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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Is There A Power Shift in Pathology?

SINCE THE END OF WORLD WAR II, the dominant practice model for the pathology profession has been the private group practice. Outside of academia and a few other settings, the vast majority of pathologists practiced laboratory medicine as physician-partners in a medical group.

During this same period, the pathology profession's major defender was the **College of American Pathologists** (CAP). As the specialty association representing pathologists, CAP has been the first line of defense against threats to the scope of practice, professional compensation, and onerous regulation of laboratory medicine. For many decades, the pathology profession has generally prospered under this arrangement. But today, we may be seeing a power shift within the pathology services marketplace.

Consider this: **Quest Diagnostics Incorporated** has more than 500 pathologist-employees. **Laboratory Corporation of America** and **AmeriPath Inc.** each have more than 400 pathologist-employees. Now that Quest is about to acquire AmeriPath, the pathology profession may be reaching a tipping point. Just two companies will employ 10% of the 13,000 members of CAP.

Over the years, national labs have invested in sales and marketing to capture additional specimens from office-based physicians at the expense of private pathology groups. National labs also invest in information systems required to manage the managed care contracting data needed to expand in a changing market. In other words, these large companies are investing in three specific areas: sales, information systems, and managed care contracting expertise.

In contrast, private pathology groups typically defer or fail to invest in these three areas. By failing to invest in the future of their own businesses, many private pathology groups have seen continual erosion of market share in their communities. All the while, national labs invest to support growth in their specimen volume and revenue.

Now here's the irony. Employee pathologists at national labs are often paid a salary and a production incentive. National labs take the difference between professional fees collected and pathologist compensation paid and invest it back in building their businesses. Private practice pathologists, if they were similarly willing to take reasonable compensation and invest the group's additional earnings back into their businesses, might well have growing practice revenues that generate larger partner incomes in the coming years. TDR

Quest Bites: Will Pay $2 Billion for AmeriPath

AmeriPath's tires have been kicked by a host of buyers, so why Quest and why now?

CEO SUMMARY: From its inception in the mid-1990s as a pathology physician practice management (PPM) company, AmeriPath was a business that its investors created specifically to be sold. Now Quest Diagnostics Incorporated is stepping up to pay a princely ransom of $2 billion to make AmeriPath's ultimate destiny become a reality. However, after the marriage, it is likely that neither the bride nor the groom will live happily ever after.

IT'S THE LABORATORY INDUSTRY'S SINGLE BIGGEST ACQUISITION EVER—in terms of dollars—and it's an acquisition that will bring the buyer several migraine headaches.

Last week, on Monday, April 16, **Quest Diagnostics Incorporated** announced that it had signed an agreement to acquire **AmeriPath, Inc.**, of Palm Beach Gardens, Florida. Quest Diagnostics will pay $2 billion, consisting of $1.23 billion in cash and assumption of $770 million in debt.

This is a record-breaking deal in the laboratory industry. The previous high price paid for a laboratory company was Quest's acquisition of **SmithKline Beecham Clinical Laboratories** (SBCL) in 1999. It paid $1.27 billion and gained annual revenues of approximately $1.05 billion. That deal also pushed Quest Diagnostic's total revenues to more than $3 billion and cemented its dominance of the lab testing market—a dominance it has maintained over the past eight years. *(See TDR, February 22, 1999.)*

Now, for $2 billion, Quest Diagnostics will get AmeriPath's "annualized revenues in excess of $800 million." That is a premium price, at 2.5 times annual revenue. In contrast, it purchased the better quality assets and revenue stream of SBCL for just 1.3 times annual revenue.

But that was 1999 and the commercial lab sector was still recovering financially from its near-death experience. In 2007, genetic medicine is hot and prices for both *in vitro* diagnostics (IVD) companies and specialized lab testing firms have been bid to record levels.

Ironically, Quest Diagnostics could have had AmeriPath for a lot less money. Since 2000, both Quest and **Laboratory Corporation of America** have kicked

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AmeriPath's tires and declined to do a deal, at valuations significantly less than the current transaction.

Much-Shopped Company

Since its founding in the mid-1990s, AmeriPath has been a much-shopped company. As one business-minded pathologist told THE DARK REPORT after learning the news about the acquisition, "AmeriPath is a dog that's been kicked plenty of times," he said, then adding, "If AmeriPath is a pathology company with such good prospects that Quest will pay $2 billion today, why didn't Quest buy it for less in recent years?"

On Wall Street, the answer to that question is more pragmatic. In recent weeks, persistent rumors surfaced that private equity investors were preparing to make a run at Quest Diagnostics. The rumors were credible enough that Quest's share price had been bid up by 5% in just a few days (representing a $500 million increase in market capitalization).

To avoid being purchased and taken private by these private equity companies, the executive team grabbed the deal with AmeriPath. The high price—$2 billion for only $800 million in annual revenues—was similar to a "poison pill" takeover defense. Investors, recognizing that the AmeriPath deal would discourage private equity takeover attempts of Quest Diagnostics, allowed the company's share prices to decline by 5% almost immediately after news of the deal became public.

Takeover Rumors Now Moot

Whether rumors of a pending takeover offer by private equity investors were true or not is now moot. Following due diligence, Quest Diagnostics Incorporated is likely to own AmeriPath by June 30. When that happens, attention will shift to how this deal is likely to alter the national marketplace for both anatomic pathology services and hospital send-out testing.

That's because AmeriPath is composed of three primary lines of business. Each of these three business segments presents Quest Diagnostics with a unique set of challenges and opportunities.

Probably the single most attractive asset AmeriPath holds is its dermatopathology division. As of the end of 2006, AmeriPath employed 84 dermatopathologists, most of whom are office-based and serving the outpatient and outreach market. Dermatopathology has produced sustained growth and ample profits for AmeriPath. It is likely that Quest Diagnostics will integrate this business division into its company with few major problems.

Hospital Send-Out Testing

The second recognizable division at Ameripath is **Specialty Laboratories**, which provides reference and esoteric testing to hospitals and similar clients. It paid approximately $334 million to acquire Specialty in January 2006. *(See TDR, October 3, 2005.)* Specialty had revenues of approximately $160 million during 2005.

Integrating Specialty Laboratories into the Quest Diagnostics network presents some interesting problems. For example, Specialty Labs could be left as is and run as an independent business unit. However, it is known that Specialty Laboratories has struggled financially, for at least two reasons. First, it has the overhead of the large laboratory facility it opened in Valencia, California, a few years ago.

Second, profit margins on hospital send-out testing have declined significantly in recent years. This is a result of intense sales competition by national lab companies. Meager profit margins on lab testing generated from new reference accounts has made it tough for Specialty Laboratories to cover its overhead and deliver ample profits to its owners.

As the new owner of Specialty Laboratories, Quest Diagnostics will have the same problem: how to generate adequate profit margins, given the revenue mix from customers and existing overhead.

It has been suggested that Quest Diagnostics, with its national esoteric testing center at **Quest Nichols Institute** in San Juan Capistrano, California, has a ready-made opportunity to consolidate testing. However, the limitations will be capacity issues at both laboratory locations, transportation logistics (because these labs are about 100 miles apart), and the need to retain skilled technical staff to perform the complex menu of reference and esoteric tests.

On the other hand, Quest Diagnostics has a large national network of laboratory facilities. That may allow it to redirect Specialty's flow of specimens away from the lab in Valencia, to be tested in other Quest facilities. That would allow Quest Diagnostics to eliminate much of the overhead that now exists in Valencia.

Another challenge will come in retaining the hospital clients now using Specialty Laboratories. A substantial number of these hospital laboratories do not want to refer their send-out work to a national laboratory which is competing against them for routine specimens coming from physicians' offices in their community.

Hanging On To Customers

Quest Diagnostics already has first-hand experience with this situation. In the years following its 1999 acquisition of SmithKline Beecham Clinical Laboratories, it lost as many as 400 of SBCL's hospital send-out clients—many of whom had switched to **American Medical Laboratories** (AML). In 2002, after purchasing AML, Quest Diagnostics found itself working once again to retain many of these same customers.

AmeriPath's third business segment involves inpatient, outpatient, and outreach anatomic pathology services. Since its inception, AmeriPath has purchased 67 laboratories and pathology practices. It now operates 40 outpatient laboratories in 19 states. It is "the exclusive provider of inpatient diagnostic anatomic pathology and medical director services for approximately 220 hospitals." As of December 31, 2006, AmeriPath employed a total of 392 pathologists and scientists (including 84 dermatopathologists).

It is this business segment which presents the most intractable challenges to Quest following the acquisition. Simply put, AmeriPath has been the owner/operator of pathology group practices that serve community hospitals. AmeriPath has found it difficult to expand the specimen volume and revenue of these hospital-based pathology groups.

Another significant issue involves managing the productivity and morale of

Up, Up, and Away! Lab Prices Are Soaring

DURING THE PAST YEAR, prices paid for clinical laboratory companies, *in vitro* diagnostics (IVD) manufacturers, and molecular pathology companies have set new benchmarks.

This is good news for owners of clinical laboratories and pathology laboratories. It is also a major validation of the economic future of laboratory medicine.

The $2 billion purchase price Quest Diagnostics Incorporated will pay to acquire AmeriPath is the most money ever paid for a company that provides diagnostic testing services to clinicians. AmeriPath's revenues through December 31, 2006, were $752.3 million. Income from operations was $79.9 million. Based on these numbers, Quest is paying 2.5 times annual revenue and 25 times cash flow.

During 2006, AmeriPath reported that 70.7% of its revenues came from "outpatient and esoteric" sources. The balance, 29.3%, came from inpatient sources. This suggests inpatient pathology revenues from AmeriPath's hospital-based group practices represented $220.4 million during the year.

employee-pathologists working in these hospitals. AmeriPath says the turnover rate of its pathologist-employees has run just under 10% per year from 2004 through 2006. Quest Diagnostics will inherit this management challenge.

AmeriPath says the turnover rate of its pathologist-employees has run just under 10% per year from 2004 through 2006.

Morale may be a big issue. Across the pathology profession, AmeriPath pathologists have told their peers that, at the annual AmeriPath pathologist meeting of two years ago, and then again this January, they were told, most emphatically, that AmeriPath would never be sold to either Quest Diagnostics or **Laboratory Corporation of America**. Those statements were reported to have been made by Paul Queally, an AmeriPath Director and a General Partner at **Welsh, Carson, Anderson & Stowe**, the majority owner of AmeriPath.

Assuming these anecdotes are true, it shows the tension that exists between AmeriPath and its employee-pathologists. In fact, there are reports that some of AmeriPath's pathologists have contract clauses that reduce the non-compete periods from two years down to one year if AmeriPath is sold to either of the two blood brothers.

Unanswered Question

There's another unanswered question that Quest Diagnostics faces once it becomes the owner of AmeriPath. Will any hospitals currently served by AmeriPath's pathologists decide that, if Quest is the new owner, they want to redirect their pathology services to another source?

The change of ownership is most likely to concern hospitals that operate laboratory outreach programs and compete against Quest Diagnostics for test referrals from office-based physicians in their local communities.

It is common for contracts between a community hospital and its pathology group to have a 90-day cancellation clause. This gives the hospital some leverage in such situations where the hospital administration decides it doesn't want a pathology group owned by Quest Diagnostics to be handling its anatomic pathology services and acting as medical director of its clinical laboratory.

Since it has evaluated AmeriPath more than once over the years, it is likely that Quest Diagnostics has identified the full spectrum of challenges facing it once the deal is closed. Thus, it should not be surprised at the variety of issues which surface. Because it has experience at integrating large laboratory operations, such as SBCL and **Unilab Corporation** (its acquisition in California in 2003), Quest may be confident that it can address these issues without much difficulty.

Raising The Stakes

What raises the stakes with this particular acquisition is the large premium Quest is willing to pay. That increases the difficulty of achieving an impressive return on investment. For example, rumors circulated that, once they got into the day-to-day operations after purchasing Specialty Labs (and paying $334 million for its $160 million or so in annual revenues), AmeriPath's executives calculated that, at current operational performance, it would take the Specialty Labs division more than 20 years to generate a return on investment (ROI).

Now Quest Diagnostics has raised that bar even higher on themselves. It is paying a proportionally higher price for AmeriPath (and Specialty Labs). That means it must swiftly and effectively boost the performance of AmeriPath's three business sectors. Further, since the core of AmeriPath's business is its 400 employee-pathologists, keeping these individuals happy and productive is likely to be the first priority. TDR

FDA Sends Warning Letter To Abbott Laboratories

Products manufactured in Irving, Texas, have not met FDA's CGMP guidelines

CEO SUMMARY: On March 13, 2007, the Food and Drug Administration sent a warning letter to Abbott Laboratories' Chairman and CEO, Miles D. White. The letter identified nine quality system violations and requested a satisfactory response by August 15, 2007. The warning letter is based on deficiencies identified by FDA inspectors at Abbott's manufacturing facility in Irving, Texas, during the period October 30 to November 17, 2006.

IN THE DELICATE DANCE between regulators and the companies they regulate, the clinical laboratory industry has become aware of new issues unfolding between the **United States Food and Drug Administration** (FDA) and the diagnostics unit of **Abbott Laboratories, Inc.** of Abbott Park, Illinois.

Last month, the FDA posted a letter, dated March 13, 2007, on its Web site. Addressed to Abbott's Chairman and CEO, Miles D. White, the letter requests specific responses to deficiencies identified during inspections it conducted of Abbott's Irving, Texas, manufacturing plant. These inspections took place between October 30, 2006, and November 17, 2006. (The warning letter can be found at *http://www.fda.gov/foi/warning_letters/b6291d.htm.*)

Chemistry Analyzers

Abbott manufactures and assembles several different models of chemistry instruments and immunoassay analyzers at its facility in Irving. The March 13 warning letter was issued after a series of letters and meetings between officials from the FDA and executives of Abbott Laboratories in recent months. In the letter, the FDA lists nine quality system violations.

The *Chicago Tribune* and news outlets including **Reuters** and **AP** reported on the FDA warning letter. Wall Street seems to be taking a "wait and see" stance. Brian McKaig, an official at **General Electric Healthcare**, which is about to acquire most of the diagnostics business of Abbott Laboratories, told reporters that GE continues to believe the acquisition will be completed before mid-year. McKaig also noted that "this is Abbott's issue to resolve and GE Healthcare is being kept informed."

News of this most recent FDA warning letter has come to the attention of a growing number of lab directors and pathologists. It reminds them of Abbott's earlier issues with the FDA. In 2000, as a result of quality system deficiencies in the manufacture of reagents and test kits, the FDA took the extreme step of directing Abbott Laboratories to cease selling more than 120 different assays.

WIthdrawal of these products from the market caused consternation across the laboratory industry. Individual labs

scrambled to find alternatives for those Abbott assays they used in their labs, but which were now no longer available. Not until 2003 was Abbott able to satisfy the FDA and restart the sales of many of these assays. That is why, having lived through this experience once before, some laboratory managers say they will closely watch how the diagnostics division of Abbott responds to the FDA's warning letter.

Abbott's Acknowledgement

In a public statement, Abbot Laboratories acknowledged that it was working with the FDA. "We take questions about our quality processes very seriously," stated Kelly A. Morrison, Director, External Communications and Corporate Public Affairs. "Abbott has already taken a number of steps to address the issues outlined in the letter since the initial general inspection, and has communicated those specific actions to the FDA in writing. We are in the process of responding to the FDA with an updated action plan to address their outstanding concerns as quickly as possible."

In its March 13 letter, the FDA stated "the Agency is not satisfied with the pace and the results of your firm's past corrective actions as they have not been effectively, timely, and globally implemented for your entire family of analyzers." The FDA requests that Abbott engage outside experts to evaluate the situation. It also asks Abbott to respond, by August 15, 2007, with evidence that the issues have been resolved.

FDA Requests Action

The FDA noted that it is "not satisfied" with Abbott's progress on resolving the current issues. It then stated that "failure to promptly correct these violations may result in regulatory action being initiated." Actions available to the FDA include seizure, legal injunction, or civil penalties.

Based on its inspections of the Irving facility's manufacturing and assembly processes for automated chemistry and immunoassay analyzers, the FDA also declared that, per federal law, these instrument systems were "adulterated...in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Your devices are also misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), because your firm submitted several late MDR reports."

The FDA's letter describes nine specific "quality system violations." These center around inadequate actions taken at the Irving facility to correct quality and performance issues affecting the instrument systems manufactured or assembled there.

"DOA" Analyzer Reporting

In quality system violation #2, the FDA letter states, "Your firm's management failed to review all quality sources and take appropriate corrective actions to address various quality issues or document their adequate justification for not taking corrective actions. For example, your Dallas ADD's site management used a 'dollar value' as the alert level for part replacements as a measure of malfunctions of the analyzers upon installation at their user sites to determine whether or not to further evaluate, conduct investigations, or take actions to address potential quality issues with your analyzers. If the cost of the replacement parts or 'bad installs' did not exceed a 'dollar' alert level, there was no investigation conducted. See your firm's Quality Metrics Report 'The Installation and Performance Metrics for the c8000, i2000, i2000SR analyzers' that characterized that a number of the analyzers were found DOA (dead on arrival) upon installation in each month from 10/2004 through 9/2006."

One conclusion that can be made from reading the nine quality system violations

Abbott Tracked "Arrive Alive" & "DOA" Instruments At Time of Installation in Customers' Laboratories

THERE'S A GENERAL ASSUMPTION in the laboratory industry. It is understood that, when a laboratory customer pays several hundred thousand dollars for a brand-new analyzer, that analyzer should arrive at the lab, be uncrated, and operate properly from the start, after the normal tweaks and attention necessary to bring it up into full operation.

Abbott Laboratories was measuring its success or failure at delivery and installation in its customer's laboratories by using monitors it called "DOA", for "dead on arrival" and "Arrive Alive." In its March 13 warning letter to Abbott, the Food and Drug Administration (FDA) called attention to this situation in item six under the section titled "Quality System Failures."

The FDA wrote about the "failure to establish and maintain adequate procedure for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria prior to releasing the devices for distribution, as required by 21 C.F.R. §820-80(d). Your factory testing failed to adequately detect and reject defective device components, including the pressure monitors and pumps, and nonconforming device functions prior to releasing the analyzers for site installation. According to your firm's DD005 Metrics Report for the period of November 2004 through October 2006, many analyzers were characterized as 'bad installs' at the user sites and their components had to be replaced. For example, this report stated that in April 2005, out of the [redacted] installations of the i2000SR analyzers, [redacted] analyzers were 'Dead On Arrival' and that the 'Arrive Alive' percentage was 76%."

Although the FDA redacted the actual number of analyzers installed in the month of April 2005 in the public release of the May 13 letter, it did leave the reference to the fact that 76% of the delivered analyzers "arrived alive." Therefore, during this particular month, one in four analyzers that Abbott delivered to customer laboratories failed to function at install on site, according to the company's quality and performance specifications.

is that the FDA was concerned that Abbott was aware that specific components of these instruments did not meet specifications, yet, over the 24 months that preceded the FDA's 2006 inspection, Abbott had not taken successful actions to correct this situation.

At this point, the FDA's March 13 letter puts Abbott Laboratories on notice that its Irving, Texas, facility has failed to meet quality system standards. The letter asks Abbott to do two things. First, the company is requested to provide information about the corrective actions it will take to address the deficiencies in performance to its quality system guidelines.

Second, the FDA asked Abbott Laboratories to submit "certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device's QS regulation (21 C.F.R Part 820) and the MDR regulations (21 C.F.R. Part 803). Deadline for submitting certification to the FDA of the outside audit is August 15, 2007."

Watching FDA's Next Move

To date, financial analysts have shown little concern over this matter with the FDA. Wall Street investors continue to support the current share price of Abbott Laboratories. Meanwhile, General Electric continues to move forward with its acquisition of Abbott's diagnostics business. Similarly, when laboratory managers and pathologists first learn about the FDA's March 13 warning letter, there is more curiosity about this issue than concern. TDR

NEWSMAKER INTERVIEW

Why Labs Will Increase Their Use of Middleware and Informatics

"Across the globe, laboratories face similar and significant challenges in how they use information technology and middleware to solve problems."

—Jacques Baudin, *Executive Vice President, Technidata America Medical Software*

CEO Summary: Middleware seems to be all the rage across the laboratory industry these days. Many lab organizations now use software provided by multiple vendors. One of the newest players in this market is Technidata America Medical Software LLC, based in Tucson, Arizona. But Technidata is not a new company. Its roots go back to the earliest days of laboratory information systems (LIS) in Europe in the late 1970s. Its parent company, headquartered in Grenoble, France, serves 700+ laboratories in 25 countries worldwide with installed laboratory information systems. No American healthcare IT company can match this installed LIS base globally. That is why THE DARK REPORT's Editor-in-Chief, Robert L. Michel, caught up with Technidata America's Executive Vice President and General Manager, Jaques Baudin. Baudin's global experience with laboratory software provides plenty of useful insights about how American labs are likely to utilize software in coming years.

Part One of Two Parts

EDITOR: Because of Technidata's years of experience providing LIS and software solutions to laboratories in France and 24 other countries worldwide, it has a perspective on healthcare information technology (IT) that is markedly different than most health IT companies in the United States. To help our readers understand your different corporate approach and business strategies, I would like to explore three general themes during our conversation.

BAUDIN: What would those be?

EDITOR: First is for you to share your views about how healthcare is evolving. That will be particularly interesting because you work with laboratories in Europe, North America, and the Pacific Rim. Second, we can discuss specific trends and market forces you now see changing how laboratories are organized and how they serve clinicians. That will set up our third theme, which is to explore the informatics strategies Technidata is developing to provide laboratories with middleware solutions that support their success at meeting the changing needs of clinicians and the healthcare systems they serve.

BAUDIN: That is an ambitious roadmap for this interview. It means we have a lot of ground to cover.

EDITOR: Then let's get started. How does Technidata see healthcare changing during the next few years?

BAUDIN: Probably the single most important change will be the growing use of genetic testing and genetic therapies. The increased knowledge that clinicians gain from genetic and molecular tests will shift healthcare away from its traditional emphasis on firefighting and move it more into a preventative mode. In fact, genetic knowledge is likely to make medicine more predictive.

EDITOR: Does your use of the term "firefighting" describe the longstanding orientation of medicine to respond to acute and episodic events?

BAUDIN: Yes. Today's healthcare system has been organized to intervene when a sick patient shows up at the doctor's office or the hospital. Genetic medicine will allow physicians to shift to preventative medicine. For example, the capability already exists to predict, with a high degree of clinical accuracy, whether some individuals have a high probability of having certain cancers in their lifetime.

EDITOR: How quickly do you think this shift from reactive medicine to proactive medicine will occur?

BAUDIN: One needs a crystal ball to make that prediction. What is indisputable is that genetic knowledge will radically transform most aspects of the healthcare system we have today.

EDITOR: What's another strategic healthcare trend on Technidata's radar screen?

BAUDIN: I will answer that with a question. Why is it that no developed country has yet demonstrated a way to control the ever-increasing cost of healthcare? Whether it's the socialized medicine model seen in Canada, the United Kingdom, and other

European countries or the more market-oriented healthcare system of the United States, no country has yet demonstrated a way to control the increasing cost of care from one year to the next and effectively provide good health care for all.

EDITOR: That is an interesting point. Do you have any ideas or opinions about how cost control might be achieved?

BAUDIN: Bruce Friedman, M.D., Active Emeritus Professor of Pathology at the **University of Michigan**, frequently refers to what he describes as "medical tourism" on his *labsoftnews.com* blog. It's the simple concept of people traveling across borders to be treated in countries where healthcare costs are much lower. I see signs that this is happening.

EDITOR: That's an interesting approach to controlling the cost of healthcare, on a scale large enough to make a difference.

BAUDIN: It's not just rising cost. Growing demand for healthcare services can outstrip the capacity of hospitals and physicians. One solution is to send patients to another country. The examples are easy to see. In my home country of France, for instance, we treat patients from the United Kingdom.

Jacques Baudin

➤"For the laboratory industry, Technidata believes these economically-flush consumers will spend quite a bit of money on proactive diagnostic testing."

EDITOR: We have the same situation in the United States. Certain Canadian provinces refer patients across the border to our doctors and hospitals because they don't have enough resources to provide care in a timely fashion.

BAUDIN: What's important in both these examples is that the health systems of the U.K. and Canada are opting to refer patients to a source of healthcare that shortens the wait time for care and costs less than adding more doctors and hospitals in their own healthcare system.

EDITOR: You make a subtle point. It costs lots of money to expand capacity. Thus, the U.K. and Canada are already practicing medical tourism as a way to shift care to a lower-cost environment.

BAUDIN: Correct. Plus there is another, inter-related trend. Growing numbers of people in Europe and North America are already traveling to Asia to be treated. These examples show how our earth is shrinking and medicine is already in the process of becoming internationalized.

EDITOR: Does this directly affect laboratory testing services?

BAUDIN: Yes. It impacts laboratory medicine on a number of levels.

EDITOR: Please explain.

BAUDIN: First, this creates a need, along with the economic incentive to serve paying customers, for patient data to flow electronically across borders.

EDITOR: That is true.

BAUDIN: Second, it creates the need for a HIPAA-type of solution that is planet-wide.

EDITOR: Is that because privacy and controlled access to patient information are universal concerns?

BAUDIN: Yes. That's why I predict electronic information systems will emerge specifically to support medical tourism.

EDITOR: If medical tourism continues to grow, would that act as a brake on increases to healthcare costs in many developed countries?

BAUDIN: That would be an expected outcome. Elements of this are falling into place. For example, Singapore and Thailand are deliberately developing and expanding their healthcare resources specifically to become an international healthcare service hub.

EDITOR: In your experience, are there other hints of this trend?

BAUDIN: You can see it in the expansion of healthcare accreditation organizations that cross national borders. They see opportunities to enhance their credibility and generate more revenue by going international.

EDITOR: Since you've addressed these planet-wide trends, what observations do you have about healthcare in the United States?

BAUDIN: Wealthy people here will pursue a high quality of life. And wealthy doesn't mean multi-millionaires. There are many, many middle class Americans with the economic capability to spend substantial dollars on things they consider to be life-enhancing.

EDITOR: That's an interesting insight. For example, during the past decade, sales of second homes have skyrocketed. It takes a significant financial commitment for someone to live in one house and buy another, whether for vacation or investment.

BAUDIN: Precisely my point. For the laboratory industry, Technidata believes these economically-flush consumers will spend quite a bit of money on proactive diagnostic testing.

EDITOR: That's consistent with existing trends.

BAUDIN: Remember, this strata of the population—me, included—wants to enhance its quality of life.

EDITOR: As another example, there are already Web sites offering genetic testing directly to consumers. And in a disturbing number of cases, the genetic tests offered by these Web sites lack valid scientific justification.

BAUDIN: There you have the good and the bad that result when consumers have money to spend and are not careful about what they buy.

EDITOR: I am curious as to whether you see patient safety as an important international healthcare trend?

BAUDIN: I do and it is a trend that directly affects laboratory testing services.

EDITOR: Please explain.

BAUDIN: Just about every developed country is actively encouraging its healthcare system to reduce and eliminate errors in patient identification, medication, and the like. What is important to note is that improving patient safety inevitably leads to improvement in outcomes.

EDITOR: Would you explain that?

BAUDIN: Because, as data is collected on medical errors, that same data now makes it possible to measure outcomes. Use of integrated IT solutions, like electronic medical record (EMR) systems, also makes it possible to collect and monitor this data in real time.

EDITOR: THE DARK REPORT has written about this development for several years. When detailed data on outcomes is available in real time, it then becomes possible to rank providers by outcomes and use this data to support pay-for-performance programs.

BAUDIN: I agree with your observations. What is important for our discussion is that most developed countries are making patient safety a priority within their healthcare systems.

EDITOR: This is a good place to shift our discussion and move to contemporary issues in the United States. We can also concentrate on the specific changes that will have the greatest impact on clinical laboratories and anatomic pathology groups.

BAUDIN: What jumps to the top of my list is the drive to adopt EMR systems.

EDITOR: That's interesting. Why do you say that?

BAUDIN: Because EMRs will form the core of healthcare integration. All relevant patient data must electronically flow into the EMR and be readily accessible to the patient's care team.

EDITOR: What should laboratories know about this trend?

BAUDIN: The best answer is that there is no answer...yet! "How" is still the unanswered question.

EDITOR: Give me some "how" examples.

BAUDIN: How will information be normalized to populate EMRs? How will EMRs be standardized in the way they present information to physicians? How will clinical decision support systems develop within EMRs to guide clinicians?

EDITOR: Why do these remain undefined?

BAUDIN: That's a question that dogs healthcare policymakers in every country. You would think that, in countries with nationalized healthcare systems, standardized solutions could be imposed. But that hasn't happened and is not likely to change soon.

EDITOR: What are other obstacles for EMR adoption?

Jacques Baudin

➤"In many settings, laboratories do not have a seat at the table when planning for the enterprise EMR occurs."

BAUDIN: People move all the time. When they do, the continuum of care is broken. That's a second obstacle that awaits an effective solution.

EDITOR: Thus, we have a "Tower of Babel" in healthcare IT, with many different EMR products, but no standardization.

BAUDIN: That is today's status quo. What is needed is a standard setter that can dictate parameters for a country or a large region. Everyone needs to utilize the same standards.

EDITOR: Ah! That is the type of answer that one often gets from information technology experts. Software development needs common standards to provide universal solutions. Any other developments on the medical records front?

BAUDIN: What about our informed, affluent consumer who wants to carry his or her medical record around on a card—or a flash drive? Not only does that shift the medical record away from the hospital or doctor's office, but how does it get accurately updated?

EDITOR: To bring up this point, you must be seeing something already happening in the marketplace.

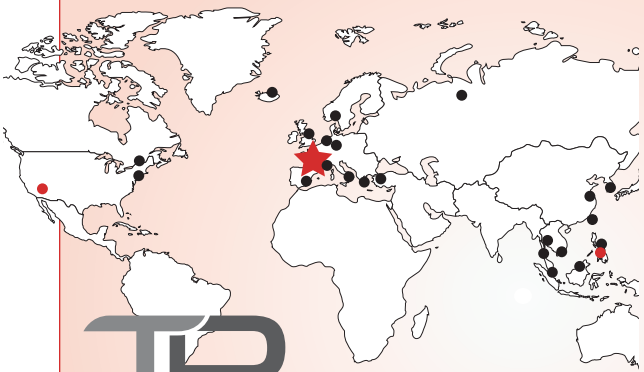
BAUDIN: Definitely. I offer the example of collecting glucose testing numbers. In recent years, there are more efforts to gather this data into the patient record, regardless of whether the testing was done by a lab, in the doctor's office, or as a patient self-test.

EDITOR: Certainly this specific trend impinges upon a traditional role for the clinical laboratory.

BAUDIN: Yes, and that's the reason laboratories should more closely track the efforts of health systems and physician groups to build a full and complete electronic health record for every patient. In many settings, laboratories do not have a seat at the table when planning for the enterprise EMR occurs. I know of one hospital where the laboratory had no role in the EMR project planning and implementation. That hospital is now spending considerable money to patch the laboratory information system (LIS) so it can get the lab test data into the EMR.

EDITOR: Jaques, this is a good place to stop Part One of our two part interview. You have certainly provided some provocative insights about the common themes and trends reshaping healthcare services in developed countries across the globe.

TechniData Builds Global Business in Laboratory Information Systems



●Countries with labs using Technicdata LIS

More than 700 laboratory clients in 25 countries worldwide currently use the laboratory information system (LIS) offered by Technidata Medical Software. Technidata's headquarters is Grenoble, France and it maintains corporate offices in Tucson, Arizona and Manila, Philippines. This map shows the countries where laboratories are using Technidata's LIS.

Technidata At-A-Glance

- **Corporate Headquarters** .....Grenoble, France
- **Corporate Offices** .....Tucson, Arizona
  .....Manila, Phillipines
- **Founded** 1992
- **President & CEO** .....François Falco
- **Executive Vice President** .....Jacques Baudin
- **Installed LIS Systems**.....700
- **Instrument Interfaces** .....450 different analyzers

Technidata's LIS Modules

- General Laboratory
- Microbiology
- Blood banking
- Transplant management
- Histology/Cytology
- Document Management
- Web Results & Requests
- Workstation
- Point-of-Care Testing

BAUDIN: Thank you. Despite the differences in local healthcare practices, the similarities from one country to the next are consistent on major points.

EDITOR: In our next session, I'd like you to discuss the remaining points we set out to cover in this interview. The first is your views about the more practical issues triggered by improvements in healthcare information technology that will alter existing laboratory informatics practices.

BAUDIN: And there are several issues which need a strategic response by individual laboratories.

EDITOR: Our final point is to discuss the third theme of this interview. That theme is Technidata's response to global healthcare trends. How is it reshaping its products and services to support the needs of clinical laboratories in meeting the challenges of both global and regional trends?

BAUDIN: That part of our discussion will be particularly interesting. It will reveal how our strategic analysis of these trends is being translated into different products and services designed to keep laboratories at the forefront of their healthcare community.

EDITOR: Good. That gives us a game plan for part two of this interview. Many thanks for sharing your insights and experiences.

BAUDIN: You are most welcome. TDR

Contact Jacques Baudin at jacques.baudin@technidata-web.com or 520-577-2872.

Joint Venture Launches Molecular Pathology Lab

➤Spectrum Health and Van Andel Institute tap Daniel H. Farkas, Ph.D. to lead effort

➤➤CEO SUMMARY: As genomic medicine advances, researchers into various diseases quickly recognize the need to incorporate molecular pathologists onto their teams. In Grand Rapids, Michigan, a large integrated health system and a private research institute have come together to jointly fund a state-of-the-art molecular pathology laboratory. The twin goals are to advance research and create new assays to offer to clinicians.

ONE OF LABORATORY MEDICINE'S EARLY PIONEERS in molecular pathology and diagnostics has taken a leadership role in a unique new organization. Recently, Daniel H. Farkas, Ph.D., was selected to be Executive Director of the **Center for Molecular Medicine** (CMM) in Grand Rapids, Michigan.

For the laboratory medicine profession, there are several noteworthy aspects about the creation and goals of the **Center for Molecular Medicine.** Its creation demonstrates the important role molecular pathology plays in genomic medicine.

➤Joint Venture Laboratory

First, CMM is a joint venture between two organizations based in Grand Rapids. The partners are **Spectrum Health** (a seven-hospital health system) and the **Van Andel Institute** (a biomedical research laboratory and facility). CMM has $6 million in funding, each party contributing $3 million of that total.

Second, CMM has ambitious goals. Its partners say that the mission "is to offer 21st century molecular technologies for investigation of such complex diseases as cancer, heart disease, mental illness, and other conditions at the DNA, RNA, and protein levels." Expertise in molecular pathology, both in research and in clinical settings, is required. That is why Farkas, who established molecular diagnostics programs at three hospitals over the course of his 20-year career, is heading up CMM.

Third, partnership between Spectrum Health and the Van Andel Institute is another example of a developing trend. The Van Andel Institute is funding primary research, but needs access to a patient population to apply new knowledge in clinical settings. For its part, Spectrum Health provides access to patients. At the same time, it participates in developing cutting-edge medical services that it can offer in its community.

The approach of partnering a research institute with a health system that provides access to large patient populations is gaining favor. **Kaiser Permanente** is one example. Another is **Geisinger Health System**, which founded the **Center for Health Research and Rural Advocacy** to conduct research and create a gene biobank.

Fourth, the Van Andel Institute's decision to invest in a molecular pathology laboratory is a sentinel event for the pathology profession. It is an early example of a family-funded foundation devoting considerable resources in laboratory medicine to advance healthcare knowledge.

Alert readers may recognize the Van Andel name. Jay Van Andel was one of the two founders of **Amway Corporation**, a private company with sales of $6.3 billion last year. Van Andel and his wife, Betty, through their foundation, created the Van Andel Institute in 1996.

Its primary goal is to advance research into cancer and Parkinson's disease and translate scientific research results into clinical applications. As genetic knowledge has advanced during the past decade, it is no surprise that the Van Andel Institute recognized the need to establish a molecular pathology laboratory to support this ongoing research.

To Benefit Clinical Services

"To fulfill the mission of the Van Andel Institute, we must move our findings from the research laboratory to the clinical laboratory," said David Van Andel, Chairman and CEO of the Van Andel Institute. "The Center for Molecular Medicine will allow us to do this in an accelerated fashion and positively impact human health. We have the research expertise and Spectrum Health has a large patient population which allows us to apply what we're learning directly into the clinical setting."

Farkas agreed, saying, "In molecular diagnostics, over the last 20 years or so, we have perfected new gold standards for infectious disease diagnostics, brought many new tests for disease-causing mutations on-line and made great strides in diagnostics and prognostics for cancer, including leukemia, lymphoma, breast cancer, and more. All of these developments and the creation of new technologies have contributed mightily to the incredible growth of molecular diagnostics—to the point where it represents today perhaps 10% of the total *in vitro* diagnostics (IVD) market. That's about $3 billion, where 20 years ago that number was zero."

"CMM accelerates the drive toward personalized medicine—the tailoring of treatment based on molecular make-up," stated Richard C. Breon, President and CEO of Spectrum Health. "We plan to offer physicians and their patients the most advanced diagnostic treatment options available, options typically offered only at the nation's largest academic medical research centers."

Multigenic Development

CMM is embarking on the next generation of molecular diagnostics tests for diseases with multigenic etiologies, Farkas said. "Science completed sequencing of

Farkas Earns Award In Molecular Pathology

On April 3, the **Association for Molecular Pathology** (AMP) revealed that the 2007 winner of its Leadership Award was CMM's Executive Director and AMP's past President, Daniel H. Farkas, Ph.D.

With this recognition, Farkas joins earlier recipients of the Leadership Award. In 2005 the winner was Jeffrey A. Kant, M.D., Ph.D. and in 2006 it was Mark E. Sobel, M.D., Ph.D.

Daniel H. Farkas, Ph.D., HCLD, CLSMB, has established three hospital-based molecular diagnostics laboratories in 20 years in the field. He has headed up molecular diagnostics labs at **Saint Barnabas Medical Center** in Livingston, New Jersey; at William Beaumont Hospital, in Royal Oak, Michigan; and at The Methodist Hospital, in Houston, Texas.

In his career, Farkas has held faculty positions at **Weill Medical College of Cornell University**, **Baylor College of Medicine**, and at William Beaumont Hospital. He is currently an adjunct associate professor at **Michigan State University**.

the human genome in 2003, which marked the beginning of the era of genomic medicine," he noted. "Single gene tests dominated the 1980s, 1990s, and the early part of this decade.

"For researchers, the next challenge is to learn the multigenic causes of complex diseases so that we will be able to diagnose and manage conditions such as solid tumors, diabetes, and neuromuscular diseases more effectively," Farkas continued. "CMM is organized specifically to implement, at the clinical diagnostics level, the fruits of this sort of multigenic research.

New Molecular Tools

"In many ways, developing 21st century molecular diagnostics is visionary," Farkas explained. "The work in this field requires a substantial financial investment. Test volumes for these sorts of tests today are low and may not be sufficient to financially sustain the laboratory immediately. That is because the tests need to establish their worth before clinicians will start ordering them in large numbers.

"Further, reimbursement by insurers at this early stage is sometimes problematic as they gain comfort with the medical necessity of these tests' value," Farkas added. "Nevertheless, the vision of CMM is to offer these assays in a clinical laboratory environment; if we're ahead of our time, we won't be for very long.

"In my work at the **William Beaumont Hospital**, in Royal Oak, Michigan, in the mid-1990s and at **The Methodist Hospital** in Houston, we realized the molecular tools we used in our work would advance remarkably in lock step with new technology," Farkas explained. "We were confident that sequencing of the human genome would open up new areas for diagnostic molecular pathology.

"CMM will make these new tests available to any physician who wishes to use them to manage his or her patients," he said. "Also, as we develop clinically useful diagnostic tests, we will accept specimens from physicians and labs around the country. At the same time, we don't necessarily plan to turn CMM into a full blown or even miniature IVD company. If we develop tests that are not esoteric, and that have significant markets, our inclination is to partner with established IVD companies and provide licenses.

"CMM also wants to offer useful technology to the entire country as opposed to just being a central reference laboratory," Farkas continued. "In that sense, our business plan is more ecumenical than the business plan of a centralized reference lab.

"Clearly, the entire lab industry is moving toward genomics, and so the creation of CMM by the Van Andel Institute and Spectrum Health makes the timing right for this venture," Farkas explained. "Our laboratory is a compelling venue for companies in genomics, pharmaceuticals, and diagnostics to use as a location for clinical trials. We have four critical elements that we can exploit: translational research, hospital resources, biotechnology, and bioinformatics.

Working With Payers

"In addition, we plan to demonstrate to third party payers that the tests we will develop should be reimbursed," he said. "We know what we have to do to demonstrate the clinical relevance of these tests, and we are eager to work with third party payers in Michigan, such as **Blue Cross Blue Shield** and **Priority Health**, and elsewhere in the country. Additionally, clinical testing and clinical trials are revenue opportunities for us."

THE DARK REPORT observes it is particularly noteworthy that a family foundation is funding a laboratory organized around molecular pathology. It demonstrates how the pathology profession is poised to be an essential resource in developing personalized medicine and improving patient outcomes. **TDR**

Contact Daniel Farkas at the CMM at 616-391-4330 or info@cmmdx.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, **Quest Diagnostics Incorporated** released its first quarter earnings, providing a first look at how the battle for **UnitedHealth** patients is unfolding. Revenue of $1.53 billion was down by 1.7%, compared to first quarter 2006 revenue of $1.56 billion. Quest notes that the number of clinical testing requisitions declined by 7.3% during this same period. Of this number, 6% was due to loss of UnitedHealth business and about 1% was due to severe weather.

Bidding War For Biosite

On April 3, **Beckman Coulter, Inc.** (BEC), offered to acquire **Biosite, Inc.**, a biomedical and proteomics company in San Diego, California, for $85 a share. However, just days later, on April 5, **Inverness Medical Innovations, Inc.**, (IMA) of Waltham, Massachusetts, topped the Beckman Coulter bid, offering $90 a share for Biosite. At press time, Biosite was evaluating the offers.

PATHOLOGIST SUES, CLAIMS THREAT FOR WHISTLEBLOWING

Last week, a former pathologist at **Magee-Womens Hospital** in Pittsburgh, Pennsylvania, sued her former supervisor, claiming the supervisor threatened her and retaliated against her for whistleblowing about quality control. According to a story in the *Pittsburgh Tribune Review*, the pathologist, Susan Silver, M.D., filed the lawsuit in Allegheny County Common Pleas Court against Trevor MacPherson, M.D., for one count each of assault and infliction of emotional distress. The former Chief of Pathology at Magee until 2001, MacPherson is the Medical Director of Perinatal Pathology for Magee. He also directs the pathology residency and fellowship program.

ADD TO: Lawsuit

While working at Magee as a staff pathologist, Silver said she observed substandard medical and administrative practices, including inadequate employee supervision and training, frequent patient misidentification and specimen reporting. The **Pittsburgh Tribune Review** reported that, in 2003, Silver sued the hospital, saying thousands of Pap smear results had been falsified, the paper reported. That case is pending. MacPherson declined to comment for the newspaper and William Pietragallo, an attorney who spoke on behalf of the hospital and MacPherson, said MacPherson would be vindicated. He also said the allegations are unfounded

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 14, 2007.

Preview #6

Executive War College

May 10-11, 2007 • Intercontinental Hotel • Miami

Update about the 12th Annual Executive War College!

With just a few weeks to go, participation at this year's *Executive War College on Lab and Pathology Management* has already exceeded any previous year. We've filled rooms in two hotels and have a third hotel taking reservations at the same conference rate. As of this date, laboratory executives and pathologists from 14 different countries around the world have registered and we've helped arrange on-site meetings and laboratory visits for many of these participants. Anyone interested in attending is encouraged to act now, to ensure their place at the world's most important gathering on laboratory and pathology management. See you in Miami!

For full agenda and program details, visit darkreport.com

UPCOMING...

- ***What's Up with ACLA? Lab Trade Group Moves on Strategies to Boost Value of Lab Testing.***
- ***Part II on Middleware: Informatics Innovations Give Clinical Labs Effective Management Tools.***
- ***Quest Diagnostics in England: Pursuing Opportunities in a Single Payer Country.***

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