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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

Threat of Medicare 20% Co-pay for Lab Looms Again

BY NOW MOST OF YOU KNOW THAT THE LATEST ATTEMPT TO REINSTITUTE the 20% patient co-payment for Medicare Part B laboratory testing services was waved off in the Senate last week. But don't relax, because similar proposals are expected to be put forward in Congress in coming months.

It was a close call for the laboratory industry last week. An economic stimulus bill in the Senate included a provision that would have imposed the application of beneficiary co-insurance and Part B deductible for clinical laboratory services. The stated justification for this provision was that it would create budget savings to offset increased Medicare payments to rural providers. Lab industry insiders close to the Washington legislative action tell THE DARK REPORT that lawmakers decided an economic stimulus bill was not the place to try and insert provisions to increase Medicare funding to rural providers. So that language was dropped from the bill that eventually passed the Senate.

Since the 20% co-payment requirement was eliminated in the late 1980s (as part of a deal to offset other Medicare cuts in reimbursement for Part B laboratory testing services), initiatives to reinstitute the 20% co-payment surface regularly. For this to happen, it means that one or more individuals within Congress and/or the Centers for Medicare and Medicaid Services (CMS) are convinced this is a way to reduce Medicare costs, regardless of its economic impact on the clinical laboratory industry.

Who are these individuals? Are they known to the lab industry lobbyists in Washington, DC? Over the years, I've never read an analysis or commentary about proposals to reinstitute the 20% co-payment which identify specific CMS officials and legislative aides to Senators and Representatives who are the prime movers behind such proposals.

I suggest that it is timely for the collective laboratory industry to adopt a different lobbying strategy. Let's publicly identify those individuals committed to reinstituting Part B co-payments. Let's invite them to lab industry meetings to explain, from a public podium, why the 20% co-pay is such a good idea. Let them circulate and network at these meetings and hear, first-hand, the problems resulting from a reinstituted co-pay. Have them tour real labs to directly experience the challenges of billing charges less than $10 and $20. I think it's time to effectively educate the root source of these unceasing efforts to reinstitute the Medicare Part B laboratory services co-pay. TDR

New Lab Management Directions Now Visible

Lab War College reveals that early-adopter lab directors are embracing "new" methods

CEO SUMMARY: Seat-of-the-pants laboratory management is on its way out, replaced by numbers-driven methods. Judging by the presentations given at this year's* Executive War College on Lab and Pathology Management*, a growing number of laboratory administrators and pathologists are actively introducing quality management methods into their laboratory operations and generating remarkable results.

By Robert L. Michel

IF THERE WAS A SURPRISE CONCLUSION to be drawn from the 35 presentations at this year's *Executive War College on Lab and Pathology Management*, it was the decided emphasis on "numbers-driven" management of laboratory operations.

Almost every faculty speaker this year stressed the importance of using accurate data as part of the decision-making process. Having accurate information was recognized as an essential component of their laboratory's management successes. This was true whether the subject was productivity improvement and cost reduction or helping clinicians get more value from laboratory test results.

Held in New Orleans on May 6-7, this was the eighth annual *Executive War College*. Each year, as many as 400 lab administrators, pathologists, and lab industry executives attend. By intent, presentations emphasize cutting-edge efforts by the lab industry's early-adopters.

For this reason, the *Executive War College* is a reliable place to gauge the state of laboratory management and identify specific trends. Each year, as speakers lay out the management challenges and strategic priorities for their laboratories, common themes emerge. These themes invariably are in response to recent changes in the healthcare marketplace and make it possible to identify new trends.

For example, last year, in May 2002, one theme which emerged was

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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, $13.55 per week elsewhere (billed semi-annually).

the statement by many speakers that the lack of accurate financial and productivity data for their hospital laboratory made it difficult to make informed management decisions. Following the 2002 *War College*, I observed that the speakers' repeated frustration over the lack of accurate and timely performance measures was, of itself, something not heard in past years.

Need For Accurate Data

This was a sign that lab managers, under pressure to improve productivity, reduce lab costs, and improve quality, needed better data than was produced by their hospital's accounting system. It was an accurate analysis, and was validated by the comments of speakers at this year's *War College*.

For the first time in the eight years that THE DARK REPORT has produced the *Executive War College*, almost every speaker declared that strategic management priorities were established based on evaluation of their lab's current performance. Reasonably accurate data was available to support these decisions, and provided the baseline for measuring improvements.

I believe two factors can explain this change. First, during the 1990s, most lab directors and pathologists were managing reactively. One big gorilla in the room was managed care, which was pushing reimbursement downward for lab tests and negotiating sole-provider contracts. The other big gorilla in the room was the boom in hospital mergers and acquisitions. As multi-hospital health systems were formed, many hospital administrators directed that individual laboratories be consolidated into a single management structure.

For most of that decade, the need for detailed and precise productivity data was less relevant than the need to swiftly align lab testing costs with lower reimbursement and deal with the human issues of a multiple-site hospital laboratory consolidation project.

These two trends eased by the end of the decade. But they set the stage for the next cycle in the clinical laboratory profession. During the past four years, hospital administration has begun to ask their laboratories to reduce the overall cost of laboratory testing, maintain quality, and add new diagnostic technology as appropriate.

To accomplish these goals, laboratory administrators and pathologists have begun to pay closer attention to the operational details of their laboratory. I believe this is why, at the 2002 *War College*, so many speakers expressed frustration about the lack of detail and accuracy of the financial data provided them by their parent hospital.

Apparently hospital CFOs have been listening. At the 2003 *War College*, most speakers provided rather complete and detailed data about lab productivity, average cost-per-test, and the lab's impact on improving clinical outcomes. I interpret this a sign that the nation's laboratory administrators are developing more sophisticated skills in laboratory management, particularly in the use of detailed productivity data to drive strategic decision-making.

Three Uses Of Data

During the 2003 *War College*, speakers talked about three distinct areas of laboratory management which were driven by laboratory data. In the pages which follow, I summarize each. First is the use of data to guide clinical use of laboratory tests. Second is the use of data to drive lab operations. The third is an emerging phenomenon: the use of data to direct extensive redesign of workflow and laboratory processes, based upon the application of quality management methods.

The "new" emphasis on accurate, detailed, and timely data about labora-

tory productivity and finances is a logical development. During the 1980s, fee-for-service medicine made it relatively easy for a laboratory to stay financially sound. Not surprisingly, during that decade lab managers generally emphasized quality and providing appropriate laboratory testing services to clinicians.

Survival In The 1990s

In the 1990s, declining reimbursement and widespread laboratory restructuring took center stage. The emphasis during this decade was on survival, in response to major financial and structural changes in laboratory operations.

In the next few years, the most successful lab administrators and pathologists will be those who are skilled at leading people and supporting sustained productivity gains in their laboratory organization.

I would suggest that the 2000s will be the time of "sophisticated laboratory management." In contrast to the 1980s and 1990s, survival and prosperity in this decade will be dependent on proactive lab management. In the next few years, the most successful lab administrators and pathologists will be those who are skilled at leading people and supporting sustained productivity gains in their laboratory organization.

The market pressure for this type of management acumen directly springs from several parallel and complementary trends. Patient safety means that providers must track outcomes and develop ways to eliminate medical errors. Public ranking of provider performance provides plenty of incentive to improve laboratory operations and deliver measurable gains in the quality of laboratory testing services. Consumer-driven healthcare only reinforces all of the above, since the consumer will spend his or her money with those labs which offer the best combination of lower price and higher quality.

During the past two years, THE DARK REPORT has been the first source in the laboratory industry to identify these trends. Our clients and readers have had early warning about these market developments, giving them time to prepare strategies in response to these trends.

As early adopter laboratories gain experience in coping with evolving trends, they are invited to speak at the *Executive War College*. This provides public access to the real-world responses by these early-adopter laboratories, along with the management lessons about what works—and what doesn't—in dealing with various evolving trends.

Based on the presentations by 35 able speakers at this year's *War College*, I believe the laboratory industry is at the verge of an interesting crossroads. For the first time ever, employers are placing specific demands upon hospitals, physicians and other healthcare providers to improve patient safety, accompanied by the threat of losing access to patients for those providers who don't respond effectively.

Impetus For Change

Further, the drive to implement evidence-based medicine reinforces this dyanamic, because it forces physicians to measure and evaluate clinical procedures in a more rigorous way. Finally, the return of big annual increases in healthcare costs creates pressure to control spending. Collectively these are reasons why lab managers want accurate and detailed financial and productivity data for their laboratory. **TDR**

Contact Robert L. Michel at 503-666.0616 or labletter@aol.com.

Executive War College 2003 • Theme #1

Emphasis on Care Protocols To Direct Clinical Use of Tests

EVIDENCE AT THE 2003 *War College* indicates that the nation's clinical laboratories can again direct lots of energy and attention to clinical excellence.

Having survived the tumultuous decade of the 1990s, with its closed-panel HMOs, capitated reimbursement, and ubiquitous lab consolidation, lab directors and pathologists are again putting significant resources into helping clinicians make better use of laboratory tests. In particular, many laboratories are engaged in significant efforts to work with clinicians to develop effective guidelines.

The contrast from past *War Colleges* is striking. This is the first year when most laboratory case studies listed clinical support for physicians as one of their primary strategic priorities. In past years, the problems of coping with declining reimbursement and wide-scale laboratory restructuring had relegated clinical support to a secondary role.

That is no longer the case. In Nashville, Tennessee, at **Vanderbilt University Medical Center** (VUMC), the health system is far along in its goals of reducing unnecessary variability in patient care. To accomplish this, it created WizOrder, a clinical decision support system for physicians.

WizOrder provides the physician with real-time clinical data, including laboratory results. It contains care protocols developed by the VUMC physician staff, along with reference information.

Implementation of this clinical decision support system has impacted VUMC's laboratory in several ways. Its pathologists and Ph.D.s play a key role in developing treatment pathways that utilize laboratory tests, boosting the value of lab medicine to clinicians. As another benefit to WizOrder, in hospital departments where the clinical decision support system is implemented, the volume of laboratory testing has declined 40%.

The laboratories at **Geisinger Health System** (in Danville, Pennsylvania) have a similar focus on supporting "best clinical practices" within the healthcare systems. The lab uses the term "stewardship" to describe its role in supporting improvements in clinical outcomes, reducing unnecessary variability in care, and controlling lab test utilization.

Across all the case study presentations made at the *2003 Executive War College*, there was a decided emphasis on using accurate data to create clinical guidelines and support physician use of these guidelines. In the two case studies referenced here, electronic medical record (EMR) systems used by both healthcare systems makes it easier to increase the value-added of laboratory testing services.

The activities of laboratories presenting at this year's gathering demonstrate how the growing pressure to incorporate evidenced-based medicine is influencing lab operations.

Executive War College 2003 • Theme #2

More Data Collection Supports General Laboratory Operations

DELIVERING IMPROVEMENTS in day-to-day laboratory operations is now a data-driven process throughout the United States.

Most speakers at the 2003 *War College* presented detailed data on their lab's productivity and financial performance. For this group of early adopters, managing "off the cuff" is passé. What set this year's crop of speakers apart from past years is their confidence that the numbers they have on their lab's performance are accurate.

That would be a sign that hospitals are improving the reliability and accuracy of their internal accounting systems. In turn, this reflects the pressures on all segments of the healthcare system to deliver better quality outcomes at lower costs.

As a theme of this year's *Executive War College*, the recognized improvement in the quality of financial and productivity data available to laboratory directors is also directly linked to the other themes presented in this article. Both the effort to provide better clinical guidance to referring physicians and the growing adoption of quality management systems from the corporate world can succeed only if lab managers are able to work with better performance data.

It is important to distinguish that this financial and productivity data is different from the measures of past years. The top-performing laboratories in the United States are *not* organizing their laboratory around traditional measures of laboratory QA/QC, often provided in peer-ranking services. To the contrary, these exceptional laboratories are organized around data sets which reflect the specific strategic goals of their parent organization. Not the least of these is customer expectations, from physicians who use the laboratory and the patients themselves.

From this perspective, there is a double-shift from the patterns of past years. First, today's "best-of-class" laboratories are getting fuller and more detailed data sets on their lab's financial performance and productivity. This improves the ability of the lab's leaders to make better decisions—and have more confidence in those decisions.

Second, these "best-of-class" laboratories are shooting for different targets than hospital laboratories of past years. Rather than managing closely to peer laboratory ranking programs, these labs are tightly organized to serve the goals—and specific quality monitors—of their parent health systems. Customer satisfaction is usually a key component.

One insight that springs from this marketplace development is that laboratory managers are building additional skills to complement their scientific training and existing management knowledge. Across our industry, a select group of laboratory leaders is mastering the art of collecting good data, then using that data to drive deliberate change in their laboratory organization.

Executive War College 2003 • Theme #3

Major Efforts Now Underway To Redesign Lab Workflow

THERE IS A SMALL, but growing number of clinical laboratories willing to undertake a radical redesign of both individual laboratory processes and overall workflow through the entire lab organization.

These early-adopter laboratories are willing to endure the considerable pain of a radical redesign of their laboratories to achieve cost savings and quality improvements of a high order. The goal is not to save 5% or 10%—the goal is to pursue savings of 30% to 50%, with measurably better quality—and realize these gains in just a few months!

What is common to these pioneering efforts to boost productivity and quality by radical amounts is the utilization of the management methods and philosophies developed by the world's best-performing corporations. These range from ISO-9000 to Six Sigma and Lean.

At this year's *Executive War College*, there were spectacular examples of laboratory organization redesign and process re-engineering. At **HealthPartners**, an integrated delivery network in Minneapolis, Minnesota, organizational redesign of laboratory services yielded a 45% reduction in annual lab expenses! During the one-year project, lab expenses declined by $3.6 million from a budget of $8.0 million.

DSI Laboratories in Fort Myers, Florida reported on its Lean project to streamline work processes at the core lab in one of its three hospitals. At the end of a 90-day project, the nine-instrument chemistry/hematology line in this core setting could be operated by one med tech at peak times. For practical management purposes, this section is now staffed with only two med techs.

Even academic laboratories are recognizing the value of management systems like Six Sigma and Lean. **Fairview Health Systems** in Minneapolis, Minnesota reported on its progress at launching Six Sigma and Lean projects in several of its hospital laboratories.

These are typical of presentations from this year's *Executive War College*. They represent the cutting edge of a developing trend in laboratory management. Because of the importance of these trends, upon request, THE DARK REPORT will make available audio cassette tapes of these presentations to current clients and subscribers, at no charge.

There is a simple reason why this particular laboratory management trend will be revolutionary: the application of quality management systems in clinical laboratory operations has the potential to generate savings of 50% and 60%, while eliminating waste, reducing errors and improving quality.

The early-adopter case studies presented at this year's *Executive War College* provide compelling proof that, not only do these management techniques work, but once lab staff understand them, it becomes their preferred management style. **TDR**

Health Lawyers News Attacks Path Part A

Triggered by debate on a lawyers listserv, story attempts to address key issues

CEO SUMMARY: Pathologists should take time to read the cover story in the May 2003 issue of* Health Lawyers News*. Although the story nominally addresses questions involving how hospitals should reimburse physicians for administrative duties, it deals mostly with clinical pathology services and makes representations about the work pathologists do which some legal experts call factually and legally wrong.

FEW PATHOLOGISTS KNOW much about the publication *Health Lawyers News*. But that may change next time they sit down with their hospital administrators to negotiate the renewal of their contract for Medicare Part A professional component for clinical pathology services.

The issue was triggered by the story "Payment for Physician Administration Service: Navigating Around the Edge of Deep Waters," published in the May 2003 issue of *Health Lawyers News*. Although the story starts by discussing issues related to compensating physicians for administrative services they provide to hospitals, it primarily deals with arguments against paying pathologists for the clinical pathology professional services they provide in directing laboratory testing operations for hospitals.

Inaccurate Information

"Essentially, this is an article we strongly disagree with," stated Richard S. Cooper, Partner at the law firm of **McDonald Hopkins**, based in Cleveland, Ohio. "Readers of this article include lawyers advising hospital administrators. Pathologists should anticipate that some hospital administrators may present copies of this article during negotiations for agreements covering Part A clinical pathology professional services."

Cooper provided examples to illustrate his conviction that the article contains inaccurate information. "The article explains that Medicare Part B payments received by pathologists take into account the fact that pathologists may be required to ensure proper calibration and functioning of laboratory equipment and that tests are being properly performed," he explained. "This is incorrect becaust Part B of the Medicare program does not reimburse for any professional component of clinical pathology services.

"In another place, the article quotes the ruling in *Parsa v. State of New York*, 64N.y.2d 143 (1985) to support the claim that 'pathologists are not entitled to directly receive a portion of the hospital's Part A DRG reimbursement.' However, the Parsa case dealt

Pathologists Should Respond Strongly To Correct the Record on This Issue

PATHOLOGISTS WHO CAREFULLY READ the story "Payment for Physician Administration Service: Navigating Around the Edge of Deep Waters" published in the May 2003 issue of *Health Lawyer News* will probably be disappointed.

The first two sentences of the lead paragraph set the tone for the remainder of the article. "A recurrent issue that gnaws at hospital administrators revolves around the seemingly incessant demand by physicians to be compensated for administrative services they perform at hospitals. These requests have ranged from demands by pathologists to be paid for overseeing the hospital laboratory to requests from OB/GYNs and orthopedic surgeons to be paid for on-call availability."

The second sentence makes two revealing characterizations. It labels pathologists' desire to be paid for clinical pathology services as a "seemingly incessant demand." It then equates the clinical pathology services rendered in maintaining a high-quality hospital laboratory as being equal to an OB/GYN or orthopedist request to be paid for on-call availability.

"Lacking in this article is a balanced and accurate presentation of evidence which supports the medical value of clinical pathology professional services," noted Richard S. Cooper, Partner at the law firm of McDonald Hopkins. "State and federal courts have recognized that, as medical directors of clinical laboratories, pathologists are providing worthwhile services on behalf of referring physicians and patients, and that these services are required by various laws and regulations.

"Within my law firm, which maintains a national practice supporting anatomic pathology groups in all areas of the United States, the view is that this article is wrong in certain key areas," declared Cooper. "We think it's important for the pathology profession to know about this article and respond strongly to it. Pathologists should not be surprised if a hospital administrator shows up at the negotiating table and wants to use this article to justify reduced or no payment for Medicare Part A professional component for clinical pathology services."

with Medicare reimbursement under the cost-based Part A methodology that was used *prior* to implementation of TEFRA. Under this arrangement, clinical pathology services at issue in the Parsa case were reimbursable under Part B. This citation is misleading and the story fails to make that clear," explained Cooper.

"At another point, the story characterizes a pathologist's clinical pathology professional services as more administrative in nature, noting that non-physician lab managers perform routine administrative tasks and day-to-day oversight of lab personnel," continued Cooper. "This characterization fails to reflect the level of laboratory medicine practiced by pathologists on behalf of referring physicians and patients. It also fails to recognize that the medical profession established a board certification in clinical pathology because of its important function within the healthcare system. Because of the inaccuracies in the article, McDonald Hopkins immediately sent a counterpoint letter to *Health Lawyers News."*

Health Lawyers News and a sister publication, *Health Lawyers Weekly*, plan to publish the McDonald Hopkins letter. To learn more about why this story appeared in *Health Lawyers*

News, THE DARK REPORT contacted co-author Michael L. Silhol, Vice President, Legal Operations at **Triad Hospitals, Inc.**, based in Plano, Texas. (Silhol co-authored the article with Jennifer Papapanagioutou, a consultant and attorney with experience in legal issues affecting hospital operations.)

Topic of High-Interest

"The genesis of this article was the volume of chatter involving this topic on one of the listservs operated by the **American Health Lawyers Association**," said Silhol. "We were surprised at the number of hits directed at emails on this subject.

"Anyone familiar with the issue of Part A compensation for hospital-based physicians knows that this is topic with passionate advocates on each side," he added. "This high level of interest is what spurred us to tackle the subject of reimbursement for these services.

"Our goal was to present a balanced view of the issue. We realize there is room for disagreement by both sides. We included a sidebar to the story which recognized specific attorneys who had contributed emails to the listserv discussion."

Different Policies

Within his own company, Silhol observed that Triad has no company-wide policy which addresses reimbursement for the Medicare Part A professional component for clinical pathology services. "Each of the hospitals Triad owns or manages is operated to meet the needs of its community and local healthcare practices," he said. "For that reason, there are a variety of arrangements between our hospitals and their pathologists."

Several times the *Health Lawyers News* article stresses a key point. The authors accurately recognize the rancorous nature of the debate, stating at one juncture: "In summary, it is unlikely that hospital counsel and hospital-based physicians will ever fully agree on whether hospitals must pay for administrative services."

Clients and long-time readers of THE DARK REPORT know that Medicare Part A reimbursement is handled differently in hospitals throughout the country. In site visits around the nation, THE DARK REPORT has found that the most successful Part A reimbursement arrangements can be consistently found in situations where the pathology group and the hospital administration are in close communication, and the full scope and impact of clinical pathology professional responsibilities are documented and understood by both parties.

Ongoing Disagreement

Unfortunately, this is not a universal situation. Since the recent story in *Health Lawyers News* did not present a balanced look at both sides of the issue, it seems likely that debate will continue in future issues of the publication. It is also likely that this story will surface in future negotiations between hospital administrators and pathologists. That's because the attorneys who advise hospital administrators are most likely to read this article.

Even with an effective public response by the pathology profession, invariably some hospital administrators will use this article to justify the reduction or elimination of existing Part A reimbursement arrangements with their pathologists. **TDR**

Contact Richard S. Cooper at 216-348-5438 and Michael L. Silhol at 214-473-7358.

A full copy of the story which appeared in *Health Lawyers News* can be obtained at healthlawyers.org.

McDonald Hopkins will provide a copy of its letter upon request. Call Richard Coopers' office at 216-348-5438.

SARS Update

Focus Technologies Offers SARS Test to Clinicians

EARLIER THIS MONTH, **Focus Technologies** reference laboratories of Cypress, California announced the development of a "first-generation, real-time PCR test" designed to detect the presence of the coronavirus associated with severe acute respiratory syndrome (SARS).

"Focus developed this test based on the methodology developed by the **Bernhard-Nocht Institute** of Hamburg, Germany," stated Mary Kay Mosch, Vice President of Marketing at Focus. "Part of our corporate mission is to be a first provider, which is why we responded rapidly to the recognition of SARS as a new disease syndrome.

"There were challenges in validating our SARS test," Mosch said. "Besides the usual difficulties in establishing clinically-relevant sensitivity and specificity, we had to insure there was no cross-reactivity with other types of coronavirus. We will continue to refine our RT-PCR assay and introduce additional SARS assays."

Accessing SARS Specimens

"To further improve the test, we are working with contacts in the U.S., Europe, and Asia to obtain SARS specimens and other materials," she added. "Additionally, as part of our SARS testing protocol, we also use methods developed by the **Centers for Disease Control and Prevention** (CDC)."

The SARS test offered by Focus Technologies is designed to complement testing done through public health laboratories. "It was reported that the CDC supplied reagents to more than 100 public health laboratories around the nation," stated Mosch. "It published a clinical definition for suspected SARS patients. If a patient fits these criteria, which includes travel within the past ten days to a region where SARS is present, then testing for that patient can be done in a public health laboratory."

Market For SARS Testing

The market for SARS testing in the U.S. remains limited. "So far, specimens referred to us come from physicians who suspect a patient may have SARS, but the clinical presentation didn't necessarily meet the criteria defined by public health authorities," explained Mosch. "Because of our 24-hour turnaround on the test, we can provide physicians with more timely information that may assist in the diagnosis of disease."

Not surprisingly, Mosch states that, to date, all specimens for SARS testing referred to Focus Technologies have been negative. "If Focus does get a positive SARS specimen, the appropriate public health authorities will be immediately contacted."

Even as Focus Technologies is first to publicize the availability of a SARS test in the United States, several other diagnostic companies are developing SARS assays to run on their instruments. **Abbott Laboratories** has a marketing agreement with **Artus GmbH** for its PCR-based SARS test. Following regulatory approvals, Abbott will market this test in the U.S. and other countries. TDR

Contact Mary Kay Mosch at 410-832-7575

HealthcheckUSA Makes Progress With Consumers

Founded in 1987, the company has plenty of experience in direct access lab testing

CEO SUMMARY: There's a story behind the story at HealthcheckUSA, one of the nation's best-known sources offering consumers direct access to laboratory testing. Its primary business is holding community screens and grocery store lab testing programs throughout the United States. Because it is a middleman, HealthcheckUSA farms out the actual testing to contract laboratories.

WHEN IT COMES TO direct access laboratory testing, **HealthcheckUSA** is one of the industry pioneers.

The company, based in San Antonio, Texas, was founded in 1987. "The original vision was to encourage consumers to take proactive steps to preserve and improve their health," stated Holt Vaughan, Executive Vice President at privately-owned HealthcheckUSA. "We started by offering screenings at grocery stores in San Antonio.

Strong Consumer Support

"Consumer response was so strong that we expanded our grocery store screening program to other Texas cities," he continued. "Next, we developed a program of community wellness screening. Once the Internet matured in the mid-1990s, it was logical to establish a direct access testing program on the Web."

The use of the term "screenings" is intentional. "The general perception is that 'health fairs' implies a free service," noted Vaughan. "By using the term 'screening', our customers expect to pay for the laboratory testing we offer. It identifies our event in an appropriate manner."

The business model developed by HealthcheckUSA has many surprises for laboratory administrators and pathologists. First, it is strictly a cash-and-carry business. HealthcheckUSA does not bill insurance companies. Second, it doesn't do any lab testing in-house. All analytical work is farmed out. Third, at its grocery store screenings, phlebotomists are present and do the draws on-site. Consumers are comfortable with the setting and regularly show up for additional testing.

THE DARK REPORT asked Vaughan to explain the details of this unique business model. There are three product offerings and each operates with fundamental differences. First is the grocery store screenings.

"This is our basic business," said Vaughan. "In Texas, we operate permanent teams in San Antonio, Austin, Houston, and Dallas/Ft. Worth. Each day these teams set up and offer testing

in a single grocery store. It takes about three months for them to rotate around all the participating grocery stores in that city. It is a circuit they continually repeat.

"Customers show up, select their tests, pay us, and have their blood drawn by phlebotomists on site. Results are reported in a variety of ways, at the option of the customer," he noted.

Community Screenings

"Our second line of business is community screening," continued Vaughan. "We frequently offer this in partnership with other entities, including not-for-profit organizations. We arrange community screenings in cities throughout the United States. Teams for these events are assembled using temporary placement agencies.

"The third business line involves the Internet. Consumers go to our Web site, select the lab tests they want performed, pay us, and are directed to collection sites in their neighborhood to have their blood drawn," Vaughan said.

Because HealthcheckUSA has no laboratory testing facilities, it subcontracts this work. "We have contracts with all of the major national laboratories," observed Vaughan. "We also use about ten smaller laboratories in selected cities around the United States.

Building A Customer Base

"Remember, HealthcheckUSA is a middleman," he stated. "We are a facilitator and a marketing specialist. Our primary strength is building customer relationships. We believe clinical labs can do the testing cheaper and better than we could if we tried to establish our own laboratory."

In fact, Vaughan says HealthcheckUSA is looking for to contract with additional laboratories. "We would like to develop collaborative relationships with more local laboratories," he commented. "We have a franchise program for local laboratories. We want to work with labs willing to proactively promote HealthcheckUSA and our lab testing program. Besides handling all the lab testing generated from screenings in its area, we refer patients into that laboratory's patient service centers for collections."

Over the years, HealthcheckUSA has responded to customer demand with three additional services related to its core offering of laboratory tests. "First, we introduced physician interpretations through the **Virtual Medical Group**. A board-certified physician will interpret the test results. The customer can request this and we charge an additional $30 for this service," said Vaughan.

"The second service we've added is on-site blood draws," he continued. "Many people wanted testing, but could not get to our screening site. For a $49 fee, we will send a phlebotomist out to their home or business to do the collection. This has met with very favorable response.

On-Line Lab Test Results

"The third service we initiated based on customer interest was on-line access to laboratory test results. Not surprisingly, a growing proportion of our customers opt to get their results this way," concluded Vaughan.

For customers using a Lab*One*-contracted collection site, results can be viewed and downloaded through the **LabDat, Inc.** system. This arrangement shows how HealthcheckUSA, in its middleman role, avoids the cost of building infrastructure needed by most labs.

HealthcheckUSA's menu of lab tests is available on its Web site: *www.healthcheckUSA.com*. On each order, it adds $12.00 for shipping, handling, and processing.

Although HealthcheckUSA does not bill insurance companies, it will provide appropriate CPT codes for customers who want to seek reimbursement through their own health insurance plan. "In general, our customers expect to pay out-of-pocket for their lab tests. There are not many folks who intend to pursue reimbursement from their health plan," explained Vaughan.

Contrarian Ideas

THE DARK REPORT observes that HealthcheckUSA is doing some contrarian things in the marketplace. Popular wisdom is that people do not want to have their blood drawn in public places like grocery stores. Yet HealthcheckUSA has built an ongoing business with exactly this service.

Contracting to use existing laboratories' testing resources and support infrastructure allows HealthcheckUSA to concentrate on marketing and the client services it provides to its customers. Healthcheck USA doesn't own the resources, but "rents" their use as appropriate.

Vision And Persistence

Of course, HealthcheckUSA was founded by an entrepreneur willing to champion an unorthodox concept back in 1987: people interested in proactively managing their health would be willing to pay out of pocket for relevant laboratory tests. Founder George Vaughan, Ph.D., M.B.A, is an organic chemist armed with business school insights. His energy and persistence was the driving force in making HealthcheckUSA one of the leading sources of direct access testing in the United States today.

Laboratory directors and pathologists should not overlook opportunities yet to come in direct access testing. Media coverage is growing. *Time Magazine* did a story last October. In the past month, *U.S. News and World Report* and the *New York Times* both did extensive stories on this topic.

This is validation that the consumer movement in healthcare continues to gather strength. Laboratories should prepare to serve this potentially lucrative market! TDR

Contact Holt Vaughan at holt@healthcheckUSA.com.

Lab Testing Gold From the Internet

HEATHCHECKUSA OF SAN ANTONIO, TEXAS has an interesting lesson to teach about building a lab testing business on the Internet.

"We are amazed and overwhelmed at how the Web's underground communication works," stated Holt Vaughan, Executive Vice President at HealthcheckUSA. "From the time we first established our Web site, the rapid growth in hits and paying customers has been astonishing.

"From the earliest days, customers found out about our company and our Web site indirectly," he explained. "They would learn about us in chat rooms. Discussion groups on disease-specific Web sites were another big source. People found us through the unlikeliest sources."

According to Vaughan, growth in Web hits has been exponential since the site became operational in the mid-1990s. "If I use the year 2000 as a base," he noted, " business attributable to Web use increased 200% by 2001 and another 200% by the end of 2002."

Vaughan declines to give specific revenue numbers. But he does acknowledge that HealthcheckUSA's mailing list includes 100,000 people and that 41% of first-time customers become repeat customers with the company.

Lab Market Milestone

Conventional Needle Sales To End at Becton Dickinson

Event marks a shift in healthcare technology and clinical practices in favor of patient safety

IN RESPONSE TO DECLINING SALES of many types of conventional needles and other "sharps" devices, **Becton, Dickinson and Company** (BD) announced plans to discontinue offering these products in the United States.

"The market in the U.S. is converting to safety-engineered sharps devices," stated Ed Thompson, Senior Director of Worldwide Health Worker Safety at BD. "We recognize the market's transition to these types of products and are shifting our emphasis accordingly.

"At the same time, there will always be a need for conventional needles and other sharps products," he continued. "Our actions are designed to support the continuing needs of clinicians and avoid any disruption."

Impact Of Federal Law

Since implementation of the Federal Needlestick Safety and Prevention Act on April 18, 2001, healthcare providers have responded by adopting safety-engineered needles. THE DARK REPORT observes that BD's announcement validates the far-reaching impact this federal mandate is having.

"Among our clients, the transition is farthest along in hospitals," noted Thompson. "We see this in our sales. For clinical areas where the federal law requires a switch, 80% of products like IV catheters, 'needleless' IV connectors, blood drawing needles, winged needle sets, and lancet devices sold to hospitals are safety-engineered. The overall transition rate in clinics and physicians' offices is much lower."

According to Thompson, there is a learning curve for providers. "In the earliest stages of this transition, we provided plenty of education and training," he said. "Once a provider has made the switch, the safety benefits are so compelling that we've seen few switch back to conventional needles. Also, the early-adopters in this effort were clinical labs and those involved in blood collection and analysis."

Canada Next To Act

Thompson says that Canada is the next country to mandate this switch. "The Province of Alberta passed a law, effective September 1, 2003," he stated. "Similar legislation is under consideration in several other countries."

Lab directors and pathologists should recognize that BD's move to discontinue sales of conventional needles and sharps devices demonstrates how rapidly the healthcare marketplace is evolving, particularly on issues affecting patient and worker safety. The benefits are measurable and significant. One study of academic hospitals demonstrated a 51% reduction in sharps injuries to nurses between 1993 and 2001. TDR

Contact Ed Thompson at 201-847-4906

Con Man Rips Off Lab In Kingsport, Tennessee

MEDex Labs' CEO discovered to be unrepentant, twice-convicted felon

CEO SUMMARY: It will certainly rank as one of the major executive frauds in the clinical laboratory industry. In the wake of MEDex Laboratories' Chapter 11 Bankruptcy filing in April, an amazing tale of deceit and deception began unfolding. At the center of the story is ex-MEDex CEO Michael E. Ladd, now cooling his heels in a Greeneville, Tennessee jail and facing eight federal criminal charges.

EVERY NOW AND THEN, life reminds us to take nothing and no one for granted. That's certainly the case in Kingsport, Tennessee, where the Chapter 11 Bankruptcy of **MEDex Laboratories** is one consequence of the fraudulent deeds of its ex-CEO, Michael E. Ladd.

Hired originally in August 2000 to be the Chief Financial Officer of MEDex, Ladd was promoted to CEO in November 2001. In his brief time at MEDex, Ladd managed to hoodwink just about everyone around him.

Twice-Convicted Felon

It started at the time he was hired. Background checks failed to turn up the fact that Ladd had one felony conviction (charge not known publicly) in 1992. It was also not discovered that Ladd was under indictment as a check forger, a felony charge to which he pled guilty in December 2001.

As a bookkeeper for a homebuilder, he admitted to embezzling between $10,000 and $60,000 from the company in 1999. During his tenure as MEDex CEO, Ladd was on probation (through 2005) for this crime.

Next to be fooled by Ladd was the MEDex Board of Directors. MEDex was jointly owned by the four-hospital **Wellmont Health System** and six Kingsport pathologists (who founded the laboratory in 1973). Ladd manipulated accounting records to keep MEDex's true financial condition hidden from the board.

For three years, Ladd managed to avoid an accounting audit of MEDex Laboratories. That changed in November 2002 when board members initiated a full audit after learning that payments to some vendors were late. The audit results were reported to the full board on March 27, 2003. Instead of the profit Ladd had reported, the audit revealed that MEDex had lost about $2 million per year in each of the preceeding three years! Ladd resigned that day.

Ladd was equally successful at fooling MEDex's bankers. In all, it is believed that he managed to extract $8.5 million in loans from banks,

Picking Up the Pieces At MEDex Laboratories

TO COPE WITH ITS UNEXPECTED FINANCIAL problems, MEDex Laboratories is concentrating on its core markets.

Ex-CEO Michael Ladd had embarked on an unauthorized lab expansion program. In Tennessee, he had opened facilities in Chattanooga, and Knoxville. These will be closed. Ladd's plans to open labs in Nashville. and Birmingham, Alabama have been cancelled. Edward Bush is now running MEDex. In closing these facilities, he acknowledges as many as 80 jobs will be lost.

MEDex will continue to operate its laboratories in four hospitals and five other locations. Its core revenue base is estimated to be around $40 million.

Another consequence of Ladd's scam is that, as a result of the lab's sizeable losses and the Chapter 11 Bankruptcy filing, the six Kingsport pathologists have transferred their 50% stake in MEDex to Wellmont Health Systems.

although the MEDex board had only authorized $2 million in bank debt. To successfully accomplish this, Ladd promised the bankers that the additional debt would be secured by the personal guarantees of the six pathologists and Wellmont Health System.

Eight Forged Signatures

This decision will cost Ladd dearly. On December 19, 2002, Ladd delivered to the bank what he represented to be the signatures of two Wellmont officials and the six pathologists. These signatures were forged. They are the basis of an eight-count federal criminal indictment for "making false statements and reports for the purpose of influencing the actions of a federally-insured bank." Ladd faces up to 30 years of jail on each count and a fine of as much as $1 million.

On Wednesday, May 7, Ladd was arrested by FBI agents and booked into jail at Greeneville, Tennessee. He was held without bond because he is in violation of his probation from the 2001 conviction. At a detention hearing last Wednesday, he waived his rights. His case now goes to the grand jury, which may review his case as early as this week.

Michael Ladd aptly fits the description of a rogue and con man. He was charismatic enough to gain the job of Chief Executive Officer at MEDex. But his lifetime pattern of fraud demonstrates that this position was an opportunity to continue scamming people around him. As of press time, there has been no public discussion that either MEDex funds or proceeds of the bank loans are believed to have been siphoned off for his personal use. But then again, that may prove to be the next revelation in this amazing story.

What Is The Lesson?

If there is a moral to the tale of Michael Ladd and MEDex Laboratories, it is that every business benefits from appropriate internal controls and outside audits. Had proper financial controls been in place, including audits by outside accountants, it is likely that MEDex's board would have uncovered his fraud in its earliest stages.

THE DARK REPORT recommends that laboratory directors and pathologists use this story of chicanery and deceit as an opportunity to remind their management teams that nothing is ever as it appears. Healthy skepticism and good management practices are always in the best interest of every laboratory organization. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an early sign that health-insurance premiums will rise by significant amounts for 2004. The **U.S. Bureau of Labor Statistics'** Producer Price Index for general acute care hospitals posted its highest-ever one-month increase, jumping 1.4% in April. For the 12 months ending in April, the general acute care hospital price index was up 6.2%. By comparison, in the late 1990s, this index increased by only 2% to 3% per year.

CHANGE AT IMPATH

There's another executive casualty in the corporate reorganization now under way at **IMPATH, Inc.** Earlier this month, the company announced that President and COO Richard P. Adelson had resigned "to pursue other opportunities." Adelson's departure follows, by three months, that of long-time Chair and CEO, Anu Saad, Ph.D., who resigned following an audit which uncovered "discrepencies" of certain expenses.

NEW OUTBREAK OF SARS HITS TORONTO HOSPITALS

Just when Toronto public officials thought they had beaten back the SARS outbreak, new cases surfaced. Last Friday, it was announced that at a cluster of at least 33 suspected SARS cases are now under observation, with three patients in critical condition. Officials think the link is a previously unknown case at **North York General Hospital**. A patient transferred from North York to **St. Johns Rehabilitation Hospital** may have been the source of SARS in that facility. At least one healthcare worker is believed to be infected and up to 2,200 visitors to the two hospitals are being asked to go into quarantine. Prior to Friday's announcement, only seven people with SARS remained in Toronto hospitals, of which five were in critical condition.

ADD TO: *Sars in Toronto*

Toronto's SARS outbreak has caused major disruptions to the healthcare system in Ontario because elective surgeries and other procedures were deferred during the first part of the crisis. The Toronto experience shows what could happen to hospitals in the United States if a SARS outbreak occurred in a major city. The experience is already leading to a rethinking of how hospital infection control teams interact with microbiology labs on site.

"SYNDROMIC SURVEILLANCE"

There's a new term circulating on the Internet, according to Bruce Friedman, Professor of Pathology at the **University of Michigan Health System** in Ann Arbor. "Because of the threat of bioterrorism, there is now great interest in monitoring constellations of signs and symptoms (i.e., syndromes) that patients present with in hospitals, particularly EDs," he says. "This has significant implications for the world of medical informatics." Dr. Friedman believes "syndromic surveillance" will boost the adoption of more sophisticated clinical information systems.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 16, 2003

THE DARK REPORT

UPCOMING...

- *THE DARK REPORT'S Annual Ranking of Public Laboratory Companies: Who's Left Standing?*
- *CytoLogix Versus Ventana Medical: Brutal Lawsuit Over Patent Infringement.*
- *Physician "Pay for Performance" in California Triggers Surprising Outcomes.*
- *Inside Look at the Nation's Most Amazing Hospital Lab Workflow Redesign Project.*

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