

From the Desk of R. Lewis Dark...

THE **RD**ARK REPORT

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

R. Lewis Dark:

Feds Lift Ban on Doctor-Owned Specialty Hospitals.....Page 1

Sonic Healthcare & CPL

Make First Acquisition..... Page 2

Bio-Reference Labs Enters

DNA Sequencing Market..... Page 4

Pathologists Contribute

To Women's Hospital Success.....Page 6

McKinsey & Co. Predicts Most Hospitals

Must Specialize to Survive.....Page 9

Molecular Diagnostics:

Bio-Rad Buys CIPHERGEN'S

Proteomics Technology.....Page 16

Intelligence: Late-Breaking Lab News.....Page 18

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



Feds Lift Ban on Doctor-Owned Specialty Hospitals

MANY OF YOU KNOW THAT on August 8 the **Centers for Medicare and Medicaid Services (CMS)** announced that it would resume issuing certificates for specialty hospitals that are owned by physicians. The timing of this decision certainly plays into the predictions of **McKinsey & Co.** that you will read on pages 9-15 in this issue of **THE DARK REPORT**.

Healthcare strategists at McKinsey believe that the 20th century business model of the integrated, full-service hospital is rapidly becoming outmoded. Replacing it in the 21st century will be hospitals organized around a limited number of clinical specialties. These hospitals will have two other primary attributes. First, they will provide patients with an experience similar to that currently provided by leading retailers and hotels. Second, in order to achieve superior clinical outcomes, the new hospital business model will involve close collaboration with physicians, including joint ventures and other types of revenue-sharing arrangements. Certainly anything that radically changes today's hospital business model will also have a dramatic impact on hospital-based laboratory managers and anatomic pathology groups. That is why **THE DARK REPORT** is providing you with a close look at the strategic reasoning of McKinsey's experts in healthcare.

My contribution to the discussion is very basic. I believe that employers, Medicare, and Medicaid are now pushing hospitals, physicians, and other healthcare providers to do three basic things. First, to continuously improve the quality of care. Second, to measure clinical care and document the fact that they are actually achieving a higher quality of care. Third, to accomplish this while holding constant, or even reducing, the cost per healthcare encounter.

For my money, that sounds a lot like the best-performing specialty hospitals we already see operating today—most of which are owned by physicians. That is why specialty hospitals are already tough competitors for the slow-responding community hospitals in their cities. Patients want to avoid going “to the hospital.” When given a more pleasant alternative by their doctor—whom they trust—patients are rationally opting to have their procedure done in a specialty hospital, whenever feasible. Pathologists and lab managers should keep an eye on this trend and be ready to provide value-added services to their local specialty hospitals. After all, that's where growing numbers of patients are likely to be found.

Sonic Healthcare & CPL Make First Acquisition

*Clinical Path Labs of Austin, Texas buys
Cognoscenti Health Institute in Orlando*

CEO SUMMARY: *Expanding from its base in Texas, Clinical Pathology Laboratories, Inc. (CPL) has acquired Cognoscenti Health Institute, LLC of Orlando, Florida. The deal was done discreetly and gives Sonic Healthcare, Ltd., parent of CPL, a solid foothold in Florida. Cognoscenti has also made impressive progress on building an evidence-based medicine service menu, something that CPL can introduce in other markets.*

IT'S A LAB ACQUISITION that was quietly negotiated and closed before the news became public last Friday. **Cognoscenti Health Institute, LLC** of Orlando, Florida, has been acquired by **Clinical Pathology Laboratories, Inc. (CPL)** of Austin, Texas.

This transaction is notable because it is CPL's first acquisition since it became a business division of **Sonic Healthcare Ltd.** of Sydney, Australia, in a sale that closed last year. (*See TDR, September 12, 2005.*) For this reason, the choice of Cognoscenti as the first lab acquisition provides clues as to the business strategy that CPL/Sonic intends to pursue as it expands in the United States.

THE DARK REPORT believes two factors contributed to the choice of Cognoscenti as CPL/Sonic's first lab

acquisition. First, the Orlando location was attractive, for several reasons. Florida is a large market for laboratory services, which meets CPL's interest in growth potential. Orlando, because of Disneyworld and tourism, has an exceptional transportation network. That makes it easier for CPL to build a regional business centered around Cognoscenti's laboratory in Orlando.

Second, Cognoscenti Health Institute brings two business resources into the CPL/Sonic family. One resource is its founder, President Philip Chen, M.D., Ph.D., who started Cognoscenti from scratch in 2002. Chen, who definitely fits the role of pathologist-entrepreneur, built his lab company into a profitable enterprise, with revenues estimated to be just under \$10 million per year.

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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, \$13.65 per week elsewhere (billed semi-annually).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • © The Dark Group, Inc. 2006 • All Rights Reserved

There is another resource that makes Cognoscenti Health Institute distinctive and sets it apart from other independent commercial laboratory companies. Under Chen's leadership, Cognoscenti has actively supported evidence-based medicine initiatives in its service market. It is Chen's conviction that laboratories should take a more active role in helping physicians get the most out of the laboratory tests they order on behalf of their patients.

Sophisticated IT Systems

To enable this type of clinical support, Cognoscenti has developed an information technology arrangement that works on three levels. First, it has a traditional LIS (laboratory information system.) Then there is a "wrap-around" tool that connects data from the LIS to other software capabilities. This makes it possible to mine data in several intriguing and useful ways. Peripheral systems make up the other major part of Cognoscenti's informatics set-up. Included is Web-enabled electronic order entry and results reporting.

During a site visit to Cognoscenti's laboratory in 2005, THE DARK REPORT saw, first-hand, how this informatics capability allows Cognoscenti to support evidence-based medicine initiatives in the greater Orlando area. The system can look at medical claims data in the billing module. Using diagnosis codes to select certain patients, it can then pull up the lab test results associated with those CPT codes and produce disease-specific data and analysis of that data.

Using what it calls "Medical Logic Modules," Cognoscenti can remind physicians and patients when it is time to retest. These "interventions" can be cued either by dates or by changes in current test results for a specific patient. The system can also check patient compliance, a feature which is actively used in the business wellness programs that Cognoscenti supports.

Going one step further, Cognoscenti is sent data by several managed care plans and can add that data to the lab test information and provide detailed information about the status, individually to clinicians and collectively to the payers (and, in some cases, employers), of the patients participating in disease management and wellness programs. This includes a financial analysis of how improved patient outcomes are saving money, calculated from actual reductions in claims.

One early example of how Cognoscenti leveraged these services to expand its laboratory testing business was its participation in workforce wellness programs initiated by the **Polk County School District**. This diabetes-focused program resulted in an impressive reduction in healthcare claims of \$456 per person annually for the employer and was featured as a model case in the 2005 Quality Profiles published by NCQA

Chen presented on this topic at the *Executive War College* in Miami last May and the CPL/Sonic executives in the audience seem to have been impressed enough to launch the discussions that led to the acquisition of Cognoscenti just 16 weeks later.

Considerable List of Benefits

By acquiring Cognoscenti, CPL/Sonic has established a solid foothold in central Florida, added a visionary pathologist to its team, and gained access to a strategic added-value laboratory medicine service that can differentiate it from other lab competitors. That's a considerable list of benefits to accrue from acquiring a young laboratory with revenues less than \$10 million per year.

With this step, CPL has also served notice that Sonic Healthcare Ltd. is ready to expand its market share in the United States and has begun to spend money to make that happen.

Bio-Reference Enters DNA Sequencing Market

Surprise purchase of GeneDX bolsters molecular diagnostics at fast-growing firm

CEO SUMMARY: Bio-Reference Laboratories has just placed an unexpected bet on the wide-open opportunities in genetic testing. The acquisition of GeneDX brings it a respected team of geneticists, capabilities in full DNA sequencing, and a proven track record in testing for rare and complex hereditary diseases. It also opens a new lab testing market niche for Bio-Reference Laboratories to develop.

LAST TUESDAY, **Bio-Reference Laboratories, Inc.** (BRLI) surprised the laboratory industry with an announcement that it would pay up to \$17 million to acquire **GeneDX, Inc.** of Gaithersburg, Maryland. On the same day, BRLI also released its third quarter, fiscal year 2006 earnings report.

BRLI's acquisition of GeneDX caught financial analysts by surprise because GeneDX offers tests that diagnose rare and complex genetic disorders, by definition a small segment of the diagnostic testing marketplace. In fact, GeneDX has annual revenues of approximately \$5 million.

GeneDX is a specialty genetics company which was established in 2000 by two geneticists who worked at the **National Institutes of Health** (NIH). The lab offers specialized tests for more than 147 hereditary conditions built around the technology of full gene analysis by DNA sequencing.

The sale is expected to close within three weeks. After the sale, Founder and President Sherri Bale, Ph.D., FACMG,

and Founder and CEO John Compton, Ph.D., will continue at GeneDX.

"GeneDX fits perfectly in our strategic business plan, in ways that are obvious and in ways that are not," explained Marc D. Grodman, M.D., CEO of BRLI. "In our conversations with analysts, most recognize that GeneDX opens up a new market niche that has great potential for us. They also recognize that BRLI has a demonstrated track record at developing such diagnostic testing niches.

Giving Meaningful Answers

"It is the not-so-obvious reason for our acquisition that is the real key to understanding our interest in GeneDX," he added. "Bio-Reference Laboratories wants to be recognized and respected as a laboratory that gives physicians and patients meaningful answers—information that supports accurate diagnoses and aids in the patient's ongoing course of treatment.

"We are partial to tests that are capable of contributing to the clinician's diagnosis—tests that are essential in the primary diagnosis of a

patient's condition," observed Grodman. "We are most interested in offering the types of laboratory tests that a physician would use in making the primary diagnosis."

Basis Of The Disease

"GeneDX adds precisely those types of tests to our menu because it is a genetic laboratory run by geneticists," he noted. "To provide an answer, GeneDX utilizes geneticists and full DNA sequencing to understand the basis of the disease. The ordering physician is getting meaningful information about the patient.

"On the spectrum of diagnostic tests, we view the testing services offered by GeneDX at one end and assays like pharmacogenomic testing and molecular tumor marker testing at the opposite end of the spectrum," continued Grodman. "If you accept my characterization of full DNA sequencing being at one end of the spectrum and pharmacogenomic and tumor marker testing being at the other, then you'll probably agree that the goal of all these diagnostic tools is to move to the middle ground, that promised land where a physician is able to diagnose and successfully treat *all* diseases.

Genetic Variation In Disease

"We prefer to be at that opposite spectrum with GeneDX, because we want to know how to identify the genetic variance in common diseases," explained Grodman. "This gives us the opportunity to be one of the first laboratory companies to close the gap between what's known in science and what is used in clinical practice.

"GeneDX is at that intersection of what science knows and how that knowledge enters clinical practice," he added. "Bringing GeneDX into the Bio-Reference family provides us with three powerful business assets: credibility, scientific rigor, and recognized expertise.

"Our strategic objective with GeneDX is to participate in the most promising discoveries involving DNA and RNA as they move from basic science into accepted clinical practice," revealed Grodman. "To that end, BRLI's business strategy is guided by two business principles and GeneDX meets both.

"First, as I've noted, genetic testing needs to provide meaningful answers to thoughtful and clinically relevant questions—questions that are well-vetted by the scientific community," he noted. "Further, these meaningful answers should support an actionable course by clinician and patient, whether it be a drug, a lifestyle change, or other therapies.

Demand By Docs, Patients

"Second—and this is an important principle—because the answers are meaningful, there is a demand for the genetic test by physicians and patients, who are willing to pay, directly or indirectly, for that test," offered Grodman. "When the information is clinically relevant and useful, then it is a genetic test that offers recognized value and payment for that test is not an issue."

Pathologists and laboratory administrators will recognize that Grodman has articulated a very sophisticated business strategy for a commercial laboratory company. Board-certified in internal medicine, he continues to see patients and views the potential of laboratory testing services with a different perspective than most of today's lab industry executives.

Moreover, Bio-Reference Labs has consistently executed its growth plan. From revenues of \$53.9 million in 1999, the lab company is on track to post sales of \$185 million this year. With that track record, odds are that Grodman's strategic vision for GeneDX is likely to prove successful.

TDR

Contact Marc D. Grodman, M.D. at 201-791-2600.

Pathologists Contribute To Women's Hospital

Same-day pathology reports are one source of value-added anatomic path services

CEO SUMMARY: *Speedier pathology reports and more active involvement with clinicians are two ways that the 15 pathologists at Pathology Group of the Mid-South help Baptist Memorial Women's Hospital meet its goals of improved outcomes and a patient-friendly environment. Even with an off-site pathology laboratory, same-day reports for most small needle biopsy reports is the norm.*

BEFORE OPENING the **Baptist Memorial Women's Hospital** (BMWH) in 2001, administrators set out to excel at meeting healthcare's three new benchmarks: reducing medical errors, improving healthcare outcomes, and achieving the financial margin necessary to sustain the clinical mission.

The new hospital in Memphis, Tennessee, had an unusual opportunity to get things right because administrators could design protocols and procedures to meet the needs of today's healthcare system. As that happened, anatomic pathologists at BMWH stepped up and made significant contributions to improving the clinician's time to diagnose and interacting with clinicians on a regular basis.

What adds interest to the story at Baptist Memorial Women's Hospital is that it was formed in 2001 as a specialty hospital in response to the trends described in the just-published study on hospital transformation, prepared by **McKinsey & Co.** and analyzed on pages 9-15 in this DARK REPORT.

That is why pathologists and laboratory administrators will find it instructive to learn how BMWH's organizational strategies motivated the anatomic pathology (AP) department to shorten turnaround time for reporting results. Also, pathologists and laboratory staff at BMWH have become attuned to "go the extra mile" to provide customized service and clinical support to the hospital's physicians and patients.

Three Strategies

Seeing that the hospital was: 1) focused on delivery of high-quality patient care; and, 2) organized to give physicians clinical and operational support to achieve those outcomes, the AP department responded with three strategies.

First, pathologists eliminated wasted time during the processing of small needle biopsies to speed up turnaround time. Second, the AP department runs molecular markers daily to provide analysis of the hormone receptors on breast cancer tissue, thus cutting the time needed by physicians to develop targeted treatment plans. Third, pathologists play an active role at the weekly tumor board meeting,

when all physicians involved in a breast-cancer patient's care meet to discuss the most effective treatment plan.

BMWH's emphasis on patient care and improved clinical outcomes has paid off. In July, Baptist Memorial Women's Hospital was awarded a national citation of merit from the **American Hospital Association** and **McKesson Corporation**.

The citation honors leadership and innovation in quality, safety, and commitment to patient care. The citation recognized BMWH's achievement in attaining improvement in the **Institute of Medicine's** six quality aims: safety, patient-centered care, effectiveness, efficiency, timeliness, and equity.

To contribute to this level of clinical performance, the pathology department organized itself around two strategic business objectives. The first is to continuously shorten processing times, particularly for small needle biopsy specimens, and speed the turnaround time for all AP reports. The second is to encourage anatomic pathologists to be more actively involved with the clinicians, throughout the course of a patient's treatment, if need be.

Reviewing Slides

To speed the delivery of AP reports, BMWH's pathology department is now organized to review prepared slides throughout the day. "Each morning, the first thing I do is review the biopsies from the preceding afternoon," stated Thomas M. Chesney, M.D., Medical Director of Laboratories at BMWH. "By 8:30 a.m., all these specimens will have been processed so I can look at them and then call the radiologist. With pathology and radiology results, attending physicians can call the patient.

"Late every afternoon I get the processed slides from biopsies that were collected in the morning," explained Chesney. "They will have come over to

us at midday for processing. By the end of the day, I am calling physicians with the results."

Chesney is President of the **Pathology Group of the Mid-South**, which provides pathology services to the five hospitals in the **Baptist Memorial Health Care** system. It operates a central processing laboratory within three miles of the Baptist Memorial Women's Hospital. This off-site laboratory processes the biopsy specimens from BMWH.

Saturday A.M. Processing

"To maintain turnaround time at the end of each week, samples collected on Friday afternoon are processed first thing on Saturday morning," Chesney said. "We have staff come in so that these women don't have to wait over the weekend for their results.

"It is unusual for any pathology laboratory to have staff come in on Saturdays," observed Chesney. "But that is one way we deliver excellent service. After these specimens are processed, a staff member from mammography is always available on Saturday to call the patient with the results.

"Our goal is to report all these biopsy results within a day or a day and a half," Chesney said. "That means that what is collected yesterday afternoon will be reported out first thing in the morning. Biopsies collected each morning are reported out that afternoon.

"The only way to achieve this is to have the entire team in pathology motivated to do whatever it takes to maintain this level of performance," Chesney stated. "One major way to shorten the time required to report these cases is to minimize time that is wasted between hand-offs. It requires us to identify waste in the work processes and squeeze it out wherever it is found.

"We have couriers who have specific times to pick up samples at the

women's health center," he continued. "All the staff at the hospital who harvest and handle the biopsy specimens are acutely aware of what those times are and that they must get them in the right place at the right time," said Chesney. "Our couriers pick them up and bring them to the laboratory, where accessioning and processing staff are anticipating their arrival.

"This whole process takes the cooperation of all of the technical, clerical, and transport people," he noted. "They know that it is absolutely imperative to waste no time in the process.

"Next, we go one step further," Chesney said. "Once we make a cancer diagnosis, physicians want to know about the hormone receptors, including HER2/neu, which is the human epidermal growth factor receptor 2. These two tests are done using immunohistochemical reagents.

"We do these molecular diagnostics five times a week. In fact, I have just signed off on a case at 3:40 in the afternoon that I received early this morning," he commented. "Once we made the diagnosis, we immediately ordered the special stains needed to evaluate these hormone receptors and now I have the results.

Benefit to Patient And Doc

"This has direct patient impact," continued Chesney, "because it means that, on the first follow-up when that woman goes back to see her doctor, she will know the diagnosis and the type of tumor. Further, her doctor will know whether it is hormonal receptor positive or HER2/neu positive.

"Because of our relationship with Baptist Memorial Women's Hospital, we process a significant volume of breast cancer samples," Chesney said. "But other samples have equally high priority, and our system is organized around the size of the tissue in the biopsy. Small

Memphis Path Group Serves Five Hospitals

THERE ARE 15 PATHOLOGISTS and 100 staff members at Pathology Group of the Mid-South, located in Memphis, Tennessee. The pathology group serves the five Memphis-area hospitals for Baptist Memorial Health Care, as well as other hospitals and clients in the greater Memphis region.

"We run the clinical laboratories, do the anatomic pathology services, and operate the blood bank for these facilities," said Thomas M. Chesney, M.D., Medical Director of Laboratories for **Baptist Memorial Hospital-Memphis** and President of the Pathology Group of the Mid-South. "There are laboratories in each of the hospitals and we have our own separate tissue processing laboratory about three miles from the women's hospital."

Pathology Group of the Mid-South does about 40,000 surgical specimens and 80,000 cytology specimens each year.

needle biopsy specimens that can be processed in just a few hours, can be expedited this way. Typically these are biopsies involving breast cancer, colon cancer, and gastric cancer. For excision specimens with large volumes of tissue, this system wouldn't work as effectively."

THE DARK REPORT observes that the adaptations made by Pathology Group of the Mid-South to meet the clinical and patient-service strategies of this specialty women's hospital are consistent with how McKinsey & Co. predicts that hospitals must evolve to survive and remain economically viable. In particular, the emphasis on same-day reports for many patients shows how speed-to-reported pathology result is a high-value contribution.

TDR

Contact Thomas M. Chesney, M.D., at 901-682-0630.

Labs and Pathology Groups To Be Affected

McKinsey Predicts Most Hospitals Must Specialize to Survive

CEO SUMMARY: *Imagine a healthcare system where successful hospitals specialize in particular clinical services, treat patients like customers at a Ritz Carlton Hotel, and have close clinical and financial collaborations with top-performing physicians. This is the American healthcare system of the 21st century, as envisioned by healthcare strategists at McKinsey & Company, one of the world's premier business consultancies. McKinsey's insights provide pathologists and lab directors with an early perspective on the major strategic changes now transforming healthcare in America.*

IF HEALTHCARE STRATEGISTS at global consultants **McKinsey & Co.** are correct, the era of the all-service, acute care hospital is ending. In its place will be a healthcare system dominated by specialist hospitals which are organized to be both consumer-friendly and price competitive.

This prediction lies at the heart of a newly-published study by McKinsey consultants Kurt D. Grote, Edward H. Levine, and Paul D. Mango. Titled "U.S. Hospitals in the 21st Century," the study was released a few weeks ago. While acknowledging that U.S. hospitals "were once a hallmark of 20th-Century

achievement," the authors argue that economic pressure, the emergence of more focused alternative sites of care, and value-conscious consumers will bring about a swift decline in the pre-eminence of the general, acute care hospital business model that dominates today's healthcare system.

Think More Like Retailers

For today's hospitals to survive and thrive in the 21st century, the study's authors predict that "many hospitals will have to re-organize around a narrower range of clinical activity, differentiate themselves on quality and service, think more like the retailers they are fast-

becoming, and overhaul their relationships with physicians."

Laboratory administrators and pathologists should pay close attention to the predictions outlined in the McKinsey study. These strategic insights are at the core of the advice McKinsey is giving to the nation's biggest healthcare corporations and organizations. DARK REPORT briefings like these give our clients and regular readers access to the same strategic business thinking that multi-billion-dollar healthcare organizations are using to craft their own business priorities.

THE DARK REPORT considers it significant that McKinsey endorses the view that successful hospitals in this century will need to "overhaul" their relationships with physicians and organize themselves around a smaller range of specialty services. These changes will fundamentally alter the way hospital-based laboratories interact with, and serve, client physicians in inpatient, outpatient and outreach settings. In a similar way, these changes will also alter long-standing clinical and business relationships that local pathology groups have maintained with hospitals and office-based physicians in the community.

Why Hospitals Will Change

For these reasons, senior laboratory leaders and pathologists who want to protect the competitive position of their laboratories and group practices need to understand why McKinsey predicts that successful hospitals will have a more limited clinical service menu and be good at competing for customers.

Authors of the study note that, during the last century, American hospitals gained their dominance by achieving vertical integration and economies of scale. They combined pharmacies, imaging departments, laboratories, and emergency rooms. They used professional nursing and aseptic procedures to deliver high-quality medical treatment. Hospitals also offered physicians a more productive practice environment than going "door-to-door."

Hospitals Are "Price Takers"

This success formed the foundation of today's problems. The study states that "Little noticed were the seeds of future problems. Hospitals never really had to depend on their most direct customers—patients—for revenue. The generosity of philanthropists and volunteers, the rise of employer-sponsored insurance in the 1930s and 1940s, and the emergence of government-sponsored insurance in the 1960s all insulated hospitals from the need to compete for patients. Today, hos-

pitals are ‘price takers’ for nearly 50% of their revenues, which is subject to the political whims of the federal and state governments. Hospitals are also required to see, evaluate, and treat virtually any patient who shows up, solvent or not.”

THE DARK REPORT considers the characterization of hospitals as “price takers” to be a significant point. Every business or enterprise, including hospitals, laboratories, and pathology groups, must be able to compete for customers by offering added value at a price that will produce a net profit over the cost of the product or service. McKinsey is observing that hospitals, in the current healthcare financing scheme, must serve a large proportion of patients at either an inadequate price, or no price at all (for uninsured and indigent patients).

Hospitals Are Vulnerable

That is why the McKinsey study authors argue that the current business model of the American hospital is vulnerable, stating that “these structural weaknesses have created openings for more focused providers that increasingly offer superior value: lower prices, higher quality, and better service. Stand-alone ambulatory service centers (ASCs), diagnostic imaging centers, endoscopy suites, and specialty hospitals have become powerful competitors. More are surely on the way as equity markets (both public and private) and physicians themselves pour capital into that sector.

“At the same time,” continues the study, “payers and consumers are becoming much better at recognizing and acting on price and value differences. Patients have much more at stake with the advent of high-deductible health plans.”

The telling observation is this: “Knowledgeable, value-conscious

patients are beginning to view some hospitals as less effective places to seek care compared with many of their alternatives, including physicians’ offices.” This is a point the THE DARK REPORT has repeatedly stressed to laboratory administrators and pathologists. Growing numbers of consumers are actively seeking the highest-quality provider and, where possible, they will avoid their local hospital and choose care that’s provided in non-hospital settings.

Financial Viability

These trends are already at work reshaping the American hospital system and undermining the financial viability of the community hospital business model. Pathologists should take careful note of this fact, since they have an ongoing clinical partnership with the hospital. As hospital-based physicians, the majority of pathologists are almost totally reliant on their local hospital remaining clinically relevant and financially viable. Anything that causes fundamental change in today’s hospital business model will have significant effects—both clinically and financially.

20th Century Hospital

Authors of the McKinsey study have important things to say on this subject. As noted earlier, the 20th century hospital model made physicians more productive, because, as they write, “hospitals put a great deal of capital at their [physicians’] disposal. Yet hospitals didn’t enforce standardized and efficient approaches to the delivery of care. At many hospitals today, doctors still bear only limited economic responsibility for the care decisions they make. Little wonder that it is often they [physicians] who introduce expensive—and sometimes excessive—non-reimbursable technologies or that hospitals not only suffer from declining

margins, but are also performing less well [financially] than other players in the healthcare value chain.”

Because today’s healthcare buyers, both payers and patients, are increasingly interested in selecting hospitals and physicians based on quality of service, the pressure on hospitals to respond to this service demand will grow steadily. As the authors declare, “Hospitals can’t respond to this shifting competitive and consumer landscape without tackling the underlying structural issues. A vital first step is to compete on the basis of strengths in specific clinical service lines rather than relying on the power of full integration.

Rationalize Activities

“In areas such as cardiology, neurosciences, and oncology,” continues the study, “it’s impossible to sustain excellence with just a few patients a day, so all but the largest hospitals will need to rationalize their activities and become more focused: only with a critical mass of patients for individual service lines will they achieve competitive quality at a reasonable cost. Several large payers are already nudging hospitals in this direction by adopting a ‘center of excellence’ approach, which allows these payers to inform patients about (and reward them for using) preferred institutions.”

This is why the general, acute care hospital is confronting market forces which encourage clinical specialization and customer-friendly services. McKinsey’s recommendations to hospitals and physicians are simple. Instead of relying on a fully-integrated healthcare institution to sustain and expand existing market share, hospitals will need to develop specialized clinical expertise. The emergence of a new generation of women’s hospitals

Forces For Change Are Visible in Many Cities

MCKINSEY & CO. BASES ITS PREDICTIONS on what it sees happening in the American healthcare system. Over the past year, THE DARK REPORT has provided its clients and regular readers with specific examples that are consistent with McKinsey’s observations and predictions.

In the preceding story, we profile anatomic pathology at **Baptist Memorial Hospital for Women (BMHW)**, located in Memphis, Tennessee. It was launched in 2001 specifically as a specialty hospital in women’s health. The facility and the organization was deliberately designed to excel in three dimensions: reducing medical errors, improving healthcare outcomes, and achieving the financial margin necessary to sustain the clinical mission. These are performance areas consistent with the new priorities in the American healthcare system. (*See pages 6-8.*)

To accomplish these strategic goals, Baptist Memorial Hospital for Women is quite patient and physician-centric. The facility and services are organized to provide a pleasant and positive experience for patients and their families. At the same time, physicians of all specialties interact closely with each other and with hospital administration to maximize outcomes and improve adherence to clinical guidelines.

The preference of patients to use healthcare services which keep them away from the hospital is the theme in a story printed in the August 28, 2006 issue of *Modern Healthcare*. Titled “Now Entering the Outpatient Zone,” the story describes how many hospitals are building “big box” centers for outpatient services, some as large as 400,000 square feet. The goal is to capture outpatient revenues and the high margins they generate. Why? Because margins are falling on inpatient services and growth in outpatient services is exploding.

in recent years is one sign of this trend, as is the growth of heart hospitals and hospitals organized specifically to serve only cancer patients.

“...since different patients want different types of improved services (such as private rooms, catered meals, and more attentive nursing), hospitals must understand what customers want and how they want it.”

The consequences of failure to accomplish this may be severe, as the McKinsey view is that “hospitals that resist organizing around a narrow set of clinical services will probably enter a downward performance spiral as they experience greater difficulty recruiting top physicians, paying for the best specialty-service and equipment providers, exploiting economies of scale, and implementing best practices consistently. But hospitals that do these things well will also capture direct financial value from the quality improvements.”

Laboratory administrators and pathologists should take note that the study’s authors are describing a more intimate clinical and operational relationship between physicians and hospitals than has been true to date. First, hospitals must offer patients and payers the highest quality clinical outcomes possible. That can only be accomplished by aligning with top-performing specialist physicians.

Well-Run Facility

For example, this implies that hospitals that specialize in obstetrics and women’s health will need to attract the best ob-gyns in the community. They can only do that by offering top-performing ob-gyns a state-of-the-art

facility that is fully staffed and extraordinarily well-run. Currently few hospitals in the United States would meet that complete definition.

Second, hospitals must provide a customer-friendly experience for patients. The McKinsey healthcare consultants are specific in the picture they paint, writing that, as “hospitals become more focused and their patients more value focused, they will start to resemble companies in other competitive service industries. Like cutting-edge retailers, they must identify the characteristics of the patients they can best serve and attract those people by creating specific value propositions. Indeed, since different patients want different types of improved services (such as private rooms, catered meals, and more attentive nursing), hospitals must understand what customers want and how they want it.”

Frontline Tasks

“Along with players in many other competitive service industries, hospitals are likely to find that a key source of differentiation is the consistent execution of frontline tasks, such as adhering to clinical protocols, maintaining efficient patient flows, administering drugs safely, and coordinating disparate activities effectively.”

There is no question that this will challenge the existing mindset of most hospital and health system administrators. “The importance of execution will extend beyond clinical activities,” states the study. “Hospitals that can’t or won’t quote prices before delivering service will drive away selective, value-conscious consumers. Hospitals with weak skills and systems for extending credit or making collections at the point of service may have higher bad debts. Better execution will require drastic behavioral

changes from physicians, nurses, administrative personnel—and senior executives, whose jobs are becoming more complex. Better training, performance metrics, and compensation structures will all be needed to help hospitals change.”

Of course, for hospitals to succeed in this strategic transformation, they will need a different relationship with physicians. The study addresses this particular point by saying “Given the central role of physicians in operational and resource allocation decisions, it will be difficult to effect change without building a much stronger cultural and economic alignment between physicians and hospitals. For many physicians—particularly clinical specialists in the service lines where hospitals hope to differentiate themselves—the traditional arm’s-length and more recent competitive relationships must give way to some sort of formal employment or gain-sharing schemes such as joint ownership of equipment or even whole facilities.”

Quality, Service, And Prices

At this point, the McKinsey consultants turn to the need for physicians to change if the new hospital business model is to succeed. “Furthermore, performance criteria for physicians must shift,” notes the study. “In a world in which transparent quality, service, and prices help patients choose places to seek treatment, metrics such as admissions volumes will become less relevant. The more important considerations will include a physician’s adherence to well-established standards of medical practice, willingness to embrace teamwork, and bedside manner, as well as a selection of services and equipment that strikes the right balance between cost and performance.”

McKinsey’s message to physicians, including pathologists, is unmis-

Watch Bad Debt Ratios Climb at Nation’s Hospitals

MUCH HAS BEEN WRITTEN in THE DARK REPORT about how the growing acceptance of consumer-directed health plans (CDHPs) is already triggering significant changes. Hospitals will be first to feel the major impact of these changes.

One prediction that McKinsey & Co. has made about the long-term effects of the CDHP trend is that the bad debt ratio of hospitals will increase. The source of this increased bad debt will be from insured patients—enrolled in CDHPs with high deductibles—who are either unwilling or unable to pay their hospital bill. This is a change from past years, when most bad debt originated from uninsured patients.

THE DARK REPORT recommends that pathologists and laboratory administrators look for published figures for hospital bad debt, by state and nationally, when the year-end financial performance of the hospital industry is evaluated at the end of this calendar year. The number of individuals enrolled in CDHPs exploded during the past 18 months and it is likely that hospitals are beginning to see their bad debt ratios climb from that category of patients.

takable. Three attributes are likely to separate physician-winners from physician-losers. First is the ability to consistently follow established clinical protocols. Second is to serve patients like retail businesses serve customers. Third is to provide clinical services in a cost-effective manner.

It’s going to be a healthcare environment where successful physicians are team players and both hospitals and physicians recognize the need to meet and exceed the expectations of patients as customers. The transition to this type of healthcare system is likely to be high-

ly stressful for hospitals, pathologists, and the clinical laboratory staff.

Since any hospital that moves to develop a clinical specialty, like orthopedics or cardiology, will rely on specialist physicians to provide these clinical services, they will need to interact more effectively with such physicians to achieve the goals of a patient-friendly institution with a published track record of superior clinical outcomes. Not every hospital administrator will find it easy to make the mental shift from the old paradigm to this newer, as yet-to-be defined paradigm.

There is another dynamic that needs to figure in the strategic planning of pathologist business leaders and laboratory administrators. The McKinsey & Co. study describes a healthcare marketplace organized around consumer choice, price competition, and the need to demonstrate value to build and retain market share.

The McKinsey & Co. study describes a healthcare marketplace organized around consumer choice, price competition, and the need to demonstrate value to build and retain market share.

Thus, over the next five years, in many clinical areas, office-based physicians will have an incentive to develop services which allow patients to bypass a visit to the hospital, while providing these patients with better services and a higher outcome per healthcare encounter. It is likely to be a healthcare marketplace where regional, consolidated primary care and specialist supergroups will have the necessary capital, a critical mass

of patients, and the economic incentive to compete more directly with their local hospitals.

All of this means it will be a confusing healthcare market in the coming years. Office-based specialists are likely to be approached by hospitals seeking closer collaboration. At the same time, larger specialist groups will have clinical opportunities that they can develop independently of hospitals and which have the potential to generate ample revenue.

Transition Will Take Time

For both hospital-based laboratories and pathology group practices, the consequences of McKinsey's predictions point to a radical change from today's status quo. Yet the transition should take enough time for savvy pathologists and laboratory directors to keep their organizations positioned as effective providers, whether the patient is served as an inpatient, outpatient, or in the outreach marketplace.

In fact, many hospital laboratories have been doing just this by creating a laboratory outreach testing program. Having a presence in the outreach market means that these hospital-based laboratories can compete for the specimens generated by patients who are not coming to any of the hospital's facilities.

Frequently the laggards are the pathology groups embedded in the same hospital. Too often they are slow to take advantage of the hospital's laboratory outreach program by creating a comparable outreach program with specialized anatomic pathology sales and marketing. More pathology groups will need to adopt a pro-active stance toward outreach and outpatient services to successfully make the coming transition in the American healthcare system. **TDR**

For a copy of the full report on hospitals by McKinsey & Co., e-mail Editor Robert L. Michel at labletter@aol.com.

Molecular Diagnostics

Bio-Rad Buys CIPHERGEN'S Proteomics Technology

CIPHERGEN retains exclusive rights to develop clinical diagnostic uses

PROTEOMICS IS EXPECTED TO BE ONE of the most active areas in molecular diagnostics and **Bio-Rad Laboratories, Inc.** has just staked a major claim to a promising proteomic technology.

In a transaction announced on August 18, 2006, Bio-Rad will acquire the proprietary proteomics instrument business of **CIPHERGEN Biosystems Inc.**, which includes the SELDI technology (Surface Enhanced Laser Desorption/Ionization), ProteinChip arrays, and supporting software.

Cash Plus Equity

Bio-Rad will pay about \$20 million in cash and will invest \$3 million to acquire equity in CIPHERGEN, which is based in Fremont, California. Once the deal is closed, probably in first quarter 2007, Bio-Rad will manufacture the SELDI instrument line and will sell this technology to the life sciences market for use in discovery, characterization, and validation of proteomic markers. CIPHERGEN retains the exclusive rights to use SELDI and its associated technologies in the diagnostics marketplace.

CIPHERGEN President and CEO Gail S. Page said the sale will allow CIPHERGEN to transform into a specialized diagnostics provider. "This is a strategic transaction which plays to the strengths of both parties," said Page. "From its inception in

1952, Bio-Rad has been organized around the study of proteins. It has an established customer base and annual sales of more than \$1.2 billion. They are well-positioned to manufacture and distribute SELDI instruments and related products to more than 70,000 customers worldwide, particularly in the life sciences arena.

"This transaction frees CIPHERGEN from the responsibilities of manufacturing and distribution," continued Page. "It allows us to focus on developing diagnostic assays for clinical use. Our initial focus is on ovarian, prostate, and breast cancer. We are also actively developing some cardiovascular tests."

Timing of this sale was related to CIPHERGEN's need to make its limited capital stretch further. "Simply stated, CIPHERGEN did not have the money necessary to develop manufacturing, expand sales of this technology to the life sciences market, and still support the research needed to bring our most promising assays through regulatory approval and into general clinical use," explained Page.

Ovarian Cancer Assay

CIPHERGEN expects its first assay will enter clinical use by year's end. "The test is an index derived from seven ovarian cancer markers to discriminate ovarian cancer from benign pelvic masses. The markers also appear to perform better

than other tests in detecting early stage ovarian cancer,” explained Page. “CIPHERGEN is currently working with **Quest Diagnostics** in their efforts to commercialize this marker set under the analyte specific reagent (ASR) regulations. At the same time, CIPHERGEN is working to obtain FDA clearance for the test kit.”

“The sale to Bio-Rad positions us to be a specialty diagnostics provider,” observed Page. “Bio-Rad is our anchor for efficient manufacturing, as well as distribution of SELDI systems to the life sciences community. In the diagnostic market, Quest Diagnostics anchors our commercialization strategy.”

CIPHERGEN was founded in 1993. In 1999, it began selling its ProteinChip System, Series PBS II. In 2000, it raised \$81.8 million in an initial public offering (IPO). In recent years, it has entered into research collaborations with such institutions as **The Johns Hopkins School of Medicine, M.D. Anderson Cancer Center, University College London,** and the **University of Kentucky** to develop its diagnostics pipeline.

Cost Of Development

Simultaneously carrying the burden of the instrumentation business and developing its proteomics technology for clinical diagnostics required CIPHERGEN to spend plenty of cash. For the first six months of 2006, CIPHERGEN reported revenues of \$12.3 million and a net loss of \$13.2 million. As of June 30, 2006, it had cash and investments totalling \$20.6 million. By selling its technology to Bio-Rad and keeping rights to develop diagnostic tests for clinical use, CIPHERGEN has reduced its ongoing capital demands.

Proteomics is proving to be the hot technology area in the drive to genetic medicine. Market researchers at **Strategic Directions International, Inc.** have published numbers that put the global genomics market at \$4.9 billion sales in 2005. For proteo-

Multi-Marker Technology For Protein Analysis

CIPHERGEN'S TECHNOLOGY IS BASED on protein separation, detection, and bioinformatics to discover multiple markers that form the basis of new assays. The system has many potential applications in the markets of both life sciences/research and clinical diagnostics.

SELDI (Surface Enhanced Laser Desorption/Ionization) technology enables selective protein retention on ProteinChip Array surfaces by means of distinct chromatographic surfaces. There are additional arrays designed for “covalent coupling of antibodies, DNA, RNA, receptors or other ‘bait’ molecules onto the array surface.”

Crude biological samples such as serum or tissue extracts are applied to ProteinChip arrays. By adjusting the binding and washing conditions, the researcher can selectively capture proteins on the array's chemical surface. CIPHERGEN's ProteinChip Reader analyzes the array, using “laser desorption and ionization of proteins from the array surface, and detection by time-of-flight mass spectrometry (TOF-MS).”

Data produced by ProteinChip Systems are analyzed using sophisticated bioinformatics software, and protein levels “can be quantitated by plotting peak intensity values against peptide or protein standards.”

omics, in 2005 the global market was \$3.1 billion.

Strategic Directions predicts genomic growth rates averaging 2% per year. By contrast, it predicts proteomic growth rates averaging almost 9% per year. It means proteomics is expected to grow four times faster than genomics during the coming years.

TDR

Contact Sue Carruthers at 510-505-2233.

INTELLIGENCE

LATE & LATENT
 Items too late to print,
 too early to report



On August 14, **AmeriPath, Inc.** released its second quarter earnings report. Revenues were \$191.7 million, an increase of 35% from \$143.6 million posted in second quarter of 2005. These numbers reflect the acquisition of **Specialty Laboratories, Inc.**, which AmeriPath acquired on January 31, 2006. (See *TDR, October 3, 2005*.) Quarterly revenues for Specialty Laboratories was \$40.2 million. For the six months ending June 30, 2006, AmeriPath's revenues were \$362.6 million. Six-month revenues for Specialty Laboratories was \$66.6 million. AmeriPath stated that same store revenues had increased 6.7% and 8.7% for the second quarter and the six-month period, respectively.

TRI-PATH & BD

On August 14, **Becton, Dickinson and Co. (BD)** offered to purchase **TriPath Imaging Inc.** for a price valued at \$350 million. BD currently owns 6.5% of TriPath. Negotiations were ongoing as of press time.

MORE BIG EMPLOYERS CONTRACT DIRECTLY WITH DOCTORS

For several decades, many large corporations have self-insured their health benefits plans as a way to better control costs and improve employee satisfaction. Now there is evidence that a growing number of major companies are bypassing managed care companies and contracting directly with physician groups to provide care for employees and their families. In Houston, Texas, **Waste Management Inc. (WMI)** signed such a contract in 2005 with **Kelsey-Seybold Clinic**. "KelseyCare is essentially an HMO product, but it's one in which doctors, not insurers, decide on patient care," observed Ben Hofman, M.D., Medical Director and Vice President at Waste Management. WMI employees can opt for KelseyCare or a **Cigna** PPO program.

ADD TO: *Direct Contracting* Waste Management's contract with Kelsey-Seybold Clinic saved considerable amounts of money. It was

determined that the direct contract with Kelsey's doctors would cost WMI 16% less than a contract with a traditional health insurance company. In Overland Park, Kansas, **Sprint Nextel** has contracted directly with doctors and four local hospitals since 2001. Savings have been in the range of 5% to 10% less than health benefit plans offered by managed care companies in the region. This trend demonstrates how large corporations are willing to bypass traditional health insurance companies to deal directly with providers if the savings are substantial. It points to the possibility that large employers would find it worthwhile to contract directly with clinical laboratories that offered discounted prices and good service.

Genomic Health, Inc., of Redwood City, California reported second quarter revenues of \$8.4 million, compared to \$1.2 million for second quarter 2005. Demand for its Oncotype DX test is increasing, with "3,250 test services delivered in the second quarter of 2006, compared to more than 1,300 in the second quarter of 2005."

*That's all the insider intelligence for this report.
 Look for the next briefing on Monday, September 25, 2006.*

THE DARK REPORT

UPCOMING...

- ***Competition Intensifies for Hospital Reference/Esoteric Testing As National Labs Offer Lower Prices, More “Goodies.”***
- ***Precise Lab Management in Real Time: How New Software Tools Help Lab Directors.***
- ***Strategic Perspectives on the National Laboratory Testing Marketplace.***

For more information, visit:
www.darkreport.com