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SPECIAL EDITION

TDR's White Paper on the Lab Industry

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

Converting Business Intelligence Into Lab Profits

AS THE NEW YEAR'S EVE CELEBRATION RINGS OUT THE YEAR 2000 and welcomes 2001, THE DARK REPORT will celebrate more than five years of service to the clinical laboratory industry and the pathology profession.

It has certainly been an extraordinary five years for laboratories throughout the United States and the world. All segments of the clinical laboratory industry have undergone traumatic and widespread restructuring. So it is only appropriate for us to devote this entire issue to our "White Paper" on the laboratory industry. If you think the rate of change in the last five years was exhausting, just wait. We are in a quiet period today. But over the next 18 to 36 months, a torrent of new diagnostics technology and cost-effective information services will hit the laboratory marketplace.

To help our clients and regular readers with their strategic planning, THE DARK REPORT offers this comprehensive look at the laboratory industry and its near term directions. As usual, Editor-In-Chief Robert Michel is provocative. I don't expect all of you will agree with 100% of what he says, but I'll bet this White Paper causes you to think differently about several key issues affecting your laboratory. If so, then we will have done our job once again.

The market insights and business intelligence you glean from this White Paper represent a lot of hard work and strategic analysis. Our editor tends to understate where he develops these ideas and conclusions. I think it is fair for you to know that he travels between 20 and 26 weeks per year visiting laboratories, pathology group practices, and lab industry vendors throughout several countries. Moreover, he is regularly engaged to participate in strategic consulting sessions with a remarkable range of companies and individuals.

It is this extensive, and in some cases unlimited, access to such a broad range of lab industry leaders and early adopters which shapes the useful business intelligence you regularly access from the pages of THE DARK REPORT. The quality of this information is a priceless asset for a lab executive who can absorb its relevance and apply it to the success of his or her laboratory organization. TDR

DARK REPORT Presents "White Paper" Summary Of Laboratory Industry

Unmet challenges of the 1990s still require appropriate response by lab industry leaders

By Robert L. Michel

INTRODUCTION: *To celebrate five eventful years of service to the laboratory industry and pathology profession, THE DARK REPORT is pleased to present its first "White Paper" on the laboratory industry. Our goal is help laboratories and their suppliers accurately identify relevant market dynamics and understand how and why these market forces will affect the stability and financial fortunes of laboratories during the first 24 to 36 months of this new decade.*

IN THE FUTURE, I BELIEVE the year 2000 will be seen as a pivotal time for the clinical laboratory industry and the pathology profession.

Calendar year 2000 is a theater curtain separating us from the tumultuous decade of the 1990s and focusing our attention on the exciting opportunities predicted for medicine during the first decade of the new century.

Whereas the 1990s were a time of consolidation and cutbacks across the laboratory industry, expect the first decade of the 2000s to be a time of relative growth and prosperity for clinical laboratories and the anatomic pathology profession.

I am among those who agree that a flood of new technologies will find direct application in diagnostic testing. But I am not a Pollyanna. Serious obstacles lie ahead for the laboratory industry. Market trends rooted in the 1990s will continue to challenge lab executives and business-minded pathologists.

Effectively, this means that lab managers must continue to develop viable business strategies for their laboratory organizations. These strategies must address and solve such marketplace pressures as: 1) the need to continuously reduce the cost of laboratory testing; 2) coping with inadequate lab testing reimbursement; 3) improving the productivity of medical technologists and laboratory instruments; 4) increasing the added value of lab test-

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

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ing for physicians, patients, and payers; and 5) meeting the demand for enhanced laboratory informatics products and services by lab users.

The goal of this White Paper is to identify and articulate the fundamental factors currently at play in the competitive marketplace for laboratory testing services. This includes hospital labs as well as commercial labs. It is my belief that, at the local level, the trend of lab regionalization will increasingly blur traditional differences between hospital labs and commercial laboratories.

Laboratory Industry White Paper Topics

This White Paper is organized into four chapters:

This White Paper offers basic premises about the organization and management of laboratory organizations in the United States. It includes a retrospective look at key market trends of the 1990s and the lab industry□s failure to respond effectively to those trends. Management lessons learned (and not learned) during the 1990s will continue to have relevance during the 2000s.

I would like to be clear on one point. This White Paper is *not* a prediction of the long term future of the lab industry. There are plenty of experts writing □what if□ pieces□ about our future.

Rather, the emphasis on this White Paper is squarely on the □here and now.□ It is about marketplace dynamics and healthcare trends directly influencing the organization of laboratories and the way they are operated. Stated another way, this White Paper is intended to help people managing laboratories and pathology group practices understand why some lab business models are successful and why others are failures.

Each chapter in this White Paper deals with a specific topic in laboratory management. Chapter One discusses the general business premises that characterize the laboratory industry. Chapter Two identifies key strategic business failures of the 1990s. These help us understand why the lab industry continues to be challenged to implement effective responses to healthcare forces and trends still shaping the market for laboratory testing services.

Different Testing Segments

Chapter Three provides an overview of the different testing segments that make up the American laboratory industry. Chapter Four is a summary and overview of the laboratory industry. It attempts to □connect the dots□ and give a fuller picture of what the laboratory industry is today and how it will evolve during the next 24 to 36 months.

Having taken on the difficult, if not impossible, job of evaluating the laboratory marketplace and its relationship to a changing healthcare system, I welcome comments and input from our clients and regular readers. The best of these responses can be printed in future issues of THE DARK REPORT. My hope is that this White Paper stimulates positive dialogue among your lab□s executive team.

lab industry White paper

Business Premises Underlying Laboratory Industry Dynamics

CHAPTER 1

This chapter addresses the characteristics of the laboratory industry which define the starting point for changes and ongoing evolution. The eight business premises listed in this White Paper describe unique situations which directly influence the ability of clinical laboratories to serve the medical community.

The relevance of these business premises becomes apparent whenever a laboratory undertakes the strategic planning process. Assuming that each of these eight premises accurately describes one element at play in the laboratory testing marketplace, then it's necessary for a laboratory to develop a strategic plan which successfully addresses the challenges or opportunities represented by these eight business premises.

Premise #1

Inadequate Management Staffing at Most Laboratories

Most laboratory organizations are staffed with inadequate management resources. This makes it difficult to run the lab's daily operations and simultaneously implement strategic management changes necessary to meet the needs of the changing healthcare marketplace.

This is a crucial point to understand. It is one characteristic of the laboratory industry which sets it apart from profitable industries outside healthcare. The form and manner of staffing middle and senior managers within Fortune 500 corporations allows these companies to competently handle daily work responsibilities and still initiate a variety of strategic business initiatives. Experience has taught these companies that it is essential to accomplish both objectives. If understaffing of management prevents that from occurring, the result is usually financial disaster.

In contrast, management staffing levels common to most Fortune 100 corporations are seldom found within clinical laboratory organizations. It is safe to say that the majority of laboratory organizations in the United States, whether hospital-based or independent commercial lab companies, do not have adequate middle and senior management resources.

This "understaffing" of management has an important consequence: managers are forced to spend all their time on daily work issues. They have

relatively little time for either strategic planning or the implementation of changes necessary to keep their lab financially viable and competitive with other laboratory providers in their community.

Metaphorically, staffing a lab organization with insufficient management resources to deal with day-to-day operational matters and still have the capability to think and act strategically is like the farmer eating his seed corn. It buys time in the short term, but proves disastrous over the long haul.

Unfortunately, the continuing cost pressures on most laboratories will make it difficult for them to beef up their management teams. This will be particularly true in the hospital laboratory segment, since hospital administration must approve requests to add additional management positions and funds are tight throughout the hospital industry.

In all probability, hospital laboratories and most commercial independent laboratories will continue to be inadequately staffed with middle and senior management during the next few years. This situation increases the complexity of responding to changing circumstances in the healthcare community served by clinical laboratories.

Premise #2

Inadequate Capital Resources at Most Laboratories

Every laboratory organization needs adequate capital, just like it needs an adequate staff of middle and senior managers. Unfortunately, most hospital laboratories and commercial independent laboratories are starved for capital.

This leaves laboratories with insufficient money to explore new technologies, set up additional testing capability, enhance laboratory information systems, and expand facilities such as patient service centers and rapid response labs. There is also inadequate money to properly invest in developing and training people. This directly affects the lab□s ability to access outside management and clinical expertise through consulting arrangements, joint ventures, and collaborative efforts with potential lab testing partners.

There are many reasons why this is true, particularly within the hospital laboratory segment. However, this does not alter the fact that most laboratory organizations lack the capital they need to invest in physical assets, staff, and worthwhile new lab testing opportunities.

Within the anatomic pathology profession, insufficient capital is a widespread phenomenon. But it should be noted that, in this case, it is generally the pathologist-partners themselves who deny their group practice the capital (and management acumen) needed to respond effectively to changes in their local healthcare marketplace.

Unfortunately, many pathologists see the □business□ of anatomic pathology as static, not dynamic. They operate their pathology group practices so as to protect existing sources of income. This mindset is one reason why they underinvest in their own business.

Sufficient capital is the lifeblood for any laboratory organization. Without adequate capital investment, laboratories and pathology group practices are limited in how they respond to new laboratory technologies and competitive changes in the healthcare marketplace.

Premise #3

Healthcare Remains A Local Service

This premise is simple: healthcare remains a service best delivered by local health providers. For clinical laboratories, this is an important business assumption.

During the decade of the 1990s, a number of national healthcare corporations emerged. Remember the business model of the "roll-up" company? This was a national corporation which purchased independent health providers in various cities and regions throughout the United States. The argument was that a unified, national corporation could gain competitive benefit because of superior management skills and economies of scale.

THE DARK REPORT chronicled the sad financial stories of many of these roll-up companies, such as **PhyCor**, **MedPartners,** and **Columbia/HCA Healthcare**. In such healthcare segments as physician practice management (PPM), for-profit hospitals, long term care, and home healthcare, national roll-up companies failed in spectacular fashion.

Of course, the commercial laboratory segment shared in this widespread financial misery. By the mid-1990s, all the publicly-traded lab companies were suffering deep losses. Many went into bankruptcy or merged. The lab companies which survived were forced to lay off sizable numbers of their employees and shrink the network of stat labs, patient service centers, and couriers that supported their lab testing operations.

The key lesson which emerged from this experience is that healthcare remains a service which is best delivered locally by people and companies who are close to the community and the people they serve. Decisions made by corporate leaders in a remote headquarters thousands of miles away are often at odds with the needs of individual communities.

This means that laboratories with direct involvement in the regional community they serve have a competitive advantage over laboratories based outside that community. This is the specific advantage the thriving hospital lab outreach programs use to their financial benefit.

Having made this premise about healthcare being local, it should also be said that there are national companies which understand how to give their local business units effective discretion to service their communities' unique needs. This is the formula Sam Walton used to launch **Wal-Marts** in small, rural towns across the country. His company rapidly grew into the nation's biggest retailer. Wal-Mart is not alone in this accomplishment.

But the lesson is consistent. Healthcare's local needs are best-served by a provider located in that city. Success as a national healthcare company only comes because local business units operate not as clones from city to city,

but as distinctive local providers closely aligned to the unique needs of their regional service area. In laboratory testing, being close to the customer is a distinct advantage, if not an essential element, of financial success.

Premise #4

Customer Returns as King; Consumer Choice Creeping Back into Healthcare

Healthcare in the United States is a uniquely contorted economic construction. The consumer has been placed at the the end of the line, with results that frequently disappoint everyone.

It is the employer which picks a limited menu of health plans for its employees and pays most of the premiums. It is the health plan which proscribes and limits how the consumer can choose his provider. The provider serves the consumer, but must look to the insurer for payment. In this arrangement the consumer has reduced power to select providers and to pay them according to the quality of service they deliver.

Sixty years ago, consumers were in total control over their healthcare options. It was the emergence of indemnity and managed care insurance plans during the past 60 years which fundamentally altered the traditional relationship between customer and physician.

Formerly the consumer chose a doctor and was responsible for payment. This created a simple accountability. If the doctor did a lousy job or was too expensive for the quality of care he provided, consumers would either refuse payment or choose other doctors.

But in the American health insurance system, a variety of parties began to interfere with this basic relationship. It caused many distortions in the economics of healthcare and the quality of services provided to consumers. Government health programs such as Medicare and Medicaid further exacerbated this problem, because bureaucrats take actions which constrain free market forces from correcting problems and encouraging experimentation and worthwhile innovation.

I believe this situation reached its worst point in the middle-1990s. At this time, a significant number of middle-class Americans found themselves in a closed panel HMO with a gatekeeper physician controlling their access to medical care□and they did not like it!

Since those years, there has been a clear trend toward: 1) higher enrollment in PPOs and similar less-restrictive health plans; and 2) liberalization by HMOs themselves in how consumers can make decisions about their providers and their care.

It is now widely recognized that growing numbers of consumers are becoming highly sophisticated and knowledgeable about health issues. These consumers are asserting more control over all aspects of their healthcare. On the Internet, searches for health information and services now outrank all other categories.

This trend of increased consumer involvement will bring a radical change to clinical laboratory practices. As regulations and state laws are changed to allow consumers access to their laboratory testing data, it will become necessary for laboratories to deal with patients as decision-makers on a level that is almost comparable to how they currently deal with physicians.

Laboratory executives and pathologists will soon see Congress and the states pass legislation that expands patients' control over their health care. Increasing numbers of patients will want to communicate directly with the laboratory doing their medical testing. These same patients will expect and demand that laboratories meet their needs and expectations. Laboratories which fail to respond to changing consumer expectations will find themselves at a competitive disadvantage in the marketplace.

Premise #5

Acceptance of Management Philosophies Emphasizing "Customer First," and Workflow Process Design

Just as healthcare is evolving away from a cottage industry and toward modern forms of corporate organization (premise #3), so also is it adopting "new" management philosophies and methods.

I use the word "new" only because most laboratory executives and pathologists are unfamiliar with these various management philosophies and methods. Outside of healthcare, industries worldwide have embraced these management philosophies and made them essential for competitive success.

These management systems emerged during the 1970s and were based on the work of such management geniuses as W. Edwards Deming, Ph.D., and Joseph Juran, Ph.D. There are many flavors and lots of acronyms, such as TQM, CQI, ISO-9000, Six Sigma, Lean Thinking and the like. Whatever the name, these management philosophies have several essential characteristics in common.

First, they require business organizations to establish a goal of providing products and services which are engineered to meet and exceed the expectations of their customers. To accomplish this, business organizations are required to interview their customers; learn about these needs; design and deliver products to meet these needs; *then regularly measure consumer satisfaction and use this information to improve the products further!* (I add the italics because most laboratories and pathology group practices devote few resources toward measuring their patient's satisfaction and responding with programs to improve patient-focused services.)

Second, business organizations are to organize themselves so that their system of producing products and services is designed to do the job right the first time. Individual work processes are established and continuously evaluated to insure that only products and services which meet specifications are produced. It is common to measure success and failures in parts per thousand (three sigma) or parts per million (six sigma).

Third, senior management must empower those closest to the work to take responsibility for designing, monitoring, and implementing individual work processes. Under this management philosophy of "customer first" and process-driven systems, the emphasis of senior management shifts away from micro-managing day-to-day operations. Instead, it shifts toward providing workers with the leadership, vision, education, and the business tools needed for them to accomplish their responsibilities.

Needless to say, this is a change in the management style of most healthcare organizations. Whether hospital, laboratory, or physician group practice, the old "top-down" hierarchical management style (think "military" or "Catholic church") is still widespread.

I believe that laboratories which are first to *effectively* embrace and implement these management philosophies will achieve competitive advantage over those which maintain traditional management systems. The evidence of this outcome is becoming visible in the laboratory industry.

Quest Diagnostics Incorporated is moving swiftly to infuse ISO-9000 methods and Six Sigma management techniques throughout its organization. Several regional laboratory divisions at **Kaiser Permanente** have achieved, or are working toward, ISO-9000 certification. Laboratory accrediting standards are evolving to include these new management philosophies.

Expect the publication of papers documenting significant gains in lab test quality, increased productivity, and ever-falling costs at these early-adopter labs to give encouragement for other lab organizations to follow the same management path. Within the hospital industry, a parallel process is occurring. As it does, this will be a positive stimulus for laboratories to adopt this new form of management thinking.

Premise #6

Miniaturization Now Changing How and Where Laboratories Perform Diagnostic Testing

New technologies in a wide range of scientific disciplines are finding application in diagnostic instrument systems and test kits. The impact of these new technologies is simple. They are shrinking the size of diagnostics instruments (and the amount of specimen and reagent needed to perform the test). They are also reducing the complexity of diagnostic instrument systems and test kits while improving the accuracy of the test results.

This process of miniaturization is easy to see and understand. Go back to 1970 and look at the size and capability of three products: computers, mobile (radio) telephones, and chemistry testing instrument systems. In just 30 years, computers shrank into laptops, notebooks, and palm pilots. The mobile telephone evolved into a digital cellular device as small as a deck of cards that is capable of accessing real time information about weather, stock prices, and current news stories.

Chemistry instruments are now sophisticated systems. They offer ran-

dom access—multiple specimen—multiple channel capability with onboard internal diagnostics. Even the largest automated chemistry systems are becoming smaller and taking less floor and counter space. They also use smaller volumes of specimens and reagents.

The examples of computers, mobile telephones, and chemistry instruments make a compelling argument that miniaturization is about to take the science of diagnostic testing into a new dimension. Technologies like the **Luminex** LabMap¤ system are engineered to do 100 bioassays on a specimen as small as 50 microliters. **Affymetrix** and several of its competitors are investing tens of millions of dollars to develop "lab on a chip" capability. A California company is even working to put diagnostic tests on a compact disk, enabling physicians to perform lab tests in their offices, using the CD-ROM player in a desktop computer!

The increasing variety, and capabilities, of point-of-care (POC) testing devices demonstrate that miniaturization is rapidly changing the location where lab testing is done, as well as how those tests are actually performed.

This situation puts laboratories into a here-and-now dilemma. In certain areas of diagnostic testing, existing POC testing technology is moving lab tests out of the core laboratory and closer to the patient, whether in hospital units, emergency departments, or physicians' offices. During the past 24 months, the FDA approved several POC instruments which offer new options for moving even routine chemistry, hematology, and immunoassay tests out of the core laboratory and into near patient and POC settings.

Lab executives and pathologists should be ready to deal with this trend. It means that laboratories must begin to organize themselves in different ways. The concept and validity of the core lab will not disappear, but the test mix done in the core lab will begin to shift. Miniaturization will allow smaller labs to do a wider range of reference and esoteric testing in-house. Meanwhile, many routine tests will migrate out of the core lab because of economics, turnaround time requirements, and better access to the patient at the time of service.

As this migration of testing out of the core lab occurs, laboratory managers will find an interesting benefit. Even as POC instruments are "dumbed down" so that non-laboratory personnel can use them to produce accurate and high quality test results, the need for experts in lab medicine—medical technologists, Ph.D.s, and pathologists—will increase.

The reason is simple. We are entering an era where someone needs to make decisions for the integrated healthcare environment. What diagnostics tests should be done in-house versus referred out? What methodologies are appropriate? Which vendors have the best solutions for the chosen methodologies? Where should the test be performed? Who does the test? Who reviews the results? Who provides the referring clinician with expert advice and counsel on how to interpret results and do follow-on tests as appropriate? It will be pathologists, Ph.D.s and medical technologists who are responsible for these functions.

The world of laboratory medicine will become more complex to manage even as new technologies make it easier to build "fool proof" diagnostic instruments that can be used successfully by non-laboratorians, including patients themselves. More than ever, the integrated healthcare environment will require trained laboratory professionals to design, manage, and trouble shoot diagnostic testing wherever it is performed—from core laboratories to physicians' offices to patient self-testing.

Premise #7

Healthcare is a Cottage Industry Converting to Modern Corporate Management Forms

Back in 1996, THE DARK REPORT quoted a Wall Street venture capitalist who said "Healthcare is a billion-dollar cottage industry now transforming into modern corporate management models."

Simply put, this observer was noting that the day of the solo physician practitioner, the small clinical laboratory, and the stand-alone hospital were ending. It was ending for a simple reason: healthcare increasingly requires a more sophisticated business organization to deliver high-quality, low-cost health services.

Cost management and economics of scale are best achieved through increasing volume, whether it be lab testing, patients, or any other health service. Volume can be increased by sales, by acquisition, or by consolidation. To properly consolidate and manage higher volumes requires laboratories and other healthcare providers to also develop specialized management services. Experts in coding, billing, collections, information services, law and contracting, office administration, sales, marketing, and accounting become essential if a regional healthcare provider is to offer quality healthcare services at a competitive cost.

It is no accident that hospitals moved to become part of integrated healthcare networks (IHN), and doctors formed independent physician associations (IPA) and regional supergroups. These providers needed volume to support more professional, sophisticated management expertise.

The impact of this premise will continue into the 2000s. In the lab industry, it will play out in two ways. First, smaller labs, including hospital labs, will have an economic incentive to collaborate with other laboratories in the local area. Regional laboratory networks, joint ventures, and shared lab organizations will be some of the business models used to allow small labs to access the more sophisticated management resources necessary for them to remain competitive.

Within the anatomic pathology (AP) profession, it will become increasingly tougher for small pathology groups to maintain their independence. The market will be seeking enhanced AP services and declining costs. Small pathology groups will be unable to meet either requirement because they lack the volume necessary to finance such capabilities.

Premise #8

Information Technology Revolution Transforms Laboratory Medicine

Here's the true wild card in the deck. Technology that supports the collection, assessment, and distribution of information is improving at the speed of light. Because information is the end product of clinical laboratories, these new technologies will revolutionize all aspects of laboratory medicine.

It is undeniable that the technologies of computer hardware, computer software, fiber optics, digital, wireless, and the Internet are already bringing radical changes to business and society. There is now widespread recognition and consensus that the collective world economy is moving from the "industrial age" into the "information age."

This has profound ramifications for the laboratory industry. The digital Internet is supplanting analog telecommunications. The price of long distance telephone service is falling rapidly and it will not be long before customers cease to pay for long distance calls by the minute. Instead, they will pay a flat monthly fee, similar to how Internet service providers (ISP) currently charge their customers (AOL's unlimited access for $21.95 per month).

These swift and ongoing changes in information management create new opportunities for clinical laboratories to add value while lowering costs. For example, vendors are just now coming to market with ASP-based software products (application service provider) for certain laboratory functions. The ASP business model means that the vendor maintains the software application in a remote host. To use the application, the client dials up the remote host using the Internet and a Web browser. The earliest installations of ASP technology in the clinical laboratory industry involve lab test ordering and results reporting between physicians' offices and the laboratory.

But laboratory executives and pathologists will see enhanced information management products transform the full range of laboratory operations and laboratory services. Using the Internet, labs will have the real time capability to report test results to physician clients and their patients even as they transmit reimbursement claims to payers. One of the most intriguing uses of new communications technology will be the ability to sort through vast databases of laboratory test data. The goal will be to identify disease indicators derived from test result patterns across a number of different types of diagnostic assays.

Because information is the laboratory's true product, this revolution in information management technologies and tools will probably have more influence on changing the organization and operation of clinical laboratories than any other single factor. As individual laboratories do their strategic planning, the "information age" and its impact on laboratory testing should receive the highest priority.

lab industry White paper

CHAPTER 2

Strategic Business Failures of the Laboratory Industry During the 1990s

Important To Understand Reasons For Failure

If analysis is to be accurate and objective, it must recognize and praise successful accomplishments while at the same time recognizing and criticizing failures. Human nature being what it is, however, criticism of failed business decisions is painful and bound to generate denials by the parties involved.

One key element of a White Paper review of the laboratory industry is an assessment of where the industry failed in its responsibilities to patients, physicians, payers, and owners—either hospitals or stockholders.

I believe it is fair and reasonable to define the period of 1985 through 1999 as the beginning and end of one major business cycle for the clinical laboratory industry. The mid-1980s were the time that Medicare DRGs were having full impact on hospitals and hospital-based laboratories. Meanwhile, independent commercial laboratories were starting to acquire small labs owned by local pathologists.

As these main trends played out during the 1990s, consolidation was completed within the commercial lab segment. Hospital mergers and acquisitions fueled widespread consolidation of hospital laboratories. By 1999, both trends were played out. It was a 15-year period of unprecedented change in the clinical laboratory industry. Not surprisingly, the collective laboratory industry failed in a significant number of important ways.

It is important to identify and recognize these failures. If the new decade of the 2000s ushers in the era of genetic and molecular testing, it will be easy for the lab industry to repeat the mistakes it made during the 1990s, when managed care wrought substantial changes to the healthcare system and the clinical laboratory industry responded quite ineffectively.

What follows is my list of significant industry failures. The purpose in identifying strategic business failures is to determine whether the lab industry has been successful in attacking the root causes of these failures. Many of the same economic and social trends present in the 1990s still influence the healthcare marketplace today. Unless the lab industry learns from its experience in the last ten years, it will repeat many of the same strategic business and management mistakes in this new decade.

Failure 1: to anticipate the impact of managed care upon the operation and organization of laboratory testing services. Compared to traditional indemnity health plans, managed care companies contracted for laboratory services in a different ways. HMOs wanted to exclude all laboratories but a select few to provider panels. HMOs also wanted to only contract with laboratories capable of servicing larger geographical areas, including statewide coverage. The lab industry was slow to recognize that the way managed care companies contracted for laboratory services would profoundly alter the financial stability of all laboratories within a given region.

Failure 2: to recognize the financial threat of capitation and limited or exclusive provider panel contracts. This is a separate strategic business issue from failure 1. The managed care industry changed the economics of laboratory testing by introducing capitated (prospective) payment for lab services and by requiring labs to assume utilization risk. Commercial lab companies eagerly offered discounted capitated rates at levels which eventually drove almost all of them into merger or bankruptcy. By rashly establishing capitated rates at unreasonably low levels early in the 1990s, these commercial lab companies accelerated widespread declines in laboratory testing reimbursement by almost all types of payers.

Failure 3: of the lab industry to speak with one effective voice to the government on matters of reimbursement and regulation of laboratory testing services. Here□s a major business battle which the lab industry ceded to the enemy. Since the late 1980s, there is almost an unbroken record of funding declines for laboratory reimbursement. When compared to other medical provider categories, laboratory testing has been the eternal whipping boy for budget-cutters. Why? Because of a lack of unified action by the collective lab industry. National commercial lab companies lobbied Congress on their issues of concern. Hospital labs did no lobbying, since they were just one of many ancillary services within the hospital industry. With no unified voice representing the interests of clinical laboratories and anatomic pathologists, the consequences were tragic.

Failure 4: of the diagnostics industry to introduce Total Laboratory Automation (TLA) products in an open, objective manner. The large diagnostics manufacturers should not escape their culpability in failing to honestly disclose the disappointing productivity and financial performance of the earliest TLA installations. By the end of 1995 and 1996, it was common knowledge among diagnostics vendors that their TLA solutions were not meeting the performance standards of productivity and return on investment required to encourage significant numbers of laboratories to acquire and use such technology. In the eyes of many lab customers, this lack of candor also eroded the credibility of many diagnostics companies on a whole range of product issues.

Failure 5: of clinical laboratory and pathology associations to respond to their members needs with effective education, lobbying, and leadership. Within any industry, it is trade groups and professional associations which have the lead role in responding to political issues and providing education on competitive changes in the marketplace.

If the success of professional associations can be measured in terms of both political lobbying and helping companies stay financially solvent, then the decade of the 1990s was not a golden age for the various professional associations supporting laboratory medicine. In the political arena, Congress has sustained 12-year track record of reducing overall reimbursement for laboratory testing. This unbroken string of funding bills is undisputable evidence that the lab industry has failed to effectively state its case to Congress.

In the business and management area, professional associations have been slow to recognize that, although the science of laboratory medicine is paramount, the application of science must be supported by effective business, financial, marketing, and management expertise.

Moreover, laboratory professional associations have virtually ignored the management gurus whose techniques have transformed the way business is conducted worldwide, and whose names and methods are hailed in business publications from *Fortune Magazine* to the *Wall Street Journal* and the *Harvard Business Review*. Information about innovative management thinking from outside the lab industry that would have direct application and benefit for laboratorians has been notably absent in the seminars, educational programs, and publications offered by lab industry professional associations.

Failure 6: to adapt principles of accepted professional corporate management into the clinical laboratory marketplace. For many reasons, some inexplicable, during the 1980s and 1990s most laboratory industry executives and pathologists believed there was little value in searching outside the lab industry for innovative management thinking and new business ideas. This left the lab industry unprepared for the challenges it faced during the last ten years. Even today, many lab managers and pathologists maintain a belief that techniques of business administration, information management, and other business functions that are successful in other industries have no useful application for laboratories. For example, during the past two decades, **Federal Express** and **UPS** both developed sophisticated ways to track packages from the moment their drivers picked up a package at the customer s office. Yet today, it is nearly impossible to find an example of a laboratory using similar systems to track the specimens picked up daily by their couriers.

Failure 7: to understand, acquire, and apply established techniques of sales and marketing to physicians and other users of laboratory testing.

All business organizations must grow profitably to survive. A laboratory with increasing volumes of specimens, priced at profitable levels, has the cash flow and operating margins necessary to invest in both its people and its operational infrastructure. In the Fortune 100 world, corporations use professional sales and marketing techniques to generate profitable growth. However, within the laboratory industry, only a handful of laboratories (both hospital outreach programs and independent commercial labs) and pathology group practices maintain and support effective sales and marketing programs.

Failure 8: to recognize the economic effects of excess (unused) laboratory capacity in regional markets throughout the United States. This failure is insidious. Because fixed overhead is such a large component of laboratory costs, the economics associated with additional specimen volume are attractive. During the 1990s, many lab companies decided to accept new lab testing contracts at prices based on the marginal costs (reagent and tech time per test) of those additional tests. For any individual lab company with excess lab testing capacity, this was rational. But with so much unused lab capacity available, it was a business decision that led to widespread financial problems once payers adopted marginal cost-based pricing as the norm. Within the hospital industry segment, hospital lab consolidation made sense because there was so much unused lab capacity and duplicate instrumentation. But after a decade of consolidation, there still exists significant amounts of excess lab capacity. The Two Blood Brothers now recognize this fact and changed certain of their business practices to avoid this problem. However, many hospital lab administrators have yet to acknowledge the problem of excess lab capacity in their own community, let alone act upon it.

Failure 9: to invest and develop effective laboratory informatics products and services. The basic product produced by all laboratories is information. Thus, appropriate investment in sophisticated information management systems is essential. But the lab industry has generally lagged behind such industries as insurance and banking in the proportion of their annual revenues which they invest in information services. It is also generally acknowledged that hospitals and other categories of healthcare providers have underinvested in information technologies, so laboratories are not alone on that count. However, as noted elsewhere in this White Paper, the single biggest critical success factor for laboratories in the years ahead is their ability to offer enhanced information services to hospitals, physicians, payers, and patients. This will require laboratories to invest substantially more funds into lab information systems than has been true in past years. Enhancement of information systems will probably become the single most important strategic business priority at many labs.

lab industry White paper

CHAPTER 3

Competitive Dynamics in the Lab Testing Marketplace

This section of the White Paper deals with the marketplace for laboratory services. For brevity and clarity, I will address five components: 1) independent commercial laboratories; 2) hospital-based laboratories; 3) esoteric, reference, and specialty testing laboratories; 4) anatomic pathology laboratories; and 5) diagnostics manufacturers and suppliers.

These groups represent the basic divisions within the competitive laboratory marketplace. Each group has characteristics that differentiate it from the other groups. However, identical economic, demographic, and clinical trends are impacting each group.

Industry segment #1

Commercial Laboratories

The most visible laboratories in the United States are independent commercial laboratory companies. These include the two blood brothers, Laboratory Corporation of America and Quest Diagnostics Incorporated, several public lab companies, and regional independent laboratory companies.

The heyday of the independent commercial laboratory passed early in the 1990s. Mergers, acquisitions, and bankruptcies caused widespread consolidation throughout the decade. As a result, the number of sizable commercial lab companies that survived is relatively small. If you take a cut-off point of $5 million in annual revenues, there are probably less than 100 independent commercial lab companies which meet or exceed that figure.

Widespread consolidation of commercial laboratories created some interesting consequences. First, independent commercial lab companies no longer dominate the physicians' office testing segment the way they did in 1990. In response to this diminished sales competition, growing numbers of hospital laboratory outreach programs are building competitive *and profitable* footholds among physicians' offices in their regional service areas.

Second, intense sales competition among public lab companies in the first half of the 1990s actually benefited the handful of surviving independent regional laboratories during the second half of the 1990s. In most major cities, there was financially-ruinous sales competition among national lab companies, such as **Damon**, **MetPath**, **MetWest**, **Nichols Institute**, **National**

Health, **Roche Biomedical Labs**, **SmithKline Beecham Clinical Labs**, and the others. To generate new business, these companies offered unbelievable deals to physicians and payers. In client-bill states, test prices where heavily discounted to doctors. Labs provided phlebotomists in physicians offices and offered offered rock bottom capitated rates to payers.

Such intense competition for new lab testing business literally ruined the market for all labs. It proved financially ruinous to all the large lab companies. The exception to this situation was a handful of pathologist-owned lab companies which never joined in the competitive, price-discounting frenzy. Instead, they emphasized good service to their physician clients, walked away from money-losing HMO contracts, and stayed focused on the needs of their local clinical community.

These pathologist-owned lab companies survived the financial turmoil of the 1990s in relative comfort. Few lost money and most have done quite well in recent years. With the benefit of hindsight, their pathologist-owners common sense in emphasizing good service and refusing to engage in loss-leader pricing allowed them to survive even as public lab companies were forced into mergers or bankruptcy.

During 2000, the commercial laboratory segment of the lab industry seemed to achieve a quiet status quo. LabCorp and Quest Diagnostics maintain focused sales and marketing efforts in the field. Both lab companies declare they are committed to only acquiring new business which is profitable. Moreover, the Two Blood Brothers are in a strategic race to reconfigure their lab testing services. Each company wants to shift away from a dependence on routine testing and its inadequate reimbursement.

In practical terms, this means that the commercial laboratory segment is in transition. The business model developed during the 1980s is no longer valid in the 2000s. The individual physician is no longer the major buyer of lab testing services. HMOs co-opted much of this responsibility during the last decade. The emergence of integrated healthcare networks (IHN) brought another class of lab testing buyer into the market. And of course, increasing numbers of consumers want control and influence over their laboratory testing.

So it remains unclear what business model will be adopted by commercial laboratories during the next market cycle. Important advances in diagnostic technology and how information is collected, stored, and accessed will create new opportunities for commercial laboratory companies. These technologies will probably allow commercial laboratories to offer a new menu of added-value lab testing services.

Until this happens, the current status quo is unlikely to change much. Lab testing will still be primarily a local product, delivered by labs which are relatively close to the ordering physician. That means the national lab companies will be strongest in cities where they operate a large regional lab. Independent commercial labs will remain a viable competitor in their specific service areas.

Industry segment #2

Hospital-Based Laboratories

Like the commercial lab segment, the hospital-based laboratory segment underwent widespread consolidation during the years 1995-1998. By the year 2000, hospital systems controlled more than 60% of the nation's 4,800 non-government, acute care hospitals.

Consolidation of hospital ownership and management directly led to hospital laboratory consolidation and restructuring. Thus, in most urban markets across the country, the primary business model for hospital laboratories is the core laboratory. It is supported by rapid response labs in those outlying hospitals which are part of the health system. There may also be a laboratory outreach program which serves physicians' office clients.

As a trend, hospital laboratory consolidation was rooted in an undeniable fact: almost every hospital had a significant amount of unused laboratory capacity, supported by redundant instrument systems to guarantee testing throughput. This "excess lab capacity" was low-hanging fruit when hospital administrators looked for ways to cut the cost of lab testing.

But once this wave of lab consolidation passed, the need to further reduce lab testing costs did not go away. Today, hospital laboratory testing is directly influenced by two major forces. First, parent hospitals want sustained reductions in the cost of laboratory testing from year to year. Second, as integrated healthcare networks (IHN) take tangible steps to integrate both clinical care and healthcare operations, the hospital laboratory must respond to the changing needs of clinicians.

Harried lab administrators are devoting the greatest part of their time and effort to developing ways to further slash expenses in the laboratory. Precious little time has remained for these same lab administrators to develop innovative strategies for enhancing the value of laboratory services for the IHN and physicians that it serves. At some point, the lack of management resources devoted to improving lab testing services will have widespread impact across the hospital industry.

There was another interesting trend which began in the 1990s and will have profound impact on hospital laboratories during the early years of this decade. This is the trend of laboratory regionalization. The earliest regional laboratory networks were formed in Detroit, Pittsburgh, and San Francisco. Between the years 1996 and 1998, at least 35-40 regional lab networks were formed throughout the country.

Issues of control and trust among participating lab administrators made the organization and operation of regional lab networks a frustratingly slow process. However, a significant number of these lab networks remain active. More importantly, the most successful of these lab networks are proving that the business model works. Regionalization of lab services through collaborative effort can both reduce costs and lead to enhanced lab testing services.

At least two lab networks now exist which offer statewide coverage and have credibility with payers and clinicians alike. In one case, a lab network recently captured its state□s largest managed care lab testing contract. In another case, a lab network is in its second year of assembling statewide HbA1c test results on diabetes patients in a clinical repository. This data base of lab test results is helping clinicians more accurately measure their diabetes patient outcomes and improve their clinical treatment pathways.

These are two of the most impressive successes from the regional laboratory network movement. They demonstrate that regional laboratory networks still have the potential to deliver enhanced lab testing services to clinicians while reducing the cost of providing those services. Economic forces and the more sophisticated lab testing needs of clinicians will create the opportunity for regional lab networks to expand their role and importance to their local healthcare community.

During the current business cycle, the organization of hospital laboratory services will undergo radical change as a result of new technologies in diagnostics and information management. These changes will mirror the needs of the parent hospital or IHN, which will be undergoing its own path of radical change. Expect lots of testing to migrate out of the core lab into near patient, point-of-care, and patient self-test settings. Information management systems will be the glue that binds this new scheme for lab testing services.

It is tough to predict, with precision, how these new technologies will change the way hospital laboratories are organized and how they deliver testing services to clinicians. The capabilities of these technologies are still unknown. Moreover, the technology improvement curve is so rapid that what was definitely impossible in 2001 may turn out to be easily attainable in 2002.

Industry segment #3

Esoteric & Reference Labs

This is probably the most interesting segment of the laboratory industry. In the year 2000, it looks very different than it did in the year 1990. I consider this segment to include the national esoteric and reference labs which provide referral testing services to hospital labs and commercial labs.

Examples of national esoteric and reference testing labs would include **ARUP**, **Mayo**, **Specialty**, and **AML**. Both LabCorp and Quest Diagnostics maintain a substantial reference testing business for hospital labs. Niche, or specialty testing companies such as **Esoterix, Inc.**, with its seven different specialty labs, would be another example. I would also include academic centers that offer specific reference and esoteric testing, as well as small niche labs closely tied to scientists responsible for developing specific diagnostic technology.

Ten years ago, it was relatively uncommon to find niche labs offering a menu of specialized esoteric tests to a national market. Typically, promising new esoteric or reference tests were licensed to national lab organizations. National labs had the resources to invest in educating the clinicians

about when, why, and how to order new tests. They also had the sales and marketing team to call on the doctors, educate them about the tests, and convince them to start referring specimens.

What changed that situation over the last ten years is the growth of the overnight package delivery industry and the increased sophistication of long distance communications. These were the preconditions that make it increasingly easier for companies to develop a proprietary test and then market it directly to clinicians nationwide.

Also, developments in molecular and genetic science are creating a new class of research specialists who are experts in their specific niche. What niche labs offer to clinicians is not just a diagnostic test, but interpretation and follow-up by the researcher who developed the test. This specialized knowledge resource is tough to match for a national reference testing company offering literally thousands of different assays. Niche laboratories are using this benefit to their competitive advantage.

Another reason for the burgeoning numbers of niche testing laboratory companies is the venture capital industry. Simply put, there are lots of investors, with lots of money, who want to back promising diagnostic testing technology. They know the story of PCR and hope they can hit a similar financial home run in the diagnostics industry. These investors provide both capital and management expertise to researchers. They also prefer to directly market their proprietary esoteric tests, rather than license them to any of the national reference laboratory companies.

It is logical to expect continued growth in niche, or boutique, lab companies which offer a limited menu of proprietary reference and esoteric tests. Continued improvement in laboratory information capabilities will further reinforce this trend. It will become increasingly common for clinicians to refer both patients and lab tests to any specialist anywhere in the country. Advances in telemedicine, imaging, and information exchange will make this possible. (State and federal laws will be changed to accommodate this shift in clinical practices.) Widespread acceptance of out-of-area patient and test referrals will support the niche laboratory segment.

Industry segment #4

Anatomic Pathology

Several interesting things are happening within the profession of anatomic pathology (AP). Competition for AP specimens is increasing and the role of pathology subspecialists appears to gaining importance in the marketplace.

Both trends work against the continued success of a small pathology group practice serving a single hospital. For that reason, there will be be continued pressure on small pathology group practices to merge and consolidate.

This process of consolidation has been ongoing since the mid-1990s, when large numbers of hospitals formed integrated healthcare networks (IHN). As several hospitals came under joint ownership and management,

eventually the pathology groups at the individual hospitals were asked to form a unified contracting and operating entity.

In most cases, pathologists formed a single, consolidated group practice to serve the needs of their IHN. It is interesting to note, however, that pathology group consolidation generally was a slower process and occurred after major consolidation and restructuring was done to the hospital□s clinical laboratory.

Also, several cities saw the formation of regional pathology practice □supergroups.□ Participating pathologists recognized the business and professional benefits from a larger practice setting and voluntarily agreed to pool their AP practices.

Even as this consolidation trend was taking root, a new phenomenon emerged. This was the arrival of pathology-based physician practice management (PPM) companies. Inspired by the early financial success of PPM companies like **MedPartners**, **PhyCor**, and **PhyMatrix**, entrepreneurs believed anatomic pathology was ready for PPMs.

At least six pathology PPMs launched in the marketplace. **AmeriPath, Inc.** was first, and went public in the fall of 1997. During a two-year period, **American Pathology Resources, Inc.**; **Pathology Consultants of America, Inc.**; **Pathology Partners, Inc.**; **PathSOURCE, Inc.**; and **USLabs, Inc.** all received substantial venture capital funding. By the end of 2000, only AmeriPath, Pathology Partners, and USLabs remained independent. The other pathology PPM companies had merged or been acquired.

Tthe second half of the 1990s also saw the emergence of national anatomic pathology companies. **DIANON Systems, Inc.**; **IMPATH, Inc.**; and **UroCor, Inc.** made anatomic pathology services a major component of their product mix. They sent sales people into every area of the United States to generate case referrals from local physicians.

Another notable effort was the formation of **Pathology Service Associates LLC**, a national organization of independent state pathology networks. Its business model is to support local pathology group practices, while giving them access to sophisticated business services necessary to be competitive in their regional market.

Taken collectively, these different business trends are reshaping the anatomic pathology profession. Pathologists are being asked to do several things simultaneously. First, both hospitals and payers want pathologists to upgrade their business skills and the management sophistication of their practice setting. The economics and structural changes to healthcare make this important for financial survival.

Second, the integration of clinical services means that pathologists must pay closer attention to the needs of their customers. This goes beyond the referring physician. It includes the patient, the payer, and the hospital. □Meeting customer needs□ properly will require a comprehensive range of anatomic pathology services, *complemented by the business tools needed to deliver and support AP clinical services*.

In other words, just being good at anatomic pathology will no longer be enough. A successful pathology group practice must offer the necessary range of AP clinical services, then deliver reports and deal with the needs of different customers—including billing, clinical data repositories, etc.

There are also early signs of a growing division in the marketplace between local pathology resources, best typified by community hospital-based pathology group practices, and the increasing number of companies providing anatomic pathology services nationally. These national AP companies are financing national sales teams to visit local physicians and solicit their business. Since most local pathology groups do not support any sales reps, this puts them at a competitive disadvantage if a local doctor decides to refer his AP cases to a national company.

When taken collectively, all the trends and forces now reshaping the anatomic pathology marketplace do send one clear message: Successful pathology groups will be those that wrap their AP services with professional business services. This allows pathologists to emphasize their pathology skills, while insuring that their pathology group practice competes effectively in the competitive marketplace for healthcare services.

Industry segment #5

Diagnostics Manufacturers & Information Vendors

It is important to consider the changes taking place among vendors serving the laboratory industry. These companies must anticipate the needs of clinical laboratories several years in advance of their customers.

It is their products which enable labs to meet the evolving needs of hospitals, physicians, payers, and patients. Historically, there has been little product crossover between the companies which produce instruments and reagents and the companies which sell software and other lab information products.

In the market for diagnostic instruments and reagents, there are several new priorities affecting the design and operation of laboratory equipment. First, the widespread shortage of trained med techs is increasing the demand for a new class of diagnostic instruments—one that is "load and walk away." In response, both large diagnostics manufacturers and smaller companies are developing a host of instruments to meet this demand. It will be easier to find instruments which place little technical demand on the operator, whether a high-volume machine in the core lab or smaller instruments used at the point-of-care or in physicians' offices.

Second, laboratories will have more choices when considering instrument systems. It is now easier for start-up companies to compete against the billion-dollar diagnostics giants. The reason is miniaturization. It is becoming increasingly cheaper and easier to build automated, stand-alone instruments that sell for a fraction of their high-volume cousins. One consequence of this trend is that the economics associated with smaller diagnostic instruments are changing. Not only will these instruments become easier to operate, but their QA/QC and cost per test will become more com-

petitive with core lab testing systems. This will give laboratory administrators more options to meet the lab testing needs of clinicians in all settings within the integrated healthcare environment.

Third, clinicians continue to demand faster lab test turnaround times. They want lab test data to feed directly into integrated data repositories and be reported in real time. These changes in marketplace expectations havealready caused diagnostics manufacturers to rethink the design of their instruments and how they feed data into the laboratory information system (LIS). Expect to see rapid enhancements to the information management capabilities of all classes of diagnostic instruments.

Changing expectations by clinicians and their laboratories are pushing diagnostics manufacturers to swiftly incorporate new technology and features into their instrument systems and test kits. But laboratory information service vendors face a more daunting challenge. The information revolution, as typified by e-healthcare commerce services, is about to make existing □fat client□ software products obsolete. □Fat client□ describes the business model where customers buy the software, run it on their hardware, and maintain it with their staff.

The information services market is shifting to □thin client□ and ASP (application service provider) business models at an accelerated pace. The reason is simple. ASP-based, thin client information solutions are cheaper and easier to use. In the short term, it is the problem of converting from fat client systems to thin client systems which will impede the introduction of these products in hospitals and laboratories.

For these reasons, the biggest healthcare and laboratory information system companies are at great risk. They must maintain revenues from the existing base of installed users (of fat client products) while simultaneously moving these same customers to cheaper, thin client products and services. In effect, they must cannibalize their own revenue streams if they are to survive.

Moreover, there will be new competitors entering the marketplace for lab information services. These new competitors will include diagnostic companies (which can accumulate the test data generated by their instruments) and reference laboratories (which are also generating test data). Even pharmaceutical companies may have an economic incentive to provide lab information services and improve their access to lab test data.

One consequence of the changes underway among diagnostics manufacturers and laboratory information service companies will be tighter supplier/customer relationships. The emphasis will shift away from purchasing based on cheapest price. Instead, it will shift to purchasing based on the overall package of added-value services a particular vendor can provide a particular laboratory. This shift is closely tied to economic transition from an industrial economic to an information economy.

In order to bring full value to clinicians, payers, patients, and hospitals, both laboratories and their various vendors will have to collaborate much more intensely than ever before. These customer/supplier relationships will grow more complex, but will will yield more value.

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CHAPTER 4

Summary and Overview of Lab Industry

Tough Challenges and A Call to Action

If there is any common theme to the different chapters of this White Paper on the laboratory industry, it is probably this: in the next couple of years, clinical laboratories will continue to have one foot in the past and one foot in the future.

Simply put, lab administrators will continue to manage a laboratory originally designed to service the "fee-for-service" healthcare system of ten years ago, yet be under pressure to offer state of the art lab testing services to an increasing complex and integrated clinical environment.

This is one of the most difficult management challenges for any business. Executive leaders must help their teams accept new methods and new management systems even while asking them to abandon many tried-and-true practices. The laboratory industry is now fully engaged in a world of continuous change.

As the first three chapters of this White Paper demonstrate, the tension in the lab industry during the next 24-36 months will center around the need to properly deal with endemic structural problems of the lab industry at large, while still retaining the flexibility to acquire and offer new diagnostic testing tools to the clinical community it serves. In the face of this continual pressure for change, most laboratories already lack adequate middle and senior managers to do the job and few have sufficient capital to acquire and offer enhanced diagnostic services.

It's a tough enough challenge to have to manage the transition from an old business model to a new business model. But there is an added factor to consider. Our world is in the midst of a true economic revolution. We are clearly leaving the industrial age and entering the earliest stages of an information age. Laboratory executives and pathologists should keep this fact in mind as they develop strategic plans for their laboratory.

The industrial age was centered on owning the assets that produced tangible products. Wealth flowed to those who owned natural resources or manufacturing plants or the retail infrastructure that delivered products to consumers.

Clinical laboratories are a creation of the industrial age. Wealth has flowed to those who own the laboratories which do the tests; who own the

couriers who pick up and deliver specimens; who own the facilities that collect lab test data and then generate lab test reports and send out bills.

These are physical assets, and were the source of wealth in the industrial age. We are now evolving into the information age. Wealth will flow to those who control information. There will be precious little profit in owning physical buildings, diagnostic instruments, and courier cars. The significant rewards will come from converting raw data into useful information and valuable intelligence.

I would ask that you consider this to be the key strategic driver for the laboratory industry during the next few years. The shift of wealth, and value, from the assets of production to the assets of information is a primary force for change in our world economy and our healthcare system.

Once lab executives and pathologists fully comprehend this dynamic, it will simplify the process of making strategic decisions. It makes the job of evolving from the former □fee-for-service□ core lab business model into the new □distributed□ virtual laboratory business model much easier.

I would also like to point out that the process of transforming from an industrial age into an information age will be necessarily muddy and confusing. We will have our Luddites who want to attack the new business production models, just as they did to the textile mills in England only a few hundred years ago. But the process of change is unstoppable. The economics of the marketplace are rational (until the government steps in) and reflect the desires of consumers for products and services they deem valuable.

Speaking of the government, this will be the greatest source of confusion and obfustication. Government□s hand in healthcare, as well as □telecommunications□ (already an outmoded term) will generally lag behind the market. Amidst all the talk of e-healthcare commerce, there are concerns about legal and regulatory hurdles. I believe that laws will be changed, albeit rather slowly, to enable the information age to blossom and flourish. Take the issue of direct access by consumers to their lab test results. Certainly there are laws forbidding this in several states. But how long will these laws stand once consumers grasp the problem and express their dissatisfaction to elected officials? Laws constraining telepathology and physician licensing will certainly end up in the dustbin.

Since brevity is a hallmark of THE DARK REPORT, it is time for me to make a final comment on this White Paper and its implications for laboratory managers. Our industry is certainly hamstrung by a number of market trends left over from the 1990s. But I would suggest that one untapped resource to meet these trends is the creativity, energy, and loyalty of the laboratorians now on the front lines. As demonstrated in this White Paper, laboratory executives have failed, in a collective sense, to develop the people resources in our industry and then unleash them on an unrestrained campaign to attack and solve the challenges of reducing lab costs, increasing productivity, and adding value to lab services. When this happens, our industry will have universal and widespread success. **TDR**

Contact Robert Michel at 503-699-0616 or email to labletter@aol.com.

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- ***Rural Hospital System Gains Major Benefits Through Web-enabled ASP Lab Information Services.***
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- ***Regional Laboratory Network Launches Lab Data-Driven Statewide Outcomes Program.***