laboratory medicine services."

Concerns about the flaws in the process used to support the recommendations for laboratory restructuring and consolidation caused Ireland's **Medical Laboratory Scientists Association** (MLSA) to commission a consulting company to do

an independent assessment of the HSE's plans for reforming pathology services across the country. **EC Harris LLP** produced that analysis in April 2009.

Based on a study of these documents and observations made during its laboratory site visits in Dublin, Ireland, last week, THE DARK REPORT can offer a few insights about this situation. First, in Ireland over the past two decades, laboratories have not been given capital at a rate comparable to what is provided to labs by government health systems in other English-speaking countries visited by THE DARK REPORT in recent years.

Labs Have Limited Capital

Thus, in a situation acknowledged by both government health policy makers and laboratory professionals, Ireland's laboratories have not had access to the capital required to acquire and operate each "next generation" of laboratory instruments and automation as it reached the clinical market.

On one laboratory site visit, for example, a laboratory manager told THE DARK REPORT that the annual budget for the clinical laboratory did not include a line item for a capital account. This is different than in the United States and Canada, where laboratory operators (and the government health programs) acknowledge the need to allow for capital (and depreciation) so the funding is available to allow the laboratory to regularly update its equipment and systems.

Similarly, the Irish system has not provided sufficient capital to allow hospitals, laboratories, and general practice clinics to acquire and deploy each generation of enhanced information technology as it was introduced into the market. For that reason, laboratories still deal with much more paper than would be seen by busy labs in the healthcare systems of other developed countries. In the hospital labs visited last week, the LIS systems in use were often installed in the late 1980s and early 1990s and had not been upgraded regularly.

Two other observations are of particular interest to pathologists and laboratory managers in other countries. First is that neither Ireland's government health program nor its laboratory testing profession seem to recognize the potential of quality management tools such as Lean and Six Sigma.

Missing in both the Teamwork consultant's full report on laboratory restructuring and the MLSA's assessment of the HSE's plans was any mention of how Lean, Six Sigma and similar quality management techniques could be used to achieve the goals of the Irish health system in a controlled, rapid, and cost-effective manner.

Given the fact that many pathology laboratories using Lean report improvements of 40% and 50% in turnaround time, quality, and staff productivity, with comparable levels of cost reduction, it seems odd that the HSE leaves this action option unmentioned and unaddressed.

Second, with all the examples of "best practices" laboratories that exist in developed countries around the world, it seems odd that the Teamwork consultants—and the pathologists and laboratory scientists participating on advisory committees—were not allowed to travel to these labs and conduct site visits. Many clinical lab organizations have developed effective solutions to the same challenges now facing labs in Ireland and the study team has missed an opportunity to avoid "reinventing the wheel."

Laboratory Restructuring

In 2008, the Irish health program broke new ground in laboratory medicine and operations by outsourcing 100% of cervical cancer testing to an overseas laboratory company. Now Irish health officials are poised to restructure the nations' entire laboratory testing infrastructure based on a consultants' report and recommendations—and without the significant consensus of pathology leaders in support of the announced plans. It is a bold restructuring of laboratory services and is certain to be closely watched as it moves forward from concept to implementation. TDR

Predict 60,000 Doctors To Adopt EMRs Each Year

Expanding EMR use by physicians creates opportunity for clinical labs & pathology groups

CEO SUMMARY: Only about 180,000 U.S. physicians have adopted electronic medical record (EMR) systems over the past 14 years—mostly in larger medical groups. Now experts believe as many as 60,000 physicians per year will begin to adopt EMRs because of new federal incentives funded by the stimulus bill passed early last year. This is a major development and requires a response by every clinical lab and pathology group practice, since physicians will need their lab provider to enable electronic lab test ordering and lab test reporting for their EMRs.

PHYSICIAN ADOPTION OF ELECTRONIC MEDICAL RECORDS (EMR) SYSTEMS is expected to skyrocket during the next 36 months as a direct result of new federal incentives. This will be an opportunity for clinical labs and pathology groups that move nimbly to offer LIS-to-EMR interfaces to their client physicians.

"The opportunity exists because EMR adoption and LIS-to-EMR interfaces have a hand-to-glove relationship," stated Pat Wolfram, an expert in EMR integration. "Once a physician group implements an EMR into its practice for the first time, it immediately wants its laboratory to electronically populate the patient's EMR record with the laboratory test results.

"Now, to qualify for recently-introduced federal financial incentives, physicians must also order lab tests within their EMRs," he said. "Physicians will need the lab's help to put both EMR lab results and lab orders in place.

"In recent years, we have seen that the clinical laboratories which do this best gain competitive advantage," he continued. "These labs do better at retaining existing clients while increasing the number of new physician clients for their lab testing outreach program."

Wolfram is Vice President of Marketing & Customer Services for **Ignis Systems Corporation**, a company in Portland, Oregon, that provides EMR integration between physicians and labs and other providers. He made these comments last week during THE DARK REPORT'S special audio conference "New Opportunities for Your Laboratory's LIS-EMR Interface: How to Profit From the 'Big Wave' About to Hit Healthcare."

Changing Doc's Use Of IT

"EMR adoption is absolutely the biggest thing happening in the way ambulatory physicians use information technology," observed Wolfram. "Since Congress passed the bill last year that funded $17 billion in incentives to encourage physicians to implement an EMR, demand for our services has increased each month.

"Keep in mind that the terms EMR and EHR (electronic health record) are often used interchangeably," he noted. "That can

be confusing. For purposes of our discussion today, my analysis and recommendations deal with the category of systems known as ambulatory medical record systems.

"It helps to understand the numbers which will drive this surge in physician demand for EMRs," he continued. "Estimates place the current number of physicians with EMRs in their offices at between 150,000 and 180,000. These are primarily larger groups, usually with 15 or more doctors in the practice, or a collection of affiliated practices. It has taken 14 years to achieve this number of EMR users.

"If the federal stimulus package achieves its goals of 90% adoption by 2015, that means 360,000 physicians that do not have EMRs today will install EMRs," he continued. "That averages out to be about 60,000 new doctors using EMR systems each year between now and 2015.

"This rapid uptake of EMRs by physicians will put a major stress on laboratories, for an obvious reason," stated Wolfram. "Almost all EMRs today utilize interfaces with providers of laboratory tests. When done right, the LIS-to-EMR interface supports computerized physician order entry from within the EMR and electronically feeds the laboratory test results back into the EMR. Thus, the nation's labs will have to scramble if they are to support 60,000 physicians during their EMR adoption process each year.

Trump Card For Laboratories

"The good news is that laboratories have a trump card to play with physicians preparing to implement an EMR for the first time," he observed. "Each physician can qualify for federal incentives that can be as much as $44,000 per doctor over several years, so long as the EMRs in use meet 'meaningful use' requirements. Lab test ordering and lab test resulting are currently requirements of the 'meaningful use' criteria.

"These requirements were published by the Office of the National Coordinator for **Health Information Technology** (ONC) on December 30, 2009," said Wolfram. "The published requirements are currently in a 60-day comment period that ends March 15, 2010. It is expected that the published requirements will become final in May 2010.

"There are several things about meaningful use that pathologists and laboratory executives should understand so they can meet the needs of their client physicians in the most appropriate manner," said Wolfram. "I am going to primarily address the incentive program offered by Medicare. Medicaid has slightly different criteria governing the financial incentives it offers for EMR adoption.

EMR Certification

"To qualify for incentive payments, the adopted EMR must be certified by one of the certification committees, such as the **Certification Commission for Healthcare Information Technology** (CCHIT)," he added. "Next, the physician is to use that electronic medical record in the care of his or her patient population in a meaningful way. Once the physician achieves the objectives required by the government, he or she can apply for the incentive payment.

"The ONC has defined 28 functions (as presented on the CCHIT checklist) that the EMR must support and the physician must use," Wolfram explained. "Laboratory testing is named in three of the defined uses within a qualified EMR.

"The first of these is computer physician order entry (CPOE), where a physician uses an EMR to order laboratory tests, imaging studies, referrals, and/or medications," he noted. "The second is electronic receipt of laboratory test results directly into the EMR.

"The third criteria of meaningful use involving laboratory testing is a somewhat new function," continued Wolfram. "In cases where a public health agency requires the physician to submit a laboratory test report, the EMR must be capable of electronically transmitting these lab reports directly to the public agency.

"During the first stage of the government's EMR incentive program, this capability only needs to be proven," he stated. "It does not need to be performed in a production environment. That will probably be a requirement of stage two or stage three 'meaningful use.'

"Those are the meaningful use criteria that most involve laboratories. But it is cash from the government that catches the attention of physicians," offered Wolfram. "Federal payments will come in three stages.

"In stage one, if a physician adopts an EMR and, for 2011 (during next year), can prove that it is being used in a meaningful way, he or she can get a reimbursement check for as much as $18,000 from Medicare. If the physician proves that same meaningful use in 2012, he or she can get an additional $12,000," he noted.

"The threshold goes up in stage two, which begins in 2013," explained Wolfram. "A different level of meaningful use will be applied at that time. Because government officials have not released this information yet, we don't know what these later rounds of meaningful use requirements will be.

"The bar gets raised again in stage three, which is in 2015," he added. "Lab managers and pathologists should anticipate that, in stage three of the federal EMR adoption incentive program, every point of patient care throughout a healthcare system would involve use of a common medical records repository. The ambulatory EMR would contribute to this repository, as would other clinical systems throughout the care network where a patient receives care.

Further Integration

"These same clinical systems would have access to this common medical record to read or retrieve the full clinical profile of the patient," speculated Wolfram. "The goal is to nurture and encourage further integration of care pathways and the information technology that providers use to view a complete electronic health record for an individual patient.

"Having laid the groundwork for the coming wave of EMR adoption, let's take a closer look at the requirements that are specific to laboratory testing," he noted. "How the EMR handles receipt of lab test results is a good starting point.

"It won't be enough for the EMR to simply interface with—and accept lab testing results from—the LIS," said Wolfram. "It will be required that 50% of the lab results accepted into the EMR be at the numeric structured level. In its simplest form, this means the specific values of, say, a cholesterol test must be presented in a database location in the EMR in a way that allows for trending, reporting, and to trigger care protocols.

Lab-Specific Requirements

"Next, there are specific requirements for lab test ordering within the EMR," he added. "For the function of computerized physician order entry (CPOE), over 80% of the orders in the ambulatory environment must be entered by the physician directly inside the EMR.

"In practical terms, we know that means a substantial number of orders placed by the physician would be lab tests. It will be impossible for most physicians to demonstrate that 80% of their orders are being placed within the EMR unless clinical laboratory tests are included. Lab directors will need to deal with this issue when developing the LIS-to-EMR integration for a physician who is adopting an EMR.

"Bear in mind that the requirement calls for the physician to order via the computer, but it does not require that the order be transmitted electronically to your lab—at least not in stage one," he said. "The physician can satisfy the requirement by printing the lab test request on paper and sending that paper to the laboratory.

"However, there are good workflow and operational efficiency reasons to make the EMR lab order an electronic one," added Wolfram. "Perhaps the best reason is that returned lab results will have the needed identifiers (patient and provider)

to guarantee a match to the right EMR chart and notification to the right provider in the medical group practice.

"Similarly, as part of the stage one requirements for reportable lab submissions, the lab report does not need to be submitted to a public health agency, but it simply has to be proven that the EMR is capable of this function," Wolfram said. "Thus, the physicians' practice only needs to prove that its EMR can submit the report to the agency if that community has a public health agency that can receive this type of data."

Wolfram has specific recommendations for laboratories that want to be effective at helping client physicians adopt EMRs. "One function that is almost mandatory is that the laboratory deliver a simple and efficient lab test results interface with the EMR," advised Wolfram.

"What we see in the marketplace is that about 90% physician EMRs go live with a laboratory interface in place that electronically delivers lab results into the EMR," he commented. "If the new EMR becomes operational without this automatic data feed for lab tests results, the doctors will ask for this capability very quickly. In our experience, we've learned EMRs do not go live and are not used by doctors unless lab results are there.

"Historically, ordering lab tests within the EMR occurs at later phases of the EMR adoption cycle," observed Wolfram. "But with the current requirements for meaningful use, lab ordering will happen sooner.

Reason For Late Adoption

"There are two primary reasons for late stage adoption of lab ordering within the EMR," he explained. "The first is ease-of-use. Ordering tests within an EMR is a significant workflow change for a practice when compared to the much simpler function of electronically accepting and reviewing lab results. Second, the setup required to install the lab's test codes and ordering rules into the EMR ordering libraries, along with compliance and other related ordering rules (ABNs and AOEs, for example) requires significant effort. Some EMR products in the marketplace today are better at this than others.

"As more and more of your practices evaluate EMRs, you can partner with them to understand the value of EMR-to-Lab integration and to make it part of the acceptance criteria," he said. "Then, help them evaluate whether the EMR can support your lab ordering rules and how to accomplish the LIS-to-EMR integration setup. It's often not prioritized as a critical element in their EMR evaluation, but it should be."

Once-In-A-Lifetime Adoption

THE DARK REPORT calls attention to the fact that this multi-year period of widespread adoption of EMRs by the nation's physicians is a once-in-a-lifetime market opportunity for clinical labs and pathology group practices. More than half of the nation's 700,000 physicians will become EMR users between now and the end of 2015.

Once a physician group embeds a laboratory's LIS-to-EMR interface into its EMR product, it becomes more difficult and time-consuming to switch to a new laboratory provider. This is an important reason why clinical laboratories and pathology group practices should want to be competent and deft at supporting the physicians' EMR implementation process.

At a time when the physician group is investing considerable time and money to make an EMR a reality, the local laboratory can demonstrate its competence and ability to support the physicians' "meaningful use" of their EMR system. Recent experience demonstrates that labs that do this earn great loyalty from their client physicians. TDR

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Health Market Update

Rate of Health Spend Increase in 2008 Was Lowest Since 1960

CMS report says a total of $2.3 trillion was spent on health during 2008, which is an increase of 4.4%

RECENTLY the **Centers for Medicare and Medicaid Services** (CMS) reported on healthcare spending for 2008. The noteworthy finding was that the rate of increase in health spending fell to 4.4% for 2008.

This is the lowest annual rate of increase in health spending since CMS first began officially tracking health expenditures in 1960. In its report, CMS noted the good news/bad news aspects of the report.

The good news was that, at 4.4%, the rate of increase for 2008 was down from the 6.0% growth rate seen during 2007. As presented by CMS, the bad news was that, for 2008, healthcare spending as a share of the nation's GDP rose to 16.2%, an increase of 0.3 percentage points when compared to 2007. This occurred because the economy only grew at a 2.6% rate in 2008, while spending on health grew by 4.4%.

$2.3 Trillion For 2008

CMS says that total spending on health in the United States during 2008 totaled $2.3 trillion. This works out to be $7,681 per person.

Authors of the CMS report explained that the slow growth rate was connected to the recession. They wrote that "The economic downturn significantly impacted health spending as more Americans could not afford to spend their limited resources on health care and instead went without care. This led to slower growth in personal health care paid by private sources of funds, which increased only 2.8% in 2008. The recession also made it difficult for many Americans to afford private health insurance coverage, leading to lower growth in private health insurance benefit spending which slowed to 3.9% in 2008."

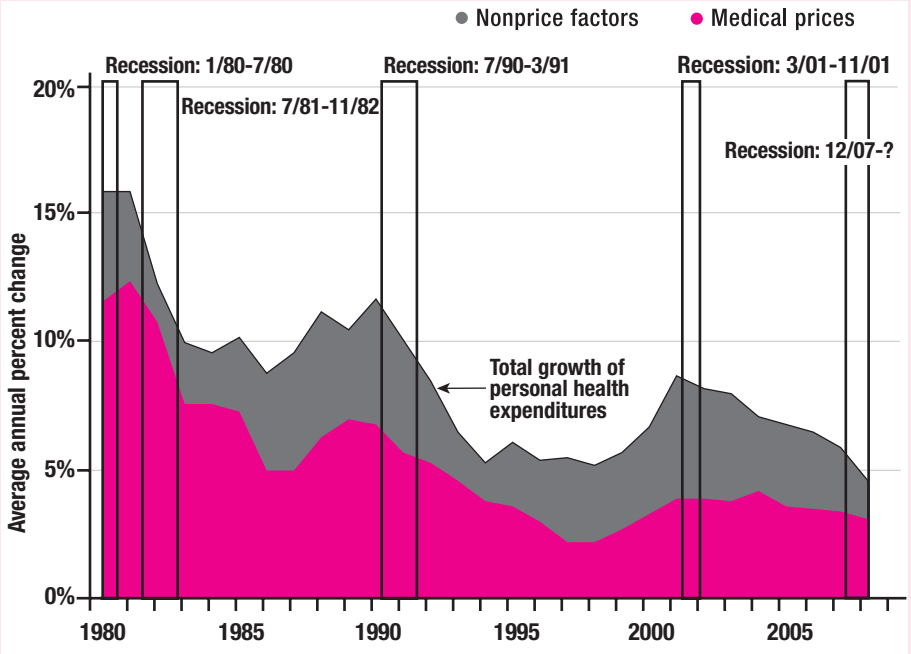
Federal Health Spending

Meanwhile, federal spending on health increased. CMS reported that the federal share of the nation's medical bill reached a record high of 35%. A rise in fee-for-service Medicare expenditures led to an 8.6% increase in Medicare spending, compared to a 7.1% increase in Medicare spending during 2007. The Medicare program spent $469.2 billion in 2008.

By combining federal and state spending on both Medicare and Medicaid, CMS says total government spending grew 6.5% percent in 2008, the same rate as in 2007.

Experts pointed to the recession to explain the health sector's stunted growth. Paul Ginsburg, President of the **Center for Studying Health System Change**, focused on the recession's immediate impact on household spending. With many consumers feeling significant financial stress, Ginsburg noted that the modest rate of increased health spending should not be a surprise. "The slowdown was strictly a result of the recession," Ginsburg said. "This isn't some new world of healthcare spending on a slower trend."

Personal Health Expenditures: Factors in 1980–2008 Period



This chart was produced by the Centers for Medicare and Medicaid Services (CMS). It shows how medical prices and non-price factors have contributed to the yearly rate of increase in personal healthcare expenditures. Each recession period is marked to show how such economic contractions affected the yearly rate of increase. One interesting observation is that this chart shows a trend of declines in the average annual rate of increase over the entire 28 years covered by this chart. Also, the era of gate-keeper model HMOs and their impact on the rate of increase can be clearly seen during the years 1992-1998.

"Despite the overall slowdown in national health spending growth, increases continue to outpace growth in the resources available to pay for it," CMS officials noted in the journal *Health Affairs*, which reported CMS's findings.

Richard S. Foster, Chief Actuary for the CMS, wrote the report. He expressed concerns that the health care reform will not sufficiently deal with the problem of increasing costs. "There is a very serious risk that the program would become unsustainable," wrote Foster.

A bit of irony can be found in the news that health spending in the United States increased at the lowest annual rate in 50 years. That's because several credible experts predict that the health legislation seemingly near Congressional approval will actually cause the annual rate of health spending to increase at a faster pace.

What is problematic for clinical laboratories is the fact that utilization of lab tests continues to increase sharply even as public and private payers continually squeeze down reimbursement. TDR

Two Big Pathology Groups Tap Investors for Capital

Each deal infuses new capital in the group, while leaving pathologists with significant control

CEO SUMMARY: Pathology supergroups in California and Tennessee have each announced major recapitalizations. Both groups will use some of the money to cash out retiring partners. The balance of the new capital will be used to expand their businesses. With so many baby boomer pathologists approaching retirement, these two transactions are likely to be studied by many pathology groups and should be considered early examples of a trend that is soon to become more prominent.

PATHOLOGY GROUPS across the United States are taking active steps to deal with the looming retirements of their partner pathologists. As this happens, it creates an opportunity for professional investors to take an ownership position in these pathology groups.

This seems to be true in several recent venture capital transactions announced in the final months of 2009. One example is the deal between **Pathology, Inc.** of Torrance, California, and a consortium of investment companies that included **ABS Capital Partners**, **England & Company**, and **Orix Venture Finance LLC**. This agreement was signed in October and the total investment amount was not disclosed.

Recent M&A Activity

A more recent example is the recapitalization undertaken by **PathGroup, Inc.**, of Brentwood, Tennessee. On January 5, 2010, it announced a $100 million funding agreement. Taking a minority investment position in PathGroup were **Primus Capital Funds** of Cleveland Ohio, and **Brentwood Capital Partners LP**, of Brentwood, Tennessee.

Included in the recapitalization was a syndicate of lenders that included **Bank of America** and **Fifth Third Bank**. Subordinated debt was provided by **Maranon Capital LP**, of Chicago, Illinois.

These transactions have at least two elements in common. First, each pathology group retained significant control of its business. Second, each pathology group will use some of the proceeds to close out the partnership interests of retiring pathologists.

These two transactions continue a pattern that has emerged over the past year. Much of the merger & acquisition (M&A) activity involving pathology groups and pathology labs during this time are motivated by the need of a pathology group to accommodate the retirement plans of partner pathologists.

For that reason, the number of pathology group practices involved in M&A activity and recapitalization deals will increase during the next few years. After all, the oldest of the baby boomer generation of pathologists have now reached the age where they can qualify for Social Security and Medicare benefits. The long-

predicted day of reckoning is arriving at many pathology groups across the nation.

What is notable about the Pathology, Inc. and PathGroup transactions is that both pathology groups rejected the option of an outright sale of their pathology group to a buyer. Instead, both groups decided to raise outside capital, using a deal structure which continued their ownership and business control.

This seems to be an emerging theme in merger and acquisition activity involving pathology groups. Last year, **UniPath, Inc.**, of Denver, Colorado, took a similar approach. It sold its histology laboratory business to **American Pathology Partners, Inc.** (APP), of Brentwood, Tennessee, while keeping 100% ownership of its professional corporation. As part of the transaction, the UniPath pathologists have an agreement with APP to provide pathology professional services. *(See TDR, February 2, 2009.)*

Looming Wave Of Retirees

Thus, the looming retirement of baby boomer pathologists is poised to drive up the number of pathology group acquisitions and recapitalizations that happen each year. This trend will be a direct response to the need to cash out retiring partners.

Increased M&A activity within the pathology profession will have another consequence. Pathology groups which sell to a buyer or accept investor money will have to adopt a more aggressive business posture in the marketplace.

That means more competition at the regional and national level within the pathology profession. Companies that purchase pathology groups will want them to increase specimen volume and revenue. Expect to see Pathology, Inc. and PathGroup—having accepted investor capital and having added representatives of the investor groups to their board of directors—take steps to intensify growth by the use of expanded sales programs.

Another source of fuel for these fires is keen investor interest in molecular diagnostics specifically and laboratory testing generally. Over the past 15 years, a succession of clinical laboratory and pathology companies have returned handsome profits to professional investors.

Investors view pathology laboratories as perfectly placed to benefit from three developments. One development is the steady introduction of genetic and molecular tests for cancer and other diseases. These allow pathologists to offer physicians more precise information for diagnostic and therapeutic decisions.

The second development is the emergence of companion diagnostics and personalized medicine. Pathologists will be a central player in these developments.

The third development is strong demand for lab testing that is expected as the population ages. This will increase the incidence of cancer and other diseases related to aging.

Collectively, this means that the pathology testing marketplace will become more competitive, more intense, and less friendly than it has been during the past two decades. Further, because baby boomers make up between 25% and 30% of the total pathologists now practicing in the United States, this trend will be widespread and will touch almost every community in the nation.

Early Warning Of New Trend

These insights provide an early warning to all pathologists and their practice administrators. The need for pathology groups to finance the buy-outs of their retiring partners is about to become an important trend.

It means that every private pathology group practice should be developing at least two strategies. One strategy is internal and should address the retirement situation within the group. The other is external and should anticipate how intensified competition for biopsies in the local service market can be countered. TDR

Pathology, Inc. Sells Equity to Raise Capital

Pathology group accesses growth capital by selling shares to professional investors

CEO SUMMARY: In looking how to propel its business to the next level, the partners at Pathology, Inc., opted not to sell their pathology group practice. Instead, they chose to raise capital by selling equity in their company to a group of investors. In this exclusive interview, executives from Pathology, Inc., share their business strategy. Among the priorities are expansion of the sales and marketing program, possible acquisitions of other lab companies, and acquiring sophisticated information technology.

IS IT A COINCIDENCE THAT, in the space of a few weeks, two of the nation's pathology supergroups raised substantial amounts of capital by selling a significant interest in their pathology groups to professional investors?

Alternatively, do these two transactions signal the leading edge of an emerging trend in the pathology profession? To learn more, THE DARK REPORT caught up with the executive team from Pathology Inc. of Torrance, California.

As reported on pages 13-14, **Pathology, Inc.**, raised an undisclosed, but substantial, amount of capital by selling a majority interest in its pathology corporation to a consortium of investment companies that included **ABS Capital Partners**, **England & Company**, and **Orix Venture Finance LLC**. This agreement was signed in October.

Participating in the following interview were Alfred Lui, M.D., Chairman of the Board; Vicki DiFrancesco, Pathology Inc.'s new CEO and President; and a new board member, Mark Anderson, who is General Partner at ABS Capital.

EDITOR: Let's begin this discussion with how Pathology, Inc., intends to use these funds? Does your business strategy include acquisitions of other anatomic pathology laboratories?

DIFRANCESCO: Yes. We intend to pursue acquisition opportunities that would support our business plan. Since we are still in the midst of evaluating all our business options, I can't be more specific. We are looking at acquisition targets that include companies in diagnostics and in IT, as well as other pathology groups.

EDITOR: As a pathology company with strong roots in Southern California, do you have plans to expand into new regions across the country?

DIFRANCESCO: We definitely want to expand in the West and have already invested in additional sales and marketing personnel specifically to pursue the goal of expanding outside of California. Several different regions are under evaluation.

EDITOR: Vicki, you have a reputation for moving swiftly and aggressively to exploit

sales and marketing opportunities. What has changed already with Pathology Inc.'s management team?

DIFRANCESCO: At the executive level, Rob Albert came aboard as our Executive Vice President, and COO. He was most recently with **Laboratory Corporation of America** and brings over 20 years of experience in operations, business development, and strategic planning. Another new member to the team is Ron Blum, Ph.D., who is Vice President of Marketing and Research & Development. Ron was with **Specialty Laboratories** for 11 years and most recently with **Diagnocure** and **Exiqon Diagnostics**. These individuals bring important management skills and experience to our company.

EDITOR: Any changes to the sales force?

DIFRANCESCO: Certainly. Previously, we had nine people in sales at Pathology, Inc., and within the next six months that number should increase to about 15 sales professionals. We have already added what I consider to be several "high-powered" sales professionals, including Michael Mosunic as the new Director of Sales.

EDITOR: Pathologists reading this interview will be interested in why the partner pathologists felt this was an auspicious time to restructure their lab company, accept money from professional investors, and put the pathology business into a faster growth mode. What are the key elements in your strategic thinking?

DIFRANCESCO: My answer may surprise some of your readers. We consider these developments to be a natural progression in the business development of Pathology Inc. in response to ongoing evolution in the marketplace. The company needed additional capital to invest in new technologies to stay at the leading edge of clinical practice.

EDITOR: What technology areas are priorities for you?

DIFRANCESCO: Ongoing advances in molecular and genetics testing require a state-of-the-art pathology company to make regular investments to acquire both the equipment and the skilled personnel to perform such assays. These services must be supported by sophisticated information technology and digital pathology capabilities.

LUI: I agree with Vicki and would like to comment on this point. One obvious trend in healthcare is to improve outcomes and be proactive in disease prevention and management of chronic conditions. Our partners at Pathology, Inc., recognized that we needed more resources if we were to continually compete successfully in these areas.

"Ongoing advances... require a state-of-the-art pathology company to make regular investments to acquire both the equipment and the skilled personnel to perform such assays."

EDITOR: Is personalized medicine and companion diagnostics on Pathology, Inc.'s radar screen?

LUI: Without question. Pathology testing will expand rapidly in support of personalized medicine. Pathologists already see a steady expansion in the number of companion diagnostic tests that support specific therapeutic drugs. We will be investing to maintain our capabilities in these clinical areas.

EDITOR: Could you address what kind of spending is planned for information technology (IT) improvements and digital pathology systems?

DIFRANCESCO: Information technology is a cornerstone of the high service pathol-

ogy laboratory and the recapitalization now gives us the resources to further develop what is already a robust IT capability. We want our use of advanced IT to be a source of competitive advantage in the marketplace.

EDITOR: Pathology, Inc., already has significant expertise in digital pathology. Do you plan to leverage this new funding to increase or change the way you use digital pathology technologies in your practice?

DIFRANCESCO: Currently, we have the ability to do digital consultations. We are preparing to launch a virtual imaging system in the near future. We want to be on the leading edge of digital pathology. Eric F. Glassy, M.D., a previous owner and current shareholder here at Pathology, Inc., sits on the advisory board of **Aperio Technologies, Inc.**, of Vista, California. This keeps him plugged in to the newest digital pathology technologies.

EDITOR: I'd like to shift gears for a moment, and ask why investors were interested in Pathology, Inc.? Would you explain why ABS Capital Partners and the other equity partners made this investment at this time?

ANDERSON: At ABS Capital Partners, we are big believers in the lab market (both anatomic and clinical). Previously, we were investors in **U.S. Labs** and **American Esoteric Laboratories**, which were sold to LabCorp and **Sonic Healthcare**, respectively. We believe Pathology, Inc., has established a good platform. Vicki has put together an excellent management team, each with a proven track record of growing a company with a focus on customer service.

EDITOR: You are obviously optimistic about the prospects for laboratory testing.

ANDERSON: That is true. We believe the demand for laboratory testing will continue to increase in coming years. Moreover, the fact that lab tests influence between 60% to 70% of all medical decisions is one factor that makes labs an essential element within the healthcare delivery system.

EDITOR: Do demographics contribute to your confidence that investments in laboratory testing have solid potential?

ANDERSON: When you combine the essential role of laboratory testing to support accurate diagnosis with projected long-term demographic trends, including the aging of the population, then you can see that these two factors will have a direct effect on utilization. Couple these elements with the shift in healthcare's emphasis on prevention and early detection of disease, and it makes for a very compelling opportunity. These trends are among the reasons we believe the laboratory market is quite attractive from an investment perspective.

EDITOR: With a major healthcare reform bill pending, do you believe that an emphasis on illness prevention and early detection of disease would boost the fortunes of laboratories?

ANDERSON: Predicting what Washington will do is best left to the experts. However, my view is that the lab industry would benefit from expanded coverage because of the emphasis on both wellness and preventative medicine. Further, I believe any lab that provides superior service and delivers a broad range of testing services will emerge as one of the leaders, regardless of what happens with healthcare reform.

EDITOR: As an investor, what do you consider the strengths of Pathology, Inc.?

ANDERSON: We think the company is particularly well positioned. One main objective of Pathology, Inc., is to be a leader in the women's health market by providing superior service and rapid turnaround times. This builds upon the lab's strong reputation in Southern

California as a respected provider of integrated diagnostic services created by Dr. Lui and his colleagues. Looking at long-term growth opportunities, they include further penetration into the existing markets that we serve with current and newly developed tests, in addition to appraising strategic acquisitions.

EDITOR: Mark, as a professional investor, could you comment on what is happening with valuations of clinical labs and pathology groups in recent years?

ANDERSON: There has been an interesting change in how investors value a laboratory company. It was common for a laboratory valuation to be based on a multiple of revenue. That is less true today. Now investors want to look at the lab's EBITDA (earnings before interest, taxes, depreciation, and amortization) and base the value on a multiple of the company's EBITDA.

> **"Investors tend to use a higher multiple when valuing labs and pathology groups that demonstrate sustained growth and profits."**

EDITOR: Is there a reason for this change?

ANDERSON: This shift occurred in part because of the recent market correction. Laboratories are like a lot of other businesses in that profitability and cash flow are key indicators of the health of a company. EBITDA can often be a more accurate indicator of a company's valuation than revenue.

EDITOR: What helps a laboratory earn a higher valuation?

ANDERSON: Lab companies that show a multi-year track record of strong growth and EBITDA margins are generally rewarded with a premium valuation.

EDITOR: What multiple of EBITDA can be expected by a lab seller?

ANDERSON: Historically, EBITDA multiples have been in the single-digit range. Investors tend to use a higher multiple when valuing labs and pathology groups that demonstrate sustained growth and profits.

EDITOR: Staying on the theme of valuation and lab mergers and acquisitions, it was known that your group had discussions with interested buyers. With other pathology groups around the country considering their different business options, would you tell us why Pathology, Inc., chose this vehicle for accessing capital?

LUI: In part, the timing of this transaction is related to the career planning of several of the previous major shareholders. Some of the previous partners recognized that their retirement was not far off. Thus, issues like the possibility of future increases to the capital gains tax rate were a factor.

EDITOR: Given the decision not to sell, I assume that one consideration was the future of the lab staff and people who have been part of Pathology, Inc., for many years.

LUI: That is true, and it is connected to another goal that I want to emphasize here. By recapitalizing Pathology, Inc., in this manner, it becomes a platform laboratory for sustained growth. That would not happen if our lab was acquired and consolidated or merged by the buyer.

EDITOR: The insights the three of you have shared about the pathology marketplace and how Pathology, Inc., is positioning itself for ongoing growth are quite useful. Thank you for taking the time to provide this information.

LUI: You are welcome. As you have learned, we are quite bullish about all the opportunities in pathology testing and Pathology, Inc., is ready to set a high standard in the marketplace. TDR

Contact Vicki DiFrancesco at 310-225-3147 or vdifrancesco@pathologyinc.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Probably few pathologists know that a musical group in San Diego, California, is performing under the name "Pathology." It is classified as an American death metal band. Alert readers will notice a theme in this band's output. In 2006, it released its debut album, called "Surgically Hacked," which featured such songs as "Postorbital Incision" and "Septic Shock." Pathology's next release was the album "Incisions Of Perverse Debauchery" in 2007, followed by the tamely-named "Age Of Onset" in 2009. The record labels were Amputated Vein Records, Grindhead Records, and Comatose Records, respectively. Anyone interested in checking out "Pathology" can visit their MySpace account at *http://-www.myspace.com/pathologydm.*

MORE ON: *Bands*

A bit of web research surfaced another band called "Pathologist." This group formed in Ostrava, Czech Republic, back in 1990. It is categorized as a death-metal/grindcore band. The group was reformed in 2008, In 2009, Pathologist released its latest offering, "Under The Mortician's Knife." It doesn't appear that any of the musicians associated with either "Pathology" or "Pathologists" are board-certified pathologists.

ADVAMED CREATES NEW DIAGNOSTICS ADVOCACY EFFORT

Last month, the **Advanced Medical Technology Association** (AdvaMed) announced formation of a new division to concentrate on issues of concern for *in vitro* diagnostic (IVD) manufacturers. Called **AdvaMed Dx**, governance will be through a Board of Directors numbering 18 members, of which eight members will form an Executive Committee. AdvaMed Dx's first Chairman of the Board will be Scott Garrett, who is the Chairman, President and CEO of **Beckman Coulter, Inc.**, of Brea, California. There will also be a full-time executive director and a director of communications.

TRANSITIONS

• **NeoGenomics, Inc.**, of Ft. Myers, Florida, appointed Jack G. Spitz as Vice President of Laboratory Operations. Spitz has served in executive positions for **Quest Diagnostics Incorporated**, **AmeriPath, Inc.**, and **Genova Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 15, 2010.

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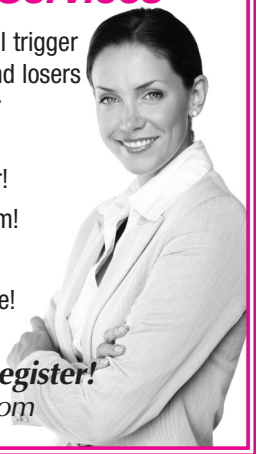

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