Volume VIII, Number 17 Monday, December 17, 2001

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

R. Lewis Dark:
American Healthcare At a New Crossroads..... Page 1

2001's Ten Biggest Stories
Presage Future Directions..... Page 2

TriPath Imaging Ready
To Roil Pap Test Market.....Page 9

Editor's Perspective: Laboratories Worth
Watching With Stories as Yet Untold..... Page 13

New Laboratory Company Ready
To Open in Orlando, Florida..... Page 14

Lab Briefs: DIANON Systems, United Health,
Aetna, Quest Diagnostics, Orchid, AmeriPath.....Page 16

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

American Healthcare At a New Crossroads

IN SELECTING OUR "TOP TEN" BIGGEST STORIES of the lab industry for 2001, we've had some interesting discussions here at THE DARK REPORT about what's happening in the American healthcare system and how it's affecting laboratories and pathology group practices.

I believe that our healthcare system is at a crossroads. All the evidence says that, during the next four years, healthcare costs will increase at double digit rates. This means that employers and the government will be paying between 50% and 75% more to provide care to their employees and beneficiaries by the year 2005. We all know that corporations, faced with a 50%+ increase in healthcare premiums, will take direct action to reduce their costs and encourage healthcare providers to do more with less money.

The last time our corporations and government faced sustained double digit increases in healthcare—the late 1980s and early 1990s—they turned to managed care as solution. Managed care's approach was to control and restrict access to care by patients, while squeezing down the money it paid providers. That worked for several years in the mid- to late-1990s. But those "gains" have been booked.

So, faced again with steeply rising healthcare costs, what solution will corporations and the government take this time? That closed-panel, capitated model of managed care has already shaken out the obvious savings and cut providers' reimbursement down to the proverbial bone. Since we can't go down that same road a second time, I believe this current crossroads is going to take us in a different direction.

For hospitals, I think there will be lots of pain. Medicare won't have adequate money to pay for care, particularly as baby boomers show up in ever-growing numbers. For physicians, it will be a mixed bag. Many will go with the flow and find themselves choked by bureaucratic and financial inadequacies. Another segment will be creative and find ways to offer value-added medical services to patients capable of paying for their own care.

As to clinical laboratories and pathology group practices, I think they will have an easier time of the 2000s than they did of the 1990s. The reason is simple. Most of the new diagnostic technology on the way will be seen as relatively cheap, even at several hundred dollars per test. It will be easier to maintain adequate reimbursement for an "inexpensive" lab test that determines whether a multi-thousand dollar drug therapy is warranted. TDR

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2001's Ten Big Stories Presage Future Direction

Radical change in the laboratory industry was not evident over the course of the year

CEO SUMMARY: During 2001, few labs found themselves under intense pressure to change or react to dramatic events in the healthcare marketplace. Like 2000, this past year was marked by evolutionary progress, not revolutionary change. However, continuing signs indicate that consumers will play a greater role in decisions involving lab tests. One surprise: slow growth of e-healthcare services.

WOW! AFTER THE BREAKNECK pace of change through most of the 1990s, the year 2001 was relatively calm. Most laboratories enjoyed their highest degree of stability in seven or eight years.

THE DARK REPORT'S pick of the "Ten Biggest Lab Stories" of 2001 reflects this "steady as she goes" environment. In fact, maybe one of the biggest stories should be that radical change was not a factor for most labs during the year.

There are two primary reasons for this, both financial. For the commercial lab sector, pressures from managed care contracting practices (and pricing) are easing. Across the nation, there is less capitation and many lab provider panels are adding providers.

For the hospital lab sector, significant Medicare budget cuts from the 1996 Balanced Budget Act (BBA) were moderated by subsequent Congresses. This increased the amount of money flowing into hospitals, thus easing the financial squeeze for many.

One big story was actually a non-story. During the year, healthcare e-commerce, in all its forms, failed to make a significant dent in the marketplace. This is particularly true of browser-based lab test ordering and results reporting, contrary to the famous prediction of THE DARK REPORT back in the fall of 1999. *(See TDR, November 1, 1999.)*

There are many interesting factors inhibiting a faster adoption of Internet-based services by the healthcare sys-

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

tem. These include technology limitations, lack of broadband access by many categories of healthcare providers, and, most importantly, failure of e-health service providers to offer compelling value.

Don't Write-Off E-Health

But it would be a mistake to write-off healthcare e-commerce. Its potential to remove significant costs from the healthcare system while boosting productivity and quality remains. Early adopters in healthcare and the laboratory industry are proving that this potential can be converted to real dollars and cents.

THE DARK REPORT includes the September 11 terrorist attacks as a "Top Ten" story for an obvious reason. Beginning on September 12, everyone began managing their businesses and laboratories with a different perspective. Certainly that day effected a pervasive and recognizable change in the way every American enterprise conducts its business.

In that same vein, the anthrax attacks are included in the lab industry's "Top Ten" story list. After all, just about everybody working in a clinical laboratory is now acutely aware that, at a moment when someone's guard is down, specimens from an as-yet unidentified victim of a biochemical terrorist attack might come into the lab for testing.

Questions Med Techs Ask

The anthrax attacks have caused most med techs to consciously think about two things, in either order. One, will I correctly identify the active biochemical agents if such a specimen should come into the lab? Two, could I be unintentionally infected by unwittingly handling such a specimen inappropriately? Tough questions—but they accurately reflect today's reality in labs around the country.

Another story on our "Top Ten" list is HIPAA. This may be the individual story which is having the greatest operational impact on laboratories and pathology group practices. Since HIPAA requires an active response, labs throughout the country are now devoting management resources to developing an appropriate compliance program.

Along with HIPAA, the med tech shortage is another "Top Ten" story which directly impacts many laboratories around the country. However, the story is bigger than lab-based medical technologists. Across the entire healthcare system, there are growing, and in some cases, acute shortages of trained technical staff in radiology, pharmacy, nursing, and other clinical areas. So the lack of adequate manpower is not unique to the clinical laboratory industry.

New Regulatory Attitudes

One of the more interesting stories on the "Top Ten" list is how the new administration is effecting changes to the regulatory environment, particularly the Medicare and Medicaid programs. THE DARK REPORT sees heartening signs that top regulators appointed by the new President want to operate their agencies in a more collaborative manner. This is a long-overdue change in attitude and may make it easier to enact many of the proposed reforms to laboratory test reimbursement policies.

Certainly this year's "Top Ten" list has mostly good news for the lab industry and pathology profession. As in past years, THE DARK REPORT suggests that laboratory administrators and pathologists use this "Top Ten Biggest Stories" list as a way to review the strategic directions of their laboratories and group practices. Clients of THE DARK REPORT who do this tell us that it always triggers a productive planning session.

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story one
September 11: The Day That Changed Everything Worldwide

SELDOM IS THERE AN EVENT which galvanizes world attention and becomes a "before and after" marker for historical events. September 11, 2001 meets that criteria.

The terrorist attacks on the World Trade Center in New York City and the Pentagon in Washington, DC caused the world to become a different place on September 12. The consequences have been profound and far-reaching.

The lab industry was affected, both in the cities that were attacked as well as throughout North America. The grounding of the air transport system stopped the flow of lab specimens. It also interrupted timely delivery of necessary reagents and other lab testing supplies. *(See TDR, September 24, 2001.)*

But those were temporary disruptions in the normal flow of lab industry affairs. The cumulative consequences of September 11—economic, social, and political—will directly and indirectly affect laboratories and pathology group practices for years to come.

THE DARK REPORT believes September 11 will cause American society to make different choices about social issues in coming years. These choices will include healthcare and will incorporate new values over those of past years.

That is why September 11 makes this year's list of important lab industry stories. It is a watershed event, rare and unusual, which forces all levels of society to think differently, act differently, and conduct business differently.

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story two
Anthrax Puts Labs Squarely in the Forefront of the War on Terrorism

BY DELIVERING ANTHRAX through the U.S. Postal System, terrorists brought clinical laboratories directly into the conflict.

Just as certain terrorists used weaknesses in the airline system to attack the United States, other terrorists used a different system—the mail—to launch their attacks. Just as September 11 is a "before and after" event for America, the anthrax attacks of late September and early October are now a "before and after" event for clinical laboratories.

That's because individual laboratorians have been given fair warning that they are on the front lines of biological and chemical terrorism. Should such attacks be launched surreptitiously, it is most likely physicians in primary care and emergency room settings who will see the patients and it is laboratorians who will be first to make, or confirm, a diagnosis related to those attacks. *(See TDR, October 15, 2001.)*

Across the United States, laboratory organizations of all types are reviewing crises and contingency plans and updating them to include biochemcial terrorist attack scenarios. At the state and federal levels, officials are moving to increase funding for lab services related to terrorist attacks.

Most of the increased attention and resources will be focused on the public health lab sector. But, clinical labs increasingly recognize they may be first to identify an event and raise the alert.

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story three Med Tech Shortage in Labs Reflects Wider Shortage of Healthcare Techs

ONE ISSUE GETTING WIDE PLAY in the clinical laboratory industry is the inadequate number of trained medical technologists and technicians available to fill open positions.

In a growing number of regional markets across the United States, larger labs are reporting difficulties in filling all open positions for med techs. There is universal acknowledgement that med tech training programs have been shutting down, reducing the supply of newly-trained med techs coming into the job market.

However, this phenomenon is not unique to the the clinical lab industry. Similar shortages are occurring in other healthcare sectors. This summer, THE DARK REPORT published a study done by the **American Hospital Association** (AHA). It surveyed 715 hospitals and looked at vacancy rates for open positions.

The AHA reported vacancy rates for lab techs exceeded those for nurses, 12% to 11%. But vacancy rates for billing/coders, radiology techs, and pharmacy techs were even higher, at 18%, 18%, and 20%, respectively. The AHA estimates there are 168,000 open jobs at the nation's hospitals. It says that 75% of these unfilled positions are for nurses.

There is good news in this for the clinical lab industry. The inadequate supply of trained technical staff is not unique. Across the spectrum of clinical care, there is a need for more trained individuals. This will stimulate the educational community to fill this vacuum.

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story four First Generation of Managed Care Proves Inadequate—What Next?

CLOSED-PANEL HMOs and full-risk, capitated contracts are no longer the prime business model of the managed care industry.

The first generation attempt at widespread managed care failed for three significant reasons. One, it could not control healthcare costs over a sustained, multi-year period. In hindsight, that generation of managed care business model represented a one-time cost squeeze, basically at the expense of hospitals, physicians, and other providers.

Two, consumers rejected the closed-panel HMO option by a huge majority. Once a large number of middle class Americans found themselves denied care and unable to easily get second and third medical opinions, they resoundingly rejected this approach to providing medical care.

Third, healthcare providers proved to be another powerful lobby against the business model of managed care's first generation. With each passing year, hospitals and physician groups in a growing number of cities and states began to reject capitated, full-risk contracts.

By 2001, even the managed care industry recognized it was time to change the way it conducted business. A definite shift towards more open types of health plans is under way. Further, employers have become emboldened to explore new and innovative ways to provide healthcare coverage to their employees.

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story five
HIPAA Arrives to Launch Reforms To Management of Healthcare Data

HERE COMES HIPAA! A long time in coming, implementation of this much-debated law is finally under way.

Much of the attention has focused on HIPAA's onerous requirements for maintaining confidentiality, privacy, and security for sensitive healthcare information. Since the stock in trade for laboratories and pathology group practices is lab data and interpretive information, compliance with HIPAA is becoming a business necessity.

Unfortunately, a significant number of laboratories and pathology group practices have yet to give HIPAA compliance the attention and resources necessary for proper compliance. As experts interviewed in THE DARK REPORT have noted, it is not a smart operational decision to defer complying with HIPAA's requirements. *(See TDR, November 5, 2001.)*

On the other hand, there is an immensely beneficial side to HIPAA. Along with the privacy requirements, HIPAA also mandates a uniform method for clinical reporting and claims submission. The goal is to create a common electronic reporting platform between payers, all classes of healthcare providers, and patients.

Labs should find this a welcome reform. It will reduce costs for the lab to report results and submit claims. More importantly, it will make it easier for payers to service "any willing lab provider," thus encouraging HMOs to include more labs in their provider panels.

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story six
Failure of E-Health to Penetrate American Healthcare System

BACK IN 1999, there was every indication that e-commerce business models were poised to transform healthcare.

Business experts were watching how **Amazon.com** and **E-Bay.com** were not just becoming dominant in their respective fields of retail book sales and auction house services, but were also creating a new business channel.

In healthcare, **Healtheon, Inc.** was targeting the paper-based flow of claims, prescriptions, lab tests, and other forms of healthcare transactions. In response, insurers, healthcare suppliers, and GPOs were scrambling to create Internet-based buying exchanges. Leading healthcare enterprises perceived that, if they did not incorporate Web-based services into their product menu, they would find themselves at a competitive disadvantage.

But a funny thing happened on the way to this new Internet-based healthcare world. The big boys stumbled and the weaknesses of existing Internet technologies became apparent. Healtheon merged with **WebMD**, then acquired a lot of "real" businesses. It lost billions of dollars. The numerous buying exchanges sponsored by insurance companies, manufacturers, and GPOs have been consolidating into a handful of surviving enterprises.

After much hype and billions of lost dollars, the healthcare community has taken a "show me" attitude towards the Web. It is cautiously adopting only Web-based services that make economic sense.

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story seven
National Anatomic Pathology Companies Come of Age

IT'S OFFICIAL! National anatomic pathology services are here to stay. The dominance of the local pathology group practice is steadily diminishing.

THE DARK REPORT makes this declaration armed with these facts: During the past six years, three companies relatively unknown in the anatomic pathology arena in 1995 will do a combined total of more than $600 million in anatomic pathology testing (AP) in 2001. Those three companies are **AmeriPath, Inc.**, **DIANON Systems, Inc.**, and **IMPATH, Inc.**

Their growth rates have been remarkable. It happened even as many pathologists nay-sayed the ability of a national pathology company to send sales reps into their community and get physicians to refer specimens to a central AP lab thousands of miles away.

THE DARK REPORT sees plenty of evidence that growing numbers of office-based physicians are willing to refer AP specimens to national companies. That is the "buyer" side of the equation.

On the "seller" side, national AP companies are often the first to introduce innovative services. They are sensitive to turnaround times and regularly measure client satisfaction.

There will always be a role for the local pathology group practice. But competition is on the increase. The historical dominance of local pathology is lessening because of national competitors.

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story eight
New Administration Changes Regulatory Environment

THERE'S A SUBTLE CHANGE in the attitude of regulators appointed by President George W. Bush. That's particularly true of Tommy Thompson, picked to head the **Center for Medicare/Medicaid Services** (CMS).

One of Thompson's first official acts was to change the name of HCFA—the **Health Care Financing Administration**—as a way to signal to providers that a new attitude would prevail. Whereas HCFA was perceived to conduct business in an adversarial manner, the newly-renamed CMS is striving to be more collaborative.

This shift, no matter how small, can have a compounding effect on the career bureaucrats who daily make the myriad decisions affecting Medicare and Medicaid policies.

This shift is rooted in the philosophical difference which marks the political right from the political left. There is an element of the political left which believes private enterprise to be fraudulent and always ready to "steal" if the opportunity presents itself. This is certainly in keeping with how the OIG pursued commercial labs in the "LabScam" prosecutions of the 1990s.

But on the political right, there is a group of thinkers who believe free enterprise is the source of innovation which improves quality and lowers costs. This is true of Tommy Thompson. Accordingly, for the balance of this administration, a number of decisions may be made that favor rational reforms to laboratory test reimbursement policies.

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story nine
Consumers Getting Savvy, Now Taking Charge of Their Healthcare

CONSUMERS ARE THE ULTIMATE beneficiaries of healthcare services. That simple truth has often been overlooked by both private health plans and Medicare.

But that's no longer true. The baby boomers, long a major change agent in American society, are scrutinizing the healthcare system. Increasingly they are taking proactive steps to direct the healthcare provided to their elderly parents, their children, and themselves.

As part of this process, they are questioning all aspects of the healthcare system. It is no coincidence that, last July, JCAHO began requiring hospitals to disclose to patients any episode where care did not meet acceptable standards. Litigation by angry baby boomers over medical errors has increased in recent years. What drives some of this litigation is anger that the healthcare establishment often tries to deny or cover up medical mistakes. *(See TDR, August 13, 2001.)*

However, for laboratories and pathology group practices, the change in consumer attitudes is expressing itself in a different way. Consumers now want more access to lab testing. They want direct access to the pathologists who have diagnosed their tissue specimens.

If labs are to meet the changing expectations of their customers—consumers—then they must begin implementing services which give patients greater access to lab test information and the experts who can explain test results.

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story ten
Happy Days Are Here Again For Public Lab Companies

STRONG STOCK PRICES for public lab companies in 2001 provided ample evidence that the explosive growth of their share prices during 2000 was no fluke.

Today **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** have credibility and respect on Wall Street that was unimaginable just a few short years ago. In fact, this credibility has rubbed off on smaller laboratory companies as well.

These smaller public lab companies are prospering too. During the past year, **AmeriPath, Inc.**; **Bio-Reference Laboratories, Inc.**; **DIANON Systems, Inc.**; and **IMPATH, Inc.** have all seen their share prices move upward.

A new crop of lab companies took advantage of this favorable time to go public. The year started with **Dynacare, Inc.**, **Specialty Laboratories, Inc.**, and **Unilab Corporation** fresh off their IPOs (initial public offering). Several other private lab companies are preparing themselves for an IPO, when they deem the moment to be most auspicious.

With investors alert to the potential that pharmocogenomics and proteomics can have in boosting diagnostic testing, THE DARK REPORT predicts that the lab industry will remain a hot sector among the professional investment community. Look for more lab companies to go public during the next few years. TDR

Tripath Imaging Ready To Roil Pap Test Market

It can now offer an integrated solution that automates both liquid prep and Pap screening

CEO SUMMARY: ***Single-handedly, Cytyc Corporation has built the market for thin-layer Pap smear testing. Executives at TriPath Imaging are now ready to challenge Cytyc's dominance by offering what they believe is a different value proposition to labs: an automated liquid preparation system married to an automated Pap smear screening system that can read both thin-layer and conventional Pap smears.***

AFTER MORE THAN TWO YEARS of obstacles and unplanned delays, **TriPath Imaging, Inc.** is now a reinvigorated competitor in the marketplace for enhanced Pap smear technology.

TriPath gained clearance from the **Food and Drug Administration** (FDA) this fall to market, as a single integrated system, its automated AutoCyte® PREP instrument for liquid preparation with its AutoPap® Primary Screening System.

Several Features Added

The FDA approval, issued October 5, actually involves several features of interest to clinical laboratories and pathology group practices. "First, the AutoPap system is immediately cleared to screen the liquid preparation slides of our PREP product," stated Paul R. Sohmer, President and CEO of Tripath, "thus allowing AutoPap to do primary screening for both Autocyte Prep slides and conventional slides.

"Second, our AutoPap primary screening system now has labeling that indicates the AutoPap is effective in ranking both PREP and conventional slides according to the potential for abnormality," he continued.

"Third, AutoPap is approved to screen slides with both glass and plastic cover slips," explained Dr. Sohmer. "Besides these three important elements, the FDA approval also recognizes a number of other elements, based on the performance of the combined automated instrument system in clinical studies at several sites."

For TriPath Imaging, based in Burlington, North Carolina, the FDA's action is a long-awaited event. In the summer of 1999, when TriPath was created by the merger of **AutoCyte, Inc.** and **NeoPath, Inc.**, company executives expected a relatively speedy approval from the FDA that would allow it to market its automated PREP with the AutoPap Primary Screener. *(See TDR, July 19, 1999.)*

"It's been a long time coming," observed Dr. Sohmer. "The original submission was September 1999. Along the way, we worked with the

FDA to revalidate certain aspects of earlier clinical studies. The FDA also did their own inspection last spring prior to announcing its decision on October 5, 2001.

"As it turned out, this additional regulatory scrutiny has worked to the benefit of our products," added Dr. Sohmer. "We can definitely say that our PREP and AutoPap technology has been thoroughly reviewed by the FDA."

Competitive Dynamics

Now that TriPath Imaging is cleared to market PREP and AutoPap as a single integrated system, it has the potential to introduce new competitive dynamics into the market for liquid-based Pap smear testing. Until now, **Cytyc Corporation's** ThinPrep® test has been the unchallenged leader in liquid preparation technology.

But TriPath believes that situation will change, because it can now offer laboratories a different value proposition. "For starters, our combined automated liquid preparation and automated primary screening will be offered to lab customers at a price that will improve the overall economics for labs currently utilizing our competitor's liquid prep," declared Dr. Sohmer.

"This advantage is further complemented by the ability of the AutoPap Primary Screener to handle both liquid prep and conventional Pap smear slides coverslipped with either glass or plastic," he added. "This improves patient care and lowers direct costs to the lab."

Integrated Systems Sales

In the last 60 days, this value proposition has already encouraged five existing AutoPap customers to step up and acquire the full integrated PREP and AutoPap system. The labs are **Geisinger Medical Center** (Danville, Pennsylvania), **Doctors Laboratory** (Valdosta, Georgia), **SouthEastern Pathology** (Rome, Georgia), **Delta Pathology** (Shreveport, Louisiana), and **Hadden Pathology** (Fresno, California).

The rapidly-developing market for HPV testing has not escaped TriPath's notice. "We have a good working relationship with **Digene Corporation**," said Dr. Sohmer. "We expect Digene to submit a supplement to its PMA (premarket application) with the FDA in first quarter 2002 that would allow its Hybrid Capture® HPV test to be run from the PREP liquid specimen collection. That's a feature many of the largest labs want."

Among the rapid-fire developments at Tripath is one particular product that THE DARK REPORT finds most intriguing. It is Tripath's next-generation of Pap smear testing technology, soon to hit the market. It represents a good example of how marketplace feedback often takes new technology in directions not predicted by its developers.

Market Shift to Liquid Prep Reflected in TriPath's Sales

AS LIQUID PREPARATION PAP SMEAR tests seized a growing share of the market from conventional Pap smears, this shift in market demand was reflected in TriPath Imaging's product sales.

In its third quarter earnings report, TriPath reported net revenues of $5.3 million, compared to $8.1 million for third quarter 2000. This was a decline of 35%, attributed to slower sales of the AutoPap Primary Screening system, which, prior to the FDA's October 5 decision, was limited to screening conventional Pap smears.

In contrast, sales of TriPath's PREP instruments and consumables were up by healthy margins, reflecting the clinical marketplace's preference for liquid prep Pap kits. PREP revenue increased by 104% over third quarter 2000.

"Our next generation Pap smear screening system is called AutoPap GS," noted Dr. Sohmer. "Basically, it is location-guided screening cued by the AutoPap analysis of individual slides. It involves a microscope station equipped with a computer-guided stage."

Lab Needs Are Changing

Dr. Sohmer says this product was developed to specifically meet the changing needs of its cytology customers. "Under its existing FDA approval, Autopap reads the Pap slides and ranks abnormality within the population of slides it is screening. It is permitted to classify up to 25% of the slides as normal," he noted. "Given the economic advantages of the instrument, intuitively, it would seem that labs would be interested in boosting the sort rate percentage, which would allow more slides to be classified as normal and not undergo human review, except for QC/QA.

"However, labs asked us to use AutoPap's evaluation of each slide in a different way," he continued. "AutoPap 'maps' cell locations on the slide and then ranks them according to their potential to be abnormal. Labs asked us to use this information to guide cytotechnologists and cytopathologists.

Location-Guided Screening

"In fact, TriPath's partner in Japan, **Nikon**, had independently developed such a system around AutoPap," Dr. Sohmer said. "In Japan, the Nikon system is reducing the time required for a cytotech to accurately screen Pap smears by as much as 65%."

TriPath found a speedy way to develop its location-guided screening product. "We were selling an imaging workstation called Slide Wizard that was developed by AutoCyte and its predecessor, **Roche Imaging Systems**," noted Dr. Sohmer. "For us, this made the ideal platform for location-guided screening. We've interfaced it with the AutoPap. The combined instrument platform, called AutoPap GS, is compatible with both AutoCyte PREP and conventional Pap slides.

"AutoPap GS was introduced into the international marketplace earlier this year," he said. "We are presently working with the FDA to design the clinical protocol for this study. We anticipate that trials in the United States will be initiated by the first part of 2002."

To prepare for the FDA's favorable ruling in October, TriPath had beefed up its sales force. There are now 85 sales reps in the field, including a nationwide "physicians' detailing" team contracted through **Nelson Professional Sales**. This marketing effort is already raising TriPath's profile within the laboratory and pathology professions.

Surprises Ahead

THE DARK REPORT predicts that the market for cervical cancer screening will undergo some surprising changes in the next 24 months. A number of research labs are attacking this problem throughout the world. Meanwhile, there is now a solution for automating both liquid preparation and primary screening. Also, TriPath's strategic plan to introduce location-guided screening for cytotechs represents a new option for lowering costs and improving care.

Beyond that, several new technologies have the potential to eventually dislodge Pap smears as the gold standard for cervical cancer screening, particularly if new technologies for HPV detection and treatment and new molecular markers for cervical cancer are developed in the near future. TDR

Contact Paul Sohmer, M.D. at 336-222-9707.

Molecular Oncology Figures Big In TriPath's Future Product Offerings

WHILE WAITING FOR FDA APPROVAL to market its PREP and AutoPap as an integrated, automated Pap smear screening system, Tripath Imaging, Inc. has not been idle. It's developed an active program in molecular diagnostics.

This summer, **Becton Dickinson and Company** (BD) selected TriPath Imaging to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer. This work is a result of BD's strategic alliance with **Millennium Pharmaceuticals, Inc.** to identify and commercialize markers for various cancers and diseases.

Focus On Several Cancers

"In this relationship, our focus is on malignant melanoma and cancers of the prostate, breast, ovary, cervix, and colon," explained Paul R. Sohmer, M.D., President and CEO of TriPath Imaging.

"As part of this strategic alliance, BD invested $25 million in Tripath Imaging," added Dr. Sohmer. "It also merged its Baltimore-based **BD Gene** division into TriPath Oncology, a new, wholly-owned subsidiary of TriPath Imaging located in Research Triangle Park, North Carolina.

"We see the explosive growth of molecular pathology as playing to the strengths of TriPath Imaging," declared Dr. Sohmer. "This was the other element behind the merger of AutoCyte and NeoPath in 1999. On one hand, there was a compelling business opportunity if PREP and AutoPap could be successfully married into an integrated, automated system for Pap smear screening.

"On the other hand, the body of imaging technology developed by AutoCyte, NeoPath, and **Neuromedical Systems, Inc.** (NSI) (its assets acquired by AutoCyte from NSI's bankruptcy) created a body of imaging technology that is unmatched.

"TriPath Oncology is the division which will directly apply this technology to the field of molecular diagnostics," he continued. "For example, as BD and Millennium focused on tissue-based assays, they needed a way to capture and evaluate a variety of markers. Our imaging technology provided a good solution to that problem."

Telepathology In Use

"This is also taking us into telepathology," noted Dr. Sohmer. "We've already linked sites within Millennium and TriPath with our telepathology solution. This allows us to link and concurrently look at the same images.

"We also envision this having value among clinicians. For example, once our Melastatin test is cleared for clinical use, our telepathology system could be used by pathologists to allow the referring dermatologist to look at the image while they discuss it," noted Dr. Sohmer.

Assays Ready After 2003

For TriPath Oncology, commercial fruits from molecular diagnostics are years away. "While we anticipate introduction of an assay for malignant melanoma in 2002," said Dr. Sohmer, "clinical home brew tests for other cancers will follow in late 2003 and early 2004 concurrent with FDA clinical trials."

Molecular markers for cervical cancer are part of the research targets of TriPath Oncology, BD, and Millennium. These firms may have a hand in developing a screening test for cervical cancer which eventually supplants the Pap smear as the clinical standard.

"New research into the causes of cervical cancer is changing our understanding of this disease," observed Dr. Sohmer. 'It would not be surprising if a new marker is found which proves better at screening for cervical

Editor's Perspective

Laboratories Worth Watching With Stories as Yet Untold

By Robert L. Michel
Editor-In-Chief

BURIED IN MY FILES are any number of magnificent examples of innovative laboratory and pathology management that have yet to reach print in THE DARK REPORT.

The limitation is space, influenced by the need to report on important breaking news. THE DARK REPORT is, by design, a compact and fast-to-read source of useful intelligence on the lab industry. That limits the space available to report on stories of lab management successes.

However, I'd like to use the excuse of a year-end retrospective to share with you some of the stories I consider worthwhile, but have not yet been able to report in detail.

Cleveland Path Group

High on my list of untold stories is **OncoDiagnostic Laboratory, Inc**, based in Cleveland. In 1993, its joint venture with **DIANON Systems, Inc.** ended, reducing OncoDiagnostic's business volume by as much as 80%. To replace these lost cases, the five pathologists developed a national sales and marketing program of their own.

Rather than hire its own sales representatives, it used a contract sales force provided by **B. J. Ness and Associates** to call on specialty physicians throughout the United States. Since 1995, the volume of cases has climbed upwards.

Pathologist Cirilo F. Galang, M.D. is the Medical Director. Back in 1995, he was willing to pioneer using colored pictures and colored text on reports. He also supported introducing patient counseling reports, two-day TAT on Bx's, and three-day TAT on liquid prep Paps. This willingness to innovate underpins the pathology group's sustained growth over the past six years.

In Richmond, Virginia, under the guidance of David S. Wilkinson, M.D., Chair, Department of Pathology, the lab division of **Medical College of Virginia** has built a thriving molecular and genetic testing business. It is developing its lab outreach sales capability. It's an example of an academic center laboratory that's moving steadily into revenue-generating lab testing services.

At **Health Midwest** in Kansas City, Missouri, following the consolidation of its nine hospital labs, L. Patrick James, M.D., Director of Pathology & Clinical Labs, focused the lab's mission on improving clinical care. One major accomplishment was to reduce pharmacy costs by more than $1 million per year through better use of microbiology test data at the time when antibiotics are ordered.

Leadership Is The Difference

The successes of these three lab organizations demonstrate that management leadership by pathologists and lab administrators is the spark that stimulates lab organizations to a higher level of performance. Their stories deserve to be told in more detail. **TDR**

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New Lab Company Ready To Open In Orlando, FL

The next generation of lab entrepreneurs has a very different vision of lab testing

CEO SUMMARY: Within the next 60 days, a brand-new clinical laboratory company will begin operations in Orlando, Florida. In the short term, it plans to offer routine testing to physicians' offices. However, the real goal is to create a laboratory organization with integrated information management capability and molecular testing services that will allow it to add significant value to laboratory test data.

DURING THE NEXT FEW MONTHS, the first of the new generation of commercial laboratories will become operational.

Cognoscenti Health Institute is preparing to open its laboratory facility and offer laboratory testing services to physicians in Orlando, Florida. When it does, it will become the first "cold start" launch in several years, a commercial laboratory with a facility but no specimen volume at the time of start-up.

Meeting Clinicians' Needs

This rare event is noteworthy for another reason. The strategic business plan of Cognoscenti Health Institute is designed to meet the anticipated needs of clinicians who will be using genomics and proteomics-based diagnostics as these types of assays become available.

"Our goal is to establish a complete menu of molecular testing supported by a fully-integrated capability of collecting and reporting detailed clinical information," stated Philip Chen, M.D., Ph.D., President of Cognoscenti.

"For us to serve the evolving healthcare system, our laboratory must be organized and operated in fundamentally different ways," he added. "That's why we are building our own facility. We are designing our systems and work flows from the ground up. It's also why we did not acquire an existing laboratory as a way to enter the business."

Cognoscenti's business strategy is to provide laboratory testing services, both routine and reference, to office-based physicians supported by a different approach to laboratory informatics. "For us, as a laboratory, to contribute to improved clinical care, we must do more for our client physicians than perform a test and report its results," noted Dr. Chen. "We want to provide clinical information and services which help physicians make better decisions about ordering lab tests and using the results.

"In practical terms, this helps physicians eliminate redundant testing, select the most appropriate test

based on how the patient presents, and know when its time to retest."

Dr. Chen's strategic vision is based on bringing to office-based physicians the same kind of decision support and informatics resources available to physicians practicing in academic centers. He has worked in laboratory services at **Brigham & Women's Hospital** in Boston, Massachusetts, where he saw how advanced laboratory information services contributed to improved clinical care.

Pendulum Swung Too Far

Dr. Chen is the entrepreneuer who's championed the business plan of Cognoscenti Health Group. He obtained venture funding and picked Orlando as the place to establish his clinical laboratory. "There are 1.6 million people around Orlando, yet there are no major commercial labs located in the immediate area," he noted. "We think the pendulum of lab consolidation has swung too far in one direction and that we can successfully compete in Orlando."

Laboratory informatics will play a key role in the business services offered by Cognoscenti Health Group. In the process of receiving lab test orders and reporting results, Dr. Chen wants to gather enriched data sets about the patients and their diagnoses, therapies, and other clinical services. This information will be used to add value in a number of ways.

Electronic Medical Record

"First of all, our laboratory must fully support the electronic medical record (EMR)," he declared. "To accomplish this, we are carefully selecting software products which will allow us to be Internet-capable. We will support browser-based lab test ordering and results reporting.

"One of our business objectives is to work with clinicians so that, as lab tests are being ordered, we are getting additional information about the patient from the physician.

"We will use this additional data to develop decision support services to help our physician-clients put the lab tests they order to better use," said Dr. Chen. "Beyond that, we envision connecting our laboratory to both pharmaceutical and biotech companies.

"This would include identifying patients for clinical trials, but our goal is more than that," he continued. "New drugs are increasingly developed under a process called rational design. This requires closer interaction between the labs doing testing on patients participating in clinical studies and the pharma companies.

"We are designing the information systems at our laboratory to give us the capability of collecting and processing the more detailed type of information required to participate in these types of programs," said Dr. Chen.

Lab Soon To Open

But before it can run, Cognoscenti Health Group must walk. That involves getting its lab open and launching routine testing services to the Orlando healthcare community. "Our laboratory is almost ready to open," observed Dr. Chen. "Most of the construction is complete and we are proceeding with validations and inspections. "We expect to have the necessary licenses and be ready to open for business in the next 60 days."

THE DARK REPORT believes Dr. Chen represents the first of a new generation of pathologists and lab entrepreneurs. His vision for Cognoscenti's lab testing business illustrates how lab testing services will broaden to serve new types of clinical service providers. **TDR**

Contact Philip Chen, M.D., Ph.D. at 407-882-0212.

Lab Industry Briefs

DIANON SYSTEMS INKS NATIONAL AGREEMENT WITH UNITEDHEALTHCARE

A NEW NATIONAL AGREEMENT between **DIANON Systems, Inc.** and **United-Healthcare** was announced last week.

The agreement allows DIANON Systems to provide pathology and genetic testing services to all the beneficiaries in health plans offered by UnitedHealthCare, a division of **UnitedHealth Group**. It consolidates a number of existing agreements between the two companies.

DIANON Systems now has full access to the HMO, PPO, and POS (point-of-service) plans operated by UnitedHealthGroup. Approximately 16.5 million people are covered by these plans.

This national agreement is a milestone event for DIANON Systems. It validates several parts of the company's business strategy. First, DIANON has generally preferred having contracts with significant managed care plans before marketing to physicians' offices in regions where those plans have lots of beneficiaries. This strategy insures that DIANON gets paid for the tests it performs.

Second, DIANON Systems' CarePath™ Health Information Service was designed to offer value to the payer, as well as the physician and the patient. DIANON's success at getting anatomic pathology carveouts with important payers, such as **Aetna** and **Oxford Healthcare**, and now UnitedHealthCare, provides marketplace proof that payers find at least some aspects of CarePath to be useful.

Once DIANON Systems has gained status as a contract provider, its sales team has been effective at convincing physicians to refer patient specimens to DIANON. This new national agreement gives DIANON's sales team access to an additional 5.8 million of the 16.5 million beneficiaries at UnitedHealthCare.

LAYOFFS AND CHANGES AT AETNA MAY AFFECT LAB TEST CONTRACTS

EXTENSIVE CHANGES at **Aetna Inc.** were announced last week. These changes may affect lab testing contracts in a number of regional markets.

The nation's largest health insurer will eliminate another 16% of its workforce, mostly through layoffs. About 6,000 of its 37,000 workers will be affected. These changes are in response to market conditions and restructuring plans made public late last year.

At that time, Aetna said it would eliminate 5,000 jobs, drop plans in certain markets, and reduce overall membership levels. Currently, enrollment numbers about 17.5 million, compared to 19.5 million beneficiaries at the end of last year.

For clinical laboratories and pathology group practices, the restructuring of Aetna's workforce will certainly have an impact. There will be changes to regional medical directors and network contracting managers. This will disrupt current business relationships many labs have with Aetna managers.

GENE THERAPY ADVANCING; QUEST DIAGNOSTICS LICENSES SNP TECHNOLOGY

Two unrelated events illustrate the speed with which genetic diagnostics and genetic therapeutics are heading toward general clinical usage. Last week, the journal *Science* published results of an experiment where

Massachusetts researchers successfully used genetic technology to cure sickle-cell anemia in mice.

A day later, **Quest Diagnostics Incorporated** announced that it had signed an agreement with **Orchid BioSciences, Inc.** to license Orchid's proprietary SNP-IT™ technology for gene-based diagnostic testing services. It is expected that SNP (single nucleotide polymorphism) testing will be a primary tool in pharmocogenomics.

In Cambridge, Massachusetts, researchers at **Harvard University** and **Massachusetts Institute of Technology** removed bone marrow from the mice. They then carefully stripped potentially harmful components out of the AIDS virus and used it to deliver a therapeutic gene to the bone marrow of the mice.

Researchers used radiation to kill the diseased cells remaining in the bone marrow, then returned the treated bone marrow cells into the mice. Following the procedure, researchers measured a high proportion of normal, round blood cells. The beneficial effects lasted as long as ten months.

Despite the technical hurdles and concerns over using the AIDS virus to deliver the therapeutic gene, **Genetrix Pharmaceuticals** believes it can commercialize this technology and have it ready for testing in humans within three years.

At Quest Diagnostics, the acquisition of SNP-scoring technology demonstrates that there is commercial potential. Differences in the SNPs of individuals are believed to be the reason some people respond better to therapeutic drugs than other people.

Quest Diagnostics intends to develop diagnostic tests with the SNP-IT technology. For Orchid BioSciences, the Quest relationship is a way for it to move its technology into the diagnostics marketplace.

SNPs, or single nucleotide polymorphisms, represent the change in one base pair of DNA bases at a specific site on the gene. Pharmacogenomics is built upon the theory that individuals with the same disease will react differently to the same therapeutic drugs because of the differences in their SNPs. Between now and the eventual arrival of FDA-approved test kits that utilize SNP technology, Quest Diagnostics is in a position to both gain experience with SNP testing and start a library of relevant SNP information.

What these two events illustrate is that advances in genetic-based technologies are bringing new capabilities closer to widespread clinical use.

AMERIPATH POSITIONED TO DO ANOTHER ROUND OF PATH GROUP PURCHASES

WITH NEWS THAT IT HAD ACQUIRED a pathology group in Birmingham, Alabama, **AmeriPath, Inc.** served notice that it's back in the acquisition mode. It purchased **Dermatology Services P.C.** and **Histology Services, P.C.**, a practice doing about $4 million per year in revenues.

In recent months, AmeriPath made changes to its line of credit. On December 10 it announced a new credit facility of $200 million. Some funds from this new credit facility have been used to retire certain existing debt instruments. The new credit agreement increased AmeriPath's borrowing power as well as positioning it to launch another round of pathology group practice acquisitions.

Since pathology practice acquisitions are an important part of AmeriPath's business strategy, it maintains an ongoing program to identify and negotiate with pathology groups in preferred regions around the country. This "deal pipeline" will be the source of its acquisitions during the next year. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Laboratorians interested in the economic paradoxes that sunk the managed care industry might be interested in a new book, *Oxymorons: The Myth of a U.S. Healthcare System*. Author J.D. Kleinke provides a lucid analysis of the contradictions in our healthcare system. For example, Kleinke describes how incentives could lead money-minded HMOs to decide not to pay for every 60-year-old to have a $1,000 colonoscopy to screen for premalignant polyps. That's because, within five years, the few resulting cancers, if overlooked, would be a Medicare problem. He also addresses the dilemma of new drugs and new technologies which offer marginal clinical benefits, but add greatly to costs.

MORE ON: OXYMORON

Kleinke's proposed solutions center around increased consumer choice and tax deductions for out-of-pocket medical expenses. He points out that, when bureacrats dictate healthcare, arbitrary decisions are made—like when New York State Medicaid established a policy of six Viagra tablets per month.

CLIMBING PREMIUMS FOR MED MALPRACTICE TO BECOME AN ISSUE

News that **St. Paul Company** is exiting the medical malpractice business presages growing problems in this type of insurance coverage. During 2001, St. Paul expects underwriting losses of $940 from its medical malpractice business. It insures 42,000 physicians in the United States, along with 750 hospitals, 5,800 healthcare facilities, and 72,000 providers, including nurses. St. Paul does not plan to cancel existing policies. It will exit the medical malpractice business by refusing to renew existing policies as they expire.

MORE ON: MALPRACTICE

As a result of several converging trends, pathologists and laboratories are seeing stiff increases in their medical malpractice premiums. Insurance experts predict this pattern will continue. In the early 1990s, profits from medical malpractice were strong and many insurance companies competed for market share by offering lower premiums. Meanwhile, throughout the decade, the number of medical malpractice lawsuits increased. As well, the average size of court judgements and settlement amounts have climbed sharply. Collectively, these factors are forcing medical malpractice insurers to raise their premiums by significant amounts.

COMINGS & GOINGS:

Eugene Heidt has left his position as President of **Genesis Clinical Laboratory**, based in Berwyn, Illinois. Brenda Van Wyhe, Vice President of Finance, is now the senior executive at Genesis. • In Kingsport, Tennessee, G. Robert Ainslie, Ph.D. resigned as President of **Medex Laboratories**. The new President is Mike Ladd. No word on Ainslie's future plans. • After many years in Lincoln, Nebraska, Larry Warrellman is retiring. He is General Manager of the **Quest Diagnostics** Lab there and has worked at that location through its acquisition by **Nichols Institute** in the late 1980s and then **MetPath** in 1994.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 7, 2002.

PREVIEW #2

EXECUTIVE WAR COLLEGE

May 8-9, 2002 • Astor Crowne Plaza • New Orleans

Topic: The Real Story Behind the Med Tech Shortage and Strategies for Hiring and Retaining Techs

There's more to the shortage of trained laboratory technologists than commonly thought. New types of employers are recruiting med techs away from clinical labs with higher salaries and more benefits. Learn who these new players are and how to counter their recruiting lures. More importantly, gain insights on how to improve your lab's hiring and retention of med techs.

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

UPCOMING...

- ***THE DARK REPORT'S Bi-Annual Review of Anatomic Pathology's Most Important Trends.***
- ***Innovative Lab Management Strategies to Boost Med Tech Productivity and Reduce Labor Needs.***
- ***Histology Takes to the Streets: How Palm Beach Pathology Uses Its Mobile Lab to Support Its Marketing for New AP Clients.***

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