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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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

How Smaller Lab Organizations Can Compete

MAYBE THE PENDULUM IS SWINGING BACK IN FAVOR of smaller laboratory organizations. During most of the 1990s, consolidation and large size seemed to generate clout. But huge size didn't always result in profitable laboratory companies.

Witness the red ink spilled from such public laboratory companies as **Corning Clinical Laboratories** (now **Quest Diagnostics Incorporated**), **Laboratory Corporation of America**, **Unilab**, and others during the years 1995-1997. And these were the companies that survived. Others filed bankruptcy and disappeared, such as **Meris Laboratories**, **Physicians Clinical Laboratories**, and **Universal Standard Medical Laboratories**.

Now the Internet and healthcare e-commerce promise to reshuffle the competitive deck. In the laboratory marketplace, this will create an opportunity for smaller laboratory organizations to regain their competitive edge. Large size and huge specimen volumes will not be the competitive advantage that it once was. Instead, being close to the customer and serving the unique needs of physicians and patients in the local community will be the critical success factors for laboratories.

That is why the business achievements of **Clinical Laboratories, Inc.** (CLI) in Throop, Pennsylvania are worth studying. *(See pages 2-6.)* It recognized the opportunities that Web-enabled lab test results reporting would create. Two years ago, when most labs were not paying attention to the Internet, Kuo Cheng and Gary Ross had the vision and foresight to recognize this opportunity. Using the internal resources of the lab, they "home brewed" their own Web-enabled lab test result reporting system for clients and had it in operation by the summer of 1998!

This is local laboratory services at their best. Good management vision, coupled with a nimble response and fast implementation, is making CLI the dominant lab competitor in its service area of Northeastern Pennsylvania. I believe that hospital laboratory administrators sit atop untapped gold mines around their hospital campus. Just like CLI, they have a natural market advantage with the physicians on their hospital staff. It is time for hospital lab administrators to harness the power of the Internet. In so doing, they can become the primary lab resource in their local community. TDR

Lab "Home Brews" Web Solution for Test Results

"Do-it-yourself" effort proves successful with physicians and other lab clients

CEO SUMMARY: Internet-enabled lab test ordering and results reporting may help independent commercial labs and hospital laboratory outreach programs become more competitive against the two blood brothers. In eastern Pennsylvania, Clinical Laboratories, Inc. introduced Web-based lab test results reporting in July 1998. Since that date, sales are up and clients are happier.

HOSPITAL LABORATORY OUTREACH programs and independent labs constantly struggle to find effective ways to successfully compete against the two national lab companies.

That may change with the arrival of Internet-based laboratory information capabilities and services. One early leader in the race to gain competitive advantage from the Internet is **Clinical Laboratories, Inc.** (CLI) of Throop, Pennsylvania. Located near Scranton, CLI put its first Internet lab service into the marketplace in July 1998.

"We introduced Web-enabled lab test results reporting to our customers in July 1998," stated Kuo Cheng, CEO at Clinical Laboratories in comments made at the *Executive War College* in New Orleans. "We have no regrets about pioneering this service. We find it easier to generate new clients for our laboratory. We also see a definite and measurable improvement in customer satisfaction and client retention."

What makes the story of CLI particularly unique is the fact that this modest-sized laboratory company was able to create its product for Web-based lab results reporting as an in-house project. It took CLI only eight months to begin design work, complete beta site testing, and launch this Web-based product to its physician office clients.

More remarkably, CLI invested just $70,000 on hardware, software and programming. The current expense to maintain its Web-based results reporting capability is only $10,200 per year!

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

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CLINICAL LABS, INC.
At-a-glance

- *Located in Throop, Pennsylvania (near Scranton)*
- *160 employees*
- *1,200 accessions daily*
- *Independent, pathologist-owned.*
- *Service area: NE Pennsylvania*
- *Founded 1958*
- *Web-based lab results reporting:*
  400 enrolled practices
  1,700 users
  60,000 reports retrieved per year

CLI's accomplishment demonstrates that virtually any hospital laboratory outreach program or independent commercial laboratory can swiftly bring Web-enabled lab test results reporting to its physician clients for a modest capital investment. CLI's accomplishment also demonstrates why the Internet may prove to be a competitive leveler within the clinical lab industry.

It was 1996 when Clinical Laboratories, Inc., guided by Managing Director Gary Ross, made the strategic decision to pursue Internet-enabled laboratory services. "We were convinced that the number of doctors using E-health services would grow exponentially," noted Cheng. "We also believed that we needed to supplement traditional line printers and PCs for lab test reporting if we were to maintain our competitive edge in this region.

Used Off-The-Shelf Items

"In addition, we were confident that, by using off-the-shelf modular software, we could do this ourself," he continued. "The major roadblock was getting our lab test data into a relational database. This was an important requirement, because our Web-based results reporting technology is not an integrated software system.

"Rather, it is a link between the clinical repository and the Internet vehicle which transmits the lab test data to the physicians' office," explained Cheng. "Thus, our necessary first step was to move our clinical data repository into a relational database.

"We did this by upgrading our outmoded LIS system," he said. "In September 1996, we became the first lab user to install and operate **SMS Corporation's** OpenLab. This was one of the first LIS products which incorporated a relational database for the clinical data.

"During the next year, we laid the foundation for our Web-based lab test results reporting capability," Cheng observed. "We installed an internal 10/100 Base T LAN (local area network) that was Internet compatible.

Four Software Applications

"The other component of the physical infrastructure was four software applications: 1) business; 2) laboratory operations; 3) anatomic pathology (Tamtron PowerPath; and 4) e-mail," he continued. "Once these were in place, we could begin to develop Web-based lab test results reporting capability. That effort began in December 1997."

According to Cheng, there are several options to permit Web-enabled user access to lab test results. First, the lab can create an intermediate data repository to pull legacy data out of the LIS repository. Because it may only download new results every two hours, the intermediate data repository is not a real-time service.

The second option is using HL-7 to connect the intermediate laboratory data repository with the LIS repository on a real-time basis. For a small laboratory like Clinical Laboratories, Inc., this is a highly complex programming challenge.

It was the third option that CLI selected. This option links the intermediate data repository to an LIS repository that is organized as a relational data base. This permits real-time data access to new test results as they are generated within the lab. It also simplifies the programming tasks needed to establish Web-enabled lab test results reporting.

By using standard, off-the-shelf computer hardware and software products, CLI could rapidly develop its Web-based lab test query capability. Beta testing started in April 1998 and the product was offered to existing CLI customers beginning in July 1998.

Marketplace Strategy

"It is important to understand our strategy in the physicians' marketplace," noted Cheng. "First, we didn't want to disturb existing procedures used by the doctors' offices to receive lab test reports. So we designed our Web-enabled lab results query product to lay on top of the existing PC or line printer used in the doctors' offices.

"This was a 'no-change' change strategy," he explained. "The physicians and their staffs would continue getting lab test results in the traditional manner. But in addition, they could now use the Internet to access any test results they wanted, at any time.

"Second, we offered this first to physicians eager to adopt new technology and seeking the benefits of Web-enabled lab results query," continued Cheng. "It was the 'least resistance' strategy. We would go where doctors were ready for this product. Once they had experience and provided testimonials, it would be easier and faster for us to introduce and install this product in other physicians' offices."

Acceptance by physicians was speedy and surprised the sales staff at CLI. "Our experience is that, once a physician starts to use the Web to access his patient's test results, he generally evolves to regularly, even exclusively, using this method to access lab results. If the physician never tries the Web, there is no regular use of this service."

Physicians' Feedback

Feedback from the physicians led to a second version of CLI's lab test results query system, implemented in April 1999. "We found most doctors were primarily using the Web to check results on their patients from the previous 48 hours," Cheng recalled. "So we changed the screens. Now we highlight a list of each doctor's patients from the past two days on the left of the screen. The physician can toggle back and forth between these patients and their test results."

Another innovation to CLI's Web-based results reporting product was spurred by several doctors. "We now have multiple physician clients who access their patients' lab test results through wireless, hand-held devices," explained Cheng. "We introduced this feature in January 2000, at the request of these physicians, who carry these devices from examination room to examination room in their offices.

Free Wireless Connectivity

"We used an independent Internet service to link our clinical repository with their wireless devices," he added. "It cost us nothing and was accomplished in days. I think it demonstrates how the Internet really does allow us to compete with the billion-dollar labs."

The issue of Web-enabled lab test requisitions was deliberately made second priority by CLI. "When we started this almost three years ago, the technology and legal issues supporting Web-based lab test ordering were more challenging," observed Cheng.

"There was the problem of authentication; i.e., do you really know who is on the Internet and ordering the test?" he said. "There was also concern that HIPPA policies on documentation were unresolved and evolving. So we decided to make Web-based lab test ordering a lesser priority.

Higher Utility For Physician

"Also, our experience tells us that Web-enabled lab test results reporting has higher utility to the physician than Web-enabled lab test ordering," added Cheng. "That is because the staff usually processes test orders. But the doctor will personally use the Internet to access his patient's lab test results."

CLI has enjoyed direct economic benefits from its early implementation of Web-based lab test results reporting. "After a client begins using the Web to access lab results, we are often able to remove the line printer or PC from the doctor's office. This saves us money.

"First, we want to give the patient the option of storing his medical records with us," he explained. "We will offer an 'electronic safe deposit box.' Since lab data is a major part of his file, this is a natural tie-in."

"Our client service reps now get fewer calls. Anecdotally, we believe active physician-users save about one hour per day," said Cheng. "They no longer have to call and wait for the rep to access test results. They can use the Web to make direct inquiries. Test results are available almost the moment they come off the bench. Doctors working from multiple office locations also like this feature a lot."

CLI is also using its Web-based lab results reporting capability to build its drugs-of-abuse business. "We match this capability with the fact that our lab is local to improve our turnaround time to getting drug testing results back to clients," explained Cheng. "As a result, we see strong growth in revenues from this line of testing."

Cheng believes mobile computing will have an exponential growth curve among doctors. "We see the healthcare marketplace moving rapidly past today's stationary computers that sit on a desktop," he predicted. "We expect that stationary computing will swiftly move to portable computing, linked by wireless services.

"To be ready for this, we are preparing to offer mobile computing services involving lab data," said Cheng. "We also see increased patient involvement in their healthcare. To meet that demand, we are developing two products at our laboratory for patients.

"First, we want to give the patient the option of storing his medical records with us," he explained. "We will offer an 'electronic safe deposit box.' Since lab data is a major part of his medical records, this is a natural tie-in.

"Second, our patients want more information about their lab tests," Cheng stated. "Thus, CLI is preparing to offer expanded patient education materials. After all, who better to teach a patient about lab tests than the laboratory who performs those tests?

ISP Connection For Docs

"Third, we are an ISP (Internet service provider) to many doctors. We want to develop and expand this relationship," he continued. "Our network of physicians is a lab asset that we want to protect and enlarge."

THE DARK REPORT believes the experience of Clinical Laboratories, Inc. demonstrates that it is feasible for small-

Web-based Results Reporting Proves To Be An Easy Sell With Physicians

GETTING PHYSICIANS AND THEIR STAFFS to accept Web-based lab test results reporting proved easy for the sales and service reps of Clinical Laboratories, Inc. (CLI) in Throop, Pennsylvania.

"It was easiest to introduce this to physician offices where they had computers and were already accessing the Internet," stated Colleen Portanova, Marketing and Sales Representative at CLI. "We did a demonstration using our laptop computers. That generally opened the door for further conversation.

"The main thing that doctors seemed concerned about was security," she added. "We had anticipated that concern, which is why we give each physician and each staff member an individual network password.

"We basically sold the benefits of this by characterizing it as an innovative free new service offered by our lab," noted Portanova. "We emphasized that it is the same system used by our client service reps to access lab results—that proved to be a real stopper with the doctors and office staff. They could see for themselves that results were available in real time.

"Having Web-based lab results reporting is a definite sales advantage," Portanova observed. "There is lots of competition for lab business in this area. We are the only lab with this system and it helps us to differentiate ourselves from competitors. Not only are we finding it easier and faster to bring aboard new client accounts, but the physicians are taking a more active role during the sales process."

"In fact, many doctors now call us about opening an account," enthused Portanova. "For example, they hear about the wireless Palm Pilots used by their colleagues. Overall, Web-based lab results reporting has really boosted our sales program."

er lab organizations to use the Internet to their competitive advantage. It took CLI just $70,000 and eight months to get their solution for Web-based lab results reporting into the marketplace.

THE DARK REPORT recommends that both hospital lab outreach programs and independent commercial labs should move swiftly to capitalize on this market advantage. Like CLI, the nimbleness of smaller labs can be a sales advantage when competing against the national lab companies.

Being first to the market with added-value services allows regional lab organizations to increase market share and build a loyal client base, besides boosting revenues and operating profits.

CLI also recognizes an important shift in the healthcare market. Every laboratory's network of physicians is now a target for the multitude of healthcare E-commerce start-ups. By being first to offer the next generation of Web-based lab services, CLI is protecting its relationship with its physician network.

That was the strategy of **Bio-Reference Laboratories, Inc.** (BRLI) of Englewood Park, New Jersey. *(See TDR, May 30, 2000).* Both CLI and BRLI are in the forefront of recognizing that the relationship each has with its physician-clients is the real asset in the age of Internet-based healthcare services.

Shrewd laboratory executives and pathologists will come to a similar conclusion. Clinical laboratories will find that timely efforts to protect their physician networks will be the single most important business strategy of the next five years. **TDR**

Contact Kuo Cheng and Colleen Portanova at either 570-340-0248 or kcheng @clinical.com and ckelly@clinical.com.

Neurology is Test Focus For Athena Diagnostics

Long term strategy is disease management services that include diagnostics & therapeutics

***CEO SUMMARY:** There are few examples of laboratory companies focused on a single medical specialty, a business model that is expected to become more common in coming years. One such company is Athena Diagnostics. For 12 years, this company has concentrated on providing diagnostic testing for neurology specialists. It grew steadily throughout the 1990s and is continuing to expand its diagnostic testing services.*

TRADITIONALLY, NEUROLOGISTS have ordered few laboratory tests. For that reason, commercial laboratories generally don't target neurologists as clients.

But neurologists are the primary sales target for **Athena Diagnostics, Inc.**, located in Worcester, Massachusetts. Athena Diagnostics has created a small, profitable market niche by focusing almost exclusively on the diagnostic testing needs of neurologists and other physicians dealing with neurology-related disorders.

Unwarranted Persecution

"Within the field of neurology, there is a growing number of laboratory tests which are useful in diagnosing the most common neurologic disorders," said Robert Flaherty, President and CEO at Athena Diagnostics. "Since our founding 12 years ago, Athena Diagnostics has developed into the primary diagnostic laboratory resource for most neurologists in this country."

Athena Diagnostics maintains a low profile within the laboratory industry. Its parent company is **Elan PLC**, a public company based in Dublin, Ireland (NYSE: ELN). Elan is primarily in the pharmaceutical business. 1n 1996, it purchased **Athena Neurosciences, Inc.**, a neuropharmaceutical company, of which Athena Diagnostics was a division.

As a specialty laboratory, Athena Diagnostics represents an emerging business model for diagnostic testing. By focusing on the diagnostic needs of one medical specialty, it differentiates itself from other laboratory providers.

Because Athena Diagnostics has an ongoing customer relationship with neurologists, by serving their sophisticated diagnostic needs, it tends to support its sister divisions at Elan, which markets pharmaceuticals to the same physicians.

"Over the past ten years, we've grown by doing two things," observed Flaherty. "First, our sales and marketing programs have steadily increased the number of neurologist-clients who regularly order tests from us.

"Second, we've introduced new assays for neurology testing," he continued. "We collaborate with several research laboratories and work with them to develop promising technologies into diagnostic tests which can be used in general clinical settings."

Developing New Assays

In this respect, Athena Diagnostics has much in common with the **Nichols Institute** of the 1970s and early 1980s. During this time, Nichols Institute maintained close ties with a number of academic research centers. It helped move innovative diagnostic testing technology out of the research laboratory by financing clinical trials and gaining FDA clearance. It would then provide the sales and marketing resources necessary to educate clinicians and encourage them to use these newly-approved assays.

"Because of our close work with neurologists, we've developed a solid reputation for quality diagnostic testing," noted Flaherty. "That is the foundation for our ongoing efforts to bring additional new tests to market and offer therapeutic drugs as appropriate."

As a laboratory business model, Athena Diagnostics has much in common with such diagnostics companies as **UroCor, Inc.** (focused on urology), **IMPATH, Inc.** (focused on oncology), and **Prometheus, Inc.** (focused on gastroenterology). These companies do a national business, but organize their diagnostic services around the needs of one medical specialty.

Sophisticated Information

Laboratories like these will be the first to develop more sophisticated information products, based upon laboratory test data. THE DARK REPORT has long predicted that lab information, presented in a different way than the traditional lab test report, will be the source of added-value for the clinical laboratory industry.

Athena Diagnostics, Inc.
At-a-glance

- ***Division of Elan Corporation, PLC (NYSE Symbol: ELN)***
- ***Main Laboratory: Worcester, MA***
- ***Founded in 1989 as Genica Pharmaceuticals, Inc., offering Dystrophin testing***
- ***In 1995, Genica was acquired by Athena Neurosciences, Inc.***
- ***In 1996, Athena Neurosciences is acquired by Elan Pharmaceuticals***
- ***Offers these testing services:***
  1. ***Alzheimer's disease***
  2. ***Neurogenetic disorders***
  3. ***Paraneoplastic neurological disorders***
  4. ***Peripheral neuropathies***

Because these lab companies are so closely involved in meeting the needs of a single medical specialty, it will probably be labs like Athena Diagnostics, UroCor, and their peers which are the first to bring such enhanced lab information products to their physician-clients.

Signposts Of Change

For that reason, lab companies like Athena Diagnostics are useful signposts of change in the healthcare marketplace. Athena demonstrates that it is possible to carve out a specific niche within the overall clinical marketplace and turn it into a financially stable business.

Laboratory companies organized, like Athena Diagnostics, to serve a specific segment of the medical community may represent tomorrow's best business model for clinical laboratory operations. Increased specialization of medical services, a flood of yet-to-be introduced new diagnostic technology, and ever-shrinking reimbursement for routine testing are the trends which will drive this process. **TDR**

For more information, contact Robert Flaherty at 508-756-2886.

CEO SUMMARY: Rapid changes to the clinical laboratory industry had equally profound impact upon the major diagnostic companies. At Beckman Coulter, Inc., market forces triggered a decade of acquisitions and internal consolidation. The company looks very different today than it did ten years ago. Here's a look at how Beckman Coulter views the near future for clinical laboratories, along with its business strategies for developing new diagnostic products.

DIAGNOSTIC TESTING REMAINS AN UNDERVALUED ASSET

Beckman Coulter's Strategy Reflects Consolidation Trends

RECENTLY **BECKMAN COULTER, INC.** announced that it would raise $500 million through a public securities offering.

To learn what Beckman Coulter intends to do with this half billion dollars and how it may affect both hospital labs and commercial labs, THE DARK REPORT traveled to Beckman Coulter headquarters and met with its executive team.

Following a decade of aggressive changes, including the purchase of **Coulter Corporation** in 1997, Beckman Coulter transformed itself into one of the world's three largest diagnostics companies. Its revenues now top $1.8 billion per year.

Growth through acquisition was a business strategy directly linked to Beckman Coulter's view of how the healthcare marketplace is evolving. This market assessment drives several individual business strategies at the company.

As the company looks at the healthcare systems of the United States and other countries, it sees an interesting development. "There's a common thread running through changes in the health systems of many countries," said Michael J. Whalen, Vice President and Director of Worldwide Diagnostics Strategic Marketing at Beckman Coulter. "Healthcare is increasingly viewed as less of an automatic birthright for all citizens," observed Whelan. "Instead, it's recognized that there is an economic connection to healthcare services. Governments are beginning to teach their citizens that the cost of care is now an essential part of the overall healthcare equation.

"What is interesting about this theme is that the cost of care has always been visible to patients in the United States," he added. "This is less true of other countries, where universal healthcare was organized in such a way that patients never learned what it cost to individually provide them with healthcare.

"If you accept the thesis that national health systems are moving toward better linkage between the cost of care and the quality of care, then the United States' healthcare system will probably be the source of much innovation that other countries' healthcare systems will copy.

"We believe that laboratory testing will benefit as national healthcare systems begin to emphasize cost-benefit analysis," stated Edgar E. Vivanco, Beckman Coulter's Senior Vice President of Diagnostics Development and Corporate Manufacturing. "Most laboratorians understand that lab testing is a highly cost-effective way to improve patient outcomes while reducing the overall cost of care.

"However, there is still a gap," continued Vivanco. "The reality is that laboratory medicine can improve healthcare quality and reduce costs. But government-run health systems around the world have yet to fully recognize this fact and take advantage of it.

Better Pricing For Lab Tests

"We predict a change to this situation," he added. "It will be increasingly recognized by both the healthcare community and legislators that laboratory reimbursement must be adequate and new laboratory technology must be appropriately priced."

THE DARK REPORT has repeatedly noted the existing ability of laboratory medicine to reduce costs while improving patients' healthcare outcomes. Whelan and Vivanco concur, but they also believe that government healthcare regulators are the fulcrum for future change.

As the economics of providing care to aging populations continues to increase healthcare spending, Whelan and Vivanco think government health program administrators will soon recognize that diagnostic testing is a tremendous, cost-effective tool for improving the cost-benefit performance of their healthcare systems.

"As this happens," explained Whelan, "government-run healthcare systems will give greater emphasis to laboratory medicine and new diagnostic technology.

That should result in two positive outcomes for the laboratory profession.

"First, it means that reimbursement and access to laboratory testing will improve," he said. "Second, it means that investments in new diagnostic technology will be encouraged and there will be faster ways to move new diagnostic technology through clinical studies and into widespread clinical use."

Cost-Benefit Analysis

But this theme of increased economic cost-benefit analysis to healthcare services worldwide has yet to play out in the marketplace. In the meantime, Beckman Coulter's business strategy also addresses existing trends within the diagnostics industry.

"Tremendous consolidation on both the provider side and the vendor side continually changes the cost-effective point that enables a diagnostics vendor to deliver top quality products and services," stated Whelan.

"Let me discuss some specific ways this impacts our laboratory customers," he said. "First, in the former business model, laboratory customers wanted several diagnostics vendors. Having multiple vendors was one way labs maintained leverage over their vendors. Also, using multiple vendors was a common technique to squeeze down prices.

New Lab Purchasing Model

"But these old business practices are giving way to a new business model," explained Whelan. "Laboratories now want ongoing, long-term partnerships with a limited number of diagnostics vendors. This is a collaborative business relationship, with both lab and vendor working together to manage costs, improve productivity, and increase the effectiveness of laboratory testing.

"This means that diagnostic vendors and laboratories have more sophisticated business relationships than they did in the old business model," Whelan stated. "It requires the vendor to have more people with advanced technical skills. These additional costs are changing the break-even point for vendors.

"It's also why having a single product line makes it difficult for a diagnostics partner to be an effective partner for a commercial laboratory or a hospital lab customer," added Vivanco. "If the vendor is going to be involved in the lab's work flow design and management, having an integrated suite of instrument and test solutions improves its ability to add value to the lab customer."

Because this is an ongoing marketplace trend, many laboratory executives and pathologists may still have vendor expectations based on the old model of multiple suppliers and contract-by-contract efforts to ratchet down prices. The collaborative purchasing model between supplier and customer has yet to arrive at many lab organizations.

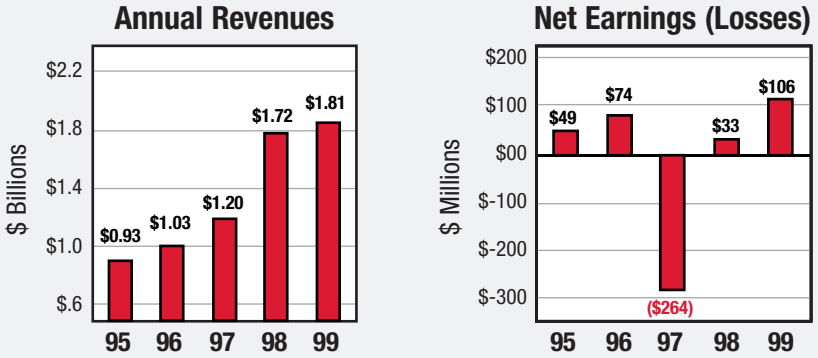
New Partnering Model

"You can see the impact of this new partnering model at Beckman Coulter," continued Whelan. "We've done acquisitions to broaden our technology and product offerings. We've built our asset base to support increased research and development, as well as customer support.

Under this new business model of long-term supplier/customer relationships, the technology offered by the diagnostics vendor becomes a critical success factor, in several important ways. "For example, laboratory customers increasingly want an instrument which is simpler to operate," Whelan noted. "That means the operator can walk up, hit some buttons to launch the test process, and walk away while the instrument does the work.

"But what most laboratorians don't understand is that, the simpler an

Beckman Coulter Demonstrates Recent Strong Revenue Growth



As the charts above demonstrate, annual revenues at Beckman Coulter climbed rapidly in recent years. Acquisitions dragged net earnings in 1997, but in 1999 the company earned twice what it did in 1995.

Major Acquisitions Fuel Increased Revenues

It was a flurry of acquisition activity during 1996 and 1997. Beckman Coulter purchased the following companies or testing technologies:

Coulter Corporation	Hematology, flow cytometry	Oct 1997
Sanofi Diagnostics Pasteur*	Access® Immunoassay product line	Apr 1997
Sagian, Inc.**	High-throughput screening, robotics technology	Dec 1996
Genomyx, Inc.	DNA sequencing technology	Oct 1996
Hybritech, Inc.	Immunoassays, cancer diagnostics	Jan 1996

**Only the Access® Immunoassay product line of Sanofi was acquired.*
***Only the Laboratory Robotics Division of Sagian was acquired.*

instrument is to operate on the outside, the more complex the instrument is on the inside," observed Whelan. "And software is the biggest factor in making a test instrument simple to operate.

Diagnostic Technology

"So basic diagnostic technology, when combined with complex software, needs more service resources to maintain it and upgrade it through each generation of new technology," explained Whelan. "The sophistication needed by vendors to support and maintain the lab's use of these instruments is a source of increased expenses. This is why diagnostic companies have consolidated and expanded the range of instruments they provide to laboratories."

Whelan's point touches on another aspect of diagnostics technology which is seldom appreciated by laboratorians. That is the backwards compatibility of each new generation of lab tests. "Currently, most laboratories keep an instrument for an average of six to seven years," commented Whelan. "We want to differentiate Beckman Coulter from other vendors by our capability of integrating new

Renamed AdvaMed Promotes Diagnostics

CLINICAL LABORATORIES HAVE an overlooked ally in the campaign to gain wider recognition of the value of diagnostic testing.

This ally is AdvaMed, the **Advanced Medical Technology Association** (formerly HIMA, the **Health Industry Manufacturer's Association)**. During 2000, its President is John P. Wareham, who is also the Chairman, President and Chief Executive Officer of Beckman Coulter, Inc.

One of AdvaMed's major initiatives is to educate governments, payers, and providers about the value of diagnostic testing. In particular, AdvaMed is advocating that HCFA (Healthcare Financing Administration) should "modernize its procedures to pay for in vitro outpatient tests." It says that "current procedures prevent 'covered' technologies from being integrated into Medicare, thus restricting beneficiary access to needed services and effectively stalling use of new technologies."

generations of assays that can run on the earlier generations of our instruments still in use by our laboratory customers.

Technology Is Essential

"This is where diagnostics technology is an essential factor," noted Whelan. "Beckman Coulters's acquisitions during the 1990s were designed to acquire bioassay technologies that are fundamentally robust and can be upgraded with future improvements. This allows our lab customers to maintain forward and backward technology compatibility even as they introduce the latest generation of tests into their lab organization."

Whelan is describing a strategy similar to that of Microsoft's business strategy of DOS/Windows compatibility. Each version of DOS and Windows was designed to be compatible with earlier versions. As a result, Microsoft customers were assured that, no matter what version they used, any other DOS or Windows user could open and use those files. Beckman Coulter wants the same kind of backward and forward compatibility to each generation of lab tests that it introduces.

The robust diagnostic technology of each testing line is designed to be compatible in another way. "For example, we want the chemistry to be the same, whether it is a large lab using our high-volume instruments or a small lab using our lower-volume instruments," noted Whelan.

Chemistry Doesn't Change

"That means if a rapid response lab in a hospital is using our Cx instrument, and the core lab is using our Lx instrument, the chemistry is the same. The chemistry doesn't change just because it is a different model of our instruments," Whelan said.

"Although many of our customers appreciate and value this technology compatibility, few realize what a complex challenge it is to maintain this compatibility across each line of instruments and between generations of instruments and tests," he added.

Since 1990, the widespread changes to healthcare worldwide stimulated equally radical changes to how Beckman Coulter was organized. "Consolidation among providers, such as commercial labs and integrated hospital networks (IHN), caused us to reorganize our company into new strategic alignments," recalled Whelan.

"We also took a bold step in Europe in 1994," he continued. "We reorganized operations into a single European corporate office. This replaced our individual, country-by-country, business

model. At the time, few companies had attempted this. But we've been successful. As the European economic market becomes increasingly unified, a regular flow of companies is visiting our European operation to study our business model."

Business Performance

Michael Whelan and Edward Vivanco have described a series of business strategies designed to improve Beckman Coulter's ability to partner with a broad cross section of commercial and hospital laboratory organizations. These strategies also position Beckman Coulter to sell in countries throughout the world.

It may be that many laboratory administrators and clinical pathologists cannot easily recognize and describe Beckman's individual business strategies of: 1) long term partnerships with customers; 2) robust bioassay technologies that can be evolved while maintaining instrument capabilities; and 3) common test technologies across different-sized instrument platforms.

But Beckman Coulter must be doing something right. In the market segments of clinical chemistry, hematology, and cytometry, its products rank one or two in overall sales. One result from its acquisitions in the 1990s is that Beckman Coulter can now offer tests which make up 75% of all hospital testing.

Research Diagnostics

Many clinical laboratorians are also unaware that Beckman Coulter has a thriving business in research diagnostics. Not only is this a profitable business, but it contributes to Beckman Coulter's clinical diagnostics sales effort. By selling a variety of products to research organizations, the company stays updated with new research discoveries.

"Our sales split between research and diagnostic testing helps us bring new technology to the clinical lab marketplace," noted Vivanco. "Several years ago, we developed a DNA sequencing instrument. In recent years, we modified the software used in our chemistry instruments and married this software to our DNA sequencer. That allowed us to introduce the first automated HIV typing sequencer instrument into the clinical laboratory marketplace."

Although Beckman Coulter executives Whelan and Vivanco were open and detailed in sharing insights about the business strategies and market analysis which guides their company, they became somewhat inscrutable when it came time to discuss the specific details of how the $500 million shelf offering will be used.

"Stay The Course"

"Beckman Coulter has not disclosed specific plans for this money," said Whelan. "Beckman Coulter expects to 'stay the course' with the business strategies we've discussed here during the next two years.

"However, we have our eye on several innovative products and services," he continued. "As healthcare e-commerce proves its viability, we are prepared to incorporate those features into our products. But the rapid changes to both the market and the technology of diagnostics make it difficult to offer accurate and specific predictions about what our company will be doing in a couple of years."

Notwithstanding Whelan's comments, once Beckman Coulter arms itself with another half billion dollars of capital, it is certainly going to be a tough competitor in the marketplace for diagnostic instruments. TDR

Contact Michael Whelan at 714-773-8314 and Edward Vivanco at 714-773-8895.

Managed Care Update

Insurers Dropping Medicare HMO Programs in Various Regions

Meanwhile, Pacificare teams up with Compaq to buy e-commerce company targeting seniors

Several of the nation's largest health insurance companies will cease offering Medicare HMOs in certain regions of the United States.

Almost 800,000 of the nature's seniors will be dropped from Medicare +Choice plans as **Aetna/US Healthcare**, **Foundation Health Systems**, **Oxford Health Systems**, **Cigna**, and **Pacificare** withdraw their Medicare HMO programs in specific regions around the nation.

Major Changes

Aetna and Cigna are making major changes. Aetna will withdraw from 11 states, including New York and Northern California. Its actions affect 355,000 seniors. Cigna will withdraw from 13 cities and states, including Atlanta, Los Angeles, and Delaware. At least 104,000 seniors will be dropped from Cigna's Medicare HMOs.

All the companies say under-reimbursement and over-regulation are the reasons behind their decisions. They hope their actions encourage Congress to increase funding for the Medicare+Choice health program.

These changes by private insurers have potential revenue impact upon clinical laboratories and anatomic pathology groups. Medicare HMOs pay labs and pathologists much less money for services. In recent years, the growth of enrollment in Medicare HMOs has shifted patients away from Medicare fee-for-service reimbursement. Instead, the HMOs enrolling these patients generally offer capitated or highly-discounted contracts to clinical labs and pathology group practices.

Thus, anything that encourages sizeable enrollment increases in Medicare+Choice plans tends to reduce revenues to clinical labs and pathology groups which had served those patients under fee-for-service reimbursement arrangements. The question is whether Congress will increase funding for the Medicare+Choice program so as to encourage greater numbers of seniors to enroll in such health plans.

Ongoing Integration

Meanwhile, Pacificare has teamed with **Compaq Computer Corp.** to acquire the Senior.com website. The two companies are investing $19 million to develop a business unit, to be called **SeniorCo**, that will offer "a broad array of products and services to senior citizens."

Pacificare wants to leverage its "incredible knowledge base of how seniors act and what their preferences are," according to Pacificare CEO Alan Hoops. Compaq wants to sell seniors its computers and related services.

This new venture demonstrates how healthcare companies want to leverage existing customer relationships to sell additional products and services. Labs have a similar opportunity. TDR

Lab Industry Briefs

PRESCRIPTION DRUG SPENDING HITS A RECORD INCREASE OF 17.4% IN 1999

Just-released data from **Express Scripts, Inc.** indicates that spending on prescription drugs increased by a record 17.4% during 1999. This compares to a 9.6% spending increase for drugs in 1998.

As most lab executives know, prescription drug pricing is a hot-button issue with Congress. The new data will support arguments that drug companies are aggressively raising prescription prices faster than the rate of inflation.

The coming battle over how to manage prescription drug costs in the Medicare and Medicaid health programs will eventually impact clinical laboratories. As HCFA and Congress establish new policies for dealing with existing and yet-to-be approved pharmaceuticals, those same policies will affect reimbursement for future diagnostic tests which are directly linked to specific prescription drugs.

Under the emerging science of pharmacogenomics, drug companies will use genetic data to determine whether an individual's genetic make-up will: 1) benefit from a specific therapeutic drug; and 2) whether or not that same individual's genetic make-up predicts negative side effects from that drug. *(See TDR, September 8, 1998).*

The study by Express Scripts indicates that prices for such widely-used drugs as Premarin (hormone replacement), Glucophage (diabetes management), and Serevent (anti-asthmatic) increased by 12.1%, 14.5%, and 14.5%, respectively.

A more significant finding was that, of the top ten categories of drugs used by elderly people to treat such chronic disorders as diabetes, respiratory illness, heart disease, and others, the average annual cost exceeded $400 in six of the ten categories and $500 in five of the top ten.

Given the widespread prevalence of these chronic conditions, new diagnostic testing with the capability of identifying individuals who may or may benefit from specific drug therapies would be seen as a cost-effective, valuable clinical resource. This would greatly benefit the clinical laboratory industry.

It is predicted that rapid increases in spending on prescription drugs will continue to accelerate in coming years. From the 1999 figure of $387.09 per person, Express Scripts predicts a doubling of prescription spending to $758.81 per person in 2004. That rate of spending growth will definitely encourage both payers and drug companies to support development of laboratory tests which better identify individuals who can benefit from specific therapeutic drugs.

DOES WALL STREET REALLY BELIEVE ITS OWN HYPE ABOUT LABS?

THIS ITEM RECENTLY CROSSED our editor's desk. It will bring a smile to laboratory executives and pathologists who have a different memory of recent years.

"Medical advances evolve each day in labs, hospitals, and universities throughout the world with all eyes on the next potential blockbuster drug or therapy. But underneath the glitter of highly publicized medical miracles, *the test and diagnostics suppliers inexorably generate ever larger revenue and profit streams* [our italics]. Recently those companies have been Wall Street's darlings."

This excerpt is from a press release issued by InformedInvestors.com. It was touting a show called "Biotalk From the Beltway," which, on June 14, interviewed representatives from **DIANON Systems, Inc.**, **Laboratory Corporation of America**, and **Quest Diagnostics Incorporated**. Stock from each of these three companies had hit new highs during the previous month.

Executives and managers of clinical laboratories would probably take issue with the characterization of the lab industry as one which "inexorably generates ever larger revenue and profit streams." Although the financial condition of most laboratory organizations is improving, the financial condition of the lab industry industry as whole remains unstable and fraught with uncertainty.

But for the investment community, any run of good news is a reason for excitement. The proof of a financial turnaround in the lab industry will be if a wider range of clinical laboratory organizations demonstrate sustained growth in revenues and net profits during the next three years.

UROCOR SELLS ACCESS TO ITS PROSTATE CANCER GENE DATA BASE

LABORATORY TEST DATA is the value-added product in a licensing agreement signed last week by **UroCor, Inc.** and **Immunex Corporation**.

Immunex will have access to the library of cancer-derived proteins developed by UroCor. UroCor has patented 23 genes that could be linked to prostate cancer. Immunex hopes to develop antibodies against prostate cancer, using antigens or drug targets that UroCor has identified.

When THE DARK REPORT visited UroCor's headquarters in 1997, it was shown an interesting research project. UroCor was searching the DNA of prostate cancer patients. It was identifying genes that appeared in prostate cancer patients that did not appear in healthy patients. *(See TDR, June 23, 1997.)*

It was this research that led to UroCor's library of gene patents. The Immunex licensing agreement shows how UroCor intends to package and sell laboratory data. It is a market indicator that shows there is demand for clinical laboratory data in other forms besides lab test results when such data is properly packaged.

ON-LINE CME'S AVAILABLE AT BRLI'S CAREINVOLVE PHYSICIAN'S WEB PORTAL

THINGS ARE MOVING SWIFTLY at **Bio-Reference Laboratories, Inc.** (BRLI) in Elmwood Park, New Jersey. Last week the company announced a contract that adds immediate, on-demand physician CME credits (continuing medical education) to its **CareInvolve.com** Web portal.

HealthStream, Inc. will provide online CME credits, along with updated healthcare training and educational materials. CareInvolve.com is a physician Web portal that BRLI developed. It is designed to strengthen BRLI's business relationship with its physician-clients. *(See TDR, May 30, 2000.)*

CareInvolve.com already provides member physicians with lab test ordering, lab test reporting, electronic payer enrollment, claims submission, remittance advice, eligibility verification, secure messaging, prescription services, and other features.

BRLI is selling this Web portal to physicians in the New York, New Jersey, and Connecticut markets. It wants to partner with regional labs to offer this service in other areas throughout the United States. TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

When it comes to laboratory information services, the Internet may indeed be a competitive leveler. THE DARK REPORT is tracking a host of small software companies that already have working solutions for Web-enabled lab test ordering and results reporting installed and operating in the field. It seems the traditional giants of the LIS industry lack the nimbleness and speed required to adapt rapidly-evolving hardware and software technology into viable solutions that are ready to install today. Tomorrow's leading companies in lab information products are today's unfamiliar names.

HEALTHEON IS DEAD! LONG LIVE WEBMD!

Sometime in the days after **Healtheon/WebMD Corp.** acquires **Medical Manager Corp.**, it plans to change its name. It will drop "Healtheon" from its corporate title and be known simply as WebMD Corporation. The idea is to signify that, despite all its many acquisitions, it is "one company."

WATCH OUT! BLUETOOTH IS READY TO HIT THE MARKET

Lab executives and pathologists interested in wireless reporting of lab test results to physicians should pay close attention to a technology called "Bluetooth." Bluetooth is designed to be a short-range wireless connection for all types of electronic devices. These range from laptops and cellular telephones to microwave ovens and blenders. Bluetooth uses a chip that's built into electronic devices. The goal is to allow these devices to seamlessly transmit data to each other. **Motorola Inc.** is preparing to manufacture Bluetooth chip sets which will be used in cell phones, two-way pagers, and hand-held computers.

MORE ON: BLUETOOTH

Bluetooth technology already has wide support from the electronics industry. Some 1,700 companies worldwide will accept the standard, including **IBM**, **Dell Computer**, **Toshiba**, **Nokia**, and **Telefon AB L.M. Erickson**. **Merrill Lynch** analysts predict that, by 2005, more than 1.7 billion Bluetooth-equipped devices will be sold annually. In healthcare, THE DARK REPORT expects Bluetooth to first show up in hand-held wireless prescription units to be used by physicians in their offices and on hospital rounds. Applications for wireless access to laboratory test results will follow almost immediately.

HUMAN GENOME MAP NEARING COMPLETION

Competition certainly makes things move faster. Most laboratorians know that **Celera Genomics Group** and the Human Genome Project jointly announced on June 26, 2000 that each group had completed the first rough draft of the complete human genome. The Human Genome Project was a government-funded project launched in 1990 and had said, as recently as two years ago, that it would not finish its work until 2005. Then Celera entered the picture, stating in June 1998 that, for less than $300 million, it would map the complete human genome in only 24 months. That timetable was met last month. Both teams decided a joint announcement of the rough draft milestone was in their mutual best interests.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 31, 2000.

SPECIAL NOTICE!

PATHOLOGIST'S INCOME SYMPOSIUM

& Reimbursement Workshop

OUR ANNUAL NOVEMBER SYMPOSIUM IN SCOTTSDALE, ARIZONA WILL NOT TAKE PLACE THIS YEAR.

(Look for the next Symposium in November 2001.)

UPCOMING...

- ***The Dark Report's Annual Ranking of Public Laboratory Companies.***
- ***Little-Known Methods for Boosting Collections and Reducing Days Sales Outstanding (DSO).***
- ***Why Tissue Banking Gives Hospital-Based Pathology Groups A New Source of Income.***
- ***What's Working and What's Not with the Most Recent Generation of Total Laboratory Automation (TLA).***