

From the Desk of R. Lewis Dark...

THE **RD**ARK **REPORT**

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

R. Lewis Dark:

“Information Therapy” Plays to Labs’ Strengths.....Page 1

Eight Trends Reshaping
Clinical Laboratory Services..... Page 2

“Local” Anatomic Pathology
Now Has Two Major Players.....Page 12

Lab Briefs: Atlas Development, Labtest.com,
Bio-Reference Labs, Cytoc, TriPath Imaging..... Page 15

Laboratory Sales and Marketing
Programs Are Changing..... Page 16

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

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



“Information Therapy” Plays to Labs’ Strengths

IT’S TIME TO PAY ATTENTION TO A GROWING AREA OF MEDICINE loosely described as “information therapy.” It is the concept of providing consumers and patients with reliable health information without requiring face-to-face visits with physicians or other healthcare professionals.

For clinical laboratories and anatomic pathologists, this is an important development. After all, information is the stock in trade for any laboratory. It seems obvious that “information therapy” would play directly to the strengths of clinical laboratories. When you learn more, I think you’ll agree.

There is a growing body of evidence which indicates that consumers who access accurate and carefully vetted medical information will generate fewer visits to either the emergency room or the physician’s office. This reduces the cost of caring for these patients. This has been the experience at **Kaiser Permanente**, which is moving rapidly to incorporate information therapy into its continuum of care. In 1996, Kaiser launched *Kaiser Permanente Online* as a pilot project. It is a password-protected site that offers a variety of services: health and drug encyclopedias, personalized health risk assessments, e-mail connections to nurses and physicians for questions and on-line appointment booking, and doctor-monitored health discussion groups. Originally started with 1,000 members, it now has almost 325,000 registered members. Kaiser estimates that 71% of its eight million beneficiaries have access to the Web, so it’s beefing up the capacity of its Website.

Another place to learn more about information therapy is **Healthwise**, a non-profit organization in Boise, Idaho. For years, Healthwise has produced pamphlets and other patient-information materials for healthcare providers. It is now expanding into Web-based health information services.

The concept of information therapy is perfect for laboratories. After all, within the healthcare system, who knows more about when and why it’s appropriate to order a specific lab test, and how to interpret the results? This is a tailor-made opportunity for laboratories to establish direct links with consumers and educate them about the importance of laboratory testing to all aspects of their personal health.

I’ll end with a provocative quote from Anna-Lisa Silvestre, Director of Kaiser Permanente Online. She says: “The Internet is becoming a triage station consumers go to first, whereas before they might have come in to the doctor or done nothing at all.”

Eight Trends Reshaping Clinical Lab Services

Disruptive technologies starting to alter the traditional role of clinical laboratories

By Robert L. Michel

CEO SUMMARY: *Once again, THE DARK REPORT's annual list of lab industry trends deals less with government regulation and influence on laboratory operations and more with the impact of new technologies and new management philosophies. Marketplace acceptance of these lab industry trends is occurring swiftly. Throughout 2000, early adopter labs moved readily to respond to these new technologies.*

THERE'S DEFINITE "IMMEDIACY" to THE DARK REPORT'S 2001 list of major trends affecting clinical laboratories throughout the United States and the world.

I use the word "immediacy" for an important reason. Each trend on this year's list describes market forces which are already at play within the clinical lab industry and the healthcare industry which it serves.

As you will read on the pages which follow, early adopter laboratories are already developing strategies and devoting capital and management resources to respond to these trends.

That is a distinguishing characteristic about this year's list of trends. These are not futuristic trends which require as-yet uninvented technology

to become reality. To the contrary, in virtually every case, each trend is happening now, propelled by technologies and market forces which exist today.

Clients and regular readers of THE DARK REPORT know that the cycle of change in the American healthcare system is becoming shorter and faster. This year's list of eight trends perfectly illustrates that fact. Each trend represents an active and dynamic force for change and there are examples of laboratories already reacting to each trend.

In fact, that statement aptly validates the value of useful business intelligence. When a lab executive is unaware of what "early adopter" labs are already doing to respond to a marketplace trend, it is easy to dismiss the

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

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher.

Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is \$10.80 per week in the US, \$11.40 per week in Canada, \$12.45 per week elsewhere (billed semi-annually).

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

© The Dark Group, Inc. 2001.

All Rights Reserved.

importance of preparing his/her lab to deal with that same trend.

It is an important responsibility of THE DARK REPORT to provide this type of early intelligence and analysis. Accurate information always makes it easier to make the right management decisions early enough in the market cycle to generate positive outcomes.

Profiles of Early Adopters

During the next few months, and especially at the upcoming *Executive War College* on May 8-9, 2001 in Cincinnati, THE DARK REPORT will be providing the first insights and information about early adopter labs dealing with the trends listed on pages 3-11.

Our coverage of *Caresoft, Inc.* and why it chose to launch a service offering consumers access to their personal lab results was a first in the lab industry. (See *TDR, January 15, 2001.*) We plan upcoming intelligence reports on several important topics, including anatomic pathology tissue banking, regional clinical data repositories, and use of lab test data to improve the quality of care while slashing the cost of care.

As we provide solid factual background to support each of the eight lab industry trends presented in this issue, our goal is to help shape and change the way our clients understand these issues and manage them. That is one of our value propositions to our clientele.

Road Map For Success

As Editor-In-Chief, I constantly travel around the country to visit many of the early adopter labs. These laboratories are doing today what all labs will need to do in the next 24 to 36 months. Their successes and failures provide us with a roadmap to confidently take the right course the first time. It allows us to avoid the mistakes which others have already made.

I would also like to say a word about some topics that go unaddressed in this year's list of important lab industry trends. The government's influence on the lab industry goes unmentioned, as does HIPAA. There are several reasons for this.

First, unless it's a radical change from past practices, much of the government's influence on healthcare, and the lab testing industry is incremental. Changes to Medicare, Medicaid, and various regulatory schemes are most frequently enacted in response to events which have already occurred in the healthcare marketplace. For this reason, THE DARK REPORT concentrates on the types of trends which usually happen first, causing a government action in response to their impact.

As we provide solid factual background to support each of the eight lab industry trends presented in this issue, our goal is to help shape and change the way our clients understand these issues and manage them.

Second, within the lab industry, there is an unmatched expert in the workings of government health programs and how their actions affect clinical lab business practices. That is Dennis Weissman and his *Washington G-2 Reports*. We believe Weissman's publication and its focus on regulatory and legal issues complements THE DARK REPORT and our focus on laboratory management issues and themes. We avoid redundancy by emphasizing our core competency.

Third, HIPAA's influence will be global, touching all aspects of the American healthcare system. But the core lab management issues represented by HIPAA are integral to, and a result of, the trends presented here.

Lab Industry Trend #1:**Consumers Are Here!**

PREDICTIONS THAT CONSUMERS would take a more active role in their laboratory testing came true in 2000.

The most visible evidence of this fact is the arrangement between **Caresoft, Inc.** and **Quest Diagnostics Incorporated.** Beginning in the spring of 2000, patients of Quest Diagnostics could view their personal lab tests results on Caresoft's Web site, *mydailyapple.com*. (See *TDR, January 15, 2001.*)

Both companies were surprised at how quickly patients responded. In the approximately 35 states where laws allow patients direct access to their personal lab test results, consumers responded to this added-value service.

But there is more to the story about consumer involvement in lab testing. Remember the company in Kansas City that set up shop in a retail strip mall and was performing lab tests for any consumer that walked in the door and plunked down the cash? The company was purchased by Quest Diagnostics, which continues to run that laboratory as a consumer-initiated testing business.

Taken together, these two developments demonstrate that Quest Diagnostics believes the time is ripe to directly engage consumers and offer them enhanced lab testing and information services. Its experience, supported by consumer focus groups and surveys, provides solid evidence that clinical laboratories must begin to give the same level of attention to the needs of patients as they do to physicians and payers.

Another factor is about to accelerate consumer involvement in their laboratory tests. Various companies want to connect the consumer with his/her physician, hospital, and other healthcare providers through e-mail and other electronic links.

One such project is under way in Winona, Minnesota. In a town of 25,000 people, the local hospital, an ISP (internet service provider company) and **Cerner Corporation** are actively working to connect all the residents with their physicians and hospitals. Certain lab test results are already available to patients in Winona through their Internet connection.

In Cincinnati, three health systems, representing 20 hospitals, have already formed a private intranet with a common clinical data repository. In the first phase of this project, Cincinnati area physicians with privileges at these hospitals can access their patients' lab test results, radiology results, and transcriptions through the private intranet. Eventually it will be possible for patients to access their clinical records, including lab test results, and communicate with their physicians.

These are important developments. Executives from both projects will be at the *Executive War College* in May to discuss issues such as privacy, security, access, and "who owns the data." The ramifications of these efforts are clear: consumers are getting wired into the healthcare system. Clinical labs and pathologists had better prepare to meet the new expectations and needs of their patients.

Lab Industry Trend #2:

Clinical Data Repositories

WHAT MAY ACTUALLY SPELL the death of clinical laboratories as they are organized and operated today is the development of a new generation of clinical data repositories.

After all, what do clinical laboratories provide to the healthcare system that has tangible value? There are at least three lab functions which have clear value. One, labs perform the tests and report the results. Two, labs store the results and maintain the integrity of the data base. Three, labs provide expertise on how to select appropriate diagnostic technology, accurately perform the tests, and evaluate the results to help individual patient diagnosis, prognosis, and treatment monitoring.

From this perspective, one of the three value components offered by clinical labs can be replaced. It is the function of data repository and reporting entity. As health systems move to the next generation of clinical data repository, they position themselves to become the primary connection between the lab and its referring physicians.

Using new technologies, it is becoming easier and cheaper to create a master clinical data repository and connect all classes of healthcare providers to this repository. This new generation of clinical data repository can handle laboratory test results data, as well as pharmacy, radiology, and other types of clinical data.

This marketplace development is both a threat and an opportunity. It is a threat because it interrupts the direct ordering and reporting link

that laboratories traditionally maintained with their physician clients. Now the unified clinical data repository is the entity which stands between laboratory and referring physician.

It is a threat in another way. If lab test data from multiple hospitals can be assembled in this master clinical data repository, it will be easier for independent commercial laboratories to add their lab test data to this master clinical data repository. By normalizing the results, it becomes feasible to give the clinician a complete lab test record for his patient, regardless of which lab performed the tests.

Of course, there is an opportunity for laboratories. As these unified clinical data repositories are organized and become operational, lab administrators and pathologists can play a critical role in helping the organizers design the data repository so that lab test data can be accessed in a number of added value ways. Any tools which improve lab test ordering patterns, help the clinician make better decisions from the lab tests he/she does order, and improves the quality of care will guarantee that the laboratory remains a key provider to the local healthcare community.

During 2000, a number of hospital systems and regionwide projects launched a comprehensive master clinical data repository combined with electronic access by physicians and other providers. In every case, lab test data was an important component of these new data repositories.

Lab Industry Trend #3:**Web-Based Test Reporting**

CERTAINLY IT WAS AMBITIOUS OF THE DARK REPORT to predict that it would take only 24 months for Web-enabled lab test ordering and results reporting between labs and physicians' offices to become the standard of practice.

That prediction, made in November 1999, now has one year to run. To date, events have played out slower than expected. But the earliest sites that implemented Web-enabled lab test ordering and results reporting have demonstrated that such services do slash costs, give physicians extra services, and speed up the delivery of lab test results.

THE DARK REPORT is preparing a detailed study of the events which have occurred since the November 1999 prediction. Early results from this study reveal that an interesting pattern has emerged.

Web-enabled lab test results reporting is the feature most frequently implemented by laboratories. It is much simpler and cheaper to implement Web-enabled lab test results reporting than it is to implement Web-enabled lab test ordering.

Web-enabled lab test ordering systems require the software to perform a variety of functions to link several different computer platforms. For example, to prepare the test requisition, the software package must draw patient demographic and billing data from the physician's practice management system. With the multitude of physician practice management software products installed in the field, this is a daunting challenge.

Getting ICD-9 codes is another issue, along with the requirement to link the test ordering software with the lab's test catalog and ordering rules and perform compliance checks. More sophisticated programs would also check the patient's insurance eligibility.

Compare that checklist of implementation requirements to those of Web-enabled lab test results reporting. The implementation requirement is relatively simple. Simply take the lab's existing data repository and develop a method to present the patient's test data in a variety of relevant ways for the physician.

Thus, it is a much simpler, cheaper, and faster process to implement Web-enabled lab test results reporting than it is to implement Web-enabled lab test ordering. That fact is reflected in the marketplace. During 2000, a growing number of labs opted to move first to Web-enabled lab test results reporting for their physician clients.

Another important factor encourages labs to choose reporting first over ordering. It is physicians who use the test results and personally review them. But most physicians do not personally complete test requisitions. They delegate that task to their nurses and staff. Thus, by offering the physicians Web access to their patients' lab test results, labs provide an added value service which builds physician loyalty.

For these reasons, expect Web-enabled lab test results reporting to become more widespread, followed, at a slower rate, by Web-enabled lab test ordering.

Lab Industry Trend #4:

Lab Regionalization 4

REGIONALIZATION of laboratory testing services will be a dominant and unchanging theme of this decade.

Economic pressures to squeeze costs out of laboratory tests will continue to encourage individual labs within a defined geographical area to collaborate. Much has been written about these collaborations, which take the form of lab consolidations, joint ventures, alliances, and regional laboratory networks.

What has been less reported is the unusual successes of specific lab regionalization projects. Once the process of lab regionalization has been started, it is seldom abandoned, even though forward progress can be frustratingly slow.

During 1999 and 2000, laboratory regionalization moved to another level of involvement and sophistication. A new form of regionalization, the "shared laboratory organization," has begun to appear in certain areas around the country.

A shared laboratory organization is created when competing integrated healthcare networks (IHN) within a metropolitan area, after consolidating their laboratories, decide the next level of cost savings and service gains can come from putting the management of their individual lab systems under common management. The biggest of these projects is the effort by **Aurora Health System** of Milwaukee and **Advocate Health System** of Chicago to operate their two consolidated lab systems under one management team. (See *TDR*, April 17, 2000.)

Also, quietly operating with little public attention are the 35 or 40 regional laboratory networks across the United States. These lab networks are delivering value to their members.

LabNet of Ohio, a network of 16 labs, has successfully insured 100% of its reference and esoteric testing to members of the network. This has reduced lab test costs to members, improved test result turnaround time, and generated more test volume for member labs.

In New England, there is a lab network supported by 100% of the hospitals in that state. These labs have normalized their test methodologies and are in the second year of a project to annually test a segment of the state's population for HbA1c and follow those patients from year-to-year. In year two, this effort has already identified undiagnosed diabetes patients and allowed their physicians to begin appropriate management of that disease.

Remember the problem of laboratory excess capacity? That is the unused laboratory capacity that someone is paying to keep on line, even though it goes unused. Every city in the United States still has excess lab capacity. That creates the carrot and the stick situation that leads to regionalization.

On one hand, pressures to reduce costs will force labs to either fill up their unused capacity or eliminate it through downsizing. On the other hand, regionalization offers mutual benefits to all participating labs, while allowing labs to fill up that excess capacity in productive ways.

Lab Industry Trend #5:**E-Health Services****5**

IDENTIFYING TRENDS IS RELATIVELY easy. The tough challenge is to accurately identify the specific ways that a particular trend will change the world as we know it today.

Last year, THE DARK REPORT added e-health services to its list of important lab industry trends. That was the easy part. After all, consumers had made healthcare their number one topic for Internet searches in 1999, dethroning pornography for the first time since the birth of the World Wide Web.

The growth of retail services on the Internet, such as **Amazon.com**, **E-Bay**, **Priceline.com**, and **E-Trade**, became a huge phenomenon. E-commerce had come of age and was a legitimate way to offer products and services to the buying public.

Attention began shifting to the business-to-business (B2B) applications of e-commerce, including healthcare. Certainly there is consensus among laboratorians that e-commerce services will transform our national and local healthcare systems in all sorts of ways. But there is no consensus on how fast this will occur, nor the specific services which will be affected.

Events of 2000 provide precious little insight into this trend. For the most part, various segments of the healthcare system began to announce e-commerce initiatives, with little understanding of what these new companies might actually accomplish. Thus, health insurers responded to the **WebMD** challenge by announcing the formation of **MedUnite**.

Medical suppliers and vendors, in various groupings, organized e-commerce buying exchanges. A host of consumer health Web sites, such as **Drkoop.com**, appeared but struggled to make money.

Accordingly, if 1999 was a year where e-health companies appeared in great numbers, 2000 was a year where many of these same companies failed or were forced to merge because they couldn't make money fast enough.

That leaves the lab industry with an interesting challenge. Without question, e-commerce is going to successfully enter the healthcare marketplace. But there is no clear consensus on when and how this will occur. That makes it difficult for lab executives and pathologists to develop viable business strategies to accommodate the arrival of e-health services.

That probably means that the best strategy is one of "watchful waiting." As events happen in the marketplace, the goal is to evaluate the impact of these events and deal with them as necessary.

Despite the lack of certainty about when and how e-health services will transform the current healthcare system in the United States, there is universal consensus among experts studying this trend that three things will be true of e-health. First, it will eliminate unnecessary costs in a ruthless manner. Second, it will put buyers (for labs, read: physicians and patients) in control of choosing their provider. Three, it will enable labs to offer a new class of added value services never before imagined.

Lab Industry Trend #6:

Incremental Automation **6**

INCREMENTAL AUTOMATION is a term to describe the movement toward automating specific steps in the lab testing process, eventually leading to total lab automation in core lab settings.

Much has been written in THE DARK REPORT about the failure of the first generation of total laboratory automation (TLA) technology to deliver the economic and productivity benefits that it promised. There is now general recognition of this truth by both the lab community and its vendors.

Less has been written about the next generation of lab automation solutions which have begun to reach the laboratory marketplace. That is not surprising. It has taken the diagnostic vendors three and four years to engineer new solutions into their instrument systems.

Only in the last year or two have the buying patterns of laboratories begun to form a clearer picture of what is working and what is not. Not surprisingly, automation solutions that labs seem to be choosing center around pre-analytical processes and workstation automation.

It is increasingly common to walk into high volume core laboratories and see an automated specimen sorting system installed between the accessioners and the bench. Instead of an automated transport line, staff generally walks specimens to and from this equipment. These labs invariably are pleased with the economics and performance of such systems.

Workstation automation is the other key theme. This generally takes the form of self-contained instrument systems which are “load and walk away” or automated component instrument systems, which link two or three related instruments and thus also offer “load and walk away” benefits.

Assuming that laboratories continue to acquire and implement these types of automation solutions, then it is likely that the industry is years away from the vision of a true “total automated laboratory;” where a human loads the specimen at the front end and all functions of testing, retesting, storage, and destruction are fully automated.

The entire field of clinical laboratory automation is going to get a big shot in the arm from a source unexpected just three or four years ago. The widespread shortage of medical technologists and medical technicians is now forcing laboratories to implement any solution which maintains throughput and quality, but uses less skilled labor. (*See lab industry trend #8, next page.*)

The shift in lab management thinking stimulated by the shortage of trained med techs leads THE DARK REPORT to make an important observation. Unexpected changes in the healthcare marketplace can stimulate a host of unimagined developments. Through most of the 1990s, acquisition of TLA solutions was primarily driven by cost reduction and ROI targets. Through the 2000s, acquisition of lab automation solutions will be driven by the need to do testing with less labor inputs.

Lab Industry Trend #7:**Med Tech Availability**

THERE'S BEEN PLENTY OF NEWS about the shortage of qualified medical technologists and medical technicians to serve in clinical laboratories.

But the news about a new phenomenon related to the shortage of med techs has gone unreported. During travels to labs throughout the United States in 2000, THE DARK REPORT observed a distinct shift in management strategies for staffing laboratories.

Virtually every laboratory of size in the United States has open positions for med techs which they are unable to fill. This situation has existed long enough to make lab administrators realize that sufficient skilled labor is now an unattainable goal. They are forced to run laboratories which are, for all intents and purposes, chronically understaffed.

To cope with an inadequate and dwindling supply of skilled med techs, lab administrators are adopting a new business strategy. They intend to redesign and restructure their laboratories to operate with less skilled labor.

This shift in management thinking is directly linked to the recognized shortage of trained medical technologists and medical technicians. Instead of attacking supply, by raising salaries and recruiting greater numbers of candidates into med tech training programs, lab administrators are choosing a different solution.

They are choosing to restructure their laboratory organizations which do the same work with less labor. This has several interesting

and important ramifications. First, it means that instrument and automation solutions will be judged less on their ability to deliver a desired economic return on investment (ROI) and more on their ability to improve specimen throughput with less overall lab labor.

This shift in purchase motivations will encourage diagnostic vendors to design equipment solutions which stress reduced labor as much as improved quality of test result.

Second, the ever-shrinking supply of med techs is going to drive a speedy revolution in lab management thinking. To operate a laboratory with minimum labor inputs, clinical lab administrators and pathologists will be increasingly required to adopt management methods from the manufacturing and distribution sectors.

Third, the shortage of trained med techs will transform near-patient and point-of-care testing into a viable and rational solution. In effect, the pool of trained med techs will staff core labs which do complex reference and esoteric testing. Routine testing will migrate outward in the clinical setting, performed on automated instruments which make it feasible for non-laboratorians to perform those tests.

Thus, headlines about "med tech shortages," have overlooked the real impact of this trend upon the way laboratories will be organized and operated. As noted above, the chronic lack of med tech manpower has already caused lab administrators to implement new solutions to solve the problem.

Lab Industry Trend #8:**Management Philosophy**

MANAGEMENT PHILOSOPHY IS included in all THE DARK REPORT's list of significant lab industry trends for an important reason.

Lab executives and pathologists face sustained pressure to reduce the cost of lab testing while simultaneously boosting the value of lab services to hospitals, physicians, patients and payers.

The old models of management philosophy cannot deliver the performance improvements demanded by today's healthcare system and the society it serves. Competitive advantage and ongoing success lies with those clinical laboratories which understand and embrace the tools and techniques of the new management philosophy.

This philosophy is rooted in a "customer-first" focus for the lab organization, combined with a work system based on developing processes which, by design, can only produce services and products of the absolute highest quality.

These are not impossible or contradictory goals. Examples from other industries provide graphic evidence. In less than 20 years, the 50¢-per-minute long distance call over a copper wire land line has been replaced by a pennies-per-minute "call-anywhere" product delivered on a miniaturized, wireless telephone.

The vinyl 12" record album of 1980, played on a bulky turntable, is now a computer music file played on a hand-held device with a miniature hard drive that holds up to 150 hours of music!

The new management philosophy is built around the principles of W. Edwards Deming and similar management gurus. It has found widespread application in the form of ISO-9000 guidelines, as well as other management systems.

During 2000, a credible beach head for these management systems was established within the laboratory industry. **Quest Diagnostics Incorporated** followed up its 1999 certification of **Quest Nichols Institute** as an ISO-9001 facility with the ISO-certification of four other laboratory divisions during 2000. (*See TDR, October 23, 2000.*)

Kaiser Permanente's Northwest Division Laboratories in Portland, Oregon attained its ISO certification in 2000. Within Kaiser, other lab divisions are actively pursuing ISO certification. THE DARK REPORT also knows of a integrated delivery network (IDN) which recently declared its intent to achieve ISO-9000 certification.

During 2000, **Ortho-Clinical Diagnostics**, the diagnostics division of **Johnson & Johnson**, launched a consulting service for clinical labs which applies the principles of "lean thinking" and Six Sigma to laboratory organization and work flow design.

These developments support a conclusion that 2000 was the seminal year for the introduction of these new management systems into the operation of clinical labs. From this point forward, a steadily growing number of lab organizations will announce that they have converted to these new management systems.

“Local” Anatomic Path Has Two Major Players

Consolidations and mergers during 2000 reduce options for local pathology groups

CEO SUMMARY: *After a lot of money and much effort, the fledgling crop of companies wanting to consolidate and manage pathology group practices has narrowed into just two market leaders: AmeriPath and Pathology Service Associates. These two companies could not be more different in their goals and operating philosophies. For local pathology groups, this is certainly an unexpected outcome.*

IT DIDN'T HAPPEN WITH MUCH FANFARE or public attention, but there are now just two important players in the battle for control of local anatomic pathology resources.

AmeriPath, Inc. and **Pathology Service Associates, Inc.** (PSA) have emerged as the “big dogs” in the market for local pathology services. The numbers tell the tale. AmeriPath employs 426 pathologists in 21 states. PSA provides services to more than 80 practices and 400 pathologists in 13 states.

New Path Business Models

This development is significant. If the trend in healthcare is toward consolidation of small provider units into larger business models, then many anatomic pathologists will find themselves working under new business arrangements in coming years.

After all, a large portion of the nation's 13,000 board-certified pathologists still work in small group practice settings, numbering from one to four doctors, often serving only a single hospital. Ongoing market forces

will continue to pressure these small pathology groups to consolidate into larger business units.

This pressure to consolidate is not welcomed by many pathologists, who value the traditional independence that their private group practice setting has provided them. Yet ongoing economic trends within the healthcare system continue to push the era of the small pathology group practice toward its end.

Given the regionalized nature of the nation's integrated healthcare networks (IHN), it is highly significant that the economic marketplace has allowed only two pathology organizations to reach large size by emphasizing local pathology.

This duopoly creates an interesting situation within the anatomic pathology profession, because the motives and goals of both companies are significantly different. AmeriPath is a publicly-traded corporation which needs to deliver regular and significant increases in revenues and earnings to

support its share price and remain attractive to investors.

PSA is a member-owned organization of state pathology networks. It describes itself as “pathology at the point of care” and its goal is to preserve the independence of local pathology groups while providing them the business tools they need to thrive and prosper in the evolving world of integrated healthcare.

Value Of Local Pathology

Although different in their ultimate financial goals, the companies share one characteristic that sets them apart from other important pathology business models: both AmeriPath and PSA believe in the value of anatomic pathology services provided at the local level and supported by an inter-regional business organization.

That means both pathology companies must develop a local pathology presence in major population centers to give them the clout necessary to negotiate favorable terms with payers, hospital systems, and large physician groups, such as IPAs. For that reason, both AmeriPath and PSA need to continually recruit additional pathology groups into their organization if they are to remain financially viable businesses.

For competition, these two companies face a marketplace sorted into five distinct business models. (*See sidebar on next page.*) At the local level that means competing against the existing small independent pathology groups and, where present in that city, either pathology “super-groups” or large academic and tertiary center pathology groups.

At the same time, the growing number of national pathology providers will be sending sales reps into these same cities to generate case referrals to their national pathology laboratories. This evolving mix of competitors for anatomic pathology

cases means that the marketplace is becoming more complicated.

That is why the apparent duopoly of AmeriPath and Pathology Service Associates is a significant event. Over the last five years, it was these two companies which survived the shakeout of the pathology PPM (physician practice management) start-ups. If the principle of “survival of the fittest” applies to the market for anatomic pathology services, then these two companies triumphed during this last market cycle.

As the pathology profession enters the next cycle of change in the healthcare marketplace, both AmeriPath and PSA will be challenged to keep their leading position. Executives at both companies will not forget the still-recent example of such market leaders as **MedPartners** and **Columbia/HCA**, whose past accomplishments were not a guarantee of future success.

Pathologists and their practice managers should remember that same lesson. Early leaders in the race do not always have the stamina at the end to finish first. The business models of anatomic pathology are undergoing evolutionary change. It is by no means settled that AmeriPath and PSA will sustain continued, profitable growth.

Better Than Competitors

The one clear fact at this point in the current market cycle is that the business model and management implementation of AmeriPath and PSA were better than their competitors. As a result, they achieved size and critical mass even as competitors withered away.

It remains to be seen whether America’s evolving healthcare market will favor one pathology business model over another. Will it be local pathology, supported by a corporate team? Or will it be national AP providers and/or regional pathology super-groups?

Market Favors Five Distinct Pathology Business Models

IN RECENT YEARS, FIVE PRIMARY BUSINESS MODELS HAVE EMERGED in the anatomic pathology marketplace. Because of ongoing changes to the American healthcare system, the long term viability of each business model has yet to be demonstrated. However, the greatest pressure for change is upon the small private group practice which typically serves just one hospital.

One revealing insight offered by this list of five pathology business models is the increased number of “employee-pathologists” now working around the country. The steady growth of national anatomic pathology companies, particularly AmeriPath, is fueling a demand for pathologists willing to work on salary as opposed to a group practice partner with a share of the net profits at year-end.

1 • Single-Hospital, Independent Private Group Practice

This is the traditional business model which has dominated the pathology profession. In today’s marketplace, it is still the predominant practice setting for pathologists, but economic pressures for change are strongest on this pathology business model.

2 • Regional, Multi-Hospital Group Practice

During the 1990s, several regional “super-practices” emerged. These are pathology groups which number more than ten pathologists and serve multiple hospitals within a metropolitan region. **Bayless Pathmark** in Cleveland and **Brown Associates** of Houston are examples of this type of pathology company.

3 • Academic/Tertiary Center Group Practice

This is a distinct business model because the size of the pathology group and its medical mission require it to have subspecialty expertise not found in other hospital settings. Its pathology subspecialty expertise enables the academic/tertiary center group to generate cases from a wider region, even nationwide.

4 • Inter-Regional “Practice Management” Company

This business model operates local pathology practices, supported by a cross-regional headquarters. It competes by using local pathology resources, drawing upon sophisticated business expertise and capital from the headquarters staff. The two biggest organizations in this category are AmeriPath, Inc. and Pathology Service Associates, Inc., but each uses a very different business plan to support its affiliated pathologists.

5 • National Pathology Company

Included in this category are all the companies which employ pathologists and offer services across multiple states. Examples are **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, **DIANON Systems, Inc.**, **IMPATH, Inc.**, and specialty lab companies which offer anatomic pathology services as part of their product mix.

Lab Industry Briefs

EARLY ADOPTERS OFFER WEB-ENABLED LAB TEST REPORTING TO DOCTORS

THERE'S A GROWING NUMBER of clinical laboratories which now provide Web-enabled lab test reporting to their physician-clients.

Dynacare, Inc. is in the first phase of a national roll-out of Web-enabled lab test results reporting. Its Seattle division was first to become operational with this service. **Atlas Development Company** is the vendor.

Last month in Honolulu, Hawaii, **Diagnostic Laboratory Services, Inc.** went live with its Internet-based laboratory test results reporting system. **Labtest.com** is the vendor.

On the east coast, **Bio-Reference Laboratories, Inc.** of Elmwood, New Jersey now has more than 400 doctors subscribing to its Web portal service, called **Careevolve.com**, which includes the feature of Web-enabled lab test results reporting.

CYTYC & TRIPATH IMAGING ISSUE EARNINGS REPORTS FOR Q-4 AND FULL YEAR

IF THE COMPETITION BETWEEN **Cytc Corporation** and **TriPath Imaging, Inc.** were a horse race, Cytc would have an early and overwhelming lead.

Cytc reported full year revenues of \$142.1 million for 2000. This is jump of 75% over 1999 revenues of \$81.1 million. Net income grew to \$38.2 million, compared to \$5.6 million in 1999.

Meanwhile, TriPath Imaging seems to have finally gotten its toe into the laboratory marketplace. Its revenues were \$32.7 million, up 77% over 1999 revenues of \$18.5 million. It is still los-

ing money, although its 1999 loss of \$32.6 million was whittled down to \$17.4 million in 2000.

Cytc's executives are exuberant. "We increased our share of the cervical cancer screening market by 90% in 2000," enthused President and CEO Patrick J. Sullivan. He noted that Cytc continues to invest in building its sales force, which he credits with much of the revenue gains earned during the past 24 months.

This is a lesson apparently not lost on TriPath Imaging. It has launched a direct-to-physician sales force to call upon OB-GYN's and educate them about the TriPath PREP™ system. At the same time, it is expanding its laboratory sales force.

THE DARK REPORT predicts that the marketing wars for enhanced Pap smear preparation kits will become increasingly intense during 2001. Clinical laboratories and pathologists will find a steady stream of sales people from both companies stopping by to sell the merits of ThinPrep® and PREP.

ANTHEM INSURANCE CO. PLANS A HUGE STOCK SALE LATER IN 2001

MAKE ROOM FOR ANOTHER managed care heavyweight. **Anthem Insurance Co.**, with sizeable health programs in nine states, has announced its intention to launch one of the largest IPOs (initial public offering) ever tried in the health insurance industry.

If successful, Anthem's seven million beneficiaries would rank it as the fifth largest public health insurance firm in the U.S. It would trail **Aetna US Healthcare**, **UnitedHealth Group**, **Cigna**, and **WellPoint Health Networks**. **TDIR**

Lab Sales & Marketing Programs Are Changing

National labs are altering sales incentives, regional labs and path firms are expanding

CEO SUMMARY: *Market evidence points to a shifting role in the sales priorities of the national labs. Meanwhile, regional laboratories and pathology companies are enjoying surprising success with their sales and marketing programs. These shifting patterns may indicate a new stratification in the laboratory services marketplace. It may be closely linked to managed care contracting practices.*

EVIDENCE IS ACCUMULATING THAT sales and marketing of laboratory testing services may be undergoing a rebirth, at least among regional independent and hospital-based laboratories.

Moreover, in the anatomic pathology segment, several companies have made adjustments to increase the effectiveness of their national sales and marketing programs. These moves will probably intensify the competition for anatomic pathology specimens.

In recent months, a number of independent commercial labs and hospital labs with outreach programs have told THE DARK REPORT that their sales programs are generating healthy volumes of new client accounts.

Two National Labs Remain

Part of this phenomenon is related to the fact that only two national laboratories remain, once **SmithKline Beecham Clinical Laboratories** (SBCL) was acquired by **Quest Diagnostics Incorporated** in 1999. Once this acquisition took a major player out of

the market, it left just a handful of cities where both Quest Diagnostics and **Laboratory Corporation of America** maintain sizeable regional laboratories.

Minimal National Presence

The remainder of cities in the United States have either just one national lab with a strong local presence, or no significant national lab presence at all. It is this “vacuum” that has created the opportunity for regional laboratories to successfully expand their sales and marketing to local physicians’ offices.

For these and other reasons, local laboratory competitors appear to be doing well. Sales reps from the local labs seem to be playing three sales cards: 1) we represent choice (the Avis “we’re number two—we try harder!” strategy; 2) we’re local, thus we know your needs better and have faster turnaround time; and 3) we have better service than those guys, who often are “out-of-towners” in the local marketplace.

Another contributing factor to this situation is the relative status quo in

managed care contracting for lab testing services. During the mid- and late-1990s, as national labs scooped up the biggest managed care contracts in city after city, local lab competitors were forced to cope with lost specimen volumes and the need to bring costs in line with lower revenues.

Having adapted to this situation over several years, these same local lab competitors now have the financial stability to aggressively move back into the marketplace. In particular, they have learned how to pick off the remaining fee-for-service business, leaving the national labs with capitulated or heavily-discounted fee-for-service contracts.

Easy Sales Environment

In some cities, the market is wide open. Along the east coast and southeast coast, three different lab CEOs have told THE DARK REPORT that they are opening up new accounts after only one sales call to the physician's office. One of these labs reports that it actually has several doctors per month calling them and asking for someone to come out and open a lab account for their office!

The sales opportunities for local labs may have become better since New Year's Day for another reason. Quest Diagnostics Incorporated implemented a new sales incentive plan for 2001. By design, many of its top lab sales producers will earn significantly less money under this new plan. As a result, a number of these sales stars are shopping for new employment.

Collective Impact

A few will surely be hired by regional lab competitors. However, it remains to be seen whether the collective impact of this situation affects the ability of Quest Diagnostics to continue generating quarter-to-quarter increases in specimen volume.

On the anatomic pathology side of the lab services market, professional

sales programs are generating significant growth in specimens and revenues for both national and local anatomic pathology firms willing to fund such sales efforts.

At AmeriPath, which is under continual pressure to deliver earnings growth to its shareholders, a new sales strategy has been announced. It will now operate two distinct sales divisions.

The new sales division will be called DermPath Diagnostics. It will market the services of AmeriPath's 67 board-certified dermatopathologists directly to dermatologists, plastic surgeons, family practitioners, otolaryngologists, and podiatrists. This will be a national effort, managed by Annette L. Bell, Vice President and General Manager. It will probably be the first time that local dermatopathologists will have sales reps from a national anatomic pathology company competing for their existing client business.

Office-Based Sales Force

The second sales division will continue AmeriPath's existing sales activities. It will be under the direction of Ed Dooling, Vice President and General Manager. Dooling came to AmeriPath as part of the **Inform DX** acquisition. (See *TDR*, November 13, 2000.) This sales division already markets to office-based specialists such as urologists, gastroenterologists, gynecologists, oncologists, surgery centers, and the like.

AmeriPath's new sales strategy is another sign that specialized sales and marketing programs will become increasingly common in the anatomic pathology marketplace. It will also provide pathologists with further evidence that sales and marketing is a good investment. Because AmeriPath must report its financial performance, its quarterly reports will provide clues as to how well this dermatology sales division performs.

INTELLIGENCE

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



This time the **Clinical Laboratory Management Association (CLMA)** looked in its own backyard to find a Executive Director. On Monday, February 12, Robert Neri will begin his responsibilities at CLMA. Not only does Neri have a long career in laboratory management, but he lives in the Philadelphia area, near CLMA's offices in Malvern, Pennsylvania. CLMA's immediate past two executive directors came from the association management industry.

NEW PRESIDENT AT IMPATH, INC.

At least one anatomic pathology company recognizes the important contribution that sales and marketing makes to sustained growth and profitability. **IMPATH, Inc.**, recently promoted Richard P. Adelson to President and COO. Adelson started with IMPATH in 1992 as regional sales manager and supervised the sales and marketing effort throughout IMPATH's formative years. Impath's former President, Anu Saad, M.D. assumed duties as Chairman of the Board and CEO.

GENERAL MOTORS USING MEDSCAPE TO CONTROL COST OF HEALTHCARE

Here's an early warning sign for clinical laboratories. **General Motors Corp.** signed a three-year pact with **MedicalLogic/Medscape, Inc.** for the purpose of reducing healthcare costs and attacking medical errors. GM will use Medscape's products for electronic prescribing and medical records. The companies will target 6,000 physicians in cities where GM has a large number of employees and retirees. Some 1.2 million people get their health coverage through GM, so this is a sizable undertaking.

MORE ON: GENERAL MOTORS

GM spent almost \$4 billion on healthcare in 2000. Prescriptions account for \$1 billion of this amount, which is why GM made this area a priority. It hopes electronic ordering systems will help physicians prescribe generics or lower-cost drugs and reduce medical errors associated with harmful drug interactions, illegibly-written pre-

scriptions, and the like. THE DARK REPORT believes that GM's migration to an electronic patient record will form the foundation for a next-generation cost cutting and quality-boosting effort which would logically involve clinical lab test data. Further, GM's efforts, if successful, will be copied by other corporations looking to control the cost of their own health programs.

QUEST, AETNA, AND HCA TO TAP MARKETS FOR \$BILLIONS

Healthcare must be riding high on Wall Street, despite recent financial doldrums. Within a week of each other, **Quest Diagnostics Incorporated, HCA-The Healthcare Co.**, and **Aetna Inc.** announced plans to raise money. Quest Diagnostics filed a universal shelf registration for \$750 million to issue various types of securities, including debt preferred stock, and common stock. HCA is selling \$500 million of high-yield bonds, and Aetna will sell \$2 billion in debt securities.

***That's all the insider intelligence for this report.
 Look for the next briefing on Monday, February 26, 2001.***

PREVIEW #2

EXECUTIVE WAR COLLEGE

May 8-9, 2001 • Hyatt Regency Hotel • Cincinnati

Topic: Improving Healthcare Outcomes Through Better Use of Lab Test Data

War College is pleased to present Richard J. Migliori, M.D., Chief Clinical Strategist at United HealthGroup's Ingenix Division. At the nation's second largest health insurer, Dr. Migliori is leading efforts to better apply lab test data and other clinical information to improve the quality of care. This work is already generating a variety of worthwhile results.

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

UPCOMING...

- ***Year-End Earnings Reports of Public Labs Reveal Surprising Developments.***
- ***Determining Anatomic Pathology's Best Regional Super-Practices.***
- ***Revisiting Total Lab Automation: First Generation Adopters Share Untold Stories.***
- ***Why Some Hospital Lab Outreach Sales Are Booming—and Others Are Not!***