Volume XVI, Number 17 Monday, December 14, 2009

2009 TOP TEN

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Utilization Is Healthcare's Ticking Time Bomb

TODAY I WOULD LIKE TO SPEAK TO ONE OF THE ELEPHANTS IN THE LAB INDUSTRY'S ROOM. It is the ticking time bomb of lab utilization. Sometime in the next 36 to 60 months, this time bomb will go off. It will catch both health policy makers and payers unprepared and, the consequences will be corrosive to the laboratory testing profession.

Going forward, three trends will drive utilization of lab testing. One trend is the increased volume of lab tests ordered by physicians who are responding to pressures and financial incentives to provide all the recommended care to 100% of their patients. For example, think of 100% of diabetic patients getting HgA1c tests annually at the same time that doctors diligently work to diagnose more of the tens of millions of undiagnosed diabetics in this country. The increased utilization of lab tests is a result that is desired by the health system.

Second is the natural uptake of lab testing that occurs as baby boomers leave their fifth decade of life and push into their sixth decade. Both payers and laboratories that bid private Medicare contracts know that, on average, an individual 65 years and older, uses more than four times the number of lab tests per year than a commercial life. Again, this increased utilization is a natural consequence of the aging process and the system should ethically be prepared to provide those services, as appropriate.

Third is the ongoing addition of new diagnostic tests to the existing lab test catalogue. As physicians have new diagnostic assays that support more precise and earlier diagnosis for an expanding number of diseases, they will naturally and appropriately order a higher volume of tests. As with the two other trends, this trend underpins higher diagnostic and treatment accuracy—which benefits the healthcare system by reducing the overall cost per episode of care.

However, in THE DARK REPORT'S travels across the United States and a number of other developed countries in Europe and the Pacific Rim, it has been unable to identify any government health system or healthcare policy maker which recognizes and discusses these approaching developments. This lack of perceptive analysis about the essential value of clinical laboratory testing, in the context of the three trends described above, represents a "black hole" for the lab medicine profession. It means that health policy makers are not likely to establish budgets and reimbursement for lab testing based on the most relevant factors. As that happens, further underfunding for lab testing will occur. TDR

2009's Top Ten Lab Stories Reflect Some Good, Bad

Year unfolds with a mixed bag of developments even as economic recession dampens activity

CEO SUMMARY: As the closing year of the first decade of the new century and the new millennium, 2009 brought neither disruption nor upheaval to the majority of laboratories in the United States. Rather, it was marked by at least two themes. One was how public disclosure of problems with lab testing services generated media headlines. The other was economic, and ranged from the effects of the recession to how specific healthcare reform proposals might negatively affect the financial status of laboratories.

TAKEN AS A WHOLE, 2009 was not an auspicious year for laboratory testing and the pathology profession. All the blame can not be attributed to the ongoing economic recession, the deepest in this country since 1981-82.

A careful review of THE DARK REPORT'S list of the "Top Ten Lab Stories for 2009" indicates that six of the most significant stories reflect negative events, either for specific laboratory companies or for the collective lab testing industry. These range from issues involving the accuracy of lab testing services at some laboratory companies to budget cutbacks at most hospital labs and unprecedented proposals to tax laboratory services as a way to help pay for reforms to the nation's healthcare system.

In fact, 2009 brought at least four important reminders to pathologists and clinical lab administrators that public trust in the integrity of laboratory testing services makes any deviation from this assumption into a national news sensation.

Two of these stories involved **Quest Diagnostics Incorporated**. *(See page 5.)* One story involved the District Health Boards of Auckland, New Zealand, and **Labtests**. *(See page 8.)* Canada had a new revelation about issues in the accuracy of breast cancer testing, this time in the province of Quebec. *(See page 7.)*

In all these situations, media coverage of laboratory issues attracted much public attention. That should be no surprise, since the quality and integrity of laboratory testing services is generally taken for granted in most developed countries. Thus, news that a laboratory may have reported inaccurate results or had service

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.)**

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes *THE DARK REPORT* plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

disruptions that affected many patients and physicians, is the kind of news that fits the "man bites dog" metaphor.

Moving to the financial domain, 2009 was not an auspicious year for the laboratory industry at large in the United States. In particular, hospital laboratories were under pressure to spend less money than authorized in their original budgets as their parent hospitals and health systems responded to declines in the value of investment portfolios and reduced admissions. These spending cutbacks had an impact on *in vitro* (IVD) diagnostic manufacturers and several other sectors of the lab service industry. *(See page 6.)*

➤$750 Million Lab Tax Averted

Another major financial hit was averted, at least for the moment, when a proposed annual tax of $750 million on laboratory testing services was deleted from the language of a health reform bill written by the Senate finance committee. However, the trade-off was for the lab industry to accept less reimbursement in coming years under the Medicare Part B fee schedule. *(See page 6.)*

One bright spot during 2009 was the fact that the Novel A/H1N1 influenza strain failed to become more virulent or lethal during the fall flu season. So far, the nation's clinical labs have not experienced an overwhelming demand for flu tests. *(See Page 7.)*

Another positive story was how **Catholic Health Systems** (CHI) of Denver, Colorado—at $8.6 billion, one of the country's largest health systems—intends to pursue a cornerstone strategy of profitable growth in outreach laboratory testing. To achieve this, it became an equity owner in **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington. Together, CHI and PAML will develop laboratory outreach joint ventures with the 78 CHI-owned hospitals located in 20 states. *(See page 9.)*

This affirmation in the value of a hospital laboratory outreach testing program is a positive sign for the laboratory industry. It is powerful evidence that hospital and health system administrators are waking up to the fact that the clinical laboratory is a valuable asset that has been underutilized in supporting their organization's most important strategic goals.

➤Decade Is Soon To End

It should be noted that we are approaching the end of the first decade of this new century and this new millennium. The 2000s is a decade that lacked many of the disruptive events of the 1990s.

The years between 1990 and 1999 were marked by gatekeeper HMOs; capitated, full-risk managed care contracts; widespread consolidation within the commercial lab sector; and rapid concentration of hospital ownership—which triggered significant consolidation within the hospital laboratory sector. Over the course of the decade, few labs were untouched by the consequences set loose by these trends.

By contrast, the years 2000-2009 were marked by a relative stability within the clinical laboratory industry. If a trend was transformative, it acted in a slower fashion. Thus, advances in the technology and performance of laboratory automation solutions came at a steady pace. The advent of Lean and Six Sigma in laboratories and hospitals has similarly occurred at a measured pace. Genetic testing and molecular diagnostics have yet to be a rapidly disruptive force in laboratory medicine.

➤Evolutionary Forces

Thus, it can be argued that 2009 was a generally quiet year for clinical laboratories and the pathology profession. But it would be a strategic mistake not to study the most significant events of the year as a way to understand how they represent the evolutionary forces that are always shaping how laboratories serve physicians, patients, and payers. **TDR**

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TOP TEN no. 1 stories 2009

STORY NUMBER ONE

Quest Diagnostics' Vitamin D Test Alert/Retest Effort Makes Headlines

DURING THE FIRST DAYS OF 2009, **Quest Diagnostics Incorporated** found itself in the eye of a national media storm due to potentially erroneous results for Vitamin 25 (OH)D tests that the company acknowledged it had reported on an undisclosed number of patients.

Starting in early 2007 and running into 2008, Quest Diagnostics stated that it had reported "potentially inaccurate results" produced by its laboratory developed test (LDT, or home brew) LC-MS/MS method for Vitamin 25(OH)D.

It was January 8, 2009, when the *New York Times* published a story about the matter titled "Quest Acknowledges Errors in Vitamin D Tests," after learning about the situation from THE DARK REPORT'S coverage of this issue just days earlier. *(See TDR, December 22, 2008.)* Public knowledge of these problems first surfaced in October 2008 when Quest Diagnostics launched a campaign to alert physicians to "questionable results" for Vitamin D tests and to offer free retesting to those patients.

For the next several days, the national media covered the story that a major lab company was contacting thousands of physicians to advise them of the situation and offer free retesting to patients.

For the greater lab testing profession, these events were a powerful reminder that trust in lab test accuracy lies at the heart of every clinical laboratory's relationship with the physicians and patients it serves. Thus, whenever that trust is breached by news of potentially inaccurate lab testing, it can become a major news event.

TOP TEN no. 2 stories 2009

STORY NUMBER TWO

Quest Diagnostics Pays $302 Million To Resolve Federal Qui Tam Lawsuit

ON APRIL 15, 2009, **Quest Diagnostics Incorporated** found itself again in the national news. That was the day that the United States Attorney's Office for the Eastern District of New York announced a settlement with the company that it characterized as one of the largest federal settlements ever to involve a medical device.

The global settlement with the federal government involved Quest Diagnostics Incorporated and its now-defunct subsidiary, **Nichols Institute Diagnostics** (NID). One part of the global settlement involved a guilty plea by NID "to a felony misbranding charge in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq" related to the problems in the performance of the NID Advantage Intact PTH Assay for about a six-year period of time ending in 2006, according to the U.S. Attorney's Office. A $40 million criminal fine was paid by NID. Quest was not charged with any crime.

The global settlement also included an agreement by Quest Diagnostics to pay approximately $262 million "to resolve federal False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly provided inaccurate and unreliable results," the U.S. Attorney's Office announced. A Corporate Integrity Agreement between Quest and the OIG was also part of the global settlement.

TOP TEN no. 3 stories 2009

STORY NUMBER THREE

Hospitals Prune Budgets, Causing Laboratories to Rein in Spending

FOR HOSPITAL LABS, 2009 was a tough budget year. In response to the long-lasting recession, hospitals and health systems slashed budgets. It meant that hospital labs were asked to reduce current spending below authorized budget levels. *(See TDR, March 16, 2009.)*

The impact of this belt-tightening was felt by the *in vitro* diagnostics (IVD) manufacturers and other lab vendors. Many hospital laboratories deferred capital spending as one strategy to cut overall spending and stay under budget. However, because many analyzers and instrument systems are sold under "per click" or reagent rental arrangements, IVD manufacturers have done better during 2009 than their counterparts in radiology and durable medical equipment.

Another consequence of budget belt-tightening by hospital labs was a decline in attendance at many laboratory meetings and conferences. At the same time, because of more stringent Medicare compliance regulations, many lab industry vendors were spending fewer dollars on promotional activities at national and regional laboratory meetings.

This was the first time since the deep recession of 1981-82 that the nation's hospitals and laboratories have had to cope with an economy in sharp decline. Economists believe that it may not be until the second half of 2010 before unemployment rates begin to drop significantly. If this proves true, labs will likely continue to carefully monitor spending throughout 2010.

TOP TEN no. 4 stories 2009

STORY NUMBER FOUR

Labs Dodge $750 Million Annual Tax Proposed in Baucus Reform Bill

EFFORTS BY CONGRESS AND THE NEW ADMINISTRATION to enact deep reforms to the existing health system have dominated headlines throughout 2009. Lawmakers targeted every sector of healthcare to seek concessions on future reimbursement as a way to find money to fund health reform proposals.

The laboratory industry was no exception. In September, it found itself in the tax increase cross hairs of the Senate Finance Committee. A version of the committee's health reform bill called for a new $750 million annual performance tax on clinical laboratories. *(See TDR, September 21, 2009.)*

This tax was to be assessed on the relative market share of clinical labs covered by the proposed legislation. The Secretary of Treasury would determine the assessment. As well as the proposed $750 million annual tax, this version of the Senate bill proposed cuts in future funding of lab testing services.

Then, in negotiations with members of the Senate Budget Committee and their staff, the laboratory industry was able to get the proposed $750 million annual lab tax dropped from the bill. However, future cuts to the Medicare lab fee schedule remain. According to current numbers provided by the **American Clinical Laboratory Association** (ACLA), the lab industry may face up to a 9% reduction in projected Medicare spending during the next 10 years.

TOP TEN no. 5 stories 2009

STORY NUMBER FIVE

Labs Experience Quiet Fall Flu Season Despite More Cases of Novel A/H1N1

FOLLOWING THE TUMULTUOUS EMERGENCE OF NOVEL A/H1N1 during the spring, it has been a relatively quiet fall influenza season for most labs across the country.

Fears that Novel A/H1N1 might evolve into a more virulent or lethal form of influenza have not been realized to date. Nor have the nation's laboratories seen a comparable demand for influenza testing as was experienced last spring, when the Novel A/H1N1 influenza strain surfaced in Mexico and went global. *(See TDR, June 8, 2009.)*

In fact, the unexpected emergence of Novel A/H1N1 flu last spring provided ample evidence of how molecular technologies and other advances in laboratory medicine now provide pathologists and laboratory scientists with a wide range of enhanced capabilities, including rapid testing.

Within weeks of identifying the new strain of influenza, a number of laboratories, ranging from the **Centers for Disease Control and Prevention** (CDC) to independent commercial labs, had developed assays that were useful in identifying Novel A/H1N1.

This was a faster response than what followed the outbreak of SARS (severe acute respiratory syndrome) and the identification of this new strain of coronavirus in 2003. It demonstrates how the steady improvements in molecular technologies are compressing the time required to identify a new infectious agent and produce a lab test that can detect that agent.

TOP TEN no. 6 stories 2009

STORY NUMBER SIX

Testing Failures in Canadian Labs Are Warning to Govt. Health Programs

DEFICIENCIES IN BREAST CANCER TESTING in the province of Quebec caused headlines mid-year. This came only weeks after a respected judge in Newfoundland released her long-awaited report on the laboratory problems that contributed to inaccurate ER/PR test results on hundreds of patients in the province.

It was March 3 when Judge Margaret Cameron released the report of her commission. The commission published a list of laboratory problems that contributed to at least 386 breast cancer patients getting inaccurate test results between 1997 and 2005. The latter date was when failures in the laboratory conducting ER/PR testing for Newfoundland and Labrador became public. *(See TDR, May 18, 2009.)*

Then, in May, health officials in Quebec acknowledged they had received a report on the results of a study on the accuracy of breast cancer testing performed by a number of labs in the province. This report indicated the existence of significant problems.

By July, Quebec's health minister confirmed that the lab results of 2,730 cases of breast cancer were undergoing review by a laboratories outside the province. This covered patients tested between April 1, 2008, and June 1, 2009.

The Canadian press has reported similar quality issues in pathology labs in three other provinces. Collectively, these issues provide evidence that decades of underfunding for lab testing services may now be a factor in these lab problems.

TOP TEN no. 7 stories 2009

STORY NUMBER SEVEN

Cost of Whole Genome Sequencing Falls as Low as $20,000 per Person

WHOLE HUMAN GENOME SEQUENCING is closing in on the $1,000 target. It is a goal that may be achieved within the next 12 to 18 months.

It could mean at least one company will be capable of quickly and accurately sequencing the 3-billion base pair human genome for $1,000 or less. Experts believe the $1,000 whole human genome sequence will initiate a gold rush for the sequencing industry.

At the forefront of this competition is **Complete Genomics, Inc.**, of Mountain View, California. It says it can now sequence the whole human genome for approximately $4,400 in materials and—for orders of eight or more genomes—will price each complete human genome sequence at $20,000.

Not far behind is **Illumina, Inc.**, of San Diego, California. This company is pricing its whole genome sequence at $48,000—and has customers at this price! *(See TDR, November 23, 2009.)*

These fast-moving events serve notice to pathologists and lab administrators that the gene sequencing business is going to change radically over the next year or two. The same technology which is rapidly cutting the cost of sequencing a single DNA base pair will find its way into clinical molecular diagnostics.

This creates a double-edged opportunity for labs. One edge is the ability to perform sophisticated molecular analysis. The other edge is to offer the information technology needed to store and evaluate the genetic sequences.

TOP TEN no. 8 stories 2009

STORY NUMBER EIGHT

Auckland Lab Contract Decision Disrupts Physicians and Patients

IT WAS A PAINFUL DOSE OF REALITY for physicians and patients in Auckland, New Zealand. Start up of a new, exclusive contract laboratory provider in the region earlier this year triggered considerable disruption to the region's healthcare system.

This began in August as **Labtests** initiated service to 12,000 patients per day from a newly-constructed, newly-equipped, and newly-staffed lab. Despite three years of District Health Board assurances that the transition to Labtests from the previous exclusive lab provider, **Diagnostic Medlabs** (DML), would be seamless and transparent, just the opposite happened when the new contract started. *(See TDR, September 21, 2009.)*

This situation is an important story for pathologists worldwide, due to at least two reasons. First, it provides an early example of what happens when a government health service pursues cost savings in spite of the risk that lesser amounts of funding for laboratory testing might be associated with widespread service deficiencies and breakdowns in patient care.

Second, the Auckland DHBs implemented a plan for lab testing services never before attempted in the world until now. They tried to build, equip, staff, and initiate, from a near standing start, service with a new clinical lab facility that would serve 12,000 patients per day. It was no surprise to laboratory professionals that widespread problems resulted.

TOP TEN no. 9 stories 2009

STORY NUMBER NINE

Companion Diagnostics Activity Gains Momentum During 2009

IT WAS A BUSY YEAR FOR COMPANION DIAGNOSTICS. A number of prescription drugs, each paired with a specific lab test, found favor in the clinical marketplace during 2009.

Herceptin and Her2neu are no longer the most compelling example of a therapeutic drug and companion diagnostic test. **Amgen, Inc.**, developed a K-RAS companion diagnostic that can predict whether a patient with metastatic colorectal cancer will respond to Amgen's drug Vectibix. Similarly, a K-RAS test is also used to predict response to the drug Erbitux, which only works for patients whose tumors are not mutated. Erbitux is sold by **ImClone, LLC**, which is owned by **Eli Lilly and Company**.

One confirming sign of the pharma industry's acceptance of the concept of companion diagnostics is an agreement announced this summer. **GlaxoSmithKline PLC** (GSK) is having **Abbott Laboratories, Inc.**, develop a PCR-based molecular companion diagnostic test to be used to qualify patients for GSK's MAGE-A3 Antigen Specific Immunotherapy (ASCI). The new test will be run on Abbott's automated *m*2000 molecular instrument system. *(See TDR, October 12, 2009.)*

All these deals point to a rosy future for companion diagnostics. As this area of clinical lab testing expands, pathologists and lab scientists will play greater roles in diagnostic and therapeutic decisions.

TOP TEN no. 10 stories 2009

STORY NUMBER TEN

Catholic Health Initiatives Invests In Pathology Associates Med Labs

IT IS NOTEWORTHY when one of the nation's largest health systems invests in a commercial laboratory company. Thus, the announcement by **Catholic Health Initiatives** (CHI) that it had taken a 25% equity ownership in **Pathology Associates Medical Laboratories** (PAML) was a major news story during 2009.

CHI, headquartered in Denver, Colorado, owns 78 hospitals in 20 states and has annual revenue of $6.8 billion. PAML, based in Spokane, Washington, is one of the largest independent laboratory companies serving the physicians' office segment of the lab testing marketplace. *(See TDR, November 2, 2009.)*

What makes this transaction significant is that a major health system is recognizing the value of laboratory outreach testing and taking steps to increase its participation in this clinical activity. CHI intends to have PAML develop a series of outreach laboratory testing joint ventures among the 78 CHI hospitals.

PAML says that plans are already complete to initiate between six and eight new lab outreach joint ventures with CHI hospitals during the next 24 months. This indicates that CHI is serious about tapping laboratory outreach testing as a way to improve relationships with local physicians, generate profitable cash flow, and create a valuable market asset from these laboratory outreach joint ventures.

DNV Offers Accreditation For Both CMS and ISO

➤DNV offers hospital accreditation that combines CMS CoP with ISO 9001 compliance

➤➤CEO SUMMARY: For about a year, hospitals and health systems have had a new choice for meeting the Medicare Conditions of Participation. This new choice is Det Norske Veritas (DNV). Because DNV offers a dual process for achieving Medicare accreditation and ISO 9001 certification, it brings client hospitals a different bundle of benefits. As hospitals adopt ISO 9001, it will require the clinical laboratory to align management and operations to the standards of this quality management system (QMS).

IT WAS MAJOR NEWS LAST YEAR when the **Centers for Medicare and Medicaid Services** (CMS) granted deemed status to **Det Norske Veritas** (DNV) to accredit hospitals in the United States. This was the first new hospital accrediting body that CMS had approved in 40 years.

But there is more to the story behind DNV's interest in accrediting hospitals in the United States. DNV wants to be on the leading edge of helping hospitals implement a quality management system (QMS). That is why its Medicare accreditation service gives hospitals the option of achieving certification after becoming compliant with ISO 9001. *(See TDR, June 8, 2009.)*

As more hospitals opt to pursue a dual objective of Medicare accreditation and ISO 9001 certification, this will change the management culture for laboratories serving these institutions. For this reason, it is helpful for laboratory administrators and pathologists to understand why DNV is gaining credibility as a resource to help hospitals meet their Medicare accreditation requirements.

According to DNV's Executive Vice President Patrick Horine, more hospital administrators are waking up to fact that, to be fully competitive in the changing healthcare marketplace, one critical success factor is to implement a QMS like ISO 9001. Horine was speaking at THE DARK REPORT'S *2009 Lab Quality Confab* in Atlanta last September.

➤Revolution Around ISO 9001

"Adoption of ISO 9001 is a revolution needed right now by hospitals and other providers across the entire healthcare system," declared Horine. "We pursued deeming authority with CMS so that we could contribute to this revolution.

"DNV has years of experience in working with hospitals," he noted. "From hospital to hospital, there was a lack of sustainability in improving clinical care and service execution. Too often, as a hospital instituted improvements and made changes to suit certain situations, it was often unable to sustain those improvements.

"We decided to take up that challenge and help hospitals achieve sustainability," said Horine. "In this regard, quality management systems, such as ISO 9001, have an established track record in many industries

and in many countries. This includes hospitals and other types of healthcare organizations in developed countries."

DNV has an ambitious goal. It wants to tie together the benefits of Medicare accreditation with the efficiency generated from ISO 9001 certification. "ISO 9001 is a quality management standard that places particular emphasis on leadership and accountability," explained Horine.

Offer Added Value

"The goal is to offer hospitals added value as they devote considerable resources to meet the CMS Conditions of Participation," he stated. "In working with hospitals in the United States, we've learned that the introduction of quality management concepts—ISO 9001 methods in particular—creates a useful way of holding hospitals accountable to a range of prescriptive measures, including CMS Conditions of Participation.

"The direct benefit is that participating hospitals get a lot more from CMS accreditation than a piece of paper that says, 'Hey, I can bill Medicare'," added Horine. "This is how we help a hospital client turn Medicare accreditation into a strategic business asset."

It is also why forward-looking hospital CEOs are interested in DNV's offer of helping hospitals meet the CMS Conditions of Participation while also gaining ISO 9001 certification. "Obviously, accreditation is the ticket to participating in Medicare and Medicaid, but is it really a strategic business asset for hospitals?" Horine asked.

Real Difference For Patients

"DNV offers something better, something that makes a real difference for patients and the community served by a hospital," he said. "We know that hospitals look at budgets, and many don't want to incur additional expenses to become ISO certified in addition to their existing expense of Medicare accreditation. However, additional expense to implement ISO 9001 is not the case. Hospitals are able to implement ISO 9001 without adding any new staff. They will have the same staff doing different things.

DNV Maintains 300 Offices In 100 Countries Worldwide

PRIOR TO GAINING STATUS from the Centers for Medicare and Medicaid Services (CMS) as a deeming authority, Det Norske Veritas (DNV) was relatively unknown in the American healthcare system, although it has operated in the United States since 1898.

Founded in 1864, it is not the typical for-profit corporation. *Wikipedia.com* writes that:

Stiftelsen Det Norske Veritas, or DNV, is a classification society organized as a foundation, with the objective of "safeguarding life, property, and the environment." The organization's history goes back to 1864, when the foundation was established in Norway to inspect and evaluate the technical condition of Norwegian merchant vessels. DNV describes itself as a provider of services for managing risk.

DNV operates 300 offices in more than 100 countries. In 2008, DNV reported revenue of approximately US$1.7 billion.

"We knew that, if a hospital had the option of achieving ISO in parallel with its CMS accreditation, this would be a budget neutral goal," added Horine. "It took five years to earn our deeming authority from CMS. Now we can offer both services to hospitals as a unified package."

DNV does recognize that many hospital administrators are unfamiliar with this approach for a quality management system and how ISO certification can benefit their organization. "It is natural not to accept what you don't understand," he said. "Thus, we devote the time necessary to help them fully understand this dual process.

"Becoming ISO compliant requires time," observed Horine. "It is something that evolves within the hospital as management at all levels gains maturity as they work to implement and sustain the QMS.

"DNV provides every hospital with an opportunity to keep its Medicare and

Medicaid accreditation while simultaneously setting up ISO methodologies," he noted. "A hospital has three years to become ISO compliant and we tell administrators to consider this to be a double-barrelled strategy. They can use their CMS accreditation process as a way to also implement ISO 9001 within their hospital."

"There are two more secrets that make this work," said Horine. "First, most hospital administrators come to see that CMS accreditation and ISO certification is a natural marriage. Second, as they gain this insight, they quickly recognize that many aspects of what their hospital needs to become ISO certified are already in place.

"These existing aspects may not be organized and operated as required by ISO 9001," he added. "ISO 9001 is the infrastructure of the organization's quality management system and describes 'what' has to be done to meet the requirements. The 'how' is left to the organization but this must be demonstrated to ensure the effectiveness of what is in place.

"DNV was founded in 1864 and its primary purpose is to safeguard life, property, and environment," commented Horine. "We bring lots of experience to this unfolding QMS revolution in healthcare. We hope to contribute to the changes unfolding in the culture of accreditation in hospitals and across healthcare."

Another Favorable Issue

Another issue may play to DNV's favor. Often hospitals feel that the overall process of meeting the CMS Conditions of Participation is adversarial. "DNV wants to be seen as a partner in these activities," observed Horine. "We want to be collaborative with hospitals to ultimately sustain a future of safety in patient care. And we want to do this with our accreditation process.

"DNV's goal is to help our client hospitals help their patients even as these hospitals are accountable for meeting requirements in place to ensure they remain compliant and effective," he noted. "Our role is to be a partner with the client hospitals to help them advance patient care and maximize their potential.

"To that end, we've done a few things to take the 'sting' out of the Medicare accreditation process," he said. "We don't have levels of accreditation status such as preliminary denial or conditional accreditation. A hospital is either accredited or it is not.

Not Focused On "Gotcha"

"If an accredited hospital does not follow through on corrective action plans, it moves into jeopardy status. It can lose its accreditation," explained Horine. "But DNV is not focused on the 'gotcha.' Our focus is to make sure each hospital addresses the things found during our survey process."

The practical benefits of DNV's approach are quickly understood by client hospitals. "Before, when a surveyor had already found a number of problems, the institution had no reason to help the surveyors find additional problems—since it could mean the hospital might lose its accreditation," observed Horine.

"By contrast, DNV wants hospital staff to be comfortable discussing concerns with their processes in order to demonstrate compliance," he continued. "Unless it involves an issue of an imminent threat to patient health or safety, an institution will have to correct the problems in order to be accredited, whether we find 5, 10, or 50 problems. We emphasize that we are here to help each institution be as transparent as possible and to use that transparency to continuously improve the services it delivers to patients. This is something hospitals are welcoming with open arms."

DNV's strategy of offering hospitals a way to earn Medicare accreditation along with a parallel effort to achieve ISO 9001 certification has attracted the attention of a growing number of hospitals. For lab directors and pathologists, this is another sign of how and why quality management systems (QMS) will become more common in the American healthcare system. TDR

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Lab Briefs

DNA NANOCHIP IS GOAL OF IBM SCIENTISTS

ADVANCES IN GENETIC AND MOLECULAR TECHNOLOGIES are giving pathologists new tools for diagnosing disease and guiding therapy. But what often receives less attention is how genetic and molecular technologies are finding applications in other scientific fields.

In the September issue of *Nature Nanotechnology*, researchers at **IBM Corp.** and **California Institute of Technology** published a paper describing efforts to build a computer microchip based upon DNA and other items. The scientists say they have found a way to use synthetic DNA and tiny lithographic templates to position carbon nanotubes, silicon nanowires and other elements to fabricate a nanochip.

The synthetic DNA allows them to place components as little as six nanometers apart. That's less than the thickness of a cell membrane. Features on the chips are as little as two nanometers wide, compared to the most advanced microchips today which have features that average 45 nanometers wide.

This technology won't be in the market tomorrow. IBM says it may take as long as 10 years to bring products incorporating this science to market. But it illustrates how technology based on DNA has the potential to find applications in a variety of non-healthcare applications.

HEALTH INFORMATION ON THE INTERNET CHANGES PATIENT–DOCTOR TALKS

IT'S TIME TO MEET THE "E-PATIENT." That is the new term to describe a patient who is getting health information from the Internet before going to visit his/her physician.

In Spain, researchers from the **Miguel Hernández University** surveyed 660 physicians who work in the **Spanish National Health System** and found that 90% of these doctors had been asked questions by their patients on health subjects the patients had studied on the Internet before their office visit.

At least 31% of the physicians in the survey stated that Internet-based health information complicates their relationships with patients and may even undermine the credibility of physicians. In fact, because of the belief that Internet information may lessen the credibility of physicians, some doctors in the survey said that they normally do not suggest web sites to their patients as a source of complementary information.

This study is a reminder to laboratory administrators and pathologists that consumer use of the Internet for healthcare purposes continues to grow. That is one reason why clinical labs and pathology groups should maintain a useful web site that has relevant and regularly-updated information about the services their organizations provide.

QIAGEN NV POISED TO BECOME NEXT IVD FIRM TO TOP $1 BILLION DOLLARS

IF NETHERLANDS-BASED **QIAGEN NV** does one more acquisition this year, it will join the elite circle of *in vitro* diagnostics (IVD) companies with more than $1 billion in annual revenue.

Since 2004, the company has spent more than $2 billion on acquisitions in the IVD space. The biggest deal was its purchase of **Digene, Inc.**, for about $1.6 billion in June, 2007. Qiagen's most recent acquisition was last month, when it paid $90 million to buy **SABiosciences Corp.**, a U.S.-based company. Qiagen has about $1 billion in funds available that can be used to finance additional acquisitions. It says it may spend up to $500 million on acquisitions during 2010. TDR

The Dark Index

Laboratory Merger & Acquisitions Saw Several Deals during 2009

Sonic and LabCorp remain opportunistic buyers, some pathology groups tap private equity capital

CONSOLIDATION OF INDEPENDENT CLINICAL LABORATORIES continued during 2009. The most active acquirer was **Sonic Healthcare, Ltd.**, of Sydney, Australia. It purchased three laboratories in the United States this year.

Just this month, Sonic acquired **East Side Clinical Laboratory** in Providence, Rhode Island. This acquisition gives Sonic a presence in New England. East Side was founded in 1949 and has a strong market share in Rhode Island. With annual revenue of about $30 million, assuming a 20% EBITDA (earnings before interest, taxes, depreciation, and amortization) and a multiple of five to eight, the sales price probably ranged between $30 million and as high as $48 million.

In August, Sonic acquired **Piedmont Medical Labs** of Winchester, Virginia. This was a lab company owned by **Valley Health**. Annual revenue at Piedmont is about $11 million. Sonic intends to integrate Piedmont Medical Labs with its existing laboratory business in Chantilly, Virginia.

Sonic Healthcare's first 2009 acquisition in the United States was in the spring and involved **Axiom Laboratories** of Tampa, Florida. This laboratory has about $5 million in annual revenue.

LabCorp Acquires Centrex

In November, **Laboratory Corporation of America** of Burlington, North Carolina, served notice that it was still a buyer of clinical laboratories by purchasing **Centrex Clinical Laboratories, Inc.**, in New Hartford, New York. Founded in 1969, Centrex was owned by **Faxton-St. Luke's Healthcare.** The sales price was not announced but Faxton-St. Luke's reported that Centrex Clinical Labs had $43 million in revenue last year. This supports a sales price ranging from about $43 million to $77 million, based on cash flow and recent rates of growth.

Pathology Labs Raise Money

Merger and acquisition activity in the anatomic pathology sector was rather limited. One transaction with a high profile was the acquisition of pathology supergroup **UniPath, LLC**, in Denver, Colorado, by **American Pathology Partners**, of Brentwood, Tennessee (APP). No sales price was announced. *(See TDR, February 2, 2009.)*

One interesting dimension to this transaction was the pathology owners of UniPath only sold the histology laboratory operations to APP. UniPath retained full ownership of its pathology professional corporation and has an agreement to provide professional services to APP.

In another transaction, **Pathology Inc.**, a multi-specialty pathology services company in Southern California, accepted an equity investment. **England Securities** served as the financial advisor to an investment group that included **ABS Capital Partners**, **Mt. Weather Capital**, and **Orix Venture Finance**. TDR

Catholic Health Initiatives Ramps Up Lab Outreach

78-hospital health system says lab outreach is right vehicle to support integrated patient care

CEO SUMMARY: Catholic Health Initiatives (CHI) wants to expand its presence in outpatient and outreach services. It sees hospital laboratory outreach programs as a key component of this strategy. It will use an equity investment in Pathology Associates Medical Laboratories (PAML) as the foundation of a series of laboratory outreach joint ventures between its 78 hospitals and PAML. Along with generating a new source of revenue, CHI expects these lab JVs will help it establish tightly-integrated electronic links with office-based physicians.

EXPANDING THE REACH and profitability of hospital laboratory outreach programs is a primary strategy at **Catholic Health Initiatives** (CHI) of Denver, Colorado, one of the nation's largest multi-state health systems.

CHI signaled its plans to aggressively develop laboratory outreach programs by becoming an equity owner of **Pathology Associates Medical Laboratories** (PAML), based in Spokane, Washington. Last month, both organizations announced their intent to develop laboratory outreach joint ventures anchored by some of the 78 hospitals CHI owns and operates in 20 states. *(See TDR, October 12, 2009.)*

To learn more about why Catholic Health Initiatives has such a strong strategic interest in building up lab outreach testing programs, THE DARK REPORT caught up with Paul Edgett, CHI's Senior Vice President, National Business Lines. Edgett explained that CHI has three goals for its new relationship with PAML. "One, CHI wants to boost the revenue our hospitals get from laboratory outreach programs," stated Edgett. "PAML excels in this area.

"CHI wants to have a robust laboratory outreach business," he continued. "We have some lab outreach programs that are very successful in selected markets. But, as a system, we consider laboratory outreach to be an undeveloped opportunity for CHI hospitals. We believe there is tremendous growth potential in the outreach markets that reside within our network.

Growing Market Share

"We estimate that we currently get about 10% of the lab testing outreach volume available in the local markets where we operate hospitals," he continued. "We are now taking the steps necessary to lift that market share to between 30% to 40% by developing a series of laboratory outreach joint ventures that would be managed by PAML as the partner in each local JV.

"Two, CHI intends to diversify its income stream from one that is currently heavily dependent on inpatient care to one that relies more on revenue from outpatient care," declared Edgett. "This strategy is built on the knowledge that inpatient care has

increased at a slower rate than outpatient care for more than 20 years. This trend in favor of faster growth in outpatient procedures is likely to continue.

"Three, CHI aims to improve patient care by integrating data from laboratory test results with information from diagnostic imaging to improve care management for pre-acute and post-acute patients," he noted. "It is much easier to achieve this type of clinical and service integration—that also bridges inpatient and outreach settings—when our hospitals have dynamic laboratory outreach programs."

First Wave Of Laboratory JVs

Catholic Health Initiatives will waste no time in ramping up the first wave of lab outreach testing programs involving its hospitals. "In the immediate next few months, we will start joint venture outreach programs with PAML in Colorado and Arkansas," explained Edgett. "This will be followed by lab outreach joint ventures with CHI hospitals in Kentucky and Oregon. "These four markets are our near term priority. We could be operating in those markets in the first quarter of next year.

"Our goal with PAML is to be deliberate in opening outreach joint ventures so that we are driving the market as opposed to reacting to it," Edgett added. "The amount of lab work that can be done locally will vary by market. To the extent that it can be done locally, we will maximize that ability. To the extent that it needs to be shipped out, we will have the infrastructure do that too.

"While negotiating our equity position with PAML, a parallel lab outreach development effort was taking place in selected regional markets," he said. "This is why, with the execution of the agreement with PAML, we can hit the ground running with the relationship. We are excited to begin this process.

"In fact, what allows us to accelerate the launch of these lab outreach programs in multiple states is that PAML already has the capability and management resources required to establish and operate a professionally-managed lab outreach program," added Edgett. "For example, when it comes to information technology (IT) and connectivity, PAML has robust systems.

"On its own, CHI was developing LIS-to-EMR interfaces to meet connectivity needs with physicians' offices, but the pace was not fast enough," he observed. "PAML has developed hundreds of interfaces for the broad spectrum of electronic medical record (EMR) systems that exist. Integrated IT is one of PAML's core competencies.

"In today's competitive marketplace, connectivity is the key to making any lab outreach effort successful. We intend to use connectivity and integrated IT solutions as a strong selling point in our laboratory outreach programs in each community."

Catholic Health Initiatives is one of the first major health systems to recognize how a thriving laboratory outreach program can contribute to better financial performance, even as it strengthens the relationships between a hospital and the physicians practicing in the local community. "The relationship with PAML is significant from a strategic point of view because it allows CHI to pursue a revenue diversification strategy," noted Edgett.

Diversification Strategy

"Currently, 52% of CHI's revenue comes from inpatient acute care services," he stated. "CHI has a deliberate strategy to get 65% of its revenue from non-inpatient acute care services. Our long-term future requires this revenue diversification so that we are not as heavily dependent on the acute care inpatient model as we are today.

"By the way, the target of 65% is a 10-year goal," emphasized Edgett. "CHI will not be shrinking its acute care side. Rather, CHI aims to reach that 65% goal by disproportionately growing non-acute care services at a faster pace than the acute care side.

"This strategy recognizes another truth in the healthcare marketplace," he

Will the New CHI-PAML Lab Partnership Prove to Be a "Marriage Made in Heaven?"

SOME MIGHT CONSIDER THE DEVELOPMENT of a joint venture between Catholic Health Initiatives (CHI) and PAML, a lab company owned by another Catholic health system, as a marriage made in heaven because of shared values. But there is more to the story.

"This venture between CHI and PAML is the natural progression of a relationship that has grown over many years," said Thomas Tiffany, Ph.D., CEO and President of PAML. "Because CHI operates the Franciscan Health System in Tacoma and is part of our PACLAB network, we have worked together for many years.

"Another source of interaction was the consulting PAML did for several CHI hospitals in eastern Oregon," he added. "As we got to know each other, that led to discussions about how to develop a national strategy involving our two organizations.

"From our standpoint, CHI's strategies align very closely with our own," commented Tiffany. "Each organization has a mutual goal of growing this venture into a successful service that advances clinical care in a financially-sustainable manner. The joint venture agreement that we have with CHI supports the missions and the ministries of both Catholic health organizations.

"What makes this venture particularly exciting is that it allows both companies to take advantage of a strategy that ever more hospitals are pursuing today," Tiffany explained. "Hospitals are investing in, and buying, physician practices.

"Because of this tighter relationship with office-based physicians, hospitals recognize that they need a link to those physicians in order to generate referrals," he continued. "If hospitals have strong diagnostics—both laboratory testing and diagnostic imaging—as part of their offerings, that has value to physicians and gives hospitals a foundation upon which they can build tighter relationships with local physicians even as they support the success of physicians' practices."

commented. "It is extremely important to have good integration of the diagnostic platforms in the care delivery model. CHI understands how the data generated from laboratory testing and diagnostic imaging must be integrated as a way to more effectively drive improvements in patient care. This is true in both the pre-acute and post-acute settings.

"As we achieve this integration of diagnostic services, we will become more effective at improving the health status of the communities we serve," added Edgett. "It is why CHI is making these active investments in strategies like laboratory outreach testing. We want to be well invested in those areas."

Turning back to the new business relationship PAML, Edgett pointed out why Catholic Health Initiatives was comfortable establishing an equity position in PAML and working closely with it on laboratory outreach joint ventures. "Just looking at the two organizations—CHI and PAML—it is clear that our equity investment is a good fit for both of us," Edgett said.

"From the standpoint of values, PAML is owned by **Providence Health & Services** of Seattle, and CHI is the second largest Catholic healthcare facilities operator in the United States," he noted. "That means we are two faith-based organizations with similar values and operating principles. That was the beginning foundation between our organizations.

"But we also have a track record of working with PAML through our long-standing relationship through the

Franciscan Health System in Tacoma, Washington," he continued. "Franciscan hospital laboratories have been members of **PACLAB Network Laboratories**, which PAML founded in 1996," he added. "Through PACLAB and other laboratory outreach joint ventures that PAML operates, they have a demonstrated track record of growing profitable laboratory JV businesses.

Long Working History

Edgett emphasized that the strength of the new business relationship is four complementary core competencies that PAML brings to Catholic Health Initiatives. "First is PAML's established track record with lab outreach testing joint ventures," he said. "For more than a decade, and in multiple markets with different hospital partners, PAML has produced sustained growth in specimen volume, revenue, and profitability.

"Second, PAML has an impressive competency in information technology and connectivity," he continued. "Its ability to seamlessly move data back and forth between physicians and multiple hospitals is state-of-the-art. This is a critical component for any hospital seeking to align the data it collects from physicians, the hospital itself, and the laboratory.

"Third is the backbone that they have developed in billing and infrastructure," observed Edgett. "In healthcare today, it is essential to have an efficient revenue cycle management (RCM) system that can handle hundreds of thousands of very small claims every day and do this work effectively. PAML does this well.

Marketing And Logistics

"The fourth competency that was attractive to us was PAML's marketing and logistics systems," he noted. "Each is well developed and effective. Marketing and sales is the essential component to expand the lab outreach business. An effective logistics effort delivers a high level of customer service.

"In addition to the advantages we saw as a result of the competencies that PAML has, other components of the relationship made it attractive to us," Edgett commented. "One example is the ability to combine a patient's lab test data from inpatient, outpatient, and outreach testing into a single electronic health record (EHR). This will allow us to better trend outcomes. It should also help us reduce repeat tests. That is a patient-friendly outcome which also makes us more efficient.

"In addition to all of these advantages that I have outlined, there is one other way in which this partnership is synergistic," Edgett observed. "Among the many strengths that PAML possesses is a strong research and development effort in laboratory testing and laboratory medicine.

New And Earlier Diagnostics

"We recognize this as a strength because CHI has an R&D function for creating various care delivery models," contrasted Edgett. "We plan to build upon the R&D capabilities of both companies to develop new and earlier diagnostics, along with new care models and new care programs. We consider the ability to bring PAML's R&D expertise in laboratory medicine together with CHI's R&D in care models to be a very exciting aspect of the relationship—and one that we could not do separately."

THE DARK REPORT predicts that the strategic business relationship between Catholic Health Initiatives and PAML will be closely watched by hospital and health system administrators across the country. Not only does it affirm the importance of hospitals addressing opportunities in laboratory outreach testing in their communities, but it also provides an example of how a respected health system is willing to engage a partner with complementary core competencies to build a successful laboratory outreach testing program. **TDR**

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Nigeria, there is an aggressive effort underway to raise the quality of medical laboratory testing. One major element involves inspection of clinical laboratories throughout the nation by teams of laboratory professionals working with the **Medical Laboratory Science Council of Nigeria** (MLSCN). During 2009, MLSCN has closed 938 substandard and unregistered medical laboratories in all regions of the country. The second major element to improve the quality of lab testing in Nigeria involves the creation of a national accreditation and licensing program.

ADD TO: *Nigerian Labs*

This summer, Nigeria sent delegates to a meeting organized by the **World Health Organization** (WHO) that was attended by 13 African countries. The goal is to establish medical laboratory accreditation in nations which have had no such program. Support from the United States is coming through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), implemented through the **Centers for Disease Control and Prevention**. The **American Society of Clinical Pathology** (ASCP) is also involved in this medical laboratory accreditation program.

TRANSITIONS

• Vijay Aggarwal, Ph.D., has become a Partner at **The Channel Group, LLC**, of New York City and its affiliate, **BioMed Transition Partners**. The Channel Group provides venture, investment, development, and management services to life science and biomedical companies. Aggarwal was previously President and CEO of **Aureon Laboratories, Inc.**

• Joan H. Logue, 73, died of lung cancer on November 20 in her home in Longwood, Florida. Logue, a principal at **Health Systems Concepts**, was best known for her long association with the **Clinical Laboratory Management Association** (CLMA). She was one of the founders of CLMA in 1976 and served as its director between 1984 and 1989. She had earlier served as Administrative Director of Pathology at **Paoli Hospital** between 1968 and 1976.

• Pathologist Donald B. Rix, M.D., 78, of Vancouver, British Columbia, died of cancer on November 6. In the 1960's, he joined what was then called **Metropolitan BioMedical Laboratories** (Metro). He is credited with growing this business, which eventually became **Metro-McNair Labs**. Rix played a key role in the transaction that made Metro-McNair part of **MDS**. He eventually served as Chairman of **MDS Life Sciences** (now known as **LifeLabs**).

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