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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

The Lab Industry's Market Share Juggernauts

MOST OF YOU KNOW THAT 2002 WAS AN UNEXPECTEDLY ACTIVE YEAR for public laboratory company acquisitions. The entire rank of mid-market public laboratory companies actively selling routine testing services to physicians' offices was swept from the board by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**.

Our office has been fielding a steady flow of questions from clients and regular readers of THE DARK REPORT asking "what comes next?" The answer to that question shouldn't be a surprise. It is "more of the same." In other words, the two blood brothers have a voracious appetite for specimen volume and market share. For that reason, they will continue to pursue acquisitions whenever and wherever they can find them.

The market segment of anatomic pathology will be attractive. LabCorp has already acquired **DIANON Systems**. **AmeriPath's** interest in selling to either of the blood brothers is ongoing. IMPATH is having hiccups and may be a possible acquisition. Blood Brother acquisitions in this market segment are long-term threats to local pathology groups and the existing client base they serve.

The most fascinating source of acquisitions will be in small, even tiny, private laboratory operations. We've written about the disappearance of the stand-alone independent commercial laboratory. There's only a handful that remain doing more than $20 million per year in business. But there remain a substantial number of small lab operations. Many serve only a single medical office building. It is these types of labs which will feed the acquisition appetite of the two remaining national lab companies. **Dynacare** was using these types of acquisitions to feed its growth and there's evidence that Quest Diagnostics and LabCorp intend to seek out similar opportunities.

The two blood brothers will not ignore hospital inpatient testing opportunities and hospital lab outreach programs. Anytime an opportunity presents itself to bid on this testing volume, one or both of the national labs shows up.

Taken collectively, I believe the nation's two billion-dollar lab giants will continue to do acquisitions at a steady pace. But these deals, by definition, will be smaller. However, the end result will be the same as in the past. The two blood brothers will continue to buy market share as a way to sustain growth in specimen volume and revenues. TDR

Needless Mastectomy Draws National Attention

Slide mix-up at pathology group practice leads to a wrong breast cancer diagnosis

CEO SUMMARY: This widely-reported case of misdiagnosis at an Allina hospital in St. Paul, Minnesota is a powerful reminder to pathology practices and clinical laboratories that breakdowns in medical quality will draw increasing attention and scrutiny. Both the patient and the community are questioning why the pathologist who made the mistake will apparently be allowed to continue to practice without serious sanctions.

BY NOW, MOST of the pathology profession knows last month's story of the Wisconsin woman whose double mastectomy proved unnecessary because of a false diagnosis of breast cancer.

It got wide play in the national media because it was the classic story of human tragedy. A woman, told by her doctor that she had an aggressive form of breast cancer, opted to undergo a double mastectomy. Two days after the operation, her doctor informed her that she never had breast cancer in the first place—the operation was unnecessary.

For pathology group practices throughout the country, this widely-publicized case of misdiagnosis should trigger a careful assessment of internal quality control protocols. Of equal importance, however, THE DARK REPORT believes that pathology group practices should use this case of cancer misdiagnosis as a catalyst to reassess and understand basic changes now occurring in the way American society views its healthcare system.

Specifically, consumers are increasingly intolerant about medical errors. There is a groundswell of support for publicizing provider performance and taking decisive action against physicians who seem to be regularly delivering substandard care.

In the double mastectomy case, the basic facts are not in dispute. Last May, Linda McDougal, a 47-year old

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accountant and mother of three underwent a mammogram at the breast center of **United Hospital** in St. Paul, Minnesota (owned by **Allina Hospitals and Clinics**). A suspicious shadow on the mammogram caused her physician to order a biopsy.

Slides Mishandled

Slides prepared from McDougal's biopsy were read by a pathologist at **Hospital Pathology Associates** (HPA), the 25-pathologist group which provides anatomic pathology services to most of Allina's 14 hospitals. At HPA, it was common practice for several patient's slides and paperwork to be placed in a single folder. While reading McDougal's slides, the pathologist mismatched the specimen slides and paperwork of McDougal and another woman.

Post-operation, no malignancy was found in the amputated breast tissue. In reviewing McDougal's case, HPA's pathologists discovered her specimen slides had been mistakenly identified as those of another woman whose slides and paperwork were in the same folder. The patient who actually had cancer was than contacted and treatment for her cancer was started.

Although these events occurred in May 2002, it was not until January 20, 2003 that McDougal felt emotionally strong enough to hold a press conference and tell her story to the public. In the months since her operation, she has been plagued by serious infections and has undergone emergency surgery. Her reconstructive surgery will be delayed for as long as two years.

Changing Public Attitudes

What pathologists and laboratory executives will find instructive about this case is how it plays into a new public attitude and intolerance for medical errors of this type. For one thing, McDougal now understands what pathologists do.

McDougal appeared on morning television talk shows and was widely quoted in the nation's newspapers. "It's important for me to get a message across to women to take control of your own medical care," she declared. "Just because a pathologist or a doctor tells you something, especially in the event of a serious diagnosis, they could be wrong. I did talk to my family practitioner. I talked to other doctors about the surgery itself, but it never occurred to me to question the pathologist report."

"They have been wrong. They were wrong with me and caused me to have both of my breasts removed," she continued. "I trusted them and I shouldn't have. Just because a pathologist or a doctor tells you something doesn't mean it's right. You have to be true to yourself and get a second opinion or a third."

Holding Docs Accountable

McDougal was accompanied during her public appearances by an attorney and is speaking out against the President's proposed limitation on medical malpractice awards. "Doctor's aren't held accountable," stated McDougal. "It has taken me seven months to get to a point where I can even talk about this."

McDougal was critical of how the medical establishment responded to her case. She noted that, although the surgeon had apologized, neither the pathologists nor the hospital had apologized until the news became public. She characterized public apologies made by officials to the media thusly: "It's so obvious that it is a public relations thing that it is meaningless."

McDougal was also upset that the pathologist, as of yet, had not been disciplined in any serious way. "I think he's got to be penalized," she declared. "He's got to be accountable, and right now they haven't even slapped his wrist."

Probability of Nosocomial Infections Not Discussed In McDougal's Case

EVEN AS LINDA MCDOUGAL'S UNNECESSARY double mastectomy grabs national headlines, neither she nor her attorneys have commented publicly on the source of her serious infections.

It was easy to track the source of her misdiagnosed breast cancer back to the pathologist who misidentified the slides of two different cases. But it is less easy for McDougal to identify the source of her infections, most likely transmitted during her stay in the hospital.

For the most part, consumers do not understand that many nosocomial infections are preventable if staff in a hospital follow well-established procedures. Consumers thus generally do not "blame" their hospital for infections contracted during their stay.

Accordingly, McDougal and her attorneys publicly decry the mistakes made by the pathologist reading her case, but have yet to attribute or speculate that McDougal's infections may be the result of a breakdown in the hospital's infection control procedures.

Changing Expectations

THE DARK REPORT believes this is a good illustration of how consumer expectations (and knowledge) play a role in demanding improvements in healthcare quality. The pathologist's error which generated the misdiagnosis is easy to comprehend and caused a human tragedy—needless removal of a woman's healthy breasts. But one consequence of that mastectomy, serious infection, has so far been accepted by the consumer and her legal counsel as an inevitable result of the surgery and is not considered a medical error that might have been avoided.

Thus, it is with some irony that the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) weighed in on nosocomial infections just two days after McDougal's case came to the public's attention. On January 22, 2003, JCAHO issued a Sentinel Event Alert calling for greater reporting of the deaths of patients who contract fatal infections while being treated for illnesses or injuries.

JCAHO's concern explains why many consumers "accept" nosocomial infections as a part of their course of treatment. In its alert, JCAHO quotes CDC estimates that more than two million patients yearly develop infections while hospitalized for other health problems. Of this number, up to 90,000 die as a result of these infections.

Remarkably Few Reports

Remarkably, JCAHO reports that, despite these large numbers, hospitals have only filed ten such reports covering 53 patients during the past seven years! "We are receiving a disproportionately low volume of reports on the number of patient deaths from infections acquired in the health care setting, possibly because many health care organizations do not view these events as 'errors' under the definition of a sentinel event," says Dennis S. O'Leary, M.D., JCAHO's President.

It is a situation that JCAHO intends to change as part of the move to improve patient safety. O'Leary explained, "...in view of the importance and high visibility of such occurrences, we are urging health care organizations to share this information with the Joint Commission, just as they might share information about other types of sentinel events with us."

JCAHO's initiative to focus attention on nosocomial infections will come to the attention of consumers—who, not surprisingly, will come to view such infections as unnecessary and a result of improper healthcare. In the future, patients such as Linda McDougal will include nosocomial infections in their list of malpractice torts. Because labs play an important role in infection control, this new emphasis on nosocomial infections will require greater awareness and involvement by laboratorians.

Because of legal issues, HPA has offered only limited public comments. Pathologist Laurel Krause has spoken on behalf of Hospital Pathology Associates. "A tragic mistake was made," she said. "We are exceedingly sorry for the pain and suffering she [McDougal] went through, and she has continued to go through."

An Exemplary Record

The pathologist who signed out McDougal's case has not been identified. But Dr. Krause did note "the pathologist who made this error has an exemplary track record. There has been no prior history of any such mistakes or errors."

HPA is revising its work procedures to prevent such errors in the future. It is now color-coding tissue samples to a patient's paperwork. In signing out cases, two pathologists are now required to sign after cross-checking the patient name and ID number on the slide with the case documentation. "It is more time-consuming and more effort," commented Dr. Krause, "On the other hand, that's not what matters here. What matters is getting it right."

Concerned Pathologists

Across the country, pathology group practices have responded to the this tragedy by launching a review of their own work procedures. Allina spokesperson Kendra Calhoun said "We've been receiving e-mails and phone calls from pathologists and labs across the country to ask what we're doing differently so they can make their own protocol changes. It's not about anything except patient safety. That's our main priority."

Many pathology group practices handle slides and paperwork in a similar fashion as was done at HPA. "There, but for the grace of God, goes any one of us," said one Minneapolis-based pathologist to THE DARK REPORT. He observed that procedural changes were rapidly implemented by his group immediately after news of the McDougal case became public.

On balance, however, THE DARK REPORT notes that the laboratory industry continues to maintain a pretty good track record on patient safety. During the past five years, only two episodes of laboratory errors have caught the attention of the national media. In Palo Alto, California, a rogue phlebotomist at **SmithKline Beecham Clinical Laboratories** was discovered reusing needles. In Philadelphia, the laboratory at **St. Agnes Medical Center** generated inaccurate test results over a seven-week period that affected patients taking Coumadin. *(See TDR, June 7, 1999 and August 13, 2001.)*

"There, but for the grace of God, goes any one of us," said one Minneapolis-based pathologist to THE DARK REPORT.

What is significant about the Linda McDougal case is that it demonstrates the ongoing evolution in public opinion toward medical errors and physician incompetence. Even as the medical community closes ranks around the pathologist who committed the unfortunate error, as has always been true in the past, strong voices in the consumer community want tough action. They want the name of this pathologist to be publicly disclosed and they want tough sanctions leveled against the pathologist proportional to the harm done to Linda McDougal.

Pathologists and laboratory directors should heed this change in public expectations. Public scrutiny of healthcare professionals who commit medical errors will continue to increase in future months and years. TDR

LabCorp Starts Tinkering With DIANON Systems

Will LabCorp preserve the elements that made DIANON such a successful growth engine?

CEO SUMMARY: For almost two decades, DIANON Systems supported one of the most successful sales and marketing programs in the public laboratory sector. However, despite its pre-acquisition statements that it would retain DIANON's operational integrity, LabCorp has already begun to implement subtle changes to DIANON Systems. Time will tell whether or not these management decisions prove beneficial.

FOR MOST OF THE 1990S, **DIANON Systems, Inc.** was the company which set the bar for selling anatomic pathology services to office-based physicians.

That era may have ended on Friday, January 17, 2003. That's the date when **Laboratory Corporation of America** took ownership of DIANON and put itself squarely in competition with local pathology groups for primary biopsies originating in physicians' offices.

To enter this market segment, LabCorp paid almost $600 million to buy DIANON, a company that was on target to post net revenues of about $190 million for 2002. LabCorp's purchase of DIANON Systems was announced last November. *(See TDR, November 18, 2002.)*

Retain Its Edge?

Now comes a question of critical importance for local pathology group practices. Will LabCorp operate DIANON Systems with the same competitive edge, thus continuing DIANON's sustained ability to capture market share from local pathologists? Or will LabCorp executives in Burlington, with their different business priorities and "better ideas," dull DIANON's sharply-honed sales and marketing program?

It is not an idle question for the pathology profession. THE DARK REPORT has noted that three public companies offering pathology services—DIANON Systems, **IMPATH**, and **AmeriPath**—grew at spectacular rates during the past five years. For 2002, these three firms will do as much as $800 million in anatomic pathology services. A substantial portion of this revenue growth has come at the expense of local pathology groups.

By paying more than one-half billions dollars to acquire DIANON systems, LabCorp has made a definitive statement that it wants to compete in this market segment. The challenge will be for the management of LabCorp to execute this business strategy at least as well as was done in recent years by the the management of DIANON Systems.

LabCorp's Relationship With Local Path Groups

MANY PATHOLOGISTS around the country point out that Laboratory Corporation of America has traditionally relied on local pathology groups to provide anatomic pathology (AP) services for LabCorp specimens originating from physicians' offices.

In many regions of the United States, LabCorp has long-standing business relationships with local pathology group practices. LabCorp refers AP specimens from its physician office-based clients to these local pathology groups. In some cases, these business relationships extend back more than 10 to 15 years.

That is why news that LabCorp would acquire DIANON Systems caused a stir among community hospital-based pathologists. DIANON has been a tough competitor. In purchasing DIANON, LabCorp made a $600 million investment to expand its share of the anatomic pathology market sourced from physicians' offices. It is reasonable to conclude that LabCorp will begin unwinding its existing business relationships with local pathology groups so that it can refer those specimens to its new DIANON division.

As that occurs, local pathology groups can not be expected to quietly watch that business migrate to LabCorp/DIANON without a competitive fight. During the next two years, as LabCorp moves to bring outsourced AP specimens in-house, some local pathology groups may be finally prodded to finally launch their own sales program in order to retain that business.

Therein lies one threat to the success of the LabCorp/DIANON acquisition. Since healthcare is local, local pathology groups should have a competitive edge against any national laboratory—so long as they provide an equal level of service and sustain a professional sales program.

Pre-acquisition, LabCorp lauded many aspects of DIANON Systems and declared that, going forward, it would retain the DIANON identity. However, that's already proving untrue for DIANON's national sales force. Rather than retaining the form, structure, and incentives of DIANON's sales program which made it the envy of most public lab companies, LabCorp has already begun integrating DIANON's sales people and sales functions into its existing national sales program.

Changes Becoming Visible

Two fundamental changes in LabCorp's integration program are becoming visible. First, DIANON's sales representatives will report directly to regional LabCorp managers and not to Martin J. Steffanelli in Stratford, Connecticut. As DIANON System's Senior Vice President of Sales, Marketing, and Business Development, Steffanelli played a key role in maintaining the high productivity of DIANON's sales force.

Second, DIANON's generous sales commission plan will be scrapped and replaced with LabCorp's existing sales compensation program. A number of DIANON sales reps currently interviewing for jobs with competing lab companies believe this will occur. When the two sales incentive programs are put side-by-side, the difference is substantial. DIANON's current sales compensation program is heavily weighted to reward profitable new business and pays about 40% more than LabCorp's sales compensation plan.

Assuming that LabCorp's compensation program is significantly less generous, then LabCorp faces a tough challenge to retain and motivate the best of DIANON's sales producers.

Top-ranked sales reps at DIANON were known to earn $200,000 per year and THE DARK REPORT has seen multiple winners of a special sales contest at DIANON get bonus checks of $80,000 apiece. DIANON was a company that wanted growth. As such, it was willing to handsomely reward sales reps who could generate profitable new specimen volume.

Early Intelligence

At a minimum, all this early intelligence indicates that significant changes are planned for DIANON's existing sales program. Even if most of DIANON's top-ranking sales producers decide to continue with LabCorp, their sales momentum will be disrupted by new reporting relationships.

The need to learn LabCorp's business policies will require DIANON sales reps to take time away from sales activity to attend LabCorp training programs. They will also be asked to sell different products to their physician office clients. In the short term, all of these activities will distract DIANON's sales reps from their prior focus on developing new client accounts.

In the short term, all these activities will distract DIANON's sales reps from their prior focus on developing new client accounts.

Another interesting area to watch is how LabCorp's access to managed care contracts can be leveraged to generate additional business for its DIANON division. Last November, LabCorp CEO Thomas P. Mac Mahon publicly stated that it holds managed care contracts in many cities where DIANON does not. It wants to use DIANON's AP testing and sales resources to piggy-back more anatomic pathology specimens on top of the existing clinical lab testing it does in these regions.

Post-acquisition, executives at LabCorp and DIANON view this as a logical and productive way to gain synergy. However, to accomplish this goal requires that DIANON's sales reps be redirected away from efforts to build their existing sales book of business.

It should be also noted that DIANON itself, in recent years, was experiencing its own internal problems. These may impact LabCorp's ability to retain DIANON's clients post-acquisition. The fact that DIANON had actively solicited buyers during the past two years can be interpreted as a sign that its executive team had doubts about the company's ability to sustain high rates of profitable growth in the near future.

Changes Already Occurring

All this early intelligence adds up to one important conclusion: post-acquisition, LabCorp will not operate DIANON as independently as was suggested last November. DIANON's sales program and an undetermined amount of its operational resources will be integrated with LabCorp's existing regional laboratory centers.

At a minimum, this means local anatomic pathology group practices have a window of opportunity to market themselves to DIANON's physician office clients. For this to occur, however, it means local pathologists must make an investment in their own group practice—something they have traditionally hesitated to do.

Thus, it remains a game which is LabCorp's to lose. In other words, lots of aspects of DIANON were working. Should there be erosion of DIANON's specimen volume and revenue going forward, then much of that can be attributed to LabCorp's management of the DIANON assets it purchased. TDR

Labs In United Kingdom Study U.S., Canadian Labs

Management strategies exchanged At laboratory War College in London

CEO SUMMARY: It was a groundbreaking first for both sides of the Atlantic. Senior pathologists and laboratory directors in the United Kingdom spent two days learning from their North American counterparts about the challenges and difficulties in laboratory consolidation and regionalization. For their part, the North American faculty gained useful insights about the way laboratory medicine is practiced in Great Britain.

By Robert L. Michel

GLOBALIZATION of clinical laboratory testing services is a reality, but the long-standing rule that "healthcare is local" continues to trump all other factors in shaping the management of clinical laboratories.

This was the consensus of more than 100 senior pathologists and laboratory administrators from the United Kingdom, Canada, and the United States following two days of presentations and networking last week in London, England.

The meeting, called *Frontiers in Laboratory Medicine* (FiLM), was conducted February 3-4 at the **Royal College of Physicians**. Co-produced by **THE DARK REPORT**, Britain's **Association of Biochemists** and **IBC** (a private conference company), the meeting was modeled after the *Executive War College* in response to the impending nationwide restructuring of laboratory testing services in Britain.

"Our **National Health Service** (NHS) is in the midst of planning for 'pathology modernisation'," stated Dr. Ian Barnes, Pathology Modernisation Advisor to the Department of Health. "The goal is for existing laboratories to collaborate in the formation of regionalized service organizations.

"In many ways, our pathology modernisation is expected to follow parallel paths of laboratory consolidation and regionalization already traveled by laboratories in Canada and the United States during the last decade," he added. Dr. Barnes addressed the conference and chairs the NHS development team which is studying how best to proceed with "pathology modernisation" in his country.

To help pathologists and laboratory directors in the United Kingdom learn more about the process of laboratory consolidation, restructuring, and networking *before* they begin implementation, THE DARK REPORT and ABC worked together to assemble a panel of speakers from North America who could speak from direct experience about the process of restructuring and consolidating laboratory testing services.

Four strategic laboratory case studies were given. From the United States, it was **Kaiser Permanente Northern California** (based in Oakland) and **Sentara Health System** from Virginia Beach, Virginia. The Canadian experience was documented by **Toronto Medical Laboratories** in Toronto, Ontario and a province-by-province overview of laboratory consolidation. Specialized presentations on different aspects of lab management included the topics of labor productivity, courier and logistics issues, point-of-care testing, standardization, organizational forms for lab consolidation and regionalization, and benchmarking best management practices.

"I can say without qualification that our pathologists and laboratory directors gained valuable insights from their counterparts in Canada and the United States," stated Dr. Michael Hallworth, Chairman of ABC and co-organizer of the event. "What proved remarkable is that the key issues in managing laboratories are so similar, despite the differences in the healthcare system and how laboratories get paid across our three countries."

Three Important Insights

Along with the "healthcare is local" theme, I could identify three additional important and relevant conclusions from this groundbreaking event. Lab administrators in Canada and the United States are far ahead of their U.K. counterparts in three important respects. First, they are much more sophisticated about the financial management and performance of the laboratories they manage.

Second, relative to their U.K. counterparts, North American lab administrators are further along in institutionalizing the process of continual improvement. They use a wider array to management tools and reports to accomplish gains in productivity and quality while lowering the cost of laboratory testing services.

Third, it is much easier for North American laboratories to get the capital budgets needed to implement productivity improvements and deploy new diagnostic technologies. This is an important component in the ongoing drive to lower the costs associated with laboratory testing.

How Labs Get Paid

These three management attributes directly result from how the Canadian and U.S. healthcare systems reimburse providers. In future years, laboratory administrators in the United Kingdom can be expected to develop similar skills as identical pressures to drive out unnecessary laboratory testing costs take a larger role in the United Kingdom.

In one important measure—-the breadth and quality of laboratory testing—there seems to be no appreciable difference between Canada, the United States, and the United Kingdom. "Both faculty and delegates were in common agreement that a patient in any of these three countries would have access to an equally high level of laboratory testing services and technology," observed Dr. Hallworth.

One significant difference that impressed the North American faculty was the specialization that seems much further advanced in British laboratories. In both clinical pathology and anatomic pathology, a much larger portion of pathologists are specialists compared to the United States and Canada.

Within Great Britain, the "pathology modernisation" project will be all-encompassing. There are approximately 300 laboratories in the country and "pathology modernisation" is expected to create around 40+ region-

al lab organizations. Each unified laboratory project will be designed to serve between 1 and 2 million of Britain's 60 million people.

Although the National Health Service has declared its intent to push "pathology modernisation" forward, it is allowing local lab clusters to develop their own restructuring plan. As some of the early adopters move ahead, diagnostic vendors and information services companies are responding to RFPs in the United Kingdom.

Britain's Baby Boomers

Not surprisingly, the U.K. has its own baby boomer demographics. This means more utilization (referred to as "demand" in the U.K.) in coming years along with an aging workforce of laboratory technologists and scientists. Many laboratories are already unable to recruit adequate numbers of med techs. As a result, a handful of automation projects have either recently been implemented or are in development.

Funding for laboratory services is probably a key reason for many of the differences in management style observed between the United Kingdom, Canada, and the United States. During the past decade, healthcare trusts in the U.K. have kept laboratory funding at consistent levels. In contrast, in Canada a number of the provincial health plans squeezed laboratory funding at various points to accelerate laboratory restructuring. In the United States, Medicare funding failed to keep pace with inflation even as private payers were using capitation and exclusive contracts to push down the reimbursement paid for laboratory testing.

Within Canada and the United States, pathologists and lab directors were forced to cope with significantly less money. They learned to pay close attention to detailed measurements of lab productivity and financial performance, even while maintaining or even improving the laboratory testing services offered to local clinicians.

However, time and again, the U.K. delegates were astonished at the emphasis North American speakers gave to increasing the number of tests performed per med tech or driving down the average cost per test. For the past decade, a relatively constant funding base in the U.K. has meant that extreme laboratory restructuring was not needed. This allowed our British colleagues to sustain their focus on clinical care and the quality of laboratory testing services.

"It was a real eye-opener for us in the United Kingdom," stated Dr. Hallworth. "Although clinical services and the state of laboratory technology seem very comparable between the three countries, we've not yet been forced to give financial management of the laboratory the same emphasis as has happened in North America."

Extensive Specialization

Among the North American speakers, similar observations had been made. "I was impressed by how pathologists in Britain have developed a level of specialization that we tend to see mostly in academic centers and larger health systems," noted Gene Pawlick, M.D., Clinical Director, Integrated Laborato-ries at Kaiser Permanente Northern California. "However, because Britain does not have the same level of venture capital activity as we do in the U.S., I'll bet that not as much of their laboratory research moves toward commercialized clinical uses as would be true here in the United States."

In addition to speeches and networking during the two days of FiLM, on Wednesday, February 5, the North American faculty met in the offices of the National Health Service to provide

Brits & North Americans Look At Lab Restructuring

TOPICS OF THE TWO-DAY *Frontiers in Laboratory Medicine* program covered all aspects of lab management strategies, tactics, tools, and methods. Here's a quick look at the program, held at the Royal School of Physicians in London, England:

Monday, February 3, 2003:

UK Modernization: Current Position
- ►*Dr. Ian Barnes, Pathology Modernisation Advisor to the Department of Health*

Development of Laboratory Consolidation and Regionalization in North America
- ►*Robert Michel, THE DARK REPORT*

Strategic Case Study: Kaiser Permanente Northern California Laboratories
- ►*Gene Pawlick, M.D.*

Strategic Case Study: Sentara Health System Laboratories
- ►*Richard Moriarty, M.D., Sylvia Richendollar*

Strategic Case Study: A Province-by-Province Look at Canada's Efforts to Regionalize Laboratory Testing
- ►*Murray Treloar, M.D., Lake Ridge Health*

Strategic Case Study: Toronto Laboratory Services
- ►*Ene Underwood, Ph.D.*

What are the Lessons: Will They Work Here?
- ►*Professor Sir John Lilleyman, Retiring President of the Royal College of Pathologists; Dr. Ian Barnes; Martin Nicholson, Past President of IBMS*

Consolidating Anatomic Pathology: Getting it Right the First Time
- ►*Mary Kass, M.D., MedStar Health*

Tuesday, February 4, 2003:

Using New Management Systems Like ISO-9000 to Design and Operate High Performance Laboratories
- ►*Dixie McFadden, Kaiser Permanente Northwest*

Informatics Issues and Solutions
- ►*Dr. Rick Jones, Leeds General Infirmary*

Positive Patient Identification
- ►*David Guthrie, St. Thomas' Hospital*

Organizational Forms That Enhance Labor Productivity
- ►*Paul Mountain, MDS Laboratories*

Courier and Logistics Issues and Opportunities
- ►*Joseph Skrisson, William Beamont Hospitals*

Point-of-Care Testing Opportunities
- ►*Lou Ann Wyer, Sentara Health System*

Adding Value to How Clinicians Use Lab Test Data
- ►*Fred Plapp, M.D., St. Lukes Medical Center*

Benchmarking the Consolidated Lab: Squeezing Out More Productivity Post-Consolidation
- ►*Theodore Mayer, M.D., ViaHealth*

Order From Chaos: Proven Methods for Standardizing Test Results, QA/QC, and Technologies Across Multiple Lab Sites
- ►*Lawrence Killingsworth, Ph.D., PAML Labs*

Key Messages From The Conference
- ►*Michael Hallworth, Chairman, Association of BioChemists, Robert Michel*

input and consultation for the NHS team responsible for establishing the framework for the nation's "pathology modernisation program." This was followed by a laboratory tour of one of the first U.K. hospital labs to implement total laboratory automation.

"These were energizing sessions," stated Richard Moriarty, M.D., Medical Director of Clinical Laboratories at Sentara Health System. "It is obvious that the United Kingdom is poised to launch the same type of laboratory consolidation and regionalization projects that were done over the last 12 years in the U.S. and Canada. Their pathologists are motivated and keenly interested to learn from our experience so they can get many more things right the first time."

In fact, the sessions were so energizing that British colleagues enthusiastically asked us to hold this mini-War College in London again next year. A management-exchange program was also established between some of the North American faculty and their British laboratory counterparts. TDR

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Lab Industry Briefs

MEDICAL TECHNOLOGISTS IN JAMAICA STAGE WALK-OUT IN JANUARY

LABORATORY TECHS ARE NOT KNOWN to be a radical component of the labor movement. But that doesn't seem to be the case in Jamaica, where more than 80 of that country's medical technologists walked off their jobs twice in January in protests against pay inequities.

The strike actions crippled the ability of several hospitals to treat patients. Without enough medical techs, the laboratories could not operate a normal schedule. At **Bustamante Children's Hospital**, for example, only emergency patients were treated.

Jamaica's med techs want wage parity with government scientific officers who do similar work. In Jamaican dollars, scientific officers start at $700,000 per year (US$13,225), while medical technologists start at $463,000 (US$8,747) annually.

When negotiations with the government's Industrial Dispute Tribunal failed to reach a settlement, the med techs walked off the job and refused to comply with court orders directing them to return to work. The latest walk-out ended after five days. The dispute is once again in the hands of the Industrial Dispute Tribunal.

KAISER TO MAKE PUBLIC TREATMENT GUIDELINES & PHYSICIAN INCENTIVES

HERE'S ANOTHER MARKER ON THE ROAD to greater public transparency about the process of delivering clinical care.

Kaiser Permanente announced last month that, as part of a legal settlement, it would become one of the first insurance plans in the country to publish the clinical guidelines which are used by its physicians to treat patients. Kaiser will also make public details about how it compensates its physicians, including any financial incentives it pays to physicians to limit the cost of treatment.

Kaiser had been sued by a coalition of consumer groups in 1999, including the **Foundation for Taxpayer and Consumer Rights**. Among other things, in its lawsuit, the coalition claimed Kaiser "interfered with doctors' medical judgement by paying them bonuses to limit services and urging them to adhere to strict treatment and length-of-stay guidelines authored by Seattle-based **Milliman & Robertson**." In court filings, Kaiser denied these allegations.

Lab executives and pathologists should view this development as another step in the road to greater public knowledge about the process of providing healthcare. Kaiser's willingness to make public its treatment guidelines reflects the changed expectations of consumers and patients, who now demand access to this type of information.

CYTYC CORP. REPORTS MODEST GROWTH IN 2002

IT WAS A ROLLER-COASTER RIDE at **Cytyc Corporation** during 2002. But things seem to be settling down for the company, best known for its ThinPrep® liquid preparation Pap smear test.

During 2002, Cytyc's attempt to acquire **Digene Corporation** was thwarted by the **Federal Trade Commission**. *(See TDR, March 11, 2002.)* Because of this and other business developments, by the early summer, Cytyc's share price was declining precipitously. From a 12-month high of

$28.00, it has traded in recent weeks in the $12.00 range.

Cytyc reported that fourth quarter 2002 revenues increased by 5%, to $66.7 million. For the full year, its revenues totaled $236.5 million, a growth rate of 7.0% over 2001's revenues of $221.0 million. This is a much slower rate of revenue growth than in recent years.

These numbers reflect the fact that market share of ThinPrep in the United States is reaching a mature stage. In past quarters, Cytyc's public earnings statements trumpeted the growth in market share for ThinPrep. That information was conspicuously absent in its press release covering fourth quarter and year-end financial performance.

Another element in the slowing rate of growth for Cytyc and its ThinPrep product may be competition. **TriPath Imaging, Inc.'s** SurePath™ liquid preparation test is quietly winning new laboratory customers.

One interesting development in the marketplace may also be a quiet revolt by Cytyc's laboratory customers against certain of its business practices. Now that there is a credible choice of liquid preparation products, some of Cytyc's laboratory customers may be voting with their feet when contracts come up for renewal.

MYRIAD GENETICS SEES INCREASE IN REVENUES FROM PREDICTIVE TESTING

DIRECT-TO-CONSUMER MARKETING of predictive genetic testing is causing revenue to climb at **Myriad Genetics, Inc.**, based in Salt Lake City, Utah.

For the quarter ending in December 2002, Myriad's total revenues increased to $17.0 million, a gain of 26%. Of greater interest to laboratorians, however, is the company's sales of predictive genetics tests. Myriad says that revenues from predictive genetics increased by 28.1% for the quarter, from last year's $6.4 million to this year's $8.2 million. For the most recent six months, predictive genetics revenues increased from $11.9 million to $16.0 million, a 34.4% jump.

Myriad is at the tail end of a five-month marketing test. Since September, the company has run direct-to-consumer ads in the Atlanta and Denver markets to raise consumer awareness of its BRCAnalysis® test, a genetic-based assay which identifies patients at high risk for breast or ovarian cancer.

However, the additional expenses of the advertising campaign, along with increased spending to upgrade gene analysis equipment in its research arm, caused Myriad Genetics to report a loss of $6.9 million for the quarter.

CLMA, BAYER DEVELOP LAB MANAGEMENT PROGRAM AT NOTRE DAME

IT'S LONG OVERDUE and its underpublicized. On April 6-10, 2003, **Bayer Diagnostics** and the **Clinical Laboratory Management Association** (CLMA) will conduct the second "Bayer Diagnostics Management Program" at the **University of Notre Dame** in South Bend, Indiana.

This five-day program is designed to provide "a core base of business skills" to diagnostic healthcare professionals. Bayer and CLMA conducted the first program last November. Response was significant, so the decision was made to repeat the program this April.

THE DARK REPORT has often suggested that a university-based, executive-in-residence training program would help technically-trained laboratory administrators add business and management skills to their scientific training. Our hat is off to Bayer and CLMA for undertaking this project. TDR

Dark Index

Quest Ready To Move On Unilab, Announces Its 2002 Earnings

Nation's largest laboratory company expects to close the long-delayed Unilab acquisition

PERSISTENCE IS ABOUT TO PAY OFF for **Quest Diagnostics Incorporated**. After ten months of effort, it expects to finalize its acquisition of **Unilab Corporation** within weeks.

But the Unilab acquisition soon to close looks different than the acquisition that was originally announced by the two companies back on April 4, 2002. At that time, Quest Diagnostics was to pay approximately $900 million in stock and cash. It would also assume $200 million of Unilab debt, giving the deal a total value of almost $1.1 billion. *(See TDR, April 22, 2002.)*

The months since last April proved expensive to Unilab and its shareholders. Because of a decline in the value of Quest's stock and a $83 million downward adjustment in the purchase price, it is now calculated that Quest Diagnostics will pay about $673 million in cash and stock, plus the assumption of the $200 million in Unilab debt.

Antitrust Issues

The deal was delayed once it became known that the **Federal Trade Commission** (FTC) had concerns about aspects of the transaction it believed would violate antitrust laws and regulations. In particular, the FTC seemed most concerned that, after acquiring Unilab, Quest Diagnostics' would have no significant laboratory competitors in Northern California. To allay the FTC's concerns, Quest Diagnostics shopped a package of laboratory assets it currently holds in Northern California to likely buyers during October and November.

On February 4, 2003, it was announced that **Laboratory Corporation of America** would be the purchaser of these assets. Although speculation was rampant that Quest had offered its laboratory in Dublin, California for sale, that lab was not in the package of assets that LabCorp purchased. LabCorp is paying $4.5 million and the sale will be consumated after Quest Diagnostics closes its acquisition of Unilab.

Northern California Assets

LabCorp is buying leases on 41 patient service centers and five rapid response laboratories. It is also buying laboratory testing contracts that Quest Diagnostics currently holds with four IPAs (independent physician associations). Quest Diagnostics has noted that these four contracts represent approximately $27 million in revenues, attributable to capitated fees and related fee-for-service testing sourced from the IPA physicians. The IPAs have consented to the assignment of the contracts.

At this time, the FTC has not completed its review of the Quest/Unilab transaction nor the asset sale to LabCorp. However, executives at

Quest Diagnostics must be optimistic that these arrangements will pass FTC review and allow it to close both transactions. On the same day it announced the asset sale to LabCorp, it commenced a cash tender offer for $101 million of Unilab's subordinated notes that bear an interest rate of 12.75%.

Strong Numbers For 2002

Although Quest Diagnostics had wanted the Unilab acquisition to close during 2002, its financial performance for the year was still strong. On January 23, 2003, the company released its earnings report for fourth quarter 2002 and the full year.

For the year, Quest Diagnostics' revenue grew 13.2%, to $4.1 billion. During Q4, revenue grew 13.5% over fourth quarter 2002, totalling $1.033 billion. Quest noted that revenue per requisition was up 3.4% for the year.

There are interesting statistics which reflect the company's strategic priorities. Quest Diagnostics reduced its days sales outstanding (DSO) to 49 days, compared to 54 days at the end of 2001. That reduction in DSOs reduced its accounts recievables balances by $54 million during fourth quarter.

Reductions In Bad Debt

Quest Diagnostics also improved its bad debt performance. At the end of 2002, its bad debt ratio stood at 5.1% of net revenue, compared to 5.8% at year end 2001. That represents increased collections of almost $29 million for the year, certainly a good payback for efforts to reduce and control write-offs from uncollectable bills.

In comments to the investment community, Chairman and CEO Kenneth Freeman observed that, during 2002, Quest Diagnostics had fully repaid the $475 million it had borrowed to acquire **American Medical Laboratories** and finished the year with cash of $93 million. It's an indication that the integration of AML with Quest Diagnostics has proceeded at least as well as expected.

Four Business Strategies

Also discussed with Wall Street analysts were Quest Diagnostics' strategic plans. Freeman outlined four basic strategies the company is pursuing.

First, it is improving customer service. Its company-wide Six Sigma program is a major tool used to raise performance levels. Quest keeps score by surveying customers each year. It disclosed that, during 2002, all its laboratory divisions showed improvement over the previous year, as measured by the company's customer service index.

Will Quest Diagnostics Ever Bid For AmeriPath?

THERE'S A QUICK ANSWER TO THAT QUESTION. Quest Diagnostics already has!

AmeriPath, Inc., headquartered in Riviera Beach, Florida, is the single largest laboratory company remaining in the United States that could be considered an acquisition candidate for either of the two blood brothers.

THE DARK REPORT knows that Quest Diagnostics seriously looked at acquiring AmeriPath during the past two years. Word is, however, that the price Quest offered at that time was not enough to trigger a sale.

Currently AmeriPath is being taken private by **Welsh, Carson, Anderson and Stowe**, an equity investment firm. However, most knowledgeable observers believe this transaction is simply to position the company for an eventual sale to either Quest Diagnostics Incorporated or Laboratory Corporation of America.

Will that happen? During recent public presentations, whenever Quest Diagnostics Chairman and CEO Kenneth Freeman is asked if Quest is interested in buying AmeriPath, the answer to the question is always "no comment!" Stay tuned, because there's probably another chapter to come in the Quest/AmeriPath story.

Second, Quest Diagnostics intends to pursue selective acquisitions. It will also build new laboratory infrastructure in areas of the country where it currently has a minimal presence. Freeman specifically indicated that expansion in the Southern United States would occur.

Third, it is concentrating on building revenues from new diagnostic technologies. In particular, Freeman said that prospects in cardiovascular testing looked good. Demand for such assays as C-Reactive Protein is increasing and the company's volume of homocystine testing increased 50% during 2002.

More Use Of The Web

Fourth is electronic connectivity. Quest Diagnostics is working to move its clients onto its latest generation of streamlined lab test ordering and resulting. It says that, for fourth quarter 2002, 10% of all its test orders were placed electronically and 15% of its lab test reports were distributed electronically.

Lab executives and pathologists should pay close attention to this last item. One major priority inside of Quest Diagnostics over the last three years has been to reduce DSOs and drive down the bad debt percentage. As most veteran laboratorians know, the single biggest source of uncollectable claims is inaccurate information provided at the time that tests are ordered.

Not surprisingly, Quest Diagnostics has realized that modest investments in changing the way lab tests are ordered by clients can lead to big payoffs in billing and collections. One way to improve the quality of the information contained in lab test requisitions to shift the ordering process onto a computer (which requires all necessary fields to be completed before the ordering client can transmit the lab test order). As noted earlier on Page 16, during 2002, Quest's lower bad debt percentage meant it collected an extra $29 million on the same base of business. Savings of that magnitude finance a lot of improvements to the billing and collections process!

Need For Phlebotomists

Another point of interest is the observation by Quest Diagnostics that growing numbers of physicians are declining to draw blood in their offices. As a result, Quest is seeing greater traffic in its patient service centers (PSC) and is hiring more phlebotomists to meet this demand. Approximately one-third of all the test requisitions handled by Quest Diagnostics pass through its network of PSCs.

Because 2002 is the last year that Quest Diagnostics and LabCorp have sizeable public laboratory competitors in the physicians' office marketplace, it will be useful to compare their financial performance during 2003 with earlier years. The disappearance of major national and regional competitors such as American Medical Laboratories, **Dynacare**, **DIANON Systems**, and, soon Unilab, during the past 14 months has to trigger changes in the competitive marketplace that benefit the two blood brothers.

Shift In Acquisition Activity

Among the consequences of this most recent wave of commercial lab consolidation will be more aggressive attempts by Quest Diagnostics and LabCorp to purchase hospital laboratory outreach programs. THE DARK REPORT has noted many times on these pages that privately-owned, independent commercial lab companies serving the physician office market are few enough in number as to almost be extinct.

Also on the competitive radar screen is anatomic pathology. In their incessant thirst for more specimens and revenues, the two blood brothers will be actively looking to build their market share of anatomic pathology. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

IMPATH, Inc. has replaced its long-time Chairman and CEO in the wake of a scandal involving expense accounts. The resignation of Anu D. Saad, Ph.D., was accepted and became effective today. In her place, IMPATH named Carter H. Eckert, an existing Director, as the new Chairman and CEO. IMPATH had conducted an accounting review of expenses submitted by Saad during the past three years. The audit revealed a "lapse of corporate integrity." Saad will be repaying $250,000 to IMPATH, but company officials refused to provide details in this matter. This scandal is another blow to the reputation of IMPATH, which has faced scrutiny over some of its financial and billing practices in recent years.

Kudos to Managing Director Douglas Buchanan and his team at **BC Biomedical Laboratories** of Surrey, British Columbia. The company was recently selected as the number one company on *The Globe and Mail's* "Fifty Best Companies to Work For in Canada" list. Last year the company placed number eight.

INK JET PRINTERS USED TO CREATE LIVING TISSUES

Here's where two unrelated technologies collide and create a paradigm-shifting capability. Researchers at **Clemson University** and the **Medical College of South Carolina** (MCSC) are using modified ink jet printers to create three-dimensional tubes of living tissue. Ink cartridges are cleaned, then refilled with suspensions of cells. Software which controls the viscosity, temperature and electrical resistance of the printer is modified, as is the feed systems. The printer will then lay down alternating layers of a thermo-reversible gel and living cells. These thin layers fuse together, creating three dimensional structures of living tissue. Hamster ovary cells have been successfully used in these experiments.

MORE ON: *Tissues*

Researchers Vladimir Mironov of MCSC and Thomas Boland of Clemson believe this method can eventually lead to the capability of creating complex tissues, even organs. The key challenge in tissue-engineering of solid organs is how to supply ample oxygen and the nutrients required to keep all the cells alive.

Doctor's Laboratory in Valdosta, Georgia just completed its audit to qualify for ISO-9000:2000 certification. Doctor's Laboratory is one of the larger independent commercial laboratories still operating and earned its ISO-9000 certification in the fall of 2001.

Might laboratory medicine have more clout in Great Britain than in the United States? During the *Frontiers in Laboratory Medicine* meeting in London, England last week, Michael Hallworth, Chairman of the **Association of Biochemists**, had to leave the proceedings for several hours to attend a reception for healthcare professionals held at No. 10 Downing Street. Tony Blair, Britain's Prime Minister, was the host and Hallworth had the opportunity to speak to him and put in a good word for laboratory testing.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, March 3, 2003

PREVIEW #2

EXECUTIVE WAR COLLEGE

May 6-7, 2003 • Astor Crowne Plaza Hotel • New Orleans

Disease Management Programs Come of Age

By the end of 2003, it is predicted that 30% of America's largest corporations will be funding disease management programs as part of their health benefits. In a *War College* exclusive, the President of the Disease Management Association of America will share the details of how this fast-growing aspect of healthcare operates. Learn how diagnostic testing plays a role in disease management programs.

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

UPCOMING...

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- ***Untold Story of Pathology Group Practice Marketing Success: Why Physicians Responded.***

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