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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...

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Founder & Publisher

Genetics Tidal Wave is Rapidly Approaching

EVERYONE IN THE CLINICAL LAB BUSINESS KNOWS that our business will soon be dominated by genetic and molecular testing technology. However, most lab administrators and pathologists believe that we are several years away from the widespread clinical use of such technology in laboratory testing.

In principle, I would agree with that part of the popular wisdom. Widespread clinical use of genetic and molecular test technology is probably five years away. But I predict that there exists today a "killer application" technology in someone's research lab that will find its way into diagnostics and transform at least one important area of laboratory medicine. My premise is simple: whatever this "killer application" technology is, its potential to outrageously improve the current medical standard of care will cause it to "fast track" through clinical trials and regulatory approval. Laboratories will find themselves with a new clinical tool which doctors want.

Ask me what this technology is and I cannot answer. My business intuition sifts through the cascade of announcements concerning genetic-based discoveries and tells me that something big is lurking beneath the public eye. When this scientific breakthrough surfaces, its impact will be swift and pervasive.

But let me offer just one example of how new discoveries in genetics are leading us to a diagnostic testing revolution. Last week, researchers at **Gemini Genomics PLC** and **Sequenom Inc.** reported that they had identified a pair of previously unknown genes which seem to play an important role in heart disease. Using genetic data gathered from thousands of pairs of twins, the two companies found one gene which appears to be associated with high cholesterol levels, and another gene which appears to be related to high density lipoprotein (HDL). The companies are preparing to license this knowledge to pharmaceutical and diagnostic companies for the purpose of developing drugs and lab tests to identify and treat various forms of heart disease.

This announcement is just one of a steady stream. We are in the early stages of the exponential curve for genetics-based medical procedures and diagnostic tests. It demonstrates why I predict that the tidal wave of genetic and molecular diagnostics is much closer than any of us understand. TDR

Year's Ten Biggest Stories Reveal Modest Changes

2000 was not a year of momentous events as labs & vendors focused on different goals

CEO SUMMARY: In many ways, 2000 was a relatively quiet year for laboratory organizations. This list of the ten biggest stories in the lab industry for 2000 demonstrates that the most innovative laboratory organizations in the United States are "raising the bar" for service and quality in the competitive marketplace. This will change the status quo in many regions of the United States.

DESPITE THE MILLENNIUM HYPE, the year 2000 arrived like any other. Widespread fears about Y2K problems shutting down the world's computers (and elevators, water supplies, electric power grids and the like) proved groundless.

Within the laboratory industry, the year 2000 has come and gone the same way—without major change and upheaval. Unlike most years of the 1990s, 2000 lacked transformational changes with the potential to impact virtually every individual laboratory throughout the country.

It is against this background of a "ho-hum" year that THE DARK REPORT offers its annual list of the lab industry's "Ten Biggest Stories" of the year. Certainly there were no blockbuster announcements, such as when **Quest Diagnostics Incorporated** disclosed that it would acquire **SmithKline Beecham Clinical Laboratories** in February 1999; or when, in early 1997, the **Office of the Inspector General** (OIG) announced that the entire lab industry would be required to develop compliance programs.

The strategic value in this year's list of "Ten Biggest Stories" derives from its ability to reveal what the healthcare marketplace is doing and how it's different today from what it was a year ago. The "Ten Biggest Stories" list helps to mark the end of ongoing business trends and identify the emergence of new business trends.

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For example, during 2000, the first group of early adopters in the clinical lab industry implemented Web-enabled lab test ordering and results reporting between the lab and physicians' offices.

It is noteworthy that, first, these labs saw economic justification in this investment and, second, after implementation, these labs are extremely happy with the performance and cost-effectiveness of their Web-enabled lab test ordering and results reporting. This story confirms there is business justification for Web-enabled services between lab and physicians' offices. In actual use, these services add value to physicians while lowering the lab's cost of serving that physician.

TLA's Failed Promise

In contrast, go back to 1995. At that time, headlines heralded the installation of total laboratory automation (TLA) systems in several early-adopter laboratories. But, after these TLA systems were installed, neither the laboratories involved nor their TLA vendors were willing to publish rigorous and detailed information about the specific productivity improvements and financial return on investment (ROI) generated by this equipment. That silence was evidence that expected cost savings and productivity gains from TLA were less than expected.

Perceptive observers made good use of the fact that news of pioneering TLA installations was followed by the ominous silence about performance details. It allowed them to steer clear of this technology until later generations of equipment could finally deliver acceptable gains in productivity and return on investment (ROI).

Keeping to this theme that the "Ten Biggest Stories" list offers relevant insights into the laboratory marketplace, THE DARK REPORT observes that one big story is the *dearth* of new laboratory joint ventures between commercial lab companies and hospitals or hospital systems. Two years ago, there was widespread evidence that a growing number of hospitals were actively entering into joint ventures and other forms of business collaboration with commercial laboratories.

Few New Joint Ventures

Yet 2000 passed without any significant announcements of new laboratory joint ventures. To the contrary, a couple of high profile collaborations were terminated.

Stories that don't appear on the 2000 list of the "Ten Biggest Stories" can be just as important. For example, the year 2000 passed without HCFA and the OIG launching another major fraud and abuse action against the clinical laboratory industry.

That's certainly a change from earlier years, but it also reflects a shift in thinking by government enforcers. It means that individual laboratory compliance programs have eliminated the "worst" abuses, or more likely, a properly-managed lab compliance program makes it more difficult for the government to successfully shake down labs with allegations of Medicare "fraud and abuse."

Top Ten Biggest Stories

As these examples indicate, much wisdom can be gleaned from the "Ten Biggest Stories" list. On the pages which follow, THE DARK REPORT highlights its picks for the year 2000. These are not presented in order of importance, because of the subjectivity involved in that kind of ranking.

In conclusion, THE DARK REPORT observes that the common link among these ten stories seems to be a "raising of the bar" for lab services. In some cases, the lab industry is seeing the first steps of what will be exponential change to lab testing services in the near future.

1 one — Arrival of Web-Based Connections For Linking Lab and Doc's Offices

INTERNET TECHNOLOGIES ARE EXPECTED to revolutionize many aspects of laboratory medicine. Ground zero in this revolution is the electronic connection between laboratories and physicians' offices.

The year 2000 arrived with a handful of early adopter laboratory organizations already using web-based lab test ordering and results reporting systems to connect their lab with physicians' office clients. *(See TDR, January 14, 2000.)*

Centrex Clinical Laboratories in upstate New York became the first commercial lab client of **Abaton.com** to go operational and link physicians' offices to the lab with web-based lab test ordering and results reporting.

In Throop, Pennsylvania, **Clinical Laboratories, Inc.** had gone live with Web-based lab test results reporting during the summer of 1998. Its accomplishment in the first months of 2000 was to enable physicians to use their wireless PDAs to access lab test results! *(See TDR, July 10, 2000.)*

Other "early adopter" labs are forging ahead with Web-based connections. Most common is lab test results reporting because of its high utility for physicians. THE DARK REPORT believes that the lab industry is now in the early stages of what will be an exponential curve for lab adoption of Internet-based services. Early reports are that such Internet-based services are generating cost savings and improved client satisfaction.

2 two — ISO-9000 Management Systems Take Root in Laboratory Industry

NEW MANAGEMENT SYSTEMS for laboratory operations are establishing a beach head in the clinical laboratory industry.

At **Quest Diagnostics Incorporated**, three additional regional laboratory divisions achieved ISO-9002 certification. These labs are located in Juarez, Mexico; Deerfield Beach, Florida; and Wallingford, Connecticut. Quest Diagnostics expects all its significant lab divisions to have ISO-9000 certification during the next couple of years. *(See TDR, October 23, 2000.)*

Laboratories within certain regional divisions of **Kaiser Permanente** are working to achieve ISO-9000 certification. The Kaiser Permanente lab in Portland, Oregon has passed its audit, and waits only for the official certificate.

THE DARK REPORT believes that laboratory organizations which embrace the management philosophies of W. Edwards Deming, ISO-9000, and similar systems will have competitive advantage over laboratories which do not. This will be equally true for both hospital labs and independent commercial labs.

It is no coincidence that **Ortho Clinical Diagnostics** now offers a "value-added" service in teaching its lab customers the techniques of "Six Sigma" and "lean manufacturing." *(See pages 9-14.)* These management systems have demonstrated their effectiveness in boosting quality, lowering costs, and most importantly, improving the satisfaction of customers, including both physicians and patients.

3 three — Stock Prices Explode on the Upside For Nation's Public Lab Companies

IT WAS A BIG SURPRISE for knowledgeable observers of the American clinical laboratory industry. Share prices of most public laboratory companies blew through the roof in 2000.

For shareholders, this was a happy event. But for the laboratory industry, it marked an important change in the competitive marketplace. Public lab companies are no longer at death□s door. To the contrary, their cash flow and operating profits is improving. This gives them the capability to fund any number of new sales and marketing programs.

In absolute terms, the performance of some lab company stocks was remarkable. **Quest Diagnostics Incorporated** started the year at $30 per share. By September it reached $141 and currently trades at $107. At **Laboratory Corporation of America**, the story was the same. After a 10-for-1 reverse split in May, share prices soared from $33 to $130 during September. LabCorp□s stock now trades at about $134 per share. Other lab companies like **DIANON Systems, Inc.** and **IMPATH, Inc.** had similar run-ups in their share prices.

Public lab companies are the most aggressive at introducing new lab testing services and putting sales people on the street. For that reason, their surging profit margins can be expected to finance more □value-added□ lab services, along with expanded sales campaigns in efforts to capture market share from independent and hospital labs.

4 four — Human Genome Project Finishes First Stage of Genetic Mapping

PROBABLY NO SINGLE AREA of medical technology will boost the fortunes of clinical laboratory testing more than knowledge of the human genome.

That is why the joint announcement about the initial mapping of the human genome this spring by **Celera Genomics** and the government-funded **Human Genome Project Team** is an important scientific milestone. As the first step in developing precise knowledge about individual genes, this draft □map□ is already helping researchers accelerate the identification of specific genes and their functions.

During 2000, Celera Genomics has also mapped the mouse genome. Researchers find the similarities between mouse and human DNA to be helpful in identifying specific gene sequences and their functions.

As most lab administrators and pathologists know, pharmacogenomics is the speedily-evolving branch of science which intends to marry diagnostics, therapeutics and patient monitoring. The goal is to use genetics-based diagnostic testing to identify, in advance, whether a patient will or will not benefit from a specific drug, and whether that patient will or will not have adverse reactions to that same drug. Now that the first map of the human genome is available, expect to see some remarkably effective new genetics-based tests hit the diagnostics market very soon.

5 five — Highwater Mark for Capitation And Closed Panel HMO Insurance Plans

EVIDENCE IN THE HEALTHCARE marketplace during 2000 makes a convincing argument that the highwater mark for capitated provider contracts and closed panel HMOs has now passed.

If true, it is a positive development for all lab organizations in the United States, whether national labs, regional independent labs, or hospital labs. The decline of these business practices should help bolster the financial stability of clinical laboratories around the country.

CEOs of both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have told the investment community that their companies are insisting on improved pricing for laboratory tests. As existing contracts renew, both lab companies are working hard to switch from capitation to discounted fee-for-service arrangements. This effort seems to be meeting with some success.

On the closed-panel HMO front, clients and regular readers of THE DARK REPORT are aware of policy changes within national HMOs such as **United Healthcare** and **Aetna U.S. Healthcare** to revise or drop onerous requirements for preapproval by physicians. There have also been provider-initiated lawsuits against major HMOs alleging deliberate □below-cost□ reimbursement policies. *(See TDRs, March 27, 2000 and April 17, 2000.)*

Taken collectively, these developments signal a major change in managed care/provider relations.

6 six — Anatomic Pathology Profession May Soon Have Its First $500 Million Firm

TRADITIONALLY, ANATOMIC PATHOLOGY has been a medical specialty delivered on a local basis by relatively small pathology group practices.

Events during 2000 demonstrate that, at least on a regional level, anatomic pathology (AP) is consolidating into business forms which are economically viable and competitively superior.

Two relevant examples of this business model are **AmeriPath, Inc.** and the former **Pathology Consultants of America, Inc.** (PCA). In recent years, both companies posted significant growth in revenues and operating profits using a similar formula: pathology group practice consolidation at the regional level, supported by aggressive sales and marketing of anatomic pathology services within that region. The evolution of their business plans ran a parallel course. PCA acquired another pathology company, **PathSOURCE, Inc.** in May and renamed itself **Inform DX, Inc.** By November, Inform DX had agreed to merge with AmeriPath. *(See TDRs, March 6, 2000, June 19, 2000, and November 13, 2000.)*

With this merger, AmeriPath is on track to generate net revenues of about $330 million in 2001. It is now the AP profession□s largest company. Sustaining strong rates of revenue growth and profits will be challenging for AmeriPath. But the company has financial resources to compete locally which cannot be matched by small pathology groups.

7 seven — Consumers Getting Savvy, Now Taking Charge of Their Healthcare

IF THE 1990S WAS THE DECADE of managed care, then the 2000s will be the decade of consumer-driven healthcare.

During the year 2000, a growing number of laboratories and diagnostics vendors began to actively court consumers. This involved advertising campaigns and marketing efforts to educate consumers about the benefits and medical importance of certain types of laboratory tests.

Certainly Cytyc□s advertisements in a variety of women□s publications promoting the benefits of the ThinPrep¤ Pap smear test is one example of direct-to-consumer marketing.

An increasing number of laboratorians have first-hand stories about patients who demanded a copy of their test results, or showed up at a draw station wanting to order their own lab tests.

At **Quest Diagnostics Incorporated**, this heightened consumer interest in lab test results did not go unnoticed. In April, through a joint venture with **MedPlus, Inc.**, Quest Diagnostics began to make lab test results available to patients on a Web site called *mydailyapple.com*. Patient inquiries to the site significantly exceeded the expectations of Quest Diagnostics and MedPlus.

There are already a number of laboratory companies advertising directly to the public. They are willing to perform tests at the request of consumers. These examples show why labs should give their consumers a lot more attention.

8 eight — Innovative Regional Lab Networks Expanding Collaboration and Services

WITHIN THE NATIONAL MARKET for clinical laboratory services, there has been one sustained theme over the past ten years: consolidation and regionalization.

Consolidation of lab organizations and regional collaborations between laboratories are a consequence of unused and excess lab capacity, for which no payer is willing to continue subsidizing.

Hospital laboratory administrators recognized this dilemma about six years ago. Their response was to organize regional laboratory networks. However, for many reasons, mostly relating to trust and control, few of these regional lab networks have provided the financial relief for which their organizers had hoped.

Yet during 2000, a handful of regional laboratory networks continued making salutary progress. In Detroit, **Joint Venture Hospital Laboratory** (JVHL) network now offers a statewide service infrastructure. Its managed care contracting skills are sophisticated enough to allow it to capture lab provider status with Michigan□s largest health insurer.

Down in Florida, the **Florida Reference Laboratory Network** (FRLN) is working to link member laboratories via Internet-based communications and maintain a common clinical data repository. It plans to offer physician office clients Web-based lab test ordering and results reporting during 2001.

These regional laboratory networks demonstrate that this business concept is a viable way to rationally use existing local lab resources.

9 nine — Dearth of Joint Ventures Involving Commercial Labs and Hospital Labs

DURING 2000, SOME IMPORTANT laboratory joint ventures between commercial lab companies and hospital laboratories came to an end. More importantly, no significant new joint ventures appeared during the year.

It is reported that the performance of several laboratory joint ventures involving national laboratory companies and hospital labs are not meeting the financial and marketplace expectations of the joint venture partners.

In Southern California, **Quest Diagnostics Incorporated** pulled the plug on the former **SmithKline Beecham Clinical Laboratories** project involving 30 **Tenet Healthcare** hospital labs. Quest Diagnostics did not like the economics of the project.

These developments are surprising. At the *Executive War College* in May 1999, all of the hospital lab case studies boasted about some form of business collaboration with a commercial laboratory. During the past 18 months, it appears these collaborations have not generated the economic rewards expected by joint venture partners.

In fact, the big news for 2000 was the increased interest of integrated healthcare networks (IHN) in establishing shared laboratory organizations. Most noteworthy was the announcement in April that **Aurora Health System** of Milwaukee (12 hospitals) and **Advocate Health Care** of Chicago (10 hospitals) would consolidate management of their lab organizations.

10 ten — Thin-Layer Pap Smears Capture Considerable Market Share

DURING 2000, **Cytyc Corporation□s** ThinPrep¤ for liquid preparation of Pap smears captured at least 20% of the American market.

Cytyc□s accomplishment is remarkable. At a time when the healthcare system is squeezed for financial resources, Cytyc has managed to position ThinPrep as a valid test option for referring physicians, while insuring adequate reimbursement for clinical laboratories.

From that perspective, Cytyc provides a business template for the introduction of new diagnostic technology into the clinical marketplace. During the same years that Cytyc was introducing ThinPrep, at least three competing firms were offering laboratories other enhanced Pap smear test technologies, with much less financial success.

One of the key differences in Cytyc□s business strategy was its willingness to invest considerable amounts of money in marketing to health insurance companies. Cytyc understood that, regardless of the clinical benefits of the ThinPrep test, if reimbursement was inadequate for the labs performing the test, then labs would decline to offer it.

Thus, Cytyc□s 20%+ share of the Pap smear testing market is a lesson in the power of sales and marketing to help labs build specimen volume and net revenue. Labs should appreciate that investing in sales is a valid way to achieve revenue goals and financial stability. TDR

Transformational Potential of Internet and Molecular Technologies

Ortho-Clinical Diagnostics Embraces New Test Services

CEO SUMMARY: Despite a decade of consolidation, competition among the world's largest diagnostics manufacturers remains intense. In response to this competition, Ortho-Clinical Diagnostics (OCD) is preparing a variety of new products and services for its clinical laboratory customers. It's already exploring diagnostic opportunities in the emerging field of pharmacogenomics. In the field of laboratory management, OCD has brought to market a consulting service built upon "Six Sigma" and "lean manufacturing" principles. Here's an exclusive look at how Ortho-Clinical Diagnostics sees the future of laboratory medicine.

EDITOR'S NOTE: This is the second in a series of interviews with senior executives of the world's largest diagnostics manufacturers. The interview which follows, is with Catherine M. Burzik, President, Americas, Ortho-Clinical Diagnostics, Inc. (OCD).

REMEMBER THAT FAMOUS COMMENT about the talents of the dancing team of Fred Astaire and Ginger Rogers? It went something like this: "Sure, Fred was a great dancer. But Ginger was the real talent. She matched Fred step-for-step, wearing high heels and going backwards!"

That statement makes a good metaphor for the clinical lab industry and its main supplier, the diagnostics manufacturers. It is certainly tough for lab administrators and pathologists to predict the immediate future for lab management and make the right decisions. But it is even tougher for diagnostics manufacturers to make those same predictions years earlier, and have the right products ready for their laboratory customers.

For this reason, one way to study the future of the clinical laboratory industry is to visit the leading diagnostic manufacturers. These companies are investing tens of millions of dollars today on the next generation of instruments and test kits. For these companies to succeed, they must have a perceptive and accurate view of the lab industry's immediate future.

Recently, THE DARK REPORT sat down with Catherine M. Burzik, President, Americas, **Ortho-Clinical Diagnostics, Inc.** (OCD). This exclusive interview focused on three main topics: 1) OCD's perspective on the current state of the market for diagnostic instruments and test kits; 2) developments with OCD and its parent company, **Johnson & Johnson**, to create effective healthcare solutions by integrating products in diagnostics, therapeutics and patient monitoring; and 3) specific business strategies within OCD that affect the types of diagnostic products and services it offers clinical laboratories and blood banks.

"The last few years were certainly difficult for all companies involved in the lab testing business," said Burzik. "Studies indicate a low overall growth in testing volume in recent years, ranging from 0% to 2% per year. Some diagnostics testing sectors actually declined during this period.

Decline In Utilization

"Certainly clinical chemistry testing was adversely impacted as utilization declined and new test panels were mandated," noted Burzik. "That seems to be changing, but year-to-year growth rates will remain modest.

"For the entire category of diagnostics, OCD's studies indicate that the situation is now changing for the better," she added. "OCD projects an annual industry growth rate of 4% for integrated diagnostics in the immediate future.

"One area of business which is important to OCD is immunodiagnostics," noted Burzik. "In our view, this segment will also see modest testing growth—probably 2% to 3% per year. However, we think specific segments of immunodiagnostics, like infectious disease testing, cardiology, and cancer markers, will experience stronger rates of growth.

Infectious Disease Testing

"Within the infectious disease segment, OCD is proud of the recent approval by the **Food and Drug Administration** (FDA) of our Anti-Hepatitis B Surface Antigen Assay (Anti-HBS)," continued Burzik. "This is designed to be run on our random access, enhanced chemiluminescence immunoassay instrument, the VITROS® ECi Immunodiagnostic System. Approval of this product now allows smaller independent laboratories and hospital labs to perform this test.

"In addition to immunoassay technology's applicability to infectious disease, cardiology, and cancer marker detection, our expectations are that molecular technologies will have widespread application

in diagnostics. It will probably be another five years before this technology begins to realize its full potential,□ stated Burzik.

Laboratory administrators and pathologists will be interested to learn that Ortho-Clinical Diagnostics has already declared molecular diagnostics to be a priority and has established an incubator group focused on this opportunity.

OCD Offers Lab Clients "Process Excellence"

DIAGNOSTIC MANUFACTURERS WANT to establish long-term relationships with their laboratory clients. To accomplish this, they must offer "value-added" services which reach beyond instruments and test kits.

At Ortho-Clinical Diagnostics, (OCD) one major "value-added" effort involves a consulting service which helps lab clients achieve "process excellence." This OCD team, trained in the techniques of "Six Sigma" and "lean thinking," is available to assist OCD laboratory clients.

Recently the BayCare Health System of Tampa, Florida, contracted with OCD to undergo "process excellence" training. This laboratory organization services ten hospitals and performs 2.3 million billable tests annually.

Victor Hruszczyk, Vice President of Laboratory Services at BayCare, reports that process redesign of lab work practices generated significant gains in productivity and quality. For example, med tech productivity climbed 44.5%, from 86,700 tests per technical FTE to 125,700 tests per technical FTE.

□Our molecular diagnostics unit is focused on opportunities that integrate nucleic acid and bioinformatic technologies and will concentrate on impact to patient outcomes, □ observed Burzik.

□There are four legs supporting this effort,□ she continued. □First is J&J□s pharmaceutical research group. Second is OCD□s focus on diagnostics. The rapid progress now occurring in the field of pharmacogenomics means these two business groups will work ever more closely together.

Detect And Monitor Cancer

□Third is a joint effort between OCD and J&J Development Corp. to look outside for appropriate technologies to bring into J&J. One of our recent investments is with **Immunicon, Inc.**, creating an alliance to develop proprietary products to detect and monitor cancers by detecting solid tumor cells in the blood and other body fluids,□ noted Burzik.

□The fourth leg of this effort is centered on healthcare informatics,□ she said. □We recognize the growing importance of collecting and managing the right clinical data. This group will create the database tools which support our ongoing research and development.□

Burzik□s comments demonstrate that Ortho-Clinical Diagnostics is actively investing to develop technology which combines diagnostics, therapeutics, and pharmaceutical drugs. This is the growing field of pharmacogenomics. *(See TDR, September 8, 1998.)* Pharmacogenomics plays a key role in the relationship OCD has with other business divisions within J&J.

Four Business Strategies

At Ortho-Clinical Diagnostics, the executive team is focusing on four main business strategies. These strategies promise to offer clinical laboratories expanded options for where and how they perform a range of clinical laboratory testing.

□First, we are investing in a new generation of clinical chemistry instruments,□ explained Burzik. □These future instruments will incorporate our proven dry slide technology along with

traditional liquid technology to offer the broadest test menu possible including immunodiagnostic assays. The business objective is to increase the menu of tests which can be done by a single instrument.

Second, there is a major push to expand the capability of our enhanced instrument systems. The clinical environment is requiring more accurate and reliable results from the laboratory, she stated.

A lack of accurate and reliable results increases lab test costs while reducing the quality of care. Across the clinical lab industry, there is a widespread acceptance of variability in test results and the retesting that is the consequence of this variability, observed Burzik. OCD wants to improve the accuracy of the *first* result, so physicians and laboratorians won t question data.

Improved Fluidic Controls

To accomplish this, we are investing in improved fluidic controls for reagent and sample metering, continued Burzik. This feature is called Intellicheck". OCD intends to be the market leader in providing smart analyzers that accurately dispense fluids and generate accurate and acceptable results on the first test, results you can trust with full process verification built into each analyzer.

Business strategy number three involves our enhanced chemoluminescence immunoassay (ECi) business. Outside the United States, we successfully launched a full menu of next generation HIV and hepatitis tests, noted Burzik. Our goal is to speedily introduce these tests into the United States to allow hospital laboratories to perform these tests on a fully automated, random access analyzer.

The fourth business strategy centers on our Hepatitis C antigen (HPC Ag) diagnostic test, stated Burzik. It reduces the window of detection from 80 days to detect the antibody to hepatitis C to less than 40 days to detect the Hepatitis C antigen. Because of the relatively widespread prevalence of Hepatitis C in the population, this test offers important clinical benefits.

There are over 4 million people in the U.S. and 100 million people worldwide with hepatitis C, added Burzik. We believe the ability to detect and treat this serious disease early will improve the quality of life for millions of people."

"We are now sharing our expertise in process management and manufacturing with our hospitals and laboratory customers."

Catherine Burzik–President, Americas, Ortho-Clinical Diagnostics

Each of these four business strategies addresses traditional products and services offered by Ortho-Clinical Diagnostics. But OCD has other significant business initiatives underway which are definitely non-traditional.

We are now sharing our expertise in process excellence with our hospitals and laboratory customers, declared Burzik. You are well aware that all clinical laboratories are under sustained pressure to reduce costs while adding enhanced lab testing services. OCD and J&J can now directly help them accomplish these goals through techniques of process excellence.

Major Commitment

This is a service that directly flows from a current J&J strategic imperative, noted Burzik. Johnson & Johnson made a major commitment to Six Sigma management and lean manufacturing methods. These are management systems which reduce process variability, thus eliminating

Reimbursement Levels for Blood Banking Products Increasingly a Concern at OCD

BLOOD BANKING IS AN IMPORTANT PART of the clinical laboratory industry. It is also a major business within Ortho-Clinical Diagnostics (OCD). But serious issues cloud the future of the blood banking business.

In fact, the economics of blood banking products may be a unique preview at what might happen in other areas of diagnostic testing if reimbursement does not keep pace with regulatory requirements affecting quality, safety, and use of diagnostic assays.

"The term we use is 'fragility of the blood industry in the United States'," noted Catherine Burzik, President of OCD. "Currently the economics of the blood banking industry are such that only two companies in this industry remain committed to provide tests for blood typing in the United States. These are the tests which guarantee the safety of blood transfusions.

"The deteriorating economics of the blood banking business are such that all but a few companies have ceased to manufacture products for this market. It is safe to say that, without adequate reimbursement levels to allow blood bank laboratories, donor centers, and suppliers to recover costs and ensure a viable business model, new technology will not find its way into the blood banking industry. The future safety and availability of blood will be at greater risk than it is today.

"The situation is deteriorating faster than most laboratorians realize," cautioned Burzik. "It now borders on becoming a matter of national interest for public health. OCD is working in a variety of way to collaborate with the American Association of Blood Banks, American Red Cross, and America's blood centers to get the message to Congress that we must see improvement in reimbursement for blood products.

"All of this is a result of the increased demand for blood safety," explained Burzik. "There are ever more requirements for mandating new tests and blood testing procedures, but no counterbalancing increases in reimbursement. It's the same cost-versus-reimbursement squeeze that laboratorians have seen in other areas of diagnostic testing."

errors, reducing waste, lowering costs, and boosting quality.

"Throughout our company, we are training existing managers to be experts in these methods," she continued. "After training, they are called "black belts" and become internal consultants to every area of our business. In the last 18 months, OCD trained over 100 black belts. Within J&J, OCD is the farthest along on the Six Sigma transformation.

"We are now training our hospital laboratory customers in these techniques," added Burzik. "The first completed projects have generated impressive gains in lab productivity, while simultaneously lowering lab costs. There is great excitement at hospital labs now participating in our "process excellence" program."

The Internet has not been ignored by Ortho-Clinical Diagnostics. Burzik has strong opinions about Internet-based diagnostic services.

"OCD believes virtually every aspect of laboratory testing will move to incorporate Web-based information management capabilities," predicted Burzik. "One of the first areas of diagnostics to adapt the Web will be reporting of test results between lab and referring physician. The Web's ability to move data instantly and at low cost will allow labs to offer ever-faster turnaround times.

Real-Time Communications

"OCD recognizes this fact. E-connectivity of our newest instruments will be reality in approximately two years," Burzik said. "We believe there will be real-time communications between OCD and our lab customers. Using this connection, OCD will monitor how the components of the instrument are functioning. OCD engineers will be able to identify malfunctioning parts, sometimes before they go bad, and schedule repairs so as to avoid instrument downtime.

"As the instrument operates in a customer's lab, OCD will also be able to monitor reagent usage," she added. "This will allow OCD to help the customer reduce inventory levels and inventory waste, further saving money.

"Of course, test results will be transmitted using the Internet. In real time, as the instrument generates acceptable test results, the data will be posted to the clinical repository and notification will be sent to physician and even potentially the patient," predicted Burzik.

Consumer Involvement

"The Internet is going to add another dimension to laboratory testing," offered Burzik. "It will make it easier for consumers to participate in all aspects of laboratory testing. Laboratories should be ready for this change.

"We think there will be a rise in the amount of direct-to-consumer marketing done by both clinical laboratories *and* diagnostics manufacturers," explained Burzik. "Pharmaceutical companies proved that direct-to-consumer advertising works.

"The day fast approaches when we believe a self-educated consumer will go to his doctor and request a specific test, for example, the Vitros HCV antigen test," noted Burzik. "At OCD, we fully expect that consumers will become a significant factor in the market for laboratory testing.

One market advantage which Ortho-Clinical Diagnostics expects to exploit during the next few years is its close working relationship with other operating divisions within Johnson & Johnson. As pharmacogenomics research develops new classes of drugs which rely on specific laboratory assays for diagnosis, prognosis, and patient monitoring, OCD's close relationship with J&J's pharmaceutical divisions should give it a competitive advantage.

New Diagnostic Capabilities

"Despite all the tough times the lab industry has endured recently, the next few years will see a steady cascade of new diagnostic capabilities which should boost the importance of clinical laboratories to the healthcare system," predicted Burzik.

"We are also excited at the potential of "Six Sigma" and "lean manufacturing" methods to help our laboratory customers boost productivity, lower lab costs, and enrich the quality of the lab services they provide to physicians and patients," concluded Burzik. "These are all tools which will help make laboratories even more important to the healthcare systems that they serve."

Ortho-Clinical Diagnostics is investing across a range of products and services, including some untraditional ones like "Six Sigma" expertise, to maintain competitive advantage. These business initiatives demonstrate how the needs and expectations of lab customers are changing. **TDR**

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The Dark Index

Dynacare's IPO is Funded, Specialty Labs' IPO is Next

IT WAS A DISAPPOINTING TRIP to the public equity markets for **Dynacare, Inc.** last month. The lab company raised only $50 million in its initial public offering (IPO).

Dynacare had hoped to harvest as much as $89 million from this IPO. Plans were to sell seven million shares at about $13 per share. But after Dynacare's "road show" to the professional investment community, underwriters placed five million shares at a price of $10 per share. The IPO closed and funded on November 7, 2000.

More Lab IPOs To Follow

With Dynacare's IPO completed, there are still two more laboratory companies which hope to place IPOs. They are **Specialty Laboratories, Inc.** of Santa Monica, California and **American Medical Laboratories, Inc.** (AML) of Chantilly, Virginia. *(See TDRs, October 2, 2000 and October 23, 2000.)*

Next to tap the public equity market will be Specialty Laboratories. As this issue of THE DARK REPORT goes to press, December 4 is the scheduled closing date for Specialty's IPO. However, because of the stock market's temperamental nature, it is very common to defer or delay an IPO until the underwriters believe the time is most auspicious.

Specialty Laboratories would like to raise $86.3 million through its IPO. Because it and AML continue to be in an SEC-mandated "quiet period," neither executives from the two lab companies nor underwriters involved in the public offerings will make public statements. However, conversations with knowledgeable individuals in the investment community seem to indicate that Specialty Laboratories is seen as a particularly attractive investment.

It is Specialty Lab's unique concentration on esoteric testing which seems to appeal to professional investors. They understand enough about diagnostic testing to realize that research into genetics and molecular medicine will find first application in esoteric lab tests. They believe an investment in Specialty Laboratories positions them to profit from such yet-to-occur opportunities.

A target closing date for AML's IPO has not been set as of this date. AML seeks to raise $115 million dollars. Because Dynacare raised only 56% of its goal, AML may believe that the stock market is not as excited about companies involved in routine testing as they are about companies involved in specialty esoteric testing. Another factor may be the recent softening in share prices for *Quest Diagnostics Incorporated.*

Competitive Position

Timing and investor interest is important for both Specialty Laboratories and AML. If both lab companies can raise their targeted amount of capital, it will strengthen their competitive position in the lab marketplace. But if they can't hit their funding goal, each lab has the option of accepting less funding or deferring the IPO until a later date. TDR

Contact Robert Michel at 503-699-0616.

Premier's Lab Vendors Hooking Up Via Internet

Goal is to move lab purchasing functions onto medibuy.com's transaction service site

CEO SUMMARY: Laboratory members of Premier will soon be purchasing instruments, reagents, and supplies through medibuy.com's Internet healthcare e-commerce site. Four major lab industry suppliers are actively working to link with the medibuy.com and Premier Web sites. For Premier, this is part of a comprehensive effort to upgrade the services it offers its member hospitals and laboratories.

HEALTHCARE E-COMMERCE is considered by many business experts to be a threat to group purchasing organizations (GPO).

But **Premier, Inc.** is aggressively embracing healthcare e-commerce solutions. Since July, it has signed contracts with four major lab industry suppliers to jointly use **medibuy.com** as the transaction vehicle to allow Premier hospital members to purchase laboratory instrument systems, reagents, and supplies.

Four Diagnostics Vendors

"We have established medibuy.com contracts with **Dade-Behring Corp.**; **Beckman Coulter, Inc.**; **Fisher Healthcare, Inc.**; and **Roche Diagnostics, Inc.**," stated John Biggers, Vice President of Corporate Development at Premier. "In the next 60 days, we expect to sign similar agreements with two or three more of our national laboratory contract business partners.

"We believe that a significant amount of money can be saved by moving the purchasing functions for laboratory equipment and supplies to an Internet-enabled buying exchange," noted Biggers. "In working with medibuy.com, our goal is to have a *single* electronic data interchange handle purchase orders, invoicing, and payments for our member hospitals and laboratories.

"To make this possible, these four national lab business partners have agreed to invest the time and money necessary to hook up their resources to the medibuy.com Web site," he explained. "Expectations are that direct savings and non-measurable benefits will be worthwhile for both Premier member laboratories and the diagnostics suppliers."

But Premier's expectations go beyond lowering the costs of simple purchasing transactions. "This is just one element in our plans to establish a full menu of added value services for Premier laboratory members," stated Biggers. "Traditionally, GPOs primarily helped their members through national contracting and similar services relating to purchasing.

"We have a different vision at Premier. We intend to offer our lab members specialized services and resources that allow them to get the most from their laboratory organizations," noted Biggers.

"For example, we have an ever-growing number of laboratories participating in our LabFOCUS" benchmarking program," he continued. "This is a comparative data tool and performance profiling service.

Lab Benchmarking

"A steadily-growing number of labs are feeding data into this benchmarking program. Our intention is to develop "best practices" guidelines based on the performance of well-managed laboratories," noted Biggers.

"We want to use the experience of the best-performing laboratories to help us understand which diagnostic instrument systems work best in different types of laboratories," he continued. "Once we have that knowledge, we can develop better national contracts for diagnostic instrument systems and help Premier member laboratories use these products to generate improved performance metrics in cost reduction, improved test quality, and overall lab productivity."

Benefits To Lab Suppliers

The medibuy.com offering at Premier also promises significant benefits to the diagnostics vendors who participate. "For the first time, these suppliers will have the ability to accumulate data in a central location," stated Todd Abner, Vice President of Global Supplier Contracting at medibuy.com.

"This will provide them more accurate information about contract compliance, for example," he explained. "They can then direct their marketing and service staff to the laboratory locations where appropriate follow-up is needed. It provides them with the opportunity to make real time decisions about a variety of business issues."

Abner expects that medibuy.com will provide a higher level of two-way communications between lab suppliers and their laboratory customers. "Remember, we are helping these diagnostic manufacturers integrate their information systems through our ASP (application service provider) functions," he said. "This will enable Premier member laboratories to send and receive messages on all business subjects, such as product notices, service issues, and the like."

THE DARK REPORT believes that this business initiative by Premier is the first major example of Web-based transaction links between a GPO's laboratory members and lab industry suppliers. Laboratory administrators and pathologists should expect to see this project spur more e-links with suppliers.

Direct Link To Customers

Once these diagnostic manufacturers invest time and money to integrate their systems with medibuy.com's healthcare e-commerce system, they are positioned to directly link with any laboratory customer. As a consequence, diagnostics suppliers will have an economic incentive to enlist other laboratory customers to work through healthcare transaction portals like medibuy.com.

This is another example of how ASP-based, Internet-enabled services can lower the cost of doing business. The impact will be to cause traditional business practices to shift over toward these new business models.

Premier expects the first lab vendor links to be operational in just a few weeks. If this system works, expect to see other lab vendors connect in this type of communications arrangement. TDR

Contact John Biggers at 704-733-5090 and Todd Abner at 615-279-2240.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Evidence continues to grow that consumers are using the Internet to actively intervene in their health care. The **Pew Foundation** released a report last week that says 52 million Americans are using the Internet □□to gain knowledge about disease, investigate how to participate in clinical trials, and find low-fat recipes.□ Moreover, 55% of all Internet users claimed to have sought health information, outranking the next highest category□online shopping at 47%. But of the people using the Internet for health information, only 9% said they had exchanged e-mails with their doctors.

ADD TO: INTERNET

These findings should be a wake-up call to both independent labs and hospital labs. It□s time for every lab to establish a relevant Web presence. Consumers and patients are already on the Internet looking for information about their particular health needs, including clinical laboratory tests and anatomic pathology procedures.

PROPOSAL TO EXPAND MEDICAID ELIGIBILITY FOR 23 MILLION PEOPLE

Here□s something that should-n□t escape the notice of the lab industry. Two longstanding enemies in the battle for national health insurance have joined forces with the A**merican Hospital Association** (AHA) to call for a $26 billion increase in yearly spending to fund Medicare eligibility for an additional 23 million people. **Families USA** (a liberal advocacy group that supported Hillarycare in 1993-94) and the **Health Insurance Association of America** (HIAA) (source of the □Harry and Louise□ ads in 1993-94) joined together with the AHA and put forward a plan to expand Medicaid to provide healthcare to uninsured individuals making as much as 200% of the federal poverty level.

MORE ON: MEDICAID

The American Hospital Association should be careful. It might get what it wishes for. Hospitals are already struggling to cope with the bureaucratic nightmare of Medicare. Imagine the chaos if bureaucrats added 23 million people to the Medicaid program.

EXECUTIVE CHANGE AT QUEST DIAGNOSTICS

In recent weeks there was a quiet change in the executive ranks at **Quest Diagnostics Incorporated.** Vijay Aggarwal, President of Quest Diagnostics Ventures, has left the company. Aggarwal was also a key executive at **SmithKline Beecham Clinical Laboratories** (SBCL). Aggarwal□s lab roots extend back 23 years. He was part of the former **Bio-Science Laboratories**, located in Van Nuys, California and purchased by SBCL in the 1980s.

PAGE HIRED BY LUMINEX

Luminex Corporation hired Gail S. Page as Executive Vice President and Chief Operating Officer. Plans are for her to contribute to developing Luminex□s proteomic bioinformatics business unit. To join Luminex, Page left a position at **Laboratory Corporation of America**, where she was Senior Vice President of Automation, Diagnostics, and Quality.

That□s all the insider intelligence for this report.
Look for the next briefing on Tuesday, December 26, 2000.

BACK BY POPULAR DEMAND!

EVERYTHING YOU NEED TO KNOW ABOUT WEB-BASED INFORMATICS

Here's the follow-up to last year's exclusive introduction to Web-enabled lab test ordering and results reporting. Hear from the first labs to use the Web to connect with physicians' offices. Learn first-hand from the leading lab informatics vendors.

THURSDAY, MAY 10, 2001
Following the Executive War College–May 8-9
Hyatt Regency Hotel, Cincinnati, Ohio
(Laboratory CEO Day—May 10, 2001)

UPCOMING...

- ***The Dark Report's Five Year Retrospective and White Paper On the Clinical Laboratory Industry.***
- ***Hospital Labs' Labor Productivity Dilemma: Automation Versus Med Techs.***
- ***Why Things Are Uncomfortably Quiet on the Laboratory Compliance Front***
- ***Exclusive Analysis of Financial Performance of Lab Industry's Leading Firms.***