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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...

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Founder & Publisher

Technology Cannot Replace Productive People

READING THE PRINTER PROOFS FOR STORIES in this issue of THE DARK REPORT, I was struck by the importance of new technology to the competitive position of clinical laboratories. Each new scientific breakthrough affecting diagnostics requires individual laboratories to assess whether or not they should adopt that technology.

In our list of the Top Ten lab industry stories for 1998 (pages 2-8), technology plays a role in automated cytology systems, mapping of the human genome, and the multiplex bioassay platform developed by **Luminex Corp**. These are the upcoming technologies which will change laboratories in ways yet to be determined.

Contrast the impending arrival of new technologies mentioned above with our assessment of total laboratory automation for 1999 (pages 9-14). In this story, our editor declares the current generation of TLA technology to be DOA–dead on arrival. Laboratories which pioneered the installation of TLA systems have not volunteered to share detailed financial information about TLA's actual performance. In fact, several labs that installed TLA have told THE DARK REPORT, off the record, that it was a mistake to have done it.

That is what brought me to an interesting observation. In my business career, I have always found that the best solution to a problem was people. If I needed a turnaround when times were bad, if I needed extra profit margin from existing operations, the solution was always to assign a person with a good mind and initiative to attack the challenge. Invariably they would find a way to accomplish the mission, on time and on budget.

Yet, when I work with laboratorians, they tend to overlook the capabilities people possess for solving problems. Many lab managers seem to believe that purchasing a new technology and putting it in their laboratory will bring about lower costs, higher quality, better service. That is why total laboratory automation was so closely-watched as it entered the marketplace. If it worked, many lab administrators believed it would help them cut lab costs, cut people, and improve quality.

Yet none of that happened. This first generation of TLA fizzled. Meanwhile, those labs which invested in their people found effective, low-cost ways to steadily reduce costs, improve quality, and keep everyone happy. It illustrates my point that "technology cannot replace productive people!" TDR

DARK REPORT Picks 1998's Ten Biggest Lab Stories

Annual year-end review provides revealing look at major influences affecting lab industry

CEO SUMMARY: Our story picks for 1998 demonstrate a broad range of subjects. Each affects laboratories and pathology practices in significant ways and should be used to trigger appropriate management strategies. Two essential themes among this year's ten biggest lab stories: continued downward squeeze on reimbursement and a flood of new technology is on the way.

Unlike 1997, there was no single compelling story during 1998 which would immediately impact every laboratory in every city.

The big story in 1997 was the requirement for laboratory compliance programs, introduced by federal regulators after their $325 million settlement with **SmithKline Beecham PLC** in February 1997.

During 1997 and 1998, every licensed laboratory in the United States found themselves immersed in laboratory compliance issues. So the fact that 1998 did not have a similar story should be considered a blessing. But the relative quiet of 1998 should not be misunderstood.

Although the year passed rather quietly, significant events were occurring behind the scenes. A careful analysis of 1998's top stories indicates two consistent themes for the future.

First, all categories of healthcare providers have entered a business cycle where money management is critical to survival. The clinical laboratory industry was the first to show the effects of this trend in 1995. During 1998, the rest of healthcare began experiencing the same phenomenon.

Second, a wave of new technology is preparing to enter clinical usage. This new technology will force healthcare providers, including clinical laboratories and pathologists, to dramatically change the way their business is organized and the way it delivers clinical services.

That's the bad news. The good news is that these two trends will not put laboratories and pathology practices under immediate pressure to change. Rather, the effects of these trends will be felt over time and each will interact to compound their

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cumulative effects upon laboratories and pathology practices.

But the cumulative and compounding effects of these two trends should not be underestimated. If one accepts the trend of increased negative financial pressure (from lower reimbursement, from changes in how HMOs and government health plans process claims, and similar factors), it becomes easy to see how that influences the impact of new technology.

Insufficient Capital

A laboratory must have money to acquire, install, and utilize new technology. If finances are deteriorating, then insufficient capital is available for the purchase of new technology.

This puts clinical labs and pathology practices in a double whammy. On one hand, reimbursement is insufficient to sustain existing operations. On the other hand, if new technology cannot be acquired, then the laboratory falls behind its competitors. That increases the financial pressure.

Since 1998 was not dominated by any single story, it signals that the clinical laboratory industry is in the midst of a transition.

Four stories on our Top Ten list reflect deteriorating financial prospects. They are: widespread HMO losses (page 5); crash of the PPM industry (page 5); decline in the value of clinical laboratories (page 7); and the stiff increase in health insurance premiums for 1999 (page 8).

Three of our Top Ten stories reflect the trend of coming new technology. They are: automated Pap smear screening (page 4); the new human genome mapping partnership (page 6); and the advent of **Luminex Corp.'s** FlowMetrix™ system (page 8).

One Top Ten story illustrates an emerging market response to these twin trends. A new cycle of hospital chain-commercial laboratory ventures (page 4) provides evidence that some organizations are attempting to forestall the effects of declining reimbursement by reorganizing themselves more efficiently.

Since 1998 was not dominated by any single story, it signals that the clinical laboratory industry is in the midst of a transition. Things are quiet because the healthcare industry is reacting to the effects of consolidation and the move toward integrated clinical services.

This is territory where no road map exists to guide physicians and administrators. In that sense, everyone is equal, because there is no "right" organizational model for the type of clinical laboratory required by clinical integration.

Reassess Strategic Position

THE DARK REPORT recommends that laboratory executives and pathologists use this quiet period to reassess their strategic position in their particular healthcare market. The relative lull provides a good opportunity to reposition the laboratory for the next cycle of market changes and declining reimbursement.

As 1999 progresses, expect the nation's largest healthcare organizations to concentrate their market clout through further consolidation. The acquisition of **Prudential Healthcare** by **Aetna U.S. Healthcare** in December 1998 is an example.

Although size does not guarantee profitibility and success, it certainly guarantees attention and a place at the table. Financially-weak providers will find themselves gobbled up by larger companies interested in growth by acquisition.

Although this may restrict provider access by hospital lab outreach programs and independent labs, THE DARK REPORT continues to believe that local testing, delivered with a high level of service, will continue to be a competitive advantage. TDR

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1 Hospital Chain-Commercial Lab Ventures Entering New Phase

DURING 1998, A NEW GENERATION of ventures between hospital chains and commercial laboratories emerged.

These new ventures represent an increasing awareness by hospital operators that the clinical laboratory can play a greater role in lowering costs and improving healthcare outcomes.

In January, **Tenet Healthcare** inked a contract with **SmithKline Beecham Clinical Laboratories** (SBCL) to reorganize Tenet's 30 hospital laboratories in Southern California *(See TDR, January 19, 1998.)* .

The next big announcement was a two-part strategic alliance between **Premier, Inc.** and **Quest Diagnostics Incorporated**. Made public in May, the alliance is designed to help hospital systems improve the productivity and clinical contribution of their laboratory organizations. *(See TDR, May 26; June 15; July 6, 1998.)*

During the year, **Dynacare** and **MDS's AutoLab Systems** continued to develop additional relationships with hospital operators. **American Medical Laboratories**, revitalized by its new owners, also began an intense campaign to develop strategic relationships with hospitals.

These developments promise to change the historical animosity between commercial laboratories and hospital-based labs. It will lead to the regional laboratory systems which economic forces dictate as an end game. But the transformation will not be immediate. Hospitals are slow to change their ways and these deals will be scratched out one at a time.

2 Automated Pap Smear Screens Enter Market With FDA Approval

PERSISTENCE CAN PAY OFF. The long and expensive effort to bring an automated cytology system to the marketplace was finally successful.

During 1998, the **Food and Drug Administration** (FDA) formally approved **NeoPath, Inc.'s** premarket approval supplement to use its AutoPap® system as a primary screener for Pap smears.

Once the FDA decision became official, the profession of cytology changed forever. Within months of the FDA's action, two of the nation's largest and most respected healthcare organizations made a major commitment to the AutoPap system.

Kaiser Permanente, with 1.4 million Pap smears per year, and **SmithKline Beecham Clinical Laboratories**, with 5.5 million Pap smears per year, each signed agreements with NeoPath. Both companies intend to move 100% of their Paps smears onto automated screening within two years. *(See TDR, November 9, 1998.)*

These developments will revolutionize the cytology profession. THE DARK REPORT predicts that future generations of automated cytology technology will transform cytology practices in the same way that **Coulter** Counters transformed blood testing. As additional cytology companies enter the marketplace with new automated cytology products, laboratorians, physicians and patients will all reap the benefits.

3 Increasing Numbers of HMOs Disclose Significant Losses

MANAGED CARE'S GLORY DAYS may now be history. As 1997 ended and 1998 began, HMOs large and small in every corner of the country posted losses. It was a dramatic turnaround for an industry which was financially flush just 12 months earlier.

This is a big story for the laboratory industry. If HMOs find it impossible to operate with acceptable profit margins, it will be difficult for HMOs to increase reimbursement for laboratory testing.

Kaiser Permanente lost money in 1997 and projects losses for 1998. **United Healthcare** was ready to acquire **Humana**, but disclosure of a $900 million charge at United Healthcare during the second quarter derailed the merger. **Oxford Health Plans** lost $508 million during the second quarter as well. *(See TDR, August 17, 1998.)*

Late in the year, Prudential sold its perennially money-losing healthcare division to **Aetna U.S. Healthcare**. The acquisition made Aetna the largest health insurer in the nation, with 22.4 million members. *(See TDR, December 21, 1998.)*

Laboratory executives should pay close attention to the financial condition of managed care companies. The profitability of the clinical laboratory industry is closely linked to that of the managed care industry. During the next 24 months, expect to see employers get hit with considerable premium increases as managed care firms attempt to regain financial stability.

4 Three Pathology PPMS Gear Up In Midst Of PPM Industry Crash

FOR PATHOLOGY PRACTICE MANAGEMENT (PPM) companies, timing could not be worse. 1998 was a disaster year for the PPM industry as a whole.

During 1998, **Pathology Consultants of America** (PCA); **Pathology Partners, Inc.**; and **PATHSource, Inc.** obtained venture capital funding and entered the marketplace. Along with **AmeriPath, Inc.**, each company had high hopes of offering pathologists another business model besides a group practice.

Through the course of 1998, the investor public was stunned by announcements that billion-dollar PPM giants such as **MedPartners, Inc.**; **PhyMatrix Corp.**; and others suffered significant losses or announced that they were quitting the physician management business.

Many Wall Street analysts now doubt the viability of the PPM concept. Pathologists seem to agree.

During 1998, the collective group of pathology PPMs struggled to do enough acquisitions to meet their original growth projections. Executives at these PPMs opted for a "go slow" strategy in buying pathology practices.

Because the PPM industry is undergoing a severe financial squeeze, it is unlikely that the PPM business model will become a significant factor in altering the practice of pathology. Going into 1998, few experts would have made such a prediction.

5 New Generation of Technology To Speed Human Genome Map

DURING THE NEXT TEN YEARS, probably no single story of 1998 promises to revolutionize the clinical laboratory industry more than that of the partnership between **Perkin-Elmer Corp**. and J. Craig Venter, Ph.D.

In May, the two parties announced a joint venture to map the human genome. Using a new generation of genetic analyzer developed at Perkin-Elmer, the partnership believes it can map the entire human genome in as little as three to four years, at a cost of less than $300 million. *(See TDR, June 15, 1998.)*

Contrast this to the federally-funded Human Genome Project, launched in 1990. Budgeted at $3 billion and projected to take 15 years, the project is at the half-way point and is ahead of schedule, with about 3% of the genes completely mapped.

If the Perkin-Elmer/Venter partnership succeeds in its goals, there will be several consequences. First, it will unleash a cascade of new genetics knowledge that will spur a variety of healthcare discoveries in both diagnostics and therapeutics.

Second, these gene-based discoveries may end up as private patents. Thus, new diagnostic assays will enter the marketplace through untraditional delivery channels. General reference labs may not be able to license rights to many worthwhile new assays.

Keep an eye on this joint venture. If it succeeds, there will be a steady stream of changes to clinical lab practices during the next five to ten years.

6 First Major Laboratory Site Earns ISO-9000 Certification

IT WAS DURING THE 1990S THAT the healthcare industry finally became aware of management techniques common to successful Fortune 100 companies.

It was not until 1998 that the first major laboratory site achieved ISO-9000 certification. It was the **Nichols Institute** Division of **Quest Diagnostics Incorporated** which earned this honor. *(See TDR, July 6 & July 27, 1998.)*

This story makes our Top Ten List for an important reason. The clinical laboratory industry, along with most healthcare providers, is finally awakening to the management philosophies and techniques used by America's most successful companies.

The importance of ISO-9000 certification at Nichols Institute lies not in the fact that they were first. Rather, the importance is that Nichols Institute is now organized around a powerful new philosophy of management.

Simply put, if the executives at Nichols use these management tools effectively, Nichols Institute will increasingly be more competitive than other laboratories. It will force competitors to adopt the same management philosophies.

The management parameters embodied in ISO-9000 guidelines are what create the world-class companies which dominate their markets. Its arrival in the clinical lab market signals that an irrevocable change is now under way.

7 Managed Care Consolidation Changes Competitive Balance

CONSOLIDATION IS A BUSINESS THEME familiar to all readers of THE DARK REPORT. For better or worse, consolidation is transforming every sector of healthcare.

During 1998, the consolidation of managed care companies followed two trails. First, the industry giants continue efforts to grow through acquisition. Second, significant losses at many small and medium-sized health plans have made them acquisition targets.

Consolidation of managed care companies will not be a positive development for the clinical laboratory industry. The larger the managed care plan, the greater the tendency to sign exclusive provider arrangements with large laboratory companies.

For example, **Aetna U.S. Healthcare's** purchase of **Prudential Healthcare** in December now gives it 22.4 million members and provider contracts with 400,000 of the nation's 600,000 physicians. *(See TDR, December 21, 1998.)* This is market clout. **SmithKline Beecham Clinical Laboratories** was the sole source laboratory provider to Prudential and is Aetna's sole source provider in nine states.

At the other end of the scale, a number of smaller health plans, after posting significant losses, find themselves acquired by stronger insurers. This also tends to concentrate market buying power to the detriment of hospital labs and independent commercial labs. The result is that more laboratories are finding themselves denied status as a laboratory services provider.

8 Sales of Clinical Laboratories Reveal Ongoing Financial Woes

ONLY A LIMITED NUMBER of commercial laboratories were sold during 1998. Those that did come to market were generally in poor financial condition.

Bankruptcy was frequently the reason a laboratory had to be sold. That was certainly the case for $28 million **Meris Laboratories** (bought for $16.5 million by **Unilab, Inc.**) and $20 million **Medilab, Inc.** (bought for $11 million by **Laboratory Corporation of America**).

These sales were consummated for about 50¢ per $1.00 of annual revenue. This is a dramatic reduction from the heady acquisition frenzy of 1990-1994, when the large laboratories were commonly willing to pay sales prices of $1.00 per $1.00 of annual revenue.

These forced sales are evidence that many independent commercial laboratories continue to operate under severe financial stress. The impact of lower reimbursement and burdensome compliance requirements is preventing them from achieving financial stability.

Laboratory sales during the year revealed another interesting development. Some of the three blood brothers are showing interest in selective acquisitions. LabCorp purchased significant laboratory business on at least two occasions. **Quest Diagnostics Incorporated** did one acquisition in December. As independent labs are forced to sell, the big labs are again potentail buyers.

9 Healthcare Premiums Jump, Providers Fight Medicare Cuts

THERE IS AN INTERESTING contradiction in the marketplace. Widespread losses caused HMOs to push stiff premium increases onto employers for 1999. This, despite the fact that prices charged by hospitals and physicians only climbed by about 2% during the year. *(See TDR, November 30, 1998.)*

Meanwhile, healthcare providers are reacting to the Medicare cuts enacted by Congress in recent years. As the impact of these cuts, particularly in home health services, hit providers, they responded immediately by lobbying Congress for relief.

Large employers are seeing premium increases in the range of 6% to 12%. It is small and medium-sized employers who are getting slammed. Companies in this size range are seeing increases of 30% to 50%.

This means that both private employers and government healthplans will soon react to the actions of HMOs and providers. There is not enough money to go around.

After several years of moderate premium increases to private industry, the staggering financial losses of the HMO industry are causing them to raise premium prices as aggressively as possible.

Laboratory executives and pathologists should monitor this trend. If premium hikes at the end of 1999 follow a similar pattern, there will be a response by private employers. Larger employers may turn to direct contracting as a way to control healthcare costs. If so, that could be to the benefit of clinical laboratories.

10 Luminex Brings "Disruptive Technology" To Diagnostics

IN THE DARK REPORT'S final issue for 1998, the cover story was about **Luminex Corp.** and its remarkable multiplex bioassay system.

It is THE DARK REPORT's prediction that Luminex has developed a bioassay technology that will eventually transform how clinical laboratories are organized and how they deliver testing services.

Called FlowMetrix™, it is a technology which can perform up to 64 individual assays simultaneously on one specimen, at a cost of literally pennies per assay. *(See TDR, December 21, 1998.)*

Although Luminex recognizes that the pharmaceutical market represents the greatest potential, it is already attracting the attention of large clinical laboratories in the United States. The reason is simple. Clinical laboratories are under great pressure to cut costs, without cutting service and quality.

Luminex's FlowMetrix has the capability to greatly reduce the costs of individual tests while maintaining or improving specificity and sensitivity.

However, it is in the long run that FlowMetrix will have its greatest impact on laboratory services. Here is a technology platform that can perform 64 discrete assays at the same time on one sample. We predict that labs will develop a wide range of value-added test panels which only this technology can make possible. **TDR**

A TECHNOLOGY WHOSE TIME "NEVER CAME"

Total Laboratory Automation: It's "DOA" In Today's Market

Story Update From 1997

CEO SUMMARY: Since 1994, thoughtful lab executives have wrestled with the concept of total automation for their laboratory. Despite concerted marketing efforts by some of the world's most successful diagnostics manufacturers, only a handful of total laboratory automation (TLA) sites are operating today in the United States. In operation, the economics of TLA failed to deliver on its promise of lower costs. As the curtain falls on this first-generation TLA in 1999, maybe now is the time to share some untold stories about TLA's pioneering efforts. Despite its limited success, TLA did spur development of a worthwhile successor: modular automated workcells. Here is THE DARK REPORT's follow-up on this important story.

PROBABLY THE GREATEST untold story in the laboratory industry today is the failure of total laboratory automation (TLA) to deliver on its promise of higher productivity, lower cost, and improved quality.

Since 1995, THE DARK REPORT has counseled that most laboratories should take a "go slow" approach towards total laboratory automation. Our reasons were clear and we felt the arguments were compelling.

The case against total laboratory automation was best presented in our classic *An Industrial Engineer Looks At Laboratory Automation And Robotics*. It was published in the February 17, 1997 issue of THE DARK REPORT (back issues available complementary to clients and subscribers upon request.)

Authored by Mark Smythe, an industrial engineer with four decades of experience in manufacturing, distribution, and clinical laboratory operations, it made three key points about TLA.

First, Smythe pointed out that the typical clinical laboratory in the United States, by the fundamental design of its organization and production throughput, does not have the intrinsic potential to benefit from total automation.

For comparison, he noted that a car manufacturing plant will operate at full production volume for three shifts (24 hours per day), six and seven days per week. A clinical laboratory operates at maximum volume only one shift per day (8 hours) and only five days per week. Thus, the opportunity to amortize the cost of automated equipment over a huge production run is severely limited for laboratories.

Second, Smythe also noted that total automation tends to "freeze" the production process of the laboratory. Once expensive automated equipment is installed, the laboratory finds it difficult to alter processes and workflows which might generate incremental productivity and cost improvements. In that respect, a TLA installation "handcuffs" the laboratory to its expensive equipment, for better or for worse.

Smythe's third point was most telling. "First, whatever automation equipment is chosen for a laboratory, the manufacturer should specify an expected return on investment (ROI)," wrote Smythe. "Calculations to arrive at this number should be clearly understood. Both the laboratory buyer and the vendor should be prepared to work together to achieve that ROI."

ROI Data Never Made Public

At the time he wrote the article, Smythe noted that public information about the ROI of existing TLA installations was notably absent. "I eagerly scan the clinical laboratory press for *detailed* financial documentation as to how laboratory automation has reduced costs, improved productivity, and delivered a market return on investment to those few laboratories which have pioneered the installation of such technology. Such documentation is not forthcoming..."

Smythe's assessment? "It would be a reasonable conclusion that neither the automation vendor nor the laboratory customer is totally satisfied with the performance of their laboratory automation systems to date."

Written in 1997, Smythe's words stand just as true in 1999. During the past two years, no vendor or laboratory user has been brave enough to publish a rigorous ROI analysis of an operational TLA laboratory installation.

Because every successful TLA installation represents $2 to $4 million in sales to a

vendor, it is reasonable to assume that laboratories with operational TLA systems would be quick to make the good news public. The lack of such public information is one good clue to the economic disaster known as TLA.

It is instructive to review the list of total laboratory automation projects which became operational in recent years. **SmithKline Beecham Clinical Laboratories** (SBCL) was probably first to get a TLA site into operation.

In the early 1990s, SBCL chose the King of Prussia laboratory to be its first TLA site. Several years of engineering effort and expense were required to get TLA into full operation at the King of Prussia laboratory.

Since TLA become fully operational at King of Prussia, SBCL has not published any detailed numbers on the costs required to develop and install the equipment. Nor has any rigorous analysis been published which measures the specific productivity enhancements against those costs.

Several articles appeared in clinical lab publications about SBCL's King of Prussia total laboratory automation package. Although complimentary about the TLA equipment in operation, these articles were silent on the subject of return on investment and cost effectiveness.

Disappointing Story

Diagnostics vendors with instruments in the King of Prussia laboratory tell a disappointing story. When SBCL originally decided to automate its first laboratory, it decided to engineer its own equipment. Over a period of as long as five years, they say SBCL spent as much as $18 million on the total laboratory automation project!

If this is true, then SBCL's TLA project at King of Prussia is a financial disaster, an economic write-off. The fact that SBCL has decided *not* to automate its other high-volume regional laboratories is strong evidence that it does not believe the current state of TLA technology is a good investment of capital.

Next to install TLA was **Quest Diagnostics Incorporated**. During the time when it was still called **MetPath**, a decision was made to install TLA at three high volume laboratories: St. Louis, Denver, and Detroit.

MetPath had an advantage over other clinical laboratories. Its corporate parent was **Corning Incorporated**, a world class manufacturer. Corning's experienced industrial engineers would aid MetPath in the design and build phases of their TLA.

In 1995, the St. Louis TLA installation became operational even as installation of TLA at the Denver lab progressed. When the economic performance of the St. Louis TLA project was assessed, MetPath allowed work at Denver to be completed, but pulled the plug on plans to automate its Detroit laboratory.

Some Operational TLA Sites In The U.S.

Only a limited number of laboratory sites have installed a total laboratory automation system. Here are some examples:

1. **SmithKline Beecham Clinical Labs:** King of Prussia laboratory.
2. **Quest Diagnostics Incorporated:** St. Louis laboratory.
3. **Quest Diagnostics Incorporated:** Denver laboratory.
4. **Beth Israel Medical Center:** Central hospital lab, New York City.
5. **Mt Sinai Medical Center:** Central hospital lab, New York City.
6. **South Bend Medical Foundation:** System core laboratory, South Bend.
7. **AutoLab & Columbia/HCA:** Regional core laboratory, Atlanta.

In the years since 1995, not only has Quest Diagnostics refused to bring TLA to any other of its laboratories, but during 1998 it downsized the St. Louis facility. Those actions, taken after careful financial analysis of the TLA installations in St. Louis and Denver, would indicate that Quest finds the return on investment for total laboratory automation fails to justify even its existing installations.

Among the three blood brothers, only **Laboratory Corporation of America** did not invest in TLA. For various reasons, LabCorp never pioneered a TLA site in the 1994-95 period. Since that time, there has been nothing to change LabCorp's financial assessment of other operational TLA installations.

One of the national reference laboratories decided to be an early TLA pioneer. Many laboratory observers know that just a few years ago, **Mayo Medical Laboratories** actually signed a contract with one TLA vendor and began installation at its core laboratory in Rochester, Minnesota.

TLA Vendor Ejected

Executives at Mayo quickly recognized that the TLA project was not going well and would not deliver the promised results in a cost-effective manner. Mayo ejected the TLA vendor and ceased work on the project.

Moving to the hospital laboratory segment of the industry, results are not much different. New York City provides a perfect example. **Beth Israel Medical Center** and **Mt. Sinai Medical Center**, both located in Manhattan, decided to be early adopters of total laboratory automation.

Beth Israel's total laboratory automation project became operational in the fall of 1997. Mt. Sinai's was turned on in 1998. Adminstrators at both sites acknowledge that their systems run at less than 20% of potential capacity. Both hospitals had declared that their excess capacity would be absorbed by increased specimen volume from two sources: test referrals from other hospitals in the region and lab outreach programs to physician offices.

More than one year after TLA start-up, neither hospital has generated any substantial increase in specimen volume. Accordingly, the return on investment for these TLA projects must be dismal.

There is an interesting anecdote which further illustrates the naivete of the TLA vendors and their laboratory customers. When THE DARK REPORT toured one of the New York hospital TLA sites, it was told a remarkable fact. Only *after* the TLA system became operational at this particular laboratory, was it discovered that 25% of the specimen volume that was supposed to go onto the automated line would not fit.

Why Truth About TLA Was Never Revealed

Did you ever wonder why lab industry rumors contained more truth about total laboratory automation (TLA) than most of the laboratory publications?

After all, the arrival of TLA in 1994 and 1995 was a major industry development. If the technology worked, it was expected that those labs with TLA would have a significant competitive advantage over those that didn't. So why didn't lab publications get the story right? Why didn't they seem to get the story at all?

One critical factor is advertising. Instrument vendors buy thousands of dollars of advertising in lab publications each year. Any lab publication which printed a story telling the truth about the problems with the pioneering TLA installations stood to lose large amounts of money from upset advertisers.

So lab publications simply ignored the real facts about TLA. That is why rumors proved to be a more reliable source of accurate information than most TLA stories which appeared in the clinical laboratory press.

Unlike specimens coming into a commercial laboratory, hospital test collections generate a wide range of variety in tubes and containers which cannot be accommodated by this particular TLA equipment.

The TLA vendor, having no prior hospital laboratory experience to draw upon, had not anticipated this situation. Consequently, there were even fewer specimens available to run on this TLA line than projected, further eroding the original economic basis of the project.

Learning From Pioneers

When **South Bend Medical Foundation** turned on their TLA installation in 1997, they had the benefit of learning from some of the pioneering laboratories mentioned above. It is reported that their TLA installation operates acceptably. But, as in all other cases, neither the vendor nor the laboratory have volunteered to publish detailed information about the ROI and productivity performance of the TLA project.

In fact, during 1998, a former employee with the vendor's TLA team told THE DARK REPORT several interesting facts about the South Bend project. First, because it was the vendor's first TLA site, the equipment was priced at discount, near cost. Since this was a pilot project, that would not be unusual. But the vendor also wrote-off expenses approaching $600-$800,000 for software programming and engineering adjustments.

As a result, the vendor did not charge South Bend Medical Foundation a price which accurately reflected the *true* manufacturing and installation cost of the TLA project. Yet, even with this discounted price structure, neither the vendor nor the laboratory customer have made public a detailed ROI and productivity analysis of the project.

There is one remaining player in the total laboratory automation marketplace that continues to be active. It is **AutoLab Systems**, a division of **MDS, Inc.** of Canada.

AutoLab's approach to marketing TLA is unique. When several years of sales effort generated no buyers in the U.S., AutoLab developed a strategy of partnering. AutoLab retains ownership of the equipment and shares in the profits and/or losses of the laboratory venture.

In partnership with **Columbia/HCA**, it constructed a totally-automated laboratory in Atlanta that became operational late last year. The partnership in Atlanta is called **Integrated Regional Laboratories** (IRL). AutoLab and Columbia are proceeding to build a similar laboratory in Miami.

AutoLab's approach overcomes the specific problems, noted by Mark Smythe that "the manufacturer should specify an expected return on investment (ROI)." If AutoLab owns the equipment, it doesn't have to promise an ROI. Instead, it must deliver financially through its own hands-on management of the TLA-equipped laboratory.

Too Soon For Evaluation

Since the Atlanta laboratory only became operational in October of last year, it is too soon to expect a detailed report on whether it has met acceptable ROI targets and delivered productivity and cost gains. But, like the other TLA projects mentioned earlier, should neither party publish detailed financial and productivity data in the near future, it can be assumed that the project was not completely successful by those measures.

On the other hand, if AutoLab is able to enter into several new partnerships with additional hospital labs during the coming 24 months, that may be evidence that the performance of TLA in Atlanta proved to be adequate.

Overall, however, this review of existing TLA sites is discouraging. During the past four years, the news has not been good. THE DARK REPORT believes that total laboratory automation will not expand its installed base

much in the coming years. There are a variety of reasons.

First, automation is most justified where high volumes of specimens are handled daily. In the clinical laboratory industry, the highest specimen volumes are found at laboratories operated by the three blood brothers.

SBCL installed TLA into one laboratory, then stopped. Quest Diagnostics put it into two regional laboratories and stopped. Its Teterboro facility is one of the largest in the world, yet no TLA project has been announced. LabCorp's facility in Burlington is also one of the world's largest, but no TLA is contemplated there.

Given the first-hand experience of the national laboratories in working with TLA, the fact that they refuse to install TLA at additional laboratory sites means that this existing generation of TLA is uneconomical and does not deliver the productivity and cost enhancements once expected of it.

Third, the diagnostics vendors learned from their TLA mistakes. All vendors are now engineering modular instrument systems and workcell clusters. These are groups of instruments which logically tie together. Upcoming generations of modular systems will harvest a cost-effective return on productivity, without incurring the seven figure expense of TLA. In other words, labs may get a lot of bang for a smaller investment buck.

Encourage Point-Of-Care

Fourth, evolving diagnostics technology will erode the dominance of central, or core laboratories. Miniaturization will encourage near patient and point-of-care testing.

More specifically, breakthrough technologies, such as **Luminex Corporation's** multiplex bioassay system *(see TDR, December 21, 1998)* will permit more testing to occur outside the central laboratory.

Taken collectively, the facts indicate that TLA cannot deliver the improvement promised by TLA vendors. These are the reasons why THE DARK REPORT declares the current generation of TLA to be dead.

Smythe's Value Analysis Tools

"In my work with clinical laboratories, I am always surprised at their reluctance to seek out and use proven industrial techniques," said Mark Smythe, Principal of ***Management Mentors.***

"The techniques of Value Analysis and Deliberate Methods Change," he continued, "when applied in a clinical laboratory, can improve processes while slashing costs by a factor of 15% to 40%. These techniques do not require staff layoffs and actually increase morale and productivity of the med techs. They can be rapidly implemented, often in less than 30 days.

"That is certainly a better way to reduce costs than investing in expensive equipment or laying off large numbers of loyal med techs," Smythe observed. "Manufacturers have used these 'secrets' for years. Maybe one day laboratorians will adopt them as well."

For TLA to be feasible in the future, diagnostics companies must engineer a higher level of performance at a much lower cost. Such TLA equipment has to deliver an unquestioned level of productivity gains and cost savings before it will be accepted by laboratory executives.

The reason is simple. The first generation of TLA badly burned the pioneers who installed it into their laboratories. An entire lab industry will be justifiably skeptical of any TLA product which does not demonstrate unquestioned capability.

In the meantime, look toward modular automated systems and emerging diagnostics technology as the most likely sources of cost improvement and productivity enhancement for today's laboratory organizations. **TDR**

(For further information, contact Mark H. Smythe at 503-694-2473.)

DIANON Wins Contract, Buys Kyto Meridien Lab

Oxford Health and Quest Diagnostics select DIANON Systems as anatomic path provider

CEO SUMMARY: Anatomic pathology took another forward step on the managed care battleground. DIANON Systems, Inc. gained status as a provider of anatomic pathology services under the new master agreement announced by Oxford Health Plans. DIANON's success demonstrates that anatomic pathology can be split from laboratory testing when ancillary contract decisions are made by managed care plans.

Many months of effort and a lot of persistence finally paid off for **DIANON Systems, Inc.** of Stratford, Connecticut.

Late in December, DIANON announced an agreement with **Quest Diagnostics Incorporated** to provide anatomic pathology (AP) services and specialized testing for **Oxford Health Plans, Inc.**

DIANON's success with the Oxford contract was followed by another. Today, January 11, 1999, DIANON announced its signing of a letter of intent to acquire **Kyto Meridien Diagnostics, LLC**, A $13 million outpatient OB/GYN laboratory with operations in Woodbury and New York City.

Lab Testing Network

Oxford Health Plans is a large managed care player, with 1.7 million members and 32,000 participating physicians in New York, New Jersey and Connecticut. DIANON joins four other commercial laboratories and a group of hospitals which Quest Diagnostics assembled as the laboratory testing network for Oxford.

"Winning a place in Oxford's lab network was a major goal for us," stated Kevin Johnson, President and CEO at DIANON Systems. "It's why we are developing into a full-service provider of anatomic pathology services."

DIANON's acquisition of Kyto Meridien has an interesting connection with the Oxford laboratory network. Both DIANON and Kyto Meridien are providers in the Oxford laboratory network.

"The decision by DIANON and Kyto Meridien to merge was something that developed from our mutual respect for each other," said Johnson. "Kyto Meridien provides a full range of cytology and cytopathology testing. Their clinical expertise and focus in obstetrics and gynecology strongly complements DIANON's scope of services.

"Both companies recognized an opportunity to realize business synergies while preserving the differentiation in our pathology services," he continued. "The addition of Kyto Meridien's resources further expands our capacity. Of equal importance, we believe Kyto's high-level of clinical expertise is recognized within the physician community and can be considered a 'brand' identity."

Provider status in Oxford's new laboratory services contract is a prize long-sought by DIANON. In its response to the RFP (request for proposal), DIANON Systems needed to convince both Oxford and Quest Diagnostics of its capabilities.

"Since DIANON already had a contract with Oxford, there was familiarity with our company," stated Johnson. "Further, our development of the CarePath™ disease management services and products helped us in the selection process.

"When DIANON's pathologists diagnose a biopsy, they are the first to know whether the patient has cancer or not," continued Johnson. "Our CarePath services are designed to help the physician present the findings to the patient while allowing the managed care plan to provide timely and appropriate disease management support to the patient.

"Each is an opportunity for pathologists to provide added value," he explained. "We believe that physicians would like the pathologist to take a more involved role in the diagnostic and prognostic stages. CarePath is a way to offer those enhanced services."

Kevin Johnson describes a business opportunity that most pathologists are beginning to appreciate. Pathologists play an essential role in the diagnosis of disease. If they will take a broader view of the integrated clinical environment, their expertise can add value in non-traditional ways.

Disease Management

For example, most managed care companies tell their employer-customers that they have disease management capabilities. The HMOs also brag about individual case managers who can help beneficiaries deal with all aspects of a newly-diagnosed disease.

Pathologists, as the first to make a diagnosis of serious disease, are in a position to communicate with both the referring physician and the HMO. Early notification has value to both. But pathologists have historically not included HMOs in their primary reporting process.

Oxford's Laboratory Network Shows An Emerging Approach to Lab Testing

Oxford Health Plans' new laboratory provider network has several interesting aspects. It is representative of an emerging approach used by HMOs to organize their laboratory service providers.

First, Quest Diagnostics is acting as the "network director." It will manage the laboratory testing and AP services. It will also handle reporting and manage the money.

Second, Quest Diagnostics, as the network director, worked with Oxford to select a panel of laboratory providers. Increasingly the large managed care companies are moving towards the concept of a laboratory services "director."

The laboratory "director" is responsible for developing an appropriate laboratory services provider panel. It must also manage, monitor, and report on the quality of services provided.

Third, this is a shared risk contract. The panel of laboratory providers all share risk with Quest Diagnostics.

Fourth, the number of laboratories on this provider panel is significantly limited from the prior contract. Each Oxford physi-cian will need to select one of the ap-proved laboratories as their sole source. Since DIANON Systems is a provider of anatomic pathology services, a physician can chose DIANON for AP and another panelist for the laboratory testing.

What DIANON has recognized is that *both* the HMO and the referring physician will support increased reimbursement for the anatomic pathologist, but only if he adds value to diagnosis and management of the patient's disease.

As a business strategy, DIANON Systems wants to learn how to package and offer anatomic pathology services which earn additional reimbursement over standard CPT code schedules. To accomplish this, it needs the opportunity to work with the more sophisticated HMOs.

Important Goal

That is why winning provider status with Oxford was such an important corporate goal. DIANON is now in a favorable position to interact with Oxford's Medical Directors in a mutual effort to develop and refine a new class of "value-added" anatomic pathology services. Over time, DIANON hopes they can learn from their customer and develop additional anatomic pathology services which generate worthwhile revenue.

DIANON Systems is probably ahead of most pathology practices in understanding what "value-added" means to managed care companies. But there is another important lesson that DIANON's experience can teach pathologists.

That lesson is simple: it takes money, time and business expertise to get an HMO to appreciate why a specific pathology practice should be included in its provider network. Most pathologists are reluctant to invest capital in marketing their practice.

However, in the integrated clinical environment of the future, the only survivors in the pathology profession will be those who invested money so that physicians and HMOs could appreciate why their brand of pathology was better than any other. TDR

(For further information, contact Kevin Johnson at 203-31-4905.)

Solving The Quandary Of Direct Contracting

Pathologists should consider DIANON's success in becoming a provider in Oxford's laboratory network as another encouraging development for the pathology profession.

One problem that impedes the field of anatomic pathology is the historical practice by health insurers of folding anatomic pathology into laboratory testing contracts. Since commercial laboratories are the usual winners of these contracts, it places anatomic pathologists at the very end of the food chain.

To reverse this situation, pathologists are going to have to convince HMOs and managed care plans that direct contracting of anatomic pathology services is necessary and appropriate. But that means overcoming inertia and the mo-tives of commercial laboratories, who cur-rently hold these contracts.

DIANON became an anatomic pathology provider because it spent considerable time and resources to educate both Oxford and Quest about the importance of anatomic pathology as a separate clinical resource, not an appendage to laboratory testing.

A similar case is being made by ***Pathology Service Associates*** *(PSA) of South Carolina. After two years of educational efforts, this pathology network is finally getting the state's largest health insurers to directly contract with pathologists for anatomic pathology services.*

In this segment of integrated clinical services, the stakes are high for pathologists. The early victories of DIANON Systems and PSA demonstrate that the pathology profession can reclaim its rightful role as a vital physician specialty. But it will require pathologists to invest in marketing and HMO education.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Not much has been heard from **Neuromedical Systems, Inc.** (NSI) recently. The company makes the PapNet® Testing System for Pap smear screening and is concentrating on obtaining approval from the FDA to use PapNet as a primary screener. It is currently approved for use as an adjunct test. This fall NSI announced a restructuring plan that involved the lay-offs of 20 employees and a related write-down. Most of NSI's business activities are focused on Europe, where PapNet can be used in several countries for primary screening of Pap smears.

Someone got a nice Christmas present this holiday season. **Laboratory Corporation of America** disclosed that Richard L. Novak was promoted to Executive Vice President and Chief Operating Officer (COO). The announcement was made December 29. The position was newly-created and Novak continues to report to LabCorp Chair and CEO Thomas P. Mac Mahon. Novak moved to LabCorp in March 1997 after a ten year career at **SmithKline Beecham Clinical Laboratories**.

ANALYST OPINES ON INTEGRATION

Is vertical integration of healthcare companies really the holy grail? Not according to one financial analyst. "Vertical integration sounds wonderful, but in reality it's difficult. Hospitals should be hospitals, medical groups should be medical groups, and health plans should be health plans. It's dysfunctional to put them together." These are the comments of Kenneth Abramowitz, healthcare analyst for **Sanford C. Bernstein Co.** of New York at the "InterHealthcare Congress and Exposition" held in New York City this fall.

LAST TAG...ABRAMOWITZ

His recommendations? Abramowitz said that healthcare executives should pare back rather than consolidate. "Focus on your best properties, and close marginal hospitals, offices, and anything else," he advised attendees at the event. Hmm, sounds like THE DARK REPORT'S theme that "large size brings clout, but doesn't guarantee profits and success." Could Abramowitz be reading TDR?

When the smell of money disappears, so do lawyers. In November, **AmeriPath, Inc.** was hit by government auditors with a Medicare refund demand of $2.95 million. Within weeks, a number of law firms filed shareholder class action lawsuits against the pathology PPM. AmeriPath successfully appealed the refund demand in December. *(See TDR, November 30 & December 21, 1998.)* After the settlement, it only took a matter of weeks before the various lawsuits were withdrawn.

Which was the fastest growing hospital or hospital system during the 1991-1996 time period? At a time when healthcare cutbacks are the norm, the **Mercy Health System** of Janesville, Wisconsin posted a five year growth rate of 177%, with revenues of $138 million in 1996. The runner-up was **Dallas County Hospital District** in the **Parkland Health and Hospital System** of Dallas, Texas. Its growth was 148%, with revenues of $280 million in 1996. It's a sure bet that the clinical laboratories of these two institutions have been adding resources and not cutting back. (Statistics from **Abendshien & Grube** of Northbrook, Illinois.)

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 1, 1999

THE DARK REPORT

UPCOMING...

- *Quiet Before The Storm: Why Clinical Labs Should Prepare For Financial Turmoil.*
- *Laboratory Data And Clinical Outcomes Remain The Goal, But Not The Reality.*
- *Modular Automation And Workcells: Ready To Prove Their Value In Operation.*
- *Pathologists Discover The Power Of Marketing, And Reap Increased Income.*