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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

Internet as Threat and Opportunity for Labs

IT'S BEEN A WHILE SINCE THIS CRUSTY CURMUDGEON WEIGHED IN ON technology changes with the potential to reshape laboratory services as we know them today. However, things are changing and today I'd like to call your attention to certain developments with the Internet and comment on their potential to trigger change in our industry.

Many of you are noticing the evolution in the way people use the Web. I believe we may be seeing the "first generation Internet" now yielding to a "second generation Internet." In the first generation, the Internet was rather simple. Businesses and people built their Web sites. The Internet allowed others to come and view those Web sites. The Internet was a big network that enabled people to find and visit sources of information that were useful to them. The personal computer (PC), however, was typically where the user downloaded the information and then interacted with it.

That's changing rapidly on today's Internet. Don Tapscott, CEO of **New Paradigm**, a think tank, writes that "increasingly computers and people can cooperate and intersect in richer ways across the Internet...We've seen the advent of Internet-connected mobile devices, the proliferation of broadband connections, the rise of collaborative software, and the increasing penetration of Internet-connected computer power into everyday objects, from cars to light switches."

For the second generation Internet, Tapscott's theme is "collaboration." He observes that the Internet is evolving from a place where firms present information into an actual computing platform itself. Certainly we see early signs of this in clinical laboratories. More and more lab instruments come equipped to connect to the Internet, either by wire or wireless. These instruments can interact in real time with the LIS, their manufacturer, and other software modules (think middleware).

Because laboratories are information factories, a collaborative, second-generation Internet that is itself a computing platform represents both a threat and an opportunity. As providers, payers, employers, and patients find ways to use this more-sophisticated Internet in useful ways, laboratories will be a rich source of both the raw data and the laboratory medicine know-how on how to best use that data. Labs that enable these new uses will maintain and increase their relevance to the healthcare system. TDR

Picking Top Ten Stories Of 2005 for Lab Industry

Unexpected insights into market changes emerge from this year's intriguing list

CEO SUMMARY: THE DARK REPORT offers its pick of the "Ten Biggest Lab Stories of 2005." This year's list of stories ranges from major consolidation in both the laboratory and health insurance industries, to "true crime" episodes that triggered criminal indictments of certain public lab executives. 2005's most important story may be the forceful arrival of consumer-directed health plans (CDHPs) in the healthcare marketplace.

PICKING THE "TOP TEN" STORIES of 2005 proved easy this year. As the editorial staff of THE DARK REPORT sifted through the year's major events, there was speedy consensus on the final list.

The number one story is the growing acceptance of consumer-driven health plans (CDHPs) in the United States during the past 18 months. We've been first to alert laboratory administrators and pathologists to this still-nascent trend and explain specific ways this will affect laboratories and pathology group practices.

One short-term consequence of CDHPs is the need for laboratories and pathology group practices to have transparent prices to quote to consumers upon request. Another is the capability to collect payment from consumers at time of service and to accept cash, credit cards, and health plan debit cards in patient service centers and other locations where specimens are collected.

Over a longer time, THE DARK REPORT predicts that CDHPs will return choice of laboratory provider back to referring physicians and patients. As that happens, community-based labs and pathology groups should regain competitive advantage that was lost during the 1990s when many HMOs excluded them from provider panels in favor of national laboratory companies.

Next on our "Top Ten" list is the arrival of a new billion-dollar laboratory competitor to the United States. With its acquisition of **Clinical Pathology**

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Laboratories, Inc. of Austin, Texas, **Sonic Healthcare Ltd.** has an operational base from which it can expand in any number of ways.

During the next few years, Sonic Healthcare has the potential to roil the competitive status quo that has existed between **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. It could decide to acquire regional laboratories as a way to build its revenue base in the United States. It has the corporate resources to expand outside the traditional markets served by CPL, using sales and marketing to capture new clients. Whichever business strategy Sonic implements, it introduces a new variable in the competitive landscape.

A number of stories on the 2005 "Top Ten" list involve efforts by state and federal healthcare officials to stimulate changes to the American healthcare system. One dimension of this is the patient safety/outcome improvement trend. Labs and pathology groups can expect to see government health administrators introduce specific quality improvement programs that involve laboratory testing services. It will take some time, because labs are always low on the list of national health priorities. But the day will come when laboratories will be measured for quality and those measurements will be made public.

Cuts In Lab Reimbursement

Another trend in government health programs is to control the cost of laboratory testing. As reported on these pages in 2004 and 2005, the often-wacky contracting schemes cooked up by Medicaid officials in Florida and California are symptoms of a deeper disease. Medicaid is bankrupting state budgets and bureaucrats are responding with the most elementary strategy: changing reimbursement policies to pay laboratories less money.

Speaking of money, some executives in the laboratory industry took too much money, and did it illegally. When ex-**IMPATH** executives were indicted in New York City earlier this year, THE DARK REPORT surprised the lab industry with the findings that, since 1990, as many as 17% of public laboratory companies had CEOs who have had been been indicted for criminal violations of federal healthcare statutes. And, for those cases that went to trial, the conviction rate has been 100%! *(See TDR, June 20, 2005.)*

Why Such Behavior?

This is a "Top Ten" story because it puts a different face on the frequency of corporate-suite crime that occurs in specific laboratory companies. It is appropriate for the laboratory industry to ask why the ethics in this sector of the lab industry are so different than that of, say hospital-based lab outreach programs.

A related story is the OIG's continuing interest in anatomic pathology arrangements between office-based physicians, pathology lab companies and pathologists. With no recent enforcement action to serve as either a guide or a warning, the lab marketplace is awash with anecdotes and stories about aggressive arrangements between referring physicians and anatomic pathology providers that, at best, skirt compliance requirements and, at worst, may be egregious violations of federal law. The OIG's continuing interest should be a major caution sign for the entire laboratory industry.

As in past years, THE DARK REPORT recommends that lab administrators and pathologists may find it useful to build a strategic planning session around 2005's "Top Ten" lab industry stories. These topics are early flags to trends that can swiftly change today's status quo in the lab marketplace.

—By Robert L. Michel and Pamela Scherer McLeod

1 Consumer-Directed Health Plans Poised To Transform Healthcare

YOU READ IT FIRST on the pages of THE DARK REPORT. Consumer-directed health plans (CDHPs) are expected to be "arguably, the most important development in health insurance since the widespread introduction of HMOs in the 1980s."

No less an authority than **McKinsey & Co.** made this bold statement in the opening lines of the first-ever comprehensive analysis of consumer behavior in the first generation of CDHPs now in operation. *(See TDR, July 11, 2005.)* McKinsey & Co. believes that CDHPs provide consumers with the economic motivation to use healthcare services in radically different ways than is true of health plans like fee-for-service or HMO.

Consumer-directed health plans are designed around several primary factors. First, consumers are responsible for more out-of-pocket expenses. Many CDHPs require consumers to pay deductibles of $1,000 before insurance benefits kick in.

Second, Health Savings Accounts (HSAs) are designed to encourage consumers to become savvier buyers of healthcare services. Consumers can accumulate unspent funds in their HSAs.

As CDHPs cover larger numbers of consumers, labs and pathology groups must be ready to quote prices for lab testing services to consumers—and to collect payment for services at time of service by accepting cash, credit cards, or health debit cards.

2 Sonic Healthcare Becomes Newest Billion-Dollar "Blood Brother" in U.S.

NOT SINCE 1999 HAS THE LAB INDUSTRY had three laboratory companies with revenues in excess of $1 billion per year.

During 2005, **Sonic Healthcare Ltd.** became the third member of this exclusive club when it acquired **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas. Sonic paid about $300 million to purchase a majority interest in CPL. *(See TDR, September 12, 2005.)*

Sonic Healthcare is a publicly-traded company based in Australia. It also owns clinical laboratories in New Zealand, Germany and in the United Kingdom. In buying its way into the United States, it presents an interesting wild card into the competitive landscape for laboratory testing services.

Sonic Healthcare has a reputation as an efficient operator. It has deep pockets to support CPL's expansion and to acquire other laboratories in the United States.

It also has a different business strategy when compared to national competitors **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. Sonic prefers to acquire local laboratories and continue operating them under their original name with the same staff.

Having placed a $300 million-bet to sit at the table and compete in the United States, Sonic Healthcare will certainly introduce new competitive wrinkles into a competitive lab services marketplace long dominated by Quest Diagnostics and LabCorp.

3 Medicare Physician Pay-to-Perform Demonstration Project Now Underway

TWO EVENTS THIS YEAR ARE PAVING the way for Medicare pay-for-performance programs involving laboratory testing services.

On March 1, 2005, CMS (**Centers for Medicare and Medicaid Services**) launched a demonstration physician pay-for-performance (P4P) program. CMS selected 10 large medical groups, involving 5,000 physicians and 200,000 Medicare beneficiaries, to participate in this demonstration program. Savings attributable to improved patient care will trigger rewards to those physician groups that generate improved outcomes. *(See TDR, February 21, 2005.)*

The second event occurred last month. In November, CMS announced the results from the first year of its demonstration hospital pay-for-performance program. In all measurements, outcomes improved.

Called the Premier Hospital Quality Demonstration Project, the program launched in October 2003 with the voluntary participation of 260 hospitals. CMS will pay $8.85 million to hospitals that show significant improvement in targeted areas over the course of the first year.

Assuming that Medicare's P4P quality initiatives involving hospitals and physicians continue to deliver measurable improvement in outcomes, it may not be long before the laboratory profession has its own pay-for-performance demonstration project.

4 Institute for Quality in Lab Medicine Is Sign of Quality Shift In Lab Industry

MEDICARE IS NOW EXPERIMENTING with pay-for-performance programs as a way to motivate providers to improve the quality of care. Is it a coincidence, then, that the **Centers for Disease Control and Prevention** (CDC) has invested considerable resources into launching the **Institute for Quality in Laboratory Medicine** (IQLM)?

THE DARK REPORT thinks not. IQLM has two primary goals in phase one of its operations. First, IQLM will develop a white paper that takes a first crack at measuring, at the national level, the quality of laboratory testing services in the United States. The second priority is to develop viable metrics for measuring laboratory quality. It then wants to collect these metrics from individual laboratories and aggregate them to create a national benchmark that can measure the year-to-year improvement in the quality of laboratory testing. *(See TDR, May 9, 2005.)*

Laboratory managers and pathologists will want to understand the ramification of federal health initiatives to measure the quality of care and to motivate providers to improve outcomes. At some point, the healthcare system will begin designing specific programs to encourage laboratories to boost their quality and improve outcomes.

The birth of IQLM is fair warning to the lab profession. Measures of laboratory performance will be introduced. Success will accrue to those labs which can "manage to the numbers" and deliver significant improvements in clinical outcomes while reducing cost of care.

5 Medicaid Lab Contract Effort Flops In both Florida and California

BY NOW IT SHOULD BE COMMON KNOWLEDGE that Medicaid costs are blowing huge holes in the budgets of many states. In particular, Florida and California face major funding challenges.

That is why, in 2004, Medicaid officials in both states proposed unorthodox, even radical, schemes to contract for laboratory testing services on a statewide basis. Designed to cut costs—and designed by bureaucrats—both contracting schemes collapsed during 2005. *(See TDRs, January 3, 2005 and October 24, 2005.)*

In both Florida and California, the complexities and arbitrary design of these statewide contracting efforts doomed them to failure. As well, the politics of how these schemes might favor certain lab companies over others triggered vociferous opposition.

For now, labs in both states are delighted that these Medicaid contracting initiatives have died. But the real message behind these unexpected and unorthodox contracting proposals needs to be understood. State Medicaid bureaucrats, desperate to shave expenses, will try to slash the cost of such tests.

Perceptive pathologists and laboratory managers should keep a wary eye out for future bureaucratic schemes that could hurt access by Medicaid beneficiaries to lab testing. They may also want to use this time to organize a more effective lobbying capability in their state to make a better case with Medicaid regulators and elected officials.

6 Physicians with Anatomic Path Labs Attracting Greater Scrutiny by OIG

IN RECENT WEEKS, the **Office of the Inspector General** (OIG) announced its work plan for 2006. For the second consecutive year, the OIG will be looking at arrangements that involve office-based physicians and anatomic pathology (AP) services provided to their patients.

That means 2005 started and ended with an OIG focus on AP compliance issues. It had issued a negative advisory opinion on a specific AP laboratory condominium arrangement in the closing days of 2004. *(See TDR, January 3, 2005.)*

In its 2006 Work Plan, the OIG indicates it will focus on pathology services performed in physicians' offices to determine if the billings for such services comply with Medicare Part B requirements. The OIG will scrutinize relationships between physicians who furnish pathology services in their offices and outside pathology companies.

The direct cause of these compliance concerns is the exploding interest by specialty physicians—urologists, gastroenterologists, and dermatologists in particular—in a variety of arrangements that cut them in on revenues and profits derived from AP services provided to their patients.

Across the pathology profession, the proliferation of business agreements designed to steer AP revenues into the pockets of referring physicians is a major concern. On one hand, it represents a compliance risk. On the other hand, it erodes the professional services revenue of pathologists.

7 Newest Wave of Lab Acquisitions Strengthens National Lab Oligopoly

THERE WAS PLENTY OF EVIDENCE in 2005 that the national oligopoly in lab testing services is strengthening.

For example, **Laboratory Corporation of America** picked off **Esoterix, Inc.** in April. In August, **Quest Diagnostics Incorporated** announced it would pay a hefty $934 million to buy **Lab*One*, Inc.** That deal was announced just weeks after **Sonic Healthcare, Ltd.** revealed it would buy **Clinical Pathology Laboratories, Inc.** of Austin, Texas. A few months later, in October, **AmeriPath, Inc.** bought **Specialty Laboratories, Inc.** and took the company private.

2005's steady parade of lab acquisitions fulfills a prediction made in 2002 by THE DARK REPORT. That was the year when the two blood brothers swept **American Medical Laboratories**, **Dyncare**, **DIANON Systems**, and **Unilab** out of the marketplace as independent companies by acquiring them.

In the three years since 2002, the two blood brothers have demonstrated their readiness to pick off any laboratory company that attains a certain size and scale. Such acquisitions represent growth to the acquiring lab—but they also remove a competitor just as it is becoming big enough to vie for significant managed care contracts and clients.

Expect the nation's largest labs to continue bidding aggressively for any laboratory company that can grow past $50 million to $100 million in annual revenues. It is unlikely that most lab firms in that size range will remain independent for very long.

8 Ongoing Consolidation Among Payers Concentrates Power In Fewer Firms

CONSOLIDATION AMONG THE NATION'S LARGEST HEALTH INSURERS accelerated during 2005.

The emerging "superpowers" are **WellPoint, Inc.**, which now has 34 million members, and **UnitedHealth Group, Inc.**, with 28 million members. Both companies announced major acquisitions during 2005. *(See TDRs, July 11, 2005 and October 14, 2005.)*

It was THE DARK REPORT which first called the attention of the lab industry to the extent and impact of consolidation among major health insurers. The market dominance of large firms has reached the point where WellPoint and UnitedHealth alone insure more than one-third of the 50 million Americans with private health insurance. This gives these companies growing clout when negotiating contract terms with hospitals, physicians, and laboratories.

THE DARK REPORT predicts that "second rank" health insurers, including companies such as **Aetna, Inc.**, **Humana, Inc.**, and **Cigna Corp.**, are likely to respond with their own acquisitions. How this eventually affects the healthcare marketplace remains uncertain.

That's because the growth of consumer-directed health plans (CDHPs) will increasingly give consumers more choice as to which hospital, physician, or laboratory they want. As that happens, contracted provider networks as we know them today will have less relevance. Health insurers will become expeditors of patient choice, not gatekeepers to access.

9 Crime in Public Lab Executive Suites Triggers More Criminal Indictments

IN A PLOT THAT MIGHT HAVE COME directly from the pages of *True Crime* magazine, six former executives of **IMPATH, Inc.** were indicted for federal crimes on March 30 in New York City. *(See TDR, April 18, 2005.)*

According to the federal attorney prosecuting the case, former Chairman and CEO Anu Saad, Ph.D., and former President and COO Richard P. Adelson, along with four other ex-IMPATH executives, had cooked the books for several years. The scale of the fraud is staggering. By the end of 2002, the indicted individuals were accused of inflating IMPATH's reported revenues of $50 million per quarter by more than 50%!

Yet this brazen scheme by lab executives is not an isolated incident within the laboratory industry. THE DARK REPORT published an analysis which demonstrated that, since 1990, of 23 publicly-traded lab companies, four have been indicted for federal crimes. This represents 17% of the total public lab firms operating during this period.

This ratio of criminal indictments to public companies may be unmatched by any other industry. It exists as a backdrop to any future federal investigations into lab industry practices. Combined with the Labscam settlements of the 1990s, the criminal behavior of specific lab executives in past years, including ex-IMPATH managers, has the potential to bias federal health prosecutors in cases yet to be filed. That's a high price for an industry to pay for the sins of a few.

10 Patient & Physician Identity Theft Is a New Risk for Labs & Path Groups

IT'S A REMARKABLE FACT that the first conviction under HIPAA statutes was of a hospital phlebotomist found guilty of stealing the identity of one of his patients.

It is even more remarkable that no one in the laboratory industry realized this fact until THE DARK REPORT published the details of the conviction of Richard Gibson, a phlebotomist in Seattle, Washington. *(See TDR, March 28, 2005.)*

That scoop was followed by an exclusive interview with the victim. Eric Drew. Diagnosed with acute lymphoblastic leukemia (ALL), Drew was fighting for his life in a Seattle cancer hospital when he discovered that someone had stolen his identity and was opening credit cards in his name. Drew's story about how no one would help, from hospital to news media to police, makes a perfect case study in what providers *shouldn't do* when their patients are victims of identity theft. *(See TDR, April 18, 2005.)*

Even today, most laboratories and pathology group practices have yet to fully recognize the threat of patient and physician identity theft. However, the consequences of being unprepared can be expensive. As in the Richard Gibson case, when the public finally learned about his crime, the hospital's name was splashed across the television news and daily newspapers. It was their good fortune that Eric Drew declined to sue them over how Gibson, then an employee of the hospital, was able to access Drew's confidential information. TDR

NEWSMAKER INTERVIEW

Middleware Provides Opportunity For Labs to Gain New Functions

"Even as more laboratories begin to use middleware, the number of functions and uses for middleware continues to increase

—Gregory R Vail, *CEO, Data Innovations, Inc.*

CEO SUMMARY: Middleware is attracting attention throughout the laboratory industry. It describes the software applications that bridge instruments and the LIS, or sit on top of the LIS to perform specific functions. Middleware is generally a fast and reliable way to automate tasks and monitor work processes in the lab. In this exclusive interview, Gregory R. Vail, CEO of **Data Innovations, Inc.**, located in Burlington, Vermont, gives lab administrators and pathologists an inside view of the middleware marketplace. Vail's company was one of the pioneers in creating middleware solutions for use in clinical laboratories. He discusses the first middleware applications by labs in the late 1980's. He also covers the evolution of middleware during the past two decades and includes insights about how today's early-adopter labs are using middleware solutions in innovative ways. The interview was conducted by Robert L. Michel, Editor-In-Chief of THE DARK REPORT.

EDITOR: "Middleware" is the new word that's altering the information technology strategies of laboratories across the country. Your company, **Data Innovations, Inc.**, seems to be at ground zero in this trend. Can you help us understand why middleware is becoming a viable business option?

VAIL: The key to understanding the growing interest in middleware lies in the economics of laboratory operations. On one side are the economics of operating the clinical laboratory. On the other side are the economics of laboratory labor.

EDITOR: Could you elaborate?

VAIL: Every laboratory organization in the United States is feeling pressure to better control its budget. The well-known squeeze of declining reimbursement for laboratory services versus the steady increase in the cost of operations, from instruments to reagents to information technologies, means that all laboratories are under pressure to perform more work with fewer resources.

EDITOR: That's a widely-accepted view. Please explain how you see the economics of lab labor as an influence.

VAIL: First, many laboratories cannot get enough technical staff to meet their labor needs at any price. In the face of declining reimbursement, it is ever-harder for laboratories to cover the year-to-year increases in labor costs, benefits, healthcare, and the like. Second, the data the laboratory is asked to process is becoming increasingly complex. Collectively, these factors give laboratory administrators and pathologists a powerful motive to look for opportunities to increase laboratory productivity. Middleware solutions can often enhance and boost labor productivity.

EDITOR: On the balance sheet, these are factors of production which fall on the expense side of the balance sheet. Looking at the revenue side, does middleware play any role there for laboratories?

VAIL: That's a perceptive question and the answer is yes. Many of our hospital lab clients are being asked by their parent health system or owner to develop ways to generate profits again. In particular, many hospital laboratory outreach programs have sprung up specifically because administrators are encouraging laboratories to develop sources of revenue that will generate net profits. By interfacing to both the hospital laboratory information system (LIS) and outreach applications, middleware allows the laboratory to process samples from both.

EDITOR: Your observation is consistent with other vendors who provide products and services to hospital-based laboratories. The number of laboratory outreach programs operating today is significantly higher than 10 years ago.

VAIL: We certainly see that among our laboratory customers.

EDITOR: Now I'd like to drill down into the core issue of laboratory information systems and what is happening in that

marketplace that encourages or discourages laboratories from using middleware solutions.

VAIL: As you know, Robert, fewer laboratories are upgrading their LIS. This trend is well established for a number of years. The primary reason why labs are deciding not to upgrade their LIS is that they believe newer generations of LIS products do not add enough improvements to justify the cost of conversion.

EDITOR: It's basic economics, right?

VAIL: Yes. Laboratories look at the extra functionality of the upgrade LIS option and decide that, for the price, they don't get much more functionality than what they already have with their existing LIS. Middleware is inexpensive, from both a financial viewpoint and in terms of time to implement and maintain. Furthermore, the better middleware products are licensed in a manner that allows labs to buy only the functionality they need at the time.

EDITOR: THE DARK REPORT has written about why many health systems are spending most of their IT (information technology) dollars on projects to get clinical data repositories to talk to each other. That is required before hospitals and health systems can accomplish another IT priority: a working electronic medical record (EMR). Then there's the mushrooming use of handheld devices, which can connect to the local area network (LAN) or the Internet by either a base station or wireless connection. Do steady improvements in hardware and software technology play a role in how laboratories view upgrades and enhancements to their informatics capabilities?

VAIL: This is definitely a factor, since laboratories must react and respond to the needs of their parent hospital or health system.

EDITOR: Seen from this perspective, these are trends now eating away at the traditional healthcare IT platform—that of a self-contained, fat-client software system that has limited interconnectivity or interface with other similar fat-client systems within the healthcare enterprise.

Greg Vail

"Middleware is inexpensive, from both a financial viewpoint and in terms of time to implement and maintain. Furthermore, the better middleware products are licensed in a manner that allows labs to buy only the functionality they need at the time."

VAIL: That's a good way to look at it. Lots of money is being spent right now, not to upgrade basic clinical software systems that are already doing the job, but to create ways for these existing information "centers" to interface in support of the clinical and operational mission of the hospital and its laboratory. This is precisely where middleware—software products designed to do a specific function—can make a big contribution.

EDITOR: You've helped us understand how the IT needs of laboratories and hospitals have evolved. Let's talk specifically about middleware. What is it and from where did it come?

VAIL: That's easy, because laboratories were the first healthcare providers to make extensive use of middleware. Middleware started as the interface engine between diagnostic instruments and the LIS. This is also where the Data Innovations' story begins.

EDITOR: Please continue.

VAIL: In 1989, **Brigham and Women's Hospital** in Boston, Massachusetts had a home-grown LIS. As their laboratory added new instruments, there was a need to write interfaces that would con-

nect those instruments to the LIS. Since Brigham's administrators did not want to distract its in-house IT staff by having them write these interfaces, they contracted with us.

EDITOR: That's interesting, because Brigham and Women's is a hospital that has always been progressive in its use of information technology.

VAIL: Yes. It gave us the opportunity to interact with a relatively sophisticated user of healthcare information technology.

EDITOR: Where did this lead you next?

VAIL: As we worked with different instrument vendors to write their interfaces with Brigham's home-grown LIS, they got to know us. They asked us to create interfaces for their instrument systems with other laboratory clients. So we found ourselves working with a growing number of the nation's largest in-vitro diagnostic (IVD) manufacturers, writing interface code to enable their instruments to feed data into the LIS products of vendors like **McKesson**, **Veterans Affairs**, and **Sunquest** (now **Misys**). The result was the genesis of our product, Instrument Manager.

EDITOR: What step came next in the evolution of middleware?

VAIL: As our product proliferated between instruments and the LIS, we began to receive requests to fill gaps in the functionality between the two. The first gap we were tasked to fill is one we call "clustering." From about 1991 forward, as laboratories placed multiple instruments in their lab, they wanted a software system that would make requests available to multiple available instruments, simultaneously. We were asked to write software programs to accomplish this task. That was our first foray into data management.

EDITOR: But not your last?

VAIL: Hardly! Middleware's next evolutionary step came when laboratories wanted a software capability to massage raw data produced by the instruments. For example, the need was to take the raw numbers from a pregnancy test, have the software run those numbers against rules, and post the result as a "positive" or "negative"—or flag the result for operator attention.

EDITOR: That sounds like a "rules engine."

VAIL: Correct, that is certainly what it has grown into. And from that simple start, Data Innovations has been developing many types of rules engines for use in laboratories in the United States, Europe, and the rest of the world. This type of software fits the definition of middleware. It is a software application that sits somewhere between a data-generating source and a data-requiring recipient and often handles delegated tasks with little or no operator involvement.

EDITOR: From this start, I would assume that you've been asked to develop software applications to handle any number of functions for laboratories. Over the past decade, did you have any experiences with laboratories that reshaped your thinking about middleware, its uses, and its potential to contribute substantially more than most laboratory administrators and pathologists can conceptualize?

VAIL: As a matter of fact, we did. However, it wasn't from a single laboratory. It was the lessons we learned when we began to develop products for use in Europe.

EDITOR: That's intriguing, since there is not much visible exchange of laboratory management techniques occurring regularly between Europe and the United States. What made Europe different and

what lessons did you learn that you now use here in the United States?

VAIL: What we discovered when we began to offer our products in Europe was that middleware was a software product that was already in broad use by laboratories there.

EDITOR: In what ways?

VAIL: In the United States, laboratory IT solutions were usually a two-tier arrangement, with instruments on one level and the LIS on the other. In Europe, most laboratories operate in three tiers. The first tier is instruments, the second tier is middleware, and the third tier is either the LIS or HIS (hospital information system).

Greg Vail

"What we discovered when we began to offer our products in Europe was that middleware was a software product that was already in broad use by laboratories there."

EDITOR: Why was Europe different in this regard? Was it because LIS products used in Europe were not so multifunctioned and complex as here? To fill that gap in functionality, were European laboratories using middleware applications to provide specific functions they needed to supplement their "basic" LIS?

VAIL: In a general sense, that is true. Laboratories had a variety of middleware products to use in creating the information technology capabilities they wanted in their laboratories.

EDITOR: Did this more extensive use of middleware cause other differences in laboratory operations in Europe? Did you learn other interesting lessons?

VAIL: From one country to the next, the differences in laboratory operations are influenced by such factors as regulatory requirements, government-versus-private sources of payment, and regional differences in how healthcare is delivered.

EDITOR: Each of those factors would play a role in shaping different approaches to operating clinical laboratories. Did anything change at your company as a result of working in European laboratories?

VAIL: Two things. One, to become a credible software vendor in Europe, we had to develop middleware applications for all the functionalities that were found there. Specimen management modules are one example. By combining the requirements of Europe and the United States, Instrument Manager now surpasses the demands of both regions.

EDITOR: And the other?

VAIL: Two, what we've learned about laboratory organization and management in Europe is allowing us to come back to the United States and introduce these management approaches to laboratories here, in combination with the middleware modules needed to make them successful.

EDITOR: Can you offer an example, besides the already-mentioned specimen management, of another successful middleware module?

VAIL: There are many, but let's use specimen routing. For many years, the mechanical systems used to route specimens around clinical laboratories lacked an effective laboratory automation system (LAS) to drive the mechanics. We have implemented an LAS in another of our rules engine add-ons, called Specimen Routing (SR). For instance, SR follows every specimen through the track and can allow for what we call "dynamic reaction" to various events. In real time, it can handle add-on tests, rerun and reflex request determination, and instruments going offline. Essentially, the track is always asking "What do I do next" with individual specimens?

EDITOR: I've heard you talk about "manual automation." Will you explain that?

VAIL: We coined this term for laboratory customers who are using SR functions without mechanical automation in their laboratory. MTs go to the computer and ask the system "what do I do next" with the individual specimen. The system gives them an answer and is tracking the progress of that specimen from pre-analytical through analytical to post-analytical processes.

EDITOR: That's fascinating.

VAIL: Our system doesn't care whether it is a mechanical system asking that question or a human. It tracks the specimen, determines the instructions for that specimen, and provides the answer when queried.

EDITOR: Greg, this is interesting background which tells us how the middleware concept first started, as well as some of the ways laboratories can use it now. Here's a tougher question, but one that interests every lab director and pathologist now reading THE DARK REPORT. How do you see the laboratory industry using middleware in the next, say, 24 to 36 months?

VAIL: My answer will surprise, and I hope not offend, most laboratorians, and it will connect powerfully with those people running laboratories who have already accepted this insight. A clinical laboratory is a manufacturing facility. The parts it works on are specimen samples. The finished product it ships to customers are test results.

EDITOR: Is this concept accepted by many laboratories today?

VAIL: Definitely! More and more laboratories see themselves as a manufacturing facility. Once that mental shift happens, they get great operational results. It gives them the freedom to look outside the lab industry for management methods, operational tools, and software solutions that are generating tremendous gains for non-healthcare businesses. We see this repeatedly with our best-managed laboratory clients.

EDITOR: Your observations are consistent with the experience of hospital laboratories that were first to use Lean and Six Sigma principles to redesign their high-volume core laboratories. In 15-week projects, these labs cut average turnaround time by 50%, while reducing errors and boosting laboratory productivity in the range of 50% each. *(See TDR, September 8, 2003.)*

Greg Vail

"More and more laboratories see themselves as a manufacturing facility. Once that mental shift happens, they get great operational results. It gives them the freedom to look outside the lab industry for management methods..."

VAIL: This is a phenomenon which is catching the attention of more and more laboratory administrators and pathologists. In fact, we've created middleware capable of supporting laboratories that operate on Lean and Six Sigma management principles.

EDITOR: Could you elaborate?

VAIL: Of course. As you know, quality management methods are built upon the principle of continuous feedback. Lab instruments are increasingly able to give us more information about individual work processes. We've recently enhanced a middleware application we call "Notifier" to take advantage of this. As our system receives data from the instruments, Notifier has the ability to alert the operator when intervention is required. For example, it will turn on a light when the instrument needs reagents. That alerts a roving med tech to come over and service the instrument.

EDITOR: Does Notifier interact with other functions?

VAIL: Sure. For example, it can tie into a quality control (QC) program such as QC OnCall from **Bio-Rad**. If a QC result violates Westgard Rules, our system can be set up to start holding the subsequent patient results from autoverification. Simultaneously, Notifier will send out an alert that this is happening. That might be an alert on a computer screen, a page, or a similar type of communication method chosen by the laboratory.

EDITOR: Is this popular?

VAIL: Absolutely. Once lab customers see how these middleware applications can monitor work processes, they bring other types of issues to us. They want middleware applications that can trigger notifications based on all types of different events. Often light poles are used as visual notification within the laboratory.

Greg Vail

"Middleware is the informatics solution that allows hospitals of almost any bed size to take their existing laboratory facility and add the software functions necessary to compete in the outreach marketplace."

EDITOR: Greg, given the middleware solutions you've described as already in use in laboratories, it seems that this management option is robust and ready for "prime time."

VAIL: That's definitely true. Middleware is simple. It is typically very robust. It can easily be reconfigured to meet the changing business needs of the laboratory, often with no additional investment. We place a great deal of emphasis on putting control of this reconfiguration in the laboratory's hands, not ours or that of a separate IT department.

EDITOR: Now that we understand how laboratories today are using middleware solutions, I'd like to circle back to ask you how middleware is being used in hospital laboratory outreach programs.

VAIL: There's lots of exciting things happening in this area of laboratory operations. When a hospital wants to launch an outreach program and make it grow, that entire business line fits the manufacturing paradigm. Hospital inpatient testing is mostly performed between 7 a.m. and 5 p.m. Outreach specimens typically come in after 5 p.m. and allow the laboratory to use its asset base for more hours each day.

EDITOR: That fits the manufacturing paradigm of using the same factory and equipment two or three shifts per day.

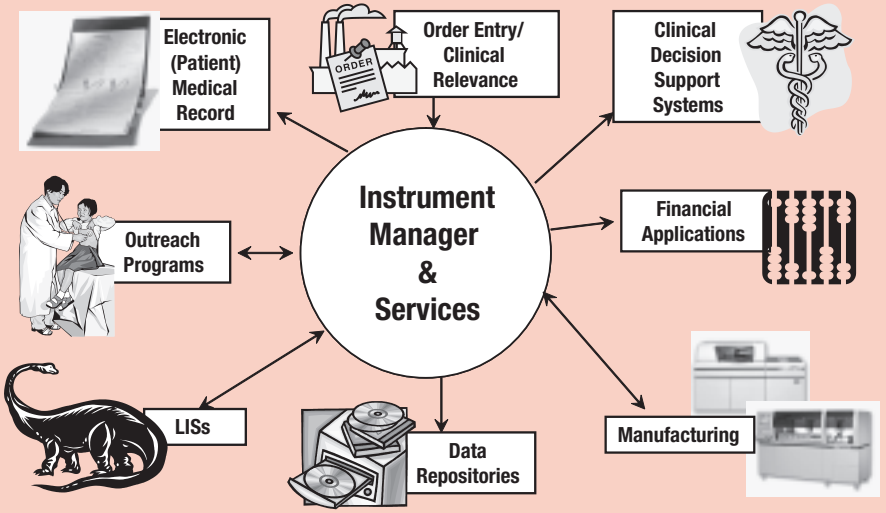
VAIL: Exactly, and this additional utilization of fixed overhead, equipment, and computer systems helps drive down the average cost for all testing done in the laboratory, including the inpatient work. Middleware is the informatics solution that allows hospitals of almost any bed size to take their existing laboratory facility and add the software functions necessary to compete in the outreach marketplace.

EDITOR: I'd like to shift gears again. How are big healthcare IT vendors reacting to the use of middleware by many of their customers?

VAIL: Let me answer that this way. In the healthcare IT marketplace, many of the largest IT vendors are emphasizing software solutions and enhancements to HIS and similar products. This is consistent with the interests and needs of hospitals and health systems to develop a fully-integrated EMR as soon as possible and their interest to provide enterprise-wide solutions. But, as a consequence, the development of traditional LIS products is lagging. That is why growing numbers of laboratories are turning to middleware as a way to

A Vision of Middleware's Multiple Functions In the Operation of Clinical Laboratories

Future view of IM in, and beyond, the Lab



Source: Data Innovations, Inc.

HERE'S A DEPICTION OF THE MULTIPLE FUNCTIONS THAT MIDDLEWARE PRODUCTS (the one above is called "Instrument Manager") can perform. It illustrates how the flow of data coming from laboratory instruments can be directed to different areas for different purposes.

Traditional points of distribution are LISs, data repositories, EMRs (electronic medical records), and outreach programs. The "manufacturing" symbol represents the increasingly common, real-time, two-way communications between an instrument and its manufacturer.

The functions of "order entry/clinical relevance" and "clinical decision support systems" play directly to the strengths of laboratory medicine. That is, helping clinicians with early and accurate diagnosis, guiding therapeutic decisions, and monitoring patient progress. The dinosaur symbol for LISs hints at how software and hardware technology innovations may, over time, cause complex, fat-client LIS installations to become obsolete.

Every laboratory and pathology group practice should be developing an informatics strategy that incorporates middleware applications in effective ways. Information is the end product of all laboratories and middleware represents a cost-effective solution to collect, package, and deliver information to those who need it within the healthcare community.

gain the functions they need to keep their lab competitive.

EDITOR: Inherent in that answer is your belief that the market for laboratory middleware solutions will be dynamic and fast-growing. That is based on growing interest by lab customers.

VAIL: I would agree. As we have done in the past, over the next few years 100% of what we develop will be in direct response to a customer's request. I say this because we have so many requests now—and these customer requests are the source of many of our innovations. This development strategy ensures that our software meets the real-life business needs of the laboratory.

EDITOR: That makes Data Innovations rather unique. You are building self-contained software applications—the middleware we've been discussing—to meet the specific requests of laboratory customers. Unlike the traditional LIS, with its myriad lines of code, I would assume that you can bring these middleware solutions to market rather quickly.

VAIL: That's correct. These are truly customer-driven products. Because of the add-on nature of the incremental modules we add to core product, we are able to add or rework one area without affecting another, making it even easier for labs to integrate into their operational environment.

EDITOR: I am curious about what you're ready to introduce next.

VAIL: Our newest add-on feature is our Maintenance Manager module. It will be available in version 8.05, set for release in early 2006. It will allow the laboratory to go paperless on its maintenance. This includes preventive and unscheduled maintenance for everything from instruments to fire extinguishers and even temperature readings on refrigerators. It includes troubleshooting help with supporting documents and full logs to aid with inspections.

EDITOR: Given all the paper in laboratories, this has to be a good thing.

VAIL: Paperless maintenance is a great example of a useful middleware solution. The goal of middleware should be to allow med techs to be as productive as they can be. It frees them up to concentrate their technical skills on improving patient care.

EDITOR: Does this type of middleware application free lab staff, both at the bench and in management, to shift to higher-value activities?

Greg Vail

"Paperless maintenance is a great example of a useful middleware solution. The goal of middleware should be to allow med techs to be as productive as they can be. It frees them up to concentrate their technical skills on improving patient care."

VAIL: Yes, middleware is something that takes the handcuffs off the laboratory and allows it to function as a business—that just happens to be in a hospital. Now they have the tools to be "business competitive."

EDITOR: Using middleware to become "business competitive" is certainly an underappreciated benefit. Also, the fact that middleware is an affordable way for even laboratories from smaller hospitals to support a competitive outreach lab testing program may eventually change the competitive marketplace. Middleware is already spurring change in laboratory operations. Greg, thanks for an enlightening discussion today.

VAIL: Robert, it's my pleasure. I appreciate the opportunity. TDR

Contact Greg Vail at 802-658-2850.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

On November 9, **Luminex Corporation** was awarded the "2005 Clinical Diagnostics Technology of the Year" Award from **Frost & Sullivan**. The award recognizes "clinical diagnostics technology that shows the potential to become an industry standard, achieve a high degree of market acceptance, and maintain a competitive posture in several market segments." Luminex's xMAP® technology was honored, in particular, for its applications in immunoassay and molecular testing. These are two of six segments in clinical diagnostics that are evaluated for this award.

MORE ON: Luminex

xMap technology supports multiplex testing. This allows multiple analytes to be evaluated in a single specimen. Luminex has licensed the technology to many of the leading IVD and pharmaceutical companies in the world. The ability of xMAP to perform both DNA- and protein-based assays makes it attractive for a number of diagnostic and research applications.

ANNUAL INCREASE IN HEALTH COSTS SLOWS FOR EMPLOYERS

Health benefit costs for employers increased by an average of only 6.1% in 2005, according to a survey recently conducted by **Mercer Health & Benefits**. Mercer notes that this is the lowest rate of increase in several years. For this year's survey, Mercer interviewed 2,999 employers. It reports that employers paid an average of $7,089 per employee to provide health benefits in 2005. This is just a 6.1% increase from the average of $6,679 paid per employee in 2004. Mercer expects that 2006 will be another year of single-digit increases in employee health costs.

ADD TO: Health Costs

Mercer identified a primary reason for the moderate increase in the cost of employee health benefits. Simply put, employers are requiring employees to pay more. However, unlike past years, where the employee was asked to pay a larger portion of the health insurance premium, most companies have switched to requiring employees to pay higher deductibles, co-pays, and out-of-pocket expenses. Among other things, this shifts more of the burden onto those employees who use health benefits the most. Mercer also reported that 22% of the companies surveyed offered some form of a consumer-directed health plan (CDHP) during 2005. Expanded enrollment in CDHPs is a market dynamic that lab directors and pathologists will want to track in their strategic planning.

THE DARK REPORT IS NOW VISITING AUSTRALIA

As this issue goes to the printer, THE DARK REPORT is in Australia, visiting laboratories and participating in strategic planning sessions for one of that nation's leading laboratory associations. It is proving to be a great learning experience. A large country when measured by geographical size, Australia's population is just 20 million—about the same number of people who live in Southern California or Florida. Because its health system reimburses private providers, there is a dynamic and competitive market for clinical lab and anatomic pathology services. More insights to come in future issues.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 26, 2005.

NEWS FLASH!

Executive War College 2006 has a NEW HOTEL & NEW CITY!

May 3-4, 2006
Intercontinental Hotel, Miami

Join us Wed/Thur, May 3-4, 2006 at the Intercontinental Hotel in Miami for all that's new in lab and pathology management!

Full program details available soon!
visit darkreport.com

UPCOMING...

- ***The Dark Report Travels to Australia: Useful Lessons from Aussie Lab Innovators.***
- ***Hospital Lab Outreach Surprise: Effective Strategies for Shaving Costs and Boosting Profit Margins.***
- ***How Unseen Forces are Undermining Financial Viability of Small Pathology Group Practices.***

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