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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Coding Edits Are a Potential Hammerblow to Pathology

DURING THE NEXT SIX MONTHS, WE WILL WITNESS an intense debate between the pathology profession and the Medicare/Medicaid bureaucracy. This battle will center around the proposed MUEs (Medically Unbelievable Edits) which place restrictions on the units of service per patient per day on key CPT codes widely used in laboratory medicine.

As you will read in our lead story on pages 2-3, news of this proposal only surfaced in mid-December, just as the holiday season kept folks from paying close attention to business issues and government proposals. It is still a matter "under wraps," because confidentiality agreements cover the information about proposed restrictions on service that was distributed by a Medicare contractor to the **American Medical Association** and medical specialty associations. It is why neither the Medicare program nor recipients of this information have made it public.

What caught the attention of pathologists was the proposal to restrict use of CPT code 88305 to two units of service per patient per day. But that is not the limit of the bad news. The Medicare contractor proposes to place restrictions on approximately 1,200 CPT codes involving anatomic pathology and clinical laboratory services. By itself, the 88305 restriction is a potential hammerblow to pathology because it covers a procedure that makes up as much as 50% of the services performed by some individual pathologists.

As the laboratory industry responds to this ill-conceived Medicare coding initiative, there are no guarantees that the final decisions affecting 88305 and other laboratory CPTs will be satisfactory to the pathology and laboratory community. This will be a major story of 2006 and you can expect to read more about it in the pages of THE DARK REPORT.

For my part, I believe the very fact that Medicare launched a contractor on a project to propose restrictions on service, based on MUE standards, across all medical specialties, represents a more serious threat. Regardless of whether this round of CPT code edits originated because of incompetence, ignorance, or intent to restrain utilization (thereby reducing costs), the fact that some Medicare officials wanted to go down this road is a sign of the growing pressure they face to control spending—and their lack of creativity in how to solve that problem. TDR

Proposed Coding Edits May Restrict 88305 Use

Full range of proposed edits promises bad news for both pathology groups and clinical labs

CEO SUMMARY: When the Medicare contractor tasked with developing MUEs (Medically Unbelievable Edits) for this year's Correct Coding Initiative work released the proposed list of edits to the AMA, it didn't take long for the bad news to reach the pathology profession. Restriction on units of service per patient are proposed for approximately 80 pathology CPTs and almost 1,100 clinical laboratory CPTs.

WORD IS FILTERING throughout the pathology profession about a proposal within the Medicare program to restrict the use of the 88305 CPT code to two units of service per patient per day.

But the bad news doesn't stop with 88305. Proposals now under consideration by the Correct Coding Initiative (CCI) would place restrictions on the units of service for a significant number of anatomic pathology, clinical laboratory, and molecular diagnostic CPT (Current Procedural Terminology) codes.

Should the proposed restrictions on units of service for CPT 88305 (Level IV—Surgical Pathology, Gross and Microscopic Exam) eventually take effect, it would be devastating to the pathology profession. Procedures performed and coded as 88305 make up the single largest component of the anatomic pathology workload.

"I have been told by our clients, both pathologists and billing companies, that the impact of the proposed restriction of service for 88305 on the compensation of the typical pathology group practice will be between 10% and 40% of total compensation," said Jane Pine Wood, an attorney and partner at **McDonald Hopkins** of Cleveland, Ohio. "The precise impact would vary, depending on the size of the Medicare population served by the pathology group and how many cases are referred by specialists, such as urologists, gastroenterologists, and dermatologists. Without question, what is pro-

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posed for this single CPT code will have an extremely negative impact."

There is a simple reason why this news has not become widespread across the laboratory industry. These proposed CCI edits are in the earliest stages of development. They have only recently been made available for review by the various medical specialties affected, including pathology. These proposed edits have not been made public and, in fact, the distribution of this information is accompanied by confidentiality agreements.

The source of these proposals is a contractor working on behalf of the **Centers for Medicare and Medicaid Services** (CMS). The list of proposed pathology and laboratory CPTs to have restrictions on units of service is part of a project to develop the next round of Medically Unbelievable Edits (MUEs) for all medical specialties.

Late last year, the contractor passed the list of proposed edits to the **American Medical Association** (AMA). Upon receipt of this list, the AMA forwarded a copy to each medical specialty association in the United States for their review and input. This occurred in mid-December.

CAP Requests Information

Once it had evaluated the proposed edits affecting pathology, the **College of American Pathologists** (CAP) issued an alert concerning this matter. CAP is asking pathologists to provide input and documentation about the negative consequences that will occur if the proposed two-unit cap on 88305 were to be implemented. This information will be delivered to the AMA.

As of press time, the deadline for CAP's comment and response to the AMA is early February. CMS is expected to implement the final list of edits in July 2006. This does not leave much time for the laboratory industry to work with the AMA and the CMS contractor to fix the more ill-conceived elements of the proposed MUEs.

"There is the potential for significant chaos between patients, referring physicians, hospitals, and pathologists," observed Wood. "From the standpoint of medical quality, what does a hospital-based pathologist do when a surgeon sends, for example, multiple tissue specimens from a breast cancer case to the pathologist?

Serious Consequences

"The proposed restriction that limits a pathologist to filing claims for only two 88305s per patient per day will trigger serious issues of medical quality and access to care by Medicare patients," added Wood. "It is likely that the Medicare patient will be asked to sign ABNs and personally pay for the additional 88305s. There will be greater liability exposure for both surgeon and pathologist, if the plaintiff's bar were to believe that physicians' actions were influenced by Medicare restrictions on service and their patient's outcome was negatively affected."

One big, unanswered question that surrounds the specific restrictions proposed for 88305 and other pathology and clinical lab CPT codes is "Why?" It is not known whether these restrictions were proposed at the direction of CMS officials, possibly to tamp down utilization—and thus reduce the amount of money Medicare pays to providers. Alternatively, it could be the result of flawed thinking by individuals working for the CMS contractor.

Expect this issue to be the regulatory "hot potato" for 2006—and that's before the clinical laboratory segment of the industry learns about proposed service restrictions for approximately 1,100 of their CPT codes! TDR

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AD PathLabs Is Closed, Assets & Clients Are Sold

Local pathology laboratory picks up pieces, but considers the transaction as fraught with risk

CEO SUMMARY: AD PathLabs, Inc. was a regional anatomic pathology company built around a unique business model: it would provide technical AP services to local hospitals and other clients and allow referring physicians to perform the professional services on the cases they referred to AD PathLabs. After four years of operations, AD PathLabs closed its doors and investors liquidated the company.

IT WAS A FASCINATING EXPERIMENT. **AD PathLabs, Inc.** was launched in 2001 as a regional pathology company that would provide anatomic pathology (AP) technical services to hospitals and other clients in the Greater Los Angeles area.

However, in the waning days of 2005, venture capitalists pulled the plug on the struggling lab company. Unable to find a buyer for the going business, the owners of AD PathLabs sold the client list and assets to **Pathology, Inc.**, an independent anatomic pathology laboratory based in Torrance, California.

"We've approached this with great caution," stated Alfred Lui, M.D., pathologist and President of Pathology, Inc. "Although the evidence shows that a national or regional anatomic pathology laboratory can convince referring physicians to use its services, it may not be as profitable a business model as some have initially assumed."

Pathology, Inc. announced in November 2005 that it had "assumed" the pathology laboratory services of AD PathLabs. "AD PathLabs provided inpatient and outpatient technical services ranging from basic to esoteric anatomic pathology," stated Lui. "They were in several lines of business that were complementary to ours. That's the major reason for our interest in the client list and assets we gained."

Service Levels Were Good

What Lui doesn't say is what caused AD PathLabs to fail. "Service levels and product quality were very good," stated Lui. "It was not a question of poor performance in the technical operation of the laboratory and the work it delivered to its client hospitals and referring pathologists."

AD PathLabs was the creation of Charles Madden. He founded the company and served as its President and CEO until investors replaced him in the final years of AD PathLab's business life. Madden had worked with Michael Danzi at the venture capital-funded company that became **US Labs, Inc.**

Taking a cue from the business evolution of Danzi's national AP company, Madden decided to create a regional version and began developing that business concept in 1999. He attracted some investors and then began to look for customers.

What gave AD Pathlabs the critical mass to launch operations was a contract with **Catholic Healthcare West** (CHW) to provide AP technical services to six of its hospitals. AD PathLabs' corporate offices were in Newport Beach, California and its laboratory was located in El Monte, California, a city central to the CHW hospitals.

Technical Service Hub

"From its central lab, AD PathLabs provided pathology technical services for local hospitals while continuing to use the professional services of pathologists based in these hospitals," observed Lui. "The idea was that this would permit the pathologists to remain independent. Beside routine services, it could provide them with esoteric services from a local laboratory, allowing them to provide greater value and faster turnaround time to referring physicians."

In February 2003, AD PathLabs received third-round funding of $8.9 million from venture capital companies, including **Pacific Joint Ventures**, **Blue Chip Venture Company**, **Forrest Binkley & Brown Capital Partners**, existing angel investors, and management.

At the time, AD PathLabs issued a press release trumpeting four "proven" success components to its business model: 1) reduced costs for the hospital, 2) improved turnaround time, 3) enhanced pathologist-referring physician relationships; and, 4) increased income for the local pathologist.

In early 2003, AD PathLabs was serving 30 hospital clients in Southern California, including its exclusive relationship with Catholic Healthcare West. one of the area's largest health systems. Even though the 14 month-old company was attracting significant numbers of specimens from referring physicians, it could not support its operational costs.

Not Covering Its Costs

Informed sources tell THE DARK REPORT that, even after four years of operation, AD PathLabs was incurring losses at a rate of $50,000 per month and that the company never had a profitable month. Sources familiar with AD PathLabs and the Southern California market for lab testing say that the young company failed to gain traction under Madden's leadership. It never attracted enough new clients to offset monthly expenses.

THE DARK REPORT is unclear whether the failure of AD PathLabs is due to a flawed business model—that of offering *only* technical pathology services—or simply poor execution of the business plan. THE DARK REPORT visited AD PathLab's laboratory during 2003, but did not write a story about this new pathology company because we had reservations about its business prospects.

For the pathology profession, there are interesting implications from the failure of AD PathLabs. These will be examined in the pages which follow. AD PathLabs represents another example of a pathology company which was able to attract a critical mass of specimens, but could not earn the profits necessary to sustain a healthy business over the long haul.

Assuming this to be true, then Pathology, Inc. is likely to be challenged as it tries to make something of the AD PathLabs' client list and assets it now has in its possession. TDR

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—By Pamela Scherer-McLeod

Failure of AD Pathlabs: Structural Weakness?

Can any AP lab business model separate AP technical and professional and succeed?

CEO SUMMARY: AD PathLabs is the latest in a string of business disappointments. Over the past decade, a number of anatomic pathology companies have proven that they can grow rapidly–attracting substantial volumes of specimens. But these companies seem to hit a financial wall that leads their owners to sell the firms to more traditional laboratory companies. Is there a fatal flaw in these business models?

OVER THE PAST 10 YEARS, national anatomic pathology companies have shown they can attract significant case volume from referring physicians. What they have failed to demonstrate is the sustained economic viability of the underlying business model.

During the 1990s, **IMPATH, Inc.**, **UroCor, Inc.**, and **DIANON Systems, Inc.**, caught the attention of Wall Street with their blistering rates of growth in specimen volume and revenue. Yet these three companies were unable to survive as independent and profitable enterprises. IMPATH entered bankruptcy and the owners of UroCor and DIANON decided to sell their lab company when profits turned meager or non-existent.

New Model Of Pathology

Since 2001, at least three anatomic pathology companies have bet on the severability of anatomic pathology technical component services to generate profits and grow revenues. They created a new business model for pathology services, based on performing technical AP services and giving referring pathologists the option of performing the professional service on the case themselves.

US LABS, Inc. launched this business model in 2000. It was a pathology physician management company (PPM), funded by venture capitalists, that was failing to grow. It decided to abandon the PPM business and compete against IMPATH, but with an essential difference. It would offer to do the technical component for referring pathologists and give them the option of performing the professional component.

This business model was made possible, in part, by a unique insight. US Labs could use the the ACIS® instrument system, manufactured by **ChromaVision Medical Imaging Systems, Inc.** (now **Clarient, Inc.**), to support splitting the case between its technical and professional components.

At that time, ACIS had recently been cleared by the FDA for sale and use in specific clinical applications. It was a digital imaging microscope, married to software designed to sup-

port "image analysis for quantitative IHC measurement." US LABS recognized that, if the referring physician had a ChromaVision workstation, the company could use the ChromaVision imaging system to digitize the slide. It could then electronically transmit the digital file to the referring pathologist. That digital image would be used by the referring pathologist to diagnose the case.

This arrangement proved popular with certain elements of the pathology profession. Between 2001 and early 2005, when US LABS was acquired by **Laboratory Corporation of America**, the company's revenues grew from about $6 million per year to an estimated $75 million in 2004.

Charles Madden, who had been employed by the PPM-precursor to US LABS, observed the rapid growth in specimens and revenues after US LABS adopted this business model. He decided to copy US LABS, but on a regional basis.

Contract For Technical Lab

Using contacts at **Catholic Healthcare West** (CHW), Madden negotiated a multi-year contract to provide pathology technical services to six CHW hospitals in the Los Angeles area. After obtaining venture capital funding, Madden launched **AD PathLabs, Inc.** in late 2001. It became the second company to organize itself around a business model of providing technical laboratory services to referring physicians and allowing them to perform the professional service component.

THE DARK REPORT visited the company's pathology laboratory in El Monte, California in 2003. At that time, Madden explained the business plan and the operational arrangements. Immunohistochemistry was a mainstay of the lab's test menu. AD PathLabs was using the ChromaVision system to image the IHC slides. Digital images were then sent electronically to the referring pathologists to be read in their hospitals or offices.

During the tour, Madden pointed out that this arrangement contributed to improved turnaround time. Each morning, AD PathLabs would process specimens picked up the previous day and transmit the digitized images by, say, 8 a.m. As pathologists read these cases during the morning, they could call or email requests for special stains. AD Path would retrieve the tissue, cut and stain the new slides, and deliver digitized images of those special slides, generally within two or three hours of the pathologists' request.

High-Water Year

2003 was the high-water year in the business life of AD PathLabs. It attracted $8.9 million of additional venture capital funding in February 2003 and had about 30 hospital clients across Southern California, including its contract with Catholic Healthcare West.

Despite this optimistic start in the early years, AD PathLabs never achieved break-even on monthly operations. Throughout 2004 and 2005, its owners looked for interested buyers. Madden was ushered from the scene and investors brought in new management. But the company continued losing money. This led to its dissolution in late 2005, when **Pathology, Inc.** of Torrance, California purchased certain laboratory assets and the client list of AD PathLabs.

Technical AP Laboratory

The failure of AD PathLabs, and the sale of US LABS in early 2005 raises an interesting question: is the business model of a regional or national pathology technical laboratory company viable—both in the marketplace and financially? Keep in mind what differentiates these entities from pathology

group practices. The pathology technical laboratory company is founded by individuals who intend to compete with local pathologists for case referrals. Thus, the company would lack the long-standing professional relationships that exist between local pathologists, their hospital administrators, and clinicians practicing in the region.

In the case of AD Pathlabs, it is known that low pricing for key clients played a role in the company's financial struggles. *(See sidebar at right.)* The other major factor seems to be ineffective executive leadership during AD Paths' formative period. For example, the sales team at AD PathLabs included a sales manager and up to seven sales reps operating in and around the Los Angeles area. Yet, for this considerable investment, the company never realized the volume of new accounts—at appropriate price levels—necessary to financially sustain AD PathLabs. Nor did Madden, as CEO, take effective action to correct this major failing.

No Buyer As "Going" Lab

A further sign that the business model of separating AP technical component from AP professional component is weak is the simple fact that AD PathLabs' owners could find no buyer for the company as a going business. Instead, its owners were forced to essentially liquidate the assets in the face of their self-imposed deadline to close the money-losing lab company outright if no buyer was found.

Assuming that low pricing, poor executive leadership, and a lack of sales performance were major contributors to the failure of AD PathLabs, what were the factors that led US LABS to sell itself to LabCorp early in 2005? After all, the company had grown rapidly between 2000 and the end of 2004.

Was Discounted Pricing Part of AD Path's Woes?

LOW PRICES FOR ANATOMIC PATHOLOGY (AP) TECHNICAL SERVICES are believed to be a significant factor in AD PathLabs' demise.

One major source of the company's specimen volume and revenues was its contract with Catholic Healthcare West (CHW) to serve six of its hospitals. This contract had to be priced at a significant discount to provide the financial incentive necessary for CHW to justify outsourcing anatomic pathology services that its local AP groups were already providing.

AD Path's business strategy was to use the CHW case volume as the critical mass needed to open the laboratory. But the company was unable to generate enough new clients, at adequate prices, to offset the inadequate profits resulting from the CHW work.

A second factor in the market likely hindered AD PathLabs' efforts to get higher pricing for AP technical services. In late 2001, as AD PathLabs launched business operations, IMPATH was operating a histology laboratory in Southern California that offered high-volume slide preparation at attractively low prices. IMPATH was pursuing a loss-leader strategy. Since it was cutting the slides and held the tissue specimens, it believed that it would be asked to do higher-priced, follow-on testing for clients.

Not only did IMPATH's low-priced technical lab suppress pricing in the region for such services, but IMPATH was employing a large number of histotechnologists. This aggravated the existing labor shortage for histotechs, raising costs to competing laboratories, including AD PathLabs.

At the time the sale was announced, US LABS acknowledged that the decision to sell was, in part, a response to the impending draconian reduction in flow cytometry reimbursement that Medicare would implement on January 1, 2005.

That reason is true, as far as it goes. However, US LABS had its own leadership issues in its executive suite. In May 2002, the company abruptly replaced Mike Danzi, who held the titles of Chairman, President, and CEO. It was Danzi who had originated the business concept of offering separate AP technical services to referring pathologists and other physicians.

Several factors contributed to Danzi's departure. Key among them was the negative cash flow of the business. Intelligence at that time hinted that US LABS' revenues were at the $20 million per year level, but its spending was at the $40 million per year level. Further, Danzi was just completing construction of a new laboratory that included the largest number of several instrument systems that vendors had placed in a single site anywhere in the world!

Operating Deficits

With US LABS outspending revenues by a factor of 100%, venture capital companies had a decision to make. Faced with this huge cash flow deficit, many of US LABS' investors wanted to pull the plug on the company. However, the decision was made to continue with new leadership. To cover the negative cash flow from operations, additional funding was put into the company over the course of 2002.

US LABS continued to grow at spectacular rates during 2002, 2003, and into 2004. But, because of its cumulative operating losses, it was struggling to achieve the kind of high profits necessary to justify the investments made by the venture capital companies. When news surfaced that Medicare would slash flow cytometry reimbursement by 60% for 2005, investors on US LABS' board made the decision to sell the business and redeploy their capital elsewhere.

Collectively, the experience of AD PathLabs and US LABS provides strong evidence that the business model both companies pursued—that of forming a company from scratch to offer AP technical services to a regional or national market—is not viable.

Viable Business Model?

It should be noted that there are a number of independent pathology laboratories around the country which operate successfully. What these companies have in common is that they were founded by pathologists who had strong clinical and professional relationships with hospitals and office-based physicians in the communities they serve. Both of these attributes were lacking in the case of AD PathLabs and US Labs.

And what of the third company founded on the business model of offering AP technical services? It is Clarient, Inc., the new name for ChromaVision Medical Imaging, Inc.

In the face of lackluster sales for its ACIS Imaging system, and having watched the spectacular specimen volume growth at US LABS (its single largest customer for ACIS), ChromaVision decided to enter the clinical laboratory testing business and use its ACIS instrument system in a similar fashion as US LABS.

To fund its expansion into clinical services, in the spring of 2004, ChromaVision raised $21 million from investors. In subsequent months, it hired a number of people who held key administrative and clinical positions at US LABS and IMPATH. Its laboratory facility was licensed in November 2004. Revenue from clinical services totaled $2.2 million that year.

In March 2005, ChromaVision changed its corporate name to Clarient, Inc. It reported revenues from clinical testing services of $1.9 million in Q1, $2.6 million in Q2 and $3.0 mil-

Local Path Groups Have Local Market Advantage, But Fail to Use Effective Sales & Marketing

SINCE 1995, THERE HAVE BEEN AT LEAST 10 venture capital-funded companies that operated in the lab services marketplace and were organized primarily to provide anatomic pathology (AP) services.

Of that number, only two have not changed ownership. One is **Pathology Partners, Inc.** of Dallas, Texas, formed in 1998. The other is **CBL Path, Inc.**, which is still a young firm, having launched in 2003.

The fact that the original owners of 80% of these enterprises were not able to sustain the business as independent, ongoing companies raises an interesting question. Why would 80% of these enterprises, funded by sophisticated investors and managed by veteran executives, be unable to continue as independent businesses?

Threat To Local Path Groups

The answer to this question is highly important to the long-term financial viability of the private pathology group practice, typically affiliated with a community hospital. That's because there is one thing that these 10 or more anatomic pathology-focused businesses have proved they can do well. They can send sales people into physicians' offices and convince a high number of physicians to refer their anatomic pathology cases to a regional or national AP laboratory company.

Through the late 1990s and into the first years of this decade, THE DARK REPORT regularly called attention to the rather amazing rates of growth enjoyed by these companies. For example, in 1997, DIANON Systems, IMPATH, and **AmeriPath** had only about $125 million in AP revenues among them. Remarkably, at the end of 2002, the combined revenues of these three firms totaled $954 million. In five years, this threesome had captured nearly *$1 billion of revenues* from local pathology groups across the nation!

I believe the business histories of the 10 or so companies that entered the AP marketplace have two lessons to teach. First, if you spend enough money, your sales force can convince doctors to steer their specimens away from local, hospital-based pathology groups and, instead, send them to a regional or national laboratory located many miles away.

Second, the combined costs of running a huge sales and marketing campaign, along with the normal costs of operating a regional or national AP company, makes it difficult for these companies to earn the profit margins needed by their venture capitalists. As they deliver unimpressive profit margins despite amazing growth rates in specimens and total revenues, investors decide to close out their AP investment and redeploy the money into more profitable opportunities.

Pathologists in private group practices should heed the knowledge provided by these two lessons. To protect their business relationships with local physicians, they need to have some type of sales and customer service program. It is essential that they contact their clients regularly and "resell" the reasons why their local group is the best option. That will protect their client base as each generation of new AP companies sends a fresh crop of sales reps into the community. *–By Robert L. Michel*

lion for Q3. Year-end earnings for 2005 have not been released.

It is likely that Clarient will report revenues from its clinical testing operation of around $11 million for 2005. That is impressive growth for an a national anatomic pathology laboratory that has only been operational for less than 18 months.

In fact, Clarient's growth trajectory is comparable to that of US LABS' growth in the 2001-2003 period. On the surface,

this is an auspicious start for Clarient. At the same time, when viewed against the experience of US LABS, and to a lesser degree, AD PathLabs, several questions must be asked.

Life Span Of Five Years

First, neither US LABS nor AD PathLabs survived past year five with their business strategy of offering primarily AP technical services. Is Clarient doing something different in its execution of this business model that may give it a different—and more positive—outcome?

Second, the market experience of AD PathLabs and US LABS must be considered evidence that the cost of operating a company that provides primarily AP technical services may not be totally recovered by the income earned from such services. Has Clarient improved productivity or removed costs sufficiently to earn adequate profit margins from existing reimbursement for AP technical services?

Third, both US LABS and AD PathLabs financed expensive sales and marketing programs to attract new clients. The average cost-to-acquire a new account can be quite expensive. Is Clarient's sales and marketing program gaining new client accounts without overspending? If too much money is spent to acquire individual accounts, those accounts may never generate sufficient profit margins to recoup their original acquisition cost.

Fourth, many of the same people who worked in important management and clinical positions at IMPATH (filed for bankruptcy in September 2004) and US LABS (sold to LabCorp in February 2005) are now working at Clarient. Will Clarient benefit from their experience, and thus not make key strategic mistakes which led both the aforementioned companies to a loss of corporate independence?

Based on the life spans of AD PathLabs and US LABS, it may take five years or longer for the laboratory industry to learn the answers to these questions. For the pathology profession, this is a subject of keen interest, for a very important reason.

The consistent inability of AP companies, some of which managed to sell their stock to the public, to remain independent over the long run indicates some type of financial weakness in the business model. These companies do share some interesting characteristics: 1) they are AP companies formed by non-pathologists; 2) they are amply funded by professional investors; and, 3) they are organized specifically to win the specimens currently going to local, pathologist-owned laboratories and group practices.

Where's the Pathologist?

THE DARK REPORT observes that all of these attributes may be a cause for failure for one reason: they have not been founded by pathologists—who understand the diagnostic needs of clinicians, who want to practice a higher level of medicine (a larger laboratory operation can fund a deeper test menu and acquire esoteric testing technology), and who intend for their business to support their medical career.

This conclusion can be supported by the host of small (under $5 million) specialty pathology laboratories that operate around the country. Owned and run by subspecialist pathologists, some have been around for almost two decades and are financially robust, even if they are not large by Wall Street standards. Might it be that an AP company—to be truly successful— really needs to be led by an anatomic pathologist? TDR

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Luminex and PerkinElmer Ink Licensing Agreement

Company known for high-volume systems will explore applications in clinical diagnostics

CEO SUMMARY: PerkinElmer's interest in the multiplex capabilities of Luminex's xMap technology led to this new licensing agreement. PerkinElmer's instrument systems played a major role in accelerating the work of the Human Genome Project. Now, besides bioresearch applications, PerkinElmer wants to look for opportunities to develop high-volume, multi-analyte assays for* in vitro *diagnostics.

IN RECENT MONTHS, Austin, Texas-based **Luminex Corporation** has licensed its xMap® multiplex testing technology to some interesting companies.

Probably the most noteworthy licensing pact—and the one with potential to make a big splash in clinical diagnostics—is the deal announced last week between **PerkinElmer, Inc.** and Luminex. PerkinElmer has licensed the right to use xMap technology to develop high-volume screening applications in life science research and *in vitro* diagnostics.

Pharma Biomarkers

In the research sector, PerkinElmer wants to develop uses for xMap technology in pharmaceutical biomarkers and ADME/Tox. The term "ADME/Tox" describes a fast-growing research discipline which specifically looks at how drugs are adsorbed, distributed, metabolized and eliminated from the body, along with any harmful or toxic properties of either the drug or its metabolites.

In the field of *in vitro* diagnostics, PerkinElmer intends to explore how xMap technology can be adopted for maternal, neonatal and prenatal health. PerkinElmer says it wants to standardize its multiplex assay development on the Luminex xMAP platform.

Laboratory administrators and pathologists may recall that PerkinElmer anchored the private sector effort that raced with government-funded researchers to complete the map of the human genome. Both PerkinElmer's money and its DNA sequencing instruments supported C. Craig Venter, Ph.D.'s company, **Institute for Genomic Research**, in its effort to map the human genome. That was in May, 1998. THE DARK REPORT was first to alert the clinical laboratory industry to this partnership and predicted that, by using PerkinElmer's newest generation of high-volume genetic sequencers, this group was likely to beat its own estimates. *(See TDR, June 15, 1998.)*

PerkinElmer and Venter estimated it would take them less than $300 million and no more than four years to accomplish the task. By contrast, the government-funded Human Genome Project, launched in 1990, was budgeted to spend $3 billion and not complete its work until 2005.

It was on April 14, 2003, that a press conference was held to recognize that the human genome had been sequenced and this phase of the Human Genome Project was completed ahead of schedule. One major factor in this acceleration of the timetable was the use, by government-funded researchers, of PerkinElmer's fastest genetic sequencing instruments.

Diagnostic Applications

This background on PerkinElmer is relevant because of the disclosure that the company intends to develop high-volume, multiplex instruments for diagnostic testing applications. PerkinElmer is a credible competitor in bioresearch. Thus, its interest in Luminex's multiplex diagnostic technology and its stated goal of developing *in vitro* diagnostic tests signals the possibility that the company might one day become a significant supplier of clinical diagnostic technology to the lab industry.

Another Luminex licensing agreement involved **Charles River Laboratories International, Inc.** of Wilmington, Massachusetts. It was announced on January 5. The Charles River Research Animal Diagnostic Services division will use xMap technology to create a "multiplexed fluorometric immunoassay (MFIA) that will be the platform for screening laboratory animal serum samples for infectious disease.

This connection is interesting because Charles River is a supplier of animals for medical testing. It also produces eggs for vaccine production. The company's interest in a multiplex assay for infectious disease testing indicates pressures in the research market for more sensitive assays that cost less money.

New Diagnostic Tests

Many IVD companies have licensed Luminex's xMap technology and are introducing diagnostic tests based on this technology into the clinical market. Just last November, **Tm Bioscience Corp.** announced the release of an upper viral respiratory panel that detects all of the major human respiratory viruses. This includes SARS Corona and the Avian Flu (H5N1).

Tm Biosciences has mated its Tag-It™ chemistry with xMap technology to create this new diagnostic panel. Tm Biosciences is probably best-known for its Tag-It™ Cystic Fibrosis (CF) Assay. This test was cleared by the FDA in Spring, 2005 and Tm Biosciences holds supply agreements for this test with **Laboratory Corporation of America** and **Genzyme Corporation**.

The business strategy at Luminex is to offer non-competitive licenses for xMap. As its licensees bring products to market, Luminex earns revenues from the sale of the instrument and consumables, and royalty payments based on test volume. It is the **Microsoft–Intel** open platform strategy.

Steady Revenue Growth

For 2005, Luminex will generate an estimated $36 million in revenues. It has licensed its technology to major pharmaceutical companies, bioresearch firms, and IVD manufacturers.

As noted earlier, PerkinElmer's interest in acquiring and developing Luminex's xMap technology may have long-term consequences for clinical diagnostics. If the company succeeds in marrying its high-volume processing technology with xMap's multi-anolyte capability, the result may be a breakthrough diagnostic system. TDR

Lab Industry Briefs

PREDICTIVE TESTING FOR RECURRENT BREAST CANCER

LABORATORY TESTS DESIGNED to predict the recurrence of breast cancer are picking up momentum. First to market was **Genomic Health Inc.'s** Oncotype DX™ breast cancer test. Now **TriPath Imaging, Inc.** is reporting favorable results from studies of its ProEx Br markers for breast cancer.

Since introducing Oncotype DX in 2004, Genomic Health has seen a steady increase in specimen volume. Through the end of September 2005, it had tested 5,000 patients. List price for this test is $3,460. Last Friday, January 13, Genomic Health announced that Medicare would cover the test, beginning February 27, 2006.

The company says that Oncotype DX is "the first genomic test that has clinical evidence supporting its ability to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis and the likelihood of chemotherapy benefit." Of the 230,000 women diagnosed with cancer each year, approximately 125,000 are candidates for this test.

TriPath Imaging's entry into the field is called ProEx Br. This panel of biomarkers consist of monoclonal antibodies "designed to detect overexpression of unique cellular proteins that are predictive of breast cancer recurrence."

Last month, researchers from the **Albany Medical College** in Albany, New York reported the results of a retrospective study of 217 archived breast cancer tissue specimens taken from women with early stage breast cancer who have been followed for at least five years since the original diagnosis. Researchers learned that, if all biomarkers tested negative, patients had a 30% chance of recurrence. If one biomarker was positive, the recurrence probability was 40%. If two of the five biomarkers in the panel studied were positive, there was a 70% probability of recurring cancer in that patient.

Based on these results, in combination with internal studies, TriPath Imaging is developing a version of its ProEX Br biomarkers to be used on the **Ventana Medical Systems'** BenchMark XT automated staining system. TriPath intends to conduct the clinical trials necessary to support a submission to the **Food & Drug Administration**.

The rapid acceptance of Genomic Health's Oncotype DX, along with the favorable study results involving TriPath Imaging's ProEx Br biomarkers, show that molecular technologies are maturing at a swift rate. If TriPath gains speedy regulatory approval to come to market, that will be an additional indication that regulators are growing comfortable with the capabilities of next-generation molecular diagnostics.

CUTS IN FLOW CYTOMETRY REIMBURSEMENT AFFECT BRLI EARNINGS

IN RESPONSE TO THE NEWS IN 2004 that the Medicare program would reduce reimbursement for flow cytometry by approximately 60% at the start of 2005, owners of **US LABS, Inc.** and **Esoterix, Inc.** made decisions to sell their companies.

Now comes an opportunity to gauge the impact reimbursement cut-

backs have had to labs with a substantial volume of flow cytometry cases. **Bio-Reference Laboratories, Inc.** (BRLI) of Elmwood Park, New Jersey announced 2005 earnings.

For its fiscal year ending October 31, 2005, BRLI reported revenues of $163.9 million, compared to $138.2 million for FY2004, an increase in revenues of 18.8%. This rate of growth was not matched in net income after taxes, which was $7.6 million, "resulting in fully taxed EPS of $.58 for the year compared to $8.5 million and $.67 in the prior fiscal year."

BRLI stated that its net earnings had been affected by "the effects of reimbursement cuts for Flow Cytometry testing, a key diagnostic used in a substantial percentage of the cases reviewed by GenPath, the Company's oncology / hematopathology laboratory." Back in 2004, BRLI was the first laboratory company to publicly disclose that reimbursement cuts for flow cytometry would have a material impact on the company's profits.

It was this disclosure that caused professional investors to pay closer attention to labs which performed high volumes of flow cytometry tests. The sale of US Labs was announced in late December 2004 and the sale of Esoterix was announced on March 30, 2005. *(See TDRs, January 3, 2005 and April 18, 2005.)*

The basic economics of laboratory operations are aptly illustrated in BRLI's 2005 financial performance. Despite an 18.8% increase in net revenues, the reduced reimbursement in flow cytometry testing triggered a reduction in the company's net income after taxes, which declined by 10.6%.

The financial impact of Medicare's reduction in flow cytometry reimbursement is highly visible, particularly given the fact that directors at both US LABS and Esoterix decided to sell their lab companies in the months following the news of those cutbacks. What has yet to be determined is the impact on clinical services and access to flow cytometry services as a consequence of these deep reimbursement cuts. It will likely take several more years to learn whether these cutbacks have caused a significant number of laboratories to reduce or even cease offering flow cytometry services.

NEWFOUNDLAND AND LABRADOR NOW OPERATE PATIENT REGISTRY

IN CANADA, the provinces of Newfoundland and Labrador have been first in the country to implement a provincial patient registry.

This registry is a database that contains information on all residents of the two provinces, as well as their eligibility for healthcare coverage. It is used by all hospitals, community health facilities, long term care facilities, and the government health system offices.

Known as the "Unique Personal Identifier and Client Registry," the first working system was introduced in 2002 and the final version was introduced last year. Efforts are now underway to connect clinical records to this system.

The population of Newfoundland and Labrador is about 500,000. By comparison, in the United States, Alaska, North Dakota, and Vermont each have between 600,000 and 700,000 people.

Like all Canadian provinces, Newfoundland and Labrador are working to develop a universal electronic health record. Steps are underway to create a pharmacy network that connects to the patient registry. Systems for accessing province-wide radiology information and laboratory test data are also under development in both provinces. TDR

New Instrument Targets Cervical Cancer Detection

Georgia company is developing diagnostic device for real-time detection of cancer in docs' offices

CEO SUMMARY: ***Guided Therapeutics, Inc. of Norcross, Georgia is working to develop proprietary technology into an improved method for detecting cervical cancer. It wants to give ob-gyns and other physicians an instrument system that can be used in the office to provide real-time results to patients. The procedure will be non-invasive and it will determine results by using both morphological and biochemical analysis.***

IT IS UNIVERSALLY RECOGNIZED that the Pap test, originally developed by Dr. Georgios Papanikolaou in the early 1940's, has been the most successful screening test in the history of medicine.

Because of the Pap smear, cervical cancer deaths in the United States and other developed countries have fallen dramatically. But, as a screening test, pathologists are all too familiar with the problem of the false positives and false negatives generated by the conventional Pap test's relatively low levels of sensitivity and specificity.

Improving upon the conventional Pap smear continues to be a goal of several biotech companies. One of those firms is **Guided Therapeutics, Inc.**, a subsidiary of **SpectRx, Inc.**, based in Norcross, Georgia.

Guided Therapeutics is developing a device for detecting cervical cancer that ob-gyns can use in their offices. The device is designed to provide several benefits. First, it would be a patient-friendly, non-invasive procedure and require no tissue sample or laboratory analysis. Second, it would improve accuracy of diagnosis while the patient is still in the office, providing peace of mind to the patient with a negative diagnosis, or immediate start of treatment for patients with positive diagnoses. Third, the device is designed to be used as a colposcope. This would allow the ob-gyn to be reimbursed for appropriate procedures that incorporate the instrument.

Several Improvements

Guided Therapeutics wants its new diagnostic device to significantly improve patient care, streamline and boost practice productivity, and contribute to enhanced practice revenues for ob-gyns and other physicians who treat women. Guided Therapeutics has begun the clinical studies needed to support a Pre-Market Application (PMA) with the **Food and Drug Administration**.

Guided Therapeutics is using spectral analysis technology in its product. The device "uses proprietary technology to identify cancers and precancers painlessly and non-invasively by analyzing light reflected from the cervix."

According to the company, "the device creates an image of the cervix that highlights the location and severity of disease. The technology distinguishes between normal and diseased tissue by detecting biochemical and morphological changes at the cellular level. Unlike Pap or HPV tests, the non-invasive test does not require a tissue sample or laboratory analysis, and results are available immediately."

Key Patent Was Granted

In December, Guided Therapeutics received a patent for a key component of its technology, which measures both biochemical and structural changes in tissue. The company developed the technology through work partially funded by research and commercial development grants from the **National Cancer Institute**. This technology combines morphological analysis of the cell structure with biochemical detection supported by advances in genetic and molecular diagnostics. To date, approximately 1,600 women have undergone testing with prototypes of the device.

"We envision the device will first be used as an adjunct to the Pap smear test," said Bill Wells, Director of Communications at SpectRx. "Physicians would use it to winnow through the false positives and false negatives of Pap screening and reduce the number of unnecessary procedures."

The as-yet unnamed device is similar to a colposcope, except that it will produce both a visual view of the cervix and a photonic view. "Using spectroscopy, the photonic technology analyzes the reflected light to distinguish biochemical and morphological changes in cells," Wells said. "The light source has a broad spectrum similar to natural light.

"The cervical cancer screening tool will do real-time diagnosis of a cervix to detect cancer and precancers," Wells said. "Using this diagnostic information, the ob-gyn would be able to treat the patient, refer for treatment, or if no cancer or precancer is detected, then he or she would be able to offer immediate relief of concern to the patient. That contrasts with Pap testing, where results are generally not known for several days.

"Since the device can be used as a colposcope, it will lend itself to reimbursement," Wells continued. "And, from a competitive perspective, we hope it would replace the colposcopy tools now in use. But, of course, the colposcope has an established market and this is a new product that would face all the usual challenges any new product would face."

While analyzing the cervix for biochemical and morphological abnormalities, the device would produce an image on a computer screen that could be stored and shared with other physicians. The image also could be archived, thus allowing a physician to analyze results over time.

FDA Submission

This year, Guided Therapeutics will complete collecting data on how the device works and submit the results to the FDA in its Pre-Market Application (PMA). "Our current timetable is to have the product on the market in the United States in 2007," noted Wells.

Like other companies developing technology to improve the detection of cervical cancer, Guided Therapeutics recognizes the potential for a successful product to generate significant sales volume. It hopes that a diagnostic procedure that is non-invasive, provides the patient with an immediate result, and makes money for the ob-gyn will catch on quickly. These would all be improvements over current cervical cancer detection methods. TDR

Contact Bill Wells at 770-242-8723.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent months, the buzz around the lab industry in Southern California has been that **Healthline Clinical Laboratories, Inc.** is up for sale. THE DARK REPORT believes news of a sales agreement is imminent. The new buyer is likely to be a pair of looking-for-work lab executives in the region, backed by private equity investors. Based in Burbank, California, Healthline is one of the larger independent lab companies still operating in the United States. It has estimated annual revenues of about $35 million.

MORE ON: Healthline Labs

Healthline Clinical Labs has not been easy to sell because of its recent settlement of Medicare and Medicaid fraud and abuse allegations. In April 2004, owners Aramais Paronyan, M.D. and Natella Lalabekyan, agreed to pay $10 million to the United States and California. This settled claims of illegal billing practices at the lab that occurred between 1996 and September 2003.

MEDICAL BOOKS AND JOURNALS ARE MUCH NEEDED IN IRAQ

Laboratorians have an opportunity to make a difference. In Iraq, healthcare professionals desperately need basic and specialty medical, surgical, nursing, pharmacy, dental, and veterinary texts and journals. They often must rely on used copies of out-of-date editions. Inside Iraq, there is no current production of medical books and educational materials. **Medscape**, the Web portal for healthcare professionals, has issued a new call for its readers to encourage medical colleagues to donate their used medical books and journals.

ADD TO: Help for Iraq

Pathologists, medical technologists and other laboratory professionals can help this effort by recycling unused medical texts and journals. Information on how to do this can be obtained by contacting *dgifford@hot.rr.com* and *syox@medscape.net*, or by visiting *www.medscape.com*. Since 2003, a "virtual" organization of military and civilian volunteers has come together to collect and transport these books and journals to the Iraqi hospitals, schools, and community clinics where they are needed most. Donors must pay U.S. postage only.

NEW COO AT LABCORP

Last month, on December 1, 2005, David. P. King assumed new duties as the Chief Operating Officer (COO) of **Laboratory Corporation of America**. King takes over for Richard Novak, who will be LabCorp's Executive Vice President, Office of Strategic Planning and Corporate Development, until his retirement, scheduled for December 31, 2006. Inside and outside LabCorp, knowledgeable observers believe that King is a prime candidate to eventually replace current LabCorp Chairman and CEO, Thomas P. MacMahon. King has served as LabCorp's General Counsel since 2001. He has been responsible for strategic planning, public policy, M&A, and licensing. He was also involved in managing **US LABS** and **Esoterix**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 6, 2006.

PREVIEW #1

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