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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Customer-Focused Labs Are Successful

AS YOU READ THIS ISSUE, YOU WILL BE AMONG THE FIRST in the laboratory industry to learn that more than 50% of the nation's hospitals are financially deficient and "technically insolvent or at risk of insolvency." That's according to **Alvarez & Marsal** of New York City, which analyzed the financial performance of 3,900 hospitals and released a report on its findings. *(See pages 10-14.)*

Certainly for hospital-based lab directors and pathologists, this may be one of the most significant intelligence briefings we bring you this year. It is a sobering fact that, by Alvarez & Marsal's estimate, "2,044 hospitals, or 53% of the sample, had negative patient care profitability." That means revenues from treating patients are not enough to cover expenses at these struggling hospitals. Alvarez & Marsal observe: "A 'flight to (perceived) quality' is occurring by both physicians and patients—creating a bigger gap between the fiscally strong and fiscally weak hospitals in a given market."

Why are successful hospitals consistently profitable and capturing market share from weaker hospitals? Experts such as Alvarez & Marsal and **McKinsey & Co.** say the better hospitals succeed because they are close to their customers and offer quality care, an attractive facility, and customer-focused personal service to patients.

Success from a customer-facing and customer-focused business strategy is one common theme heard in many of the presentations delivered at this year's *Executive War College on Lab and Pathology Management*, which took place in Miami earlier this month. As you will read on pages 3-6, lab industry leaders, innovators, and healthcare experts from such diverse, respected companies as **Microsoft**, **Cerner Corporation**, and **DNA Direct** all had a common element in their strategic recommendations to lab directors and pathologists. It was that providers and laboratories must be close to their customers to survive and thrive as ongoing reforms alter and transform the American healthcare system.

If you ask me, it's not a coincidence that, in two different intelligence briefings in this issue of THE DARK REPORT—and within two entirely different segments of healthcare and laboratory medicine—the "customer-focused" strategy is identified as a critical success factor. Observant lab executives and pathologists will want to act upon this highly useful insight. It can play a vital role in contributing to clinical excellence and financial viability in the coming, tough years. TDR

War College 2008 Theme: Get Close to Customers!

What's hot in laboratory and pathology is customer-facing organizations and integrated IT

CEO SUMMARY: Over the course of two days, pathologists, lab directors, and other laboratory professionals repeatedly heard speakers urge them to work hard to ensure that customers are the top priority for their laboratory organization. Another theme is the need for labs to organize their data so that they can send actionable information to referring physicians and other partners in the healthcare system. Forward-looking labs and pathology groups are already forging ahead with enriched consultative services for client physicians.

THERE WAS A SURPRISING THEME that emerged at this year's *Executive War College on Laboratory and Pathology Management*, conducted in Miami earlier this month. Contained in many of the 42 presentations during the two-day event was this consistent message: "clinical laboratories and anatomic pathology groups need to get up close and tight with their customers to survive and prosper through the coming healthcare storms!"

This common thread in so many presentations should not surprise clients and regular readers of THE DARK REPORT. For more than a decade, these pages have documented the converging trends which place consumers (patients) in the primary role of, one, deciding which providers to use and, two, spending greater sums out-of-pocket to pay providers directly for their care.

The fact that so many speakers at this year's *Executive War College* emphasized the need to be customer-focused is thus not a coincidence. It is tangible proof that shrewd healthcare executives and laboratory leaders already see tangible evidence in their own communities that those providers who are best at meeting and exceeding the needs of their patients will be clear winners.

This "consumer first" imperative was crystal clear in each of the presentations made by three speakers at one special general session. Leading off that morning was Trisha Brown, Vice President of **DNA Direct** *(www.dnadirect.com)* in San Francisco, California. She provided attendees with a detailed overview on the explosion of Web-based companies organized to offer genetic testing directly

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to consumers. According to Brown, consumer interest in genetic testing is increasing sharply from year to year.

Lots of entrepreneurs recognize this trend, along with the willingness of consumers to spend $1,000 or more for genetic tests. But the downside to this development is that many genetic tests offered by these Web-based start-ups fail to measure up to rigorous scientific standards long-recognized by the medical community as necessary to deliver clinical value.

In her remarks, Brown provided examples of intelligent, informed consumers who come to DNA Direct with a genuine need for a scientifically valid test—often because their personal health provider was either unknowledgeable about such genetic tests or was unwilling to order the genetic assays.

Brown also flashed a series of slides that showed the seamier side of genetic tests on the Web. These ranged from genetic tests on hair baldness at **HairDX.com** to genetic love match testing at **ScientificMatch.com**.

In his remarks at the closing session, *Executive War College* Founder Robert L. Michel observed that "Trisha Brown showed us something profound when she explained the growing consumer interest in buying genetic tests over the Web. If such well-financed companies as **23andMe** (owned by **Google**), **Navigenics** (also with some Google funding), and **DeCode Genetics** are willing to do genetic tests for consumers who find them via the Internet, then clearly, a Pandora's box has been opened.

Lab Profession Loses Control

"But laboratory medicine is not in control of this Pandora's box," Michel continued. "For the first time, both sophisticated genetic testing and charlatans advertising their own version of genetic tests, can be accessed directly by consumers doing a Web search. Physicians and laboratories will no longer be the recognized gatekeepers for diagnostic testing.

"Moreover, how long will it be before patients begin to wonder why clinical labs in their cities do not have a presence on the Web and why they cannot go down the street and have their local lab perform a genetic test they see offered on the Internet?" asked Michel. "The entire lab profession should recognize the red flags raised by these early genetic testing land grabs on the Internet."

Opportunities for Labs

Following Brown on the podium was Paul Smolke, Director, Health Industry Strategy & Solutions at **Microsoft Corporation** in Redmond, Washington. He was there to discuss key trends in healthcare informatics and describe likely paths to full digital integration of health information.

He discussed three trends. First is business intelligence, which is how companies use information technology to gather the "right information at the right time in the right format" so that managers can make informed, correct decisions.

Smolke's second trend is communications convergence. Essentially, this trend involves creating a unified identity for an individual across devices and networks. Smolke demonstrated how companies are spending money today to achieve this unified identity to make it easy to reach an individual in the work, mobile, and home environments.

For laboratory directors and pathologists, the third and most important of Smolke's trends is consumerism. He identified four areas of attention: 1) focus on health and wellness; 2) focus on self-directed care; 3) obtaining relevant on-line health information; and, 4) consumer-centric collecting, storing and sharing of health information.

Smolke then explained Microsoft's vision of consumers as aggregators of their health information. Thus, Microsoft's strategy is to use informatics integration and communications convergence to cut across the existing silos of information that exist in today's health-

Lab Industry's First Mergers & Acquisitions Day Reveals Lots of Interest, More Lab Sales Ahead

By Robert L. Michel

IT'S ALWAYS AN EXPERIMENT to bring together pathologists and put them in the same room with professional investors and other Wall Street types. Yet that formula generated lots of energy, enthusiasm, and networking earlier this month at the lab industry's first-ever "Mergers & Acquisitions in Pathology and Clinical Laboratory" conference.

This special day took place in Miami on May 15, following the *Executive War College*. A sell-out crowd of almost 200 folks jammed the room and networking was at a high pitch throughout the day. For laboratory owners and pathologists who are partners in group practices, there was keen interest in what experts on valuation, finance, legal, and operations had to say about the right and wrong ways to prepare a laboratory for sale.

In organizing this unique conference, I had three primary objectives. First was to break down the wall that seems to separate the professional investment community from the general rank and file of laboratory owners and pathology group partners. Too often, when laboratory owners decide to sell the business, they fail to get the first-rate advice and experience they need to properly prep and offer their laboratory for sale.

Learning Environment

Second was to create a learning environment for all types of laboratory owners. To achieve that, the program offered four distinct learning tracks: 1) clinical laboratories and pathology practices; 2) hospital/health system laboratory outreach programs; 3) specialty/niche laboratories and those labs offering patent-protected or proprietary diagnostics tests; and, 4) a general learning track for lab owners.

The third objective was to offer all this information in a setting that would encourage senior laboratory executives attending the *Executive War College* to stay over and participate in the Mergers & Acquisitions day. This would be a different opportunity, since standard practice generally means these individuals must travel to investment conferences in New York in order to meet investment professionals and explore opportunities for the sale of their laboratory.

How Much Is My Lab Worth?

If there was one single topic of greatest interest, it was about the high prices paid for clinical laboratories in the past 24 months. Laboratory sellers are curious about the value of their lab and what motivates sellers to pay high multiples of EBIDTA (earnings before interest, depreciation, taxes, and amortization).

For that reason, the acquisition of **AmeriPath, Inc.** by **Quest Diagnostics Incorporated** last year, at a multiple estimated to be around 17 times EBIDTA, triggered lots of questions and discussion. Most Wall Street experts who had studied the deal told the audience that this particular sale represented a unique opportunity to this particular buyer. Overall, there seemed to be consensus that, in today's market, a valuation of 10 times EBIDTA seems to be common for a profitable, growing, and well-managed laboratory—with a caveat that many factors can affect a lab's value positively or negatively.

Another surprise was the attendance of a number of hospital laboratory outreach program directors. It seems that recent sales of **DSI Laboratories, Inc.** in Fort Meyers, Florida, and **Pathology Laboratories, Inc.,** of Muncie, Indiana, have made hospital and lab administrators aware that they own a valuable asset—one that can be worth tens of millions of dollars to an interested buyer.

At the urging of attendees and our faculty, we plan to conduct more such programs on this topic. Your suggestions for speakers and topics are welcome. Send them to me at rmichel@darkreport.com.

care system—thus allowing the consumer's health information to flow as needed throughout the health system of the future.

Next speaker during this session was Bill Wing, Vice President, Health*e* Services, of **Cerner Corporation** in Kansas City, Missouri. He took *Executive War College* attendees on a fascinating tour of how Cerner is transforming its health benefits program into a customer-facing/customer-first model. A full description of the Cerner Health*e* program, which Cerner Corporation now actively sells to other companies, follows on pages 7-9.

➤Emphasis on Consumers

What linked Wing's presentation to the earlier speakers during this session was his continual emphasis on developing services that are customer-friendly and engage the consumer (employee) to be more responsible for making healthcare decisions, for paying a larger share of costs out-of-pocket to providers, and to be motivated to participate in wellness and disease avoidance programs.

Most of the laboratory and pathology group strategic case studies presented at this year's *Executive War College* had an unmistakable emphasis on moving the laboratory organization to a closer customer/patient orientation. For instance, Nate Headley, Chief Executive Officer of **Spectrum Laboratory Network** in Greensboro, North Carolina, described his lab's strategy of using integrated informatics to build loyalty with client-physicians, to reduce errors on test requisitions that irritate physicians and adversely affect patients, and to generate significant financial and operational benefits.

As Michel noted during his closing remarks, "Few laboratories are willing to spend the money for staff, resources, and the capability to electronically connect a new doctor in one day and regularly interface with his EMR in as little as 48 hours. Yet, Spectrum's investment in making such connections with physicians in such a short time brings it a handsome return on its investment, beside fueling a steady growth in market share, specimens, and revenue."

If Spectrum Laboratory Network can claim to be at the head of the class in integrating its LIS and informatics platforms with referring physicians, then **Pathology Associates Medical Laboratories** (PAML) in Spokane, Washington, can claim to be at the head of the class in its use of integrated informatics to support an impresive, world-class level of customer service.

Rosalee Allan, Chief Operating Officer, at PAML "wowed" the *Executive War College* audience as she explained how PAML's strategy of using client relationship management (CRM) software, in tandem with digitized, real-time operational data flows, has boosted PAML's customer service performance far past the lab industry standard.

The genesis of this strategy was the loss of a $1 million-per-year client several years ago. PAML made the decision to drive down the number of pre-analytical errors and give management real-time monitoring capabilities to directly improve the daily customer service it provides to clients and patients. After spending heavily to implement the CRM and install middleware to capture and feed real-time data into the CRM, PAML has cut the number of lost clients to zero, while boosting client satisfaction.

➤Other Important Themes

Of course, with more than 75 topics and speakers spread out over the two-day *Executive War College* and the Merger & Acquisitions Conference that followed on the next day, there was a wide range of innovations, operational successes, and business strategy breakthroughs presented. Along with the customer focus, other clear and distinct themes were use of integrated informatics, using Lean/Six Sigma methods to drive operational excellence, and how labs are utilizing new technologies in automation and diagnostic instruments to achieve further clinical and operational gains. TDR

Cerner's Market-Driven Employee Health Program

Meet "Healthe", Cerner's innovative effort to motivate employees to improve their health

CEO SUMMARY: Cerner Corporation is using a variety of strategies to reduce the cost of health benefits and improve the quality of care for its workers and dependents. Gluing the entire effort together is an integrated patient health record (PHR) and a host of electronic services, ranging from real time eligibility verification and claims adjudication for physicians to preventive and wellness programs for employees. Last year, Cerner tracked $2.6 million in savings from this Healthe initiative. It also began selling this innovative health benefits program to other corporations.

DISCUSSIONS ABOUT REFORMING the American healthcare system to improve quality of care and reduce costs mainly focus on what government should do.

Yet, many advocates of reform seem to ignore the innovations unfolding at some corporations. Faced with steady increases in health benefits costs—and observing how chronic conditions affect workplace productivity—these companies are developing innovative and highly effective health benefits programs and services.

One example of such innovation can be found at **Cerner Corporation** of Kansas City, Missouri. For the past three years, Cerner has achieved remarkable results in controlling the year-to-year increase in the cost of health benefits. At the same time, the quality of care delivered to workers and their family members has improved measurably.

To produce these results, Cerner has: 1) opened a medical clinic, a pharmacy, and a fitness center at its corporate site; 2) developed a sophisticated, integrated electronic patient health record, supported by innovative e-based services; and, 3) offered programs to its employees designed to help individuals with chronic, or pre-chronic, conditions to improve their health and gain financial incentives as they do.

An advocate of consumer-directed health plans (CDHPs), Cerner offers employees a high-deductible insurance plan, paired with a health reimbursement account (HRA). Cerner calls its program "Healthe" and is marketing this integrated employee health benefits program to other employers. To give pathologists and lab directors an inside look at how corporate health benefits programs are likely to evolve, Bill Wing, Cerner's Vice President, Healthe Services, spoke at this year's *Executive War College* in Miami on May 14. He opened by saying "Employers will be the early leaders in the efforts to transform healthcare." He explained the six keys behind the company's success in managing health costs *(See sidebar next page)*.

The Healthe program delivers impressive results. Wing described how, last year, Cerner saved $2.6 million in spending for health benefits. Included in this amount are $1.2 million in medical cost savings,

$791,337 in pharmacy savings, and $568,575 in productivity savings. Gains in productivity during 2008 could reach $1.3 million.

Cerner has the scale to demonstrate the effectiveness of its innovative health benefits program. Revenues for 2007 totaled $1.5 billion. It has 7,600 employees working in 23 countries, all of whom are connected with common Internet tools. Of the total workforce, 6,200 are in Kansas City. The average worker is 34 years old, and 30% are in engineering, 30% in IT services, 10% are clinical specialists, and 30% are in sales or administration. Last year, Cerner spent $32 million on health benefits for 11,151 workers and dependents.

A health information technology company, Cerner knows something about healthcare and productivity. "As we digitize healthcare, there is a great opportunity to save 10% to 30%, including 10% through automation, 10% by connecting and sharing data, and 10% by using data to improve performance in financial, operational, and clinical areas," Wing said.

Cerner calls its healthcare program Health*e* Employer Services. The program includes the Health*e* Record (a personal health record or PHR), Health*e* Advisors who counsel workers on wellness and illness prevention, Health*e* coaches who specialize in helping patients manage chronic conditions, and the on-site Health*e* Pharmacy and Health*e* Clinic.

Consumer-Driven Plans

Cerner's health benefits program is a market-driven solution to problems that plague healthcare, in part because it uses consumer-driven health plans exclusively. "In 2004, 73% of our workers were enrolled in preferred provider organizations (PPOs) and 27% were in HMOs," stated Wing. "Next, in 2005, Cerner introduced an HRA and 48% of workers participated, cutting PPO enrollment to 30% and HMO participation to 22%. In 2006, HRA enrollment rose 72%.

"Last year, it hit 99% allowing the company to eliminate its PPOs and HMOs," added Wing. "The remaining 1% of workers had a health savings account (HSA). This year, 100% of workers have an HRA. Regardless of the plan an employee chooses, Cerner pays 70% of healthcare costs while the employee pays 30%."

Each worker gets a Health*e* card which functions as a health plan identification, debit, and credit card. The card contains some personal health information as well. "Cerner provides a card reader to physicians to speed up electronic settlement for physicians and other providers and cut costs by providing real-time eligibility verification, claims adjudication, and next-day payment," explained Wing. "A physician can swipe a patient's health plan card to verify eligibility and collect payment during the same visit.

"The card facilitates point-of-sale payment so that we can pull a claim through

Cerner Corp. Has Six Keys to Improving Healthcare

CERNER CORPORATION AIMS TO IMPROVE the delivery of healthcare by implementing six key strategies whenever possible, said Bill Wing, Vice President, Health*e* Services, for Cerner Corporation in Kansas City, Missouri.

The first key is to reduce healthcare friction by making it easier for providers to deliver and get paid for delivering care.

Second, is to build trust and transparency by collecting and using data on the delivery of care.

Third, is to promote a person-centric healthcare experience, meaning one that serves patients.

Fourth, is to leverage technology by using efficient electronic systems throughout the process of delivering and paying for care.

Fifth, is to improve health status and reduce costs by focusing on high-cost illnesses to help reduce expenditures.

The sixth key is to develop repeatable and deployable processes that contribute to more efficient systems.

and adjudicate it within 30 seconds," Wing noted. "Payment goes to the doctor the next day and this electronic transaction costs $1 instead of the $12 to $14 that it normally costs to process a claim.

"In addition, when a patient visits a doctor, the card creates an electronic clipboard for the doctor to see, thus facilitating the provision of care," he added. This *e*clipboard contains a medical history, allergies, and medications.

Patient-Centered Approach

Cerner uses sophisticated technology to support a patient-centered approach to care. Since 2006, the company's goal has been to improve the health of its workers through its Health*e* Advisors. These professionals help Cerner employees focus on wellness and illness prevention. In 2006, the company introduced a health risk assessment and 94% of workers participated. Last year, the company had biometric screening and 92% of workers participated.

Cerner now has baseline data on cholesterol, glucose, and blood-sugar levels; hypertension, body mass index; and tobacco use among workers. By combining these data with evidence-based recommendations, Cerner can help workers and dependents set goals to improve their health, Wing said.

Use of this data helped Cerner recognize, for example, that the annual cost per member with metabolic syndrome is $3,108. About one third of workers in the United States aged 20 to 49 have this syndrome, which involves a combination of factors, including high triglycerides, high blood pressure, and high glucose levels. Cerner also found that five conditions account for 40% of all medical and pharmaceutical costs: cardiac care, low back pain, asthma, diabetes, and cancer.

"Among workers and dependents with diabetes, annual cost per member is $13,243, versus $2,560 annually for each member who does not have diabetes," Wing said. To address these costs, the company implemented a diabetes care plan of patient education, blood pressure checks, and glucose monitoring. Such education empowers workers and dependents to provide self care."

Another example of patient empowerment comes from Cerner's use of pharmacy data. A Web-based tool allows workers to see at a glance what a community pharmacy charges for a medication against what the worker would pay at: 1) Cerner's in-house pharmacy; 2) through a mail order pharmacy; and 3) by choosing an alternative generic medication. Many generic medications cost workers 80% less than brand name drugs.

"One of Cerner's most successful strategies has been the on-site Health*e* Clinic," stated Wing. "Among other services, the clinic offers health assessments, advice on illness prevention and wellness, primary care, a laboratory, and physicals. It is open weekdays, and a provider is on-call 24 hours a day and seven days a week.

Boosting Productivity

"The on-site clinic and in-house pharmacy has been a significant source of improved productivity," stated Wing. "These on-campus services helped boost productivity simply by saving workers from having to travel to a doctor's office or offsite pharmacy," Wing said. "The average on-site visit time is 30 minutes versus about three hours for a trip to an off-site doctor. In 2007, the on-site clinic and pharmacy generated savings to Cerner of $2.6 million through a combination of lower medical and pharmacy costs, along with increased productivity."

THE DARK REPORT observes that Cerner's innovative health benefits program shows how employers may play a major role in improving health outcomes and reducing the cost of care. It also shows how the unorthodox approach of an on-campus medical clinic and pharmacy, combined with integrated health information technology and the right financial incentives, can motivate employees and providers to improve the health of individuals.

TDR

Contact Bill Wing at 816-201-2590 or

Not Enough Patient-Care Revenue to Cover Costs

New Report Says Half Nation's Hospitals Have Financial Woes

➤➤ CEO Summary: In a groundbreaking study just released, consulting firm Alvarez & Marsal determined that as many as half of the nation's hospitals are failing to generate enough patient revenue to sustain expenses! With a median occupancy rate of 43%, these hospitals are likely to experience a wave of bankruptcies, financial restructurings, and forced mergers. This is the second major report in 24 months to describe how and why many hospitals are failing to compete effectively against physician-owned facilities and why consumers are voting with their feet.

ABOUT HALF OF THE ACUTE-CARE HOSPITALS in the United States are insolvent and teetering on the edge of bankruptcy, according to a recent study conducted by **Alvarez & Marsal, LLC**, a restructuring and consulting firm in New York. Of the 3,900 acute care hospitals studied, at least 2,000 were not making a profit on patient care.

These findings should catch the attention of pathologists and laboratory directors working in hospitals and health system laboratory organizations. THE DARK REPORT believes the findings in the Alvarez & Marsal (A&M) study, titled "Hospital Insolvency: The Looming Crises," presage a coming overhaul of the hospital industry in the United States. Should that scenario occur on the scale A&M's findings indicate, then these events could directly affect—and dramatically change—the clinical laboratory and anatomic pathology professions.

Alvarez & Marsal, LLC, prepared the report after studying the financial operations of 3,861 of the 4,900 acute-care hospitals operating in the United States. Out of the total 3,861 hospitals studied, Alvarez & Marsal said 2,044 don't make a profit on patient care. *(See study methodology in sidebar on page 14.)*

The bad news doesn't stop there. Alvarez & Marsal determined that 744 hospitals in the study earn so little that they cannot fund day-to-day operations, make needed repairs, or support basic capital expenditures. These findings led the study's authors to estimate that capital expenses in U.S. hospitals are underfunded by as much as $20 billion.

A&M identified two characteristics about the most financially troubled hospitals, saying, "737 hospitals, or 19% of the sample, had *both* negative care profitability and EBITDA margins below 4%. Hospitals with 100 to 300 beds represented 44% of the universe, but 46% of potentially insolvent hospitals."

Access to sufficient numbers of patients is a major reason so many hospitals are failing to generate adequate revenue to fund daily operations, make necessary repairs, and provide the capital needed for major facility improvements. A&M observed that, "Potentially insolvent hospitals had a median occupancy rate of 43%, compared to 53% for the remainder of the universe."

For many hospital-based laboratory managers and pathologists, A&M's conclusions are not good news. "Similar to competitive markets in other industries, second-tier and third-tier competitors (small and mid-size urban hospitals) are rapidly losing ground to the dominant medical centers and integrated delivery systems in their service areas," wrote A&M. "A 'flight to (perceived) quality' is occurring by both physicians and patients—creating a bigger gap between the fiscally strong and fiscally weak hospitals in a given market.

➤ Losing Patient Admissions

"Lower-tier hospitals cannot offer the competitive equipment and amenities available from their larger, better-capitalized rivals," continued the study's authors. "Physicians cannot justify admitting to second-tier and third-tier facilities when the market leading hospitals have beds available."

In a surprising finding, A&M determined that urban hospitals are under greater economic pressure than are rural hospitals. "Contrary to conventional wisdom, urban hospitals have a greater chance of being insolvent than rural hospitals," declared A&M. "While rural hospitals enjoy quasi-monopolistic markets, the 100- to 300-bed urban hospitals must face the brutal competition offered by well capitalized academic medical centers and integrated delivery systems located in population centers. It is this group of hospitals where decisive and immediate strategic decisions must be made to ensure survival."

The unbroken 30-year trend of double digit growth in outpatient procedures is also a major factor in the failing finances of

many hospitals. A&M stated that, "In an effort to preserve income levels, physicians are banding together and stripping profitable services out of hospitals and establishing alternate settings [outpatient services]. Services such as MRI and day surgery, once big money-makers for hospitals, are now cash cows for physicians."

Intense, New Competition

Hospitals face intense, new competition for patients by better-managed hospitals and physicians. At one time, of course, all patients stayed in hospitals for a number of days and many hospitals, particularly those in small towns, had little if any competition. But the relentless focus on cost control over the past two decades drove down length of stay and made hospitals compete for patients. At the same time, physicians and entrepreneurs have taken patients away from hospitals by developing alternative facilities such as ambulatory surgery centers and outpatient clinics.

A&M predicts an epic struggle lies ahead between hospitals and the physicians that refer patients. "With dwindling reimbursement, a Darwinian drama may play out as physicians will be more inclined to satisfy their own income demands, regardless of the consequences to the hospital," stated A&M. "For the over-leveraged group of potentially insolvent hospitals (debt to assets of 71%, compared with 43% for all other hospitals), it will be difficult-to-impossible to find the investment dollars needed to improve amenities and re-attract physicians. Hospitals must explore alternate organizational structures that create an alignment of physician and hospital incentives with institutional mission."

The need for hospitals to align themselves with physicians is exactly what Paul Mango, Consultant at **McKinsey & Company,** predicted. THE DARK REPORT was first to introduce the laboratory profession to McKinsey's strategic predictions for the hospital industry. *(See TDR, September 5, 2006.)*

In a 2006 report titled, "U.S. Hospitals in the 21st Century," Mango and his colleagues laid out radical strategic transformations that will occur to the nation's hospital industry. In the report, McKinsey stated, "[1] many hospitals will have to re-organize around a narrower range of clinical activity, [2] differentiate themselves on quality and service, [3] think more like the retailers they are fast-becoming, and [4] overhaul their relationships with physicians."

McKinsey further explained the problems created by competition from physicians and the effect of consumer choice. On physician competition, McKinsey wrote that "these structural weaknesses [of hospitals] 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."

Value-Conscious Patients

In explaining why consumers increasingly prefer other treatment settings over hospitals, Mango and his colleagues wrote, "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."

Reinforcing this new consumer attitude is the change in health benefits plans, which the McKinsey report described, stating, "at the same time, 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 [HDHPs]."

In many ways, the A&M report validates McKinsey's strategic assessments by documenting how: 1) the same trends McKinsey

Lackluster Executive Leadership in Hospitals Is A Significant Factor in Poor Financial Performance

IN EXPLAINING WHY SO MANY HOSPITALS are teetering on the edge of insolvency, the authors of the Alvarez & Marsal study were extremely critical of the performance of hospital and health system administrators.

"As a result of the predominantly nonprofit nature of the hospital industry (and the corresponding lack of equity-based compensation), the industry has not attracted the best and the brightest management talent," wrote the A&M study's authors. "Without true economic stakeholders, [hospital] management and boards across the industry have been accountable typically only to themselves and more vaguely, their 'community missions.' This has created a situation where distressed hospitals limp along on life support at 43% occupancy. In most industries, a plant running at 43% capacity would be closed or consolidated.

"Not so in healthcare," they continued. "The tangle of religious, governmental and community missions allows the industry to tolerate excess capacity that would be unheard of in rational economic markets.

"The hospital industry, for the most part, has tolerated decades of incremental performance change, with few institutions showing the willingness to embark on more significant change-driven measures," said the study's authors, "such as restructurings, mergers or recapitalizations, that occur regularly in other industries to turnaround troubled organizations and improve financial and operational performance. Soon they may no longer have a choice—unless the choice is to simply shut down."

described (and A&M corroborated) have already eroded the financial stability of half of the nation's community hospitals, leaving them at dangerous levels; and, 2) what effect inadequate capital has on the ability of financially weak hospitals to attract patients.

"Physical plants at many community hospitals have deteriorated since capital spending has been necessarily curtailed due to lack of funds," A&M reported. "We estimate that capital expenses in the hospital industry are $10 billion to $20 billion underfunded. *Like it or not, the practice of medicine is a consumer-facing business. (Italics by TDR.)* The lack of attractive—or even acceptable—physical facilities is a contributing factor to the decline of many hospitals."

This next A&M prediction should catch the attention of laboratory directors and pathologists working in any financially-struggling hospital. "There are scores of hospitals that are slowly asphyxiating and slipping into insolvency as they divert capital dollars to fund operations," wrote the study's authors. "For most of these hospitals, it is only a matter of time before they hit a 'sudden' liquidity crisis and cannot make payroll without entering insolvency and being forced into restructuring their finances and operations."

Decades Of Underinvestment

In a written statement, George D. Pillari said, "The findings of this study underscore the sobering reality that decades of incremental change have not ensured the long-term viability of our nation's hospital system." Pillari is Managing Director in Alvarez & Marsal's Healthcare Industry Group. "With a government safety net becoming less and less reliable and non-patient sources of funding becoming fragile, it has become critical for hospital management and boards to deal with these troubling issues head on and take urgent steps—such as restructurings, mergers or recapitalizations—to improve their finances and allow hospitals to execute on their missions. In the absence of such action, hospital insolvencies will increase and community after community could be forced to

grapple with a steady decline in access to care," he wrote.

Hospitals At Financial Risk

In addition, Pillari had another, more frank prediction: "Today there is a large—and growing—number of hospitals at risk for insolvency if their sources of nonpatient funding falter. While such subsidies have been easily accessible and almost guaranteed during the boom times of the past two decades, strains on government coffers and broader economic forces will put an end to the trend. Management and boards of hospitals must take action quickly to ensure long-term solvency. The alternative as experienced in New York State—is that the government will take steps independently to deal with over-leverage, underutilization and excess capacity."

This is the second time in 24 months that THE DARK REPORT has alerted lab directors and pathologists to the looming financial crisis in the nation's hospital industry. It is important to note that, in every sizeable community, tertiary care and academic hospitals are generally doing quite well. However, most of the American public does not recognize that as many as half of the second-tier and third-tier hospitals in the same community are operating on a razor-thin financial margin.

Labs Should Be Watchful

This situation offers both an opportunity and a challenge for hospital lab administrators and pathologists. An effective laboratory outreach program can make important contributions to the hospital's cash flow and cost structure. But the parent hospital may not have the capital necessary for the outreach program to build the infrastructure needed to support and grow the business TDR

Clients of THE DARK REPORT interested in obtaining a complimentary copy of the full Alvarez & Marsal report "Hospital Insolvency: The Looming Crises" should e-mail their request to rmichel@darkreport.com.

Alvarez & Marshall Started With 4,510 Hospitals in Study

To conduct its study of hospital finances, Alvarez & Marsal (A&M) gathered data on 4,510 hospitals. These data included operating expenses and net revenue for fiscal years ending in 2005 and 2006 for each short-term acute care hospital in the U.S. with more than 25 beds. If data for a hospital were unavailable, A&M eliminated that hospital from its study.

This reduced the final sample from 4,510 to 3,861. To ensure the sample was representative and unbiased, A&M then compared this sample to the universe, as published in the **American Hospital Association's** directory, Hospital Statistics.

Alvarez & Marshal used two key measures to analyze hospital performance. First was patient care margin, calculated as (net patient revenue less operating expenses)/ net patient revenue. The second was EBITDA margin, calculated as (net income + depreciation + amortization + interest + taxes) /operating revenue, where operating revenue is net patient revenue + all other revenue. Also defined in the A&M study was how certain financial ratios would limit the strategic options of hospitals, as follows:

Patient Care Margin less than 0.0%— If a hospital cannot earn a profit on its patient care services, it must rely on non-patient care sources of funding to remain viable. Hospitals not earning a profit on patient care will become insolvent when they can no longer sell or borrow against assets, or receive emergency governmental aid to fund losses.

EBITDA Margin less than 4.0%—A minimum level of profit and cash flow is required for a hospital to fund daily expenses and re-invest in necessary, nondiscretionary capital expenditures. Capital investment needed to remain competitive is estimated at 6.0% to 8.0% of annual operating revenues. This analysis identified a level of 4.0% as the minimum level of profitability for a hospital under pressure to fund day-to-day activities, as well as a "survival" level of capital expenditures.

Ruling Against UroPath Signals More Fed Action

Expect CMS to develop new anti-markup regs, based on federal court ruling in UroPath case

CEO SUMMARY: It was a signal win for federal healthcare officials when a federal district court judge in Washington, DC, dismissed a case brought by UroPath, LLC. UroPath had sued HHS Secretary Michael Leavitt seeking to challenge the physician fee schedule final order and the anti-markup rule. The judge's decision provides Medicare officials with useful guidance on how to craft new regulations to possibly further limit the way anatomic pathology condominium (pod) labs operate. Two lab industry attorneys offer insights about what may happen next in this case.

WHAT'S NEXT FOR ANATOMIC PATHOLOGY CONDOMINIUM (POD) LABORATORIES? The recent federal court case decision that went against **UroPath, LLC,** and its co-plaintiffs opens the door for federal officials to further regulate this anatomic pathology (AP) business model.

It is likely that federal healthcare officials are reading the judge's decision closely while they consider new rules for regulating anatomic pathology condo (pod) labs, according to lawyers who have read the decision. In fact, the decision is likely to bolster the efforts of the federal **Centers for Medicare & Medicaid Services** (CMS) to limit the activities of AP condo (pod) labs.

Anti-Markup Rule Changes

"I suspect that this decision will give CMS more confidence to prepare new regulations, but, from a rulemaking standpoint, it will also make CMS more careful about dotting every 'i' and crossing every 't,'" observed Jane Pine Wood, a health law attorney with **McDonald Hopkins**, a national law firm with its largest office in Cleveland. "In addition, I would expect CMS is carefully anticipating legal challenges, and trying to preemptively address those challenges."

Rick L. Hindmand, Wood's colleague in McDonald Hopkins' Chicago office, agreed with her assessment. "CMS faces substantial challenges in its quest to revise and clarify the anti-markup rule," he said. "CMS must address the core concerns without leaving too many loopholes for abusive arrangements and without casting the net so broadly as to discourage arrangements that promote better and more efficient care.

"Last December, CMS acknowledged that it was discovering unintended consequences of the rule as published in November," continued Hindmand. "In light of public comments CMS received late last year, and in considering the decision handed down in the UroPath case, CMS should be in a better position to consider the likely consequences of the various alternative approaches and to develop a rule that is more finely tuned."

The court decision against UroPath was made by U.S. District Court Judge Rosemary M. Collyer in Washington, DC, last month. Collyer's decision was significant for two reasons. First, she effectively tossed the case out of court, telling the plaintiffs to pursue their grievances through CMS' administrative procedures. *(See TDR, April 14, 2008.)*

Judge Rules On Standing

In her decision, Collyer ruled that UroPath and its affiliated physicians and pathology groups did not have standing to challenge Medicare on its Final Order. Earlier this year, plaintiff UroPath, along with its affiliated labs and physician groups, had sued Leavitt in the U.S. District Court for the District of Columbia, challenging HHS' final rule, issued January 3, 2008 (known as the "Final Order"), and the anti-markup rule, issued November 27, 2007. UroPath and its affiliates had said the Final Order and the anti-markup rule would essentially put them out of business.

Another reason Collyer's ruling could prove to be significant is because, in her 21-page decision, she suggests that AP condo (pod) laboratory arrangements between pathologists and referring physicians are designed not so much to improve patient care but to increase profit.

In her ruling, Collyer wrote: "The Centers for Medicare & Medicaid Services have been publicly concerned since at least 2004 about a growing tendency of physician groups to utilize so-called 'pod' [condo] laboratories for pathology and lab work, miles from the physicians' offices, and then to claim that doctors in both locations are 'sharing a practice' for purposes of billing Medicare. From the perspective of CMS, these arrangements violate the spirit, if not the exact language, of the anti self-referral provisions of the law and regulations. The administrative record indicates that many physicians also believe that 'pod' [condo] laboratories are inappropriate ways for doctors to refer lab work to a business they own and from which they profit."

Collyer explained the development of AP condo (pod) labs, writing, "Never say the American entrepreneurial spirit is dead. Faced with this exception to the anti-referral provisions of the Stark act, certain physician groups that order a significant number of patient biopsies—typically dermatology, gastroenterology, and urology groups—began to develop what are called 'pod' [condo] laboratories. Plaintiff physician groups are urology practice groups that regularly order prostate biopsies. They formed plaintiff UroPath to manage pod [condo] laboratories for them and other practice groups. UroPath operates pod [condo] laboratories in Arlington, Texas; Leesburg, Florida; San Antonio, Texas; Sarasota, Florida; and Philadelphia, Pennsylvania. UroPath has '15 labs, three pathologists, and a full and part time staff totaling 30 employees. Its customers represent nine states and 162 urologists.'"

Lack of Jurisdiction

In addition, Hindmand noted that Collyer pointed out that since UroPath (as a management company) does not participate in Medicare, it has no standing to challenge the anti-markup rule. Further, the judge held that any objections to the anti-markup rule must first go through CMS' administrative process. The physicians could submit their reimbursement claims, note any disagreement with the application of the anti-markup rule, and then pursue an administrative challenge. "Therefore, the judge ruled that the plaintiffs' claims challenging the anti-markup rule must be dismissed for lack of jurisdiction," Hindmand said.

THE DARK REPORT observes that the next round of federal rulemaking on anti-markup issues is likely to further restrict the way AP condo (pod) labs may bill the Medicare program. **TDR**

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Federal Court Rules on Specimen Ownership

Growing research value of human specimens leads to lawsuit between physician and university

CEO SUMMARY: Recently, a federal appeals court affirmed a district court ruling concerning who owns human tissue specimens that are stored for research and other uses. While most clinical laboratories routinely discard many types of human specimens after use, any research facility or IVD manufacturer that retains specimens should review the new legal issues raised by this court decision. The case of* Washington University versus Catalona *demonstrates how legal battles over ownership and control of human specimens may lead to significant new legal precedents.

LABORATORIANS OFTEN ASSUME that their labs own and control any human specimens that the lab has analyzed. However, a recent court decision last year signals that legal rights governing who owns human specimens may soon undergo important changes.

For any laboratory or research organization seeking to collect and store specimens for ongoing research, the implications of the federal court decision in *Washington University v. Catalona* need to be studied and understood. Attorneys Anne Marie Murphy and Jeffrey N. Gibbs of **Hyman, Phelps & McNamara**, a law firm in Washington, DC, are closely tracking these developments.

Is Patient Consent Adequate?

In an interview with THE DARK REPORT, Murphy explained that, for pathologists and clinical labs, legal issues of specimen ownership may be limited because these labs generally discard on a regular basis the specimens collected for clinical testing. But the court case raises important questions about whether labs and research facilities that collect samples have adequate consent agreements in place with each patient.

"For normal chemistry and other clinical laboratory testing, everything is typically discarded at the end of each shift or within a specified number of days," said Murphy, who had worked in a hospital-based clinical laboratory before going into law. "That's typically the standard procedure in clinical labs. So, unless a clinical laboratory is collecting specimens or holding specimens in a repository of some kind for research purposes, this ruling may not be applicable.

"But for any laboratory doing research, this ruling could be applicable," she continued. "That holds true for a clinical lab using human specimens to conduct research or gathering human specimens to establish some kind of repository of tissue or body fluids."

In the case in question (*Washington University v. Catalona*), an appeals court affirmed a district court's decision that study subjects *do not* retain ownership rights of their biological tissue samples

that are provided for research. "At first blush, the case appears to support a broad right for research institutions to use banked tissues," wrote Murphy and Gibbs in an article recently published in *IVD Technology*. "But the court was careful to limit its conclusions to the specific facts of the case."

Because of this court decision, Murphy & Gibbs say that the diagnostics research industry should not assume that researchers and institutions can use collected human tissue specimens under all circumstances. "Rather, this case underscores the importance of having clear documentation that study subjects intend to voluntarily contribute their tissue for research purposes," explained the two attorneys.

Facts Of The Catalona Case

Here are the facts of the case. William Catalona, M.D., a prostate cancer researcher formerly at the **Washington University** in St. Louis, along with other researchers at the university, had collected prostate tissue samples for cancer research. When Catalona moved to **Northwestern University**, in Chicago, he wrote to his patients and research subjects to say that he would transfer their specimens and continue his research.

Seeking to retain the specimens, Washington University claimed that those patients had voluntarily donated their biological specimens to the university for research. But Catalona and his patients argued that the patients retained ownership rights of the specimens and could allow them to be transferred or used by others.

Seeking a declaratory judgment, Washington University sued, saying it owned the specimens. The federal district court ruled for the university, and Catalona and his patients appealed. After hearing oral arguments in 2006, the U.S. Court of Appeals for the Eighth Circuit upheld the lower court's decision in June, 2007. In so doing, the appeals court limited its ruling to the facts in the Washington University case.

Consistent Legal Findings

In response to this federal district court decision, Murphy and Gibbs recommend that the diagnostics research industry should not assume that researchers and institutions can use human tissue specimens after collection under all circumstances. "The result of the case—that research participants retained no ownership in the biological specimens they contributed—is consistent with legal precedent," observed Murphy and Gibbs. "But this case appears to be the first to address the ownership of the biological specimens themselves."

THE DARK REPORT observes that any lab collecting and storing human specimens should be aware that ambiguous consent agreements can create legal uncertainties. Murphy and Gibbs suggest that, "Given the narrow and fact-specific holding of the appeals court, before embarking on projects involving tissue repositories, IVD companies should review documentation of the study subjects' intent to ensure that it is consistent with the company's goals with respect to the use of specimens."

The decision in this federal case shows that it could be important to have a lawyer review the patients' consent form. Legal review is often warranted, and generally any company that collects and stores human specimens would have legal affairs staff who could provide the legal consult. Other companies have outside counsel do such review and could prepare a consent form that could be used to protect the lab or research facility's interests.

As genetic research intensifies the need for access to human tissue and other types of specimens, laboratories should expect more legal challenges to longstanding specimen retention practices. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

A simple telemedicine system that incorporates cheap cell phone cameras is being developed by researchers in the United States and Brazil, according to an article in the May 15 issue of the **American Chemical Society's** journal, *Analytical Chemistry*. The goal is to capture medical data, including lab test results, which are transmitted via cell phones to physicians and other medical experts for analysis and diagnosis.

MORE ON: Cell Phones Aid Diagnostics

Researchers in Brazil designed a prototype that combines cell phone cameras with paper-based diagnostic tests that change color when exposed to disease markers. In the study, paper test-strips reacted in contact with artificial urine samples, allowing researchers to identify diseases. Using a cell phone camera, the scientists took pictures of the color-changing test-strips and transmitted them remotely to an off-site expert. The expert accurately measured glucose and protein levels from the test-strip images. Researchers noted that similar tests can be conducted on other body fluids, including teardrops and saliva.

RFID TO TRACK LAB SPECIMENS

The U.S. Air Force (USAF) Surgeon General has asked **Shipcom Wireless, Inc.**, of Houston, Texas, to review the use of RFID technology in Air Force medical facilities. Shipcom also will install RFID systems at the **Medical Center at Keesler Air Force Base** in Biloxi, Mississippi, for tracking laboratory specimens, medications, and possibly patients. Currently, the USAF uses RFID for asset tracking.

TRANSITIONS

• **Lakewood Pathology Associates**, of Lakewood, New Jersey, appointed **David Pauluzzi** as its new President and Chief Operating Officer. Pauluzzi has held executive positions in finance, marketing, operations, and sales for such lab companies as **Quest Diagnostics Incorporated**, **US LABS**, **Ventana Medical Systems**, and the diagnostics division of **Abbott Laboratories**.

TRANSITIONS

• **Donal Quinn** was appointed Chief Executive Officer, **Siemens Healthcare Diagnostics**, a division of the **Siemens Healthcare Sector** in Erlangen, Germany. Since 2007, Quinn has served as Executive Vice President and Chief Customer Officer of the Diagnostics division. Quinn also held a number of executive positions at **Dade Behring** prior to its acquisition by Siemens in 2007.

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DARK DAILY UPDATE

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...the new three-year diagnostic testing pact between **General Electric** and **Eli Lilly**. GE will research and develop companion diagnostic tests for selected Lilly therapeutic drugs that target certain cancers.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, June 16, 2008.