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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

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Money Pours into Clinical Diagnostics

THIS IS AN AMAZING ISSUE OF **THE DARK REPORT**! In the past four weeks, there's been an unusual surge of corporate mergers and acquisitions. Individually, some are noteworthy, but collectively, the message is undeniable.

A flood of money is currently flowing into clinical diagnostics and the laboratory industry. Look at this issue's roll call: First up is the sale of **Focus Diagnostics** to **Quest Diagnostics** for a price of $185 million. *(See pages 2-5.)* Next is the merger of **Fisher Scientific International**, Inc. and **Thermo Electron Corp**., to the tune of $9 billion in market value. *(See pages 12-13.)* And, by the way, I should note that Fisher Scientific is acquiring **Athena Diagnostics, Inc.**, for $283 million in a deal announced in March. Then, there's the recently-announced sale of **Diagnostic Products Corporation** (DPC) to **Siemens Medical Solutions** (SMS) for $1.86 billion. *(See pages 14-15.)*

A simple calculation indicates a total of $2.32 billion was spent to buy laboratories or lab vendors, plus the $9 billion in the Fisher-Thermo deal! That's a lot of money flowing into the laboratory space in just a few weeks. It sends an unmistakable message: Wall Street likes laboratory medicine and clinical diagnostics. It sees plenty of opportunity and is ready to place big bets on the table to hold its place as the game develops.

There is another message, which I think is equally important. It is that consolidation is continuing, both within the laboratory industry and among IVD vendors. This means the biggest will continue to get bigger, competitors will get fewer, and anytime a company manages to avoid being acquired long enough to reach a certain size, likely buyers will offer its owners such a large premium that it will end up being sold.

Hospital-based laboratory administrators and pathologists should pay particularly close attention to these developments. First, it means they are competing against a different type of laboratory owner/operator than in past years. Second, it also means that the number of suppliers from which they can shop for products will continue to shrink.

And maybe you want me to close by answering an obvious question...how much consolidation will take place? My crystal ball is a bit cloudy on this issue, but I can say, with some confidence, that it is likely to be as much as the anti-trust regulators will allow. TDR

Focus Diagnostics, Inc. To Be Acquired by Quest

Sale's timing is no surprise, but what's unexpected is the price paid—three times annual revenues!

CEO SUMMARY: Another national laboratory company loses its independence and consolidation of the lab industry continues. Last Friday it was announced that Quest Diagnostics Incorporated would acquire the laboratory testing and diagnostic manufacturing divisions of Focus Diagnostics, Inc. of Herndon, Virginia. Quest Diagnostics will pay $185 million for about $65 million in annual revenues.

ONCE AGAIN, ONE OF THE TWO BLOOD BROTHERS has scooped up a fast-growing specialty test provider. This time the target is **Focus Diagnostics, Inc.** of Herndon, Virginia. The acquirer is **Quest Diagnostics Incorporated**.

In a deal announced just last Friday, May 19, Quest Diagnostics will pay $185 million to acquire the laboratory testing business of Focus Diagnostics, which generates annual revenues of about $65 million per year. Excluded from the sale is a pharmaceutical testing division, called **Focus Bio-Inova**. The acquisition is expected to close during third quarter 2006 and is subject to the usual regulatory review and due diligence.

It's no surprise that Focus Diagnostics is being sold at this time. Having owned the company for more than five years, the equity investors in Focus Diagnostics needed to liquidate their ownership and pay back their own investors. The surprise came from the willingness of Quest Diagnostics to pay $185 million for just $65 million in annual revenues. That's almost three times net revenue.

"In general, sales of laboratories are based on more than just the historic financial results," stated Chris Jahnle, Managing Director of **Haverford Healthcare Advisors** in Paoli, Pennsylvania. "Value can be based on more than just the two dimensions of revenue and operating profits. A higher valuation multiple can be supported by factors such as sustained and rapid growth of the acquired company in

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

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recent years or synergies that have value to the acquiring company."

Based on Jahnle's remarks, THE DARK REPORT believes that Quest Diagnostics is willing to pay a premium price for Focus Diagnostics because of several ways it can benefit from the acquisition. First, it is believed that Quest Diagnostics is a big, if not the biggest, customer of Focus Diagnostics. From this perspective, it knows which are the fastest-growing lines of tests it sends to Focus Technologies and, going forward, it wants to capture the additional profit margin that will come from doing these tests in-house.

Second, the client list of Focus Diagnostics includes a substantial number of hospital laboratories. Quest Diagnostics may assume that it can use these existing relationships with Focus Diagnostics to cross sell and encourage client hospitals to refer more reference and esoteric tests to its **Quest Nichols Institute** division.

Consolidate Testing

Third, Quest Diagnostics sees the opportunity to consolidate the testing Focus Diagnostics currently does in its Cypress, California laboratory and move those tests to other sites in its national lab network. Not only does that eliminate redundant overhead, but with its substantial economies of scale, Quest Diagnostics is likely to generate greater profit margins on the same volume of tests.

Fourth, Quest Diagnostics may have a keen interest in several proprietary tests and services developed by Focus Diagnostics that can be considered "added value" and capable of generating additional revenue when sold by Quest's hundreds of sales reps. For example, Focus has a product called GenomEx™ that is designed to give referring physicians a more detailed interpretation of genetic tests. The report is built upon data that includes personal history, family history, ethnicity, and other elements. The first offering on the menu addresses Cystic Fibrosis carrier analysis and is designed to allow referring laboratories to report this enriched information to their client physicians.

Vaccine Response Testing

Another service Focus Diagostics is developing involves vaccine response testing. This technology is designed to assess how the patient's immune system is responding to vaccines. The company offers these assessments for six viruses, including influenza, Japanese encephalitis, *Streptococcus pneumoniae*, and West Nile. Both GenomeEx and vaccine response testing are examples of value added assays and services that could be leveraged on a larger scale by Quest Diagnostics.

Fifth, the reality is that, for this slice of the lab testing menu, Quest Diagnostics will be removing an effective competitor from the national marketplace. Because of anti-trust and related regulatory issues, neither the buyer nor the seller involved in this acquisition will comment on this aspect. However, the fact remains that, over time, financial gains can accrue to companies serving a market with fewer competitors.

Losing Its Independence

In acquiring Focus Diagnostics, Quest Diagnostics removes a respected specialty testing company from the national marketplace as an independent provider. Founded in the 1978 as **Microbiology Reference Laboratories**, it provided a full menu of reference and esoteric tests centered around microbiology. During the 1990s, it changed its name to **MRL Reference Laboratory**.

Focus Diagnostics, Inc. Started As a Microbiology Reference Lab

Focus Diagnostics, Inc. At-A-Glance

Founded:.....1978

Headquarters: .....Herndon, VA

2005 Revenues:.....$77 million

By Division:

Laboratory Testing .....$45 million
Diagnostic Products.....$15 million
Pharma Testing.....$17 million

Accessions per year:.....600,000

Locations:

Laboratory and diagnostic manufacturing: Cypress, VA
Pharma Services: Herndon, VA and Paris, France

Executive Team:

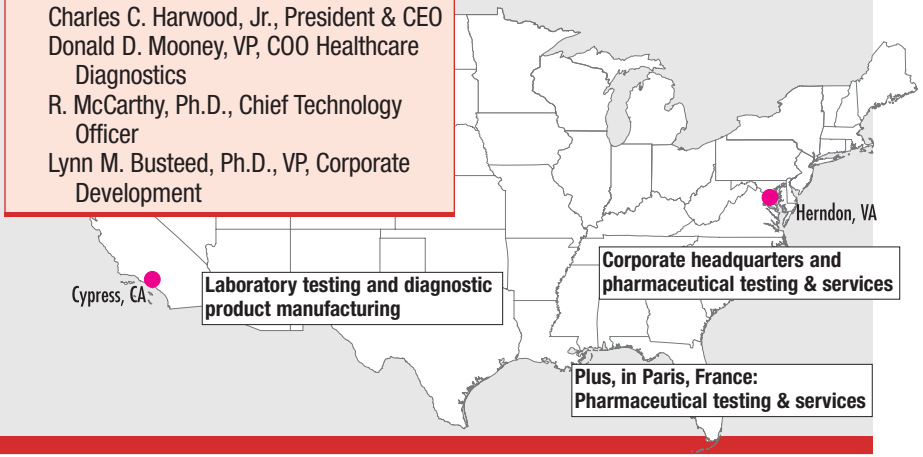
Charles C. Harwood, Jr., President & CEO
Donald D. Mooney, VP, COO Healthcare Diagnostics
R. McCarthy, Ph.D., Chief Technology Officer
Lynn M. Busteed, Ph.D., VP, Corporate Development

Since its founding in 1978 as Microbiology Reference Laboratories, Focus Diagnostics has become a respected provider of reference and esoteric testing in microbiology, and, in recent years, immunology and genetics.

The company's clients include clinics and physician offices, hospitals, other laboratories, and the national lab companies. It holds an ISO-9000 certificate.

Focus Diagnostics' Locations

As the map shows, Focus Technology's laboratory and diagnostic manufacturing facility is located in **Cypress, California**. Its main office in **Herndon, Virginia** also provides pharmaceutical testing and services, as does a facility in **Paris, France**.



In 2000, the company sold a sizeable interest to two private investment companies. One is **DLJ Merchant Banking Partners** (**Avista Capital Partners**) and the other is **Sprout Group** (**New Leaf Venture Partners**). As part of this sale, MRL's name was changed to Focus Technologies, Inc. (and later to Focus Diagnostics, Inc.).

Since 2000, Focus Diagnostics has broadened its test menu, with proprietary tests in autoimmune and genetics. It has also tried to be first to market with assays incorporating new diagnostic technologies. Examples have been SARS, West Nile Virus, and Lyme Disease. Current revenue from reference testing is estimated to be about $49 million per year.

What Is Unfolding At Nichols Institute Diagnostics?

SINCE IT IS SOON TO ACQUIRE another diagnostics manufacturing business, also located in Southern California, there will be greater interest in how Quest Diagnostics Incorporated decides to resolve the problems with its existing diagnostics manufacturing division, Nichols Institute Diagnostics (NID), located in San Juan Capistrano, California.

In the winter and spring of 2005, the FDA published multiple recalls for NID products. Then, on June 16, 2005, NID issued "Customer Bulletin CR-0520," titled "Product Inventory Hold." Sent to NID laboratory customers, it basically said that production and shipment of its diagnostics products had ceased until further notice. *(See TDR, July 11, 2005.)* Since that date, no product has been shipped.

In January 2006, John Hurrell, Ph.D., assumed duties as the Vice President and General Manager of NID. Hurrell has IVD manufacturing experience, having served in past years as Senior Vice President, Research and Development Operations at **Boehringer Mannheim Corporation**. Along with several new executives in Quality and Regulatory Affairs, the team has yet to announce a date when products will again be shipped to NID customers.

In public filings, Quest Diagnostics has disclosed that "During the fourth quarter of 2004, Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID), our test kit manufacturing subsidiary, each received a subpoena from the United States Attorney's office for the Eastern District of New York. Quest Diagnostics and NID have been cooperating with the United States Attorney's Office.

"In connection with such cooperation, we have been providing information and producing various business records of NID and Quest Diagnostics, including documents related to testing and test kits manufactured by NID. This investigation by the United States Attorney's Office could lead to civil and criminal damages, fines and penalties and additional liabilities from third-party claims."

Preceding this disclosure in Quest's public filings is a paragraph which discusses pending known and unknown *qui tam* claims and other types of "whistle blower" action. The paragraph ends by stating that "In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount."

This statement is followed by the disclosure of the fourth quarter 2004 subpoena involving Quest Diagnostics and NID. The sequence of disclosures might indicate that it was whistleblowers with knowledge of problems at NID that caught the attention of federal regulators, including a U.S. Attorney and the **Food & Drug Administration** (FDA).

These facts are likely to fuel much speculation. What remains undisputed is that, one year after the FDA recall notices, NID has yet to resolve its problems and resume production of its diagnostic products.

Focus Diagnostics also has a business unit that sells diagnostic products. Included in the product line-up are 18 FDA-cleared diagnostic kits, 14 kits for research use only (RUO), and 28 products with the CE mark ("Conformité Européen," a French term which indicates the product can be used throughout member countries of the European Union). Revenue from this business unit is estimated to be $16 million per year.

It will be interesting to watch what Quest Diagnostics does with the diagnostic manufacturing business of Focus Diagnostics, given the product quality problems in the manufacturing line at its Nichols Institute Diagnostics business. *(See sidebar above.)* Another interesting question will be how Quest Diagnostics uses the Focus Diagnostics name and goodwill. Increasingly, the national labs are willing to continue using the business name of the acquired lab company. TDR

New Lab Firm Life Cycle Demonstrated by Focus

Competitive laboratory marketplace dominated by a new lab business model

CEO SUMMARY: When an investment group bought Focus Diagnostics, Inc. in 2000, its business objective was to increase the value of the business and sell it between year five and ten of its ownership. Thus, the announcement last Friday that Focus Diagnostics would be acquired by Quest Diagnostics. Focus Diagnostics is a prime example that confirms the existence of the new lab business life cycle.

By Robert L. Michel

IN RECENT YEARS, **THE DARK REPORT** WAS FIRST TO IDENTIFY AND DESCRIBE the new business life cycle for independent laboratory companies.

Last Friday's announcement that **Quest Diagnostics Incorporated** would acquire **Focus Diagnostics, Inc.** is the latest confirmation that this new business life cycle is active and dominant in the laboratory industry. Not only does this transaction further consolidate the laboratory industry in the United States, but it makes it easier to predict similar acquisitions in future months and years.

The consequences of this new business life cycle for laboratory companies touch every dimension of the laboratory industry. For this reason, laboratory managers and pathologists will want to understand the details of this new business life cycle. That's because it will affect the strategic planning of their own laboratory organization.

In simplest terms, the new business life cycle for independent laboratory companies involves three phases. In phase one, professional investors find experienced laboratory executives, develop a business plan, then enter the business by either starting up a lab company or acquiring an existing laboratory. Phase two is operational execution. Using the ample capital placed at their disposal, the executive team builds the business. The objective is to develop a growing base of clients, generate a continually-growing flow of specimens, and produce net profits.

Eventual Need To Sell

In phase three, it is time for the professional investors to liquidate their investment in the laboratory company. They need the money in order to pay off the venture capital and investment funds they tapped in order to capitalize the new laboratory company. These investment funds usually have a term of five to 10 years from inception to closing.

Typically, there are three options for liquidating the investment in the laboratory company. First, some or all of the lab company can be sold to other investors. Second, the company can attempt to sell its stock to the public in

an IPO (initial public offering). Third, the company can be sold to another laboratory company. In recent years, that buyer has often turned out to be **Quest Diagnostics Incorporated** or **Laboratory Corporation of America**.

The new business life cycle for independent laboratory companies is that simple. What sets this business cycle apart from that seen in the 1980s and early 1990s is that the majority of new laboratory companies are *no longer founded by pathologists* who are motivated by an interest in expanding the laboratory medicine services they provide to their physician-clients.

For the past 10 years, most new laboratory companies have been launched by investors, armed with ample cash, who bring aboard experienced lab industry executives and then acquire an existing lab or create a brand-new laboratory company. Their primary motive is to make a profit by offering laboratory medicine services. That subtle difference from the pathologist-founded and operated laboratory drives the different outcomes.

In the old business cycle, the founding pathologists ran their laboratories conservatively. They offered a dense network of patient service centers and rapid response labs to maintain a high quality of service. They expanded their business step-wise, generally using internally-generated profits to fund this expansion.

Pathologists With Passion

The pathologist-founded laboratory company reflected their professional interest: to offer physician-clients high-quality and personal laboratory testing services. These pathologists were not motivated to sell their lab companies five years after start-up, since their laboratory was the profession and passion of the founding pathologists. Not until decades later, as retirement approached, did most pathologist-owners seriously consider the sale of their laboratory as the most likely way to get their investment out of the lab company so it could fund their retirement.

In direct contrast, the new business cycle for independent laboratory companies has an "automatic" sell date, usually between five and 10 years from the launch of the laboratory company. That means, from day one, the new laboratory organization is focused on its ever-approaching sale date.

Intent To Divest

It also means that hospital outreach programs and the remaining independent laboratories owned and operated by pathologists face a new type of competitor in the marketplace. Instead of competing laboratories owned and run by pathologists who intend to be around for a decade or more, increasingly the competition is from a lab company funded by investors, generally managed by non-pathologists, and organized to maximize growth and profits in the quickest time possible—since the business must be able to do an IPO or sell most of its equity in as little as five years.

It cannot be said that the competitive laboratory marketplace has become "better" or "worse" because of this new business life cycle for laboratory companies. It is certainly true that compliance boundaries are pushed to dangerous extremes by the most aggressive lab operators. It is also true that loss-leader pricing and sales practices such as the TC/PC split in anatomic pathology originate primarily with these types of firms. What is true is that, until more pathologists decide to start their own labs, for all the classic reasons, the lab industry will be dominated by this new laboratory business archetype. TDR

Laboratory Business Life Cycle Changed By Investors in the Last Half of 1990s

IN THE MIDST OF LAB BANKRUPTCIES and forced mergers among the best-known commercial lab companies during the second half of the 1990s, some perceptive investors aligned themselves with experienced laboratory executives and went buying–at what proved to be bargain basement prices.

In Chantilly, Virginia, the venerable **American Medical Laboratories, Inc. (AML)** was acquired in early 1997 by Timothy Brodnick, Jack Bergstrom, and Jerry Glick, using capital provided by **Golder, Thoma, Cressey, Rouner, Inc.** *(See TDR, May 12, 1997.)* It was just a year earlier, in 1997, that **AmeriPath, Inc.** of Riviera Beach, Florida began acquiring pathology groups, spending capital provided by **Summit Partners** and commercial bank financing. By October 1997, AmeriPath had successfully raised $89.6 million in an IPO (initial public offering) and intensified its acquisitions of pathology group practices. *(See TDR, October 27, 1997.)*

Another benchmark deal was the acquisition of Tarzana, California-based **Unilab Corporation** in 1999 by veteran laboratory executive Robert Whalen, using capital provided by **Kelso & Company**. *(See TDR, June 7, 1999.)* In a similar fashion, lab companies like **Dynacare, Inc.**, several pathology physician practice management (PPM) companies, and others got significant equity investments from private sources during these years.

And don't forget some private laboratories which obtained capital from private sources to finance growth and the retirement of pathologist-owners. Two examples of labs which went this route are **Path Lab, Inc.** of Portsmouth, New Hampshire and **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas.

All these companies are the first examples of firms organized under the new business life cycle for laboratory companies. The outcomes are instructive. Purchased for about $25 million and the assumption of some debt in 1997, AML was sold to Quest Diagnostics in 2002 for $500 million in January 2002, not quite five years later.

Unilab was next on the sales block. In April, 2002, Quest Diagnostics paid about $1 billion to acquire Unilab, a company that Kelso had bought less than three years earlier for more than $400 million.

There were similar outcomes for Path Labs, Inc. and CPL. LabCorp purchased Path Labs in 2001. For its annual revenues of $51.6 million, LabCorp paid $99.6 million. Last year, in August, CPL was acquired by **Sonic Healthcare, Ltd.** With annual revenues of $185 million, the purchase price for an 80% interest was $300 million. *(See TDR, September 12, 2005.)*

This list of "first generation" examples doesn't include the successful sales of companies like **DIANON Systems, Inc.** (annual revenues of $190 million and price paid by LabCorp of $598.6 million in early 2003), AmeriPath (annual revenues of $478.8 million in 2002 and price paid by **Welsh Carson, Anderson & Stowe** of almost $800 million), and **Lab*One*, Inc.** (annual revenues of $500 million and price paid by Quest Diagnostics of $934 million in 2005. *(See TDRs, November 18, 2002, March 3, 2003, August 22, 2005.)*

These examples make a compelling argument that lots of money can be made from laboratory testing. Over the past five years, Wall Street has noticed and professional money managers now constantly comb the laboratory industry for investment opportunities. Any lab company with a good business plan can attract ample funding.

IT Update

Terabytes Will Soon Arrive In Pathology IT Systems

As digital imaging generates data to be stored, terabyte-sized storage systems will be required

IN MANY PATHOLOGY GROUP PRACTICES across the country, digital imaging is playing a bigger role. That's the message from Mark Newburger, CEO of **Apollo Telemedicine, Inc.**, based in Washington, DC.

Newburger's firm was initially launched in 1993 to support the evolving needs in healthcare for real time digital images. Over time, Apollo Telemedicine developed systems to support "full motion, full color, real time robotics imaging."

"To work with maximum success, telemedicine must be supported by real time images," observed Newburger. "Physicians at each end need to see the same things, in enough detail and resolution to support effective diagnosis.

Suggesting Care Options

"This is what engaged us in anatomic pathology," he continued. "It is a subset of telemedicine that is ideally suited for working with digital images. However, technology has not yet reached the point where it is simple to digitize an entire slide in a way that allows any pathologist with access to that image to use it just as they would a real slide.

"Another challenge is the the ability to store all the data generated by digitizing an entire slide," said Newburger. "It's been estimated that it would require 50 petabytes of data storage to handle digital images of just 10% of the pathology slides produced each year. To put that into perspective, two petabytes would be enough to store the entire contents of every college and university library in the United States! By contrast, a single pathology practice will need terabytes of storage to handle basic 'field of view" digital images of their slides." TDR

Contact Mark Newburger at 703-288-

IEC Standards

Below are the standards for the specific prefixes for binary and decimal multiples. These were developed by the **International Electrotechnical Commission** (IEC) in 1998. This naming scheme accounts for measurements in both a binary and and a decimal system.

Bit	bit	0 or 1
Byte	B	8 bits
Kibibit	Kibit	1024 bits
Kilobit	kbit	1000 bits
Kibibyte (binary)	KiB	1024 bytes
Kilobyte (decimal)	kB	1000 bytes
Megabit	Mbit	1000 kilobits
Mebibyte (binary)	MiB	1024 kibibytes
Megabyte (decimal)	MB	1000 kilobytes
Gigabit	Gbit	1000 megabits
Gibibyte (binary)	GiB	1024 mebibytes
Gigabyte (decimal)	GB	1000 megabytes
Terabit	Tbit	1000 gigabits
Tebibyte (binary)	TiB	1024 gibibytes
Terabyte (decimal)	TB	1000 gigabytes
Petabit	Pbit	1000 terabits
Pebibyte (binary)	PiB	1024 tebibytes
Petabyte (decimal)	PB	1000 terabytes
Exabit	Ebit	1000 petabits
Exbibyte (binary)	EiB	1024 pebibytes
Exabyte (decimal)	EB	1000 petabytes

Letters to the Editor

Technical/Professional Billing Has Risks for Labs, Doctors

IT'S A HOT TOPIC ACROSS THE ANATOMIC PATHOLOGY PROFESSION. Increasing numbers of physician groups are hiring laboratories to perform the technical component of an anatomic pathology case and engaging pathologists to diagnose the cases.

This phenomenon is often called TC/PC, to represent how the technical component (TC) is being performed and billed independently of the professional component (PC). The following letter was written in response to a letter on this subject published in the February 27, 2006 issue of **THE DARK REPORT**.

Letter To The Editor

Dear Editor,

I read with interest your February 27, 2006 issue and the letter to the editor regarding technical/professional billing for anatomic pathology services (AP). While the letter was accurate and factual, I believe that it may have not painted a full picture of the risks and benefits of what is generally known as TC/PC billing.

We agree that most simple TC/PC billing arrangements raise little risk of the laboratory violating federal law. However, these types of arrangements do raise serious concerns for the local non-pathology practice providing the professional component. And there are cases where the laboratory or the pathologist may place themselves at risk of violating compliance laws and regulations. One example would be the consulting and advisory services often provided by laboratories for little or no charge to physician group practices engaging in TC/PC billing.

Finally, the letter did not consider the impact of TC/PC billing on the quality of care provided to the patient, ultimately the most important consideration in what we do as healthcare providers.

The writer of that letter, while noting that a growing number of physician groups are establishing TC/PC arrangements, particularly in certain regions of the East, did not address the many issues faced by a physician group practice engaging in these types of arrangements.

For example, prior to billing for the professional component of pathology services, the practice must ensure that its arrangement with a local pathologist complies with the Stark law's in-office ancillary exception. This compliance requires a complicated, case-by-case, fact-specific determination which can only be addressed by counsel for the physicians' practice.

Furthermore, compliance requires that the pathologist–whether employed or contracted–must perform the interpretation inside the practice's office or in space controlled and used exclusively by the physician practice.

In addition, arrangements paying the pathologist on a "per slide" basis" risk violating the fee-splitting laws currently on the books in many states. As a result,

physician practices are well-advised to at least seek specialized legal counsel on this issue and, in many states, should obtain a written opinion from their state's licensure authority prior to paying any pathologist in this fashion.

We have also seen many laboratories providing extensive consultation services to assist local practices' efforts to provide and bill for the professional component. These efforts often include helping the practice purchase necessary equipment and assisting the practice to engage and train a pathologist.

Most importantly, we have also seen laboratories providing physician practices with access to expensive, full-function laboratory information software at little to no charge. This is clearly an inappropriate kickback to the physicians' practice because it is intended to induce the referrals of the technical component to the laboratory.

Finally, by relying on an employed or contracted pathologist, the physician practice exposes itself to increased exposure to malpractice risks associated with the pathologist's professional interpretation.

Similarly, it appears that the patient's best interest is often forgotten when structuring such TC/PC arrangements. Instead of referring the pathology services to the most qualified pathologist, the practice looks to find a local pathologist willing to work on a part-time basis in the practice.

As always, I want to express my appreciation for the role that THE DARK REPORT plays in providing insightful, timely, and important information to the pathology community. By publishing these letters and encouraging more public discussion, I believe you have started an important dialogue regarding TC/PC billing. However, for the writer of the February 27 Letter to the Editor to state that there is little compliance risk tells only the story of the laboratory's risk in this type of arrangement. It does not tell the story of the serious concerns faced by a physicians' practice involved in a TC/PC arrangement involving their patient referrals.

Sincerely,

William W. Curtis
Chairman and Chief Executive Officer
CBLPath, Inc.
Ocala, Florida

Editor's Response

It is relevant for readers to know that CBLPath, Inc. was the company which filed a request for an opinion with the **Office of the Inspec-tor General** (OIG) on the subject of "anatomic pathology laboratory condominiums." This resulted in OIG Advisory Opinion 04-17, which was a negative ruling for the specific business arrangement as presented. *(See TDR, January 3, 2005.)*

This background adds understanding to the comments of Mr. Curtis, since his executive team and legal counsel spent about one year in discussions with the OIG as the OIG did its research prior to issuing Advisory Opinion 04-17. They have recent experience at responding to compliance issues the OIG considered relevant in the business model of the anatomic pathology lab condos.

THE DARK REPORT invites others with information, comments, or opinions to join this discussion. Until the OIG issues more specific guidance, or takes enforcement action against laboratories and physician groups engaged in TC/PC arrangements it considers to be non-compliant, there will be labs and physicians willing to push compliance boundaries. **—Editor**

Contact the editor at: labletter@aol.com

Thermo Electron, Fisher To Do "Reverse Merger"

"Thermo Fisher Scientific Inc." will be new name for the post-merger company

CEO SUMMARY: Bigger is expected to be better as Fischer Scientific International, Inc. and Thermo Electron Corporation come together by year's end and form a $9 billion behemoth in the laboratory supply industry. With 350,000 customers in 150 countries, it is likely that just about every laboratory and pathology group practice in the United States will see changes related to this merger.

IT'S THE BIGGEST CONSOLIDATION ever to occur among laboratory suppliers. **Fisher Scientific International, Inc.**, with annual revenues of $5.7 billion, will merge with **Thermo Electron Corporation**, which has revenues of $2.7 billion.

It is a merger that has ramifications for most clinical laboratories and research labs around the world. That's because most laboratories buy a wide variety of products from both Thermo Electron and Fisher Scientific. As the two companies streamline their product offering and integrate their sales and service staffs, laboratories will see changes that are a direct result of this merger.

It is a merger of equals, with both companies issuing a statement that their boards had "unanimously approved a definitive agreement to combine the two companies in a tax-free, stock-for-stock exchange." However, the twist is that Thermo Electro, the smaller company, will be acquiring all the stock of Fisher Scientific.

The merger will be accomplished as a "reverse merger." Fisher Scientific shareholders will receive two shares of Thermo Electron for each Fisher Scientific share they own. When completed, Fisher Scientific's shareholders will own about 60% of the outstanding stock in Thermo Electron. Prior to the merger, the market value of Fisher Scientific was about 50% greater than the market value of Thermo Electron.

Headquarters In Waltham

The merged entity will be known as "Thermo Fisher Scientific Inc." and will have its headquarters in Waltham, Massachusetts, current home to Thermo Electron. Fisher Scientific is based in Hampton, New Hampshire. Subject to regulatory and other approvals, the merger is expected to be completed before the end of the year.

Chairman will be Paul M. Meister, who is currently Vice Chairman of the Board at Fisher Scientific. Marijn E. Dekkers will be the President and CEO of the combined company, the same position he held at Thermo Electron. Fisher's current Chairman

and CEO, Paul M. Montrone, will step down after the merger and provide consulting services to the company.

Wall Street analysts consider the merger to be a positive development. Both companies sell different products to many of the same customers. These products are equipment and consumables used by clinical laboratories and scientific labs. Combined, the two companies have 350,000 customers in 150 countries.

Vendor Consolidation

The consolidation strategy was explained by John Sullivan, a financial analyst with **Leerink Swann & Co.**, based in Boston, Massachusetts. "The best deals in this industry are the ones where you are left with the ability to sell more products to your existing customers," he observed. "It allows companies to sell to their customers more efficiently. Laboratories that are customers are trying to become more efficient too. They want to do business with bigger companies and concentrate their business with a smaller number of vendors."

Another analyst concurred. "If you were to use the kitchen analogy, Thermo would be supplying the appliances and Fisher would be the supermarket," declared Quintin Lai, Senior Life Science Research Analyst with **Robert W. Baird & Co**. "Right now, in the life sciences tool space, we don't have any company that has this all under one roof."

Similar Deals To Come

Sullivan believes that more consolidation lies ahead. "The land grab in life science tools is officially under way," he noted, predicting that more deals would occur in this sector.

Most lab managers and pathologists are familiar with both companies. Thermo Electron makes equipment that is used extensively in chemistry and medical research, ranging from mass spectrometers to autopsy tables. It has a sizeable business in industrial tools, with customers in the oil, geology, and power industries.

Fisher Scientific is well-known in the clinical laboratory profession. Its 2,600-page catalog is a fixture in almost every laboratory and it sells an amazing variety of products. However, many lab managers who buy from Fisher do not realize the company was founded more than 100 years ago, in 1902. It has sold chemicals to Thomas Alva Edison, provided products to the Manhattan Project during World War II, and was a supplier to Jonas Salk, M.D. as he developed his vaccine for polio.

Alert lab administrators and pathologists will recall that Fisher Scientific had just completed another acquisition of its own. News of Fisher Scientific's sale to Thermo Electron comes just 58 days after Fisher announced it would pay $283 million to acquire **Athena Diagnostics, Inc.**, a lab testing company that offers proprietary assays in neurology and other clinical areas. That deal had only closed weeks before announcement of the impending merger of Fisher Scientific and Thermo Electron.

Visible Changes In 2007

During 2007, lab managers and pathologists will begin to see changes directly linked to this merger. As Thermo Fisher Scientific, the combined firm will need to integrate its product lines, its regional sales teams, and its customer service capabilities.

It should also be remembered that a consolidation of two large vendors like this tends to trigger other mergers and acquisitions among competitors. Everyone needs the size and scale to compete more effectively. So the coming months are likely to bring more consolidation. TDR

More IVD Consolidation: DPC Sells to Siemens

Siemens Medical Solutions decides its time to enter the in vitro diagnostics business

CEO SUMMARY: It is a significant acquisition, and not just because Diagnostic Products Corporation has a major presence in immunodiagnostics. Siemens Medical Solutions is one of the dominant competitors in radiology. Its willingness to pony up almost $2 billion to enter the clinical diagnostics market signals a serious intent to develop services that support individualized patient therapies.

IT'S AN ACQUISITION THAT REPRESENTS more than just consolidation within the *in vitro* diagnostics industry. On April 27, **Siemens Medical Solutions** (SMS) announced that it would acquire **Diagnostic Products Corporation** (DPC).

Siemens will pay approximately $1.86 billion for DPC, which is based in Los Angeles, California and has annual sales of about $520 million. Financial analysts noted that the price paid was almost four times DPC's sales, and Klaus Kleinfeld, President and CEO of **Siemens AG**, defended the high price by saying, "That's the multiple in the sector. We can only ask, 'Will we take part or won't we?'"

Intense Competition

The aggressive price is just one intriguing aspect to Siemen's interest in acquiring DPC. As one of the world's leading players in radiology and medical imaging, the company is competing intensely against the two other huge competitors in this market, **General Electric** and **Phillips**. Thus, its motives for spending almost $2 billion to buy an *in vitro* diagnostics (IVD) manufacturer has triggered much speculation. In recent years, General Electric has acquired **Triple-G Corporation**, an LIS vendor, as well as **IDX Systems Corporation**, a software vendor for medical group practices and hospitals. In 2003, it also paid $9.5 billion to acquire **Amersham PLC**, a major source of contrast agents used in medical diagnostics.

For its part, Siemens Medical Solutions has been acquiring firms as well. For example, in 2005, it paid $1 billion to buy **CTI Medical Imaging Inc.**, in part because it was conducting "next-generation molecular diagnostics research and the development of new imaging technologies and biomarkers."

This background information on GE and SMS is relevant in understanding why Siemens will pay $1.86 billion to buy DPC. Both GE and SMS are heavily involved in radiology, but want to move upstream and downstream in the diagnostic and therapeutic process. Each has a vision

of offering physicians a "total solution" for diagnostics and therapeutics. Moreover, each company understands the need to have electronic integration for the data generated by its clinical and medical support services.

Acquisition Motives

In discussing the motives behind the DPC acquisition, Erich R. Reinhardt, Ph.D., CEO and President of Siemens Medical Solutions, told analysts on a conference call that SMS wants to expand its portfolio of healthcare solutions, along with pursuing its objective of enabling early and specific diagnosis of disease, particularly in support of individualized patient therapy.

Reinhardt further stated that another goal behind the DPC acquisition is to bring together *in vitro* and *in vivo* diagnostics. Healthcare information technology plays a role, he added, because the healthcare industry generates growing volumes of data and, in order to use this data efficiently, a company must have the algorithmic systems necessary to process and analyze it. Proteomics and biomarkers may be a link between the *in vitro* diagnostic stage and the *in vivo* imaging state of diagnosis, Reinhardt also declared.

Personalized Medicine

THE DARK REPORT believes the key to understanding the DPC deal is Siemens' use of the term "individualized patient therapy." The company recognizes that continuing advances in genomics, proteomics, and a variety of other scientific fields will produce the ability for clinicians to offer "personalized medical services" to patients.

Just as an MRI can be more specific than a black and white X-ray film in diagnosing many conditions, the newest generation of diagnostic assays provide more information about the unique circumstances of a specific patient, than, say, the traditional chemistry panel or CBC test.

This same dynamic is happening on the therapeutic side. The pipeline is full of therapeutic drugs, compounds, and other agents which can be customized to the specific circumstances of an individual patient.

In recent years, industry experts have closely watched the moves of GE Healthcare and Siemens Medical Solutions in an attempt to understand how each firm wants to use its strong position in radiology as a springboard into other areas of healthcare.

The question is an important one for clinical laboratories and anatomic pathology group practices. That's because both companies have vast amounts of capital and intellectual resources to bear—if they were to decide to enter the laboratory testing marketplace in a big way.

DPC May Be A Good Fit

In acquiring DPC, Siemens Medical Solutions comes one step closer to the laboratory testing market. DPC is likely to make a good fit with the Siemens corporate culture. It was a profitable company with a strong balance sheet. As a primary competitor in immunodiagnostics, it has earned a good reputation with both customers and competitors.

Although it is still too early to know the strategic thinking behind Siemens' interest in DPC and willingness to pay almost four times annual revenue for the company, one fact stands out. Consolidation is ongoing in the IVD industry. Just weeks ahead of the sale of DPC to Siemens Medical Solutions, **Athena Diagnostics, Inc.** was sold to **Fisher Scientific International, Inc.** *(See pages 12-13.)* Together, these two deals affirm that larger companies want to expand their diagnostic test menu through acquisitions.

At the same time, all of these deals are a reminder that the pace of change remains constant throughout the laboratory industry. **TDR**

MDS Sells Calgary Lab, May Spin Off Other Labs

Plus, facts about the "rest of the story" concerning MDS' U.S. lab testing business

CEO SUMMARY: Nine months after it declared that it would exit the laboratory testing business in Canada by selling its laboratories, MDS, Inc. has finally closed its first sale. Calgary Health Region, already a 50% owner of Calgary Laboratory Services, has purchased the 25% interest owned by MDS. However, the laboratory business divisions in British Columbia and Ontario have yet to be sold.

SALE OF ITS 25% INTEREST in **Calgary Laboratory Services** was announced last month by **MDS Diagnostic Services** of Toronto, Ontario.

Terms of the deal were announced on April 4, 2006, the day after the sale became effective. As expected, the purchaser was **Calgary Health Region**, which already held a 50% interest in Calgary Laboratory Services. The remaining 25% interest is owned by **Dynacare Kasper Medical Laboratories**, based in Edmonton, Alberta. This is a laboratory business unit of **Laboratory Corporation of America**.

MDS Diagnostic Services was paid US$19.0 million for its interest. During 2005, MDS booked revenue of US$62.3 million and net income of US$1.3 million from its share of the Calgary Laboratory Services joint venture.

MDS Inc., parent of MDS Diagnostic Services, had announced in September 2005 that it planned to exit the laboratory testing business. This was significant news, since laboratory testing was the company's central business at its founding 30 years ago. Further, in fiscal 2005, its diagnostic business still represented 22% of the company's consolidated revenues and 29% of its adjusted EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization).

More Labs Yet To Be Sold

This leaves unsold two major laboratory business units and some smaller joint ventures. In British Columbia, **MDS Metro Laboratory Services** is one of the province's two largest independent laboratories. Its main lab facility is in Burnaby and a smaller lab is located in Victoria. The other major laboratory division is **Toronto Medical Laboratories** (TML), a joint venture partnership between MDS and **University Health Network** (**Toronto General Hospital**, **Toronto Western Hospital**, and **Princess Margaret Hospital**). TML also includes two community hospitals and four specialty hospitals.

Also in Ontario are other MDS laboratory ventures. **Integrated Health Laboratory Services** is a partnership between MDS and hospitals in the Windsor area. The company also partners with hospitals in the Niagara region, as well as several other organizations in Ontario.

MDS executives are determined to finalize sale or disposition of all the remaining laboratory assets by the end of 2006. If it cannot find buyers on satisfactory terms, it may spin its remaining laboratory business off as a separate company, issuing stock to existing MDS shareholders. In a public filing, MDS said, "We expect to find an alternative ownership structure for our diagnostics business and to complete our exit from this business by the end of the calendar year. We are considering a number of alternatives, ranging from an outright sale to a tax-efficient distribution to shareholders."

It's Tough Finding Buyers

This is a notable statement. As THE DARK REPORT has pointed out in earlier intelligence briefings on this subject, the fact that MDS is now into its ninth month of divestiture activity says that buyer interest in these laboratory businesses is minimal—at least based on a purchase price that MDS considers acceptable. Thus the statement of a "tax-efficient distribution to shareholders." *(See TDR, February 27, 2006.)*

MDS may need to spin off at least some of its lab assets to its shareholders. Certainly the two blood brothers from the United States, and even **Sonic Healthcare, Ltd.** from Australia, would be considered likely buyers for these laboratory businesses. But over nine months, no deal has been announced, which is a sign of either their unwillingness to pay the price requested by MDS or just a general lack of interest in the Canadian lab testing marketplace.

MDS Laboratory Testing Foray Into USA Came Up a Cropper

IN 2004 AND 2005, MDS, Inc. sold its four laboratory divisions in the United States. These were located in Poughkeepsie, New York; Atlanta, Georgia; Memphis, Tennessee; and Ft. Lauderdale, Florida. Some of these were joint ventures with hospital organizations.

Cumulatively, the U.S. laboratories of MDS were a money-losing operation. In 2003 and 2004, revenue from its U.S. laboratory business was US$107 million and US$112 million, respectively. But losses were significant. MDS acknowledged that the combined losses for the U.S. labs and its generic radiopharmaceutical business in Europe totaled US$9.6 million in 2003 and US$13.6 million in 2004.

In March 15, 2004, Laboratory Corporation of America acquired the MDS laboratory interests in Poughkeepsie and in Atlanta in an asset purchase transaction. MDS says it incurred a loss of US$8 million in the sale of the two labs, but in the year following the sale, it realized US$1.6 million in contingent payments. MDS also disclosed that, during first quarter 2004, the two labs had operating losses of US$2.4 million on revenues of US$5.6 million.

Next to be sold was MDS' equity interest in **Memphis Pathology Laboratories, Inc.**, which was purchased on September 24, 2004 by **American Esoteric Laboratories, Inc.** for US$20.4 million. MDS says it booked a US$7.2 million gain on this sale.

The final lab sale came in 2005, when **HCA** purchased MDS's 50% equity share in **Integrated Regional Laboratory** (IRL), the joint venture laboratory located in Ft. Lauderdale. The price paid by HCA is estimated to be around US$9 million.

It may be that MDS is having a difficult time finding buyers for its Canadian labs because of the ongoing reimbursement squeeze. Potential buyers recognize that provincial health plans cannot afford to reimburse lab testing at historic rates. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another investment firm has acquired an anatomic pathology company. It was announced today that **Water Street Capital Partners** of Chicago, Illinois, has acquired a majority ownership in **Lakewood Pathology Associates**, located in Lakewood, New Jersey. Under new ownership, Raza Bokhari, M.D., a founding pathologist of Lakewood Pathology, wil continue as President and CEO. Purchase price was not disclosed, but it was stated that Water Street has "committed $50 million in equity financing...to acquire small and mid-size surgical pathology services providers nationwide."

MORE ON: Lakewood

This development intensifies competition on the national scene. As disclosed recently in THE DARK REPORT, James New, formerly CEO of **AmeriPath, Inc.,** is in the midst of launching a national anatomic pathology company, also with funding from private equity investors. *(See TDR, May 1, 2006.)*

CMS RECONSIDERS PROPOSED MUES FOR LAB AND AP

Last year's list of MUEs (Medically Unbelievable Edits), currently proposed for implementation in January 2007, will be "much less restrictive" to the current proposal, according to a release distributed today by the **College of American Pathologists** (CAP). CAP reports that, in testimony before the Practicing Physicians Advisory Council (PPAC), Lisa Zone stated that the initial phase of the proposed MUEs will "focus largely on anomalies and obvious typographical errors." Zone is Deputy Director of the Program Integrity Department of the Centers for Medicare and Medicaid Services (CMS). Zone disclosed that, in August, a shorter list of proposed MUEs will be made available for public comment.

ADD TO: Proposed MUEs

These developments represent positive progress for anatomic pathology group practices and laboratories. The proposed MUEs included some onerous caps on service, include a limitation of two units of service per patient per day for CPT 88305. *(See TDR, January 16, 2006.)* Opposition and criticism to the proposed MUEs was immediate and intense. In her public comments, Zone also indicated that CMS is seriously evaluating how modifiers will be used and what kind of appeals process would be appropriate.

TRANSITIONS

• After many years as Managing Editor of *Laboratory Industry Review* and *Diagnostic Testing & Technology Report*, JonDavid Klipp recently resigned his position to form his own company, based in Poughkeepsie, New York. He now publishes *Laboratory Economics*. The first issue of the monthly newsletter hit the street in April.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 12, 2006.

UPCOMING...

- ***Collecting Big Deductibles from Patients in CDHPs: Why Bad Debt from Insured Patients Is Soaring at Some AP Groups.***
- ***Metabolomics is the Newest Testing Discipline and Why It's Important for Labs.***
- ***Update on Crime and Punishment in the Laboratory Industry.***

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