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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

Pathologists, Clin Labs, Pharmacogenomics & PPMs

AT MY AGE, I AM LEARNING THAT PEOPLE TEND TO HOLD ONE OF TWO OPINIONS about me. It seems that I can frequently be considered a doddering old fool who is totally unhip (although I recall an even earlier generation calling it "unhep"). On the other hand, there are those who grant me great respect. For them, I am a wise elder with experience and insight. My long years on the planet give me a certain sagacity and judgement that they find valuable.

I mention this for one reason. As Publisher Emeritus of THE DARK REPORT, it is my job to provide our editorial staff with perspective and continuity about the events and forces now reshaping the profession of pathology and the clinical laboratory industry. Our long-time clients know that I can get a bit ornery now and then in these columns. I do believe there is value in speaking bluntly about issues which need a public debate. Our industry is no different than the national political arena.

Just as there are vested interests in government and politics, so also does our industry have its vested interests. The result is that public debate is frequently not based on facts, reality, and an objective discussion about both sides of an issue. Rather, it is manipulated, spun, and controlled in a way that protects the powers that be. Our industry is not served well by its thought leaders when rational, objective, far-ranging discussion fails to take place in the public domain.

Why do I mention these facts? Because it has been a goal of THE DARK REPORT, since its inception, to bring to the public forum an appropriate airing of the issues and trends which affect pathology practices and clinical laboratories. As you read this latest issue, I hope you respect the fact that we are willing to study the facts, state our opinions, and take a position which might not be popular, but best represents our belief about what is true.

THE DARK REPORT is firmly committed to the success of pathologists and clinical laboratories. Even as managed care wrecks the infrastructure of our former fee-for-service healthcare system, new technology, new management models, and new economic developments promise better quality, better outcomes and improved finances. Only those pathologists and laboratory executives willing to push their personal boundaries, and those of their co-workers, will harvest the benefits of these new discoveries. That is why THE DARK REPORT strives to bring you the earliest news and opinion about subjects such as pharmacogenomics *(pages 2- 6)* and physician practice management companies *(pages 15-17)*. Your future success is also why, even at my age, I still offer whatever perspicuous horse sense my experience deems appropriate within these pages. **TDR**

Pharmacouenomics Is The Coming Wave

New technology promises major benefits for clinical laboratory and pathology

CEO SUMMARY: It may be gloom and doom today in the clinical laboratory industry, but long term prospects for diagnostic testing are brightening. Increased understanding of human genetics drives new discoveries about how and why the same drug affects individuals differently. Biotech companies like Oncormed, Inc. are positioning themselves to apply this knowledge to diagnostic testing.

HERE' s A NEW WORD that will soon be familiar to all laboratory executives and pathologists. The word is "pharmacogenomics" and it takes practice to pronounce it correctly.

In its simplest definition, pharmacogenomics refers to the process of using genetics-based technology to evaluate the affects of pharmaceutical compounds on the body.

"Pharmacogenomics actually can be used to describe two primary uses," said Doug Dolginow, M.D., President and COO of Oncormed, Inc. in Gaithersburg, Maryland. "Drug companies consider pharmacogenomics as a method for using genomic information to discover and identify effective drugs. In this sense, it is a tool for creating new pharmaceutical compounds which they can bring to market.

"The other meaning of pharmacogenomics involves its clinical use for diagnostic and prognostic purposes," he explained. "In this application, pharmacogenomics allows a clinician to identify specific way s that an individual might react to a specific drug.

"Obviously, the ramifications to healthcare are significant," continued Dr. Dolginow. "Imagine being able to know, in advance, that a particular patient would benefit from a specific drug. Of equal value, what if the clinician knew in advance that a specific patient would have negative reactions to a drug?"

This is the reason why pharmacogenomics is a rising star on the healthcare horizon. For drug companies, pharmacogenomics promises to be the "philosopher's stone" which alchemists

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

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believed could convert base elements into gold. For diagnostics companies and clinical laboratories, pharmacogenomics may unleash a new generation of diagnostic "super-tests" that bring immense value to both physicians and their patients.

It will be pharmaceutical companies that make this technology viable. They are under immense financial pressure to deliver sizeable revenues and profits to their 1,tockholders. They will invest huge dollars to make pharmacogenomics pay off. Dr. Dolginow explains why.

"The drug industry needs to hit a home run with pharmacogenomics," he observed. "The reason is simple. None of the major pharmaceutical houses has a blockbuster drug in the development pipeline. Traditional methods of drug development are now uneconomical or ineffective. The problem is further compounded by the fact that a number of highly profitable drugs are coming off patent."

"80% of drugs currently fail in clinical trials. If you could do something about that failure rate, you are going to have a real impact on the economics of drug development."

Fred Ledley, M.D.

President & CEO, Variagenics, Inc.

"Both developments mean that drug companies will struggle to generate increased revenues and profits," he continued. "Pharmacogenomics is believed to have immense potential to change this situation and deliver big profit dollars to the drug companies."

Laboratory executives should pay close attention to the comments of George Poste, the chief science and technology officer for **SmithKline Beecham, PLC** in London. "Pharmacogenomics is a logical progression of medicine. It will render healthcare increasingly rational, address the economic challenge of infinite demand versus limited resources. By identifying the relatively small proportion of the population that accounts for high costs, it will bring about a profound shift from reactive to proactive treatment."

Poste, addressing 4,000 biotechnology researchers and companies at a June meeting, described current drug development methods as a "crap shoot." He believes that pharmacogenomics will evolve, and "should become the rational foundation of rational therapy."

Drug Development Pipelines

Poste's comments confirm that major drug houses are rapidly incorporating pharmacogenomics into their drug development pipelines. The large amounts of money these pharmaceutical companies are investing in molecular and genetic research will rapidly advance the capabilities of this science.

Dr. Dolginow concurs, but thinks practical application in diagnostics will not happen overnight. "Despite all the headlines trumpeting the discovery of new genes which are related to specific diseases and cancers, we are several years away from tangible application of this knowledge," noted Dr. Dolginow. "Pharmacogenomics is an emerging branch of science which has yet to deliver practical benefits. No company has yet to make money because of pharmacogenomics.

"There are several reasons for this. New discoveries in molecular medicine usually take between five and 15 years before they evolve into effective and economical clinical procedures," he said. "Another complicating factor is basic variation in the genetic make up of individual humans. Each time we identify a specific gene, individual variation complicates how that identified gene is expressed."

"For example, we know the BRCAl gene is a predictor of breast cancer," noted Dr. Dolginow. "But at the same time, we've already detected 400 different mutations in the gene. Scientists suspect that there may be as many as 8,000 mutations of that single gene!

"This range of genetic variation, combined with our current level of science, makes it difficult to precisely predict any individual's true risk of developing breast cancer," he said.

Dr. Dolginow is intimately familiar with this subject. Oncormed has positioned itself to be a resource that links pharmaceutical research with clinical trials involving human subjects. As a result, he comes in daily contact with thought leaders from both groups.

"Explosive growth of pharmacogenomic technology will happen after one drug company uses pharmacogenomics to develop a blockbuster drug like Viagra," predicted Dr. Dolginow. "If that drug delivered $500 million or $1 billion per year in sales, then all the major drug companies would begin pouring hundreds of millions of dollars into this area of research."

Doubling Of Productivity

"Even now, the state of genetic research is already rapid," he continued. "We see the same phenomenon as the silicon chip industry. Moore's Law says that the productivity of a computer chip doubles and its price falls by half every two years. DNA-based technologies are experiencing the identical outcomes. Every two to three years, the productivity of basic processes doubles while the cost drops by half.

"But it must be remembered that our DNA-based technology is at the 'vacuum tube' stage," he added. "It took a while for transistors to replace vacuum tubes. It took time to move transistors onto silicon-based chips. Even as DNAbased technology advances, it will take time for the marketplace to evaluate the economics and clinical efficacy offered by this technology." THE DARK REPORT considers pharmacogenomics to be the convergence point for a variety of technologies which, in combination, will create the next several generations of diagnostic testing. We expect this convergence to create a new class of incredibly precise diagnostic assays. They will provide added value to both clinicians and patients, at a lower cost. TDR

(For further informati on, contact Doug Dolginow, M.D. at 301-208-1888 or email to: ddolginow@oncormed.com.)

Pharmacogenomics Based On Polymorphism Variation

ALL HUMANS HAVE VARIATIONS in their genetic make up. These variations are called polymorphisms. Polymorphisms are increasingly believed to be responsible for why individuals react differently to the same drug.

The essence of pharmacogenomics is to first identify polymorphisms, then determine how these polymorphisms affect the way an individual reacts to a certain drug. For example, early research in Canada indicates that a subset of the apolipoprotein E (APOE) gene in Alzheimer's patients is also a good indicator for the effectiveness of the drug tacrine. Individuals who were homogeneous for the APOE e4 allele had a much poorer response to tacrine than patients with other APOE subtypes.

This example indicates why polymorphisms and pharmacogenomics represent new areas of science which can dramatically increase the volume of diagnostic testing and add value to the clinician. This technology is several years away from widespread clinical usage. Nonetheless, laboratory executives should carefully watch developments in this field. Opportunities for profitable new lines of testing will appear at unexpected intervals.

Genetic Testing Almost Accented In Market Place

Oncormed's pioneering experiences illustrate that many hurdles still remain

CEO SUMMARY: Advances in molecular and genetic science have generated the first generation of diagnostic assays for clinical use. As these assays reach the public, acceptance is not immediate. Obstacles are many: ethical, cultural, clinical, and economic. Oncormed's experience during the last five years provides valuable insights about the challenges of being first to the marketplace with cutting edge diagnostics.

FUTURE DIAGNOSTIC ASSAYS BASED on genetic science represent the clinical laboratory industry's "New Frontier." These yet-to-be-developed assays may be the industry's best opportunity to regain financial stability.

In the coming months and years, laboratory executives will begin encountering two new words: pharmacogenomics and polymorphisms. (See pages 2-4). These are the technologies expected to underpin upcoming generations of diagnostic assays.

To get a peek into this future, The Dark Report recently visited **Oncormed, Inc.** in Gaithersburg, Maryland. Oncormed was founded in 1993 to offer services in two areas: gene characterization and molecular profiling.

Breast Cancer Test

Among Oncormed's accomplishments was the development of a test, based on the BRCAI gene, for determining the susceptibility of women to breast and ovarian cancers. More importantly, during the past five years Oncormed also developed specialized resources to take cancer-related genetic discoveries from the research laboratory and develop them into clinically useful products.

"We want to accomplish our business goals through strategic partnerships," stated Doug Dolginow, M.D., Oncormed's President. "Several such partnerships are already in place. A further development is our impending acquisition by **Gene Logic, Inc.** within 30 days. The strategy was to match our proprietary technologies and clinical experience in pharmacogenomics with Gene Logic's genomics and bioinformatics capabilities."

The combined company expects pharmaceutical companies to be their primary customers. "The reason is simple," stated Dr. Dolginow. "The current state of genetics-based diagnostics is still not ready for widespread clinical application. Our experience with breast cancer susceptibility testing illustrates why that is true.

"First, such testing is not appropriate for every patient," he said. "Individual patients must undergo a preliminary evaluation to determine if their background and circumstances

warrant a genetics-based susceptibility test for breast cancer. Oncormed had to develop a protocol for identifying women whose background, family history of disease, and other factors indicated the appropriateness for our test. "It was at this stage of the process that we made a surprising discovery," continued Dr. Dolginow. "At least 50% of the individuals who met o.ur protocol and were appropriate for this testing declined to -go further. As it turns out, these individuals had many issues, each with no easy answer."

Cancel Health Insurance

"They were concerned that insurance companies would learn of their susceptibility and figure out a way to deny coverage or cancyl their health insurance," noted Dr. Dolginow. "They had similar concerns about getting and keeping life insurance coverage.

"Even their kids were a consideration," he said. "Many patients were worried that their susceptibility to breast cancer, once the tests were completed, would be used to deny their children health insurance and life insurance, now or in the future. Of course, some patients simply decided not to proceed with the test because they didn't want to know what their susceptibility to breast cancer would be."

Oncormed's experience is mirrored by Genzyme Genetics, a leading provider of pre/postnatal genetics testing. When a patient is referred to Genzyme for genetics testing, counselors are provided to help prospective parents deal with the ethical and emotional issues that accompany the test results.

"Another factor inhibiting wider clinical use is that the underlying science for these assays is quite new," added Dr. Dolginow. "That makes many clinicians hesitant to order the tests. Also, because of constraints on their time, most physicians have not yet been trained in the science and clinical applications of these tests."

As a pioneer in offering genetics-based diagnostic testing, Oncormed's experience demonstrates an essential point to clinical laboratory executives and pathologists. When genetics-based diagnostic assays of the future prove to be accurate, amazingly cheap, and highly effective at predicting, diagnosing, and staging various diseases, they add a new complication for laboratories: the need to address ethical, moral, and emotional issues with patients undergoing these tests. **TDR**

(For fu rther infor mation, conta ct Doug Dolginow, M.D. at 301-208-1888 or email to: ddolginow@ oncormed.com.)

Introduction Of New Technology Is Like "Wildcatting"

NEW TECHNOLOGY from the research laboratory requires tremendous work before it can enter clinical use.

"Lots of laboratory research emerges before it is ready;• stated Doug Dolginow, M.D., President of Oncormed, Inc. "Right now there are huge pots of money chasing newly-developed technology in research laboratories all over the world.

"Research grant money competes with venture capitalists and private investors for any technology that looks promising," he said. "On the plus side, venture capitalists are shrewd and good at evaluating risk. They tend to move viable t'e.chnology into the mar .etplace faster than researci;iers backed by rese.ar ch grants.

"But the process of transforming research technology into clinically viable products remains highly speculative," added Dr. Dolginow. "It is exactl y like wildcatting ... drilling for oil. Just like many exploratory wells come up dry be.fore a gusher is drilled, so also does much of this new technology prove inappropriate for clinical use. "At Oncormed, our speciality is working with the research labs to apply the technology to live patients;' he explained. "That is where we help reduce the financial risk while demonstrating the level of effectiveness this technology can have with patient populations."

DIANON Shoots At Urocor, Makes Unwelcome Offer

"Overaggressive and ungentlemanly" says UroCor as relations with DIANON tum sour

CEO SUMMARY: It pays to know your friends. Last month DIANON Systems announced an unsolicited offer to acquire UroCor. The offer, following months of ongoing discussions between the two companies, was clearly unwelcome at UroCor. Both companies are pushing hard to evolve disease management products from diagnostics testing and compete nationally for urologist referrals.

ON AUGUST 19, NEWS BROKE TIIAT **DIANON Systems, Inc.** of Stratford, Connecticut was making an unsolicited bid to acquire **UroCor, Inc.** of Oklahoma City, Oklahoma.

DIANON offered to acquire all outstanding shares in UroCor for $7.50 per share. UroCor's shares closed at $4.87 on August 19, so the DIANON offer represented a 54% premium and was worth $80 million. Although both companies acknowledge that they have conducted ongoing discussions about a variety of business arrangements in recent months, DIANON's offer was clearly unwelcome at Urocor.

Declined The Offer

"DIANON's offer was received on August 17, the day of our regularly scheduled directors meeting," stated William Hagstrom, Chairman and CEO at Urocor. "UroCor's board carefully considered every aspect of this unsolicited offer and declined to accept it. At this meeting the board passed a Shareholder Rights Plan. This agenda item was already scheduled for action and had been under development since last February."

DIANON made public its offer on August 20 and Urocor r(ibonvened its board and considered DIANON's offer a second time, with the same result. Since the flurry of events in August, no further action has been taken by either company. UroCor has made it clear that the company is not for sale. DIANON has made no additional public announcements regarding the acquisition offer.

Clients and readers of The Dark Report know that each company represents a different business model for the clinical laboratory of the future. DIANON Systems is respected for its consistent ability to introduce new diagnostic assays and new technology into the clinical marketplace. (See TDR, March 2, 1998.)

In recent years the company has beefed up its anatomic pathology capabilities, with great success. DIANON is also developing disease management products built upon diagnostic testing technology. For 1997, DIANON's revenues topped $61 million.

UroCor is familiar to clients of The Dark Report. Organized completely around the concept of disease management, UroCor is using diagnostic testing services as the platform to develop and offer increasingly sophisticated disease management products. UroCor's target customers are urologists. *(See TDR, June 23, 1997.)*

Competition For Urologists

Urology is the link between DIANON Systems and UroCor. During the past five years, both companies competed aggressively for urologists' business. Each company will boast of its success in this market niche. However, UroCor's rapid pe.netration of the urology market in 1993 and 1994 was one factor in DIANON's decision about that time to expand and emphasize anatomic pathology services.

Laboratory executives should understand that the ongoing battle between these two companies has less to do with evolving trends in the clinical laboratory marketplace and more to do with the internal challenges confronting DIANON Systems and UroCor.

Limited Resources

Combined, the revenues of both companies are less than $100 million per year. That limits the financial resources of each company. It is difficult for them to invest in new product development and have sufficient capital to bring those products to the marketplace.

Limited resources to fund sales and marketing constrains both companies' growth potential. For example, UroCor expanded its sales force from 42 to 65 sales reps during the last 12 months. It takes considerable time and expense for these new reps to build sales volume.

Another relevant factor is their status as public companies. Stockholders and financial analysts expect public companies to show sustained growth of 5% to 15% per year as a minimum. This is a challenge for DIANON and UroCor, since reimbursement is declining and there is pressure to reduce utilization. These are the reasons why DIANON's rejected tender offer will probably not end their long-running love/hate relationship. **TDR**

(For further information, contact DIANON Systems at 203-381-4000 and UroCor at 405-290-4000.)

All Pathologists Should Heed Marketing Lessons

MUCH OF THE REVENUE GROWTH AT DIANON Systems and UroCor comes from anatomic pathology. As national providers of AP services, both companies market themselves aggressively at the community level.

Most pathologists who practice in community hospitals would like local urologists to refer AP -specimens to them. That allows local specimens to be handled by pathologists in that community. Yet when sales reps from DIANON and UroCor began soliciting business from urologists in the community, most pathologists react like "deer in the headlights." They freeze, do nothing and lose the business.

It is time for pathologists to heed the lessons of the marketplace. In the new world of managed care, pathologists will only achieve financial stability and revenue growth by proactively marketing their services. Community-based pathologists must compete, in their own way, with DIANON, UroCor, AmeriPath and other companies.

This means that pathologists must invest some of their practice revenues in marketing and sales. Pathologists must bring in business management expertise capable of running their practice profitably, making it grow, and increasing its profits.

The examples of DIANON and UroCor demonstrate that professional sales and marketing can cause clinicians to refer AP specimens to national providers. It is now time for local pathologists to study this success and use marketing as the tool to build their practice profits.

VA Lab Network Restructures Using Pannering, Telepathology

CEO SUMMARY: Economic pressures are forcing even the traditional and staid Veterans Ad ministration to extensively reconfigure its laboratory services. At this year's Executive War College in New Orleans, participants learned how one eight-hospital VA region consolidated testing around two core labs, entered into a partnership with a commercial laboratory, and used telepathology to serve a remote VA hospital after the retirement of its sole pathologist. The region's goal is to reduce expenses by 20% while maintaining and enhancing lab services.

INNOVATION AT MILWAUKEE & CHICAGO

RADICAL RESTRUCTURING of hospital laboratory services is not limited to the private sector. Even the hide-bound and often-bureaucratic **Veterans Administration** is energetically embracing laboratory consolidation.

"Reality finally hit us square in the face," stated Bruce Dunn, M.D., Chief of Pathology and Laboratory Medicine at the **Milwaukee and Iron Mountain Veterans Administration Hospitals**. "The VA system is clearly under the gun to improve performance. Congressional cutbacks to the VA:s medical budget are quickly changing the way we do business at VA hospitals throughout the country."

Dr. Dunn was in New Orleans this May to address the *Executive War College*. His hospitals are part of VISN 12, one of 22 regional laboratory networks in the VA's healthcare system.

Laboratory operations in all VISNs are undergoing major restructuring. However, both the pace of laboratory consolidation and the degree of innovation varies dramatically from one VISN to another.

"The direct impetus for change came from two sources," explained Dr. Dunn. "First, funding for laboratory services was to be reduced by 5% in 1997 and another 5% in 1998. Second, in meetings with hospital and laboratory administration, we agreed on a goal of reducing laboratory expenses by 20% over a three year period.

"These are radical goals for a medical I organization built upon predictable, year. to-year increases in funding. It is important I to recognize that medical and technical staff in our laboratories were not used to extensive change," he added. "That is why we expected them to resist any restructuring plans that affected them personally."

VISN 12 is comprised of eight hospitals in Northern Illinois, Wisconsin and the Upper Peninsula of Michigan. These laboratories also serve a network of VA outpatient clinics located throughout these areas.

"Our challenges were no different than any other hospital-based laboratory," stated Dr. Dunn. "We have redun/dant laboratory services. We've got multiple, independent pathology resources with excess capacity. We've had different standards of efficiency and quality at our various laboratory sites.

"So it should not surprise you that we adopted many things from private hospital laboratory restructuring projects," he noted. "We didn't want to reinvent the wheel and we also wanted-to know that the types of cost-cutting measures we adopted had been successful in other laboratories."

This "borrow from the best" philosophy triggered three fundamental restructuring strategies. First, core laboratories were to be created in Milwaukee and Chicago, so testing could be consolidated at these sites. Second, a unified system for logistics and laboratory data needed to be developed as a necessary step for further enhancements to lab services in the region. Third, excess capacity in both clinical laboratories and pathology departments had to be eliminated, using tools like downsizing and increased specimen volumes.

Along with Dr. Dunn, key players in the planning and implementation of this project were Gregorio Chejfec, M.D., Chief of Laboratories at **Hines VA Hospital** in Chicago; Thomas O'Donohue, Laboratory Manager at Hines; John Heffner, Laboratory Manager at Milwaukee VA Hospital; and Edward Sasse, M.D., Consultant Biochemist forVISN 12.

'In the planning stage we realized the importance of aligning incentives and motives at all sites where laboratory testing and pathology is performed," observed Dr. Dunn. "Our goal was not a 'one-time' costsaving program. Rather, we wanted to create a new culture and a new organization within VISN 12 that would foster ongoing improvements to the services we offer while consistently whittling away at expenses."

Dr. Dunn's observation reveals that leadership within VISN 12 understood that survival and success would only come from a new culture and a new attitude within the laboratory network. Thus, any strategic management plan for regionalization needed to address ongoing incentives and the operational culture for the newly-revamped laboratory system.

"One complicating factor in our planning effort was simply to identify who was in charge at each site," said Dr. Dunn. "Was it the VA itself? Was it the affiliated medical school? Now that we have a network, was it the network director? Was it the hospital lab director? Frankly, this is one challenge that we are still trying to work through.

"Remember that several things are unique to the VA medical system," he continued. "Our mission at the VA is patient care, teaching, research, and one other unusual function: the VA is here to back up the medical services provided by the Depar tment of Defense, particularly during war or other times of hostile action."

Patients Tend To Be Older

"Unlike most hospitals, which serve a range of patients from the general population, our primary patient is a veteran. Our patients also tend to be older, and come to us with multiple medical problems. They are challenging patients, and very expensive compared to a general patient population."

As a result, the VA medical centers treat a patient population with very different characteristics than the typical hospital. "This unique patient population requires us to offer a specific mix of laboratory services," noted Dr. Dunn. "The regionalization effort had to maintain those capabilities. "Prior to consolidation, our laboratories, for all intents and purposes, acted independently of each other," he explained. "Six of the hospital laboratories were affiliated with medical schools, and that influenced where and why they referred send-out testing. Across the region, there was no consistency in laboratory operations at individual sites. "We also have the problem of extensive geography. Iron Mountain is 300 miles from Chicago and 220 miles from Milwaukee. Even Madison is 90 miles away from Milwaukee. This far-flung , geography is why courier service was determined to be a critical success factor.

"The decision was made to create two core laboratories, one at Milwaukee VA Medical Center and the other at **Hines VA Medical Center** in Chicago. This consolidation process was made easier by the fact that all eight hospitals use the same information system.

"Another fundamental decision was to rely on outside laboratories for reference and esoteric testing, rather than the academic centers affiliated with our various hospitals," added Dr. Dunn. "This may not sound like a big deal to most labs, but for us it was, and continues to be, revolutionary thinking. Sending specimens to an outside laboratory provider runs contrary to the close relationships between the VA hospitals and their medical school affiliates."

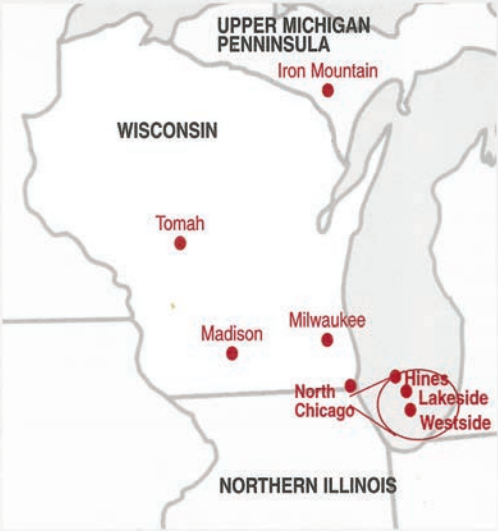
By choosing one reference lab partner to perform all send-out testing, VISN 12 expected to see a significant reduction in the cost of reference testing. "Not only would centralizing reference testing allow us to drive down the cost," observed Dr. Dunn, "but concentrating the send-out work from eight hospital labs gave us the option to possibly bring those tests in-house, to improve both costs and turnaround times."

Other Advantages

"The search for a single reference laboratory provider turned out to have other advantages as well," he continued. "During the RFP process, we decided what we needed was not a low cost, qual-

VISN 12 Laboratory Regionalization Targeted Several Operational Areas

Map of VISN 12



VISN 12's Desired Outcomes For Lab, Pathology Consolidation

- VISN labs function as a single entity.
- Improved efficiency (goal: 20% budget reduction in three years.)
- Standardization of equipment.
- Consolidated purchasing.
- Reduced staffing.
- Primary labs (limited menu) refer many test to core labs.
- Single reference laboratory.
- Automated transmission of results from core lab and reference lab back to referring lab.
- No reduction/selected improvements in laboratory testing:
- Specimen transport (reference lab partner).
- More frequent batch testing at core lab.
- Improved TAT and services for some batched tests.

Initial Status FY 1996

FTE Pathologist:	30.5
FTE MT/MLT:	438.
Workload: Surgicals:	18,000
Cytology:	8,000
Billable tests:	6.2 Million
Budget:	$32.5 Million
Unique Patients:	147,000

VISN 12 provides a good example of how laboratory consolidation and laboratory regionalization mutually reinforce goals of enhanced services and lower costs. VISN 12 is midway through budget cutbacks during 1997 and 1998 of 5% for each year. The executive team at VISN 12 targeted a 20% reduction in costs over a three-year period as its internal objective.

ity reference laboratory provider. Rather, we needed a business partner who could provide us more than just laboratory tests. For example, given the distances between our eight hospitals, we realized that it would be prohibitively expensive to create a courier system capable of meeting our needs. A reference lab partner could provide us better courier service at a lower cost than if we did it ourselves.

"Our selection process determined that **Quest Diagnostics Incorporated** offered services which best matched our needs," stated Dr. Dunn. "They are our primary source for reference and esoteric testing. We utilize, and pay for, their courier services to move specimens between our clinics and hospital laboratories. Their LIS is being adapted to provide a direct host-to-host interface with our laboratories.

"This partnering relationship allowed us to move faster at implementing our consolidation, while savings us considerable money in several operational areas," he said. "It permitted us to focus our management time on other projects necessary to complete the consolidation."

Even though most lab testing was consolidated at the Milwaukee and Chicago hospitals, VISN 12 did take advantage of the expertise that existed at various sites. For example, all electron microscopy is done at Madison. Flow cytometry was done at three sites and now is performed at only one of our laboratories."

Keep Expertise

"This concentration of specialty testing allowed us to keep expertise at certain teaching centers," explained Dr. Dunn. "It also has helped us generate more specimens. For example, Milwaukee operates a bio-safety level three lab in mycobacteriology. It is one of only two such labs in the state of Wisconsin. As a result, other hospitals are referring mycobacteriology specimens to us."

Pathology consolidation involved several interesting issues. "At the start of this project, we had 18,000 surgical cases per year and 30 pathologists," observed Dr. Dunn. "It was recognized that these numbers could be improved.

"Over the last two years, the number of pathologists fell to 18," he said. "This reduction came mostly as a result of retirement. It might be said that 18 is still a high number for the annual case load, but given the other responsibilities of our pathologists, it certainly brings us more in line with the existing workload."

Telepathology Solution

One of the more fascinating aspects of the pathology consolidation involves telepathology at Iron Mountain VA Hospital. "Iron Mountain generates 1,000 surgical specimens and about 40 frozen sections per year. Historically, we've maintained one full-time pathologist at this hospital.

"A telepathology system was installed two years ago to help us cover the work whenever this pathologist was away for meetings or vacations," said Dr. Dunn. "When he retired at the end of 1996, the decision was made not to fill that position. Instead, we trained a medical technologist to be a pathologist assistant.

"Our telepathology system is real time and dynamic," he noted. "We are in control of the microscope. The system allows us to change the focus, change the X-Y axis, change the lighting, and change the objective.

"We look at the consolidation of our laboratory and pathology services as a work in progress. This three-year project is the start of an ongoing effort to align services in ways which improve quality and control costs."

Bruce Dunn, M.D.
Chief, Path & Lab Medicine, Milwaukee VA

"Our telepathology arrangements now allow o\u Milwaukee pathologists to handle the Iron Mountain workload in just two pathologisthours per day," he said. "From a cbst standpoint, it is somewhere between having an on-site pathologist and sending all the cases to Milwaukee. As it turns out, the telecommunications cost is surprisingly expensive."

The telepathology system allows the Milwaukee pathologists to guide the pathology assistant (PA) in preparing the specimen. "We have a camera that allows us to look at the gross specimen and direct the PA as to where to take the sections," explained Dr. Dunn. "Thus, the pathologist oversees all activities. It works exactly as if the PA was at the same site with the pathologist.

"Two years ago, with an on-site pathologist, turnaround time for AP specimens at Iron Mountain was four days. Now it averages 1.3 days," Dr. Dunn said. "Most importantly, the physician staff at Iron Mountain can get even faster service if the need arises." VISN 12's laboratory restructuring project demonstrates several of the marketplace trends currently under way in the United States and Canada.

Lab Consolidation

First, laboratory consolidation is a necessary step to simultaneously eliminate excess laboratory capacity while lowering average cost per test. VISN 12 used the double core lab and a single reference laboratory provider as primary consolidation tools.

Second, laboratory regionalization must occur as a parallel process. The best combination of maximum service and lowest cost is achieved only by taking all the existing lab resources within a region and integrating them in rational ways. VISN 12 looked at the three-state service area and restructured existing laboratory and pathology resources to create an integrated laboratory network.

Third, pathology consolidation is an inevitable consequence of laboratory consolidation. There is excess pathology capacity in every city, just as there is excess laboratory capacity. The marketplace is forcing hospitals to eliminate that excess capacity. VISN 12 saw the number of pathologists decline from 30 to 18 without a decline in service or quality.

Speedy Implementation

Fourth, speedy implementation of the consolidation/regionalization project is critical to success. Taking too long to make the project happen and generate cost benefits can mean failure instead of success. VISN 12 established specific target dates for implementing its consolidation plan and has pushed hard to meet those dates. Fifth, partnering is a legitimate, even desirable way, to speed up consolidation and maximize the savings. VISN 12 used Quest Diagnostics as a way to quickly launch a three-state logistics system, centralize send-out testing, and create direct computer interfaces between all major laboratory sites in the network. Another interesting feature about VISN 12's regionalization plan is that it was developed and implemented in a matter of months, without the help of high-priced consultants. It demonstrates that innovative laboratory management can spring from home-grown sources. Laboratory executives should also lreep in mind that VISN 12 is just one of 22 VA laboratory regions which are dealing with the challenges of lower reimbursement. Across the country, laboratory consolidation and laboratory regionalization efforts are under way. Some of these VISN s will have their own brand of management innovation. **TDR**

(For further information, contact Bruce Dunn, M.D. at414-384-2000, Ext. 1296.)

FIRST CAP INSPECTION OF LABORATORY NETWORK

MUCH OF THE REVENUE GROWTH AT DIANON Systems and UroCor comes from anatomic pathology. As national providers of AP services, both companies market themselves aggressively at the community level.

Most pathologists who practice in community hospitals would like local urologists to refer AP -specimens to them. That allows local specimens to be handled by pathologists in that community. Yet when sales reps from DIANON and UroCor began soliciting business from urologists in the community, most pathologists react like "deer in the headlights." They freeze, do nothing and lose the business.

It is time for pathologists to heed the lessons of the marketplace. In the new world of managed care, pathologists will only achieve financial stability and revenue growth by proactively marketing their services. Community-based pathologists must compete, in their own way, with DIANON, UroCor, AmeriPath and other companies.

This means that pathologists must invest some of their practice revenues in marketing and sales. Pathologists must bring in business management expertise capable of running their practice profitably, making it grow, and increasing its profits.

The examples of DIANON and UroCor demonstrate that professional sales and marketing can cause clinicians to refer AP specimens to national providers. It is now time for local pathologists to study this success and use marketing as the tool to build their practice profits.

Analysis & Insight

Problems In PPM Industry Affect Pathology Practices

Experts now raising serious questions about the viability of PPM companies

By Robert Michel
FIRST IN A SERIES

DURING 1998, THE FINANCIAL WOES of many physician practice management (PPM) companies caught healthcare experts, investors, and financial experts by surprise.

Problems with the PPM industry could not come at a worse time for the pathology profession. At the very moment that several pathology-based PPMs are bidding strong prices for selected pathology practices, the PPM industry is doing poorly.

Financial analysts and venture capitalists, whose expertise is devoted to studying successful businesses, have made revealing comments about the PPM industry during the last 40 days.

"I have yet to find a PPM that adds value," stated Larry Feinberg, partner at **Oracle Partners**, a healthcare investment fund in New York City. "The only winners in this game have been the investment bankers."

"To make a profit, PPMs have to pay doctors a below-market compensation, "observed Michael Thomas, Principal at the healthcare consulting firm of **BDC Advisors** in San Francisco. "This isn' t a very durable business proposition unless they [PPMs] enhance operating performance. No one has been able to do that."

The comments of these two experts strip away the hype and exiose the key weakness of the typical PPM business plan. PPMs, as they operate today, do not enhance the doctor's ability to practice better medicine. Nor does the typical PPM add value to the services its doctors provide to customers: patients, hospitals, and insurers. In some cases, it actually adds costs.

Critics say PPMs haven't lived up to their promise and may even raise costs by adding a layer of bureaucracy...

The Wall Street Journal

Physicians, pathologists understand better than any corporate executive that medicine is about more than money. Yet, the larger PPMs have failed to demonstrate that they can combine the business skills of the corporate executive with the clinical skills of the physician and create added value in the marketplace.

So how did MedPartners, PhyCor, FPA Medical Managemen t and other PPMs grow into multi-million and multi-billion dollar companies? The answer is simple and carries a warning to any pathologist considering the sale of a practice to a pathology PPM.

PPMs grew into billion-dollar companies by acquisition,' not by operational excellence. The financial arithmetic of acquisition permits them to do this. But once a company gets large, it must still compete one day at a time, one customer at a time. None of the large PPMs deliver healthcare on a day-to-day basis any better than a wellmanaged group or clinic practice.

Partnership Emerges

"Acquisition strategy" should raise a red flag to any pathologist currently considering the sale of his/her practice to a PPM. It means the PPM wants to get big, and do it fast. But the ability of that PPM to convert its size into valueadded services is probably lacking.

Growth through acquisition can best be illustrated by the **Columbia/HCA** example. Former President and CEO Rick Scott leveraged two hospitals in El Paso into a $20 billion company with 400+ hospitals in about ten years. How did he do it? He bought hospitals using debt and Columbia stock.

As he acquired new hospitals, he amortized the purchase cost over a multi-year period. This increased his cash flow from the hospitals' unchanged revenue b ase. He also inst alled new hospital CEOs who squeezed 10% to 20% cost savings from the hospital in the first year or two after Columbia became owner.

As investors saw cash flow and operating profits increase, they bid up Columbia's stock price. Scott turned around and used the more valuable stock to purchase more hospitals. It was a self-financing loop ... so long as profit margins increased each quarter.

Pathology Income Symposium Deals With Money & Profit

*PATHOLOGISTS WILL HAVE the opportunity to learn effective strategies to preserve and enhance their income when the **1999 Private Pathology Income Symposium and Workshop** convenes in Scottsdale on November 13-14, 1998.*

Attendance is exclusively limited to pathologists and their business advisors. Due to the sensitive nature of the techniques and savvy business methods to be discussed, the symposium is closed to hospital administrators.

This year's event will include presentations about pathology PPMs and how to negotiate for the best sales prices. Also to be covered are strategies for contract negotiations, how to increase AP and CP revenues through value added pathology services. Those interested in registering or more information can call the offices of The Dark Report at 503-699-0616.

This is how the acquisition cycle works. Buy assets and use accounting rules to write them off over a long time period. It gives the buyer more cash flow from the revenue than the seller got. The buyer uses the additional cash flow to increase operating profits and earnings. Investors respond by bidding up the stock price. Now the company can use its higher-priced stock to buy more assets.

By itself, there is nothing inherently wrong with the acquisition business. model. Currently entrepreneurs are acquiring individual auto dealerships and "rolling them up" into mega-dealerships. A similar acquisition wave during the 1980s consolidated regional department stores into national corporations.

But the acquisition strategy cannot succeed beyond a few years unless there is recognizable economic value to

a larger business unit. That supports the acquisition phase with an operational plan to generate added value from day-to-day operations. This seems to be true of auto dealerships.

It was not true in an industry familiar to all pathologists: the commercial laboratory industry. From the rnid-1980s through 1995, the large commercial laboratories pursued an acquisition strategy, buying up small labs and moving that testing to their regional hub labs.

Size Not A Guarantee

Unfortunately for the large commercial laboratory operators, size did not guarantee that their huge laboratories could offer discernably better service than the local pathologist-owned lab down the street.

Pathologists watched the commercial lab industry vigorously pursue the acquisition strategy. Pathologists know the resulting national laboratories have not brought added value to the day-to-day service they provide their customers.

Which brings us to the jackpot question: Why would pathologists sell their practice to a pathology PPM, if they understanding the following facts:

1) An acquisition strategy for growth only works in the long run if the resulting company offers true added value to its customers that smaller competitors cannot.

2) Columbia/HCA followed an acquisition strategy, but could not deliver added value as a large corporation.

3) Commercial laboratories pursued the acquisition strategy from 1985 through 1995. But since 1995, when it became impossible to do further acquisitions, none of the remaining laboratories has brought added value to day-to-day services, nor have these labs made adequate operating profits.

4) Med partners was the $5 billion darling of the PPM industry. It almost pulled off the granddaddy acquisition of them all, a merger with $1.4 billion PhyCor last fall. But the merger fell apart and MedPartner's losses in the last year have topped $1 billion.

Given these facts about the performance of healthcare companies which relied on an acquisition strategy, is it a sound business proposition for a pathologist to sell a practice to a PPM at this point in time?

Here's what the leading observer of the PPM industry has to say. "The $IO-billion physician practice management industry-battered by bankruptcies, litigation and physician discontentmust scrap its losing strategy of growth by acquisition and show that it can actually manage doctor's practices better," stated Efrem Sigel, publisher of the Physician Practice Management Report.

THE DARK REPORT subscribes to that adage "those who ignore history are doomed to repeat it." If the history of business teaches us any one thing, it is that an acquisition strategy alone means strong success for several years, followed by financial turmoil.

Of course, these are our opinions, based on our business experience and ongoing study of the healthcare marketplace as it relates to the pathology profession and the clinical laboratory industry.

There are those who hold different opinions on this subject and possess war chests with tens of millions of dollars earmarked for the purchase of pathology practices. In future issues we will look at the reasons why they are convinced that pathology PPMs can succeed. TDR

For further information, contact Robert Michel at 503-699-0616.)

COMING NEXT ISSUE ...

***PART TWO:** A comparison of the differences and similarities between pathology-based PPMs and other PPMs.*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

If any one individual was to be credited with creating the modern commercial laboratory organization, it would be Paul Brown, M.D., founder and former Chairman of **MetPath, Inc.** (now **Quest Diagnostics Incorporated**). Where is he now? For ten years, he served as a Director for **UroCor, Inc.** of Oklahoma City. (See Pages 7-8.) Dr. Brown recently resigned from UroCor's Board to spend more time at **HeaRX, Ltd.**, where he is Chairman and CEO.

Another recognized pioneer of the commercial laboratory industry has affiliated with a pathology-based company. **Pathology Partners, Inc.** of Dallas, Texas announced this summer that James Powell, M.D., was joining its board of directors. Dr. Powell was founder and former Chairman of **Biomedical Laboratories** (now **Laboratory Corporation of America**). Dr. Powell remains a director at LabCorp.

AETNA TO PAY FOR GENETICS TEST

Last month, **Aetna U.S. Healthcare** agreed to provide genetic susceptibility testing for breast and ovarian cancer to its members. **Myriad Genetics, Inc.** will provide the testing.

Here is an interesting aside on the topic of genetics research. Iceland, settled by 10,000 Vikings in the year 874 A.D., now has a population of 270,000. Its people are considered to have the cleanest bloodlines on the planet. **DeCode Genetics, Inc.** was founded two years ago to capture genetic data from this population and make it available to drug companies seeking to identify genes related to specific diseases. Apparently the effort is helped because genealogy is a passion in Iceland. As early as the year 1000, Christian priests began keeping detailed records of births and deaths. Drug giant **Hoffman LaRouche** signed a $200 million contract this year with DeCode to begin research into several specific disease states.

MORE ON ... GENETICS: Apparently there is competition even in this type of genetic research. Inbred societies in Finland, Costa Rica, and some of Utah's Mormon communities have been the source of DNA samples for **Myriad Genetics** and **Millennium Pharmaceuticals**. Of the above, however, only the Mormons kept detailed demographic records, and these extend back only 150 years.

LAST TAG ON...GENETICS: We believe this interest in genetic data across a cross-section of any population has a parallel in laboratory testing. Laboratory test results for any cross-section of the population will have similar added value to genetics researchers, managed care companies, and clinicians. Each will use the information in different ways. The three blood brothers, **LabCorp, SmithKline**, and Quest, recognize this opportunity. Each is actively pursuing ways to develop salable products from their extensive access to large numbers of test results.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 28, 1998

THE DARK REPORT

UPCOMING...

- *Value-Added Power: How One Hospital Lab Became a Key Player In Infection Control...And Increased Its Institutional Role.*
- *Losing Local Anatomic Pathology Specimens To National Providers: The Battle For National Managed Care AP Contracts.*
- *The Dark Side Of Laboratory Consultants: Why They Promise More Than They Deliver*
- *Laboratory Consolidation Prepares To Enter A New Market Phase.*