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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

TennCare's Collapse and Its Lessons for Labs

HOW MANY OF YOU HAVE HEARD ABOUT THE IMPENDING COLLAPSE of **TennCare**, the radical Medicaid experiment launched by Tennessee in 1994? It now consumes one-third of the Tennessee state budget and Governor Phil Bredesen announced that the program will probably be ended. It is likely that Tennessee will reinstate a standard Medicaid program.

I believe TennCare is a major healthcare story. It frames the upcoming Congressional battles on Social Security and Medicare reform proposals. On one hand, employers who pay health benefits and consumers now aggressively question the quality of healthcare and the inability of hospitals and physicians to control costs. On the other hand, a group of intellectuals want healthcare to be a "public good." They want to create a healthcare system which offers equal access and equal quality to all.

That's why I believe the collapse of TennCare as a Medicaid managed care experiment is relevant. As I understand it, it was crafted to conform with most of the now infamous Hillarycare proposals of the first Clinton administration. That would be logical, since then-Vice President Al Gore has close connections with Tennessee and its political establishment.

If it is true that TennCare was structured to conform with the fundamental elements of the Hillarycare proposals, then its failure is of even greater significance. Tennessee's experiment with this healthcare delivery system model is a real-world test. It can educate us about the downstream consequences of this philosophical and operational model for healthcare.

Laboratories and pathology group practices will be greatly impacted by any type of deep reforms to the existing healthcare system. That is why the debate on how to reform healthcare in general, and government-funded healthcare programs specifically, should get wide play in the laboratory press. I, for one, would like to see a detailed and objective analysis of why the TennCare health scheme failed in such a spectacular manner.

However, because it was born of political decisions ten years ago, I don't think comprehensive coverage of TennCare's failings will be widely reported by print or broadcast media. For my part, I consider TennCare's impending collapse as a first-round event. Both the Medicare and Medicaid programs face intractable problems which will inevitably force lawmakers to soon enact extensive reforms. TDR

Change Beneath Surface Marks 2004 Lab Stories

Lack of disruptive events during 2004 belies deeper forces triggering change

CEO SUMMARY: Presented here are THE DARK REPORT's "Ten Biggest Lab Stories of 2004." These are the events we consider most important to the lab industry during the year. However, in contrast to past years, 2004 lacked the types of blockbuster events which radically change and reshape the competitive landscape. Instead, 2004 was a relatively quiet year and change occurred at a slower pace.

By Robert L. Michel

LOOK BACK ON 2004 AND IT'S EASY to decide that there were no significant changes or disruptions to the laboratory testing marketplace. Ergo, it was a quiet year.

I would only partially agree with that conclusion. It is true that, at the end of 2004, the lab industry looked and acted much like it did just 12 months ago. However, I would argue that several major blips appeared on the lab industry's radar screen which will directly trigger major change.

In particular, I would like to comment on three of these "radar blips." Each is included in our picks for the "Ten Biggest Lab Stories of 2004." That's because, although not a transforming force during this calendar year, each represents the first steps of an evolutionary force that we expect to inexorably force significant change upon the laboratory industry.

One story which meets this criteria involves the growing embrace by healthcare providers, including laboratories, of quality management methods and philosophies. It is no longer accurate to say that only a handful of hospitals or laboratories are committed to quality management (based upon systems such as Lean, Six Sigma, and ISO-9000).

During 2004, the executive leadership of a substantial number of hospitals, health systems, and laboratories made a commitment to fully implement some form of quality management system into their organization. Because these initiatives are still in their infancy,

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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).

it remains mostly invisible to the media and healthcare commentators. They continue to tell isolated stories about the experiences of early-adopter hospitals with Six Sigma. But the larger picture eludes them.

Improving Lab Performance

I believe this is a significant development—and worthy of inclusion on our "Top Ten Lab Stories for 2004"—because as more hospitals and laboratories deploy quality management systems, it raises the competitive bar. If leading laboratories continuously reduce error rates, substantially improve quality, and lower costs, won't other laboratories in that region be forced to match that performance to remain competitive?

I am firmly convinced that wide-scale adoption of quality management systems in the laboratory industry will create a new class of winners and losers. The winners will be the labs which move quickly to implement quality management methods. The losers will be those laboratories which cling to their status quo as long as possible. In today's world, "as long as possible" is often too late.

I am firmly convinced that wide-scale adoption of quality management systems in the laboratory industry will create a new class of winners and losers.

Pathology group practices are not immune to this trend. National anatomic pathology companies are expected to lead the drive to use quality management methods. As their quality improves and as their costs decline, it will give them a competitive advantage over those hospital-based pathology group practices which do nothing because they decide they have neither the time nor the inclination to invest in such quality management systems.

My next "radar blip" trend involves healthcare's goal of the universal electronic medical record (EMR). Sometimes this is also called the "paperless" healthcare system. On page 6, you will read how President George W. Bush is calling on the federal government to lead the effort to achieve a universal EMR within ten years. Certainly we covered that story for you in May. But we also were first to alert you to this back in the summer of 2003.

Federal IT Health Initiatives

At that time, we explained the significance of the newly-signed contract between the **Department of Health and Human Services** (DHHS) and the **College of American Pathologists** (CAP). The five-year, $32.5 million pact gave DHHS access to CAP's SNOMED® CT system, which contains a standardized medical vocabulary containing precise terms for 340,000 medical concepts. *(See TDR, July 7, 2003.)*

Further, during the past three years, THE DARK REPORT has been first to explain the importance of the **Veteran Administration's** move to an all-electronic healthcare information system and the American military's use of LOINC as the necessary precursor to its universal EMR. The armed forces want an EMR that will follow service personnel and their dependents anywhere on the globe. *(See TDR, June 24, 2002.)*

THE DARK REPORT hopes that your laboratory connects these dots before your competitors do. Healthcare will go paperless. Federal health programs will drive this change. Laboratories, as information factories, should position themselves to be enablers and leaders

in this movement. To be followers cedes important dimensions of control to some other sector of healthcare.

The third "radar blip" trend I think worthy of your special attention involves a couple of our "Top Ten Lab Stories for 2004." One is the criminal indictments of three ex-**UroCor** executives for violations of federal anti-kickback laws and securities fraud. *(Page 6.)* The second involves changes in lab contracting practices by Medicaid programs in Florida and California. *(Page 7.)*

...government health programs are becoming more aggressive in their efforts to control or stamp out any activity deemed to be in violation of laws and regulations.

Both stories are based upon efforts by government officials to crack down on activities which cost government health plans lots of money. In some cases, the activities are clearly fraudulent. In other situations, due to the lack of clear statutory or regulatory guidance, the same activities might be defended as legal, but fraud investigators have a motive to make the opposite argument.

Government Regulators

My interpretation is more pointed. Collectively, the actions by Florida and California Medicaid program managers, the criminal prosecution by one federal attorney, and the OIG's publication of proposed language to change the calculation of usual and customary fees all point to one conclusion: government health programs are becoming more aggressive in their efforts to stamp out any activity deemed to be in violation of laws and regulations.

Within the laboratory industry, there will continue to be plenty of debate about compliance requirements and what does and doesn't meet the letter of the law.

But this debate doesn't address three larger points. One, government health programs don't have the money to adequately fund services. Two, the public is increasingly intolerant of healthcare providers who "rip off" Medicare and Medicaid. And three, there is political hay to be harvested when providers deemed to have abused Medicare/Medicaid are publically identified and punished.

That means it is likely that the environment between government-funded healthcare programs and laboratories (indeed, all providers) is likely to become more adversarial during the next 24 months. Thus, 2004's developments are a cautionary sign that laboratories should review their business practices and improve their compliance programs.

Use In Strategic Planning

As you read through our summary of the "Top Ten Biggest Lab Stories of 2004," relate these events to your laboratory or pathology group. Each year a significant number of our clients use this list in their strategic planning process. Not only does it provoke worthwhile discussion, but it helps executive teams better understand how these lab industry stories are directly influenced and shaped by developing trends and evolving competitive pressures.

Finally, what topics didn't make the Top Ten list? Nothing revolutionary happened to point-of-care testing (POCT) in 2004. There were no breakthrough LIS or Web-based lab test order/resulting products to disrupt the existing marketplace. Experts continue to predict that no paradigm-shifting lab test technology will hit the clinical marketplace. These are useful signs that the pace of change in the lab testing marketplace is likely to remain stable, at least through 2005.

top 10 no. 1

Quality Management Systems Make Big Inroads In Labs and Healthcare

THROUGH 2003, EXAMPLES of laboratories and hospitals which fully adopted quality management systems like Six Sigma, Lean, and ISO-9000 were extremely limited. That changed in 2004.

During the past 12 months, a sizeable number of hospitals, health systems, and laboratories have made strategic decisions to adopt and implement a system of quality management. Most of these organizations are still in the study and decision stage. Actual implementation has yet to begin in earnest. For that reason, this phenomenon is invisible to most of the public. Only after significant improvements result from actual implementation does the public start to pay attention.

The adoption rate is driven by the results generated from early adopters. THE DARK REPORT has covered the experience of clinical laboratories which benefited from Lean and Six Sigma. *(See TDRs, August 30 and September 20, 2004.)* It has also profiled the hospital-wide Lean initiative at **Virginia Mason Medical Center** in Seattle, Washington. *(See TDR, November 22, 2004.)*

What these organizations have in common are gains of 50% from quality improvement projects which take just weeks to implement. It is these swift, deep, and long-lasting gains which are forcing other hospitals and laboratories to take their own steps toward implementing a quality management system.

What these early-adopters are doing is raising the bar. Their improved quality and higher performance will force competitors to respond in kind.

top 10 no. 2

More Office-based Docs Take Steps To Bring Anatomic Pathology Services In-house

IT'S A BIGGER THREAT to the anatomic pathology (AP) profession than managed care contracting practices were during the 1990s.

Over the past 18 months, an incredible number of specialist physician groups took decisive steps to capture, in one form or another, the anatomic pathology revenues generated by their patient referrals. This was seen primarily in the specialties of urology and gastroenterology. *(See TDRs, July 19 and August 9, 2004.)*

The most visible sign of this trend is the emergence of anatomic pathology laboratory condominium complexes in Florida and Texas. Under one roof, up to 12 identical histology laboratories, each owned by a different physician group, would be operated by the condo complex operator. Notwithstanding a host of compliance issues triggered by this particular business scheme, an impressive number of urology and GI groups jumped at the chance to own their own AP laboratory and earn profits from this source.

However, AP lab condos mask a wider trend of specialist groups approaching local pathologists with the specific goal of crafting some type of discounted pricing or joint venture arrangement that allows them to share in AP revenues generated from their patient referrals.

To date, the pathology profession has not developed an effective strategy to counter these initiatives. Until it does, it can expect continued erosion of specimens and revenues from this source.

top 10 no.3

Federal Government Leads Drive To Accelerate Health IT Adoption Pace

ANY MAJOR SHIFTS in the adoption and use of information technologies by hospitals, physicians, and payers has huge consequences to laboratories.

That's because the end product created by all laboratories is information. For that reason, the federal government's role in pushing the American healthcare system toward a paperless information technology capability—the universal electronic medical record (EMR)—bears close watching. The evolution to that "perfect state" will profoundly change the way laboratories interact with physicians, payers, and patients.

THE DARK REPORT was the first and only lab industry source to point out the significance of President George W. Bush's press conference on April 26, 2004. He called for adoption of a universal EMR within ten years, asked Congress to double funding for this effort to $100 million in FY2005, and created the sub-cabinet level post of National Health Information Technology Coordinator. *(See TDR, June 7, 2004.)*

Remarkably, this press conference was ignored by both the *New York Times* and *The Wall Street Journal*. However, that's not the case for clients and regular readers of THE DARK REPORT. As healthcare's major provider of useful clinical information, they are on notice that they should prepare their laboratories to accommodate the American healthcare systems' evolution to a universal electronic medical record.

top 10 no.4

Criminal Anti-kickback Indictments Of Ex-UroCor Executives Is New Threat

NEWS THAT THE FEDERAL ATTORNEY in Oklahoma City had filed criminal indictments against three ex-UroCor executives caught the lab industry off-guard.

That's because these charges claim UroCor violated federal anti-kickback statutes. The indictments are based on UroCor's practice of offering a urologist-client deeply discounted client-bill arrangements to induce Medicare patient referrals from him/her.

Veteran lab industry attorneys believe this is the first time a federal attorney has indicted a laboratory executive for anti-kickback violations. In contrast, the billion-dollar settlements of "Lab Scam" in the 1990s resulted from allegations that Medicare fraud and abuse statutes were violated.

Discounted client billing is a common practice within the laboratory industry, which makes these criminal indictments alarming. Were the jury to find UroCor's client bill discounting policies in violation of anti-kickback laws, then this court case would create a new level of uncertainty. Any laboratory offering client bill arrangements to physicians at deeply discounted pricing might be at risk of criminal violations.

It should be noted that, because it takes two to violate anti-kickback statutes, a guilty verdict in the UroCor case has ramifications for urologists who were clients of UroCor. Also, going forward, that same risk would be true for physician-clients who benefit from discounted lab test client bill arrangements.

top 10 no.5

FL & CA Medicaid Officials Effect Radical Lab Contracting Changes

MEDICAID PROGRAMS in both Florida and California are making significant changes to how laboratories are allowed to provide testing services to Medicaid beneficiaries in each state.

In Florida, there is an attempt to implement a bidding process that would award an exclusive, three-year contract to one laboratory. The winning laboratory would perform all outpatient testing for all Medicaid beneficiaries in the state.

In California, Medi-Cal officials are halfway into a new contracting process. Licensed laboratories currently providing testing services to Medi-Cal beneficiaries have been required to submit an application. Based on a variety of criteria, Medi-Cal will select and execute a contract with some of the lab applicants. Labs not selected will not be allowed to provide testing to Medi-Cal patients. *(See TDRs, April 26, May 17, and November 22, 2004.)*

Competitive bidding of laboratory testing services is another trend that will reshape the lab industry. Medicare is moving forward with its demonstration program for competitive bidding of laboratory testing. Results are to be reported to Congress by December 31, 2005. A similar competitive bidding initiative is unfolding in British Columbia's health program.

Collectively, these examples are powerful evidence that government health programs will use such techniques to wring substantial cost reductions from laboratory testing services.

top 10 no.6

Medicare's New Director Ready To Infuse Market-based Philosophy

THIS HIGHLY SIGNIFICANT development has gone mostly unreported by the nation's media. Few people understand that Medicare's new Director of the Medicare program has radical and different perspectives on how market incentives can help the agency better achieve its mission.

Mark McClellan, M.D., Ph.D. was installed as Director of the **Centers for Medicare and Medicaid Services** (CMS) in March 2004. Since then, he has brought a market approach to crafting solutions to problems facing the government healthcare programs.

One example is McClellan's evolving policy of having Medicare reimburse for new medical procedures, new therapeutic drugs, and new diagnostic tests, so long as patients receiving these treatments agreed to participate in studies to measure the clinical effectiveness of the new technologies and these studies are funded by outside entities, including companies and organizations providing such services. *(See TDR, November 22, 2004.)*

McClellan believes that market incentives will stimulate private enterprise to develop effective clinical services that improve healthcare outcomes while lowering the overall cost of care. THE DARK REPORT believes such policies will prove particularly beneficial to the laboratory industry. That's because, under this policy, Medicare is more likely to cover and reimburse for those new diagnostic test technologies validated to be effective by rigorous clinical studies.

top 10 no.7

Lab Breakdown at Baltimore Hospital Draws Scrutiny to Accreditation

LABORATORY ACCREDITATION PROGRAMS found themselves under congressional scrutiny this year following the spectacular operational failures inside the laboratory at **Maryland General Hospital** (MGH) in Baltimore.

MGH's laboratory was accredited by the **College of American Pathologists** (CAP). Despite significant problems with its HIV and HCV over a 14-month period, neither CAP inspectors nor inspectors from the **Maryland Department of Health** uncovered these problems, despite multiple visits during this time frame. *(See TDRs, April 5, April 26, May 17, 2004.)*

Several Congressional hearings took place in the months following the discovery of problems within the MGH lab. At every hearing, there was criticism of the laboratory accreditation process and its reliance on peers to do inspections.

At the same time, newspapers in the Baltimore area prominently featured this story, since the lab at MGH may have reported inaccurate HIV and/or HCV test results on as many as 2,000 patients. It was public recognition of how established institutions could neither detect nor correct the continuous flow of medical errors generated by this laboratory.

THE DARK REPORT believes the intensity of public debate over this situation, and the scrutiny given to laboratory accrediting processes, demonstrates a fundamental change in public tolerance of medical errors. There is decreasing tolerance for any lab which fails a patient.

top 10 no.8

Cancer Diagnostics Attracts Major Investment Dollars from Wall Street

WALL STREET SENT A BIG MESSAGE to the laboratory industry during 2004. "It's about cancer, stupid!"

During the year, some big money was invested in cancer-based diagnostics and therapeutics. **Genzyme Corporation** paid $215 million to acquire **IMPATH, Inc.** from bankruptcy court. Three days earlier it paid $1 billion to purchase **Ilex Oncology, Inc.** and seven months earlier it had spent $600 million to acquire **SangStat Medical Corporation**. Both of these companies have therapeutic drugs used to treat lymphoma and leukemia. IMPATH does lots of lymphoma and leukemia testing, which makes it first to know about patients who will need therapeutic drugs. *(See TDR, March 15, 2004.)*

Genzyme's investment of $1.8 billion must be viewed in context with two major deals in 2003. One is **Laboratory Corporation of America's** $598 million purchase of **DIANON Systems, Inc.** and the other was **Welsh, Carson, Anderson & Stowe's** $840 million investment to purchase **AmeriPath, Inc.**

Wall Street's willingness to provide $1.65 billion to fund the acquisitions of IMPATH, DIANON, and AmeriPath confirms that oncology is expected to be one of the most profitable areas of healthcare. Clinical laboratories and pathology group practices should "follow the money" and reassess their own lab's strategy for cancer diagnostics. It's a market segment expected to yield significant profit margins in coming years.

top 10 no.9

Molecular Diagnostics' Steady Growth Portends Many Impending Changes

MOLECULAR DIAGNOSTICS IS POISED for a big market shift. Because of unfavorable economics, clinical testing based on molecular technologies has been mostly limited to national reference labs, specialty lab companies, and academic center labs.

That is changing swiftly. Increasing numbers of community hospital laboratories are setting up molecular tests and offering them to clinicians. That's because of two reasons. First, a still-small number of molecular assays have very high clinical value. Second, refinements in technology now make it easier and less complex for a community hospital laboratory to perform certain molecular assays and offer faster turnaround times.

2004 was probably not the watershed year for clinical molecular diagnostics. Payers remain reluctant to cover these high-priced assays in the absence of clear and compelling clinical evidence of their value. The supply of laboratory scientists trained in molecular technologies is much less than demand.

However, progress in this field is swift. New understanding about DNA, RNA, and proteomics is fueling intense development efforts. Laboratory administrators and pathologists can expect to see an explosion in the number of brand-new molecular-based assays which hit the market. The challenge will be to identify the ones which have clear clinical benefit, because payers are more likely to cover those tests.

top 10 no.10

Subtle and Important Shifts Appear In National Lab Contracting Practices

FOR TWO FULL YEARS, just two lab companies have dominated the national market for laboratory tests referred by office-based physicians and by hospitals. Payers and group purchasing organizations (GPOs) are now beginning to respond to this limited choice of laboratory providers.

Obviously, one major factor that drives contracting decisions by health insurers and GPOs is lowest price. With their economies of scale, both in purchasing and in production, the two blood brothers hold a major competitive advantage over smaller laboratory competitors. But it seems that service still matters too, maybe more than many would admit.

During 2004, **UnitedHealth Group, Inc.** selected **Esoterix, Inc.** as a lab services provider on its national contract. Esoterix thus joined **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** on the United Health provider panel.

UnitedHealth took this step because it had complaints from physicians about their limited choice of labs and service issues from the contract labs. It was also a step to reduce off-contract leakage and leverage lower prices from its existing lab panel.

Later in the year, **Premier, Inc.** added **Specialty Laboratories, Inc.** as a fourth lab provider for its national reference testing contract. Viewed together, the actions by UnitedHealth and Premier show that other factors may allow smaller labs to carve out provider status in these types of contracts. TDR

British Early-Adopter Labs Respond to New Trends

Shift in ER and primary care emphasis is parallel to health trends in the U.S.

CEO SUMMARY: On which side of the Atlantic are clinical labs better operated? This February will be the third consecutive year that progressive lab leaders from the USA and the United Kingdom convene in England to explore each country's laboratory best practices, to swap innovations, and to expand their professional networks. "Frontiers in Laboratory Medicine" (FiLM) takes place in Birmingham, England on February 1-2, 2005.

DESPITE MAJOR DIFFERENCES in the healthcare systems of Great Britain and the United States, laboratories in both countries continue to confront remarkably similar challenges.

In particular, the **National Health Service** (NHS) in the United Kingdom (UK) is instituting major efforts to boost the quality of care provided in emergency departments. At the same time, the NHS is shifting significant budget dollars to primary care clinics.

"For emergency departments, the objective is to do a better and faster job of treating patients," stated Mike Hallworth, Consultant Biochemist at **Royal Shrewsbury Hospital** in Shropshire, England. "In primary care settings, the goal is to improve early detection of disease and encourage more effective intervention and management of patients with chronic illnesses."

If this sounds familiar, it is because employers, payers, and government health programs in the United States have uncannily similar goals. For emergency departments, recently-introduced guidelines and clinical standards are designed to reduce medical errors and improve both the accuracy and speed of diagnosis.

In primary care, there has been an explosion of disease management programs within the United States. The emphasis is to better manage patients susceptible to chronic conditions. Not only will this improve the quality of their lives, but it will prevent acute events that cause severe impairment or loss of life while reducing the cost of treating those patients.

ED & Primary Care

"In the United Kingdom, the new emphasis on emergency department medicine and primary care has significant consequences for laboratories," observed Hallworth. "It shakes up a comfortable status quo in unpredictable ways."

Despite the unknowns, early-adopter laboratories in both the United Kingdom and the United States are already responding to this situation. They are pushing forward with initiatives to meet the changing needs of the

US, United Kingdom Labs To Share on Feb 1-2, 2005

AMERICAN LAB MANAGERS AND PATHOLOGISTS always get a warm welcome from their counterparts in the United Kingdom (UK). Before the advent of the first "Frontiers in Laboratory Medicine" FiLM meeting in February 2002, there was no formal way for lab management innovators in both countries to share their experiences.

FiLM is the result of a collaboration between THE DARK REPORT in the US and Association of Clinical Biochemists (ACB) in the UK. FiLM brings together early adopters in lab leaders from both countries to identify breakthroughs in the management and operation of clinical laboratories.

US laboratories are ahead of their UK counterparts in using aggressive management techniques to control lab testing costs while maintaining and improving high quality. However, UK laboratories are far ahead of their US counterparts in clinical pathology relationships with referring physicians. In the UK, clinical pathology makes a substantially greater value-added contribution than is currently true in the United States.

All laboratory managers and pathologists in North America are welcome to attend the next FiLM meeting. It will be held February 1-2, 2005 in Birmingham, England. A site visit to a large hospital laboratory will also be arranged for those interested. Full details about the FiLM event can be found at *www.darkreport.com*.

emergency department and primary care medicine. A number of such early adopter laboratories will be making presentations at the third annual "Frontiers in Laboratory Medicine" (FiLM) meeting, scheduled for February 1-2, 2005. *(See sidebar above for program details.)*

"Because of the close parallels in laboratory medicine which exist in both the UK and the USA, our faculty represents lab innovators from both countries," stated Hallworth, currently the immediate past Chairman of the **Association of Clinical Biochemists** (ACB). "We have a side-by-side case study involving the laboratories of Cleveland, Ohio-based **University Health System** and **North Middlesex University Hospital** of London, England. The goal is to identify best practices in each country which can be utilized by other labs on both sides of the ocean.

Adopting the Universal EMR

"Another important issue challenging laboratories in both countries is the drive to implement the electronic medical record (EMR)," added Hallworth. "Labs from both the US and UK will share their strategies and successes in supporting this effort."

FiLM will also bring the first public information about how three UK laboratories are implementing Six Sigma/Lean quality management methods. There will be side-by-side comparisons of laboratory direct access testing (DAT) programs operated by laboratories in both the US and the UK.

"We invite laboratory managers, pathologists, and laboratory suppliers in the United States and Canada to join us at FiLM," declared Hallworth. "This is a high-energy, motivating event, with lots of value-added for lab managers keen on keeping their laboratories ahead of the curve."

THE DARK REPORT will help any clients interested in either attending FiLM or accessing presentations following the program. Contact our office at 512-264-7103. TDR

Mike Hallworth can be reached at mike.hallworth@rsh.nhs.uk

"Frontiers in Laboratory Medicine" is at *www.acb.org.uk* and *www.darkreport.com*.

Direct Access Testing Must Serve Consumers

Using the name "ResultsDirect," PAML offers public access to lab tests

CEO SUMMARY: As growing numbers of people enroll in consumer-directed healthcare benefit programs, laboratories will need to develop ways to directly service the needs of patients interested in ordering their own laboratory tests. That's one reason Pathology Associates Medical Laboratories was motivated to develop and offer direct access testing to consumers in Spokane, Washington during the past two years.

DESPITE HIGH INTEREST in direct access testing (DAT), only a handful of laboratories currently offer such programs to consumers. Consequently, both labs and consumers have more questions than answers about DAT.

To fill that information vacuum, THE DARK REPORT recently caught up with Lawrence Killingsworth, Ph.D., who has a major role in *ResultsDirect*™, the DAT program operated by **Pathology Associates Medical Laboratories** (PAML). Located in Spokane, Washington, PAML's DAT program launched in September 2002.

"Dealing directly with consumers creates new opportunities and new challenges for the lab," said Killingsworth. "It takes a different mindset to appropriately serve the needs of consumers. Also, both operational protocols and the service infrastructure of a DAT program are different from traditional arrangements used to support the testing needs of office-based physicians."

In making the decision to offer laboratory testing to consumers, PAML knew it was entering uncharted territory. "The *ResultsDirect* team did a consumer-readiness survey, consulted with area physicians, then spent months planning and designing our DAT program. When we launched *ResultsDirect*, it was with the notion that we would listen to our customers and learn as we go," said Killingsworth. "There were plenty of unknowns, but that didn't deter us."

Reaction of Physicians

One big question was whether physicians in the area would react negatively to the fact that consumers could order laboratory tests without having to visit their doctor. "This turned out to be a non-issue," Killingsworth said. "There was little concern within the physician community, either prior to our DAT program launch or during the two years of its operation.

"A few physicians were concerned that people might substitute lab test results for a full medical examination. This could lead to over-utilization of lab tests or false reassurance from normal results. Some doctors were also

Direct Access Test Menu Weighted to Cholesterol

OVER THE PAST TWO YEARS, the most popular test ordered by consumers from Pathology Associates Medical Laboratories' (PAML) *ResultsDirect* program has been the Cardiac Lipid Panel. The list below shows the comparative rankings, by percent, of the tests most commonly ordered by consumers

Test Panel	*% of Total Procedures*
Cardiac Lipid Panel	27%
Thyroid Survey Panel	12%
Chemistry Survey Panel	12%
CBC (Complete Blood Count)	10%
Five-Drug Forensic Tox Panel	10%
Total % for Top Five Panels	**71%**

concerned about the potential liability of receiving results on patients they had not seen," he explained. "Although *ResultsDirect* encourages customers to share their test results with their doctors, we only send the results to the customer. By not sending a report directly to the physician, we avoid putting the physician in a position of liability."

Most consumers interested in ordering their own laboratory tests can be described as the "worried well," observed Killingsworth. "Not surprisingly, these consumers are well-educated baby-boomers. They are health-conscious, have the discretionary income to pay for laboratory tests, and are motivated to monitor the status of their health.

"Despite the sophistication of many of our customers, it seems they have little interest in accessing their laboratory test results via a Web-based reporting system," stated Killingsworth. "To date, our experience is that most customers prefer to either pick up their lab test results in person or have them mailed to their home address. What makes this particularly curious is that a significant number of our customers visit our Web site to view the test menu, check prices, and find a draw site.

"Our Web site also allows them to complete and print a lab test requisition form. They can then bring this with them when they come to the patient service center," noted Killingsworth.

PAML's *ResultsDirect* DAT testing program does use the Internet in a unique way. "DAT puts the laboratory in the retail business. This means we must collect payment from the customer at the time they order the test," said Killingsworth. "To handle cash, we needed a system that allows the patient service center to conduct these transactions. That's why we created a 'Web-based cash register' for them to use. This solution turned out to have other benefits. When we offer testing at remote locations, like health fairs and at community events, our 'Web-based cash register' is available to process consumer payments.

Tracking DAT Activity

"This is an example of the creativity required to establish a direct access testing program," he added. "In fact, we developed comprehensive financial accounting software using Microsoft.Net. It allows several levels of detail. We offer this software package, called "Go Retail," for sale to other labs interested in the DAT business."

Establishing pricing for tests offered directly to consumers was another challenge. "Our goal was to develop pricing appropriate for our marketplace," noted Killingsworth. "Our pricing strategy is to use the patient list price of our laboratory as a starting point and base the DAT retail price within a close range of that price. A factor in that decision is to know our fully-loaded cost per test. When selling at retail like this, it is

Consumers Like PAML's DAT Program

IN THE TWO YEARS SINCE LAUNCHING *ResultsDirect*, Pathology Associates Medical Laboratories (PAML) has served a steady, even loyal, cadre of customers interested in ordering their own laboratory tests and willing to pay for them.

PAML offers direct access testing (DAT) services through five patient service centers (PSCs) in the Greater Spokane area, along with PSCs in Yakima, Washington. It does not spend much money on advertising to promote the program, preferring to take advantage of health fairs and other community events to build awareness.

Here are prices for lab tests ordered most frequently through ResultsDirect. Payment is collected from customers when they order their tests.

Test Panel	*DAT Price*
• Cardiac Lipid Panel	$35.00
• Thyroid Survey Panel	$35.00
• Chemistry Survey Panel	$40.00
• CBC (Complete Blood Count)	$20.00
• Urine Drug Screen (Central Lab)	$45.00

important to charge a price that allows the laboratory to make a reasonable profit margin."

From its inception, PAML had modest expectations for *ResultsDirect*. "Like other laboratories, we recognize that consumer-directed healthcare is a growing trend. We believed our DAT program would give us first-hand experience at meeting the needs and ever-higher expectations of consumers," observed Killingsworth. "It has certainly worked out that way.

"From its initial launch, *ResultsDirect* continues to attract a steady flow of customers," he explained. "They have a high level of satisfaction with our services. From a revenue standpoint, specimen volumes are stable and ample enough to support the program.

"To promote *ResultsDirect*, we have paid for a modest amount of advertising. Remember, this is a consumer market—the more you advertise, the more business comes in. Direct access testing requires a laboratory to adopt a retail mindset. We've also participated in health fairs and even given away free tests to promote *ResultsDirect*," said Killingsworth.

Experience With DAT

PAML's experience with direct accessing testing is similar to that of other laboratories which have implemented this program. There is small core of consumers keenly interested in regularly ordering tests. But DAT must be considered a niche business for most clinical laboratories.

"That's certainly been our experience," offered Killingsworth. "We've kept our expenditures to a minimum and developed a DAT program that complements our regular clinical testing activities. It's been a cost-effective way for us to learn. It's also allowed us to start building public awareness about our laboratory and prepare for the day when consumers will play a larger role in deciding which doctors and which laboratories will serve them." **TDR**

Contact Lawrence Killingsworth, Ph.D. at lkillingsworth@paml.com.

Lab IT Update

Less Complex IT Technologies Will Propel Use of The Internet

EXPERTS in information technologies (IT) predict that the next paradigm shift in IT will come from reducing the complexity of software and hardware.

Analyst Steven Milunovic of **Merrill Lynch** states that, as complex IT systems are simplified for users, every single employee will be expected to use IT technology. This will increase the number of Internet and computer users by a factor of ten.

The Economist, in a "think piece" about IT, declared that "the boundaries between office, car and home will become increasingly blurred and will eventually disappear altogether. In rich countries, virtually the entire population will be expected to be permanently connected to the Internet, both as employees and as customers. This will at last make IT pervasive and ubiquitous, like electricity or telephones before it, so the emphasis will shift towards making gadgets and networks simple to use."

Trend In Lab Info Systems

Bruce Friedman, M.D. concurs. "We already see this type of evolution in how laboratories upgrade their laboratory information system (LIS) software," he said. "Instead of a full upgrade, many laboratories look for function-specific software modules that add capability to the basic LIS while allowing easy interfaces to other computers and the Internet."

Friedman is Professor of Pathology at the **University of Michigan Medical School** and an expert in laboratory information systems. "This is a major trend and it will be a theme at the upcoming LabInfoCom conference, scheduled in Las Vegas for March 2-4, 2005," he noted.

Lab managers and pathologists will be interested in one expert's demographic breakdown of computer users. Pip Coburn, a technology analyst at the investment bank **UBS**, categorizes 70% of the world's population as "analogues." These are people terrified of technology. Their pain is not rooted in "just the time it takes to figure out new gadgets but the pain of feeling stupid at each moment along the way."

Coburn says 15% are "digital immigrants." These are individuals, usually 30-somethings who have been comfortable with technology since their teen years. The remaining 15% are "digital natives," teenagers and young adults who have grown up knowing nothing but e-mail, IM (instant messaging), and other Internet services. He predicts that, within a decade, "virtually the entire population will be digital natives or immigrants, as the aging analogues convert to avoid social isolation."

The concept of characterizing people as analogues, digital immigrants, and digital natives illustrates why it is important for laboratories to have a sophisticated IT strategy which is updated regularly. Because laboratories are information factories, it is essential that they maintain their IT capabilities to meet the needs and expectations of physicians, payers, and patients. **TDR**

Bar Codes vs. RFID Tags: Labs Will Need Both

RFID technology improvements promise rapid deployment in labs and healthcare

CEO SUMMARY: Take everything you liked about bar code tracking. Eliminate the problems of reading bar codes. What results is the promise of radio frequency identification devices, or RFIDs. In the United States, it is already finding uses in blood transfusion, patient identification, and specimen tracking. Moreover, experts predict RFID costs will decline rapidly, further encouraging its adoption.

EVEN AS MANY LABORATORIES have yet to implement their first bar code systems, a new identification technology is showing the potential to become dominant.

That new technology is RFID, which stands for radio frequency identification devices. RFID systems are now in use within the military health system, and at hospitals such as **Massachusetts General Hospital** (Boston, Massachusetts), **Johns Hopkins University** (Baltimore, Maryland), and the **University of Pennsylvania** (Philadelphia, Pennsylvania). Among other functions, RFID tags are already used to track laboratory specimens and to support certain blood banking functions.

RFID tags are composed of a microchip that contains data linked to a miniscule antenna which sends information to a reader using low-frequency radio waves. They have an important advantage over bar codes. For bar codes to be read, a scanner must be physically oriented toward the code. In contrast, an RFID tag must only be within range of a reader.

Most people are familiar with RFID. It is the technology in various "speed pass" systems used on the nation's toll roads. It is also the alarm sound generated when someone leaves a department store with an item that still contains an active RFID sensor.

Currently, the immediate barrier to wider adoption of RFID over bar codes in healthcare settings is its higher cost. Passive RFID tags currently cost about 20¢ apiece. That discourages use of this technology to track individual doses of prescription medicines and laboratory specimen tubes.

RFIDs Track Patients

The **United States Navy** uses RFID to track the status and location of wounded service personnel, prisoners of war, refugees and others arriving to be treated at its **Pensacola Fleet Hospital** in Iraq. It purchased the "Tactical Medical Coordination System" (TacMedCS) from **ScenPro, Inc.**, located in Richardson, Texas.

Patients are banded with an RFID upon arrival at the hospital. The RFID

RFID Tags Can Do More Than Bar Code Systems

RADIO FREQUENCY IDENTIFICATION DEVICES (RFIDs) can be either passive or active. A passive RFID tag consists of a microchip and an antenna. It is activated by radio waves from the reader brought within range.

Active RFID tags include a battery which allows it to be continously monitored. When applied to an EKG monitor, for example, the active tag allows the monitor to be located in seconds by using a reader.

Bar code scanners must be physically positioned to read the bar code. Improper positioning or smudges on the bar code label make it impossible to scan. RFID tags easily overcome those problems and have a higher reliability in use than bar codes.

tag enables patient identification. It also sends automatic updates of their status, location, and medical information to the systems' "whiteboard." The RFID system has eliminated the manual patient tracking system.

At Massachusetts General Hospital, RFID tags are used in blood transfusion applications. Since last March, **Georgetown University Hospital** in Washington, DC has used a patient wrist band that contains both bar codes and RFID tags for transfusion patients. Nurses now carry a scanner that can read both the bar code and the RFID tag. Nurses prefer the RFID technology and no errors have been reported since introduction of the dual-technology system.

Surprising Preference

Some hospitals have decided to leapfrog bar codes and go directly to RFID. The **Bon Secours Health System** of Richmond, Virginia recently put RFID tags on approximately 12,000 pieces of movable equipment in three hospitals. This includes IV poles, pumps, wheelchairs, stretchers, and hospital beds. The system allows an employee to go to any computer station, click an icon, and locate needed equipment. The system has been live since last July and is expected to generate cost savings of $200,000 per year over the cost of the system.

2003 Malcolm Baldrige award-winner **St. Luke's Health System** of Kansas City, Missouri has its own RFID project. In January 2006, it will open a brand new hospital in Lee's Summit, Missouri. It is considering using RFID to go "bedside" with laboratory specimen tracking, intravenous drugs, prescription drugs, and other applications.

Fast-Improving Technology

It is timely for laboratory managers and pathologists to start watching and learning about RFID technology. Big retailers like **Wal-Mart** are driving acceptance in the private sector. The **U.S. Department of Defense** is a major proponent of RFID use. A host of experts believe the cost of RFID tags and systems will fall dramatically in a relatively short time. That is expected to further speed up the adoption curve.

For laboratories, the benefits are obvious. RFID can improve both the speed and accuracy of patient identification at time of specimen collection. Specimens, tubes, and slides tagged with RFID markers can be tracked automatically through the lab. The lost specimen issue disappears, since an RFID tag on a tube broadcasts its location.

THE DARK REPORT believes RFID technology has the potential for more rapid acceptance than currently acknowledged by experts. One reason is its potential to reduce medical errors and improve patient safety in a variety of ways. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

THE DARK REPORT once again was first with timely intelligence. This time we scooped *Business Week* and other national business sources with our analysis of the impending arrival of HPV vaccines—presented in our November 22, 2004 issue. *Business Week* published their HPV vaccine story a full week later, on November 29, 2004. Several readers alerted us to the fact that our HPV coverage not only scooped most of the business press, but also provided a more cogent analysis of how HPV vaccines will change the clinical landscape.

LABCORP & CHIRON IN HCV PATENT FIGHT

Laboratory Corporation of America and **Chiron Corp.** signed an agreement earlier this month which resolves a patent dispute. Chiron had claimed LabCorp was violating certain of its patents involving the hepatitis C virus (HCV). Chiron was first to clone the virus in 1987 and identify it as a cause of liver disease. The agreement extends non-exclusive rights to LabCorp. to use Chiron's technology in blood screening tests.

MORE PHYSICIANS GET PAID FOR E-MAIL CONSULTATIONS

Here's an update to an intelligence item we published last year. **Blue Cross/ Blue Shield of Massachusetts** (BC/BS) is expanding its "Internet-based" office visit program. Primary care physicians in three Massachusetts health systems will be reimbursed for Internet-based consultations with patients. When this pilot program started in March 2003, it included 185 physicians. After this expansion, more than 500 physicians will be included. When a participating physician conducts an Internet-based consultation that meets BC/BS guidelines, he/she is reimbursed $19 and the patient makes a $5 copayment.

ADD TO: *E-mail Consults*

BC/BS of Massachusetts finds e-mail consults to be effective. That is why it is expanding the program. One physician willing to make Internet-based consultations says he averages about 10 hits per day, but there are only one or two e-mails per day for which he charges a consultation fee. Both BC/BS and the physicians have learned that email consults are effective in serving patients who travel or snowbirds who spend the entire winter far from Massachusetts. BC/BS's willingness to expand this program is a sign to lab managers and pathologists that growing numbers of patients—and their physicians—are willing to conduct healthcare business on the Internet.

PAY-FOR-PERFORMANCE

Will pay-for-performance soon be available for pathologists? The number of financial incentive programs is increasing nationally. The **Leapfrog Group** lists 86 pay-for-performance programs on its Web site. At the request of the **Center for Medicare and Medicaid Services** (CMS), early next year the **National Quality Forum** (NQF) will conduct a workshop in Washington, DC to begin developing benchmarking baselines. The goal is to properly align outcome measurements with performance incentives for physicians.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 3, 2005.