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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Why There's "Bad Blood" Against National Labs

I AM FREQUENTLY ASKED BY WALL STREET TYPES why there seems to be latent, even deep-seated animosity between a large number of local laboratories and both of the two blood brothers. They wonder why, for example, hospital laboratories aren't more interested in doing collaborative ventures with either of the two national laboratories.

Of course, the answer to this question is quite complex. In fact, many hospital labs have amicable relations with the two blood brothers. But it is equally true that a large number of hospital labs around the country view the two blood brothers with disdain. Those of us with at least a decade in the lab industry recognize the sins of many (now defunct) public lab companies in past years were the direct cause of untold problems for all labs. The negative legacy of those public lab companies lingers even today in the areas of Medicare compliance, managed care contracting, competitive pricing, and a host of other issues.

What triggers my thoughts today is a recent example of the type of blood brother behavior often responsible for this lack of respect among local laboratory competitors. Recently THE DARK REPORT visited a major tertiary hospital center in the South. A highly-respected institution, it has found it difficult to establish the collegial business relationship with one national lab that is traditionally found among all laboratory competitors in a community. Because space is limited, the gist of the story is this. Hospital lab uses one brand of liquid preparation Pap smears. National lab uses another brand. When a physician sends, by error, a specimen using the hospital lab's liquid prep kit to this national lab, what do you think happens? Does the national lab send a courier over to the hospital with the specimens in question? No! Does the national lab set the specimen aside and notify the hospital lab that its courier can come by and pick it up? No! The national lab sends that specimen *back to the referring physician* with a note stating that he/she "used the wrong collection kit."

It has always been common courtesy for even intense lab competitors to reroute misdirected specimens in a timely fashion back to the correct laboratory. Why does this national lab perpetuate a practice that only generates ill-will with its laboratory peers in town? Moreover, doesn't the delay in testing caused by this policy affect patient care? Certainly this national lab's local policy in the Southeast United States contradicts the clear public statements on this matter by both national lab CEOs.

For my part, I'd like to offer this as one example as to why public lab companies generally are not well-respected by their local lab peers. It also raises my curiosity about what other examples of uncollegial or uncooperative business practices may be happening around the country. Thus, I invite clients and readers to email, voicemail, or fax their experiences to me at our Oregon headquarters office. I'll be glad to report the results of this informal poll to you.

New Trends in 2003 Affect Clinical Lab Services

Macro trends collectively emphasize a shift in several key aspects of lab management

By Robert L. Michel

CEO SUMMARY: Here's our current list of macro trends that affect clinical laboratories, updated from the last list in January 2000. One bold prediction is that Medicare, as we know it, is on the verge of a major meltdown. Employers and consumers are also new forces to be reckoned with by healthcare providers. Factors other than technology seem to be driving the fastest changes in healthcare today.

FOR THE FIRST TIME since THE DARK REPORT began presenting its list of influential laboratory industry trends, this year's picks are mostly broad-based healthcare trends, affecting the entire healthcare system as well as the clinical laboratories that serve it.

This year's list of ten clinical laboratory industry macro trends contains some surprises. At least seven trends are driving change across the entire American healthcare system—thus affecting clinical laboratories. Only three macro trends are specific to the clinical laboratory industry.

Across the broad range of healthcare services, I see clear and unmistakable signs that lead me to believe that the American healthcare system is about to begin an entirely new and different cycle. The changes wrought during this cycle will be just as deep and radical as those of the last cycle.

That last cycle lasted from about 1988 to 1998. During this period, managed care was the dominant change agent. The widespread adoption of the closed-panel, gatekeeper model HMO during that ten-year period caused deep changes to virtually every aspect of healthcare in the United States.

Because this managed care business model had many failings, it played out. By 1998, PPO enrollment was rising and HMOs were dropping onerous restrictions in an effort to retain beneficiaries and market share.

Now, after four or five years of relative quiet, I predict the American healthcare system has already entered the ear-

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liest stages of another change cycle. Economics will be the overarching driver in this cycle for a simple reason. Employers—as a major source of funding for healthcare services—must control the year-to-year double-digit growth of healthcare spending.

Cut Errors, Save Money

Employers are starting at the place where it is easiest to achieve cost savings: eliminating medical errors. This goal has another advantage; it is difficult for any hospital administrator or physician to be against the concept of "patient safety."

From a cost-management perspective, employers view medical errors as economic "waste." It is money expended to provide a clinical service that failed to meet quality standards. That is why the **Leapfrog Group** and similar employer consortiums have declared that documenting improvements to patient safety is a goal to which all healthcare providers must commit.

It sets up two desirable outcomes for the nation's employers. First, reductions in medical errors will benefit patients. Second, the same reduction in medical errors will cut healthcare costs.

Exceptional Unity

The "patient safety" movement also supports another goal I believe employers have for the American healthcare system. The nation's largest corporations are showing exceptional unity in their intention that hospitals, physicians, and other healthcare providers adopt the management principles of quality that have proved successful for the world's leading firms.

During the past two decades, the American healthcare system has virtually ignored the revolution in business management that has changed commerce worldwide. Less than 25 hospitals have ISO-9000 certification. At the end of 2002, probably 20 hospitals nationwide had a serious Six Sigma program under way.

Not surprisingly, I think you will see one theme woven through many of the ten clinical lab industry macro trends presented here. It is the need for laboratories (and all healthcare providers) to do a better job of collecting accurate and timely data about work processes and using this data to implement improvements which boost quality.

There is plenty of evidence that the American healthcare industry is entering a new cycle of radical change. Such change cycles are not accidental or serendipitous. They are driven by identifiable forces. It is my contention that the main force driving this new change cycle in healthcare are employers.

Employers are starting at the place where it is easiest to achieve cost savings: eliminating medical errors.

This year's list of ten clinical lab industry macro trends are very different in character and impact than our lists from earlier years. It is my view that the forces about to pressure clinical laboratories during the next 12 months will have less to do with specific technologies and more to do with evolution occurring within the overall healthcare system.

That means clinical labs will have little ability to block or influence these trends, because they are occurring "upstream" from laboratory services. However, laboratories do have the opportunity to shape their destiny. These ten macro trends give perceptive lab executives and administrators early warning about the nature of coming changes. This useful business intelligence puts them ahead of the game, but only if timely action is taken.

Lab Industry Macro Trend № 1

one

Patient Safety and Reducing Medical Errors Is Clear Priority

EFFORTS TO IMPROVE patient safety within the American healthcare system will take center stage in 2003.

The most direct impact will be felt within hospitals, larger clinics, and skilled nursing (SNF) facilities. For that reason, hospital laboratories and those labs serving bigger physicians' offices and LTC facilities will become directly involved.

Under the twin banners of "reducing medical errors" and "improving patient safety," a powerful movement is gathering momentum. Various healthcare accreditation and certification bodies are already issuing revised requirements designed to address patient safety concerns.

For example, effective January 1, 2003, the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) instituted a new program titled "National Patient Safety Goals." This program has six specific goals and requires accredited institutions to implement 11 required actions.

During calendar 2003, laboratories will be required to devote time and resources to the subject of patient safety. It is a macro trend which is here today and requires immediate action. THE DARK REPORT identified this trend earlier last year. *(See TDR, January 28, 2002 and July 15, 2002.)*

It is important for laboratory executives and pathologists to understand that the "patient safety movement" is but one management theme connected to a more deeply-rooted trend: increasingly overt and direct actions by employers to change the American healthcare system in ways that lead to better quality outcomes while lowering the overall cost of care.

A closely-related theme and macro trend is the measurement, ranking, and public reporting of provider performance. *(See Macro Trend No. 10, page 13.)* Employers and consumers are asserting their right to know which hospitals and physicians get better outcomes.

The movement to improve patient safety is not a one-time blip on the radar screen for laboratories, hospitals, and physicians. All health providers are embarking on what will be a sustained program of continuous improvement.

Management systems will need to accomplish three goals. First, sources of medical errors must be identified. Second, the management system must have a mechanism that allows the provider to reduce the rate of medical errors over time. Third, the management system must be able to measure and document that the rate of medical errors is declining as a result of deliberate management actions.

THE DARK REPORT believes this will be a management day of reckoning for many healthcare administrators and physicians. The ability to manage in a sophisticated, knowledgeable way will become a key success attribute for all laboratories and pathology group practices.

Lab Industry Macro Trend № 2

two

Accreditation & Certification Requirements Undergoing Shift

EFFORTS TO IMPROVE patient safety will accelerate the work of a small band of champions who've quietly been pushing to reform healthcare accrediting and certification standards.

In recent years, certain dedicated individuals have diligently worked to imbed the principles of quality management into accrediting and certification guidelines. They were united in one goal: to bring into the American healthcare system the same kind of management philosophies and methods used successfully by the world's greatest corporations.

THE DARK REPORT has tracked this little-noticed movement for several years. *(See TDR, July 6, 1998.)* Progress through these years has been painfully slow. But reaction to the **Institute of Medicine's** (IOM) well-publicized report on the excessive number of medical errors is changing that situation. Making the right kind of reforms to accrediting and certification requirements is now a high priority for every healthcare governing body.

All these changes and reforms will have a simple and unifying theme. Healthcare providers will shift away from requirements to provide voluminous documentation that policies and procedures exist and are being followed (with little attention given to outcomes.)

Instead, emphasis will switch to measuring outcomes of work processes, with an additional requirement. Providers will also have to demonstrate (document) that: a) work processes are improving continuously toward desired goals; and, b) these improvements are attributable to deliberate and continuous improvements made to work processes.

One particular element of these reformed requirements represents a tectonic change in the management styles of many healthcare administrators. Accredited providers will have to demonstrate that they are regularly surveying the satisfaction of their patients and other users of their services, and that their patients are receiving increasingly better levels of service.

In short, the eventual consequence of these revamped accreditation requirements is that hospitals, laboratories, and physician groups will become customer-focused. Progressive laboratories and pathology groups that embrace these new management systems will gain competitive advantage as the impact of accrediting reforms ripples through the American healthcare system.

For guidance in understanding these new management perspectives, laboratory managers and pathologists need look no further than their largest vendors. For more than a decade, these companies have been evolving into customer-focused organizations. They understand the process—along with the predictable ups and downs that come with such change.

Lab Industry Macro Trend № 3

three

Employers Taking Direct Action To Control Healthcare Costs

FOR THE FIRST TIME IN DECADES, employers are taking a direct role in reshaping the form and structure of the American healthcare system.

THE DARK REPORT was first in the laboratory industry to identify this important trend. *(See TDR, January 28, 2002.)* One visible sign of this powerful trend was the **Leapfrog Group's** public posting of hospital responses to questions about patient safety-related initiatives beginning January 12, 2002.

Further confirmation of this trend came on June 11, 2002. That day, the **Midwest Business Group on Health** announced its recommendation that corporate members should begin actively telling hospitals and physician groups how to operate their businesses.

One national newspaper characterized the Midwest Employers Group's directive thusly: "an influential health-care group representing many Midwestern industrial giants is urging companies to crack down on medical costs through the same quality-control techniques they employ on the factory floor."

Members of this group include large and influential corporations such as **Bank of America**, **Ford**, **General Motors**, **Kraft Foods**, **Sears**, and **3M**. They are serious about reining in healthcare costs.

The Midwest Business group is telling their members to be more assertive and tell hospitals and physicians how to run their operations. The group is suggesting that hospitals set numerical targets for medical errors and punish low-performing hospitals and medical plans by withdrawing their business. It also wants companies to encourage hospitals and physicians to adopt "continuous improvement" types of programs to standardize treatment of common diseases and boost preventative care.

Providers need to pay attention to this employer trend. A failure to respond may mean loss of access to patients. Over the past seven years, **Motorola** has cut the number of health plans it deals with from 45 down to 25, based on performance. Motorola grades health plans on quality and customer satisfaction.

THE DARK REPORT observes that, since employers are the source of most healthcare payments, their insistence that hospitals and physicians provide accurate data on quality of outcomes, cost, and patient satisfaction carries clout. It is one reason why hospital administrators are suddenly acquiring a new interest in management tools such as Six Sigma and Lean. These tools not only produce this data, but help hospitals achieve higher levels of performance in quality, cost, and service.

This macro trend is closely intertwined with several others, such as improving patient safety and changes in provider accreditation and certification. Collectively, these trends are beginning to change the management systems in all classes of healthcare providers.

Lab Industry Macro Trend № 4

four

"New" Management Systems Arriving Within Healthcare

UNTIL 2003, the number of laboratories operating under a rigorous quality management system numbered in the low double digits.

That changed in 2002. For many reasons, some closely related to other clinical lab industry macro trends described in this issue, growing numbers of hospitals and hospital laboratories have begun to explore and embrace quality management systems like ISO-9000, Six Sigma, and Lean.

In recent years, THE DARK REPORT has chronicled the efforts of early-adopter laboratories to embrace and benefit from these management systems. Among public commercial laboratories, **Quest Diagnostics Incorporated** was first to earn ISO-9000 certification at several regional laboratory sites. *(See TDR, July 6, 1998.)* The lab company is now several years into a corporate-wide Six Sigma Program.

Within **Kaiser Permanente**, at least one laboratory division has earned its ISO-9000 certification. Kaiser Permanente Northwest Laboratories, in Portland, Oregon, has even designed a new lab facility using ISO-9000 principles. THE DARK REPORT believes at least 25 hospitals nationally are certified as ISO-9000 compliant.

Six Sigma and Lean management systems are working their way into hospital laboratories. At **Grant Memorial Riverside Hospital** in Columbus, Ohio, Sandy Hood became the first hospital laboratorian to earn the Six Sigma Black Belt designation. *(See TDR, April 1, 2002.)* **Banner Health** in Phoenix, Arizona now has laboratory Black Belts doing Six Sigma projects in its hospital laboratories.

Until now, most laboratories which adopted management systems like ISO-9000 and Six Sigma did so as a way to improve productivity and increase quality. These laboratories report great satisfaction with the outcomes and have no intention of abandoning these management systems.

Within the hospital sector, what is now giving quality management systems a boost is the drive to improve patient safety and reduce medical errors. Hospital and laboratory administrators recognize they must measure the quality of their outcomes, then take proactive steps year after year to improve that quality. These healthcare executives now recognize the value of management systems developed outside of healthcare in helping them achieve these results.

As noted on the previous page (Macro Trend no. 3), various healthcare accreditation and certification agencies are diligently working to incorporate the principles of modern management into their guidelines. This trend will further pressure hospitals, physicians, and laboratories to adopt the management philosophies infused in ISO-9000 and Six Sigma-types of management systems.

Lab Industry Macro Trend № 5

five

Provider Performance To Be Measured & Publicly Ranked

HOSPITALS AND PHYSICIANS have ardently opposed past attempts to measure performance or make public information about disciplinary action taken against doctors by regulatory agencies.

This time around, it's a battle they've already lost. THE DARK REPORT predicts that measurement of provider performance will become commonplace. Moreover, providers will be ranked on various measures of clinical quality and operational excellence and these rankings will be posted where consumers can easily access them.

Examples of provider measurement are growing monthly. The **National Committee on Quality Insurance** (NCQA) which accredits health plans maintains a Web site that contains a program called the "Quality Dividend Calculator." Based on HEDIS and other measurement data, the program provides employers and health plans with detailed estimates on how much money a company can save by using an accredited HMO.

California's **Department of Health Services** (DHS) now issues "HMO Ratings." These are available on the DHS Web site. **Walgreen's** also posts them in its pharmacies. The ratings are based on statistically-valid measurements of several key HMO quality parameters.

Larger insurers in several other states are instituting incentive compensation programs to provide additional money to physicians who score better on measures of patient satisfaction, HEDIS parameters, and other relevant factors.

In California, the **Integrated Healthcare Association's** (IHA) physician incentive program is called "Pay for Performance." Six of the state's largest health plans are participating. The incentive is paid based on 50% clinical outcomes, 40% patient satisfaction, and 10% information technology usage. The program became fully operational on January 1, 2003.

In New York, it's the **Independent Health Association** of Buffalo that offers physicians more income based on five measures. **Hawaii Medical Service Association** (HMSA), the state's **Blue Cross Blue Shield** plan, has an incentive program that's paid on a mix of measurements that include clinical and patient satisfaction scores, plus administrative processes that include electronic claims filing.

THE DARK REPORT was first in the lab industry to identify this important trend. *(See TDR, January 28, 2002.)* Laboratory executives and pathologists should carefully track the progress employers and providers make in measuring and rewarding physicians and hospitals who do a better job for their patients.

That's because, before long, they will probably see the name of their laboratory or pathology group included in public performance rankings of like providers in their service regions.

Lab Industry Macro Trend № 6

six

Consumers Put Themselves Into Healthcare Driver's Seat

CONSUMERS' direct involvement in how healthcare is delivered to their children, their elderly parents, and themselves continues to grow.

It is hard to quantitate the year-to-year change in consumer behavior relative to healthcare services. But one overlooked fact is key to understanding why laboratories and pathology group practices should pay much closer attention to the needs of healthcare consumers.

According to the **Institute for the Future** (IFTF), a consulting think tank located in Menlo Park, California, about half of the yearly increase in healthcare expenditures is attributable to the use and cost of new technologies. It asks "is 15% of GDP our self-imposed ceiling on national expenditures on health and health care? If an additional 5% would buy proportionately better health, would we be willing to spend up to 20% of GDP on health?"

The IFTF's conclusion is that, because consumers want better health, they will willingly pay additional money to access improved healthcare technologies. For this reason, healthcare spending will probably increase.

Moreover, IFTF believes our healthcare system is already evolving into a consumer-driven industry, one *driven by demand, not supply*. Most physicians, hospitals, and Medicare/Medicaid bureaucrats are not prepared to deal with the consumer as customer—and payer.

IFTF characterizes the consumer succinctly. "New consumers today demand choice, want lots of information, and insist on being treated with the same respect and courtesy that they receive at the **Ritz-Carleton** [pathologists—take note]. They have the analytic skills of a college graduate, a family income of at least $50,000, and computer skills and access to the Internet."

IFTF continues: "Consumers expect to take control of their health by avoiding or preventing illness and by *taking charge of their own healthcare* [TDR italics]. Because a larger portion of healthcare costs is being shifted from employer to employee, the consumer as patient has suddenly become price-sensitive. Finally, consumers are demanding a *Consumer Reports* for health plans, hospitals, medical groups, and individual physicians. Clearly things are not as they used to be."

Laboratories and pathology group practices have fair warning. A consumer-driven system of healthcare, based on what consumers demand, not what health professionals supply, requires that providers adopt a different mindset if they are to remain financially viable.

Because consumers spend their money rationally, it may not automatically be a bad thing if healthcare spending climbs from year-to-year—but only if this increased spending represents consumers getting more benefits for their healthcare dollars!

Lab Industry Macro Trend № 7

seven

Dwindling Supply of Med Techs Changing Laboratory Operations

IT IS WIDELY-RECOGNIZED that the number of technically-trained laboratorians will be inadequate to meet the needs of the laboratory industry in future years. This situation is occurring for two primary reasons. One is demographics, the other is supply.

Much attention has been given to the fact that, of the certified medical technologists (MT) and medical laboratory technicians (MLT) working today in laboratories, a large portion are over the age of 40.

It is a demographic bulge that mirrors the Baby Boomer bulge. This demographic group is moving toward retirement in large numbers. At the same time, the supply of newly-certified lab techs remains inadequate to fill the number of open positions currently posted by the nation's laboratories.

This situation is well-known to almost all laboratorians. What is less understood is the different impact this will have region-by-region across the country, as well as to the laboratory profession as a whole.

THE DARK REPORT believes that med tech staffing will not reach a crisis point—where certain laboratories in the United States must decline to perform tests because they have insufficient technical labor resources to do the work.

Instead, the economic forces of supply and demand will come into play. Many laboratory administrators already tell THE DARK REPORT they've raised med tech wages and enriched recruiting bonuses to attract new hires. In many cities around the United States, laboratory administrators from different labs are banding together to support local community college and university training programs—with both extra funding and help in recruiting candidates and providing them on-the-job training opportunities. *(See TDR, October 7, 2002.)* These steps will increase the supply of trained technical labor for laboratories, although it will take several years to accomplish.

The other main strategy now used by laboratories to cope with a limited labor supply is to make existing technical labor more productive. One approach is to substitute automated instrument systems and reassign the med techs freed up to other areas of the laboratory.

Boosts to labor productivity can also be accomplished by intelligent redesign of work flow through the laboratory. Independent of laboratory automation, there are many ways to make technical labor more productive. This is exactly what the management systems like ISO-9000, Six Sigma, and Lean have done for companies outside healthcare during the past two decades.

In site visits to laboratories throughout the United States, THE DARK REPORT sees these solutions coming into play. Higher wages, more astute workflow redesign, and shrewd use of targeted lab automation projects are becoming increasingly common.

Lab Industry Macro Trend № 8

eight

Incremental Automation Finds Growing Favor in Laboratories

PROBABLY NO SINGLE AREA of lab management has been as frustrating as laboratory automation over the last decade.

Introduced under the banner of "total laboratory automation" (TLA) in the first half of the 1990s, the earliest attempts with first generation TLA equipment were often financial and operational disasters.

Over two-year and three-year cycles since the mid-1990s, diagnostic instrument manufacturers have introduced incremental improvements in TLA equipment, along with stand-alone solutions for task-oriented automation, modular automation, and workstation consolidation.

Judging by the sales of products which can be loosely described as "automated solutions" over the past 24 months, an expanding number of laboratories are taking first steps to restructure their lab operations and incorporate automation in their new workflow configurations.

A good term to describe this trend is "incremental automation." That's because laboratories are buying just one piece of the overall lab automation package. Once implemented, labs are free to pursue another automation project. But each of these "incremental automation" projects are much cheaper than the full TLA solution.

Most importantly, these incremental projects are easier to implement and the economic costs and benefits can be more accurately predicted. Each successful automation project makes it easier to automate other work processes in the laboratory in future projects.

In contrast to the "incremental automation" approach, the number of laboratories willing to convert to the full TLA solution remains tiny. THE DARK REPORT believes this is true for two reasons. First, most larger laboratories remain skeptical about their ability to successfully implement a cost-effective TLA installation.

Second, it remains difficult for any prospective buyer of TLA to get accurate, full, and reliable information about the costs, benefits, and ROI (return on investment) from the existing generation of TLA products. Neither existing customers nor vendors have been willing to publish rigorous data about the performance of these products in real lab settings.

Thus, many lab buyers assume, rightfully, that the lack of thoroughly documented information in the public domain means that the performance of existing TLA installations still has room for much improvement.

In the meantime, "incremental automation" is proving to be an effective way for labs to improve labor productivity, work around shortages of technical labor, and expand capacity to meet testing growth in their hospital or health system. THE DARK REPORT believes management systems like Six Sigma will encourage more lab automation, because such systems allow lab directors and pathologists to deploy such solutions with greater effectiveness.

Lab Industry Macro Trend № 9

nine

Different Marketing Models For New Diagnostic Assays

HERE'S A TREND with the potential to radically change the way laboratories buy test kits and offer assays to physicians and consumers.

As this trend unfolds, it will shift the budget emphasis within clinical laboratories. It may alter the basic test menus offered by today's higher-volume laboratories.

This trend fundamentally changes how new diagnostic technology is brought to the clinical market. Traditionally, most new test assays were marketed through the major diagnostic manufacturers. New assays were developed to run on existing instrument platforms and were offered, virtually without restriction, to any laboratory willing to buy the test and offer it to their physician-clients.

The new marketing model for diagnostic tests is radically different. It starts with a proprietary test that may be patent-protected. The objective is to maximize profits generated by the clinical use of this specific test technology. In many cases, the new test technology must be run on custom-designed instruments, a separate source of revenue to the manufacturer.

In most aspects, these diagnostic test developers are using the pharmaceutical industry's marketing model. So, the diagnostic test company has its own sales force which visits physicians' offices and "details" the doctors with information about the lab test and how to use it on their patients.

The diagnostic test company wants to build brand awareness for its lab test. Just as "Prilosec®," "Claritin®," and "Viagra®" have become well-known among consumers, the makers of "ThinPrep®," "TruGene®," and "OraSure®" want similar consumer recognition for their lab tests.

To date, one of the best examples of this new diagnostic test marketing model is **Cytyc Corporation's** ThinPrep test. It is patent-protected and has brand recognition with both physicians and consumers. It is a premium-priced test relative to the conventional Pap smear and, in the earliest stages of its market launch, only selected laboratory "partners" were allowed to buy the test and offer it to their lab's clients.

THE DARK REPORT has covered this emerging trend in earlier issues. HIV mutation and viral load test assays have many elements of this new marketing model. *(See TDR, June 24, 2002.)* Hospitals and health system laboratories are already experiencing the budget-busting aspects of this esoteric testing business strategy. On pages 14-17 of this issue, THE DARK REPORT provides a detailed briefing on how specialty esoteric test companies are bypassing local labs and marketing high-priced, multi-panel tests directly to physicians.

For the laboratory industry as a whole, there are many troubling aspects involved in this new marketing model. As time passes, their full financial impact will be revealed.

Lab Industry Macro Trend № 10

ten

Medicare's Impending Meltdown Will Scramble Healthcare

MOST EVERYONE AGREES THAT Medicare has serious problems that require significant reforms as soon as possible.

THE DARK REPORT concurs, and is willing to go out on a limb and prophesy that a meltdown of the Medicare program as we know it today will happen soon, in as few as five years.

Medicare has become the dominant force in the American healthcare system for two reasons. First, it covers a growing number of the nation's population, with aging baby boomers soon to swell that number at accelerating rates.

Second, Medicare's regulations, policies, and price schedules for provider reimbursement have increasingly been incorporated by private payers into their own reimbursement criteria. Thus, major changes to the Medicare program immediately cause similar ripples throughout the private health insurance industry.

Medicare's impending meltdown is rooted in the disconnect between Medicare's pricing structure and reimbursement guidelines and the private marketplace. In an editorial published on December 31, 2002, *The Wall Street Journal* described Medicare as a "federal insurance program that evolved into a system of Soviet-style price controls in the 1980s. Medicare pays a fixed amount for a treatment, regardless of costs..."

Laboratories are familiar with the negative consequences of Medicare's pricing structure. Part B lab test pricing is based on a 1984 menu of lab tests (that has never been updated in 18 years) which is reimbursed at well below Medicare's median national price. In only three of the past 16 years has the lab fee schedule received an increase that equals or exceeds the CPI (Consumer Price Index).

Even as Medicare officials acknowledge the negative impact that recent reductions in physician professional fees will have, neither they nor Congress took action to forestall these cuts. In Oregon, THE DARK REPORT is hearing anecdotal stories about surprisingly large numbers of physicians giving service termination notices to their Medicare patients. These physicians are responding to lower Medicare fees by excluding Medicare patients from their practice.

Because Medicare has mutated into a bureaucratic price-fixing colossus, it has lost touch with the marketplace. Just as the Soviet Union collapsed 13 years ago, Medicare as we know it today is headed for a similar economic meltdown.

At a minimum, bureaucrats at Medicare will soon meet the buzzsaw of baby boomer consumers—who want physician choice and access to the latest technology. These consumers, as taxpayers and voters, will drive reforms to the Medicare/Medicaid system we know today. What the final picture will look like is anyone's guess. But choice and access to new healthcare technology will certainly be part of the post-reform Medicare scheme. TDR

New Market Channel For Esoteric Testing

Firms with new esoteric tests bypass laboratories to go direct to physicians

CEO SUMMARY: It's a new marketing model for specialty esoteric tests that presents both clinical and financial challenges to hospital and health system laboratories. Niche labs offering esoteric tests are sending sales reps directly to physicians and bypassing pathologists and lab directors at local hospital laboratories. These tests come bundled in high-priced panels and often offer only limited clinical utility.

HOSPITAL LABORATORIES FACE a new challenge to their budgets: high-priced esoteric lab tests marketed directly to physicians.

It's a marketing model that bypasses local hospital laboratories. A small, but growing, number of specialty laboratories send sales reps directly to physicians to offer high-priced esoteric tests that frequently must be ordered in multi-test panels.

The consequences of this marketing model on hospital labs are several. Physicians begin ordering esoteric tests which may have limited clinical value. Pathologists, intentionally left out of the educational loop by the esoteric testing provider, are unable to provide effective support to clinicians ordering such tests. High prices of these tests are budget-breakers to many hospital and health system laboratories.

Not surprisingly, pathologists and laboratory administrators view this developing trend with concern. On one hand, this new marketing model comes between the traditional relationships local laboratories maintain with physicians, both in and out of the hospital. On the other hand, it creates budget-busting bombs for hospital labs when the bills for these high-priced esoteric tests are presented.

Taking Decisive Action

In some health systems, pathologists are instituting policies designed to avoid the unpleasant outcomes of this new lab test marketing strategy. In Detroit, Michigan, the ten-hospital **St. John Health System** is among the first to take decisive action.

Its laboratory division now maintains extra vigilance on all esoteric reference laboratory testing. "Less than 2% of all lab tests are referred outside the St. John Health System," stated Bruce A. Jones, M.D., Director of Clinical Pathology at **St. John Hospital and Medical Center**. "We closely monitor tests with high-ticket prices and low reimbursement that cost the laboratory significant dollars.

"We believe this direct-to-physician marketing trend will only in-

New Management Issues For Clinical Paths As Test Vendors Adopt Drug Sales Model

TAKING A PAGE from the pharmaceutical industry, diagnostic test vendors and specialty esoteric testing lab companies are changing the way new laboratory assays are marketed to the clinical community.

One consequence is the potential overuse of high-priced multi-test panels that offer limited clinical value and even less reimbursement. The referring laboratory is stuck paying "list price" to the testing lab, an amount which is frequently several thousand dollars. Frequently the patient may have to pay as many as 20 or more deductibles, or—depending on their insurance—bear the entire cost of these specialty esoteric tests.

Test Utilization Controls

This is a portent of the future as laboratory medicine branches more into the realms of genomics, proteomics and pharmacogenomics. Already pathologists, and laboratory specialists recognize that they need to develop better controls over utilization of esoteric tests. To do nothing means that a growing portion of the lab testing budget is absorbed by specialty esoteric testing.

The laboratory industry went down this same road with point-of-care testing (POCT). The solution turned out to be proactively working with physicians on education, utilization review, outcomes assessment, and disease diagnosis. In such activities, the pathologist plays a key role controlling these new healthcare costs.

"More than ten years ago, companies were marketing POCT directly to physicians and hospital administrators," stated Bruce A. Jones, M.D., Director of Clinical Pathology at St John Hospital and Medical Center in Detroit, Michigan. "We recognized that, if we weren't careful, it would become a significant lab budget issue and the laboratory would have little control over both the type of tests and the location where these tests were to be performed.

"Within our health system, the laboratory and clinicians worked together to consider issues such as turnaround time, processing the patient more quickly in ER, using POCT to help ICU patients transfer more rapidly to an area with a lower level of care, quality control, proficiency tests, knowledge of staff performing the test, drawing blood, and the like," said Dr. Jones.

"We've come a long way in ten years, and our education to the nursing staff and physicians has paid off," declared Dr. Jones. "We have a multidisciplinary committee that looks at the whole picture. Our nurses are now more knowledgeable and very sophisticated about POCT.

"Seldom do we see an unreasonable request for a new POCT," he added. "The process is simple. They complete a form, the committee reviews the request, they plead their case to the committee, and all parties are usually satisfied with the outcome because they recognize all interested parties played a part in providing the appropriate level of patient care."

Collaboration With Labs

In many hospitals and health systems, point-of-care testing has become an accepted part of the laboratory test menu. Generally this has been accomplished because POCT vendors collaborated with laboratory professionals in their marketing efforts to introduce such tests into clinical use.

But the direct-to-physician marketing tactics employed by some specialty esoteric test vendors cuts laboratory professionals "out-of-the-loop." The marketing model which worked for pharmaceutical companies may not translate successfully for esoteric testing. Early indications are that pathologists and laboratory administrators will be forced to develop management controls over physician ordering of specialty esoteric lab tests in their hospitals or health systems.

crease, which is why St. John's decided to take a proactive stance," he added. "There are aspects of this esoteric test marketing model which should give pathologists and all clinicians pause."

Niche Lab Marketing Ploys

Dr. Jones explained some of the marketing strategies used by niche esoteric test providers. "In the Detroit marketplace, sales reps from these niche lab companies go directly to specialist physicians and attempt to develop a consultant relationship with them. Among other things, these sales reps suggest and imply there may be some benefit gained from the relationship by involvement in possible clinical trials. At all times, they leave the referring laboratory out of the loop," he said.

"To physicians, these sales reps portray their esoteric tests as having perceived value, offering cutting-edge technology, and eligible for reimbursement by payers," added Dr. Jones. "Their tests are available only as 'disease panels'—no single tests allowed. Frequently we find that only one or two tests in the panel are truly useful for effective treatment of the patient.

Costly To Referring Lab

"In explaining reimbursement, these niche esoteric lab companies provide physicians with appropriate CPT codes, but the sales reps invariably fail to state that reimbursement may be only 10% to 50% of what the testing lab charges for the panel of tests," Dr. Jones noted. "Consequently the tests are costly for the referring laboratory. Because some of these panels are priced at thousands of dollars, this can be a major problem for small community hospitals."

Complexities of billing and payment mechanisms within a hospital system create additional challenges for pathologists attempting to maintain budget control. "Within the hospital, all too often there is a disconnect regarding reimbursement for these specialty esoteric tests between laboratory administration, the finance department that issues payment to the esoteric testing lab, and patient accounting," he said.

"Frequently there is no direct comparison between third party reimbursement for a CPT code and the charge for the test from the niche labs," he continued. "The reimbursement may be significantly different than the niche lab's charge for the tests. Unless someone within the hospital devotes careful attention to the detail of these transactions, significant dollars can be lost. Referring hospital labs cannot afford to subsidize niche labs."

Real-Time Intervention

Within the St. John Health System, pathologists devised a real-time active intervention step. The goal is to better assess true needs of the physician and patient before proceeding with a test send-out. "Whenever a niche laboratory panel test is ordered, our sendout personnel complete a form," explained Dr. Jones.

"It includes the cost of the panel, individual tests in the panel, CPT codes, and expected reimbursement," he said. "A pathologist reviews this information, along with the diagnostic usefulness of the tests, then contacts the ordering physician before the test is sent out."

St. John pathologists have called several physicians to make them aware of the true cost and reimbursement of a panel, possible patient responsibility for the tests' costs (depending on their insurance), and the diagnostic usefulness of the tests. "We discuss the panel's value to the treatment of the patient," he noted. "All we try to do is make them aware of what they have

ordered, *before* we send the test out. The majority of physicians we've contacted with this information have cancelled the panel of tests."

St. John Health System is not alone in developing a response to this new marketing model for specialty esoteric tests. Across the country, THE DARK REPORT sees a growing number of hospital and health system labs initiating similar protocols for educating clinicians about the complete details of an esoteric test panel's clinical efficacy, true cost, and actual reimbursement.

Trend To Increase

THE DARK REPORT predicts that direct-to-physician marketing of specialty esoteric testing will continue to increase. Within the biotech community, there are relatively large numbers of companies working to develop diagnostic assays. Their business plan is to protect these tests with patents, brand them to physicians and consumers, then sell them at premium prices. *(See TDR, June 24, 2002.)*

Because existing laboratory administrators and pathologists are savvy about the clinical benefits and the true costs of these tests, they are resistant to sales efforts to encourage them to embrace such tests and offer them to client-physicians. The specialty esoteric test companies understand this, which is one reason why they take their sales and marketing message directly to physicians.

Among the companies most frequently identified with using these business practices are **Athena Diagnostics**, **Myriad Genetics**, and **ViraCor Biotechnologies**. One of the fascinating unknowns about this unfolding story is whether these types of esoteric testing companies create substantial ill will among established hospital and health system laboratories because of the budget-busting effect this new marketing model has on their finances.

If this happens, it will not be good for labs, for physicians, nor for patients. As Dr. Jones observes "Technology is advancing in the areas of molecular diagnostics, proteomics, and pharmacogenomics. As it does, clinical and anatomic pathology should be at the forefront of educating physicians in areas of detection of genetically-based health risk factors, evaluation of treatment options, and effectiveness and monitoring of patient risk factors. To accomplish these goals, the lab community needs to work in a collaborative fashion with esoteric testing sources."

Further, general trends in the healthcare system may work against this strategy of high-priced, all-or-nothing specialty test panels. The market strategy may be most profitable for the lab company, but it doesn't provide the most cost-effective care for individual patients.

Resistance By Payers?

At some point, payers will weigh in. Once utilization becomes a bigger issue, and lab computers and insurance companies get better at monitoring ordering patterns, high-cost testing without adequate clinical justification will be challenged more often.

In the short term, vendors who choose to circumvent the longstanding role of the local laboratory as longstanding gatekeeper for tests ordered within the hospital or health system risk alienating laboratory professionals. In the long term, the healthcare system may accept the direct-to-physician market channel for introducing specialty esoteric tests—but only if the tests deliver recognizable clinical value at a reasonable price. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

December proved to be an eventful month for many companies in the lab industry. Here's some key items of interest, many to be followed in more detail in coming issues of THE DARK REPORT:

• **AmeriPath, Inc.** is to be sold to **Welsh, Carson, Anderson & Stowe**, a private equity firm in New York. Welsh Carson will pay approximately $840 million and take AmeriPath private. However, a dissident shareholder believes the deal is structured to favor Welsh Carson and AmeriPath executives over existing shareholders. A spicy legal fight may be brewing.

• **Cytyc Corporation** was hit with numerous shareholder suits in December. Even the infamous **Milberg Wiess Bershad Hynes & Lerach** piled on. Cytyc was accused of issuing "false and misleading statements to the market." Cytyc's share values plummeted during 2003.

• **Beckman Coulter, Inc.** purchased SNP genotyping instruments and other assets from **Orchid BioSciences, Inc.** as a way to beef up its genomics-based technology and product offerings for research and clinical use.

CONSUMER USE OF PAYER WEB SITES GAINS FAVOR

During 2002, consumer use of on-line self-service options offered by health insurers increased by an average of 8% per month! In the sixth semi-annual survey conducted by **Cap Gemini Ernst & Young**, 23 payer Webmasters managing 97 managed care Web sites were interviewed. More payers are increasing the Web-based services they offer their beneficiaries. Cap Gemini Ernst & Young report that 30% more payers now allow members to order prescription drugs online, 10% more offer online explanations of benefits, 8% more allow patients to change physicians online, and 8% more allow online claims tracking.

MORE ON: Web Services

A monthly growth rate of 8% in consumer use of Web-based health insurer services is significant and will soon affect laboratories and pathology group practices. As consumers become Web-savvy and use the Internet to conduct more business with their health insurers and physicians, it is logical to expect that they will want to interact with their laboratories in the same fashion. Labs should be developing a Web strategy that responds to these changing consumer expectations.

Major laboratory consolidation and restructuring is under way in the United Kingdom. It involves almost every hospital in the nation. To help educate our British cousins about the lessons of lab consolidation learned in the United States and Canada *before* they embark on consolidation projects, THE DARK REPORT and its editor, Robert Michel, will be in London on February 3-4, 2003 to co-produce "Frontiers in Laboratory Medicine" (FiLM). This meeting will bring British laboratory leaders face-to-face with their North American counterparts to learn what really works—and what doesn't—when consolidating multiple hospital laboratories. It will be the first opportunity for most British laboratorians to learn the best and worst of the Canadian and American lab consolidation experience.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, February 10, 2003

PREVIEW #1

EXECUTIVE WAR COLLEGE

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Case Study: Michigan Co-Tenancy Laboratories

It's the nation's largest laboratory co-tenancy. Owned by 17 health systems and hospitals, it numbers 24 participating hospital laboratories. Its extensive menu of routine, reference, and esoteric tests improve lab services while generating substantial savings. Continuing growth at Michigan Co-Tenancy Laboratories (MCTL) demonstrates its viability as a way to create regionalized lab services among competing hospitals.

Full program details available soon—call 800.560.6363
or visit darkreport.com

UPCOMING...

- ***Assessing Medicare Compliance In Physicians' Office Testing Segment: How Competition Is Lowering Standards.***
- ***Is Cytyc's Position as "King of Liquid Prep" Threatened by Recent Events?***
- ***How AmeriPath's Pending Sale May Affect Local Pathologists.***

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