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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

Why Do Michigan Hospital Labs "Have it Together?

WHAT MAKES HOSPITAL LABORATORY ADMINISTRATORS AND PATHOLOGISTS in Michigan so willing to be both innovative and collaborative in creating sophisticated and financially successful regional laboratory organizations?

As you will read on pages 2-6, **Michigan Co-Tenancy Laboratory** (MCL), founded in 1997, is owned by 17 competing hospitals and provides shared testing services to more than 30 participating hospitals. The Ann Arbor-based laboratory is organized in such a way that its hospital owners have powerful incentives to feed ever-growing volumes of specimens into the shared laboratory as a way to improve the quality of lab services while simultaneously lowering costs.

Michigan Co-Tenancy Laboratory runs in parallel with **Joint Venture Hospital Laboratories** (JVHL), based in Detroit. JVHL is a regional laboratory network that has as many as 150 Michigan hospital labs participating in specific managed care contracts. Few states can boast of even one sophisticated and successful regional laboratory collaboration between competing hospitals. That is why Michigan, with two such lab models, is noteworthy.

Commendations are in order for the hospital laboratory administrators and pathologists participating in both regional lab organizations. They've proved willing to move beyond the issues of control and mistrust which frequently prevent hospital lab leaders in other cities from moving discussions about regional laboratory networks into operational reality, even after years of meetings. MCL and JVHL provide persuasive evidence that collaboration among competing hospital laboratories can benefit patient care—the primary goal of laboratory medicine—while returning important financial benefits to the participating hospitals.

As clients and long-time readers of THE DARK REPORT know, hospital laboratories in Michigan have used JVHL to become the dominant provider of physicians' office testing throughout Detroit and other cities in the state. Their willingness to collaborate is helping them roll back the inroads made by national laboratory competitors. I believe MCL reinforces the strategic market position of its participating laboratories in a similar way.

Both of Michigan's collaborative regional lab organizations provide hospital labs in every part of the country with an undeniable reminder that local lab testing services, delivered professionally to physicians' offices, are the match for any national lab competitor. TDR

Hospitals in Michigan Build Unique Shared Lab

Use of "co-tenancy" business model benefits participating hospital owners

BY JUNE SMART, PH.D.

CEO SUMMARY: This operational model for a collaborative regional laboratory organization makes "profit" irrelevant. Serving 30 hospitals in four midwestern states, Michigan Co-Tenancy Laboratories is consistently expanding lab testing services, lowering costs, and emphasizing the laboratory's contribution to better patient care in participating hospitals.

WORKING QUIETLY and without much fanfare during the last 17 years, a group of hospitals in Michigan created the nation's most unique collaborative regional laboratory organization.

No, it's not **Joint Venture Hospital Laboratories** (JVHL), the thriving and well-known regional laboratory network based in Detroit. It's **Michigan Co-Tenancy Laboratories (**MCL—which operates in parallel with **Warde Medical Laboratories**), based in Ann Arbor, Michigan, only 45 miles from Detroit. MCL is owned by 17 hospitals and involves 30 hospital laboratories.

Three noteworthy attributes mark this collaborative regional lab venture. First, it delivers sustained yearly reductions in laboratory testing costs. Second, it provides participating hospitals with an enriched menu of reference and esoteric testing, accompanied by high quality and fast turnaround times. Third, it operates as a "co-tenancy" and is believed to be one of only three co-tenancy laboratories in the United States.

This successful co-tenancy laboratory is posting impressive numbers. It performed more than 1 million esoteric tests for fiscal 2002. In the past five years, MCL reduced its cost-per-RVU (Relative Value Unit) by 21.7%, declining from $7.47 in 1997 to $5.85 in June 2002.

What is particularly intriguing about the Michigan Co-Tenancy Lab story is that, despite its successes, it has escaped the notice of other hospital laboratorians seeking to create collaborative regional lab networks.

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

That surprises two MCL executives who believe this business model is well-suited for hospital labs wanting to develop collaborative testing operations within a region. Paul N. Valenstein, M.D., Chief Operating Officer and Dennis R. Hodges, Manager of Business Development, are both convinced that co-tenancy is an ideal business model that can be easily replicated by hospitals throughout the United States.

"Co-tenancy, in which owners share assets as tenants-in-common, is a longstanding business concept," explained Hodges. "There are plenty of examples outside the healthcare industry, such as laundry services firms owned and operated by competing hotels. The premise is that you are willing to cooperate with your competitors to achieve a common goal.

"MCL evolved out of Warde Medical Laboratories to meet the changing needs of the hospitals it served," noted Hodges. "It was David Keren, M.D., Warde's medical director, who recognized that Warde had only begun to tap the regional demand for specialized testing services. Many hospitals did not want to completely outsource a service as critical as laboratory testing. Co-tenancy was a solution that allowed these hospitals to achieve economies of scale while maintaining control of their laboratory operations."

Reduce Lab Testing Costs

"The original intent of Warde Medical Laboratory was to consolidate esoteric testing to lower the cost to hospitals in one healthcare system," continued Dr. Valenstein. "Pathologists held a one-third share of the partnership. **Mercy Health System** owned the remaining two-thirds. Not all Mercy hospitals were part of the original partnership. Of the participating hospitals, some used Warde Medical Labs as their primary reference lab. Others used it for just a portion of their send-out testing.

"Because we offered a high level of service and good turnaround time as a local lab provider, we were competitive with the national reference labs," he said. "Growth was steady from our founding in 1985 through 1997. In that year WML's partners decided to recast laboratory operations as a co-tenancy.

Changing Healthcare Market

"Participating hospitals, responding to a changing healthcare market in Michigan in the 1990s, wanted to refocus laboratory services," stated Hodges. "They recognized that, despite the substantial economic benefits that WML was delivering, there was yet more unrealized opportunity for savings.

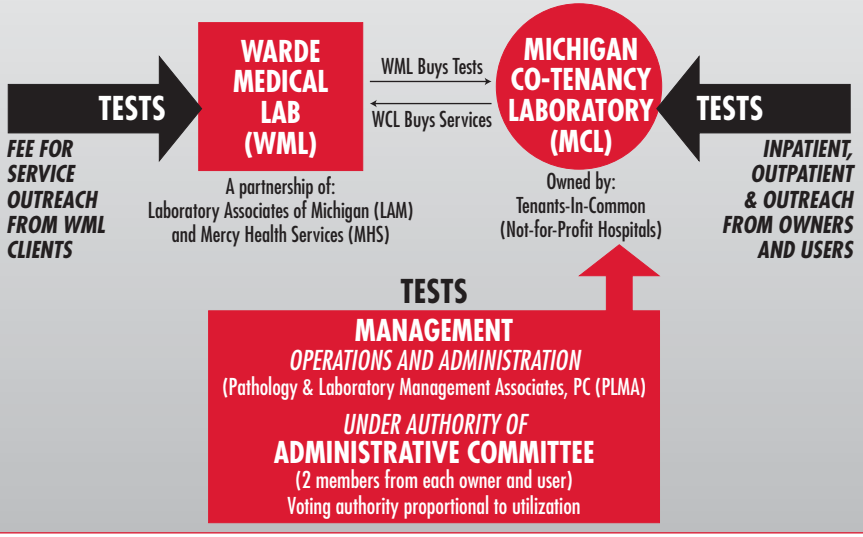
"Hospital CEOs asked our pathologists a fundamental question. 'WML still has excess lab capacity despite our past growth. Doesn't that excess capacity mean that our hospitals are not realizing *all the benefits* of higher productivity and lower costs that would come from a fully-utilized laboratory?'," recalled Hodges.

This question launched an intense period of study and strategic planning in the mid-1990s. During the evaluation process, pathologists from all Mercy Hospitals in Michigan met and considered a variety of options. The strategic decision was to create a regional "superlab" that would operate in support of original owner hospitals' laboratories and would also allow new owners to use the facility on an equal footing. The assets of Warde Medical Laboratory were transferred to the four Mercy owner hospitals and operated under a co-tenancy arrangement.

"Thus was born Michigan Co-Tenancy Laboratories," stated Dr. Valenstein. "Because only non-profit entities can participate in our co-tenancy agreement, only hospitals would hold equity. New hospital owners have joined the shared lab operation since

Michigan Co-Tenancy Laboratories

Using the co-tenancy model, hospitals in Michigan created a regional "superlab" that delivers a broader test menu at lower costs to participating hospitals. As a shared-testing vehicle, co-tenancy is working well and provides positive incentives for participating hospitals to increase the number of specimens referred to the central lab. Warde Medical Laboratories buys testing from the co-tenancy laboratory and provides a variety of services under contract to Michigan Co-Tenancy Laboratories.



its inception. However, the Warde Medical Laboratory partnership still exists. Warde leases excess capacity from the owners of the co-tenancy and sells it to smaller hospitals that are not yet ready to become co-tenants."

CEOs of the participating hospitals were not put off by the fact that a co-tenancy laboratory was an "untried" concept. "This was not a lab organized to generate profits," declared Dr. Valenstein. "It was organized to serve the hospitals' mission to provide quality care to hospital inpatients and outpatients."

To meet this objective, the hospital CEOs wanted an operational form that encouraged hospitals to feed specimens into the regional "superlab." This growing specimen volume would generate lower overall lab testing costs while supporting a steady expansion in the menu of tests done locally.

"Co-tenancy allows the owners, all of which are not-for-profit health systems or hospitals, to share a cost center in common," continued Dr. Valenstein. "What the hospital owners choose to charge their customers for the lab testing services is beyond the scope of the co-tenancy. Our job is to run the shared lab operation with high quality and efficiency."

"This is an important concept," emphasized Hodges. "Michigan has a law called the *Laboratory Purveyor's Act* that forbids a provider, including a laboratory, to mark up the price of a test performed by another laboratory. However, under the co-tenancy agreement, all participating hospitals are owners of the shared lab operation. Because testing done in the central reference lab is an intrinsic part of a hospital's own operation, it can price tests based on its own business economics.

This feature preserves competition between participating hospitals."

In the MCL model, each co-tenant owns an undivided interest in the assets formerly held by WML. There is a minimum capital contribution of $50,000 to secure an ownership position. This is placed in the shared asset pool.

"Testing on behalf of each co-tenant occurs on what is legally considered to be that co-tenant's share of the equipment, using its share of the reagents and its designated share of the staff. Both the marketing and the billing for such testing is the responsibility of the co-tenants under their own names," said Hodges.

"All shared assets are carried on the books of the participating hospitals," observed Dr. Valenstein. "MCL is an agreement, not a corporation. Therefore it has no 'corporate books.'

Shared Assets

"Each MCL co-tenant lists its ownership interest in the shared assets on its books as a single line item designated 'Investment in Michigan Co-Tenancy Laboratory'," he continued. "The initial capital contribution is deposited in a tax-exempt checking account and the co-tenants receive interest on the assets they've contributed to the shared lab operation, in the form of a credit subtracted from their cost allocation.

"This credit represents the opportunity cost of each hospital's capital contribution and equitably recognizes those hospital-owners that contributed larger amounts of capital. The co-tenancy checking account is used to pay for approved capital purchases, supplies, and external reference lab services. Payments from from co-tenants are deposited into this account."

The governing body of MCL is the Administrative Committee. It meets quarterly and is chaired by the COO, Dr. Valenstein. Each co-tenant has two representatives on the committee. The Administrative Committee oversees the shared operation.

New owners are admitted following the approval of existing co-tenants. "To date, no interested hospital has been refused entry into the co-tenancy," noted Hodges. "We cover Michigan, Northern Ohio, Northern Indiana, and we even have one owner in Des Moines, Iowa."

Owners have complete autonomy in how they make use of the shared lab facility. Some send a higher proportion of tests than others. All owner-hospitals continue to operate their own on-site laboratories. MCL offers its own-

Simple Formula Used For Sharing Test Costs

COST ALLOCATION FOR EACH OWNER is straightforward. Each test performed in the co-tenancy lab is assigned an RVU (Relative Value Unit) based upon in-house micro-costing principles. Interim payments are made by each owner on a monthly basis, based on the volume and types of tests the owner has sent. At the end of each quarter, the total cost of the shared lab operation is divided by the total RVUs in that quarter to arrive at a cost per RVU.

Each individual co-tenant's total RVUs for the quarter are calculated and multiplied by the cost per RVU. The resulting number is a particular hospital-owner's allocated cost of testing. A rebate is sent to the co-tenant for the difference between the amount of the owner's interim payment and their actual allocated cost for the quarter."

What happens when a new test needs to be added to the menu? Dr. Valenstein responded. "Keep in mind that the co-tenancy makes no profit. The test is assigned an RVU based on its complexity. The test is not brought in-house unless the RVU is equal to, or less, than the cost to send the test to an outside reference lab. Our volume of esoteric testing is so high that most of the tests we can bring into the shared lab operation have already been moved in-house."

ers a full menu of reference and esoteric testing. This menu also includes some routine assays because several hospital owners want to use the shared lab facility to lower costs for more commonly-performed tests.

There is no predetermined or expected test mix for participating hospitals. However, each hospital is expected to send at least $50,000 worth of testing to the shared lab facility each quarter.

"What makes MCL work is the collaborative attitude among the hospital owners," said Dr. Valenstein. "This type of operation requires a high level of trust, because some owners compete with other owners. Operations are conducted openly and the finances are laid bare every quarter for all to see. As a result, our co-tenancy laboratory is delivering substantial benefits to our hospital owners."

United In Common Purpose

Michigan Co-Tenancy Laboratory is a remarkable example of a collaborative regional laboratory organization. It demonstrates what motivated hospital CEOs, laboratory administrators, and pathologists can create when united in common purpose.

However, THE DARK REPORT believes the most notable aspect about MCL may be how the participating hospital CEOs created a subtle and sophisticated laboratory testing tool to support their institutions. By its very design, it encourages participating (and often competing) hospitals to willingly feed larger numbers of specimens to the regional core laboratory as a way of expanding the local test menu and lowering overall laboratory costs.

The contribution made by pathologists and lab administrators in these hospitals should also not be overlooked. They supported the co-tenancy operational model. The creativity of this group and its willingness to strike into unknown territory must be recognized. Most laboratorians would consider it unnecessarily risky to be first in the United States to build a sizeable laboratory around the co-tenancy organizational model. The willingness of these Michigan hospitals CEOs and their laboratory leadership to pioneer this concept is commendable

Sophisticated Strategy

The Michigan Co-Tenancy Laboratory is also an example of a very sophisticated business strategy. It is not organized to generate and distribute profits from the sale of laboratory tests. Nor does it hold assets which can grow in value as the lab test volume increases. To the contrary, MCL neither reports profits nor holds assets. It is organized for the exclusive purpose of enhancing the laboratory testing services each hospital owner provides to its inpatients and outpatients. MCL is an organizational tool that generates higher productivity, a broader test menu, and lower costs for its hospital owners.

Since its founding in 1997, Michigan Co-Tenancy Laboratories has delivered measurable value to participating hospitals. There is ongoing growth in its test volume and test menu. MCL is demonstrating that the concept of co-tenancy is a viable operational model for developing collaborative regional laboratory organizations.

More Hospitals Want In

The merits of this co-tenancy laboratory model continue to attract hospitals. "Currently we have seven new owners reviewing paperwork," stated Hodges. "Four currently buy some testing from WML, but Warde is not their primary reference lab. Our last owner was added in July. We expect to add more new owners soon!" TDR

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MT/MLT Training Insights From Calif. University

MT training programs require additional resources to coordinate career placement

CEO SUMMARY: Laboratory administrators from 15 San Francisco Bay Area hospitals recently approached their CEOs and requested a five-year funding commitment of $1.5 million to train and expand the supply of CLSs and MTs. One key element in this effort was the enthusiastic support of those local colleges and universities willing to restart dormant laboratory training programs.

Part Two of a Series

EDITOR'S NOTE: Part One of this series discussed the strategies and actions taken by 15 hospital laboratory administrators in the San Francisco Bay area to convince their CEOs to fund $1.5 million over five years to train clinical laboratory scientists and medical laboratory technicians. Part Two looks at CLS and MLT training from the perspective of a university offering such training programs.

WHEN HOSPITAL LAB DIRECTORS in the San Francisco Bay Area squared off to address the growing shortage of trained technical staff in their region, two-year and four-year colleges and universities were essential partners in the resulting plan.

The objective was to expand the number of clinical laboratory scientists (CLS) and medical laboratory technicians (MLT) in the southern area of San Francisco Bay. Following less than one year of planning and study, 15 hospital CEOs agreed to provide $1.5 million over five years to fund recruitment and training of CLS and MLT personnel. *(See TDR, October 6, 2002.)*

"We were involved from the very beginning," said Sally Veregge, Ph.D, Chairman, Department of Biological Sciences at **San Jose State University** (SJSU) in San Jose, California. "We were enthusiastic about the opportunity to restart the CLS training program at SJSU. It had been shut down during the state's budget crunch in 1992.

Cost Of Training Med Techs

"This type of training program is expensive because it requires lots of support," she added. "Budgets for a CLS training program cover a lot more than just classroom instruction.

"There are additional expenses in the classroom because expensive supplies and equipment are needed. The student/faculty ratio is low, raising the cost to educate a student. Government requirements add to the cost. The program also needs a coordinator. This individual handles recruitment of students, arranges their placement in hospital labs,

works with government regulatory agencies, and coordinates all this with the colleges and universities," said Veregge.

"For us to restart our med tech program, we needed at least a five-year funding commitment to cover these costs," she continued. "During this time, SJSU will be working to line up other funding sources to cover this training on an ongoing basis."

"Although we stopped our CLS training program in 1992, SJSU has always offered the pre-requisite classes," observed Veregge. "So we have an untapped pool of B.S. graduates with those classes from which we can

Two-year colleges were also part of this project. "MLT training will be done at **Hartnell College** in Salinas and **De Anza College** in Cuppertino," explained Veregge. "Discussions were required to coordinate MLT training programs so that graduates could move on to SJSU and obtain CLS certification. We wanted to create a career ladder for individuals interested in the clinical laboratory."

Lots Of Student Interest

Student interest was immediate. "The hospital CEOs approved funding for med tech training in June. When our fall term started in late August, four students were enrolled here at SJSU," noted Veregge. "We already have nine applicants for the winter term and interest in Fall 2002 is growing."

Efforts to reactivate CLS training at SJSU revealed an unappreciated asset. "Although we stopped our CLS training program in 1992, SJSU has always offered the pre-requisite classes," observed Veregge. "So we have an untapped pool of B.S. graduates with those classes from which we can recruit. As our program director contacts these people, she is getting very favorable responses."

In fact, overall interest in CLS training at SJSU has been high. "This is true particularly of students in biosciences," Veregge noted. "We also see people in the workforce who want to come back and get their CLS certification. That may be due to the weak economy here in Silicon Valley."

Hospital CEO's Decision

Veregge was quick to point out that it took considerable work to convince the 15 hospital CEOs that investing $1.5 million over five years to train CLS and MT personnel was justified. "There was a team of hospital lab managers and administrators who crunched numbers and did a detailed analysis of how much money the hospitals were already spending because of unfilled CLS and MLT positions in their laboratories," explained Veregge.

"These numbers were compelling and the hospital CEOs could not ignore them," she added. "Executive Vice President Barbara Harrelson at the **Hospital Council of Northern and Central California** and the community college administrators also played key roles in these presentations."

This successful project to fund and expand med tech training in the south San Francisco Bay area can be copied by hospital lab administrators and pathologists in other regions. One critical success factor is to involve educators at local colleges and universities early in the process.

The rapid and significant response by students at SJSU to recruiting efforts for its CLS training program also confirms that a proactive marketing program touting the benefits of a career in the clinical laboratory does attract students. **TDR**

Contact Sally Veregge, Ph.D. at 408-924-4880.

"Dade Behring is the largest company in the world focused exclusively on clinical labs and diagnostics."
—James Reid-Anderson, M.D.

NEWSMAKER INTERVIEW

Major Changes at Dade Behring Soon to Be Visible In Lab Market

Its recent financial restructuring now complete, Dade Behring prepares a "brand building" campaign

CEO SUMMARY: Dade Behring is poised to become a tough and high-profile competitor in the laboratory diagnostics marketplace. Earlier this month, it finalized a major financial restructuring. Following two years of negotiations with its banks and bondholders, Dade filed a "pre-packaged" Chapter 11 bankruptcy in August. The goal was to swap $700 million of debt into equity, preserve valuable tax benefits, and, through the Chapter 11 filing, emerge, upon discharge, with publicly-tradable stock (without the need for a public offering). *(See TDR, August 5, 2002.)* That goal was met on October 3 when the judge discharged Dade's Chapter 11 filing. From this date forward, hospital lab administrators and pathologists will see a different Dade Behring. To understand these changes, **THE DARK REPORT** recently traveled to Dade Behring's headquarters in Deerfield, Illinois to meet with President and CEO Jim Reid-Anderson. This interview was conducted by Editor-in-Chief Robert L. Michel.

EDITOR: This interview is timely for an important reason. Last month **Dade Behring, Inc.** completed a major financial restructuring. Armed with a strong balance sheet, Dade Behring now has plenty of financial strength to intensify both research and sales and marketing. What's going to be different about the newly-energized Dade Behring?

REID-ANDERSON: We think the main difference is that Dade Behring now has the opportunity to develop its brand of clinical diagnostics. Our emphasis will be to expand the impact of our brand to the benefit of our laboratory customers.

EDITOR: Dade Behring is already a recognized company throughout the lab industry. More specifically, what do you mean by "develop its brand of clinical diagnostics?"

REID-ANDERSON: In strategic terms, "brand" implies the attributes of a company and its products. For example, say "Rolls Royce" and people immediately understand the attributes of this brand, which involves high quality. Another brand with different attributes might be "McDonalds," known for a predictable quality of food anywhere in the world, speedily served in clean surroundings. Dade Behring has its unique attributes. In this context, promoting the brand helps the lab industry better understand Dade Behring and the value it represents.

EDITOR: Okay, let's get more specific. If I say "Dade Behring," what attributes do you want to come to mind?

REID-ANDERSON: As a starting place, we'd like to be recognized as the largest company in the world solely devoted to clinical laboratory services and diagnostics. Other large competitors have extensive business operations in pharmaceuticals and bio-research. We believe our single-minded dedication to serving the needs of clinical laboratories is a major point of differentiation.

EDITOR: That certainly is a unique attribute. What other elements will you emphasize as part of the Dade Behring brand?

REID-ANDERSON: Within our company over the past two years, we've used the term "customer excellence" to describe the attributes that differentiate us from our competitors. One key strategy is to become known as a source of the "total lowest cost solution" for laboratories.

EDITOR: How will Dade develop that as a point of differentiation?

REID-ANDERSON: To meet our objective as the "total lowest cost solution," we are designing instrument systems that provide additional benefits beyond quality of test result, throughput, competitive cost per test and the like. We're engineering our systems to better support the evolving new models of clinical laboratory operations. So not only are we designing our instruments to maximize their effectiveness at performing assays while reducing costs, but we want them to reduce the management complexity of the lab itself.

EDITOR: Meaning that you want your instruments to become tools for enabling work flow process redesign, for example.

REID-ANDERSON: Conceptually, that's correct. Our design teams are looking at the laboratory as an organic whole. Part of our design criteria now includes the impact certain designs can have in helping a laboratory manage workflow in the simplest way possible to support high quality, high productivity and the total lowest cost solution.

EDITOR: Let me stray from the subject of branding for a moment. You've just described a different design approach for diagnostic instruments, one that goes beyond traditional features of accuracy, volume, and consumables priced according to volume. What other elements are changing the way you design instruments for the next generation of laboratories?

REID-ANDERSON: Good question! We are furiously engineering a higher level of informatics capability into our instrument systems. Our instruments will be Internet-capable. Our guiding design goal is to help our lab customers eliminate paper and further reduce both the cost and complexity of managing their laboratory.

EDITOR: Do you believe you have a functionality in this area that differentiates you from other manufacturers?

REID-ANDERSON: Yes, because our development efforts are conducted under a program we call "CCPD." CCPD stands for "customer-centered product development." For the past two years, we've had customer teams helping us develop our next generation of

NEWSMAKER INTERVIEW

instrument systems. These teams include both Dade Behring customers and customers using only our competitors' products.

EDITOR: Since we are speaking about "next generation" diagnostics, I'd like to ask which key healthcare trends you believe will have the greatest impact on clinical laboratories in the next few years.

REID-ANDERSON: That's easy. I believe that the healthcare industry as a whole—and the clinical laboratory industry—will be most influenced by two fundamental trends. First is the inadequate supply of trained medical professionals. Second is a sustained pressure to drive down costs.

EDITOR: It's interesting that you emphasize two rather broad trends as the primary drivers of change in healthcare in coming years.

REID-ANDERSON: Put the two side-by-side. If there is an inadequate supply of technically-trained medical professionals, it doesn't matter what type of advanced medical technology is available. Healthcare is a people-based service. Acute shortages of technically-trained medical professionals affects the ability of consumers to access care.

EDITOR: We see the effect of that shortage in certain regions around the country. Without adequate MT and MLT staffing, labs in some cities are forced to send out substantial volumes of testing. That affects both cost and turnaround time.

REID-ANDERSON: Definitely we will see more of that type of situation. On the cost side, all demographic trends point to an ever-higher demand for healthcare and the inability of governments, employers, and patients to pay for it. There will be intense pressure to eliminate unnecessary costs in every segment of the healthcare system. Laboratories, with their high labor component, are one of the first healthcare sectors to directly feel this pressure to reduce costs.

EDITOR: From my perspective, the wholesale consolidation of independent commercial laboratories in the early 1990s, followed by similar consolidation in hospital laboratories during the second half of the 1990s, is an example of cost-cutting. Declining reimbursement forced lab directors to eliminate costs. Reducing laboratory staff by consolidating specimen volume was an obvious way to do that.

REID-ANDERSON: Take that example one step further. In today's laboratory marketplace, widespread consolidation is a fact. How do laboratory administrators and pathologists achieve the next round of significant cost reductions, while still maintaining high quality and a full menu of testing?

EDITOR: Is the answer to your question found in your earlier statement? You mentioned that Dade Behring wants to engineer instruments which not only improve the quality and integrity of testing, but can also be used as tools that help lab administrators reduce management complexity in clinical laboratories.

REID-ANDERSON: Yes! We recognize a move within healthcare to adopt the quality management systems and methods which other industries have used so successfully to reduce costs while improving product quality. Laboratories, with their daily high throughput of specimens, are one of the first areas of healthcare to pull in this management philosophy and put it to work.

EDITOR: THE DARK REPORT has published many stories about the growing number of laboratories which have been first to implement quality systems like ISO-9000, Six Sigma, and Lean.

REID-ANDERSON: Among our lab customers, we see a growing interest in learning more about these management and quality systems and how to use them. In response to this demand, we established a management consulting resource to provide our customers with more sophisticated techniques they can use to deploy resources in their laboratory.

EDITOR: This ties in with the engineering philosophy of designing diagnostic instruments which, by their form and function, enable lab directors to simplify work processes by using ISO-9000 and Six Sigma principles. Is that right?

Among our lab customers, we see a growing interest in learning more about these management and quality systems and how to use them.

REID-ANDERSON: Yes.

EDITOR: To bring us back on topic, cost-cutting pressures in healthcare are causing clinical laboratories to change many long-standing management philosophies. Outside the United States, what other signs tell you that cost control is intensifying?

REID-ANDERSON: Internationally, you see it in Europe. Germany is using DRGs (diagnostic related groups) to control costs. The approach in France is to base reimbursement on cost. Most European countries have an aging population, just like Canada and the United States.

EDITOR: What role do you see for government in influencing the direction of healthcare in the United States?

REID-ANDERSON: My sense is that the government will be more involved in policy matters than specific reimbursement issues. It doesn't seem like Congress is inclined to take actions that might trigger "radical change."

EDITOR: Are you saying that we are unlikely to see politicians take a strong hand in recasting the American healthcare system?

REID-ANDERSON: In recent years that has certainly been true. Congress has struggled to enact legislation which addresses such issues as rising drug costs, growing numbers of uninsured, and obvious, common-sense reforms to the Medicare and Medicaid program. It is unlikely that our government institutions will initiate changes considered bold and daring. Within the United States, those types of initiatives will probably come from employers. As their healthcare costs increase, they will be willing to experiment with new models for the delivery of healthcare to their employees.

EDITOR: Let's move our discussion from influences shaping the overall healthcare system down to a specific look at the clinical laboratory industry. Given your belief that a shortage of technical staff and cost-pressures will be primary drivers of change, what will these trends do to clinical laboratories as we know them today?

REID-ANDERSON: We've already discussed how lab directors will be adopting more sophisticated management methods to drive down costs while sustaining high quality lab services. That certainly changes the way labs buy diagnostic instruments and deploy them in the laboratory.

EDITOR: Keeping in that theme, let's look at diagnostic technology. Genomics and proteomics certainly have attracted most of the attention. What is Dade Behring's take on technology trends?

REID-ANDERSON: One major emphasis will be a demand by clinicians

and patients for increased accuracy from lab testing.

EDITOR: That's a fascinating insight. Are you referring to a growing awareness by consumers that lab tests are generally less accurate in the real world than consumers have traditionally believed?

REID-ANDERSON: It's not that tests have been inaccurate. A high level of accuracy already exists. There simply is a need to raise the standards to even higher levels of accuracy.

EDITOR: I can offer conventional Pap smear testing as an example of a shift in consumer perceptions. The direct-to-consumer advertising done by **Cytyc Corporation** educated consumers to the flaws of the conventional Pap smear and offered ThinPrep® as a "better" Pap test. That's certainly been a factor in demand for this test.

REID-ANDERSON: It illustrates the trend that labs will need to deliver a higher level of accuracy to meet the changing needs of clinicians and consumers.

EDITOR: What is Dade Behring's strategy to respond to this trend?

REID-ANDERSON: First, let me say this about "accuracy." As our industry makes diagnostic tests which are more accurate, two benefits result. First, the quality per episode of care improves. A more accurate test result allows the physicians to practice a better quality of medicine. Second, a more accurate test cuts costs because it eliminates the need for additional testing and the costs related to an imprecise diagnosis.

EDITOR: Both benefits are appropriate responses to the pressure for better quality at lower cost.

REID-ANDERSON: Yes. In responding to the demand for improved accuracy, we have technology which allows us to move test accuracy to higher levels with each generation of products.

EDITOR: Please explain.

REID-ANDERSON: A good example is an instrument system we call Epsilon. It's being engineered to meet lab needs in four ways. First, it will offer the "total lowest cost solution" that we discussed earlier. Second, it will combine routine chemistry, immunoassays, and nephelometry in one system. Third, because space is a premium in most labs, it will occupy a footprint that's half of the products offered by competitors. Fourth, the assays run on this instrument will be noticeably more sensitive. The technology to accomplish this came through our acquisition of Behring.

EDITOR: You indicate that there is core technology within Dade Behring that you expect to generate successive generations of more precise diagnostic assays.

...laboratories will need to deliver a higher level of accuracy to meet the changing needs of clinicians.

REID-ANDERSON: That's right. We are focusing these technologies on applications for the central laboratory. We want to help that customer move to higher levels of diagnostic performance.

EDITOR: Is there a core competence at Dade which strategically underpins your market directions?

REID-ANDERSON: Currently we are the number one company in protein testing in the world today. We believe it opens the door for us to be a major player in proteomics. But that will take at least ten years to occur.

EDITOR: Explain your proteomics strategy, please.

REID-ANDERSON: We have a protein-based technology called "LOCI."

We consider proteomics to be at a "cradle" stage and we have the cradle. As research labs identify new proteins, we expect LOCI technology will enable us to adopt that research into assays for use in clinical laboratories. It's a convergence strategy that will marry our LOCI technology with new proteomic assays.

EDITOR: These are certainly ambitious business plans. Could you talk about how Dade's financial restructuring impacts the implementation of your business strategies?

REID-ANDERSON: Dade now has a strong balance sheet to go along with the strong revenue growth we've posted in the past two years. This allows us to boost the money we spend on research and development. For example, three years ago we spent 6% on R&D. This year it is 9% and it will continue at that level.

EDITOR: Other examples?

REID-ANDERSON: We are investing substantially in our people. It is one place we can differentiate ourselves. Remember the strategy of the Dade Behring brand? We want to be known as an organization where the people and the products contribute equally to bringing our customers the "total lowest cost solution."

EDITOR: With your emphasis on quality of people and quality of products, I'd like to ask about Dade's relationship with the **Food and Drug Administration** (FDA). That's been a hot issue in the diagnostics industry.

REID-ANDERSON: Quality costs—and we are spending to achieve quality. Our lab customers understand how much quality costs within their own lab. I'd like our customers to know this. We invest the necessary resources to insure a high level of quality with our products and services. To insure our compliance with FDA good manufacturing practices, we have internal teams that do "surprise audits" at our plants using FDA rules. Because of this and other investments in quality, field corrections within our company are down one-third in the past two years. This type of activity to boost quality costs a lot of money. Our clients will never see much of this because it goes unnoticed for all the right reasons.

EDITOR: Those are interesting insights into Dade's corporate culture. Jim, we've covered quite a few subjects during this conversation. Is there anything you'd like to add about the Dade Behring story and why it will be a different company following its financial restructuring?

REID-ANDERSON: There is one additional point I'd like to communicate. For me, this entire restructuring process was amazing in unexpected ways. For the past two years, Dade's employees and customers responded to the circumstances with unwavering support. During the entire process, we've had the full understanding and confidence of everyone—vendors, employees, and customers. These relationships confirm that Dade Behring has solid roots in the marketplace. I'd like to thank everyone for their patience and support.

EDITOR: Not every company enjoys such loyalty. That is a good starting place to build the Dade Behring brand.

REID-ANDERSON: Yes. Thanks for the opportunity to talk about the changes and business strategies unfolding within Dade Behring. We are excited about the opportunity to do more in the marketplace. TDR

Contact James Reid-Anderson at 847-267-5300.

Lab Industry Briefs

HCA WANTS TO BUY HEALTH MIDWEST FOR $1.25 BILLION

FOR-PROFIT HOSPITAL BEHEMOTH **HCA Inc.** announced an agreement in principal to acquire **Health Midwest**, a 14-hospital system based in Kansas City, Missouri.

Subject to further negotiations and due diligence, HCA will pay an estimated $1.25 billion for Health Midwest. HCA also committed to a five-year capital investment program totaling $450 million. Health Midwest is a not-for-profit system. The deal must clear regulatory review and Missouri law requires that most of the sale proceeds be placed in a charitable foundation.

Both HCA and **Tenet Healthcare Corporation** were asked to bid. Health Midwest has struggled financially in recent years. It is the largest health system in Kansas City. This acquisition marks the return of HCA as a market consolidator. It currently operates 181 hospitals throughout the United States.

Times are good at HCA. For third quarter, it reported revenue growth of 11%, to $4.9 billion, compared to $4.4 billion during third quarter 2001. It said that same-facility revenues increased 12.2% during third quarter. Same facility admissions grew 3.4% for the quarter.

REVENUES AND PROFITS UP AT TENET HEALTHCARE

IT MAY HAVE LOST in the bidding process to acquire Health Midwest, but **Tenet Healthcare Corporation** continues on a financial roll.

Tenet reported third quarter revenues of $3.7 billion, an increase of 12.3% over third quarter 2001. The company also noted that it was the eleventh consecutive quarter where earnings growth exceeded 20%.

Like HCA, Tenet is seeing a increased demand for services. Its hospitals reported a 4.1% increase in admissions overall and a same-facility increase in admissions of 1.8%.

Of particularly interest to hospital laboratorians and pathologists, Tenet reports a shift toward higher acuity cases. It noted that same-facility patient addmission for sub-acute services declined 4.2%. Tenet is deliberately shifting its medical service emphasis toward high acuity services like cardiology, orthopedics, and neurology.

SPECIALTY LABS ISSUES REPORT ON THIRD QUARTER FINANCIAL PERFORMANCE

THINGS APPEAR TO BE QUIETING DOWN at Specialty Laboratories. The company's third quarter financials were in line with expectations.

Its revenues were $32.5 million, a decline of 28% from $42.8 million in third quarter 2001. It reported a net loss of $3.3 million, compared to its net income of $2.9 million in third quarter 2001.

The declines in revenue were mirrored by a drop in specimen volume. Specialty accessioned 685,000 specimens for the quarter. This was a drop of 13% from third quarter 2001 and a drop of 7% from first quarter, 2002.

Specialty attributes its revenue and specimen volume declines to "client uncertainty generated by the recently-concluded regulatory compliance issues." It acknowledges that it is "now fully engaged in the effort to rebuild relationships with hospital clients and expand its customer base." TDR

Disease Management Relies On Lab Testing

Early successes with disease management programs require regular laboratory testing

CEO SUMMARY: Predictions are that 30% of large corporations will offer disease management programs for their employees by the end of next year. Disease management seems to be the next form of managed care, where prevention and early detection are the primary goals. Laboratories should be alert for opportunities to add value to these programs.

IF THE 1990S WAS the "managed care" decade, then the 2000s may turn out to be the "disease management" decade.

The use of disease management programs is growing steadily among both employers and payers. Early efforts report worthwhile gains in healthcare outcomes, particularly when measured against the cost of the disease management program.

Hewitt Associates, a human resource consulting firm, reports that the number of large corporations offering disease management programs doubled since 1997, increasing from 9.5% in 1997 to over 19% in 2002. It predicts that as many as 30% of large corporations will have disease management programs in place by the end of next year.

"Growth of these programs has been exponential in the last two years," observed Bruce Kelly, Senior Consultant of **Watson Wyatt Worldwide**, another large human resource consulting firm. All the major health insurers are ramping up disease programs in response to interest by employers. One disease management company, **Cor-Solutions Medical, Inc.** of Buffalo Grove, Illinois, reports that, this year, programs it manages for large insurers have 300,000 patients enrolled. This is up from only 12,000 enrolled patients five years ago.

Significant Opportunity

Use of disease management programs on a wide scale is a recent development, so most providers, including local laboratories, have felt little impact. THE DARK REPORT predicts that disease management programs represent a significant opportunity for clinical laboratories. Because these programs heavily emphasize preventive medicine, diagnostic testing usually plays an integral role as physicians use lab tests for screening, diagnosis, and patient-monitoring.

Expect the widespread use of disease management programs to create a new class of customer for clinical laboratories. The needs of this new lab cus-

tomer will be different. On one hand, physicians and program managers will require more comprehensive access to lab test data for patients enrolled in a disease management program.

On the other hand, patients—the primary customer—will be actively involved in their personal healthcare and will expect laboratories to provide them not just with lab test results, but also relevant information about lab testing that helps them better manage their health care. For many disease states, this will include patient self-testing.

Regardless of whether individual lab tests were done in a central lab, the physicians' office, or as a patient self-test, the disease management program will want that lab data integrated into a single patient record.

A properly run disease management program will require a seamless flow of information between physician, payer, employer, and patient. Because laboratory test data is the major component of the typical patient health file, there will be a strong demand for laboratories to have the informatics capability to serve the needs of these users in new ways.

More specifically, the goal of having all laboratory test data end up in the patient's primary medical record will require the integration of lab test data. Regardless of whether individual lab tests were done in a central lab, the physicians' office, or as a patient self-test, the disease management program will want that lab data integrated into a single patient record.

Within the lab industry, there will be innovative laboratories that recognize this need and invest the money necessary to develop a laboratory information system that provides these enhanced capabilities. By their design and goals, disease management programs should see clinical laboratories as natural allies. That's because lab testing is the most cost-effective way to detect most common diseases.

Benefits In Health And Cost

One existing disease management program demonstrates the benefits that can accrue. The city of Ashville, North Carolina, is enrolling employees with diabetes into a management program. Besides reducing the number (and cost) of frequent visits to physicians, patients in the program cost the city an average of $4,651 per year, versus $6,127 per year before this program was launched.

Results like these demonstrate that disease management programs can be an effective vehicle for improving the quality of care in a cost-effective manner. It should be no surprise that employers have begun to deploy these programs on a fast track. The return of double-digit increases in annual healthcare costs provides employers plenty of motivation and incentive to offer their employees and dependents a full menu of disease management programs.

Labs As Essential Partners

The trend toward implementation of disease management programs appears to be in full swing. Laboratories and pathology group practices should develop strategies for serving this new type of healthcare provider. The ability of laboratory medicine to offer preventive and predictive guidance to clinicians and their patients should position laboratories to be an essential partner in the care continuum. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

IBM continues to muscle its way into healthcare informatics using the concept of "grid computing." It's already working with the **University of Pennsylvania** to create a computer network and data repository that will store mammograms and allow a patient's past mammograms to be retrieved for study at any of several participating clinics. This month IBM announced a similar project with **Oxford University** and the United Kingdom. The goal is to create a network across six sites that will expedite studies of how location, diet, age, and other factors influence breast cancer and its treatment. These types of networks will be eventually used to access and study lab test data.

Corrections & Clarifications

In the October 6, 2002 issue of THE DARK REPORT, on page 17 under the subhead "Dwindling Path Influence," the first sentence starts out "the proposed merger between Quest Diagnostics and LabCorp." The sentence should properly say "the merger between Quest Diagnostics and Unilab."

NIH TO CREATE HUMAN PROTEOME DATABASE

With the basic human genome now mapped, attention is turning to the human proteome. In response to concerns that commercial restrictions on biological information are hampering research, the **National Institutes of Health** (NIH) announced this month that it would create the "United Protein Database," or UniProt. Modeled on existing DNA repositories, it will combine protein data currently held in three separate repositories.

ADD TO: Protein Database

The proteome repository was announced after a Swiss corporation announced it would charge researchers to access its protein data. The NIH effort is projected to take three years and will catalog two million proteins. Because proteomics are expected to yield a treasure trove of diagnostic and therapeutic uses, laboratories should closely follow this rapidly-advancing area of medicine.

FELON GIVES IT A TRY!

Here's a fascinating story for labs that perform drugs-of-abuse testing. The **Associated Press** reports that a federal prisoner in Massachusetts is challenging the accuracy of **PharmChem's** sweat patch, used by federal courts across the country to test for drugs of abuse. Henry Alfonso was on probation for charges related to his purchase of OxyContin from an undercover agent. He was recently returned to prison after his sweat patch tested positive for traces of cocaine. He claims that this latest positive test, along with the other five positive drug results he has had since April, were caused either by cocaine residue left in his apartment by the previous tenant (a known drug dealer) or by the cash his wife brings home from her job as a stripper. He filed a challenge to the sweat patch's accuracy in federal court. Pharmchem says it requires considerable quantities of a drug to penetrate the patch's membrane. Instead of challenging the accuracy of the test in court, Alfonso might be best advised to move to a new apartment next time he's out of jail!

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 18, 2002.

News About The Next War

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