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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

Hey! We Are Halfway Through the 2000's

WITHOUT SPLITTING HAIRS ABOUT WHETHER THE NEW MILLENNIUM started on January 1, 2000 or January 1, 2001 (although official millennium celebrations heavily favored the former date), I would like to call your attention to an important fact: 2005 is the half-way point in the current decade.

Look what has changed since 2000. No longer do **American Medical Laboratories**, **Dynacare**, **DIANON Systems**, **UroCor**, **IMPATH**, or **Unilab Corporation** operate as independent laboratory companies. Liquid preparation Pap tests dominate in the market. HPV is now considered a primary cause of cervical cancer and an effective HPV vaccine may be approved for clinical use within 18 months. The first clinical test utilizing microarray technology was cleared by the FDA last month. Quality management systems such as Lean and Six Sigma are finding their way into growing numbers of hospitals, health systems, and laboratories. Patient safety, which received scant mention in the 1990s, is today a major force for change in the American healthcare system.

This list of marketplace developments only touches a small number of milestones achieved in the first half of the 2000s. I ask you to pause for a moment and consider this fact: the pace of change in laboratory management and lab medicine remains swift. This has implications and ramifications for strategic planning.

It means that lab directors and pathologists consciously following a business strategy of maintaining some type of status quo (read: I want my lab to stay "as is" and I hope nothing upsets the lab before I retire) may be dooming their laboratory, and its staff, to any number of negative consequences.

In contrast, those laboratory administrators and pathologists earnestly working to position their laboratories at the front edge of the change curve will likely enjoy the best downstream results. That's because much of the change happening in laboratory medicine and healthcare today actually enhances the ability of a laboratory to provide value-added clinical services to hospitals, physicians, and patients.

With our new decade now half-gone, it is a reminder that laboratories and pathology groups should be managed with a sense of urgency. Failure to use time wisely can lead labs and pathology groups down a losing road. TDR

Bi-Annual Look at Trends Reshaping Clinical Labs

Going into 2005, clinical laboratories face significant changes in operations and markets

CEO SUMMARY: Among other things, we declare the end to the heyday of the independent commercial lab company which offers a broad test menu to all types of office-based physicians. In its place springs forth the specialty or niche testing laboratory. Small and focused on a specific number of reference and esoteric tests, the number of these specialty labs is mushrooming across the United States.

By Robert L. Michel

WOW! AT THE START OF 2005, we can identify 14 distinct market trends actively reshaping laboratory testing services.

That's up from ten trends that we identified in January 2003, when we last looked at market dynamics acting on clinical laboratories. *(See TDR, January 20, 2003).*

For new clients of THE DARK REPORT, it is our custom to review clinical laboratory market trends in January of odd-numbered years. We update anatomic pathology market trends in January of even-numbered years. The passage of 24 months between these reviews tends to make it easier to identify which new influences are pushing into the laboratory services marketplace.

Our goal in presenting these trends is to help you better recognize what specific market forces are exerting pressure on your clinical laboratory or pathology group practice. Armed with that insight, you can develop more effective business and clinical strategies to respond to these forces. Some trends represent threats to the status quo. Other trends represent opportunities—but require strategic vision and proactive action.

It is my assessment that one consistent theme underlies most of the 14 primary trends we see in today's clinical laboratory marketplace. That theme is "the need to control and reduce the cost of healthcare." Those

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.65 per week elsewhere (billed semi-annually).

who pay healthcare's bills—employers and Medicare/Medicaid—are taking unprecedented steps to ameliorate the rate of year-to-year increases in healthcare costs.

Connecting The Dots

Allow me to now connect the dots between most of the 14 trends you will read about on the pages which follow. For the moment, accept my statement that the need to control/reduce costs is a primary theme in the American healthcare system.

With this agreement, I ask you to take a walk of logic with me. First we start with patient safety. Since THE DARK REPORT first called your attention to the **Institute of Medicine's** (IOM) November 1999 report on the number of deaths attributable to medical errors, improving patient safety has become a universal requirement in most facets of healthcare. To improve patient safety, healthcare accrediting agencies are steadily moving their emphasis away from "documentation" and to "outcomes." *(Macro Trend #12, page 15.)*

Here our walk of logic moves to the next connection. To identify the existing state of patient safety, a provider must first measure outcomes of various processes and clinical procedures. That is one reason why evolving accreditation guidelines require providers to capture outcome data and demonstrate that, over time, they are improving their outcomes.

Provider Outcomes Ranking

However, measuring outcomes enables something else to occur. Now it becomes feasible to rank providers by their outcomes performance. Such provider rankings make it possible to reward providers who consistently produce better outcomes than their peers. We see this expressed as "pay-for-performance" programs now sprouting up among private payers and Medicare. *(Macro Trend #8, page 11.)*

This walk of logic can proceed to another stage: measuring outcomes allows providers to be ranked from "best to worst" or "most to least." These rankings can now be made public. This allows employers to decide which hospitals, physicians, and laboratories they want to include in their provider networks. It also allows consumers to compare clinical quality versus cost when they select providers.

Our walk of logic can now move forward. Since the healthcare system is shifting to an outcome-measurement mode, this introduces a new management need in hospitals, physician groups, and laboratories. That new management need is the ability of the provider to deliberately and continuously improve outcomes.

Embracing Lean & Six Sigma

That explains why growing numbers of hospitals, health systems, and laboratories are adopting quality management systems such as Lean and Six Sigma. They recognize that these management methods can allow them to reduce errors, improve quality, lower costs, and boost patient/physician satisfaction with their services. *(Macro Trend #1, page 4.)* They also understand the capabilities of these systems to continuously lower the cost of healthcare services.

In fact, our walk of logic has come full circle. This last stage connects directly to healthcare's biggest challenge: reducing the rate of increase in the cost of healthcare.

As you read and study our 2005 list of Lab Industry Macro Trends, I think you will be surprised at how tightly they interrelate. Whether it is lab automation or the electronic medical record (EMR), each trend promises to improve outcomes while controlling or reducing the cost of healthcare.

Lab Industry Macro Trend

1 More Laboratories and Hospitals Adopt Lean/Six Sigma Methods

OVER THE PAST YEAR, a sizeable number of laboratories, hospitals, and health systems made the commitment to adopt some type of quality management system into their organization.

As this occurred, a clear preference emerged. ISO-9000 does not seem to be the quality management system of choice. Instead, the overwhelming majority of laboratories, hospitals, and health systems selected quality management systems based upon the principles of the Lean and Six Sigma management schools.

THE DARK REPORT also asserts that 2004 was a "tipping point" year in the trend to adopt quality management systems. By tipping point, we mean the point where a business concept ceases to be considered experimental, risky, or unproven by an industry. In passing the tipping point, that business concept is now accepted as useful and necessary for any business enterprise to be successful.

THE DARK REPORT believes the laboratory industry is now on the other side of that tipping point in regards to quality management systems. No longer will it only be early-adopter labs and innovators which adopt, deploy, and enjoy the benefits of a quality management system.

To the contrary, quality management systems such as Lean and Six Sigma are now on the march to become mainstream in healthcare. Each time a laboratory which introduced Lean and Six Sigma methods reports on outcomes, the gains in productivity, reduced waste, improved quality, and faster turnaround time provide compelling evidence that such methods work in powerful ways.

At this stage, the Lean/Six Sigma trend has set its deepest roots into clinical laboratories. Pathology group practices are behind on this curve. But pathology groups will be pushed down this path in two ways. First, re-engineering of histology laboratories using Lean/Six Sigma methods will inevitably require pathologists to alter their own workflows and procedures. Second, as hospital administrators introduce quality management systems throughout the entire hospital, pathologists will again find themselves required to alter their own work processes to support workflow redesign initiatives.

THE DARK REPORT predicts that this will be an unstoppable trend. In fact, because these tools can so dramatically improve a lab's performance, it is likely that widespread adoption of Lean/Six Sigma methods will change the competitive landscape in the lab industry.

Laboratories which adopt a quality management system and use it to maximum effectiveness will have competitive advantages over laboratories which don't. That's because such labs will have better quality, lower costs, and higher productivity over laboratories which continue to operate from traditional management mindsets.

Lab Industry Macro Trend

2 Accreditation Shift Continues, Improving Outcomes is the Goal

HEALTHCARE ACCREDITATION PROGRAMS continue to shift their emphasis to documenting outcomes and measuring how an organization improves those outcomes over time.

This change in accrediting philosophy can be easily recognized. Since publication of the **Institute of Medicine's** Report on medical errors in November 1999, the **Joint Commission on Accreditation of Health Care Organization** (JCAHO) has steadily moved its emphasis away from documenting operational and clinical procedures and replaced these with requirements that providers measure outcomes and show year-over-year improvement in their outcomes.

The trend to measure and improve outcomes does mirror the heightened interest by the public in the quality of healthcare. Journalists are digging for stories of medical errors and giving them wide play. Legislators in many states are enacting laws requiring hospitals and physicians to publicly report medical errors as they are discovered.

During the past three years, THE DARK REPORT has been first to provide intelligence and analysis on this unfolding trend to the laboratory profession. It is an important trend for at least four reasons.

One, laboratories themselves will eventually be measuring outcomes in operational processes that directly influence patient care. These outcomes will be reported and made public. Accordingly, outcomes performance will be one criteria used by physicians and patients to choose their laboratory provider.

Two, as hospitals and physicians feel the pressure to improve their outcomes, it will cause them to place new value on the laboratories which serve them. Those laboratories which are capable of helping a physician improve his/her patient healthcare outcomes will have a competitive advantage over laboratories which do not.

Three, measuring outcomes means laboratory administrators and pathologists will need to manage their laboratories in fundamentally different ways. Continuous improvement in relevant outcomes will become a major management objective. Old management habits will have to be unlearned. It will be necessary to learn and master new management methods.

Four, in coming years, reimbursement is likely to be connected to outcomes. *(See Macro Trend #3 on page 6.)* That will allow laboratories which achieve higher outcomes to earn more money than those that don't. In the future, profitability in lab operations may be linked to this ability to deliver higher outcomes to patients and physicians than competing laboratories.

Therefore, the change in accreditation standards should be viewed in this strategic context. These changes presage initiatives to link reimbursement levels to outcomes.

Lab Industry Macro Trend

3 Provider "Pay for Performance" Is on the Verge of Exploding

SHOULD THE SYSTEM REWARD physicians and hospitals that consistently produce better healthcare outcomes with extra reimbursement?

Advocates of this concept say it will contribute to higher quality healthcare while controlling costs. These advocates include Medicare, which has implemented a sizeable pilot program involving 1,700 of the nation's 4,800 hospitals.

Medicare's hospital pay-for-performance program will reward hospitals which improve their outcomes in certain types of procedures with extra reimbursement at the end of the program's three-year term. Hospitals which show a decline in outcomes in those procedures during the same period will see a reimbursement decline of .5%.

In recent years, THE DARK REPORT has identified and explained some of the earliest physician pay-for-performance programs. California's five largest managed care companies started "Pay for Performance." Launched at the start of 2003, it paid its first incentives to medical groups in the state during August and September 2004. It is now entering its third year and shows no signs of disappearing.

Laboratory managers and pathologists should understand the implications of this trend. Employers and insurers paying the bill for healthcare services want accountability for their dollars. A pay-for-performance plan that rewards providers who achieve better outcomes than their peers demonstrates a willingness by payers to "put their money where their mouth is."

The pay-for-performance trend is linked with the trend to improve patient safety and the trend to measure outcomes. Collectively, these three trends are ways to progress toward a goal of improving the quality of healthcare while controlling or reducing healthcare costs.

The laboratory industry is about to embark on its own patient safety/outcome measure initiative. On April 29-30, 2005, the **Institute for Quality in Laboratory Medicine** (IQLM), an organization incubated within the **Centers for Disease Control and Prevention** (CDC), will announce national indicators to be used to measure the quality of laboratory testing services. This announcement will take place at IQLM's second national meeting, to be held in Atlanta, Georgia.

This will be a significant development. It is an attempt to craft a system that can appropriately measure and evaluate the cumulative performance of the nation's laboratories in contributing to improved patient safety and better healthcare outcomes.

That system can become the basis of pay-for-performance programs that reward those laboratories which achieve measurably higher outcomes than the industry average. How fast such pay-for-performance programs arrive in lab and pathology is uncertain. Thus, lab managers and pathologists have time to respond.

Lab Industry Macro Trend

4 More Employers Expand Health Choices for Employees

UNDER THE TERM "consumer-directed healthcare" there are ever-increasing options for the savvy patient.

In the private sector, each year a greater number of employers expand their healthcare benefits options to give employees more choice—while asking them to pay more for primary coverage, deductibles, and out-of-pocket requirements. Healthcare debit cards and similar innovations are gaining traction in the market.

Private insurers are making it easier to find new health plans designed to maximize consumer choice—even as the consumer is asked to be a smarter buyer of his/her healthcare. State insurance commissioners are under pressure to reform laws which currently restrain such options.

Within the federal government, the existing administration wants to encourage consumer choice as a way to reduce the long-term costs of the Medicare and Medicaid programs. Its sponsorship of legislation that created Health Savings Accounts (HSA) is another effort to encourage the consumer to be a better buyer of his/her healthcare.

The Health Savings Account is basically a healthcare IRA. Funded each year, monies unspent on healthcare at the end of a year roll into the investment portion of the account. As these funds grow, they are available to pay for future medical expenses. At a certain age, the individual can withdraw these monies as retirement income.

This is a powerful incentive for consumers to spend these healthcare dollars wisely! Any money not spent on healthcare during a year can roll into the retirement portion of the HSA.

When is the last time any of us asked a physician how much a procedure would cost—and whether it could be done cheaper at the same quality? HSAs have the potential to motivate consumers to pay closer attention to the cost of health care services provided to an individual and his family.

For pathologists and laboratory directors, this is a positive development. It means that managed care contracts which exclude physicians and patients from using the laboratories of their choice would disappear. Physicians and patients would have more freedom of choice about which laboratory provides their testing services.

Most lab executives and pathologists would agree that exclusionary managed care contracts for laboratory testing services did great damage to the laboratory industry during the past decade. So it follows that laboratory administrators and pathologists should generally be in favor of laws and healthcare reforms which encourage freedom of choice by physicians and patients. After all, that is one way to re-establish a "level playing field."

Therefore, the fact that employers are structuring health benefit plans to encourage patients to shop for their own health care should be a favorable development for the lab industry.

Lab Industry Macro Trend

5 Evolution in Lab Instruments Triggers Operational Changes

ONGOING IMPROVEMENTS to diagnostic instruments are giving laboratory administrators and pathologists new options to re-engineer their labs' workflow.

Diagnostic instruments with expanded capabilities are reaching the market in a steady stream. At the same time, technologies that shrink the size of instruments and allow them to operate effectively in less complex laboratories create additional re-engineering opportunities.

These developments have yet to gain wider recognition within the laboratory profession, due to three factors. First, manufacturers more heavily promote laboratory automation equipment. The lab automation message emphasizes significant and swift improvements in a laboratory's performance. That is why it tends to draw attention to itself.

Second, new capabilities of each generation of diagnostic instruments often are incremental—not breakthrough. That tends to understate their potential, particularly over a multi-year period.

Third, the steady flow of new information technology (IT) products is altering the relationship between diagnostic instruments and a laboratory information system (LIS). These IT products give newer diagnostic instruments the ability to operate with greater independence from the LIS—even as the lab test data generated is directed into the laboratory test data repository.

A handful of early-adopter laboratories have recognized this development. In response, they are reconfiguring the form and function of their laboratory to take advantage of these new capabilities.

One obvious example are the systems which pair chemistry and immunoassay instruments into an integrated workstation. Smaller instruments with higher throughputs and expanded test menus can also enable laboratory work flows to be re-engineered in useful ways.

Similarly, point-of-care (POC) test instruments also play a role. As new clinical standards in emergency departments create the need for the lab to respond with faster turnaround times, greater use of POC testing and other non-core lab testing solutions become appropriate.

Labs that were early to incorporate such next-generation instruments into their laboratories are reaching an interesting crossroads. They now have a laboratory with work cells which utilizes stand-alone, internally-automated instruments.

To harvest further gains in productivity and efficiency, these laboratories are beginning early explorations of how automation can move specimens more efficiently between work cells. These labs also want to connect pre-analytical automation to analytical and post-analytical functions.

New diagnostic instruments are already anchoring major re-engineering of the lab's operational design and work flow. This trend will only increase as more next-generation instrument solutions hit the market.

Lab Industry Macro Trend

6 "Do-All" Commercial Lab Model Is No Longer Dominant Form

IT'S THE END OF AN ERA! The heyday of the independent regional laboratory company that provides a general and broad menu of tests to all specialties of office-based physicians is over.

This is a bold statement for THE DARK REPORT to make. But look at the evidence. In city after city across the United States, what types and numbers of laboratories are competing to provide broad testing services to office-based physicians?

A decade and a half ago, every city and town of some size generally had multiple laboratory competitors—independently-owned and operated—competing to serve office-based physicians. Today, the two national laboratory companies have a presence in most population centers. But their competitors are likely to be hospital laboratory outreach programs, not independent commercial laboratory companies.

Most lab managers and pathologists know how this situation occurred. Throughout the 1990s, public laboratory companies had voracious appetites for acquiring smaller laboratories. National lab companies were willing to purchase just about any laboratory with adequate revenues and a stable client list.

It was laboratory consolidation on a major scale. The survivors are **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. Both companies continue to be interested in acquisitions, but few independent commercial lab companies remain that can be bought.

There are several reasons why it is important to recognize that the market dominance of the full-menu independent laboratory company serving all medical specialties has ended. One, it demonstrates that the economics of today's healthcare system make it difficult for smaller, independent laboratory companies to compete and earn a profit. On one hand, managed care contracting practices can restrict a smaller lab's access to patients. On the other hand, reduced reimbursement means it is necessary to have enough specimen volume to produce the economies of scale necessary to generate black ink.

Two, recognition that this laboratory business model is no longer predominant allows existing laboratories to make better strategic decisions. It is not wise to devote scarce capital and management resources into laboratory activities which find no favor in today's marketplace.

Finally, it is important to make a distinction. Declaring an end to the heyday—the dominance—of this business model does not mean it is heading to extinction. The two blood brothers will certainly continue to operate profitably and hold their market position. The same is true for hospital lab outreach programs because office-based physicians do need lab testing services. However, the decline of this laboratory business model opens the door for a new one to take its place.

Lab Industry Macro Trend

7 Specialty Test Labs Becoming A Significant Market Trend

IN TODAY'S LAB MARKETPLACE, specialty testing laboratories comprise the industry's hottest area of growth.

In most metropolitan markets, at least a few small lab companies can be found. What they have in common is specialization in a defined area of laboratory medicine.

Because the large majority of these laboratory companies are tiny, they attract little attention outside their service area. Annual revenues may range from $500,000 to a few million dollars. They are operated by pathologists and laboratory scientists with a keen clinical interest in a specialized area of laboratory medicine.

Signs of this trend have been visible to keen observers over the last decade. For example, one factor in **IMPATH, Inc.'s** spectacular growth rates between 1994 and 2002 was its regular acquisition of niche oncology testing laboratories.

These types of laboratories have not attracted much attention because they tend to be very small. They often serve a regional market and they do little sales and marketing. Their case volume originates from personal relationships and their lab's reputation for subspecialty expertise.

This trend is a direct consequence of new diagnostic assays and technologies. Throughout the 1990s, there was a steady flow of such new lab tests into the clinical marketplace. Most of these new assays were complex to perform accurately. Laboratories which offered these tests needed an expensive mix of sophisticated instruments and highly-trained specialized technical skills.

This was the foundation of the specialty testing laboratory trend. As pathologists and Ph.D.s took proactive steps to bring such complex tests up in their laboratory, they often became the only regional source for that testing. In addition, they had personal relationships with clinicians. This allowed them to educate local physicians about the value of such tests and provide personal consultations.

Essentially, these pathologists and Ph.D.s became the champions for such new tests within the local healthcare community. For these nascent laboratory operations, outreach specimens supplemented specimens generated by hospital inpatients. This added important economic stability to such specialized, niche testing laboratories.

This market phenomenon has happened without fanfare or hype. It was dedicated pathologists and Ph.D.s working to offer their subspecialty skills to clinicians in the local community. The laboratory business which emerges is a direct result of their interest in practicing better medicine.

THE DARK REPORT expects to see more niche specialty laboratories emerge. What is unclear is how motivated these pathologists and Ph.D.s will be to sell these labs if interested buyers dangle lots of cash. That could trigger a new wave of laboratory consolidation.

Lab Industry Macro Trend

8 Med Tech Skill Sets Shifting Toward New Lab Technologies

INNOVATIVE LABORATORIES report significant changes in the technical skill mix required to support their menu of lab tests.

Increasingly, the challenge is not where to find enough laboratory staff to operate the high-volume, routine testing departments, such as chemistry and hematology. Instead, laboratories find themselves struggling to recruit, hire, and retain laboratory staff with the technical skills to perform increasingly complex reference and esoteric testing.

In that sense, the supply-demand gap for staffing high-volume, routine testing departments continues. But now it is compounded because laboratories need ever-increasing numbers of lab staff who possess the specific technical skills required to perform new diagnostic assays built on highly-complex technologies.

Moreover, many of these new assays require ongoing and close interaction between medical technologists (MTs), Ph.D.s, and pathologists. From a recruitment standpoint, this complicates the situation. To appropriately support a new menu of testing requires hiring individuals with different levels of education and experience.

This creates a laboratory staffing challenge with two distinct dimensions. One dimension is the widely-recognized difficulty in recruiting adequate numbers of MTs and MLTs (medical laboratory technicians) required to support standard testing operations in the high-volume chemistry/hematology core lab and other standard lab departments.

The other dimension involves staffing to support newer, more complex test menus. Besides the need to find pathologists and Ph.D.s with the right skills and experience, the lab must recruit and hire a very scarce laboratory resource: MTs with the education and experience required to perform these complex reference and esoteric assays.

This is one often-unrecognized facet of the staffing shortage facing laboratories in many areas of the country. It is a problem which will become more serious over time. That's because the volume of work will increase (more new tests and more utilization of existing tests) even as the supply of appropriately-trained labor lags behind demand (because most MT training programs are not yet teaching the science and technology inherent in these new molecular assays).

This staffing shortage fuels greater interest in laboratory automation solutions. After all, a properly-targeted lab automation project can free up valuable MT staff—who can then be assigned to other positions within the laboratory.

However, there is no obvious solution to solve the supply-demand gap for MT staff with the skills to perform complex reference and esoteric testing. As long as this situation exists, the laws of supply and demand predict that wages will increase for individuals with these skills.

Lab Industry Macro Trend

9 Fewer & Fewer LIS Upgrades As Labs Opt for "Middleware"

FEWER LABORATORIES WILL BE implementing major upgrades to their LIS (laboratory information system) in coming years.

Instead, improvements in the laboratory's information technology capabilities will come from acquiring and installing "middleware." These are software packages which have specific functions.

Middleware is installed atop the LIS and operates as data processing nodes. The middleware pulls needed data from the LIS, manipulates it as desired, and transmits the output to the end user.

Why are laboratories opting to purchase middleware instead of a major LIS software upgrade? It's because hospitals and health systems are spending most of their information technology dollars on other initiatives—rather than upgrading primary information systems in clinical areas like laboratory.

Over the past two years, THE DARK REPORT has noted that hospitals and health systems are investing heavily to connect their clinical data repositories, to create a seamless patient health record, and to enable wireless access to relevant information. Patient safety initiatives, such as electronic pharmacy ordering systems, are also a major source of IT spending.

As a result, fewer hospitals and health systems are willing to commit the several millions of dollars necessary to upgrade a laboratory information system. Where functionality must be added or enhanced, the solution is often to install middleware.

The **University of Michigan Health System** (UMHS) in Ann Arbor, Michigan is a good example. It operates with a **Cerner** LIS product that was originally installed in 1988. Administrators within the health system have directed capital funding to projects other than an LIS upgrade.

According to Bruce A. Friedman, M.D., Professor of Pathology at UMHS, the laboratory is successfully using middleware to add functions and capabilities. A recognized expert in laboratory information services, Friedman sees other major health system laboratories following the same course as UMHS.

THE DARK REPORT can identify a number of signs in the marketplace that validate this trend. It is consistent with the "thin client" movement in IT, where an application service provider (ASP) provides the software necessary to perform a function. "Thin client" applications free the customer from having to own and maintain hardware and software on-site.

For laboratory administrators and pathologists, these developments are consistent with a greater trend in healthcare, which is to use new technology to more fully integrate how data is captured, stored, processed, and distributed to users. Better middleware may offer a least-cost option to allow laboratories to add state-of-the-art IT capabilities.

Lab Industry Macro Trend

10 Drive to the Universal EMR Will Require Response by Labs

LABORATORIES THAT IGNORE the drive to create a universal electronic medical record (EMR) do so at their long-term peril.

During the past two years, THE DARK REPORT has chronicled important developments on the road to a national, universal EMR. Because laboratory test data is the predominant element of a patient's medical record, the march toward the universal EMR promises to radically alter existing relationships between laboratories and the hospitals and physicians they serve.

The universal EMR will require laboratories to push laboratory test data directly into the patient's master health record. Which healthcare entity will hold and maintain this universal EMR? In the near term, it will be office-based physicians and hospitals. In the long term, the Internet creates opportunities unrecognized today.

Both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** recognize this need. Each company is investing substantial capital to advance their information technology capabilities in ways that will allow them to interface with EMRs. In the marketplace, LabCorp and Quest Diagnostics are pushing IT services that allow them to interface and pass lab test data directly into the practice management information systems used by their physician-clients.

THE DARK REPORT was first to alert and brief lab managers and pathologists on how the Armed Forces laboratories are using LOINC (Logical Observation Identifiers Names and Codes) to link their different laboratory information systems. Their goal is to standardize the test data across the global system of military laboratories. This will make it possible to then create a universal EMR for all active duty military personnel and their dependents. *(See TDRs, June 24, 2002.)*

Some innovative laboratories are taking proactive steps to achieve a similar capability. In Washington State, **PACLAB**, a regional laboratory network with nine hospital laboratories and **PAML**, is preparing to deploy a software capability that will allow any PACLAB client-physician to open a Web browser and see all the laboratory test data for his/her patient. A middleware solution instantly pulls the relevant data from each of the ten member labs' LIS (laboratory information systems).

The federal government is taking a lead role in the effort to achieve a universal EMR. Most of the **Veterans Administration** VISNs (Veterans Integrated Service Network) already operate their hospitals and clinics with paperless IT systems.

These examples show that early-adopter laboratories are already positioning themselves to support the universal EMR. All laboratories should recognize this trend and develop a response strategy.

Lab Industry Macro Trend

11

Lab Contract Bid Models Are New Medicare/Medicaid Threat

MEDICARE and some state Medicaid programs are taking active steps to use new contracting models to lower laboratory testing costs.

Medicare is moving forward with its demonstration project for competitive bidding of laboratory testing services. *(See TDR, November 22, 2004.)* MediCal, California's Medicaid program, is in the midst of a major laboratory contracting process. Florida's Medicaid program's effort to award a three-year statewide lab testing contract to a single laboratory is ongoing, and stimulating plenty of controversy. *(See TDRs, April 5, April 25, 2004 and January 3, 2005.)*

THE DARK REPORT believes these are warning flags that reflect a fundamental dilemma facing Medicare and Medicaid officials. Because of population demographics, they face steady and significant increases in demand for healthcare services. However, after years of financing the rapid growth in spending on such programs, federal and state governments are hitting a wall. The tax base cannot generate the higher levels of funding needed to sustain these programs, as they are currently operated.

Most importantly, it must be recognized that, in the year 2005, Medicare and Medicaid officials have just about exhausted their ability to manipulate the system as a way to constrain spending. For almost 40 years, elected officials and bureaucrats have shifted costs, under-reimbursed providers, and set arbitrary rules to restrain utilization. It is obvious to any observer with common sense that the system is in crisis.

Absent political will to enact deep and effective reforms to Medicare and Medicaid, officials managing these programs are left to find additional ways to squeeze dollars out of the existing system. That is what brings them to competitive bidding, statewide contracting, and similar schemes at this moment in time.

These observations serve to establish an important conclusion: Medicare and Medicaid, having exhausted and overused its options during the past 40 decades, is now prepared to experiment with contracting models as a way to help contain healthcare costs.

Laboratory testing services will not be singled out for special treatment in this scenario. However, because it is easier to transport specimens than it is to transport patients, lab testing will be a high-profile target for all sorts of experiments in contracting models by Medicare and state Medicaid programs.

THE DARK REPORT predicts the financial pain will be universally felt across the entire laboratory industry. Every lab test contracting scheme that misfires will cause as much grief to physicians and patients as it does to labs. It will take several years for these events to play out. At least, because of THE DARK REPORT, laboratories have early warning of what lies ahead.

Lab Industry Macro Trend

12 Clinicians Expand Acceptance of Molecular-based Lab Tests

THERE IS EVIDENCE THAT physician acceptance of diagnostic tests based on molecular technologies is growing, but with a caveat.

The caveat is that clinician acceptance of any molecular-based diagnostic test is widespread and rapid only when there is good clinical research that validates its accuracy and clinical value. In other words, a diagnostic test based on molecular technology doesn't find clinical acceptance just because it utilizes molecular science.

This was demonstrated by the introduction of HIV mutation and viral load testing. Used in the right situations, these tests allowed physicians to create impressive clinical improvements with their AIDS patients. It didn't take long before such HIV tests were incorporated into the standard of care.

The same dynamic can be seen in oncology. Sophisticated diagnostic assays, many utilizing molecular technologies, now make it possible to identify different types of leukemias and lymphomas. This diagnostic precision drives therapeutic decisions and cure rates for these cancers are steadily improving.

Every month there are announcements of new cancer markers. As clinicians see studies which validate the clinical effectiveness of such markers, they are willing to incorporate them into their practice.

This is good news for the laboratory industry. It provides convincing proof that physicians are willing to expand their practice patterns to utilize diagnostic tests which incorporate molecular technologies. On the reimbursement side, insurers generally establish reasonable coverage and reimbursement policies, once they are satisfied that such lab tests are effective at improving clinical outcomes. Insurers want to see credible clinical studies which validate the usefulness of such tests.

This is an auspicious development for the laboratory industry. The promise of the genetic revolution is that new knowledge about DNA, RNA, and proteomics will give physicians and patients very precise information. Laboratories are the gatekeepers to this information.

Despite naysayers who have grave misgivings about predictive genetic testing and manipulation of the human genome, there has yet been no societal crisis over early use of molecular diagnostics. Physicians have accepted tests they deemed useful and effective. Patients have reacted similarly.

THE DARK REPORT predicts that molecular diagnostics will expand in a multi-dimensional manner. The number of clinically-useful assays will increase steadily. At the same time, ongoing advances in enabling technologies will produce lab instruments that remove the complexity of performing the test. Together, these forces will allow even smaller labs to offer and perform a sophisticated menu of molecular assays.

Lab Industry Macro Trend

13

Automation is Soon to Hit Histology with Hurricane Force

HISTOLOGY LABORATORIES will soon become highly-automated operations—if a variety of new instrument systems arriving in the market fulfill their potential.

Automation in histology will have several consequences. Traditionally, the histology laboratory has been a labor-intensive operation which relies on work processes that are mostly manual.

As it becomes feasible to automate histology, laboratory administrators and pathologists will need to act differently in two ways. First, they must invest capital to acquire and deploy automated histology solutions. Because heretofore the histology laboratory was a minor user of capital, hospital and health system administrators will need to be educated about the benefits of histology automation.

Second, histology labs preparing to automate will need to simultaneously re-engineer work flows, sometimes in major ways. By its nature, automation offers opportunities to realize gains in productivity and quality. But that is only if the well-known adage "don't automate bad work processes" is followed.

At the *Executive War College* in New Orleans last May, attendees heard Azorides Morales, M.D. describe how innovative use of automation in the histology laboratory at **Jackson Memorial Hospital** in Miami, Florida enables pathologists to issue same-day reports on a high volume of cases.

Moreover, Morales, Jackson's Chief of Pathology, had established an automated "point of care" histology laboratory upstairs next to the surgery suites. Using these new instruments systems, pathologists were able to deliver pathology reports to surgeons even as the patient was being wheeled out of the recovery room.

It is no coincidence that companies such as **DakoCytomation**, **Sakura Finetek**, and **Ventana Medical Systems** each have histology automation solutions entering the marketplace. It is a direct consequence of the rapid development curve for a host of technologies.

Advances in microwave technology, miniaturization, software processing capabilities, and core science involving tissue preparation were necessary to support such a breakthrough. Lab executives should recognize that the technology adoption curve will likely accelerate through the remainder of the decade.

In that sense, the ability of new automation solutions to transform longstanding work processes in the histology laboratory demonstrate how evolving technologies are likely to accelerate the pace at which laboratories must recognize new technology and decide when and how to deploy it.

Moreover, THE DARK REPORT recommends those labs evaluating histology automation should do it in tandem with an evaluation of how Lean and Six Sigma management techniques can help in re-engineering. That would ensure that the automation project generates a grand slam home run for the lab.

Lab Industry Macro Trend

14 Anti-Kickback Indictments May Trigger New Compliance Risks

TWO EVENTS DURING 2005 raise interesting questions about whether or not the **Office of the Inspector General** (OIG) is developing new interpretations of how certain laboratory industry practices might violate Medicare anti-kickback laws.

First was the news that ex-executives of **UroCor, Inc.** had become the first employees of a publicly-traded laboratory company to face criminal indictments for anti-kickback violations. On June 17, 2004, the Federal Attorney of Oklahoma City filed an indictment in federal court accusing UroCor's former CEO and its former National Sales Manager of violating Medicare anti-kickback laws. *(See TDR, July 19, 2004).*

This anti-kickback criminal indictment came at an interesting time. Months earlier, the appearance of anatomic pathology (AP) laboratory condominiums owned and operated by specialist groups had caught the attention of the OIG and other government healthcare authorities.

On December 17, 2004, the OIG released its Advisory Opinion 04-17 which explained how the operation of AP laboratory condominiums could violate anti-kickback statutes and the Stark Law. Veteran healthcare attorneys interpret 04-17 as raising the level of compliance risk in this type of contractual joint venture between pathologists and specialist physicians. *(See TDR, January 3, 2005.)*

Can these two events be linked? Even if there is no link, is each event an early sign that federal health program enforcers are reassessing ways in which pathologists and laboratories either offer discounted services to referring physicians or enter AP/clin lab joint ventures with referring physicians?

Regardless of current official policy and pronouncements, these two events should be interpreted in context with the proposed regulations, published in the fall of 2003, which would further define how a laboratory calculates "usual and customary charges" to determine whether or not it is billing the Medicare program in compliance with existing law.

Collectively, these are signs that federal healthcare regulators are studying such marketing methods as client billing discounts, heavily-discounted managed care contract pricing, and joint ventures between pathologists, labs, and referring physicians. They want to understand how such practices might trigger over-utilization, violate anti-kickback statutes, and involve access to Medicare patients as an economic motive to justify the lab offering a client-physician discounted pricing on his/her private and self-pay patients.

THE DARK REPORT believes these events are signs that federal healthcare enforcers may be rethinking their view in how such lab marketing practices might violate compliance laws. Remember how the concept of "inducing the ordering of medically unnecessary tests" evolved? Could client billing soon be a similar target for compliance action against labs? TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Blood-alcohol testing in the emergency room can generate surprising results. That was certainly the case in Plovdiv, Bulgaria on December 20, 2004. A 67-year old pedestrian, hit by a car, was taken to the emergency room. Using a breath analyzer, his blood-alcohol level registered at .914! Physicians and police were amazed, since the patient was conscious and speaking with them. The breathalyzer test was confirmed after each of five separate lab tests conducted that day confirmed the .914 blood-alcohol level. This is almost double the .55 blood-alcohol level that is considered fatal. It is also eight times the .08 legal limit for driving in many states here in our country.

LAB NEEDS COO

In the Western United States, a successful laboratory seeks a Chief Operating Officer. This lab's CEO is infusing new energy into a proven lab management team and wants an effective change agent to lead the effort. Interested and qualified parties can contact Editor Robert Michel in confidence at 512-264-7103 or by e-mailing labletter@aol.com.

VA PATIENTS RECEIVE RECOMMENDED CARE MORE OFTEN THAN GENERAL POPULATION

It's a startling statistic! Patients treated in the **Veterans Administration** (VA) Health System receive recommended care 67% of the time while the general population gets recommended care only 51% of the time. This is the conclusion of a new study recently published in the *Annuals of Internal Medicine*. Researchers at **RAND Corp.**, the **University of California at Los Angeles**, and the **University of Michigan** evaluated 348 clinical indicators of quality linked to 26 medical conditions. As an example, VA patients with diabetes received the care recommended for their condition 70% of the time. This contrasts with diabetes patients in the general population getting recommended care only 57% of the time.

ADD TO: *VA Care*

These findings indicate that the VA Healthcare System is making progress on its strategic goal of improving healthcare outcomes and reducing medical errors. To support this goal, the VA has spent considerable resources to move to an all-electronic health record. *(See TDR, June 7, 2004.)* The findings in this study complement those released by **RAND Health** in the summer of 2003. At that time, researchers reported on a study that involved phone interviews with 13,275 people, followed by examination of the physical health records of 6,712 of these individuals. In this study, researchers determined that patients get the care recommended for their condition only 54.9% of the time. Further, researchers reported that, 11.3% of the time, people received care that "was not recommended and was potentially harmful." *(See TDR, July 7, 2003.)*

TRANSITIONS

• On December 1, 2004, **Focus Technologies, Inc.** adopted a new name: **Focus Diagnostics, Inc.** Based in Herndon, Virginia, the company was founded in 1978 and built a national business by specializing in reference and esoteric microbiology testing services. For many years, Focus was known as **MRL Reference Laboratory**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 14, 2005.

PREVIEW #2

EXECUTIVE WAR COLLEGE

May 3-4, 2005 • Astor Crowne Plaza Hotel • New Orleans

Pathologist Productivity and Compensation: Using Proven Formulas to Maximize Both

Join us for an exceptional opportunity. We've coaxed recently-retired pathology business consultant Dennis Padget to prepare a special presentation on the best ways to encourage the productivity of individual pathologists and link that to compensation. One of the profession's most experienced experts will provide real-world insights and advice on this tough issue. Useful for pathologists and practice administrators working in academic, hospital, and commercial laboratory environments.

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UPCOMING...

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