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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

New Blood Entering the Lab Industry

SURPRISE! THERE'S A QUIET MANAGEMENT REVOLUTION UNDER WAY in both the clinical laboratory industry and pathology profession. During the past few years, a steady flow of new-thinking Presidents and CEOs have taken control of laboratories, pathology group practices, and vendor companies.

From CEO Ken Freeman of **Quest Diagnostics Incorporated** to CEO James New of **AmeriPath, Inc.**, these are executives whose thinking and perspectives were shaped by a career *outside* the laboratory world.

But I believe the most significant influence upon laboratory medicine and pathology will come from an emerging class of companies—companies unfamiliar to virtually all of us because they didn't exist two years ago. These are the companies building their future around information management. They believe the future lies in Internet-based technologies and a yet-to-be defined healthcare system dominated by e-commerce.

These are newly-minted companies, with high hopes, lots of enthusiasm, and, in some cases, oodles of venture capital money. Their names are beginning to appear on the pages of THE DARK REPORT. What makes these companies a threat to the established order in the laboratory and pathology world is that they don't know "how things are supposed to be." They see the world as it is today. They are intensely-focused on making money by bringing new services and products to market.

The established order is struggling with this. The professional associations are always a bellwether of change, and they face challenges. From the **College of American Pathology** (CAP) to the **Clinical Laboratory Management Association** (CLMA) and **American Association of Clinical Chemistry** (AACC), there is concern over membership retention and the fact that national conventions seem to be losing the importance they once held for the entire industry. The concerns of the lab industry professional organizations are just the top of this particular iceberg. Most of the serious change still lies unseen, below the surface.

I believe we are witnessing a transfusion of new management blood into the laboratory industry and pathology profession. As these new executives build the influence of their companies, they will surely alter the laboratory marketplace. It may be that they will successfully infuse that silicon valley entrepreneurial spirit into both clinical laboratories and pathology group practices. TDR

Pathology Profession Facing New Directions

Our "State of the Profession" overview identifies forces now reshaping pathology

By Robert L. Michel

CEO SUMMARY: Big changes ahead during the next decade. Among the predictions: the number of two and three-pathologist group practices will radically diminish; pathology centers of excellence will achieve new market dominance; and...ever more intense competition for anatomic pathology specimens! At the same time, expect this decade to bolster the professional status of pathologists.

IF THE 1990S WERE A ROLLER-COASTER ride for the pathology profession, then expect the first decade of the new century to be more like a rocket trip into space!

Most changes to the pathology profession will be directly stimulated by new technologies in informatics, communications, and genetics. The industry-wide "reorganization" of the American healthcare system will be ongoing, continually shaped and influenced by new technologies.

All of this is good news for both anatomic pathologists and clinical pathologists. After a decade of declining clinical influence and shrinking compensation, those trends will reverse during the upcoming decade, to the benefit of pathology.

But radical change does have a consequence. It creates new classes of winners and losers. Within the pathology profession, there will be highly prosperous pathology group practices.

Common to the success of these pathology winners will be at least two factors. First, they understand the need for professional management in the areas of administration, finance, sales, and marketing and include these skills within their practice.

Second, winning pathology practices in the next decade will be market-perceptive. They recognize shifts in how healthcare is organized. They anticipate how new clinical procedures alter traditional patterns of care and shrewdly reposition their pathology group practice to benefit from these developments.

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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).

In short, the pathology profession's winners during the next market cycle will be open-minded and willing to change how they organize and deliver pathology services. They will be ever ready to adopt new clinical procedures and offer them to clinicians.

Pathology's Losers

Obviously, pathology's losers during the next market cycle will be those group practices which clung to traditional ways and habits. As their ossified view of the healthcare marketplace inhibits their ability to change, these pathology practices will lose their independence.

Effectively, the "losing" group of pathology practices will find themselves acquired or merged into larger group practice companies which have demonstrated their market responsiveness.

In this "state of the pathology profession" analysis, THE DARK REPORT identifies six major themes to the early years of this new decade. Pathologists will find themselves dealing with a wide range of influences on how medicine is organized and practiced.

Moreover, this pathology "state of the profession" should be evaluated in conjunction with all the factors highlighted in our overview of the clinical laboratory industry. *(See TDR, January 3, 2000.)* The specific market drivers acting upon the clinical lab industry will also have some influence upon the pathology profession.

Professional Skills

But the pace of change in pathology is somewhat slower than with the clinical laboratory industry. That is partly because pathology is deeply rooted in professional skills, whereas clinical laboratories can more easily replace humans with machines and computers to generate test results.

For that reason, THE DARK REPORT's list of prime trends in pathology has many key differences from the list prepared for the clinical laboratory industry.

There is one fascinating aspect about this year's pathology "state of the profession" overview. Each major trend is closely linked to the others on this list. The emergence of national pathology firms *(page 5)* contributes to increased regionalization of pathology services *(page 9)*. Branding of pathology services *(page 6)* supports the success of pathology centers of excellence *(page 7)*, as does the expected increase in molecular and genetics-based pathology *(page 8)*.

E-Commerce Is Wild Card

If there is any wild card in our list of major trends, it is the growth of healthcare e-commerce. THE DARK REPORT predicts that the Internet and the World Wide Web will stimulate a transformation of healthcare in ways beyond our comprehension today.

The Internet makes it easy for businesses and customers to connect with each other. The cost of access and the cost of transacting business over the Internet is falling at a rate that exceeds Moore's Law for Semicon-ductors (computing capacity on a chip doubles every 24 months).

No one fully comprehends how the Internet, and related technologies, will change the way humans conduct every aspect of their personal and business affairs. But there is consensus among the experts that the Internet, and all that it unleashes, will be a boon to human society.

Given that remarkable prediction, pathologists should keep a watchful eye on healthcare e-commerce. More than any other major trend presented here, healthcare e-commerce represents the biggest opportunity for success, as well as the greatest threat of failure!

State of the Pathology Profession-Key Trend #1

Healthcare E-Commerce

DURING THE NEXT FIVE YEARS, healthcare e-commerce will be the single most transformational force that reshapes the pathology profession as we know it today.

It is too early to predict exactly how e-commerce will change healthcare and the profession of pathology. The concept of e-commerce is too new and enabling technologies are rapidly evolving.

Despite these facts, the expected explosion in healthcare e-commerce rests upon an undeniable fact: the Internet makes it economically feasible to move information between companies at continuously-decreasing costs. Ongoing improvements to hardware and software make it possible to collect and analyze data in ways heretofore impossible.

Better information, generated at lower cost, will unlock new ways to provide healthcare services. Moreover, enhanced information capabilities have immense potential to increase productivity within the American healthcare system, because, during the last 30 years, spending by American healthcare organizations on information management lagged behind other industries by a significant amount.

For pathologists, enhanced and lower cost information capabilities are precisely the tools they need. After all, the basic function of a pathologist is to create data, analyze it, and report the resulting knowledge to clinicians. Unlike other clinicians, pathologists do not see patients. Instead, pathologists use specimens to create information and knowledge which is put to use by other segments of the integrated healthcare environment.

E-commerce will transform healthcare, as it is now transforming other industries. For pathologists, the arrival of e-commerce services will give them a new way to provide value-added services to clinicians, hospitals, payers, and patients.

Pathologists should view healthcare e-commerce as a tool which reduces the cost to gather data, create useful information, and communicate that information to interested parties. For example, instead of sending a report just to the physician, e-commerce will make it possible for the pathologist to simultaneously send appropriate versions of this report to the patient and his health insurer.

As noted above, one impact of healthcare e-commerce will be to disrupt the traditional relationships pathologists have with hospitals and physicians. Because of the lower cost of processing data and transmitting it, new types of relationships will develop between the pathologists and non-physicians.

For example, the baby-boomer generation is already demanding a greater role in their own healthcare. It is logical to expect that they will want to interact with any pathologists who are referred specimens by the attending physician.

Thus, pathologists should embrace healthcare e-commerce as a useful tool for providing new added-value services to the healthcare community. It is the kind of positive change that will bring welcome benefits to the pathology profession.

Key Trends

State of the Pathology Profession-Key Trend #2

National Pathology Firms

EXPECT THE FINANCIAL SUCCESS of the first group of national anatomic pathology companies to spawn a host of competitors during the next several years.

The age of national pathology companies has arrived. It is heralded by the accomplishments of **DIANON Systems, Inc.**, **IMPATH, Inc.**, and **UroCor, Inc.** throughout the 1990s.

Each of these companies sells to a very different niche within the marketplace. But each offers some form of anatomic pathology services to the national market.

During the second half of the 1990s, all three firms maintained a steady growth in the volume of anatomic pathology specimens flowing into their companies. More importantly, these anatomic pathology specimens generated significant revenues and operating profits to the three companies listed above.

Even if this experience has gone unrecognized by the pathology profession, it has not been overlooked by Wall Street investors and venture capitalists. They've spotted a good way to make money, and they want to invest in more anatomic pathology-based firms.

It will be outside investors, not pathologists, who fund the next crop of national anatomic pathology companies. THE DARK REPORT predicts that these companies, utilizing the capabilities of such technologies as healthcare e-commerce, will bring about a national market for anatomic pathology services. In the process, pathology as a clubby profession will disappear forever.

What replaces it will bring greater recognition and income for anatomic pathologists who are accomplished at their craft. The reason is simple. Pathology's most gifted practitioners will have a national reputation. They will be referred specimens from across the nation and the globe.

However, as the market demand for national anatomic pathology services develops, it will cause problems for local pathology groups wanting to capture specimens from physician offices. Since local pathology group practices are reluctant to hire sales and marketing people, they will find their physician accounts slipping away to sales reps employed by the national AP companies.

For hospital-based pathology group practices, the arrival of national anatomic pathology companies will not trigger much change, at least in the short-term. The initial goal of the national AP companies will be to generate specimens from physician offices.

But at some point, the national AP companies will want to acquire hospital contracts. It is the same sales pattern seen by the national laboratories. From about 1985-1995, their emphasis was on physician office business. But once they scooped up most of that business, they began approaching hospital labs to pitch joint ventures, contract management contracts, and similar arrangements.

The arrival of national anatomic pathology service firms will occur in tandem with most of the other trends listed in this intelligence briefing. It is a trend that will be unstoppable.

State of the Pathology Profession-Key Trend #3

Branding Path Services

COMPARED TO OTHER PHYSICIAN specialties, pathologists have mostly avoided the public eye, both inside and outside the healthcare community.

Marketplace forces to change this situation are already under way. During the past six months, two anatomic pathology companies have publicized their relationships with noted pathologists.

In July, **AmeriPath, Inc.** announced that A. Bernard Ackerman, M.D. would participate with the company in creating a dermatopathology center of excellence. *(See TDR, July 19, 1999.)* That was followed in December by **IMPATH, Inc.'s** press release touting its contract relationship with Juan Rosai, M.D. the pathologist now affiliated with **National Cancer Institute** in Milan, Italy. *(See TDR, January 3, 2000.)*

THE DARK REPORT interprets these actions, along with other forces now visible in the marketplace, as evidence that "branding" of pathology services is about to occur on a larger scale. In order to gain competitive advantage, certain anatomic pathology companies and group practices will begin to advertise the talents of their most skilled anatomic pathologists.

The movement to brand anatomic pathology services is a direct result of the emergence of professionally-managed companies which are profit driven. These companies must differentiate themselves from competing anatomic pathology providers. To gain competitive advantage over other pathology providers, they will invest in advertising to convince clinicians that their company is the best source for AP services.

Community hospital-based pathology practices have already been the victims of this branding strategy. During the 1990s, national AP providers such as **DIANON Systems, Inc.** and **UroCor, Inc.** sent hordes of sales people into doctors' offices around the country.

These sales people were successful. A steady and ever-increasing flow of biopsies was diverted away from the local pathology practice and sent instead to national labs in Connecticut (DIANON) and Oklahoma (UroCor).

THE DARK REPORT sees compelling evidence that the sales competition for anatomic pathology specimens from local physicians' offices will increase during the next 24 months. Local pathology groups will be unprepared to respond to this competition.

The two blood brothers, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, have also realized that there is profit in anatomic pathology. Expect them to devote more sales resources into this market niche.

AmeriPath has already told the investment community that it wants to increase its national AP business. With its $250 million in annual revenues, it has the financial strength to pursue this goal.

All of this sales competition will focus around "branded" anatomic pathology services. It may soon be that some pathologists become as renowned as the most famous cardiologists and sports orthopedists!

Key Trends

State of the Pathology Profession-Key Trend #4

Path Centers of Excellence

SPECIALIZATION IS A CONSTANT theme in both industry and healthcare during the past four decades.

Evidence of increased specialization can be seen in the variety of medical specialties and subspecialties that exist today, compared to those of 1960. Pathologists have seen this same dynamic at work. Over the years, a variety of pathology subspecialties has emerged. These new subspecialties are a direct result of increased knowledge about certain disease states, along with improved technologies.

As specialization increases, its logical consequence are specialized skill centers. In the medical world, these have come to be called "centers of excellence." To accept the premise of increased specialization of anatomic pathology services it is necessary to accept the development and growth of anatomic pathology centers of excellence.

It is the belief of THE DARK REPORT that the decade of the 2000s will see the flowering of AP centers of excellence. However, it cannot be assumed that such centers will emerge only from well-capitalized, national AP companies.

To the contrary, new communications technology, such as the Internet and healthcare e-commerce tools, will make it possible for *any* community hospital-based pathology group to develop its own unique anatomic pathology center of excellence.

Internet technology makes it easy for any size of healthcare provider to enter the marketplace and provide clinical services. The Internet will prove to be the great equalizer, but only for those pathologists who recognize its potential and actively strive to take advantage of its capabilities.

Against the background of increased specialization of medicine in general, and pathology in particular, centers of excellence will be the expected consequence. Internet technology will make it possible for even small, local pathology group practices to offer specialized anatomic pathology services on a national, even international, basis.

Further, this view of anatomic pathology centers of excellence still permits practicing pathologists to operate a "dual" practice. On one level, they can continue to live in the community of their choice and practice in a small hospital setting.

But on another level, they can take their particular area of specialized pathology expertise and offer it, via the Internet and other methods, to a national marketplace.

The trend toward anatomic pathology centers of excellence is reinforced by other trends listed in this "state of the pathology profession" briefing. Branding, emergence of national anatomic pathology companies, and regionalization of anatomic pathology services are all trends which support and encourage the creation of AP centers of excellence.

What will determine whether community hospitals-based pathologists can make a successful center of excellence is their ability to implement professional management and sales and marketing into their group practice.

State of the Pathology Profession-Key Trend #5

Molecular/Genetic Path

Key Trends

ADVANCES IN MOLECULAR and genetic science during the next decade will provide the pathology profession with its most powerful clinical tools.

One consequence of this development will be the diminishing importance of the microscope to anatomic pathologists. Better knowledge about the genetic make-up of different diseases will allow for a more precise diagnosis using tests based upon genetics and molecular science.

Pharmaceutical firms will be the driving force in developing genetic and molecular knowledge. Each year, these companies pour greater amounts of money into primary research. Their goal is to understand the genetic and molecular operation of the human body.

The word "pharmacogenomics" was coined to describe this emerging field of study. *(See TDR, September 8, 1998.)* At its simplest, pharmacogenomics refers to the process of using genetics-based technology to evaluate the effects of pharmaceutical compounds on the body.

On one level, pharmacogenomics describes how drug companies use genomic information to discover and identify effective drugs. This is the process of creating new pharmaceutical compounds.

On another level, pharmacogenomics describes its clinical use for diagnosis and prognosis. The clinician uses pharmacognomics to identify specific ways that an individual might react to a drug.

As the human genome project identifies genes, and their functions, there will be a cascade of new tests and procedures for both diagnosis and prognosis.

For the pathology profession, this scientific revolution will increase the value of pathologists to clinicians. Just as the arrival of MRIs, PETs, and other sophisticated scanning technologies made radiologists essential partners with clinicians, so also will new genetic and molecular-based procedures do the same for pathologists.

THE DARK REPORT explored these trends in earlier stories. For example, 20 years ago, lymphomas represented a more serious disease than it does today. Now tests can distinguish between Hodgkin's, non-Hodgkin's, B-cell, T-cell and other types of lymphomas. These tests allow pathologists to present a patient with biological specificity. Treatment is then targeted to that specific patient.

On pages 13-14 of this issue, we report on **Digene Corporation**'s HPV test, which uses antibodies to detect DNA:RNA hybrids. New clinical studies suggest that, with further improvements, this HPV test might someday equal or exceed the specificity and sensitivity of the traditional Pap smear in screening for cervical cancer. Should that occur, the microscope could yield to a genetic-based assay as the preferred method for this type of screening.

As genetic and molecular-based medicine expands its scope, pathologists will be provided with new opportunities to add value. This will enhance compensation for pathology procedures. It will also foster the increased specialization that supports pathology centers of excellence.

Key Trends

State of the Pathology Profession-Key Trend #6

Pathology Regionalization

REGIONALIZATION of anatomic pathology services is an inexorable trend. Nothing will stop the ongoing consolidation of small group practices into regionalized pathology provider organizations.

The concentration of hospital ownership and control is the prime mover. Now that 604 integrated healthcare systems (IHS) control 3,760 of the nation's 4,800 non-government, acute care hospitals *(See TDR, April 5, 1999)*, consolidation of the individual pathology practices serving an IHS is almost a forgone conclusion.

A separate market phenomenon is the growth of single-specialty physician practice management companies focused on anatomic pathology. Among the better known are **AmeriPath**, **Pathology Consultants of America**, **PathSOURCE**, **PathGroup, Pathology Partners**, and **USLABS**.

None of these firms are reported to be in financial difficulty and the best of them are prospering. Each company has a different strategy for growth, but they all need to achieve this growth by consolidating small pathology groups into larger, regionalized clusters.

Another source of pathology regionalization is the growing number of statewide pathology networks. For the most part, these are organized under the banner of **Pathology Service Associates** (more than 80 pathology practices and 400 pathologists in at least eight states).

The need to offer pathology services across a specified geographical area is the common thread which links each of these three distinct categories of pathology practice regionalization. This movement is a reaction to the consolidation of all segments of the healthcare community.

The days of a profession dominated by pathology groups of 2-5 physicians are ending. Over the next five years, the pathology profession will increasingly be marked by larger pathology group practices, averaging more than ten physicians, and serving multiple hospitals and multiple hospital systems in a metropolitan area.

Most big cities will have several of these regionalized pathology group practices. Competition for hospital contracts will become more intense. The need to diversify revenue sources will cause these pathology groups to compete earnestly for specimens from physicians' offices.

Perceptive pathologists understand why the cumulative impact of all the forces now acting upon healthcare makes it inevitable that regionalization of anatomic pathology must occur. Those pathologists who act proactively to position themselves, and their group, will tend to control events in their community.

Those pathologists adopting a "wait and see" strategy will generally find themselves offered less generous opportunities. After all, reward is commensurate with risk. Pathologists willing to be first to drive the regionalization process first are taking the most risk. They will see the greatest return.

Regionalization of anatomic pathology services is probably the game with the highest stakes during the next five years. That is why every pathology group should have a regionalization strategy. TDR

Lab Industry Watch

Park City Solutions Acquires Chi Lab Systems of Ann Arbor

Golder Thoma-financed company moves to expand its reach into the lab industry

THERE'S A NEW PLAYER in healthcare and laboratory consulting. **Park City Solutions, Inc.** of Midway, Utah wants to become a recognized name in the lab industry.

As one step toward this goal, it announced the purchase of **Chi Laboratory Systems, Inc.** of Ann Arbor, Michigan. The deal was made public on December 28, 1999.

Park City Solutions (PCS) is one of a new breed of service companies emerging to serve the healthcare marketplace. It is neither a software vendor nor a traditional consulting company. Instead, it is a blend of several types of core business services, bundled as a single solution.

Comprehensive Solutions

"There is a clear need by integrated health networks (IDN) and other healthcare companies for comprehensive solutions," said Terry A. Pitts, President and CEO at Park City Systems. "Piecemeal consulting resources are no longer adequate to address the rapid changes now reshaping the American healthcare system."

Asked to describe his company, Pitts responded with a simple answer. "Park City Solutions has the capability to help with integration, followed by implementation. The entire process; before, during, and after, is supported by our 'best practices' expertise."

Pitts is describing a wholistic approach to healthcare problem-solving. It is consistent with the management philosophies of ISO-9000 and other quality improvement systems. Because of the importance of lab data to healthcare services, PCS knows it must have expertise in this area.

Patient Health Record

"Lab administrators and pathologists know that lab data comprises 70% of the typical patient record," observed Pitts. "We believe healthcare systems will increasingly turn toward laboratory testing as the place to improve the quality of care, lower costs, and improve both clinical and operational integration.

"That is one reason we acquired Chi Laboratory Systems," he continued. "We believe that Chi possesses a clean, comprehensive data base on laboratory operations. Its people are also a strong resource. PCS needs these types of capabilities to provide a comprehensive solution for IDNs and other healthcare entities."

Formed early in 1999, Park City Solutions has something in common with several laboratory organizations. It is backed by the investment firm of **Golder Thoma Cressey and Rauner**, LLC (GTCR), based in Chicago, Illinois. GTCR is the firm which provided financing used by **Dynacare Inc.** to

purchase its public stock and become a private company in 1996. GTCR also provided funding for the buyers of **American Medical Laboratories, Inc.** of Chantilly, Virginia in 1997. *(See TDR, May 12. 1997.)*

PCS Executive Team

PCS was founded by three individuals, each with a background in healthcare companies. Terry Pitts, President and CEO, was a key executive for several years at **Shared Medical Systems, Inc.** (SMS). Scott Holbrook, Executive Vice President at PCS, was formerly the Chief Operating Officer at **Sunquest Laboratory Systems, Inc.** Scott Remley, Chief Financial Officer at PCS, has 24 years of management experience in various healthcare firms.

Laboratory executives and pathologists should see Park City Solutions as a new type of healthcare consulting service company. It is combining expertise in software systems, data management technologies, and project implementation into a single package.

PCS's business strategy is to help its clients improve the collection, management, and storage of data, then use that data to drive performance outcomes in a variety of ways. This is certainly consistent with THE DARK REPORT's prediction that real value-added for clinical laboratories is converting raw lab data into useful knowledge.

Emphasis On Best Practices

The other interesting aspect about Park City Solutions is its emphasis on best practices. "Best practices" is a concept from quality management systems. It requires careful measurement of relevant work processes which can then be compared against the best practices of that industry's leading companies.

For PCS, offering "best practices" solutions means that it will enjoy long-term relationships with its clients, including clinical laboratories. Once PCS helps to solve a client's problems, it continues the relationship by helping that client achieve performance levels equal to the best practices in the healthcare industry.

Until its purchase of Chi Laboratory Systems, Park City Solutions had kept a relatively low profile within the laboratory industry. Expect that to change. PCS intends to energize Chi and expand its service capabilities. That may lead to increased sales efforts by competing lab consulting companies. Certainly such firms as the **Wilkerson Group**, **Healthcare Development Services**, and **Superior Consultants** will not let PCS/Chi get a jump on them.

Park City Solutions has ambitious goals. Because it is well-organized and well-financed, it should be considered as a credible new competitor. TDR

Park City Acquiring Several Companies

To create a one-stop solution for healthcare organizations, Park City Solutions (PCS) has purchased a number of companies. Here is a list of the operating divisions at PCS to which the recently-acquired Chi Laboratory Systems will be added.

- *PCS/Healthcare Technologies*, Cincinnati
  Integration management
- *PCS/AmeriNet*, Salt Lake City
  Services for AS/400 technology platforms
- *PCS/First Choice*, Wichita
  Implementation services
- *PCS/Custom Integration Cnsltnts*, Las Vegas
  Data integration services involving interface engines
- *PCS/Lab Information Systems*
  LIS and scheduling services
- *PCS/Decision Support System Consulting*
  Application and technical consulting services for Eclipsys/TSI, HBOC Trendstar, and HCM decision support systems.

Digene Corp's HPV Test Attracts More Attention

Recent studies published in JAMA spur increased interest by national lab firms

CEO SUMMARY: Evidence accumulates that HPV testing may be an effective way to identify women at risk for cervical cancer. Both Laboratory Corporation of America and Quest Diagnostics Incorporated recently added Digene's Hybrid Capture® II HPV test to their menu. The intent is to offer physicians a follow-up test for patients with Pap smears that are judged ASCUS or have "borderline results."

HERE'S A NEW TWIST IN THE RACE to improve Pap smear testing. **Digene Corporation's** Hybrid Capture® II HPV test gained more respect with the publication of two new clinical studies.

Published in the January 6, 2000 issue of the *Journal of the American Medical Association* (JAMA), the two studies "suggest that human papillomavirus (HPV) testing may be viable for cervical cancer screening in some populations of women."

Major Competitor

Digene's HPV test is approved by the **Food and Drug Administration** (FDA) for secondary, or confirmatory, cervical cancer testing. The FDA approval allows it to be used with Pap smears prepared with either a liquid preparation or in the conventional manner. It is not approved for primary screening or for self-collection.

Some media reports interpreted these clinical studies as a demonstration that it may soon be feasible for women to collect their own specimen for cervical cancer screening. However, medical experts involved in the studies had only observed that, in countries where a woman's access to healthcare is limited, Digene's HPV test might be used as a primary screen for a specimen collected by the patient.

Increasing Evidence

Digene's HPV test is designed to capitalize on the increasing evidence that 13 of the 70 types of HPV are associated with cervical cancer. A 1999 study indicates that HPV is present in 99.7% of all cervical cancers. Another clinical study demonstrated that, used in conjunction with the Pap smear, HPV testing can detect 97% of moderate or high-grade disease compared to a 76% detection rate with the Pap smear alone. (JAMA, May 5, 1999.)

With the publication of these clinical studies, both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** felt it timely to issue press releases touting the availability of Digene's HPV test through their laboratories.

Digene's HPV test utilizes proprietary signal amplification of antibodies to detect DNA:RNA hybrids. During 1999, Digene obtained clearance to sell its panel of women's cancer and infectious disease tests in almost every major European country, plus Brazil and Argentina.

Liquid Prep Collection

Moreover, from a single specimen, Digene's patented tests can detect HPV, chlamydia, gonorrhea, and herpes. It is non-invasive and can be automated on standard testing equipment. This single-sample system is cleared and available in Europe. It awaits FDA action on Digene's 510(K) application to become available in the United States. The test can use commercial liquid Pap smear collection devices.

As a next step, Digene "intends to submit a PMA supplement with the FDA to obtain market clearance for use of our Hybrid Capture II HPV test as a primary cervical cancer screening test, either in conjunction with, or separate from, Pap smear testing."

However, the company acknowledges that data submitted to the FDA to support this application "may not be adequate to support the use of the Hybrid Capture II HPV Test as a primary cervical cancer screening test in the United States."

Disruptive Technology

Clients and regular readers of THE DARK REPORT will recognize that Digene has potentially disruptive technology. Digene's patented technology joins that of **TriPath Imaging, Inc.** and **Cytyc Corporation** as challenging the traditional way that Pap smears have been collected and diagnosed.

THE DARK REPORT expects that Digene's HPV test will undergo the same intense scrutiny as did the first generation of enhanced Pap smear technologies that were offered by Cytyc (ThinPrep), **NeoPath** (AutoPap), and **Neuromedical Systems** (PapNet) back in 1996.

These technologies must be battle-tested in real clinical settings before a true evaluation of their accuracy, cost-effectiveness, and ease-of-use can be made. That is Digene's next challenge.

In the meantime, here is another example of an emerging technology with the potential to transform the way cervical cancer screening is conducted. It shows how molecular and genetic-based technology can complement, or even supplant, visual-based cytology procedures.

Viewed from this perspective, Digene's HPV assay demonstrates how rapidly the field of molecular pathology may displace more traditional anatomic pathology procedures. TDR

Contact Digene Corporation at 301-944-7000.

DIGENE CORP. At-A-Glance

- *Incorporated:* 1977
- *Employees:* 129
- *Headquarters:* Gaithersburg, MD
- *Share Price:* $28.00 as of 1/21/00
- *Product Areas:*
  women's cancer/infectious diseases
  blood virus
  pharmaceutical research
- *Revenues and Net Profit (in 000s):*

1999	$17.0	-$ 9.3
1998	$12.0	-$14.1
1997	$ 9.4	-$ 6.0

- *Chairman & CEO:* Evan Jones
- *President, COO, CFO:* Charles Fleischman
- *Distribution agreement with Abbott Laboratories for certain products in the United States and overseas.*

NY Labs Achieve Repeal Of Onerous Surcharge

Lengthy effort to gain legislative repeal of laboratory test surcharge finally succeeds

CEO SUMMARY: Clinical laboratories in the state of New York demonstrated that the lab industry can effectively influence legislation when the state legislature finally repealed the onerous laboratory test surcharge first enacted in 1997. Lab industry leaders should apply the lessons learned from the New York experience to improve the laboratory industry's track record in working with Congress.

CLINICAL LABORATORIES in New York state won a major victory at the close of 1999. Legislation was passed and signed by the governor to repeal the 8.18% tax surcharge assessed on laboratory tests.

"This is a major victory for clinical laboratories in New York," stated Thomas R. Rafalsky, President of the **New York State Clinical Laboratory Association** (NYSCLA).

"Not only did we succeed in getting this unwarranted 8.18% surcharge repealed," he explained, "but our ability to generate sustained public response against this tax surcharge has made state legislators, officials and regulators respect us and pay attention to our needs."

The tax surcharge was first assessed on January 1, 1997. It was slipped into state legislation that reformed hospital financing arrangements. Its passage caught New York laboratories by surprise. "Since clinical labs have never been part of the old hospital financing scheme, we didn't expect to be included in the reform legislation," recalled Rafalsky.

As first reported in THE DARK REPORT, laboratorians hit upon a clever way to get the attention of state legislators and government officials. Laboratories printed a notice to patients on their lab bill, and requested that they contact their elected official and demand a repeal of the tax surcharge. *(See TDR, December 16, 1996 and February 17, 1997.)*

1,000 Phone Calls Per Day

At its peak, this lab-inspired campaign was generating 800 to 1,000 telephone calls per day just to the Department of Health! The Governor's Office and state legislators were also inundated by calls from irate constituents. They couldn't ignore the message from their voters.

"There were two phases in our campaign to repeal this tax surcharge," noted Rafalsky. "During the first phase, we were aggressive. Participating labs sent out patient bills asking them to directly call and request the repeal of this tax. As part of this effort,

we established a toll-free 800 telephone number. When patients called this number, we connected them directly to their particular state senator or assemblyperson.

Attention Of Legislators

"Once it was clear we had the attention of both the state legislature and state regulators, we moved to a more educational phase," he added. "This involved having patients contact us, and we then sent a fax, in their name, to their elected representative."

Several times during 1997 and 1998, the lab industry was promised by state officials that the tax surcharge was definitely scheduled for repeal. "It was clear that they wanted to be done with us," Rafalsky stated. "But each time we were close to repeal, something would happen to the political scene that bottled up our particular piece of legislation.

"However, we never stopped the flow of constituent messages going to state legislators," he said. "They always knew we were there and not going away. During 1999, as the reform legislation expired under its sunset clause, the laboratory tax surcharge was the only ancillary surcharge dropped from the new hospital financing bill."

Labs Can Work Together

THE DARK REPORT believes that clinical laboratories in New York have demonstrated how the national lab industry can work together to get the attention of Congress and regulators on issues affecting laboratory medicine and pathology. Rafalsky concurs.

"There is no reason that what we did in New York cannot be accomplished on a national basis," he declared. "We developed a lobbying plan that included personal contacts by laboratory executives with state officials and state legislators. This was supported by having participating laboratories educate their patients about the tax surcharge, using patient bills as the method.

"Just in New York State, we estimate than more than 100,000 patient bills are mailed daily," continued Rafalsky. "On a national basis, that number probably exceeds 1,000,000 per day. This demonstrates the extraordinary reach that clinical laboratories have within the general population. We used that as an asset throughout the entire lobbying campaign."

Rafalsky does have a word of advice about the lobbying process. "You must be prepared for the long haul," he said. "When it comes to politicians and regulators, nothing happens overnight. The process almost seems designed to wear people down, and government officials know this."

Proven Blueprint For Action

THE DARK REPORT observes, as it has during the course of the lab tax surcharge repeal campaign, that the New York experience gives the national commercial laboratory industry a proven blueprint for accomplishing legislative change. This change came about because the majority of commercial laboratories in the state worked together for a common purpose. This demonstrates that concerted action can get the right kind of attention from legislators.

In fact, the lab tax surcharge repeal was mostly due to grass roots efforts by independent lab owners. This is a powerful message to a segment of the lab industry which frequently feels powerless to influence legislation affecting the industry. There is a way to get the attention of Congress. But it will require unified action. The question is, will traditionally independent lab owners be willing to work together for common cause? TDR

Contact Thomas Rafalsky at 212-245-3555.

Lab Industry Briefs

EPITOPE RAIDS LABONE FOR NEW PRESIDENT/CEO; READIES DRUGS OF ABUSE MARKET LAUNCH

DURING THE YEAR 2000, **Epitope, Inc.**, based in Portland, Oregon, plans to introduce a drugs of abuse test based on its patented OraSure® oral collection technology.

To aid in this new product launch, Epitope raided the executive ranks of its biggest customer. Robert D. Thompson, formerly the COO and Chief Financial Officer of **Lab*One*, Inc.** in Lenexa, Kansas. Thompson will become President and CEO at Epitope. He is to assume his duties there today, January 24, 2000.

Prior to joining Lab*One* in 1993, Thompson had been Chief Financial Officer at **MetWest, Inc.**, a clinical laboratory then based in Dallas. Thompson played a major role in helping Lab*One* return to financial health in recent years.

Epitope's sales currently range about $10 million per year. Most of this comes from its OraSure HIV-1 test. It has FDA approval to use OraSure with enzyme immunoassays manufactured by **STC Technologies, Inc.** to test for cannabinoids (marijuana), amphetamines and methamphetamines, opiates, and cocaine. This product is called Intercept™. Epitope is working to obtain FDA clearance for a phencyclidine (PCP) test.

Epitope and Lab*One* enjoy a tight relationship. Lab*One* is the nation's dominant provider of lab testing for life insurance companies. This is a big market for Epitope's HIV testing.

This relationship will apparently continue into the drugs of abuse arena. Last May, Lab*One* and STC Technologies signed an agreement for Lab*One* to market and provide oral fluid analysis for the Intercept Drugs Of Abuse product line in North America for work-site drug testing.

During Thompson's management stint at Lab*One*, it enjoyed steady growth in revenues and operating profits. It also successfully diversified its revenues by entering several different segments of the laboratory testing marketplace. *(See TDR, April 29, 1996 and November 17, 1997.)*

With Thompson at Epitope's helm and a drugs of abuse product ready for launch, Epitope may be poised for steady growth. Further, Thompson will probably push Epitope to distribute its OraSure-based tests into other segments of the laboratory industry, both in the United States and abroad.

One of the interesting aspects about Epitope is that its test technology is non-invasive and cost-competitive. As a patient-friendly HIV screening test, it has found ready acceptance in the life insurance industry and AIDs clinics around the country.

CARESIDE, INC. BEEFS UP MANAGEMENT TEAM WITH THREE NEW HIRES

ANOTHER COMPANY IN THE MIDDLE of a product launch is **CARESIDE, Inc.** of Culver City, California. Like Epitope, it is beefing up its management team as it prepares to officially launch sales of its point-of-care system for routine chemistry and hematology. *(See TDR, November 22, 1999.)*

Careside is bringing three new executives to the company. Dennis Rieger will be Senior Vice President of

Information Technology and Chief Information Officer. Sandra Twyon is now Vice President and Chief Operating Officer. Grant Frazier became Vice President of Marketing.

Careside has a point-of-care product for routine chemistry and hematology testing. It wants to place these instruments in hospitals, laboratories, clinics, doctors' offices, nursing homes, and other types of healthcare facilities. It has been hiring sales representatives and started to actively market its point-of-care solution.

PHARMACOGENOMICS IS TARGET OF PARTNERSHIP BETWEEN QUEST AND BIOINFORMATICS COMPANY

HAVE YOU HEARD of computational proteomics? That's the process used to develop a pharmacogenomics data base that **Quest Diagnostics Incorporated** will market in conjunction with **Structural Bioinformatics, Inc.** of San Diego, California.

Both companies announced the availability of "two structural pharmacogenomic databases targeted at HIV-Protease and HIV-Reverse Transcriptase," effective February 2000.

Each database consists of a "large-scale collection of high-quality protein structures generated from the genetic sequence variants (polymorphisms) of a single drug target derived from many individuals."

The database will be used by drug companies, researchers, and others to understand the differences in interactions between a drug and the structural variations of its intended target.

The co-marketing of this database by Quest Diagnostics and its creator, Structural Bioinformatics, shows the intersection between clinical testing and pharmacogenomic research. With the increased volume of HIV typing and viral load testing, Quest Diagnostics has access to biosamples which can be used to identify new mutations.

In fact, the two companies claim that up to 1,000 sequences/structures are being added monthly to this database. Its intended use is to help combat HIV drug resistance and provide researchers with more comprehensive data than currently available in "mutation tables" which list amino acid positions and mutations which may correlate to drug resistance.

THE DARK REPORT expects that there will be an increased number of these kinds of relationships announced by the two blood brothers during the next years. To maintain sufficient profitability as reimbursement for routine testing continues to decline, both Quest Diagnostics and Laboratory Corporation of America need to develop revenues from the information generated by clinical testing and the specimens submitted to their laboratories.

INVESTORS RESPOND TO UROCOR'S MOVE INTO THERAPEUTICS

INVESTORS GAVE A VOTE OF CONFIDENCE to **UroCor, Inc.**'s move into therapeutics. The company's share price doubled after the **FDA** and the Nuclear Regulatory Commission cleared UroCor's radioactive prostate cancer treatment for clinical use.

Called ProstaSeed, the product will be co-marketed by UroCor, **Mallinckrodt Inc.**, and **Prostate Services of America**. UroCor offers diagnostic testing services to urologists nationwide.

UroCor's expertise in urological diseases, combined with its relationships with urologists, may make it successful in offering therapeutic services as well as diagnostics. Rapid gains in Urocor's stock price indicate that investors agree. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Financial progress at **Tenet Health Corp.** provides a glimpse at how the hospital industry is faring. Tenet announced a 7.2% increase in revenues for fiscal second quarter, fueled primarily by an increase in patient admissions at its 113 hospitals. Tenet also reported an average increase of 3% to 6% in payments from managed care companies. One of its corporate priorities is to aggressively deal with unpaid bills or slow insurer payments. It has sued one managed care company over slow payments.

ADD TO: HMOs

Financial analysts expect the nation's HMOs to report respectable earnings during fourth quarter 1999. Despite the spate of class action lawsuits alleging consumer fraud, analysts believe that HMOs will benefit from aggressive increases to health insurance premiums. It is believed that premiums are increasing faster than the cost of medical care and prescriptions.

UWE RHEINHARDT SURRENDERS TO MEDICARE REGS

Remember Uwe Rheinhardt? He's the managed care guru and healthcare economist from **Princeton University**. In the January 21 edition of the *Wall Street Journal,* Rheinhardt wrote an opinion piece titled "How Medicare Can Turn Anyone Into a Crook." In commenting on the latest fraud and abuse settlement (**National Medical Care, Inc.'s** civil settlement of $325 million and a criminal fine of $101 million), Rheinhardt asks "...what has happened to our renowned healthcare system? Has it become host to widespread malfeasance?"

His conclusion? No. It's Medicare regulations that make any provider into a potential crook. But what is disappointing from one of the nation's better known healthcare policy wonks is his conclusion: "Given the tangled web of Medicare legislation, more fraud investigations are inevitable. Rather than engaging in a long, protracted fight to set the record straight, throughout which share prices suffer and business slumps, a health company's best bet may be to hand over the fines and get on with business."

TDR ON RHEINHARDT:

Although THE DARK REPORT tries to stay away from things political, Uwe Rheinhardt's willingness to sacrifice the constitutional rights of the healthcare industry on the altar of Congress and Medicare bureacrats is shameful. Physicians and healthcare executives should consider this fair warning. Rheinhardt and other intellectuals certainly do not represent the best interests of patients. Unfortunately, too many intellectuals like Rheinhardt have the attention of Congress and the President. That is not a good thing for the future of the American healthcare system.

Despite problems with the FDA and a big fine, **Abbott Laboratories, Inc.** posted a revenue increase of 5.3% during 1999. Its diagnostics division showed a healthy 8.9% increase, with revenue of $3.038 billion. The FDA ban on diagnostic kit sales will cut into Abbott's sales during 2000.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 14, 2000.

PREVIEW #1

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- ***Slashing Lab Costs Without Dismissing Employees: Proven Methods That Work In any Hospital Laboratory.***