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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Patient Safety is Related to "Quality Management"

REMEMBER BACK IN 1997 WHEN LABORATORY COMPLIANCE PROGRAMS were mandated by Medicare officials? That was a big thing in the laboratory industry. Every laboratory organization in the United States scrambled to assess their laboratory's operating practices, develop policies, and create a compliance manual that met regulatory requirements.

THE DARK REPORT was first to predict this would happen, following the announcement that **SmithKline Beecham Clinical Laboratories** had agreed to pay a $325 million fine to settle allegations of Medicare fraud and abuse. *(See TDR, March 10, 1997).* I mention this because I am ready to make another prediction. It is a prediction that will have similar impact, touching every laboratory organization in the United States.

My prediction is that the growing drive to improve patient safety will require clinical laboratories (indeed, all classes of healthcare providers) to measure errors affecting patients. Further, having measured these errors, laboratories will be required to have management systems in place which allow the lab to identify the sources of those errors in their work processes, and, most importantly, reduce or eliminate them.

If this has a familiar ring to it, it is consistent with a theme we've discussed on these pages and at our *Executive War College* for more than seven years. Under the banner of patient safety, the healthcare system will move rapidly to embrace and implement the same types of quality management systems used outside healthcare by the world's most respected corporations.

Even as I write these words, any number of healthcare accrediting bodies are in the midst of rewriting their guidelines. The new guidelines will increasingly call for labs, physicians, and hospitals to accurately measure outcomes which affect patient care, then show how they are improving their work processes to raise quality and reduce unnecessary errors (and costs).

For most practitioners in the American healthcare system, this is a very different mindset. However, within the clinical laboratory segment, the payoff from these quality management systems is huge—both in outcomes and employee morale. Early adopters already introducing such quality systems into their labs universally report that their labs enjoy greater productivity, lower costs, and fewer errors that affect patients. They also report that the laboratory team becomes energized and enthusiastic at the opportunity to fix long-standing problems and do a better job for their local community. TDR

Several Major Surprises Mark Events of 2002

"Ten biggest lab industry stories" for year cover wide spectrum of laboratory activities

CEO SUMMARY: It was a year when the two blood brothers got much bigger and expanded market share by buying their largest competitors. With patient safety as the goal, employers began active steps to force hospitals, physicians, and other healthcare providers to use quality management systems to reduce errors. Unpredictable in many ways, 2002 set the stage for accelerating change in our healthcare system.

THERE'S LOTS OF DIVERSITY in this year's selections for the "Ten Biggest Lab Stories of 2002." Topics cover a broad spectrum of management issues for lab administrators and pathologists.

THE DARK REPORT prepares its "Ten Biggest Lab Stories" each year specifically to help laboratory administrators and pathologists with strategic planning. Each top ten story recognizes important developments and trends that are reshaping the way laboratory services are organized and delivered.

The range of subjects on 2002's "Ten Biggest Lab Stories" list reflects the challenges facing the nation's laboratories. Some stories involve widescale changes to the healthcare system. Other stories relate to specific areas of laboratory operations. But each story represents a significant driver for change that directly affects clinical laboratories across the United States.

Within the American healthcare system, employers are no longer willing to accept the status quo. Faced with huge year-to-year increases in healthcare costs, employers are taking direct action to change the way hospitals, physicians, and other providers operate their organizations. *(See Story No. 3–page 5).*

Employers are the driving force behind patient safety. But their efforts go beyond simply reducing unnecessary errors. The nation's largest employers have launched a major drive to embed quality management systems into the nation's hospitals and physician group practices. Meantime,

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on their own initiative, a growing number of hospital laboratories are introducing ISO-9000 and Six Sigma-types of quality management systems into their organizations. *(See Story No. 4–page 5.)*

Impact Already Visible

Laboratories already see the impact of broad initiatives aimed at reducing medical errors. There's more talk of patient safety by hospital administrators. New guidelines proposed by healthcare accrediting agencies are shifting the emphasis away from documentation and toward accurate measurement of outcomes.

Another major story of 2002 was the acquisition appetites of the two blood brothers. Between the two, they paid $2.9 billion to remove four of their largest publicly-traded lab competitors from the marketplace. *(See Story No. 1–page 3.)*

The impact of this unexpected major wave of commercial lab consolidation was to create a national oligopoly in the market segment of physicians' office send-out testing. The two blood brothers now have unprecedented dominance across the country. In various large cities, each holds a monopoly position.

Are Service Declines Ahead?

THE DARK REPORT believes the national oligopoly-regional monopoly in physicians' office testing has close parallels with the airline industry, also a national oligopoly-regional monopoly. Like the airline industry over the years, will the lab industry see a similar decline in basic services, a lackadaisical attitude toward customers, and increased prices? Many local lab people believe these consequences can already be seen in national lab services provided in their particular city.

There is wide recognition of the growing MT/MLT shortage. But THE DARK REPORT is first to call attention to the even more pernicious shortage of histotechnologists. This shortage is here, it's universal, and it has yet to get the attention and resources necessary to resolve it. *(See Story No. 5–page 6).*

Each of the "Ten Biggest Lab Stories of 2002" represents a significant development or trend now actively shaping and influencing some aspect of laboratory operations. THE DARK REPORT recommends that clients use this list as the basis for a strategic planning session involving their lab's key management thinkers. Each lab needs to craft its response to these trends and market dynamics.

Lab Opportunities Abound

Ample opportunities for success remain in today's marketplace. Examples of growing hospital lab outreach programs are easy to find. Local pathology groups which launch well-managed outreach sales programs invariably generate good returns.

For hospital labs focused inward, on inpatient activity, there are comparable opportunities to add value, reduce costs, and expand useful clinical services. Adoption of quality management systems is one important way to attract the capital and manpower resources required to accomplish these goals.

Taken collectively, THE DARK REPORT believes the "Ten Biggest Lab Stories of 2002" demonstrates how the laboratory industry will soon be shifting its management emphasis. The drive for patient safety, efforts to measure outcomes, and the introduction of quality management systems into hospitals and physicians' offices will generate important changes in the customers served by clinical labs. Laboratories should use the insights provided by this "Ten Biggest Story" list to develop effective strategies that meet the changing needs of their laboratory's customers.

1... story one

Lots of Consolidation Among Public Laboratory Companies

IF THERE WAS ANY SINGLE SURPRISE of 2002, it was further consolidation among the nation's largest laboratory companies.

During 2002, **Quest Diagnostics Incorporated** acquired **American Medical Laboratories** and awaits FTC approval to buy **Unilab**. **Laboratory Corporation of America** bought **Dynacare** and in November announced an agreement to purchase **DIANON Systems**.

These four acquisitions represent almost $1.3 billion in annual lab revenues. To complete these transactions, the two blood brothers will pay about $2.9 billion! And these are just the four biggest lab acquisitions done during calendar 2002. The two blood brothers also purchased a number of smaller private lab companies in 2002.

Both LabCorp and Quest Diagnostics remain active and motivated buyers of any lab business that comes on the market. This includes outreach testing operations owned by hospitals. In recent months, both companies have made offers to purchase hospital lab outreach business in different cities around the United States.

Conclusion? The nation's two biggest laboratories intend to get bigger. They are willing and aggressive buyers of any laboratory testing business which comes onto the market. By offering high purchase prices, the two blood brothers guarantee they'll have first crack at buying these lab assets.

2... story two

National Oligopoly-Regional Monopoly Becomes Laboratory Industry Fact

THIS YEAR'S WAVE of commercial laboratory consolidation has transformed the market for physicians' office send-out testing into a national oligopoly between the two blood brothers, supported by specific regional monopolies favoring one company or the other.

THE DARK REPORT was first to identify and describe this competitive development. **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** now dominate the national marketplace for physicians' office send-out testing. At the national level, this lab testing market segment has become an oligopoly. *(See TDR, May 13, 2002.)*

At the regional level, LabCorp and Quest Diagnostics' national oligopoly becomes a regional monopoly. In many cities, one or the other controls more than 50% of the tests coming out of physicians' offices.

By this analysis, the market for physicians' office send-out testing is now a national oligopoly supported by regional monopolies. It is similar to the national air transport system, where nine airlines comprise a national oligopoly and each airline holds a monopoly market share in selected "hub" cities. Economic theory predicts that oligopolies and monopolies reduce services and increase prices because of a lack of effective competition. Some would argue that these consequences can already be seen in the physicians' office testing marketplace.

3... story three
Public Measurement of Hospital And Physician Performance Is Here

FORMAL EFFORTS by healthcare accrediting bodies to reduce unnecessary medical errors is about to have an additional consequence: the same data used to measure reduction of medical errors will make it possible to measure and make public the performance of hospitals, physicians, laboratories, and other healthcare providers.

This development is attributable to two major dynamics. First involves the public response to the **Institute of Medicine's** (IOM) recent report that estimated between 48,000 and 100,000 patients die as a result of unnecessary medical errors in hospitals.

Second, the return of double digit increases in healthcare costs to employers is motivating corporations to take a direct role in how healthcare is administered and delivered. More specifically, employers are organizing to educate and help hospitals and physicians "run their business" with the same management methods used in manufacturing and services outside of healthcare.

THE DARK REPORT was first to identify how the **Leapfrog Group's** campaign to reduce medical errors would also be a major step toward measuring provider performance. *(See TDR, January 28, 2002.)* Anatomic pathologists and clinical laboratories will eventually be measured on a variety of cost and quality variables. This information will be made public to help employers and patients select health providers which best meet their needs.

4... story four
Quality Management Systems Gain Traction In Growing Numbers of Labs

DURING THE NEXT 24 MONTHS, the American healthcare system will begin a historic shift toward quality management systems common in business and industry.

Employers are driving this change. The nation's largest employers, reacting swiftly to the reappearance of double-digit increases in healthcare costs, are taking active steps to change the way the nations' hospitals and physicians organize and operate their businesses.

Employers, having seen how quality management systems like ISO-9000, Six Sigma, and Lean boosted quality while driving sustained cost reductions, want hospitals, physicians, and other health providers to adopt these techniques. Employers believe that use of these techniques will reduce unnecessary medical errors, thus improving patient care and reducing healthcare costs.

The nation's healthcare accrediting bodies have begun a mad scramble to incorporate quality management methods into their guidelines. The emphasis will shift away from documentation of processes toward measurement of outcomes.

Early adopter laboratories are already implementing these changes. **Quest Diagnostics Incorporated** is introducing Six Sigma throughout the company. During 2002, a handful of hospitals and hospital laboratories began introducing ISO-9000 and Six Sigma. That number is growing monthly.

5... story five

Forget the MT/MLT Staff Shortage: Histotech Shortage is Here Now!

GROWING SHORTAGES of licensed medical technologists (MT) and medical laboratory technicians (MLT) grab headlines nationwide. But little recognized is the already acute shortage of histotechnologists in the nation's clinical laboratories.

Region-by-region, the vacancy rate for med techs can range from almost zero to 20%. Labs in some cities are adjusting to a permanent vacancy rate of 15%+ while labs in other cities continue to have no problems recruiting adequate numbers of MTs and MLTs.

That is not true when it comes to histotechnologists. In its many site visits to labs around the country, THE DARK REPORT has yet to find a lab which confirms it has enough histotechs to meet existing work demands. The staffing crisis in histotechnology is already here, but has not received the publicity given to the growing shortage of MTs and MLTs.

The shortage of histotechs is the unreported story behind the big headlines about MT/MLT staffing trends. Moreover, histotechnology is involved in many of the fastest-growing segments of the diagnostic testing menu.

The testing supply-demand curve predicts more testing requiring histotechnology services even as the number of certified histotechs proves inadequate to meet existing test volume. Strategically, labs should take steps to anticipate and deal with this trend.

6... story six

Heavily-Discounted Lab Test Pricing Again Proves To Be a Poor Strategy

USING MARGINAL COST PRICING to win new clients and expand market share has always been a dicey strategy in the laboratory testing business.

In 2002, the financial fortunes of two lab companies demonstrated that lesson once again. In the market for hospital send-out testing, **American Medical Laboratories** (AML) and **Specialty Laboratories** found themselves at competitive disadvantage due, in some important measures, to the consequences from selling new clients by offering aggressively low prices for laboratory tests.

In the case of AML, although the company grew rapidly, its pricing made it difficult for the company to amortize its sizeable debt and still pay for the high costs of the national sales and marketing blitz it had mounted in recent years. As a result, it was vulnerable to an acquisition offer by one of the two blood brothers.

At Specialty Labs, "thin" profit margins on new testing business caused its executives to manage lab operations in a manner which seems to have contributed to its widely-publicized problems with state and federal lab regulators.

These experiences are a reminder that it is difficult for any laboratory to deliver top-quality lab testing services and recover the expenses of sales and marketing if the tests prices offered to a new customer do not have enough profit to cover direct testing costs plus all the necessary overhead.

7... story seven
Laboratory Automation Gains Credibility, But Far From True TLA

EFFORTS TO INTRODUCE total laboratory automation (TLA) into clinical labs have been ongoing for almost ten years. During 2002, these efforts gained traction, but in an unexpected way.

Sales of laboratory automation products are finally showing growth, but it is not TLA which leads the way. Rather, hospital laboratories are buying modular, task-oriented, or workstation consolidation solutions to automate selected work processes.

This is the consequence of two marketplace developments. First, the "next-generation" of automated diagnostic instruments that vendors showed at lab conventions in 1999 and 2000 are finally available for use in clinical laboratories. Second, as the shortage of MTs and MLTs hits individual hospital laboratories, targeted lab automation solutions are increasingly viewed as a viable solution. Using automation to substitute for the unavailable labor supply becomes a cost-effective strategy.

The introduction of various types of automated solutions into the nation's clinical laboratories is still in its infancy. The number of "automated labs" in the United States remains relatively small.

One reason is that many skeptical hospital lab customers, cautious because of TLA's early failures, still find it tough to get detailed, accurate, and comprehensive information about the true costs of implementing and operating various laboratory automation solutions.

8... story eight
"Proprietary" Lab Test Technology Designed to Cost Lab Customers More

IT'S A SIGNIFICANT TREND in its earliest stages. Manufacturers of new diagnostic tests are creating patent-protected tests with the goal of charging lab customers more money per test.

The earliest efforts to achieve this have been regularly chronicled on the pages of THE DARK REPORT throughout 2002. The emerging diagnostic technology business model involves these two primary elements.

1) patent protection, which means labs must pay significant royalties to use the test or the diagnostic technology. **Roche's** PCR was an early success of this strategy.

2) branded test, recognized in the marketplace by both physicians and consumers. By creating brand awareness and affinity, the diagnostic test manufacturer gains loyalty among the healthcare community. **Cytyc Corporation's** ThinPrep® has built this following, allowing it to charge labs more while making it more difficult for a lab to switch a physician to a competing, lower-priced liquid preparation cervical cancer screening product.

This new market model for diagnostic technology also emphasizes restricted distribution to clinicians. The manufacturer grants selected labs exclusive rights to market and perform the test, giving them competitive advantage over labs which do not have this access.

The common theme underlying these dynamics is the goal of manufacturers to develop tests for which labs, payers and patients must pay more. This will threaten many hospital lab budgets.

9... At Long Last, a Major City Dominated By Hospital Lab Outreach Programs

story nine

IN ITS TENTH YEAR OF OPERATIONS, Detroit-based **Joint Venture Hospital Laboratories** (JVHL) reached an important milestone in its collaborative sales and marketing outreach program.

On May 1, 2002, it became the exclusive contract laboratory for **Health Alliance Plan** (HAP), an HMO with 125,000 lives. With implementation of the HAP contract, JVHL now holds every major managed care contract in the Greater Detroit area. *(See TDR, March 11, 2002.)*

Organized in 1992 specifically to pursue managed care contracts, JVHL is owned by eight of Detroit's nine integrated delivery networks (IDN). As many as 150 hospital labs in the state of Michigan participate in certain of JVHL's managed care contracts. Its 15 largest HMO contracts cover 1.35 million lives.

The fact that JVHL's major hospital labs in the Detroit metropolitan market have become the city's dominant lab serving physicians' offices is a milestone worth recognizing. Yet, this accomplishment, because it is the exception, is a sad comment on the inability of hospital lab administrators in other regions of the United States to collaborate to their mutual benefit.

JVHL demonstrates it is possible for competing hospital laboratories to band together and, by collaborating, successfully capture market share in physicians' office send-out testing.

10... LabCorp Gobbles Up DIANON Systems, Ready to Challenge in Anatomic Path

story ten

NO SINGLE EVENT OF 2002 WILL HAVE a more direct impact on community hospital-based pathologists than the acquisition of **Dianon Systems, Inc.** by **Laboratory Corporation of America**.

DIANON Systems, along with **UroCor, Inc.** (acquired by DIANON in 2001), pioneered the business model of a national lab company organized to provide primary biopsy services to office-based physicians. This is a market traditionally dominated by local pathologists.

By acquiring DIANON, LabCorp is signaling its intent to expand its share of the primary biopsy market that originates in physicians' offices. *(See TDR, November 28, 2002.)* This is a market that Quest Diagnostics covets as well. If both LabCorp and Quest Diagnostics succeed in their efforts to capture more primary biopsy business, the losers will be local pathologists.

Most community hospital-based pathologists are vulnerable for two reasons. First, outreach specimens often comprise a small portion of their group's total billings, so they don't place much emphasis on retaining it. Second, few local pathology groups will invest in the sales resources necessary to protect their existing business from national lab competitors.

With the two blood brothers eying this market segment, it is timely for local pathologists to review their vulnerability and prepare to defend their turf. TDR

Docs' In-Office Testing Showing Mixed Trends

New technologies and the need to improve patient care may stimulate growth in POLs

CEO SUMMARY: Despite the burdens of CLIA certification and reduced reimbursement for lab tests, many medical practice experts are advising doctors to expand in-office testing. However, diagnostic technologies for near-patient testing are still not robust enough to support this trend. Early attempts to expand testing in physicians' office laboratories show the technology is still not quite ready for "prime time."

IN-OFFICE LAB TESTING by physicians remains a substantial portion of the estimated $36 billion that's paid each year for clinical laboratory testing.

At the beginning of the 1990s, it was believed that physicians' office laboratories (POL) accounted for about half of all lab testing done on behalf of patients outside of hospitals. However, that percentage shrank throughout the 1990s.

Two factors contributed to this decline. The implementation of CLIA certification requirements early in the decade increased the cost and effort of operating a physicians' office laboratory. At the same time, the well-documented decline in reimbursement for laboratory testing throughout the 1990s changed the economics of POL testing for the worst.

Yet the number of CLIA-certified laboratory sites has trended upwards in recent years. Some experts attribute this increase to the number of waived tests that have become available. Also, the obstacles to operating a POL may be overcome by the introduction of new technologies in information systems and diagnostic instruments. One source of valuable insight into the POL testing segment is C. Anne Pontius, President of **Laboratory Compliance Consultants, Inc.**, based in Raleigh, North Carolina.

Developing Opportunities

Her company provides a full range of consulting services specifically targeted at physicians' office laboratories. "Although POL activity trended down immediately after CLIA, I see several developing opportunities that would make POLs more attractive to physicians in the future," observed Pontius.

"There's obviously a recognition that CLIA certification requirements and falling reimbursement make it more difficult for physicians to support in-office lab testing. But the remaining POLs have value to their physicians and I've not seen many examples of physicians abandoning existing POL testing activities in recent years.

Careside's Routine Testing Systems Fail to Sell in Physician's Office Market

ONE AMBITIOUS ATTEMPT to introduce routine laboratory testing into smaller physician office settings has fizzled.

Careside, Inc., based in Culver City, California, developed an instrument system capable of doing blood chemistry, electrochemistry, and coagulation testing in 15 minutes in near-patient settings. The company obtained FDA approval in 1999 and began marketing its Careside Analyzer primarily to physicians' offices. *(See TDR, November 22, 1999.)*

But Careside was plagued with numerous problems. Early in 2000, performance issues surfaced with Careside units in the field. These involved both the software and hardware of the system. There were also technical problems with the electrochemistry tests. Careside stopped selling units until these problems were corrected.

In October 2002, the company filed for protection under Chapter 11 bankruptcy laws. It had placed less than 100 instruments over the past several years. The company has downsized significantly and its future plans are uncertain.

Careside's attempt to bring a point-of-care testing solution to the physicians' office market is instructive on several points. In speaking with a variety of experts about its use in physicians' offices, THE DARK REPORT identified three main problems.

First was cost. The instrument itself was relatively expensive for the specimen volume it could handle. That was equally true of the cartridges required to run the tests. Because it was a new company and lacked manufacturing economies of scale, it could not offer more competitive pricing.

Second, in actual use in physicians' offices, the Careside Analyzer proved to be more complex than anticipated. Since throughput was slow, it was difficult for multiple users to share one instrument.

The third issue is quite fascinating and involves proficiency testing. It took Careside a long time to develop an effective proficiency testing network among its users. Without this type of resource, and in combination with the recognized problems of the early generation's software and hardware, this made the product vulnerable during the early stages of its market introduction.

These observations demonstrate that introducing more sophisticated diagnostic testing technology into physicians' offices remains a tricky proposition. Physicians need simplicity, reliability, and productivity from a near-patient testing solution. Careside's solution was a credible attempt to meet these requirements, but the product did not meet the expectations of its prospective physician customers.

"In fact, many physician specialties are being told that in-office testing is a good way to offset reimbursement declines in other portions of their practice, while offering the important benefit of allowing them to provide their patients with a higher level of clinical care," explained Pontius.

"Doctors are hearing this recommendation in a variety of settings and from any number of experts," she continued. "In-office lab testing is a topic often addressed at medical specialty meetings and in specialty medical publications. It is recommended as a key business strategy to replace or supplement revenue declines in other areas of a physician's practice."

Even as physicians hear advice about increasing in-office lab testing, Pontius says that diagnostic testing technology has yet to provide effective

solutions for physicians' offices that might want to test smaller volumes of specimens. "This seriously limits the ability of smaller group practices, with less than five providers, to expand in-office testing," she noted. "The cost and complexity of doing an expanded menu of routine testing continues to be a hurdle for physician groups of this size."

New Technology

Genomic and proteomic technology is expected to produce a flood of new diagnostic tests in coming years. However, Pontius believes these types of assays will probably not find their way into POLs in the near future. "The complexity of many of these tests will lead them to be performed in core lab settings, not POLs," she predicted.

"However, I do think it is reasonable to expect the total volume of in-office testing to increase over time," added Pontius. "As testing technology and information systems become simpler to use and more cost-effective, more tests will move closer to patients."

Pontius believes at least one wild card exists that could stimulate big increases in POL testing. "The growing movement to reduce patient errors and improve the quality of healthcare outcomes is closely linked to effective use of laboratory tests," she said.

In-Office Testing Solutions

"As doctors come under pressure to reduce measurable errors and do a better job of using the right diagnostic tests, many will see in-office testing as a solution. For example, we all know what happens to many lab specimens when, after collection, they must be transported long distances, accessioned at a central laboratory, then moved through that laboratory for testing and eventual storage.

"Doctors know the frequency with which lab specimens are lost or their integrity is compromised as they are handled by a send-out lab," continued Pontius. "The ability to maintain control of the specimen by keeping it within the physicians' office, along with the faster turnaround time for results, can certainly encourage many physicians to increase in-office lab testing as a way to reduce patient errors and improve their clinical outcomes."

THE DARK REPORT believes another factor may encourage more in-office lab testing by physicians. The steady evaluation towards clinical integration of healthcare services may provide new justifications for near-patient testing, such as in physicians' offices. As it becomes possible to collect clinical data closer to the patient and allow it to follow the patient throughout the health system, that capability may well motivate more physicians to expand in-office testing.

Slow Changes To Status Quo

In the meantime, Pontius believes that swift changes to the status quo for in-office testing by physicians is unlikely to happen in the near future. "For the most part, POLs I work with are not planning a major expansion in either their specimen volume or the menu of tests they perform on site," she said.

"I believe it would take either a healthy boost in lab test reimbursement or some hot new 'must-have' diagnostic technology to get doctors to expand their POL operations," added Pontius. "At this time, neither of those two developments are likely to happen."

Since it's unlikely that reimbursement for laboratory tests will be boosted by any significant amount, it will take improvements in diagnostic technology to stimulate more POL testing. TDR

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Quiet Changes To Ripple Drugs-of-Abuse Market

Evidence grows that two blood brothers are gradually de-emphasizing DOA testing

CEO SUMMARY: Drugs-of-abuse (DOA) testing is an intensely-competitive market poised for significant change. Historically, national lab companies have been the major players and used rock-bottom prices to control the nation's biggest corporate DOA clients. But since this line of testing yields meager profits at best, indications are that the nation's two largest labs intend to quietly reduce their DOA testing business.

SIGNIFICANT CHANGES APPEAR to be underway in the national market for drugs-of-abuse (DOA) testing. These changes may favor smaller laboratories which support this type of testing.

Information from a variety of sources over recent months indicates that both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have assessed the revenue potential of drugs-of-abuse testing. Both companies recognize that, at best, this type of testing generates meager profits and has limited growth potential.

Intense Competition

If true, it is a situation that the national lab companies brought on themselves. During the past decade, public lab companies were willing to offer the nations' largest corporations at-cost and below-cost pricing for drugs-of-abuse testing as a way to build market share and develop economies of scale that would lower overall testing costs.

But the end result of this competitive battle has meant that LabCorp and Quest Diagnostics earn meager margins from their drugs-of-abuse testing divisions. As genomic and proteomic testing opens new opportunities for higher margin testing, it should be no surprise that the two blood brothers may have decided to shift resources away from their drugs-of-abuse testing programs.

Because of these facts, it appears each company has taken steps consistent with an internal decision to gradually exit this line of business. For example, during 2002 Quest Diagnostics is reported to have reduced its drugs-of-abuse sales force and reassigned customer service reps to handle major corporate accounts.

THE DARK REPORT speculates that the two blood brothers are in the earliest stages of "bleeding down" this line of business. Neither company wants specimen volume to decline so rapidly as to negatively impact quarterly earnings statements. But each company would like to gradually reduce its activities in the national drugs-of-

MedTox Quietly Building National Market Presence

IN RECENT YEARS, MedTox Scientific, Inc. has posted strong growth rates and expanded its presence in many cities around the country.

The company, based in St. Paul, Minnesota, offers a full range of testing services in drugs-of-abuse (DOA), therapeutic drugs, and environmental testing. It is also involved in clinical trials. The point-of-care DOA testing devices it developed and manufactures address two markets. One product line is called "Profile®-II" and is designed for use in workplaces and hospitals. The other product line is "Verdict®-II" and targets the government, rehabilitation, and criminal justice markets.

MedTox is also introducing Six Sigma and Lean into its laboratory. It selected **Johnson & Johnson's Ortho-Clinical Diagnostics** as the vendor to provide on-site support and Black Belt training for its employees. MedTox's first Six Sigma/Lean projects involve redesigning and remodeling its main laboratory facility in St. Paul.

abuse testing marketplace over a period of years.

If true, this would be similar to how the then "three blood brothers," exited the nursing home business starting in the mid-1990s. After looking at the profitability of long term care (LTC) facilities, LabCorp, Quest Diagnostics, and **SmithKline Beecham Clinical Laboratories** each began dropping accounts. In some cases, LTC accounts in a region were bundled and literally given to a local hospital lab outreach program willing to service the business.

Other Labs May Benefit

Who benefits from this competitive shift in drugs-of-abuse testing? THE DARK REPORT believes **MedTox Scientific, Inc.** is best positioned to reap maximum advantage. Also, hospital-based laboratories already running aggressive drugs-of-abuse testing programs could gain easier access to regional corporate accounts, particularly if non-NIDA testing is involved.

In recent months THE DARK REPORT visited MedTox. Located in St. Paul, Minnesota, MedTox is a public company with annual revenues of about $40 million. Its primary business is drugs-of-abuse testing, with an interesting twist.

MedTox provides traditional DOA screening services, which involves the patient providing a specimen which is then sent to MedTox's central laboratory in Minneapolis. The screen is performed and any positive findings are confirmed using more sensitive technology. So far, this is like any other drugs-of-abuse testing laboratory.

What sets MedTox apart is that it developed, patented, and now manufactures its own FDA-approved point-of-care (POC) tests for drugs-of-abuse. A client can use these POC test kits on-site. If a POC test reads positive, then a specimen is sent to MedTox for confirmation. Thus, MedTox offers its own brand of product for either type of DOA screening and confirmation.

Quiet Changes In Market

Just as there was no public announcement by any of the national laboratories that they were abandoning the long term care testing market in the mid-1990s, it is not expected that LabCorp and Quest Diagnostics will make a public statement about their plans for the drugs-of-abuse market.

For that reason, laboratories active in the drugs-of-abuse market should watch developments involving LabCorp and Quest Diagnostics during the next 24 months. **TDR**

Contact Susie Lu at 650-498-6954.

Patient Safety Update

Tech Shortage Plays Role In More Drug Dosing Errors

INCORRECT ADMINISTRATION OF DRUGS is one major source of errors in hospitals and evidence indicates that children and emergency-room visitors are most likely to be affected.

That's the conclusion of a study done by **U.S. Parmacopia's** Center for the Advancement of Patient Safety (CAPS). Researchers identified 105,603 medication errors during 2001 in 368 hospitals participating in the study. Of these errors, 2,539, or 2.4%, resulted in patient injury, which included 14 deaths.

Researchers identified workload increases as a major source of errors by doctors and nurses. They also identified that inexperienced staff or inadequate staff contributed to 43% of medication errors in 2001. This was a substantial increase from the error rate of 33% in 2000 and 27% in 1999.

Parallel Link To Laboratories

But the most interesting aspect of this study which directly touches clinical laboratories can be found in a researcher's comments. "We've heard a lot about the nursing shortage, but what we are seeing is there are errors from shortages of respiratory therapists or pharmacists," observed Diane Cousins, a Vice President at CAPS.

Cousins attributes one important cause for medication errors to be the inadequate technical staff in non-nursing and non-physician positions, specifically respiratory therapy and pharmacy. THE DARK REPORT believes this is an early example of how the movement to reduce patient errors will benefit clinical laboratories.

The Pharmacopia study of medication errors is instructive on how other studies—involving laboratory testing—will identify the sources of medical errors and generate findings on how to reduce these errors. The Pharmacopia study determined that either inexperience or inadequate staffing of technical positions contributes to medication errors. It is reasonable to expect that studies of medical care that involve how laboratory testing is used may uncover parallel examples of errors caused by issues of laboratory staffing.

Once these problems are identified, efforts will be made to develop solutions that prevent patient errors. If inexperience or inadequate staffing of technical positions in the laboratory is an issue, it is reasonable to assume that funds and resources will be forthcoming to correct those problems.

That is why the Pharmacopia study's findings on technical staff sources of medication errors is relevant. It demonstrates that, where it is learned that inadequate staffing of laboratories has become a source of patient errors, steps will be taken to correct those staffing problems.

For the right reasons, this means laboratory staffing issues will eventually come to the attention of hospital administrators in such a way that they cannot be ignored. In the long term, this will be positive for hospital-based laboratories. TDR

Dark Index

It's a Feud in North Carolina! LabCorp Versus Spectrum

Battle for docs' office business intensifying as each company wants to build market share

OVER IN NORTH CAROLINA, one of those good, old-fashioned southern feuds is under way.

Like the fabled feud between the Hatfields and the McCoys of years past, **Spectrum Laboratory Network** and **Laboratory Corporation** are in a full-fledged shoot-out over market share of physicians' office testing in the Tar Heel State.

This feud is instructive in a variety of ways. THE DARK REPORT believes it illustrates a number of truths about both the potential of hospital laboratory outreach programs and some of the the intrinsic business weaknesses that dog the national laboratory companies.

Moreover, this ongoing feud involves personalities that shape it in interesting ways. The human side of this story may be just as important as the business lessons it teaches.

Hospitals Own Spectrum

Spectrum Laboratory Network is a laboratory joint venture owned by three hospital systems, **Moses Cone Health System**, **High Point Regional Health System**, and **Novant Health System**. Based in Greensboro, North Carolina, Spectrum is located just 25 miles from LabCorp's headquarters in Burlington.

In the past two years, Spectrum's laboratory outreach program began to grow rapidly. Because Spectrum is in LabCorp's "backyard," most of its revenue growth has come from physician's offices formerly served by LabCorp. Spectrum states publicly that net collected revenues from outreach testing will reach $47 million for 2002, so its growth has been substantial.

Few Knew About Spectrum

Until recent months, Spectrum's continued attacks on LabCorp's home markets were little known outside of North Carolina. This all changed on October 3 when LabCorp announced it would fall about 2% short of revenue expectations for third quarter. Following that disclosure, LabCorp's stock price dropped by almost 33%.

To put this in better perspective, within 24 hours of LabCorp's disclosure that it would fall about $10+ million short of third quarter revenue estimates, the market value of its outstanding stock fell by $1.7 billion! Not surprisingly, Wall Street investors deluged LabCorp with calls and questions. *(See TDR, October 7, 2002.)*

LabCorp officials attributed the revenue shortfall to business lost to a hospital outreach program in North Carolina and identified Spectrum Laboratory Network by name. This created instant fame for Spectrum, which found itself also deluged by telephone calls from financial analysts attempting to understand LabCorp's revenue problem.

For its part, LabCorp has acknowledged that its service level in North Carolina had failed to keep pace with Spectrum's on such measures as turnaround time, the network of patient service centers, and in-office phlebotomy services. Spectrum's use of discounted pricing in North Carolina, a client-bill state, was also viewed to be a factor.

Win Back Business

Having made Spectrum famous on Wall Street, LabCorp realized that, to restore lost credibility, it must win back the physicians' office business it lost in to Spectrum in North Carolina. To accomplish this, LabCorp has launched what it calls "Project Hurricane."

In the short term, LabCorp has transferred sales reps from other regions into North Carolina. These sales reps have been given special pricing packages and the ability to offer expanded services to win back lost clients. In the long term, LabCorp is recasting its sales management and field sales team covering that region. LabCorp also says it will add patient service centers and put more phlebotomists into physicians' offices.

Trading Same Clients

Long-time veterans of the commercial laboratory marketing wars of pre-1994 era know what this means. LabCorp and Spectrum will begin trading client accounts. However, new accounts will generate less profit because: 1) of the more aggressive use of discounted pricing; 2) additional expenses incurred to service these new accounts; and, 3) additional sales and marketing costs to close and set-up new accounts.

This establishes the business background for the ongoing marketing war unfolding between Spectrum and LabCorp. But it's the people involved that make the "Hatfield and McCoy Feud" an apt metaphor.

Spectrum's surging outreach program is not an accident. It is directly linked to the arrival of its new CEO, Nate Headley. Headley was an executive at **National Health Laboratories** during its go-go days. Through most of the 1990s, he served as CEO of **Physicians Clinical Laboratories, Inc.** (PCL). Based in Sacramento, California, PCL was a publicly-traded lab until it went into Chapter 11 bankruptcy in November 1997.

This means Nate Headley is an experienced hand at marketing com-

LabCorp-Spectrum Battle Offers Useful Insights

AS THE BATTLE IN NORTH CAROLINA between **Spectrum Laboratory Network** and **Laboratory Corporation of America** unfolds, it provides several valuable insights about the physicians' office testing segment.

1. Spectrum, as a hospital lab outreach program, demonstrates that such programs have several competitive advantages over national labs when service levels are at least equal.
2. Spectrum's lab outreach program has been around for years, but had languished. Upon the arrival of a strong management leader, these same resources were deployed in support of a professional sales and marketing program. Experienced management leadership was a missing ingredient.
3. Spectrum's success illustrates how vulnerable the national labs can be in regional markets where they've faced little effective competition.
4. LabCorp's declaration that it will add patient service centers and other service infrastructure in North Carolina is a clue as to how service levels have been allowed to erode in areas where the national labs hold large market shares and face little competition from local labs.
5. North Carolina is a client bill state. Going forward, both LabCorp and Spectrum may overuse discounted pricing to protect and increase market share and make the resulting business marginally profitable for all laboratory competitors.

mercial laboratory services to physicians' offices, particularly in California, where the marketing battles were extremely intense. It also means that some LabCorp executives and Headley served together at National Health Labs years ago.

Human Face To Every Feud

Each side of the feud has a human factor. On the Spectrum side, Headley probably wants to give his former NHL colleagues within LabCorp a good run for their money—healthy competition like Army playing Navy in football every year. On the LabCorp side, it's now a serious goal to regain lost market share and restore credibility with Wall Street.

What will make the LabCorp vs. Spectrum feud interesting to watch in future months is how the human elements play on top of the business dynamics. At a minimum, THE DARK REPORT can identify these useful business lessons:

1) Spectrum's expanded market share of physicians' office testing demonstrates that a hospital lab outreach program has several competitive advantages over the national lab companies when all things are equal. It demonstrates that if the outreach services are better, physicians respond enthusiastically to a local lab option.

2) Spectrum's strong growth rates and recognized service advantages (as acknowledged by LabCorp) show the importance to a hospital lab outreach program of a chief lab executive who understands how to organize a professional sales and marketing campaign that is complemented by good lab testing operations.

3) Spectrum's success at expanding market share reveals the vulnerability of the national labs in markets where they've held a monopoly share with little competition. Essentially, when physicians in North Carolina were offered a credible choice, they opted at high rates for the local hospital lab outreach program.

4) In many regions, the national labs have reduced service levels downward. The evidence of this in North Carolina is LabCorp's statement that it must add patient service centers and put more phlebotomists in physicians' offices if it is to match Spectrum's service infrastructure.

5) Aggressive low pricing for lab tests in a client bill situation is destructive to all laboratory competitors. If this happens in North Carolina, over time, either LabCorp or Spectrum may find themselves the market share victor—but the profit margins from that book of lab testing business may be so low as to barely cover the costs of providing such testing.

Presbyterian Lab Outreach

For long-time clients and readers of THE DARK REPORT, competition in North Carolina between LabCorp and an aggressive hospital outreach program is deja vu. During the first half of the 1990s, **Presbyterian Laboratory Services** of Charlotte, North Carolina, was the aggressive competitor, stealing big chunks of LabCorp's business in Charlotte. *(See TDRs, October 27, 1997 and November 17, 1997.)* However, Presbyterian Laboratory Services lost much of its support from administration when **Presbyterian Health** became part of Novant Health System in the mid-1990s.

For the present, the feud between LabCorp and Spectrum Laboratory Network is now a high-profile affair. Both Wall Street and the laboratory industry are watching. As both labs devote more resources to defending their existing client base and enlarging their share of the market, the risk is that this may become a Pyrrhic victory for the eventual winner. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

This morning **AmeriPath, Inc.** announced that it would be purchased by **Welsh Carson Anderson & Stowe**, a private equity firm based in New York City. Welsh Carson will pay $21.25 per share, a 30% premium over AmeriPath's closing NASDAQ price of $16.45 on Friday, December 6. Welsh Carson already owns 4.9% of AmeriPath and will pay $627 million to acquire the remaining AmeriPath Shares.

MORE ON: *AmeriPath's Sale*

From the facts released today by Ameripath, it appears that Welsh Stowe intends to take AmeriPath private. Early speculation is that Welsh Stowe wants to build up AmeriPath and, at some future point, sell it or do a public stock offering. During the past two years, a variety of potential buyers, including **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**, have looked at Ameripath. It is believed that both companies were interested in purchasing AmeriPath, but did not offer a high enough price.

TRADE GROUP ISSUES GUIDELINES TO DOCS FOR "E-CONSULTS"

Pathologists may want to get a copy of newly-issued guidelines regarding on-line consultations between doctors and patients. Among other things, these guidelines recommend that physicians restrict e-mail consultations only to their existing patients. The guidelines were issued by the **eRisk Working Group for Healthcare**. This task force includes the **American Medical Association** and 40 other physician associations. Most notably, it also includes malpractice carriers representing more than 70% of all insured physicians. For that reason, pathologists may find helpful guidance on how to deal with the increasing numbers of consumer requests for information about laboratory tests.

DOCTOR INCENTIVES

In California, there's a "pay-for-performance" initiative under way for physicians. Six major health insurers covering eight million people in HMOs are using money from insurance premium increases to pay physicians for improving the quality of their care. **Integrated Healthcare Associates** of Walnut Creek, California announced the three measures which will be used to determine incentive payments. They are: 1) clinical quality (50% of the score); 2) patient satisfaction (40% of the score); and, 3) investment in information technology (10% of the score).

SIX SIGMA/LEAN MOVES AHEAD AT OHIO HOSPITAL

Six Sigma project successes in the laboratory at **Grant Memorial Riverside Hospital** in Columbus, Ohio have motivated administration to expand the program to other departments, including radiology, pharmacy, and emergency room. There are now six certified Black Belts in the Six Sigma program at Grant Riverside Hospital and there will be 17 when the latest Black Belt class graduates. Among them is Sandra Hood, identified by THE DARK REPORT earlier this year as the nation's first hospital-based laboratory Black Belt.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 30, 2002.

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