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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

Proposed Federal Budget Threatens Laboratories

BY NOW MOST OF YOU KNOW THAT PRESIDENT CLINTON'S FY01 BUDGET is not kind to the clinical laboratory industry. It seeks to restore the 20% copayment for lab services, cuts 30% out of the reimbursement for four tests, and institutes the Medicare competitive bidding concept for lab services.

Over the last 15 years, the track record of lab and pathology professional associations has been poor at lobbying Congress for reasonable changes in year-to-year reimbursement arrangements. Every year or two, Congress succeeded in taking another significant chunk out of the calculations used to establish Medicare laboratory fees.

This 15-year track record would indicate a similar outcome for this budget cycle, assuming that nothing else changes. After all, the same leadership at the same professional associations will be responding to President Clinton's newest budget proposals.

How can the lab industry change its "defeatist" pattern of the last 15 years? Our editor, Robert Michel, believes that only a lobbying effort led by independent commercial laboratory owners will be effective. The two blood brothers maintain their own lobbying effort and support their "own" trade association. Pathologists tend to look to the AMA and their professional associations. Hospital laboratorians aren't directly connected to the lobbying process. That leaves independent commercial lab owners.

Michel notes that individual effort, properly directed, can generate substantial change. For example, Medicare's recent increase to Pap smear reimbursement is a directly linked to the efforts of a Hawaiian pathologist and his local Congressman. In New York State, independent laboratories banded together and achieved a repeal of the notorious 8.18% laboratory test surcharge tax (even if it did take 36 months to accomplish).

Against this historical background of ineffective lobbying, I suggest that clients of THE DARK REPORT form a grass roots, ad hoc effort to lobby Congress in a different, and more effective way. I know a number of our clients have already volunteered to fund a war chest for such a non-bureaucratic, action-oriented campaign. Any laboratory executives willing to participate and support such an effort should contact Robert Michel (503-699-0616 or labletter@aol.com). With the upcoming *Executive War College* only 14 weeks away, it will provide a good opportunity for interested executives to gather and start this process. TDR

Quantum Dots Targeting Multiplexed Bioassays

New technology has potential to create a variety of multiplexed diagnostic tests

CEO SUMMARY: Here's another exciting new technology which promises to expand the capabilities of diagnostic testing while lowering laboratory costs. Based on research originally done during the 1970's, quantum dots™ are nanometer-sized semiconductors with unique properties. Quantum Dot Corporation wants to use an "Intel Inside" strategy with diagnostic partners to launch new assays.

DIAGNOSTIC TESTING technology may soon get a boost from Qdot™ nanocrystals, a new technology offered by **Quantum Dot Corporation** of Palo Alto, California.

"Quantum dots (Qdots) are nanometer-sized crystals made of semiconductor material such as cadmium selenide," stated Bala S. Manian, co-founder of Quantum Dot Corporation (QDC). "These crystals light up like molecular-sized LEDs and make it possible to detect biological materials ranging from DNA to proteins."

Manian's company believes that quantum dots can play a useful role across the entire spectrum of bioassay applications. "Qdots are water soluble and will attach to cells, proteins, and nucleic acids," he noted. "They make excellent tags and multiplexing agents for all types of bioassays."

Founded in November 1998, QDC is moving rapidly to engage its technology across all types of bioassay applications. "During 1999, we signed our first agreement with one of the major diagnostic companies," said Joel Martin, Ph.D., President and CEO at QDC. "A public announcement about this agreement is expected sometime in April."

Martin is confident that Qdots will find rapid acceptance in a wide variety of bioassay applications. He predicts at least one additional agreement with a major diagnostics company will be signed by year's end. Agreements with pharmaceutical and research companies are also expected.

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

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

Martin's confidence is based upon the performance of Qdots in lab trials conducted at QDC. "Virtually every application of Qdots to different bioassays has worked extremely well on the first attempt," explained Martin. "There is sharpness of color and better detection limits. Now we are moving beyond 'proof of principle' efforts to further refine the performance of Qdots."

Variety Of Problems

Quantum dots solve a variety of problems that plague fluorescent dye markers. First, quantum dots will not photobleach under the light source.

Second, existing fluorescent dye markers generate a broad color emission spectra which overlap and make it difficult to simultaneously detect a number of markers. In contrast, quantum dots produce sharp colors at specific wavelengths. This makes them ideal for multiplexed assays.

Third, fluorescent dye markers will photo-degrade in the specimen over time. This causes problems if the specimen needs to be retested at a future date. Qdots remain photo-stable over long periods of time.

"Another benefit of quantum dots is the fact that a single light source is all that's required to light them up," stated Manian. "This eliminates the need for a blue laser to excite blue dyes, a red laser to excite red dyes, and so forth. Instead, a single, inexpensive ultraviolet or even a blue LED will light up all quantum dots."

Business Strategy

"Our business strategy is to be like 'Intel Inside', where Qdots are the engine that powers our partners' products," explained Manian. "We intend to carefully chose our partners and collaborate in the development of diagnostic tests built upon Qdots."

"I would like to emphasize that our technology is available to all comers, on the right terms," added Martin. "However, we will closely participate with our partners to add value. We want to share in the profits generated by the use of Qdots in various applications, including diagnostic testing."

QDC's "Intel Inside" business approach is different from that of **Luminex Corporation** of Austin, Texas. Luminex would like to position its LabMap™ multiplex test platform as an open technology system for use in diagnostics, pharmaceutical research, and other purposes. Luminex wants to emulate how the open technology of the IBM-compatible PC and **Microsoft** Windows formed the technology backbone for the personal computer industry. *(See TDR, December 21, 1998.)*

"Our business strategy is to be like 'Intel Inside', where Qdots are the engine that powers our partners' products."

"We expect quantum dots to find a ready application in diagnostic testing," said Manian. "This technology can be adapted to existing laboratory instruments, minimizing the need for special equipment and training. It also can support reduced sample sizes and less expensive reagents."

Quantum dots were discovered at **Bell Laboratories** and later developed for biological applications by researchers at **Lawrence Livermore National Laboratory**, **Massachusetts Institute of Technology**, and the **University of Melbourne**. QDC has licensed all major biological patents held by developers. This gives QDC an unchallenged position for developing the quantum dot technology.

QDC was formed in November 1998, by Martin and Manian, two veteran entrepreneurs. It obtained first-

round venture capital funding of $7.5 million in January 1999.

Within the diagnostics category of bioassays, QDC has a specific objective. "Together with our diagnostic partners, we would like to accomplish two things with Qdots," noted Martin.

Start With Approved Tests

"First, we want to start with approved assays and combine them into multiplexed assays which can be moved from expensive, sophisticated lab instruments and performed on smaller, less expensive lab instruments," he said. "This would generate superior results, from multiplexed assays, at lower cost.

"Second, we believe that a huge reagent business will spring from our Qdot technology," continued Martin. "For example, ELISA-like assays can substitute Qdots for the enzymes. Analyte A is the color red, Analyte B is orange, and so forth."

E-Commerce Is Wild Card

Lab executives and pathologists who investigate quantum dot technology will find that it is simple and robust. It is poised to demonstrate its effectiveness in a number of diagnostic applications.

There seems to be no major hurdle preventing Qdots from entering the marketplace for laboratory testing. Since Quantum Dot Corporation already has one agreement with a major diagnostics company, it would be reasonable to expect that assays built around Qdots will be available within the next 12 to 18 months.

Both Quantum Dot Corporation and Luminex demonstrate that there are technologies, not based in genetic or molecular science, which can lower the cost of diagnostic testing while improving the quality of results. TDR

Contact Joel Martin and Bala Manian at 650-812-7390 or through www.qdots.com.

Many Potential Uses For Quantum Dots

Executives at Quantum Dot Corporation expect Qdots to find applications in research, drug discovery, diagnostics, and genetic analysis. The list below shows the wide range of potential applications:

- Genotyping
- Whole blood assays
- Multiplexed diagnostics
- RNA expression analysis
- Fluorescence microscopy
- High throughput screening
- Multi-color flow cytometry
- Immunoassays

Selected References & Publications

1. Alivisatos, AP, Nanocrystals: Building blocks for modern materials design, *Endeavour* 21, 56 (1997).
2. Alivisatos, AP, Perspectives on the Physical Chemistry of Semiconductor Nanocrystals, *J. Phys. Chem* 100, 13226 (1996).
3. Alivisatos, AP, Semiconductor Clusters, Nanocrystals, and Quantum Dots, *Science* 271, 933 (1996).
4. Bruchez, MP et. al., Semiconductor Nanocrystals as Fluorescent Biological Labels, *Science* 281, 2013 (1998).
5. Chan, WC et. al., Quantum Dot Bioconjugates for Ultrasensitive Nonisotopic Detection, *Science* 281, 2016 (1998).
6. Colvin, VL et. al., Light-Emitting Diodes Made From Cadmium Selenide Nanocrystals And A Semiconducting Polymer, *Nature* 370, 354 (1994).
7. Empedocles SA et al, Three Dimensional Orientation Measurements of Symmetric Single Chromophores using Polorization Microscopy, *Nature* 399, 126 (1999).
8. Empedocles, SA et al, Photoluminescence Spectroscopy of Single CdSe Nanocrystallite Quantum Dots, *Phys. Rev. Lett.* 77(18), 3873-3876 (1996).

Abaton's Web Solution In Use at Allina, Centrex

In race to web-connect labs & docs' offices, Abaton among the first with working sites

CEO SUMMARY: Abaton.com was among the first companies to actually have Web-based information products linking hospital labs and physician offices. As early as 1997, the Allina Health System was working with Abaton.com to implement a laboratory test requisition/test results system using Web browsers. Centrex Clinical Labs is another Abaton client now implementing a Web-based, thin client solution.

IT'S A RACE TO BRING THE INTERNET to clinical laboratories and the physicians they serve. One early leader in this race is **Abaton.com**, based in Minneapolis, Minnesota.

Abaton.com offers Web browser-based clinical network applications that do more than just laboratory test ordering and results reporting. They can handle pharmacy transactions and develop a universal patient record.

During the past 24 months, Abaton.com installed at least one of its products in **Allina Health System** (Minneapolis), **Norton Health** (Louisville), **Fairview Health Services** (Minneapolis), and a clinic of the **American Health Network** (Kokomo).

In upstate New York, **Centrex Clinical Laboratories** is now rolling out the Abaton.com product to its physician office clients. This is the first use of Abaton's ClinLabs.com™ system in a commercial laboratory.

Although Abaton.com is a young company, founded in January 1997, **McKessonHBOC** was impressed enough with Abaton.com's Web-based clinical information products that it acquired the company last November. This acquisition demonstrates how important it is that traditional hospital IS vendors have a menu of viable Web-based products to offer their lab customers.

Thin Client Concept

"All of Abaton's information products are built upon the thin client concept," stated Donald Connelly, M.D., "The user's 'client' PC only requires a browser to run the application.

"With a thin client, users don't need to buy and install software at their location. This also eliminates the cost of maintenance and upgrades," continued Dr. Connelly. "We believe Abaton.com is the first operational provider of clinical information services to labs which is totally based on Internet technology."

Allina Health System was Abaton.com's first installation. "We installed the results reporting and viewing product at Allina in February 1998," stated Dr. Connelly. "In August 1998, Allina Labs rolled out order

entry, one clinic at a time. Currently more than 20 clinics use the Abaton system, with more locations becoming operational each month.

"Every test result generated by Allina Labs, for both the health system's inpatients and outpatients, is fed to the Abaton repository, he noted. "Since February 1998, about 48,000 new lab results have posted daily. Using a Web browser, any workstation connected to Allina's intranet can order lab tests and view lab results."

Using Hospitals' Intranet

Because most integrated healthcare delivery systems already have intranets, Abaton.com usually runs over the hospital's intranet rather than the public Internet. One reason for choosing this approach is concern about protecting the confidentiality of patient data on the Internet and changing federal guidelines on privacy.

"In contrast, Centrex is totally Internet-based," observed Dr. Connelly. "Its operational sites are using Web-browsers to access our server via the Internet. The federal government recently defined acceptable approaches for achieving data security. Abaton.com has implemented these new standards for Centrex. "

Electronic Test Ordering

Abaton.com's ClinLab.com is a "browser-based laboratory order entry and automated results management system." It lets physician practices electronically order tests, verify laboratory benefit eligibility and receive test results.

It verifies compliance with Medicare's medical necessity rules for lab tests in real-time and supports the necessary documentation. The system has embedded display capabilities that consolidate test results over time and display them graphically.

"There is also a workflow management feature," observed Dr. Connelly. "This allows users to designate how patient clinical data will be distributed and to assign follow-up tasks to specific individuals. Our system is designed by doctors to be used by doctors and this workflow feature has proved to be a hit."

The modular design of Abaton.com's product offerings is based upon the high demand for access to lab data. "It seems that, in every clinical environment, there is widespread agreement that access to laboratory test result data is necessary and worth pursuing," said Dr. Connelly.

Abaton.com's Roots Lie With Univ. of Minnesota

It was a group of clinical pathologists at the **University of Minnesota Medical Center** who did the development work which led directly to Abaton.com.

"As early as 1979, we were building information management tools that doctors wanted to use," noted Donald Connelly, M.D., Professor of Laboratory Medicine and Pathology at the University of Minnesota and Director of Clinical Applications Design at Abaton.com. "In 1979, we had doctors online at one inpatient ward, linked by the Plato system, which allowed them to graphically view results.

"Our move up was touch-screen reporting, initiated in the neonatal intensive care unit in 1985," he continued. "Clinicians loved this. In 1994, we saw the potential of the Mosaic Web browser. We used this, and HTML, to give our hospital access to lab results in late 1994."

By 1996, current Abaton.com Chairman and CEO James Bradley entered the scene. Dr. Connelly and his colleagues needed more money to develop their software products. To obtain the necessary capital, Abaton.com was launched in January 1997. It signed its first contract with Allina Health In October 1997.

"That is why most integrated healthcare systems start with a laboratory test results reporting system," he explained. "Later on, they may want to add a prescription writing system and finally a system for doing the ambulatory patient record."

Complete The Installation

When a clinical laboratory decides to acquire a Web browser-based system for ordering tests and reporting results, it will need to do several things to complete the installation.

"First, the lab's test catalog and ordering rules need to be mapped to our system,' said Dr. Connelly. "We use LOINC codes to map the 400 most frequently-appearing test results. This allows us to bring past results together, regardless of where the test was performed or whether it was part of a panel.

"Second, we develop an interface with our client's LIS and in some cases, the LIS of the reference labs used by our client," he continued. "Because this can be a challenge even with HL-7, we have a dedicated interface team.

The thin server business model, also known as ASP (application service provider) is a major threat to the established IS vendors.

"Implementation goes faster when the healthcare system has an existing intranet, because it generally means the laboratory organization is already familiar with networking technology and the benefits it brings," said Dr. Connelly.

Abaton.com seems to be capable of speedily installing Internet-enabled installations. Centrex Clinical Labs told THE DARK REPORT that its first user site was operational less than 18 weeks after the contract with Abaton.com had been signed. *(See sidebar on next page.)*

The much-awaited ability to match laboratory data with pharmacy prescriptions and other clinical data has yet to be realized by Abaton.com's earliest customers—for a simple reason. "None of our first clients have implemented both the laboratory product and the pharmacy product in the same setting," explained Dr. Connelly. "But this is being considered at three sites even now. We fully expect that effective blending of lab results and pharmacy information will generate worthwhile improvements to clinical care."

Early Leaders In The Race

Abaton.com is one of the early leaders in the race to bring Web-based laboratory test ordering and results reporting to the marketplace. With four major clients now up and running, Abaton.com's early product placements illustrate that the market for Web-based lab services remains undeveloped.

On the other hand, the speed with which Abaton.com developed its thin client/Web browser product suite demonstrates how rapidly new technology is moving from theory to practice application. Here is a company that was incorporated in January 1997, had its first product go live in 1998, and was acquired by a large healthcare IS company (McKessonHBOC) before the end of 1999!

The thin server client approach is very conducive to the emerging software business model of ASP (application service provider). With the ASP model, the customer buys a service and doesn't have to worry about the capital expense of a new computer system.

ASP is a major threat to established IS vendors. Companies such as **Cerner**, **Meditech**, **Sunquest**, and **SMS**, have substantial businesses based upon thick client technology.

Centrex Happy with First Installations, Wants Competitive Advantage from Web

"WE HAVE ABATON.COM'S full clinical laboratory package now in place," said Lee Barnard, Chief Information Officer at Centrex Clinical Laboratories in New Hartford, New York. "It's tangible and it works!"

Centrex issued RFPs in February 1999 for a Web-based test ordering and results reporting system. "We signed our contract with Abaton.com in August 1999. In only 18 weeks, they had our first link operational and in clinical use," noted Barnard.

"As of this date, we have one hospital using both test ordering and results reporting," he continued. "Two other sites utilize results reporting. Our strategy is to use Web-based test ordering and results reporting as a competitive advantage to attract new clients. We will also use it to defend our existing clients from competing labs."

Centrex feels the cost of its Web-based capability is competitive with the current "thick client" technology. "I did a rigorous analysis of our return on investment," noted Barnard. "Using a five-year payback and plugging in everything but the kitchen sink, we believe our cost per requisition will be less than 40¢. Higher usage volumes reduce this number even further."

Centrex bought a license from Abaton.com for a specific number of sites. Thus, it has purchased this system for a fixed price and will pay an annual maintenance fee.

"Users already love this system," stated Barnard. "In fact, once our clinical pathologists saw it, they insisted upon internal access to test results. They like the clinical view feature. We wired them in and they use it to view graphs and trends on individual patients."

Barnard noted another benefit to the Abaton.com product that was unexpected. "It has a workflow management capability. This is valuable. It allows users to assign each task to a specific individual.

"For example, Nurse Mary might be designated as the one to view abnormal test results," he explained. "Thus, each batch of abnormal test results will be flagged for her to review and handle. It works so well that we've put the workflow feature to good use in our own lab!"

There is conflict within these companies about how to transition to the thin client model without cannibalizing their existing revenues and profits. Any delays resulting from these internal debates will give nimble new entrants, like Abaton.com, a big head start.

Clients and regular readers of THE DARK REPORT know that we predict the transition to Web-based links between labs and physicians' offices to occur in as little as 24 months. *(See TDR, November 1, 1999.)* This will be a major shift in the competitive advantage that one lab has over another. The example of Centrex Clinical Labs demonstrates how quickly even a modest-sized lab company can implement Web-based services with its clients. **TDR**

Contact Donald Connelly, M.D. at 612-814-7171 and Lee Barnard at 315-797-0791.

Centrex and Abaton.com to be at the EXECUTIVE WAR COLLEGE

Centrex Clinical Labs and Abaton.com will present case studies and share their experience at the upcoming *Executive War College*, May 17-18 at the Fairmont Hotel, New Orleans. Call 800-560-6363 to register or for information.

CEO SUMMARY: Although the financial travails of the physician practice management (PPM) industry are widely known, there is little recognition that a number of single-specialty PPMs are doing well. This is true of pathology, where at least six pathology-based PPMs still remain in business. The best of them demonstrate strong revenue growth and good profits. Their business achievements provide solid evidence that the market for anatomic pathology services is rapidly changing.

PATHOLOGY PPMS STILL AROUND

Single-Specialty Path PPMs Posting Strong Growth, Profits

RISING FROM THE ASHES of the ravaged physician practice management (PPM) industry is a different type of PPM company. It is the single-specialty PPM.

The PPM industry's behemoths were companies like **Medpartners**, **PhyCor**, **PhyMatrix**, and **FPA Medical Management**. All were multi-specialty PPMs, attempting to serve the divergent needs of thousands of doctors, practicing in almost all specialties.

Their financial collapse, between 1997 and 1999, was spectacular. Huge write-offs, messy bankruptcies, and basic mismanagement took its toll on participating physicians and investors alike. Many Wall Street analysts declared the PPM industry to be both irrelevant and dead.

Today, this conclusion ignores the continuing evolution of the single-specialty PPM. These are firms, both public and private, which focus exclusively on supporting the business, management, and clinical needs of a specific medical specialty.

During the same 1997-1999 time period that was so disastrous to multi-specialty PPMs, a number of single-specialty PPM companies posted strong growth and impressive profit margins.

Profitable single-specialty PPMs include **TeamHealth**, organized around emergency room physicians, and **Ortho-Link Physicians Corporation**, which supports orthopedic surgeons.

Within the pathology profession, there are at least six PPM companies. Of this group, only one company successfully completed an initial public offering (IPO). That company was **AmeriPath, Inc.** of Riviera Beach, Florida.

Since funding its IPO in October 1997, AmeriPath has aggressively used acquisitions to fuel rapid growth. At the start of 2000, its annual revenues are about $250 million. It employs 305 pathologists and another 1,500 people. It operates in 13 states and has contracts with at least 160 hospitals.

But AmeriPath's success is not exceptional. At least one other pathology PPM, **Pathology Consultants of America, Inc.** (headquartered in Nashville, Tennessee) is also posting strong profit growth and expanding its presence in selected markets.

Business Performance

THE DARK REPORT believes the ongoing business performance of these two companies demonstrates that, despite the failure of the multi-specialty PPM business model, the single-specialty PPM business may yet be a viable answer to the needs of pathologists in today's hostile healthcare environment.

If this is true, then anatomic pathologists and their group practice administrators need to reassess the existing business strategy of their group. The continued viability of the pathology PPM business model creates both a threat and an opportunity for small pathology practices.

Sustain Early Successes

Should pathology PPMs sustain their early successes, they will be active consolidators of independent pathology practices. This is the threat, for it means that any small pathology group practice, anchored to a single hospital contract, will find itself at a competitive disadvantage within its local market.

However, the success of pathology PPMs also represents an opportunity. Pathology PPMs are an external threat which should scare local pathologists enough to motivate them to form regional consolidated super-practices.

In so doing, local pathologists create the business and financial clout necessary to compete against all comers in their local market. Apparently there are some pathology groups which already recognize this combination of threat and opportunity.

THE DARK REPORT believes that partners in **Associated Laboratory Physician Services** of Wauwatosa, Wisconsin (18 pathologists) and **J.J. Humes M.D.**

and Associates of Detroit, Michigan (13 pathologists serving the **St. John Health System**) decided to sell to AmeriPath late last year precisely because they recognized their relative weakness to deal with competitive market forces in their metropolitan areas.

The need for individual pathology practices to reassess their existing business strategy rests on more than just the threat of local consolidation and the entry of an outside pathology PPM into a metropolitan area.

By joining a pathology PPM, these practices immediately accessed more sophisticated management support, sales and marketing resources, and improved billing and collections capability. It also improved their access to capital to finance growth and enhanced pathology services.

Throughout the United States, consolidation of hospitals, physician groups, and managed care plans is concentrating power. Two and three-physician pathology groups are inherently powerless in this kind of environment.

That is why pathology practice consolidation continues to occur. It is also why the handful of private and one public pathology PPMs continue to expand. Pathologists need a critical business mass if they are to maintain their place at the negotiating table with a multi-hospital health system or a major HMO in the region.

Critical Business Mass

Pathologists can create critical business mass in one of three ways. First, they can consolidate their practices into a regional superpractice. This was the method used by **Bayless Pathmark, Inc.** of Cleveland, Ohio. During the 1990s, Bayless Pathmark grew from a 2-man practice into a regional pathology resource with 22 pathologists serving 10 hospitals. *(See TDR, February 22, 1999.)*

The second way for pathologists to create critical mass is to form a provider network. This allows them to negotiate for managed care contracts as a group, while maintaining their independence and local service emphasis.

Prime example of the network model is **Pathology Service Associates LLC** (PSA), a national organization of state pathology networks. Currently there are eight state pathology networks, with 85 pathology groups and 400 pathologists as members.

The network model can create critical mass. In South Carolina, 22 of the state's 24 pathology practices are members of the PSA network.

Six Pathology PPMs

The third way to create critical mass is for a pathology group practice to become part of a pathology PPM. Currently, THE DARK REPORT is aware of six pathology PPMs. (See sidebar, next page.) Of this group, AmeriPath is the biggest, by a large margin.

The need for individual pathology group practices to reassess their existing business strategy rests on more than just the threat of local consolidation and the entry of an outside pathology PPM into a metropolitan area. There are several other important developments acting to transform the profession of anatomic pathology.

THE DARK REPORT presented these key trends in the preceding issue. *(See TDR, January 24, 1999.)* They range from national branding of anatomic pathology services to pathology practice regionalization.

Several examples of "new generation" pathology companies demon-

strate that these principles are in play. They further demonstrate that pathologists can increase their clinical contribution and personal incomes if they properly respond to these trends.

As evidence, THE DARK REPORT offers four examples, in alphabetical order: AmeriPath; **DIANON Systems, Inc.**; **IMPATH, Inc.**; and **UroCor, Inc.**

Different Business Strategy

Each of these companies is organized around a very different business strategy. For example, AmeriPath is a PPM. It wants to own and operate pathology practices. DIANON Systems offers anatomic pathology services to a national marketplace and does most of its work at one main laboratory. IMPATH supports community hospital-based pathologists in the diagnosis of difficult-to-diagnose cancers. UroCor focuses exclusively on the diagnostic and therapeutic needs of urologists throughout the United States.

Despite the different way each of these companies services the anatomic pathology marketplace, each has at least five common elements of success. All are linked to how they deliver anatomic pathology services to referring physicians.

ONE: Each company views the market for its anatomic pathology services as national, even if AP work in every city is done locally. This national perspective drives their business strategy and helps them to identify which types of anatomic pathology services have a growing demand and represent the best opportunity for profits.

TWO: Each company invests a significant amount of money in professionally-designed and managed marketing and sales programs. Pathologists connected to these companies have learned that sales is not a bad word. To the contrary, effective sales programs create financial stability and contribute to improved profitability.

THREE: Each company is consciously building a reputation for specialized, high quality anatomic pathology services. They are educating the clinical community and consumers about what anatomic pathology is, and how to recognize high quality.

This is where marketing programs and advertising plays a critical role in educating clinicians and consumers. To further emphasize the quality of their particular brand of anatomic pathology, each of these four firms maintain close relationships with nationally-respected academic pathology subspecialists.

Six Pathology PPMs Continue in Business

Most of these companies obtained venture capital funding just as the PPM industry started its financial nosedive. The business environment for these companies remains difficult.

- **AmeriPath, Inc.**
  Riviera Beach, Florida
- **Pathology Consultants of America, Inc.**
  Nashville, Tennessee
- **PathGroup, Inc.**
  Memphis, Tennessee
- **Pathology Partners, Inc.**
  Dallas, Texas
- **PathSource, Inc.**
  Port Chester, New York
- **USLabs, Inc.**
  Laguna Niguel, California

Pathology Service Associates of Florence, South Carolina, offers pathology group management services through state networks.

FOUR: Throughout the 1990s, each company enjoyed solid year-to-year growth in the volume of AP specimens performed at its lab. This specimen growth could only be maintained by offering a satisfactory level of AP services in tandem with an aggressive sales program.

FIVE: Throughout the 1990s, each company had solid year-to-year increases in revenues. Regardless of overall company earnings, it is important to note that the anatomic pathology AP segment of their business was consistently profitable.

The sidebar at right shows how these four companies benefited from marketing anatomic pathology services to an inter-regional and national marketplace. It is noteworthy that these four companies posted healthy revenue and profit growth during the same years that the clinical laboratory industry, along with healthcare in general, struggled just to break even.

It should also be noted that these companies, as national anatomic pathology providers, are excluded from many local and national HMOs. Like most laboratories, they fight the same never-ending battle to gain provider status. This makes their sustained growth in specimen volume and revenues even more convincing.

The old loyalty to the community hospital pathologist is disappearing. This is only because physicians (and hospital administrators) believe they can get "better service" from regional or national pathology providers.

The market successes of these four different companies demonstrate that the profession of anatomic pathology is shifting away from its traditional roots. Each company provides AP services across regional and state lines, some to a national market. The fact that each company is growing steadily is important evidence that the day of the single, small pathology practice providing services exclusively to one hospital is ending.

Instead, multi-hospital systems now want a single consolidated pathology provider to cover all their anatomic pathology needs. Physicians in private practice are increasingly willing to refer AP specimens to pathologists working hundreds or thousands of miles away.

The old loyalty to the community hospital pathologist is disappearing. This is only happening because physicians (and hospital administrators) believe they can get "better service" from regional or national pathology providers.

"Better Service" Defined

This "better service" is more than just the diagnosis of the anatomic pathology specimen. "Service" covers the full range of physician/patient education, courier and logistics, turnaround time, the customized report formats issued to physicians, customer service responsiveness, and accurate billing.

The local AP group practice must realize that it is competing on more than: 1) a personal relationship with a local physician; and 2) the basic diagnosis of the specimen.

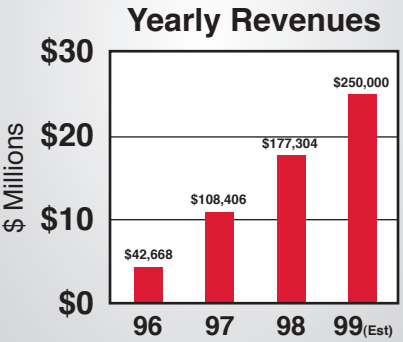
In today's hectic healthcare world, the office-based physician is looking for every service edge that benefits his practice. The national AP companies understand this and compete by meeting these needs. Local AP groups must respond at a comparable level or they will be outsold by companies offering anatomic pathology services nationally. TDR

Contact Robert Michel at 503-699.0616 or email: labletter@aol.com.

Four Prospering Companies Offer AP Services Nationally

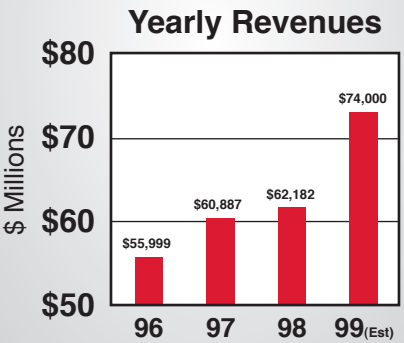
AmeriPath, Inc.

The only public pathology PPM, AmeriPath is using pathology group practice acquisitions to fuel its growth. During the last four years, it has built a substantial presence in Florida and Texas. It's now expanding into the Midwest.



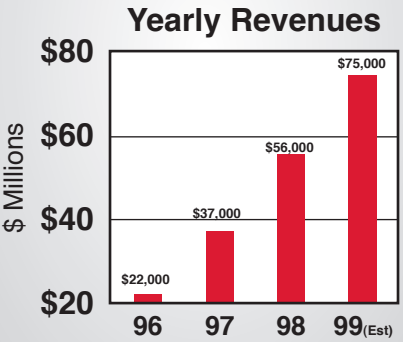
DIANON Systems, Inc.

DIANON began to expand its emphasis on anatomic pathology about four years ago to the national marketplace. Now anatomic pathology makes up about 75% of DIANON's revenue, accounting for almost $60 million per year.



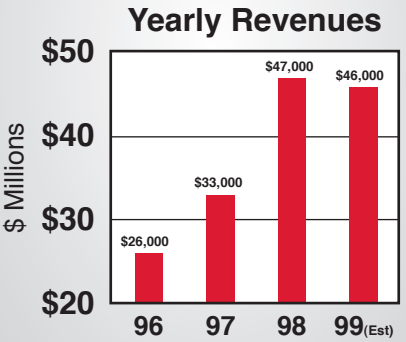
IMPATH, Inc.

This company provides services to help community hospital-based pathologists with "hard-to-diagnose" cancers. It serves a national market. As the graph below demonstrates, IMPATH's revenues have skyrocketed upward in the last 48 months.



UROCOR, Inc.

Unlike the other companies on this page, UroCor exclusively serves the needs of a single specialty: urology. It offers diagnostic testing and therapeutics. Anatomic pathology is an important part of its service menu.



Client Bill Pricing Policy Rises To Medicare Level

UroCor appears to be first lab firm in nation to make client bill prices equal Medicare fees

CEO SUMMARY: Within the laboratory industry, there has been a decade-long debate over whether offering discount prices in client bill states could violate some Medicare regulations. UroCor, Inc. decided that an OIG opinion issued in December to a pathology company signaled a potential change in how HCFA and the OIG might begin to view client bill discounting practices by the laboratory industry.

FOR MANY YEARS, THE WIDESPREAD lab industry practice of discounting client bills has caused uneasy debate in the closed conference rooms of more than one laboratory.

Now **UroCor, Inc.** has squarely confronted the issue of client bill discounting and decided to cease the practice. The Oklahoma City-based company recently sent letters to all its physicians announcing this policy change.

Amended Client Accounts

UroCor's letter stated that "new guidelines from the federal government have prompted us to re-evaluate the potential risk of federal scrutiny of even the most compliant laboratory account billing arrangements… Therefore, our recent decision to amend our Client Bill accounts was made in keeping with UroCor, Inc.'s mission to provide high quality items and services in compliance with all federal, state and local laws and regulations." *(See sidebar on next page.)*

UroCor's action came at least partly in response to Advisory Opinion 99-13, posted by the **Office of the Inspector General** (OIG) on December 7, 1999. The Advisory Opinion was in response to the request by an anatomic pathology company for guidance on the practice of "account billing" physicians on a monthly statement, where the physicians would then turn around and bill third party payers and patients for the purchased pathology tests.

It was noted that the discounted prices to the physicians were always lower than the Medicare allowable amount. Sometimes the discounted prices were below the cost of providing that item or service.

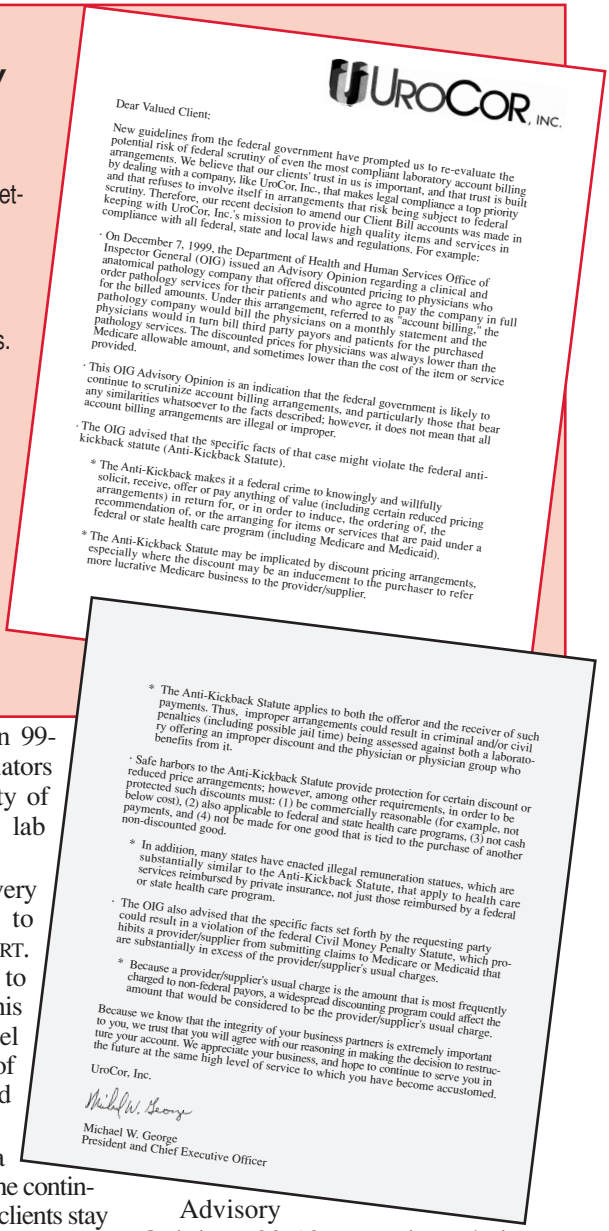
The OIG's response was that the specific facts of that case might violate several aspects of the Anti-Kickback Statute. It did not comment on other potential code violations that might be triggered by the billing arrangements referenced in the Advisory Opinion.

Apparently UroCor decided that increased scrutiny by the OIG into all aspects of healthcare coding and billing arrangements, combined with the con-

UroCor Changes Discounting Policy For All Client Bill Accounts

UroCor, Inc. recently sent this letter to its clients explaining the reasons why it was ceasihg to offer discounted pricing below Medicare fees for lab tests and services billed directly to clients.

The letter references Advisory Opinion 99-13, posted by the Office of the Inspector General (OIG) on December 7, 1999. This Advisory Opinion was issued after a request by a three-man pathology practice to address the issues involved in discounting prices and services to clients.



UROCOR, INC.

Dear Valued Client:

New guidelines from the federal government have prompted us to re-evaluate the potential risk of federal scrutiny of even the most compliant laboratory account billing arrangements. We believe that our clients' trust in us is important, and that trust is built by dealing with a company, like UroCor, Inc., that makes legal compliance a top priority and that refuses to involve itself in arrangements that risk being subject to federal scrutiny. Therefore, our recent decision to amend our Client Bill accounts was made in keeping with UroCor, Inc.'s mission to provide high quality items and services in compliance with all federal, state and local laws and regulations. For example:

· On December 7, 1999, the Department of Health and Human Services Office of Inspector General (OIG) issued an Advisory Opinion regarding a clinical and anatomical pathology company that offered discounted pricing to physicians who order pathology services for their patients and who agree to pay the company in full for the billed amounts. Under this arrangement, referred to as "account billing," the pathology company would bill the physicians on a monthly statement and the physicians would in turn bill third party payors and patients for the purchased pathology services. The discounted prices for physicians was always lower than the Medicare allowable amount, and sometimes lower than the cost of the item or service provided.

· This OIG Advisory Opinion is an indication that the federal government is likely to continue to scrutinize account billing arrangements, and particularly those that bear any similarities whatsoever to the facts described; however, it does not mean that all account billing arrangements are illegal or improper.

· The OIG advised that the specific facts of that case might violate the federal anti-kickback statute (Anti-Kickback Statute).

* The Anti-Kickback makes it a federal crime to knowingly and willfully solicit, receive, offer or pay anything of value (including certain reduced pricing arrangements) in return for, or in order to induce, the ordering of, the recommendation of, or the arranging for items or services that are paid under a federal or state health care program (including Medicare and Medicaid).

* The Anti-Kickback Statute may be implicated by discount pricing arrangements, especially where the discount may be an inducement to the purchaser to refer more lucrative Medicare business to the provider/supplier.

* The Anti-Kickback Statute applies to both the offeror and the receiver of such payments. Thus, improper arrangements could result in criminal and/or civil penalties (including possible jail time) being assessed against both a laboratory offering an improper discount and the physician or physician group who benefits from it.

· Safe harbors to the Anti-Kickback Statute provide protection for certain discount or reduced price arrangements; however, among other requirements, in order to be protected such discounts must: (1) be commercially reasonable (for example, not below cost), (2) also applicable to federal and state health care programs, (3) not cash payments, and (4) not be made for one good that is tied to the purchase of another non-discounted good.

* In addition, many states have enacted illegal remuneration statues, which are substantially similar to the Anti-Kickback Statute, that apply to health care services reimbursed by private insurance, not just those reimbursed by a federal or state health care program.

· The OIG also advised that the specific facts set forth by the requesting party could result in a violation of the federal Civil Money Penalty Statute, which prohibits a provider/supplier from submitting claims to Medicare or Medicaid that are substantially in excess of the provider/supplier's usual charges.

* Because a provider/supplier's usual charge is the amount that is most frequently charged to non-federal payors, a widespread discounting program could affect the amount that would be considered to be the provider/supplier's usual charge.

Because we know that the integrity of your business partners is extremely important to you, we trust that you will agree with our reasoning in making the decision to restructure your account. We appreciate your business, and hope to continue to serve you in the future at the same high level of service to which you have become accustomed.

UroCor, Inc.

Michael W. George

Michael W. George
President and Chief Executive Officer

clusions of Advisory Opinion 99-13, meant that federal regulators may be rethinking the legality of at least some longstanding lab industry billing practices.

Officials at UroCor were very specific in their responses to inquiries by THE DARK REPORT. "UroCor definitely wanted to maintain the high road on this ambiguous issue," stated Joel Brandon, UroCor's Manager of National Accounts and Managed Healthcare Systems.

"Full legal compliance is a high priority at our company," he continued. "We also want to help our clients stay compliant with all laws and regulations and clear guidelines make this easier."

Feedback from UroCor's physician clients is favorable. "Clients agree that it's the right thing to do," noted Brandon. "Doctors share our concerns about compliance and our decision to be proactive on this rather fuzzy issue."

Advisory Opinion 99-13 was issued in response to a request by attorney Jane Pine Wood of Cleveland-based **MacDonald, Hopkins, Burke & Haber** on behalf of her client, a three-partner pathology group.

"My client was seeing client bill discounts of as much as 50% of Medicare,"

said Wood. "Where deep discounting can only be sustained if the client also refers the Medicare business to the discounting lab, there is a potential to trigger inducement issues and potential anti-kickback violations.

Clients Support Decision

"I had many conversations with the OIG as they developed this Advisory Opinion," continued Wood. "Their final opinion does indicate that, at some level, deeply discounted client bill pricing for tests would become a violation. The easy test for this would be if the laboratory would continue the account at those discounted prices even if they got no Medicare referrals whatsoever."

Wood believes that UroCor's new policy on client bill discounting is a reasonable response to ongoing changes in how HCFA and the OIG view laboratory billing practices. "I'm glad to see UroCor take this public position," she said. "I expect the OIG to increase their scrutiny of deeply-discounted client bill pricing practices. As they do, larger laboratories will have the most risk. I also believe that, along with the anti-kickback law, Medicare's 'usual charge rule' may soon become an issue."

Discounting Client Bills

Commercial labs began the practice of discounting client bills during the 1980s. It was a competitive tool for capturing physicians' business and expanding the market share of labs offering discounted test prices to clients.

However, this strategy backfired against the lab industry. In states which permit physicians to mark-up and bill third-party payers and patients for lab tests, prices for routine tests were bid down to unprofitable levels.

Thus, many laboratories found themselves in a double dilemma. First, discounted client bills were proving unprofitable. But ceasing the practice gave competing labs, still willing to discount, the opportunity to steal away those accounts. Second, the ambiguity about whether discounting the prices of client-billed tests violated any of several Medicare regulations made many lab managers uneasy at the possibility that federal prosecutors might one day declare such billing arrangements to be in violation.

UroCor's decision should be hailed as bold, farsighted, and honest. It is the first publicly-traded laboratory company in the United States to openly declare that it will not discount client bills.

UroCor Will Benefit

UroCor will benefit from this decision in the long run. Physician clients who are only interested in the cheapest price will flock to competitors. Physicians who continue to refer tests to UroCor will be doing so because they value UroCor's quality and service.

For the clinical laboratory industry, UroCor's decision to cease discounting of client bills now raises ethical standards to a higher level. Will laboratories which continue offering discounted prices to clients find themselves under increased scrutiny by federal investigators?

Further, are federal investigators now beginning to view discounted prices on client bills as a violation of Medicare statutes? Remember, test bundling was thought to be legal in the late 1980s and early 1990s. But when federal prosecutors came to believe it was illegal, it cost the lab industry billions of dollars in settlements and fines, along with at least a couple of jail sentences. **TDR**

Contact Attorney Jane Pine Wood at 508-385-5227 and Bruce Hayden, UroCor's CFO, at 405-290-4293.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Interesting things are afoot at **Dynacare's** joint venture in Houston, Texas with **Memorial Hermann Healthcare System**. Bill Pesci, Chief Operating Officer of **Dynacare Hermann Laboratories**, resigned in January to take a new position on the east coast. That seems to have triggered an exodus of the management team in Houston. Within the last three weeks, resignations were received from the Chief Financial Officer, the Sales and Marketing Director, the Billings and Collections Manager, the Controller, the IS Manager, and the Human Resources Director. It is highly unusual to turn over this many key managers in such a short period of time.

ADD TO: DYNACARE-HOUSTON

It's expected that Pesci's replacement will be John Smith, who worked at **National Health Labs** with Dynacare-U.S. executive Bert Koch. Meanwhile, Bill Pesci will become Executive Director of the **Carolina Lab Network**, based in Charlotte, North Carolina. This is a 21-hospital lab consortium.

QUEST MAY MOVE ST LOUIS OPERATIONS TO CHICAGO

Although **Quest Diagnostics Incorporated** has made no formal announcement concerning its consolidation plans for the Quest and **SmithKline Beecham Laboratories** (SBCL) in St. Louis, there are plenty of rumors. Grapevine buzz says that Quest intends move all St. Louis testing to its Schaumberg laboratory located next to Chicago's O'Hare Airport. Quest's St. Louis lab would be shuttered and only drugs of abuse testing would remain at the SBCL St. Louis facility.

TDR ON ST. LOUIS MOVE

It's estimated that about 16,000 requisitions per night would be shifted from Quest's St. Louis labs to Chicago. At $28 per req, that adds another $107 million dollars per year in testing to Quest's Schaumberg laboratory. Should these rumors prove true, there will certainly be a glut of med techs in the St. Louis marketplace as former Quest and SBCL laboratorians begin searching for new jobs.

INFO WANTED

Insider news and tips about labs are always welcome. Call or email in confidence: 503-699-0616 or labletter@aol.com.

Remember the concept of industry consolidation? It's still an ongoing trend. Latest healthcare industry to undergo a new wave of consolidation is the pharmaceutical industry. **Pfizer Inc.** and **Warner-Lambert Co.** will merge in a $90 billion deal. That announcement was followed the news that **Glaxo Wellcome PLC** and **SmithKline Beecham PLC** would combine. This transaction is valued at $76 billion. Analysts predict more consolidation among big pharma firms. In particular, **Abbott Laboratories, Inc.** is believed to be vulnerable to a take-over due to its depressed stock price.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 6, 2000.

PREVIEW #2

EXECUTIVE WAR COLLEGE

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UPCOMING...

- ***1999 Financials for the Two Blood Brothers: What the Numbers Reveal About Lab Industry.***
- ***Pathology Physician Practice Management Companies Survive 1999's Problems.***
- ***Rural Regional Laboratory Network Surprises Managed Care Plans.***
- ***Hitting the Automation Home Run: Early Adopters of Modular Systems Share Successes and Setbacks.***