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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

Winners and Losers in the Lab Industry

Nothing was easy for commercial and hospital labs during the past decade. Reimbursement for lab tests was slashed. Onerous compliance requirements for Medicare increased costs and added to the legal risk of operating a laboratory. Patient access was restricted through exclusive HMO and managed care contracts. These problems took a huge toll on our industry. There are a lot fewer laboratories operating today than in 1990.

On the positive side, a number of laboratory organizations got it right during the 1990s. In the face of all these negative forces, they developed a business strategy that works in the reality of today's healthcare marketplace. Within the hospital laboratory sector, the winners are those lab organizations which did two things: they consolidated hospital inpatient testing for a number of hospitals and launched a professional outreach program to physician offices. The combined volume reduced their average cost per test, while outside revenues contributed increased profits to their lab operation.

Within the commercial laboratory sector, those independent labs which did not sell to the nationals generally maintained a high level of service to their physician clients. This was enough to help them survive the decade. But the best among this class flourished, demonstrating healthy growth in revenues. Among them were labs like **Clinical Pathology Laboratories, Inc.** of Austin, Texas; **Pathology Associates Medical Laboratories, Inc.** of Spokane, Washington; and **Associated Pathologists Laboratories, Inc.** of Las Vegas, Nevada. In each case, these companies developed a business strategy that made them a preferred resource in their chosen service region. They also diversified revenues by exploiting market niches. **Lab*One*, Inc.** of Lenaxa, Kansas is a prime example of this.

The emergence of a new class of "specialty" laboratories should also be recognized. These lab companies identified customers with unmet needs and grew rapidly by meeting precisely those needs. **UroCor, Inc.** of Oklahoma City, Oklahoma; **IMPATH, Inc.** of New York City; **DIANON Systems, Inc.** of Stratford, Connecticut all finished the decade with strong revenue growth and generally robust profits.

As the next decade creates a new class of lab industry winners and losers, it is useful to stand back and recognize that there is still opportunity to prosper, so long as the laboratory positions itself to provide enriched services that meet the evolving needs of clinicians and the healthcare system. TDR

"State of Lab Industry" Holds Surprises for All

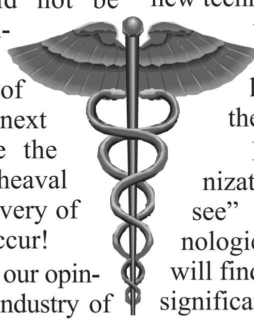
Annual review of laboratory industry's future predicts widespread upheaval

By Robert L. Michel

CEO SUMMARY: Say goodbye to several of the trends which shaped the lab industry during the 1990s, such as consolidation and government compliance programs. Although these trends won't completely disappear, they will be superceded by a number of new transformational influences. During the next 48 months, these influences will bring lightning change to clinical labs of every size and shape.

ONLY ONCE IN 1,000 YEARS is it possible for THE DARK REPORT to speak to you at a moment which simultaneously marks the birth of a new year, a new decade, a new century, and a new millennium.

The symbolism should not be ignored by you, your executive team, or your laboratory staff. It is the opinion of THE DARK REPORT that the next 48 months will introduce the most *radical* and *rapid* upheaval to the organization and delivery of laboratory testing ever to occur!



As future events validate our opinion, the clinical laboratory industry of 1999 will divide into two camps: winning laboratories and losing laboratories. The reason is simple. New technology and business models now arriving in the marketplace will require laboratory executives to evaluate, act, and implement at lightning speed.

Laboratory organizations willing to act rapidly in acquiring and harnessing new technology will be first to provide their lab users with improved value-added. These laboratories will flourish in the coming years.

In contrast, laboratory organizations which adopt a "wait and see" approach toward new technologies and new business models will find themselves consistently at a significant competitive disadvantage.

The new classes of winning and losing laboratories that we predict will be identified faster than ever before. It

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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).

means that any laboratory organization that is not continually improving and evolving will probably disappear. The most likely mechanism is that it will be placed under the ownership and direction of a lab organization willing to respond as fast as the marketplace requires.

Critical Success Factor

But speed in analysis and action is not the only critical success factor. Today's crop of laboratory executives and administrators will also need to think and react in a multi-dimensional manner. They will be confronted with unorthodox opportunities to reshape the way their laboratories perform tests, report results and contribute to successful healthcare outcomes.

The coming upheaval in the clinical laboratory industry must be viewed from the perspective of economic and political events now unfolding worldwide. The Internet and its enabling technologies are literally causing a revolution in how business and government organize and deliver services.

In hindsight, the years of 1998 and 1999 were relatively quiet for the clinical laboratory industry. These were years where most laboratory executives and pathologists concentrated their efforts on implementing necessary projects. Issues like laboratory compliance, post-consolidation clean-up, and LIS projects were the primary priorities for many laboratory organizations.

Need For Major Decisions

That will not be true for 2000 and 2001. Laboratory administrators will need to make major decisions about laboratory automation, enhanced LIS capabilities, Web-based links to clients, joint ventures with other lab organizations, and regional laboratory network proposals.

All of this will be happening against a backdrop of steadily declining reimbursement for lab tests, more complicated compliance guidelines, and a cascade of new diagnostic tests.

In this year's "state of the laboratory industry" report, there are eight trends highlighted. Unlike in the past, most of the trends presented have the potential, in and of themselves, to be paradigm-shifters.

This is noteworthy. Each trend represents a significant aspect of laboratory operations. Lab executives will be required to make decisions as to how their laboratory should respond to each of these trends. It means that most laboratory organizations will have several major management projects under way at the same time.

Challenging Environment

For example, think of the complexity of dealing with the implementation of Web-based lab test ordering/reporting with physician office clients while also evaluating and implementing routine testing at the point of care. Add to this the normal responsibilities involved in compliance, ongoing cost reduction efforts, and clinical integration, and it will create a challenging environment for all lab managers.

This year's "State of the Laboratory Industry" report is designed to draw attention to those market forces which will have immediate impact on laboratory organizations throughout North America.

For that reason, THE DARK REPORT recommends that laboratory administrators use this year's major trends as the basis for strategic planning with their management teams. It is important for each lab's leadership team to develop a winning plan of action.

Upcoming in TDR:
State of the Pathology Profession

State of the Laboratory Industry-Key Trend #1

Pace of Change

INDEPENDENT OF OTHER FORCES acting to transform the organization of clinical laboratories is a separate dynamic: the pace of change.

Throughout the 1990s, the pace of change steadily quickened. Each new cycle of change took less time to achieve widespread impact among clinical laboratories.

THE DARK REPORT places this trend at the top of our list of transformational forces. The reason is simple. An ever-shortening cycle of change requires lab executives and pathologists to make swifter decisions and implement necessary responses on an accelerated basis.

As each cycle of change in the clinical lab industry becomes more compressed, it places greater responsibility upon lab administrators and directors. Failure of these officials to respond in a timely fashion can spell failure for their lab organizations.

Compare two lab industry change cycles and it becomes easier to understand why the cycles are compressing into short time frames. The cycle of commercial laboratory consolidation required about nine years to complete. Starting in the mid-1980s, a group of national lab companies began acquiring independent regional labs.

In the early 1990s, the names of these companies were familiar to all. **Allied**, **Damon**, **MetPath**, **MetWest**, **National Health Labs**, **Nichols Institute**, **Roche Biomedical Labs**, and **SmithKline Beecham Clin Labs** were all recognized brands. The culminating year for commercial laboratory consolidation was 1994. MetPath acquired both Damon and Nichols Institute to became a $1.7 billion company. Roche acquired National Health Labs and created **Laboratory Corporation of America**, with $1.5 billion in annual revenues.

Another change cycle was consolidation of hospital labs, which required about four years to accomplish. Prior to 1995, only a handful of consolidated hospital lab organizations could be found. Between 1995 and 1999, hospital lab consolidation was widespread across the United States and Canada.

New trends and change cycles will sweep through the lab industry in less time than the 48 months required to achieve widespread consolidation of hospital laboratories. For example, THE DARK REPORT predicts it will take as little as 24 months to complete the transition to web-based lab test ordering/reporting between physicians' offices and laboratories. *(See TDR, November 1, 1999.)*

Similarly, THE DARK REPORT believes that a new generation of point-of-care instruments for routine lab tests, such as chemistry and hematology, will lead to rapid decentralization of routine testing. This change cycle may require as little as 36 to 42 months to have industry-wide impact.

As change cycles to the lab industry accelerate their impact, it requires management of every laboratory to respond respond faster and faster. Expect the pace of change to create more pressure on lab decision-making than any other single trend in the foreseeable future.

State of the Laboratory Industry-Key Trend #2

Web Ordering/Reporting

NUMBER TWO ON OUR LIST OF important trends are Web-based links between physicians' offices and clinical laboratories for lab test ordering/results reporting.

During the next several years, THE DARK REPORT believes that Web-based links between doctors' offices and labs will have tremendous impact on the way lab laboratory services are organized and delivered.

The direct and immediate benefit will be to reduce the cost and improve the efficiency of submitting test requisitions and delivering test results. During the course of 1999, each of the three blood brothers signed contracts with companies to develop and deliver Web-based information links between their labs and their physician office clients.

DIANON Systems, Inc. and **UroCor, Inc.** did likewise. As public companies, these laboratory organizations are under continual pressure to reduce costs, increase profits, and capture more business. It is no coincidence that, during 1999, the five largest public lab companies committed to converting to a Web-based system for lab test ordering/results reporting with their physician office clients.

These lab companies believe they will gain competitive advantage and direct financial benefit from Web-based links to their clients. Competitive pressures will force other labs to quickly convert doctors' offices to this kind of ordering/reporting system.

THE DARK REPORT predicts that virtually all physician offices generating large volumes of laboratory tests will be using Web-based test ordering/ results reporting within 24 months. *(See TDR, November 1, 1999.)*

But there is another, equally important aspect to this trend. Laboratory executives and pathologists should view Web-based links between labs and physician's offices as "enabling technology."

THE DARK REPORT sees Web-based links as a platform for delivering new and more sophisticated value-added services to laboratory customers. During the next several years, new developments in data base management and enhanced data processing software will give laboratories an unprecedented ability to create useful information from raw laboratory test data.

Combine this capability with Web access, and clinical laboratories will be able to deliver compelling data set analyses to clinicians, managed care plans, government regulators, and integrated healthcare system operators.

There are already early efforts to apply existing technology towards this type of information management. DIANON Systems, Inc.'s CarePath® product is one example. It's a comprehensive, lab test-based disease management information suite. Although developed independent of Internet technology, it is being adapted for Internet access by payers, physicians, and patients.

THE DARK REPORT believes Web-based lab test ordering/results reporting will find rapid acceptance among physicians. This is a lab service which is definitely "physician-friendly."

State of the Laboratory Industry-Key Trend #3

Consumer Involvement

NEVER UNDERESTIMATE the power of consumers. After a decade of taking a back seat in decisions about their healthcare, American consumers are about to reassert themselves.

For laboratories, this will be a paradigm shift of immense proportions. After all, clinical pathologists and lab executives have traditionally viewed the referring physician as their primary customer. With the arrival of managed care, HMOs and other players also gained importance as customers of the laboratory.

That kind of thinking placed the patient last on the priority list for most clinical laboratories. In fact, as labs got patient complaints about bad draws, lost specimens, and similar issues, efforts to fix the situation were usually motivated toward keeping the physician and payer happy. After all, it was they who chose the laboratory, not the patient.

That's now changing! Baby-boomers have a different attitude toward healthcare than their parents. Baby-boomers take an active, educated role in every aspect of their healthcare. They do primary research before visiting their doctor. They want to understand the nature of their diseases and participate in decisions affecting their care and that of their family (including their now-elderly parents).

Evidence of this fact is compelling. Since the birth of the Internet, pornography had generated the largest volume of Internet traffic. Not so in 1999. Healthcare eclipsed pornography as the subject of greatest interest. Consumers by the tens of thousands are using the Internet to research medical issues affecting themselves and their families.

Within the laboratory industry, many clinical pathologists have reported an increase in the number of customers who want to order their own lab tests, independent of their doctor. There is even a laboratory in Kansas City which is located in a retail shopping mall and caters to these kinds of patients.

Foresighted laboratories will begin to include patients in the information loop along with the physician who referred the test. Laboratories will use the Internet to notify patients when test results have been delivered to the doctor. Labs will provide patients, in advance of the draw, detailed information about the lab tests which will be performed and how they are used in diagnosis, prognosis and patient monitoring.

Further, THE DARK REPORT believes that some clinical laboratories will begin to educate consumers in their service markets about the types of lab technologies and quality steps utilized internally to produce a quality test result. In other words, the same techniques used by commercial companies to educate consumers about product quality will occur in the clinical lab industry.

Moreover, the power of consumers to alter the way lab testing services are offered and performed should not be underestimated. The consumer is king and has lots of money to spend. More than a few labs will be willing to profit by targeting lab services to these customers.

State of the Laboratory Industry-Key Trend #4

Lab Decentralization

IF THE DECADE OF THE 1990s can be described as a decade of laboratory consolidation, then the decade of the 2000s will be described as the decade of laboratory decentralization.

The enabler for this trend will be point-of-care (POC) technology. The first target for laboratory decentralization will be high-volume, routine lab tests. If a POC instrument performs such tests at acceptable quality and a lower price, it creates the incentives to move routine testing out of the centralized core lab and into near-patient and point-of-care settings.

The first generation of routine POC instruments is now in the marketplace, led by **Careside, Inc.'s** POC chemistry analyzer. Careside expects to introduce its POC hematology instrument by second quarter, 2000. *(See TDR, November 22, 1999.)*

This development is notable. For the first time ever, laboratory executives now have a choice: routine chemistry and hematology tests can be done either in a central laboratory or at the point of care.

Moreover, THE DARK REPORT predicts that Careside's products will stimulate competition from other diagnostics companies. Certainly existing manufacturers are not going to cede their market shares to Careside without a fight.

Assuming that Careside's technology and cost structure proves cost-effective in clinical usage, then competing diagnostics companies will be forced to respond with their own POC solutions.

THE DARK REPORT calls this the "Pandora's Box Effect." Once Pandora lifted the lid and released all the plagues into the world, there was no way to "put them back in the box." In the same manner, any POC solution for routine testing that demonstrates acceptable quality and a competitive cost will be like opening the lid to Pandora's Box. There will be no way to return laboratories to the way they once were.

That is why the introduction of Careside's POC solutions for routine testing should be seen as a significant event. It gives laboratory executives and pathologists a new option for performing testing. It also encourages competing diagnostics vendors to bring their own POC solutions to market.

Moving routine testing to the point of care is a paradigm shift in the current organization of clinical laboratories. Once the option to decentralize routine testing is proven to be viable, every segment of the clinical laboratory industry will be affected.

If doctors install these instruments in their offices, it will reduce the flow of specimens to commercial laboratories. If integrated healthcare systems move routine testing to POC settings, it converts the remaining core lab into a reference and esoteric center. That certainly reduces the need for laboratory capacity and will trigger significant changes in how labs are organized.

Here is technology with the potential to support the "distributed laboratory" of which so much has been written. It will bring new opportunities for laboratorians to become more involved in clinical integration.

State of the Laboratory Industry-Key Trend #5

Lab Regionalization

REGIONALIZATION of laboratory services goes hand-in-hand with most of the trends presented here.

THE DARK REPORT has long predicted that laboratory regionalization would emerge as the predominant organizational model. Regionalization of lab services is a rational response to most of the fundamental forces acting upon healthcare.

The emergence of national laboratory companies in the first half of the 1990s demonstrated that it was possible to regionalize laboratory testing in a profitable manner. The surviving two blood brothers continue to prove that current levels of reimbursement are enough to sustain their regionalized lab systems.

During the first half of the 1990s, the first consolidated hospital laboratory organizations sprouted in a number of cities. These early experiments further validated the feasibility of a regionalized lab infrastructure.

Detroit was probably the first metro market to see this phenomenon on a wide scale. Each of its nine healthcare systems had consolidated lab testing as early as 1992.

Next came regional laboratory networks. During 1995 and 1996, these were the hot topics. Again, Detroit was early on the map, with **Joint Venture Hospital Laboratory Network** (JVHLN) becoming operational by 1992. In 1995, two other high profile networks launched operations. One was Pittsburgh's 40-hospital **Regional Laboratory Alliance** (RLA). The other was San Francisco's **Bay Area Hospital Laboratory Network** (BAHLN).

Time has demonstrated that many daunting hurdles face a lab network composed of independently owned and operated hospital laboratories. Yet the concept of regionalizing laboratory services is sound and the network movement has not disappeared.

In fact, the lab industry is gaining much practical experience from its attempts to organize and operate lab networks. Progress has been frustratingly slow. Few lab networks are willing to boast of mighty accomplishments. Yet among the 30 to 50 individual networks in some form of organization or operation, there is optimism. Their leaders recognize that the era of the regional lab network is approaching.

THE DARK REPORT predicts that Internet technology, movement of routing testing to POC, and clinical integration will support and foster the regionalization of laboratory services. There will be interesting consequences to these trends.

For example, Web-based lab information links will reduce the cost and complexity of moving information between network laboratories and physicians' offices. As routine testing moves to the point of care, the remaining volume of reference and esoteric testing means a reduced test volume may not support the existing number of laboratories in most cities.

As a result, central labs in most metro areas will become reference/esoteric testing centers and will serve extended geography. That is why regionalization will be the logical end game for lab services.

State of the Laboratory Industry-Key Trend #6

Clinical Integration

INTEGRATION OF CLINICAL SERVICES will continue throughout the next decade. This means that laboratories will be required to provide testing services and diagnostic information to an expanded list of healthcare entities.

Historically, laboratories have played a very defined role within the American healthcare system. The primary users of lab testing were hospitals, certain office-based physician specialties, and facilities like nursing homes.

During the coming decade, laboratories must become "customer-responsive" to the needs of all players within the integrated healthcare system. It will no longer be sufficient to offer a single menu of services and let lab users "take it or leave it."

To the contrary, the successful clinical laboratory of the next decade will be adept at spotting the unmet needs of each segment of the healthcare community. It will create and offer customized services to those unique segments. As a result, different types of laboratory customers will get different menus of laboratory services.

This will emulate the changes in how personal computers are sold. Originally, personal computers came in a limited number of configurations. It was Michael Dell, of **Dell Computers**, who first allowed the customer to specify his/her computer. Then Dell's company would manufacture that personal computer to fit the customer's unique requirements.

Dell's innovation is now the standard for the computer industry. Any consumer can get a customized PC from any serious computer retailer. THE DARK REPORT believes that clinical integration will drive a similar "service customization" for laboratory organizations.

The earliest models of "customer-responsive" laboratories can be seen in a number of evolving integrated healthcare systems (IHS). **Kaiser Permanente** is one example, particularly in its Northern California and Southern California divisions. Another good example is the **Penn State/Geisinger Healthcare System**, headquartered in Danville, Pennsylvania.

Each of these IHSs are pushing their clinical laboratories to expand from the central core laboratory. To meet objectives for increased integration of clinical and operational services, pathologists and lab managers now find themselves interacting with clinicians in untraditional ways.

What is constant, however, in the function of these laboratories is that they continue to be recognized as the intellectual resource and "guardian" of laboratory medicine. In this role, the laboratorians guide and assist clinicians in evaluating how laboratory tests can be used to improve patient outcomes while lowering the cost of care.

THE DARK REPORT believes that clinical integration, far from being a threat to clinical labs, will usher in a golden age of diagnostic medicine. Pathologists, Ph.D.s, and medical technologists will find themselves ever more involved in the patient care continuum.

State of the Laboratory Industry-Key Trend #7

E-Commerce Services

E-COMMERCE is transforming retailing, manufacturing, and distribution throughout the world. E-commerce will also transform healthcare as we know it today.

Laboratory executives and pathologists should not underestimate the radical transformation which E-commerce will bring to healthcare. Economic transactions based on Internet technology represent a new "Internet Age."

The first Industrial Age moved the world economy away from its agricultural foundation. Now the Internet Age is about to move the world economy away from its industrial foundation. The Internet Age represents an economic model where information is both power and the source of profits!

THE DARK REPORT cannot predict the exact form and shape of the Internet Age. That will be determined in the worldwide marketplace. But there are early clues to how healthcare, and the clinical laboratory industry, will be reshaped by the Information Age.

First, knowledge and information will represent power and added-value. This is different from the industrial age, where land, buildings, and equipment meant power. For labs, this means who performs the test is less important than who has access to the test results—and can convert those test results into useful information.

Second, transactions which generate laboratory test results (and information) will be non-traditional. Early evidence of this can be already seen in the marketplace. For example, companies already allow customers to place orders over the Internet. The companies then manufacture that order, precisely to the customer's specifications, on a real-time basis.

This type of ordering arrangement is such a serious threat to the automotive industry that car manufacturers are preparing to sell their cars this way. Soon it will be possible for car buyers to log on a web site for **General Motors**, **Ford**, **Mercedes**, etc. and order a car exactly the way they want it: color, interior, extras, and engine.

Their car will be custom manufactured. How local auto dealers participate in this process has yet to be determined. This business model is changing daily, as technology and customer expectations change.

Recently, it was announced that two advertising agencies had purchased clinical trials companies. Why? Because they wanted to learn how new drugs are tested for efficacy and safety. With the growth of direct-to-consumer advertising by pharmaceutical companies, these ad agencies want to acquire the knowledge and information necessary for them to serve their drug company clients.

These are just a couple of revolutionary changes now occurring because of E-commerce. Many of our readers shopped for Christmas presents on the Internet this year. This is certainly a paradigm shift and eliminates trips to the shopping mall.

E-commerce will soon reshape the "buying habits" of payers, physicians, and patients. Clinical laboratories will find it necessary to respond to the new world of E-commerce.

State of the Laboratory Industry-Key Trend #8

Management Philosophy

MANAGEMENT PHILOSOPHY WAS a trend that was also on THE DARK REPORT'S last "State of the Lab Industry" list.

THE DARK REPORT believes that a fundamental change in the philosophy of clinical laboratory management has been ongoing throughout the 1990s.

The dominant model of hospital and commercial laboratory management has been the pyramid. It's a "top down" management model. People at the top tell people lower on the pecking order what to do and how to do it.

Since 1980, that traditional management model has been increasingly superceded throughout the world by a different management system. This new model is customer-focused, and encourages "empowering" employees at all levels to take responsibility.

There are any number of ways to describe this new management model. Most laboratorians have heard or read about the various systems. They go by monikers such as ISO-9000, Total Quality Management (TQM), Continuous Quality Improvement (CQI), and others.

At its foundation, this is a management model which emphasizes respect for the customer and the employee. It emphasizes meeting the customer's needs and expectations as the right way to guide the progress of the company. It also encourages senior management to empower employees to become more involved in designing and managing the processes over which they are directly accountable.

Within the American healthcare system, most provider organizations, including clinical laboratories and hospitals, have been slow to adopt this management model.

In contrast, most healthcare suppliers, manufacturers, and distributors, are already deep into this new management model. For example, almost all the diagnostics companies have achieved ISO-9000 designation.

What is important to understand about this new management paradigm is that it establishes an entirely new game in the marketplace. It is not the old game with new rules.

The American automobile and copier industries learned this lesson the hard way in the 1970s, when Japanese companies invaded American markets. The Japanese companies were close to the customer and made better quality products. They captured so much business that a number of America's most respected corporations almost went bankrupt.

The message for laboratory executives and pathologists is simple. The new management paradigm represents an entirely new game, with its own rules. Those companies organized around this new management paradigm have a competitive advantage over those companies which haven't yet changed.

It is imperative that management leaders in the clinical laboratory recognize this trend and respond to it. Success in this effort should guarantee a financially stable and productive laboratory organization. TDR

Lab Industry Briefs

SWARM OF LAWSUITS NOW PLAGUES ABBOTT LABS

PAYING A $100 MILLION FINE TO THE **Food and Drug Administration** (FDA) did not end **Abbott Laboratories, Inc.'s** problems related to its diagnostic test kits and reagents.

Since payment of the FDA fine last month, Abbott has been served by a number of lawsuits. Most of these suits involve unhappy shareholders. Abbott's stock prices declined 11% during 1999. Plaintiffs claim that Abbott Chairman and CEO Miles White, who assumed that position in April 1999, intentionally hid details of the FDA's investigation from stockholders and the public. *(See TDR, October 11, 1999.)*

One interesting twist to this current round of lawsuits is the fact that Abbott had a similar problem a few years back. In a separate FDA investigation, the FDA's report criticized Abbott's manufacturing procedures. The company never revealed this to shareholders. In July 1994, A federal jury awarded $15 million to shareholders who sued Abbott over this matter.

Under the consent decree, Abbott is removing over 100 diagnostic tests from the market. These tests generate about $250 million of Abbott's annual $2.79 billion in diagnostic sales. Laboratories around the country have been scrambling to replace those tests.

IT'S OFFICIAL: CARESIDE'S POINT-OF-CARE SYSTEM NOW READY FOR SALE

LOTS HAPPENED DURING THE MONTH OF December for **CARESIDE, Inc.** of Culver City, California. The young company officially launched sales of its point-of-care system for routine chemistry and hematology. *(See TDR, November 22, 1999.)*

On December 13, the company also announced FDA clearance for use of its CARESIDE Analyzer® in point-of-care settings. This permits the instrument to be used in clinics, doctors' offices, nursing homes, and other types of healthcare facilities.

In December, CARESIDE further disclosed that it had purchased **Texas International Laboratories, Inc.** (TIL), a private company which manufactures a hematology analyzer, ancillary reagents, controls, calibrators, and accessories. TIL's analyzer is cleared by the FDA for human use and will be mated with CARESIDE's chemistry instrument.

This combined POC instrument suite has FDA clearance for 52 chemistry and hematology tests. It will include a data network system. Retail price for the POC instrument suite is $24,000. The instruments require 12 to 15 minutes to perform tests.

BIO-REFERENCE LABS MAKES MAJOR MOVE INTO E-HEALTH MARKET

WHO SAYS ONLY THE BILLION-DOLLAR lab giants can play in the E-health game? **Bio-Reference Laboratories, Inc.**, based in Elmwood Park, New Jersey, is busily diversifying away from clinical lab testing.

The $46 million public company announced two acquisitions in December. The first purchase was **DoctorNY.com**, a local New York-area portal which connects consumers and physicians. The second acquisition was **Right Body Foods, Inc.**, based on

Long Island, New York. Right Body Foods manufactures and distributes no-starch, low-fat foods which are sold though physicians, nutritionists, and other healthcare professionals.

Bio-Reference intends to have its sales force market these products to its existing physician office clients. In this respect, it is following a page from **UroCor, Inc.'s** book. UroCor provides diagnostic services to urologists. Over the last two years, it has also begun to use its sales force to sell therapeutics and pharmaceuticals to its urologist-clients. Both companies recognize the potential to use their sales forces to sell additional products to their existing client base of physicians.

Bio-Reference President Marc Grodman, M.D. intends to expand the cross-sell opportunities available to his laboratory company. He wants to use the established relationship with his physician office clients as the foundation to sell other products and services.

Bio-Reference has been moving swiftly to develop Internet-based services for its physician office clients. The acquisition of DoctorNY.com complements this effort. This Web portal provides access to a directory of physicians and physician websites. It allows Bio-Reference to interact directly with consumers as they seek to connect with physicians.

DIANON SYSTEMS EXPECTS HIGHER REVENUES FROM REVISED MEDICARE FEES

REVISED MEDICARE FEE SCHEDULES ARE generally not good news for the laboratory industry. But that was not the case for **DIANON Systems, Inc.** at the close of 1999.

The Connecticut-based company expects a significant financial benefit in 2000 from the new fee schedules for Medicare that become effective on January 1, 2000. As most pathologists know, Medicare reimbursement for outpatient pathology services is scheduled to increase in fiscal year 2000.

"DIANON currently generates approximately 95% of its pathology revenue from procedures performed in outpatient settings," observed David R. Schreiber, CFO at DIANON. "Given the upward revisions in outpatient codes, we feel comfortable increasing our year-over-year earnings per share [EPS] growth targets to 40%, from 30%."

That's a hefty increase in profits for DIANON shareholders. Clients of THE DARK REPORT are familiar with DIANON's big sales push into anatomic pathology services in recent years. For 1999, DIANON's revenues will reach about $75 million. At least 75% of that, or about $56 million, will come from anatomic pathology services, not lab testing.

DIANON's success at selling pathology services on a nationwide basis is an early warning sign to the pathology profession. Its experience is mirrored by UroCor, Inc. and **IMPATH, Inc.** All three companies offer anatomic pathology services nationally.

During the last five years, each of these three companies experienced strong, consistent growth rates. By investing in sales and marketing, all three companies have succeeded in getting increasing numbers of doctors to refer anatomic pathology specimens to their labs.

The marketplace is validating that physicians are just like any other category of consumers. When a professional sales force educates them about the benefits of a product or service, they will buy. For this reason, local pathology practices interested in additional revenue should launch their own sales program. That's one way to insure that AP specimens stay in the community. TDR

Pathology Update

Individual Pathologist "Branding" Promoted by National Firms

IMPATH is latest pathology company to tout affiliation with a noted pathologist

IN THE EFFORT TO GAIN COMPETITIVE market advantage, **IMPATH, Inc.** of New York City publicized the recent signing of an exclusive partnership agreement involving renowned pathologist Juan Rosai, M.D., also of New York City.

Dr. Rosai has a world-wide reputation for his books, book chapters, and monographs on surgical pathology. Until recently, he was the Chairman of the Pathology Department at **Sloan-Kettering Cancer Center** and Professor of Pathology at **Cornell University**. He left to become Chairman of the Pathology Department at the **National Cancer Institute** in Milan, Italy.

Under terms of the agreement, Dr. Rosai will use IMPATH as his exclusive partner for analysis of biopsies and surgical specimens from U.S.-based physicians. Dr. Rosai's existing U.S.-based business, estimated at about $1.5 million per year, will be serviced by IMPATH. Dr. Rosai will also serve as consultant to IMPATH. In that role, he will be available for diagnostic consults with pathologists, physicians, and others.

Publicize A Relationship

With this announcement, IMPATH becomes the second national pathology company to publicize a relationship with a leading pathologist. Only last July, **AmeriPath, Inc.** of Riviera Beach, Florida announced a services agreement with A. Bernard Ackerman, M.D., the renowned dermatopathologist. Under this agreement, AmeriPath and Dr. Ackermann were co-founding the **Ackerman Academy of Dermatopathology** in New York City.

"Branded Pathology"

For pathologists throughout the United States, these two developments are early evidence that a new era of "branded pathology" is about to commence. Both IMPATH and AmeriPath, as publicly-traded companies, established these relationships with famous pathologists to gain credibility, boost the quality of their anatomic pathology services, and generate new business.

THE DARK REPORT expects to see additional publicity surround the affiliation of noted pathologists with these and other pathology companies. Further, these companies will advertise their relationships with famous pathologists. This advertising should pay dividends as technology enhancements and market forces make telepathology not only feasible, but desirable.

As that occurs, famous names in pathology will have a market advantage over lesser known pathologists. It might be described as the "Drs. Cooley and DeBakey Effect," where publicity generates more patients, which generates more publicity. TDR

Dynacare Buys LabSouth as Gateway into Alabama

Canadian lab company pursues growth by implementing "Southern strategy"

CEO SUMMARY: WIth the acquisition of ARL/LabSouth, based in Birmingham and Montgomery, Dynacare immediately becomes a major player in the Alabama marketplace. Several interesting aspects to the sale demonstrate that it is becoming increasingly difficult for independent commercial laboratories to access the capital needed to continually upgrade capabilities and fund expansion efforts.

ONCE AGAIN **Dynacare Inc.** is on the move. The Canadian-based laboratory company announced the acquisition of **ARL/LabSouth, Inc.**, headquartered in Birmingham, Alabama.

The transaction is expected to close during the first quarter 2000. ARL/LabSouth is a major player in the Alabama marketplace. It operates laboratories in Birmingham and Montgomery. Annual net revenues are approximately $40 million.

Major Competitor

"Acquiring ARL/LabSouth immediately makes us a major competitor in Alabama," said Osama Sherif, Executive Vice President at Dynacare. "It is a high quality lab company with a strong reputation in the markets it serves. ARL/LabSouth provides us a good foundation for further growth and expansion in Alabama and neighboring states."

This is consistent with Dynacare's emerging "Southern strategy." During the last two years, it has done lab acquisitions in Louisiana, Arkansas, and Mississippi. *(See TDR, November 29, 1997.)* According to Sherif, the eastward march will continue. "We expect to have lab operations in Georgia before too much longer. There are also negotiations under way which would bring us into the Carolinas," he noted.

Dynacare is pursuing a strategy that THE DARK REPORT defines as "go where they ain't." Neither of the two blood brothers operates a regional lab in Louisiana, Arkansas, and Mississippi. There is a **Laboratory Corporation of America** regional lab in Birmingham. Dynacare's string of regional laboratory hubs across these four states makes it a dominant provider without having to go head-to-head with the nationals in any city except Birmingham.

"Our plan is to use the ARL/LabSouth facilities in Alabama as core labs," explained Sherif. "They are ideally situated to support Dynacare's operations across the South. Also, our laboratories in Baton Rouge, Louisiana and Meridian, Mississippi currently operate in facilities

Dynacare's Osama Sherif Comments On Future Plans, Industry Changes

"The future for Dynacare will probably revolve around two themes," stated Osama Sherif, Executive Vice President at Dynacare, Inc., based in Toronto, Canada.

"First, we will continue to do small, fold-in laboratory acquisitions," he said. "These will be labs typically doing about $5 million to $10 million per year in net revenues. These acquisitions will be done selectively, to support our market coverage and expansion plans.

"Second, Dynacare continues to believe that joint ventures with hospitals make good economic sense. Certainly these do not happen quickly, but we are patient and willing to invest the time necessary to help hospital administrators evaluate our proposals and develop a winning partnership plan.

"During the next few months, we expect to announce additional lab acquisitions and more hospital partnerships," added Sherif. "We are hopeful that hospital partnerships in West and Middle Tennessee will happen shortly. This will complement our existing partnership in Knoxville with the University Health System."

Another milestone for Dynacare is the passing of Y2K. "Now that the New Year has come and gone, we can redirect our efforts away from Y2K projects and toward E-commerce activities," Sherif noted. "We believe there is lots of opportunity to use the Web to enhance laboratory services and generate worthwhile revenue from these services. This will be a priority for us throughout 2000."

When asked about changes to managed care contracting for laboratory services, Sherif had an interesting response. "For us, managed care contracting has never been an impediment. In our experience, where we have strong operations in a region, the managed care players will carve us out of their national contracts. We expect this to be equally true in Northern Alabama, following our acquisition of ARL/LabSouth."

that are somewhat dated. Acquiring ARL/LabSouth gives us new options on how to upgrade those locations."

ARL/LabSouth was a private company created from two independent labs. In 1995, LabSouth (formed in 1990 in Birmingham) was merged with **Alabama Reference Labs** (formed in 1974 in Montgomery). Its three owners are Robert B. Adams, M.D.; Ronald Elliott; and Alton Sturtevant, Ph.D. They decided to sell after carefully considering upcoming changes to the Alabama healthcare marketplace.

Solid Operation

"We've done pretty well during the past four years," observed Elliott. "Despite declines in reimbursement and all the other problems familiar to lab managers, ARL/LabSouth maintained a solid operation.

"But every analysis we did indicated that it would require a significant amount of capital to push us up to the next level," he continued. "The effort and cost of raising that capital is becoming prohibitive when measured against the steady erosion in laboratory reimbursement.

"Further, **Blue Cross of Alabama** announced an arbitrary and sizable reduction in laboratory pricing, effective January 1," added Elliott. "They insure about one third of the population in our service areas. Add to that the increasingly onerous Medicare requirements for getting reimbursed, and we decided it was a smart time to change.

"We had three goals in selling ARL/LabSouth," Elliott noted. "First, we wanted job stability for the hard-working, experienced people who've contributed to the success of our laboratory.

"Second, it was important to affiliate with a company which has the capital and resources to invest in ARL/LabSouth's continuing growth," offered Elliott. "We wanted a new owner that would commit to building this laboratory organization.

"Third, Dr. Adams is preparing to retire," he said. "After closing, both Dr. Sturtevant and I will continue on with Dynacare here in Alabama. Dr. Adams will also continue after the sale to Dynacare."

Need Access To Capital

During 1999, a number of independent laboratories were sold. Along with the sale of ARL/LabSouth, these transactions confirm that independent laboratories now need access to additional capital. Without it, their ability to maintain market share and adequate profits becomes increasingly difficult.

Most independent lab owners who sold their company during 1999 still ran profitable operations. This was a consequence of the lab's history of high service levels relative to competing labs, strong customer loyalty, and conservative financial management through the last half of the 1990s.

Given the existing profitability of their labs, what motivated these owners to sell was their assessment of the future. For their independent laboratories to remain competitive during the next several years, it would require a substantial investment of capital and resources. Unfortunately, the expected return on this capital was projected to be meager.

That is why existing independent commercial laboratory owners are making rational decisions to sell their companies. Buyers are invariably better-financed, more aggressive, and willing to make the sizable investments required to push that laboratory organization to a higher level of revenue and profits.

Two Reasons For Selling

Since only a handful of independent labs remain in the $25 million+ category, there won't be many lab acquisitions during 2000 and 2001. Any sales of independent laboratories which do occur will generally be for one of two reasons.

First, existing owners of some independent laboratories are ready to retire. By selling, they can extract their equity while providing their loyal employees with continued employment. The hospital owner of **Louisiana Reference Laboratory** in Baton Rouge sold to Dynacare for these reasons. It wanted to extract its equity to invest in other projects, while insuring ongoing employment for the laboratory employees.

Second, existing owners are unwilling, or unable, to invest the significant capital required to upgrade information systems, acquire new testing technology, and fund expanded sales and marketing. Selling to stronger hands permits these owners to continue working with the lab, even while the buyer invests more capital to support further growth.

Continue As Managers

This is certainly the primary reasons why the original owners of both **American Medical Laboratories** in Chantilly, Virginia and **Associated Pathologists Laboratories** in Las Vegas, Nevada sold their laboratories, but after the sale continued as investors and active managers. TDR

Contact Osama Sherif at 416-322-2318 and Ron Elliott at 205-251-4191.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Recent developments prove that the feds are serious about health care fraud and abuse! Sentencing was announced last month for the two **Columbia/HCA** hospital executives convicted last July 2 on charges of conspiring to defraud Medicare and other government healthcare programs. On December 22, the judge sentenced Jay Jarrell, 43, to 33 months of jail, a $10,000 fine and restitution of $1.7 million. This follows the December 3 sentencing of fellow executive Robert Whiteside, 48. Whiteside was handed a two-year jail sentence and ordered to pay a fine of $7,500 and restitution of $645,796 to the healthcare programs.

ADD TO: CONVICTIONS

Prosecutors convicted the two men of cheating government health plans out of $3.5 million. Stiff jail sentences send a clear signal to all healthcare executives. If fraud and abuse can be proven, prosecutors will recommend prison. In retrospect, lab execs involved in Labscam cases during the 1990s may have been lucky that they avoided jail.

BECKMAN COULTER MOVES TOWARD PHARMACOGENOMICS

Recognizing the market potential attached to pharmacogenomics research, **Beckman Coulter, Inc.** announced a technology partnership with **Third Wave Technologies, Inc.** of Madison, Wisconsin. The companies will pair Third Wave's Invader® DNA/RNA analysis technology with Beckman Coulter's SAGIAN® high throughput platform. The finished product will speed research into single nucleotide polymorphisms (SNP). Beckman Coulter's automated platform is capable of performing 100,000 Invader reactions per day.

MORE ON: SNPs

SNPs are differences in an individual's genetic code. These variations from person to person are believed to be why some people are more susceptible to disease than others. Of equal interest to drug companies, it is believed that SNP differences between individuals are responsible for their responsiveness to therapeutics.

Pathologists affiliated with Detroit's **St. John Health System** recently sold their practice to **AmeriPath, Inc.** of Riviera Beach, Florida. There are 13 pathologists affiliated with **J.J. Humes, M.D. and Associates, P.C.** The group practice serves three hospitals and the St. John outreach laboratory. This is AmeriPath's first foray into Michigan.

It's a second patent for **Associated Pathologists Laboratories** (APL) in Las Vegas, Nevada. *(See TDR, July 19, 1999)*. The United States Patent Office granted the patent covering APL's "unique method of detecting drugs of abuse in hair samples." The patent protects APL's unique method of detecting marijuana in hair samples. The APL process uses enzyme linked immunosorbant assay (ELISA) technology. Among other benefits, APL's hair-based drug screen avoids the increasingly common problem of a patient adulterating his/her urine specimen at time of collection to interfere with the lab's analysis of the specimen.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, January 24, 2000.

SPECIAL: FIRST LOOK AT WEB-BASED NEW LABORATORY INFORMATION TOOLS!

EXECUTIVE WAR COLLEGE DATES

MAY 16-17, 2000

Fairmont Hotel, New Orleans

(Laboratory CEO Day—May 18, 2000)

UPCOMING...

- ***The Dark Report Offers a Unique "State of the Pathology Profession" Review.***
- ***Why HEDIS and NCQA Requirements Are Changing the Way HMOs buy Laboratory Testing.***
- ***Clinical Laboratory Homegrows its Own Web-Based System to Connect With Clients.***
- ***Making Money the Old-Fashioned Way: Chicago Hospital Outreach Program Hits Home Run and Drives in Big Profits.***