

From the Desk of R. Lewis Dark...

THE R. LEWIS DARK REPORT

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

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R. Lewis Dark
Founder & Publisher



Building the Better Mousetrap for Lab Outreach

IS THERE A BLUEPRINT for building a thriving, successful hospital outreach program in a new market? If so, it would certainly be a best seller among hospitals seeking new sources of revenues and profits from outreach testing.

While it's not exactly a blueprint, **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington, has developed both a unique strategy and the "better mousetrap" for hospitals wanting to create a new lab outreach program or significantly expand an existing outreach program. At the same time, PAML demonstrates that it is possible to build a series of long-lasting laboratory joint ventures with hospitals—joint ventures that grab market share from national labs and return ample cash distributions to their partners.

This is significant for the laboratory industry. Lab executives universally recognize that hospital laboratory outreach programs can consistently compete with the best laboratory companies in the nation. That is, if they are properly capitalized, professionally managed, and good at both service and sales. What PAML has figured out is a way to offer precisely those four things to hospitals willing to partner with it in a laboratory joint venture.

Seen from this perspective, the newly-formed laboratory joint venture between PAML and two hospitals of the **MountainStar Health Network** in Salt Lake City, Utah, is the latest validation of PAML's vision and business strategy. (*See TDR, November 19, 2007.*) As you will read in our interview with PAML executives on pages 10-16, PAML invested gobs of money on service enhancements and integrated software solutions that allow it to provide world-class levels of service to referring physicians—and install this same service infrastructure into its different laboratory joint ventures.

I believe PAML is creating a new business template for laboratory joint ventures between hospitals and independent lab companies. Its success over the past 12 years with multiple laboratory JVs indicates that the business model has staying power. But can other independent laboratories emulate the more successful aspects of PAML's approach to developing and managing laboratory JVs? If they can, then the stage would be set for more hospitals and health systems to participate in such laboratory outreach joint ventures. As that happened, it would also increase the number of local laboratory testing options for patients and physicians.

Busy Year Demonstrated By Top Ten Lab Stories

➤ **Lab industry's Top Ten Stories for 2007 point to accelerating change in coming years**

➤➤ **CEO SUMMARY:** *As it turns out, 2007 has been an action-packed year with lots of events, plenty of changes, and the promise of even faster evolution across all sectors of the lab testing marketplace. THE DARK REPORT's "Top Ten Lab Stories of 2007" show the full intensity and pace of activity within laboratory medicine. One big driver in these events is the tidal wave of investment money flowing into diagnostics and lab testing. It is a time of high expectations and confidence in the future of lab medicine.*

WHAT A YEAR FOR LAB MEDICINE! Big things happened in every corner of the lab industry. Billions of dollars changed hands as every sector involved in laboratory testing consolidated, grew larger, and transformed.

Our list of the "Top Ten Lab Stories for 2007" backs up this observation. It ranges from an obvious pick—**UnitedHealth Group, Inc.**'s 10-year exclusive national contract with **Laboratory Corporation of America**—to an overlooked, but important development: **Procter & Gamble's** \$325 million dollar investment to form a joint venture with **Inverness Medical Innovations, Inc.**, involving what the two companies call "consumer diagnostics."

P&G is betting that consumers will walk into retail stores and readily pur-

chase self-test diagnostic kits. In fact, the joint venture, named **SPD Swiss Precision Diagnostics GmbH**, immediately became the world's largest seller of home pregnancy tests and fertility/ovulation monitoring products. The brand names include Clearblue, Persona, Accu-Clear, Fact Plus, and Clearplan.

Will retail sales of diagnostic test kits to consumers rapidly develop into a major market? No one knows. The point of this top ten story is to alert clients and readers of THE DARK REPORT about this new joint venture so that laboratories can respond as appropriate to any marketplace threats and opportunities.

In fact, collectively, our picks for the "Top Ten Lab Stories of 2007" have a compelling message for laboratory administrators and pathologists, which is

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R. Lewis Dark, Founder & Publisher.

Robert L. Michel, Editor.

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that progress across the length and breadth of laboratory medicine is unfolding at a faster and faster pace. This pace has several business implications.

For one, sustained consolidation activity across the clinical lab, anatomic pathology, *in vitro* diagnostics (IVD), and molecular sectors means that existing companies in these spaces must be nimble and responsive. New competitors pop up and existing competitors grow bigger in unexpected ways. For example, early last year, **Siemens AG** had a negligible presence in IVD. Today, it is the world's second largest IVD company, trailing only **Roche Holdings**.

So, in just 16 months, companies competing against **Diagnostic Products Corp.** (DPC), **Bayer Diagnostics**, and **Dade Behring** now find themselves competing against **Siemens Medical Solutions Diagnostics**. That shift is a radical one in the marketplace.

It's a similar story in the clinical laboratory sector. At the start of 2005, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** were the two huge national lab companies. Now, at the end of 2007, **Sonic Healthcare Ltd.** is the owner of regional labs in the United States that collectively generate almost \$500 million in annual revenues. Sonic is not only an active bidder against the two blood brothers for laboratory companies that come to market, it is a well financed competitor in regions where it has laboratories.

➤ **Rapid Changes In Market**

As these examples show, in less than 24 months, radically different market dynamics have emerged in both the IVD sector and the clinical lab sector! And it doesn't stop there. Our top ten story list identifies other lab industry sectors evolving in similarly swift fashion.

Another business implication identified in this year's top ten lab stories is the significant role government plays in the financial stability of the laboratory profession. Two of the top ten stories illustrate

this trend. One top ten story involves the implementation of new federal rules that restrict how physicians can mark up work for certain diagnostic procedures. It is an attempt by federal healthcare regulators to control the rising costs and increased utilization connected to in-house pathology and radiology services that office-based physicians have established. The other top ten story addresses the steps Medicare has taken to implement the "Demonstration Project For Competitive Bidding of Clinical Laboratory Services," including the selection of the San Diego area as the first demonstration site.

➤ **Lean And Six Sigma "Arrive"**

One top ten story that deserves attention is the burgeoning support among hospitals, health systems, and laboratories across the United States for quality management systems. In response to pressures to reduce and eliminate medical errors while boosting healthcare outcomes, providers are turning to Lean, Six Sigma, and other process improvement techniques.

As noted in our coverage on page 7, this year's *Lab Quality Confab* not only was able to assemble 60 presentations on the use of quality management systems in labs and pathology groups, but attracted a large crowd from seven countries around the globe. These results would not have been feasible just 24 months ago, illustrating how swiftly this trend is taking root within the laboratory industry.

As in past years, we encourage laboratory directors and pathologists to use this "Top Ten Lab Stories of 2007" list as the basis for a strategic review session with their management teams. It is a powerful tool to expose weaknesses in the business plan and identify emerging opportunities that might otherwise go unnoticed amid the crush of daily activities. The clear message from this year's top ten list of lab stories is the need to be proactive, not reactive!

TDR

Contact Robert L. Michel at 512-264-7103 or at labletter@aol.com.

TOP TEN OF 2007

1

UnitedHealth Deal with LabCorp Upsets MC Contract Status Quo

PROBABLY NO SINGLE NEWS EVENT during 2007 captured the attention of the entire laboratory profession as did the decision by **UnitedHealth Group, Inc.** to grant **Laboratory Corporation of America** an exclusive, 10-year, national contract, while excluding **Quest Diagnostics Incorporated** as a national contract provider. (See *TDR*, December 10, 2007.)

It was a story that everyone watched closely because it clearly upset the long-standing status quo in managed care contracts for laboratory testing services. For almost a decade, there had been little change in how the nation's largest health-care insurers granted contract status to the two blood brothers.

Following UnitedHealth's decision, **Aetna, Inc.**, signed an exclusive national

contract with **Quest Diagnostics** and shut out **LabCorp** as a national provider. **Cigna Corp.** decided to renew multi-year national contracts with both **LabCorp** and **Quest Diagnostics**.

Many lab directors and pathologists are concerned that intensified competition between the two national lab companies for exclusive national contracts will unleash a wave of heavily discounted pricing. *THE DARK REPORT* does not believe heavy discounting will happen in a way that is destructive.

Rather, it is likely that evolving business strategies at **LabCorp**, in particular, could lead to a different contracting model that puts **LabCorp** in the lead role in managing regional lab networks organized to serve specific payers. That scenario could negatively affect local labs.

TOP TEN OF 2007

2

New Investors Drive Up Valuations for Laboratory Testing Companies

ONE IMPORTANT TREND in the laboratory industry is the steady increase in the prices buyers will pay for laboratory companies that provide testing services to referring physicians. A number of lab company sales during 2007 demonstrated the power of this trend.

The year's single biggest deal is a dramatic illustration of these higher valuations. **Quest Diagnostics Incorporated** proved willing to pay \$2 billion for **AmeriPath, Inc.**, which had revenues of \$750 million in 2006.

Similarly, **Sonic Healthcare Ltd.** of Sydney, Australia, another new competitor in the U.S. market, has pulled out its checkbook and paid strong prices for selected laboratory acquisitions. One recent example was **Sonic's** acquisition of **Sunrise Medical**

Laboratories of Hauppauge, New York. It paid approximately \$148 million for **Sunrise**, which posted revenues of about \$75 million in 2006.

New buyers for labs continue to emerge. One example is **Laboratory Partners, Inc.**, of Palo Alto, California. It acquired three lab companies during the year. Another buyer is **Aurora Diagnostics, Inc.**, of Palm Beach Gardens, Florida, which bought a number of pathology groups and labs in 2007.

These events signal a shift in the buyer mix. Relative to just a few years ago, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** were the primary buyers for lab companies. Now there are additional buyers willing to bid for lab companies that come to market.

TOP TEN OF 2007

3

Medicare Competitive Bid Demo Moves Toward Implementation

SINCE MID-YEAR, when Medicare officials conducted an informational conference on the “Demonstration Project For Competitive Bidding of Clinical Laboratory Services,” progress toward implementation has been steady.

In October, federal officials announced that the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) would be the first demonstration site. (See *TDR*, October 29, 2007.) Last week, the **Centers for Medicare and Medicaid Services** (CMS) conducted the first bidder’s conference in San Diego.

These are significant developments for the laboratory industry. First, whether the demonstration project succeeds or not, it represents the efforts of

healthcare policy makers to move the Medicare program forward in ways that constrain spending and utilization. If not competitive bidding for lab testing services, then another scheme to achieve these goals would soon take its place.

Second, competitive bidding strikes at an interesting Achilles’ heel for the lab industry: the fact that private payers are given lower prices by labs in exchange for access to large patient volume. In some cases, it is Medicare work, reimbursed at higher levels, which subsidizes the pricing of these private contracts. Will Medicare officials succeed in using competitive bidding to bring down the prices it pays for lab testing? If so, that could lead to major upheavals in how the private sector sets prices for lab testing services.

TOP TEN OF 2007

4

IVD Industry Attracts New Players, Prices for Molecular Firms Skyrocket

NEWS THAT SIEMENS AG had spent \$14.1 billion to become the world’s second largest *in vitro* diagnostics (IVD) company was just one of several major developments in the IVD industry. (See *TDR*, August 6, 2007.)

To achieve this, Siemens bought its way to the top by acquiring, in order, **Diagnostic Products Corp.** (\$1.9 billion), **Bayer Diagnostics** (\$5.2 billion), and **Dade Behring Corporation** (\$7 billion). These three acquisitions were done over a 16-month period.

Not to be overlooked is the \$8.3 billion acquisition agreement that would have seen **General Electric** acquire most of the diagnostic businesses of **Abbott Laboratories, Inc.** The deal, announced

in January 2007, was voided by the two parties in July 2007.

There was equally significant news from **Roche Holdings**. In June, Roche made a hostile tender offer for **Ventana Medical Systems, Inc.**, offering to pay \$3 billion for a firm that posted revenues of \$282 million. Then, weeks later, in July, **Hologix, Inc.**, agreed to pay \$6.2 billion to acquire **Cytec Corporation** (which had 2006 revenues of \$602 million).

These transactions send a message: big labs and investors alike are bullish on the future of *in vitro* diagnostics and molecular test technology. In context with other top ten lab stories for 2007, it affirms the importance that lab testing will play as healthcare evolves.

TOP TEN OF 2007

5

Lean/Six Sigma Techniques Gain Mainstream Acceptance by Labs

IT'S ALWAYS DIFFICULT TO IDENTIFY the specific moment in time when an emerging trend reaches a tipping point and becomes mainstream.

For hospital and laboratory acceptance of quality management methods, such as Lean and Six Sigma, that moment was 2007. It's when the use of quality management systems moved beyond first mover and early adopter hospitals and labs and went mainstream. (See TDR, October 8, 2007.)

As proof of this development, THE DARK REPORT offers the *Lab Quality Confab* conference, which took place in Atlanta on September 19-20, 2007. A sold-out crowd of 275 people showed up, including lab directors from Argentina, Australia, Brazil, Canada, Sweden, and

the United Kingdom. More than 60 sessions focused on the use of Lean, Six Sigma, ISO 15189, and similar quality management programs in hospitals, health systems, clinical labs, and pathology groups.

Moreover, the collective lessons provided by these sessions demonstrated that these quality management methods are extremely effective at unlocking gains and improvements in reducing errors, boosting productivity, raising quality, and lifting patient satisfaction.

THE DARK REPORT expects to see a steadily growing number of hospitals, health systems, and laboratories embrace Lean, Six Sigma, and other process improvement tools. As they do, they will gain competitive advantage.

TOP TEN OF 2007

6

EMRs in Doctors' Offices Trigger New Demands on Competing Labs

IT'S A TREND THAT THREATENS the strong competitive successes many hospital laboratory outreach programs have enjoyed in recent years.

As larger physician groups take steps to implement electronic medical record (EMR) systems in their practices, they are fundamentally changing how they demand to interact with their laboratory providers. Quite simply, the EMR is a major step toward a paperless office and that motivates physicians to approach their laboratories and request electronic interface gateways that supports electronic test ordering and lab results reporting.

Should the laboratory provider drag its feet on implementation of such an interface gateway between the LIS

and EMR, then the advantages are significant enough that physicians will talk to competing laboratories.

When this year's *Executive War College* conducted a one-day program on LIS-EMR Electronic Gateways, a full audience of 300 lab executives and pathologists packed the room to hear from early-adopter labs, EMR firms, and laboratory informatics vendors. Most attendees freely admitted that their laboratory was already responding to requests from larger clients to install gateways to enable electronic test ordering and result reporting between the LIS and the EMR.

The message for lab directors is that it is time to craft a strategy for electronic connections to clients' EMRs.

TOP TEN OF 2007

7

Speedy Change in Six Lab Sectors Points to Accelerating Evolution

ONLY THE DARK REPORT HAS IDENTIFIED a remarkable development within the world of laboratory medicine. It is compelling evidence that the pace of evolution is accelerating across six identifiable sectors of the laboratory industry.

This analysis provided the facts and evidence to demonstrate how, within the past 24 months, each of these six lab industry sectors had undergone changes that were rapid, if not revolutionary! (See *TDR*, August 6, 2007.)

The sectors are: 1) managed care contracting for laboratory test services; 2) acquisitions of clinical laboratories; 3) new business formations and acquisitions within anatomic pathology; 4) new business formations and acquisitions

of firms with molecular diagnostic technologies; 5) consolidation among the 15 largest *in vitro* diagnostics (IVD) companies; and, 6) consolidation and integration within the healthcare IT industry. Each sector involved companies serving the laboratory industry.

For laboratory directors and pathologists, this insight has important strategic implications. It demonstrates that a tidal wave of new technologies—ranging from molecular to software to automation—and fueled by a river of venture capital dollars, are creating an accelerating rate of change in laboratory medicine. That raises the stakes for any lab that adopts a “do nothing” or “wait and see” business strategy. Tomorrow’s lab winners will be those that respond proactively to the market.

TOP TEN OF 2007

8

TC/PC Batters Anatomic Pathologists, New CMS Rules Offer Some Relief

IN 2007, PATHOLOGY’S BIGGEST STORY was the accelerating erosion of specimen referrals as many office-based physicians took steps to capture, for themselves, revenues from anatomic pathology (AP) services generated by their patients.

TC/PC is the term often used to describe a variety of arrangements that allow referring physicians to profit from either TC (Technical Component) or PC (Professional Component) or both. Over the past four years, THE DARK REPORT has regularly reported on this important trend. (See *TDRs*, July 19, 2004; July 23, 2006; September 17, 2007.)

In its simplest form, it involves urologists, gastroenterologists, and similar specialists deciding to build

their own pathology laboratories as a way to capture anatomic pathology revenues for themselves. Since these are the high-referring specialists for most pathology groups, loss of these case referrals can be financially devastating.

Some relief may be on the way. Effective January 1, 2008, new Medicare rules take effect that will restrict the circumstances under which physicians can mark up anatomic pathology services provided to their patients. (See *TDR*, November 19, 2007.)

It is unlikely that this round of new federal regulations will completely stamp out TC/PC arrangements. But it does put physicians on notice that federal health officials are concerned about this situation.

TOP TEN OF 2007

9

Hospital CEOs Realize Capital Value By Selling Lab Outreach Businesses

FOR YEARS, MOST HOSPITAL CEOs have failed to recognize the capital value that is created by a profitable lab outreach program. However, that may be changing.

During 2007, two very successful hospital laboratory outreach programs were put on the market and sold so that the parent hospital or health system could tap the accumulated capital value of the revenue stream and apply those proceeds to other uses.

Coincidentally, **Laboratory Corporation of America** was the buyer in both sales. In June, it acquired **DSI Laboratories, Inc.**, of Fort Meyers, Florida, from **NCH Healthcare System**, followed in September with the purchase of **Pathology Associates**

(PA Labs, LLC) of Muncie, Indiana, from the joint venture which included **Cardinal Health System**.

The sale prices paid were not made public. But it is estimated that the sale price of DSI Labs was as much as \$75 million. That is a big chunk of change for NCH Healthcare System, which, at the time the sale was announced, projected losses of as much as \$20 million for 2007.

Of course, it shouldn't be overlooked that **Carilion Health System** of Roanoke, Virginia, has a strategy to build its outreach testing business—and is bidding for these acquisitions as they come to market. These are all signs that hospital CEOs are learning that lab outreach can be a lucrative endeavor.

TOP TEN OF 2007

10

Procter & Gamble Positions Itself To Retail Diagnostic Tests in Stores

PROBABLY ONLY CLIENTS and regular readers of **THE DARK REPORT** are aware that, during 2007, **Procter & Gamble** invested a third of a billion dollars to position itself to sell diagnostic test kits to consumers in retail stores.

On the same day last May that **Inverness Medical Innovations, Inc.**, announced that it was the successful bidder for **Biosite, Inc.**, Inverness and **Procter & Gamble** announced the formation of a joint venture between the two companies. In this joint venture, called **SPD Swiss Precision Diagnostics, GmbH**, Inverness and Procter & Gamble will cooperate to develop and market what they call “consumer diagnostics”—self-test kits to be sold to consumers in retail outlets. (See *TDR*, June 4, 2007.)

This development is important and is one that pathologists and laboratory executives should not overlook. That is because Procter & Gamble is one of the world's most respected consumer products companies. When it selects a product category to develop, it invariably succeeds.

Thus, P&G's interest in positioning itself to have access to diagnostic technology that will allow it to create and sell diagnostic test kits to consumers in retail outlets is significant for two reasons. First, it shows that P&G expects diagnostic technology to develop rapidly to support accurate, off-the-shelf test kits that consumers can use with confidence. Second, it shows that P&G believes that demand by consumers for such test kits will grow steadily. **TDR**



Thomas
Tiffany,
Ph.D.



Noel
Maring

NEWSMAKERS

INTERVIEW

How PAML Built a Major Business In Lab Joint Ventures with Hospitals

“A well-structured laboratory joint venture helps the hospital partner tap the unrealized value of its laboratory, because the independent lab partner provides capital, along with experience, and expertise to serve and build outreach market share.”

—Thomas Tiffany, Ph.D., CEO, Pathology Associates Medical Laboratories

►► **CEO SUMMARY:** Earlier this month, MountainStar Healthcare Network of Salt Lake City, Utah, and Pathology Associates Medical Laboratories (PAML) of Spokane, Washington, announced a new laboratory joint venture, called MountainStar Clinical Laboratories, LLC. Two things are notable about this development. First, because MountainStar Healthcare Network is owned by Hospital Corporation of America (HCA), it represents a significant step by that for-profit hospital company to further expand its laboratory outreach programs. Second, with this agreement, PAML extends its track record as a joint venture partner in multiple laboratory outreach programs. In fact, not in two decades has the lab industry seen an independent laboratory company become a “serial joint venture partner” with so many different hospitals and health systems. In this exclusive interview with PAML CEO Thomas Tiffany, Ph.D., and Chief Marketing Officer Noel Maring, TDR Editor Robert L. Michel investigates the reasons behind PAML’s success in creating lab joint ventures.

EDITOR: Laboratory testing joint ventures between a hospital and an independent laboratory company are uncommon events. In my view, that is one of three reasons why the new laboratory joint venture created last month by Pathology Associates Medical Laboratories (PAML) and

MountainStar Healthcare Network in Salt Lake City, Utah, is a significant development. (See TDR, November 19, 2007.) The second reason is that MountainStar is owned by Hospital Corporation of America (HCA), the nation’s largest for-profit hospital company. The third reason

is that PAML has created a string of laboratory joint ventures over the past decade, which makes it unique in the United States today. Laboratory joint ventures like these are difficult businesses to create. Would you share some of the strategies that PAML uses to make these lab joint ventures happen with such regularity?

TIFFANY: Certainly. And although you are correct in pointing out that just a handful of successful, long-lasting laboratory joint ventures involving hospitals and independent lab companies operate today, we think that many more ventures are possible.

EDITOR: That comment would seem to fly in the face of 20 years worth of lab industry experience. Since the mid-1980s, only a limited number of such lab joint ventures were created, and few survived past a five-year period, typically when the first operating agreement expired.

MARING: That is an accurate characterization of those years for the lab industry at large. By contrast, PAML has five operational joint ventures right now, with 17 hospitals as participants. The oldest of these were launched 12 years ago.

EDITOR: Only one independent lab company that I know of created and sustained

a comparable or greater number of similar lab joint ventures with hospitals. That was International Clinical Laboratories (ICL) and it was acquired by SmithKline Beecham Clinical Laboratories (SBCL) in the mid-1980s. By the early 1990s, Damon Clinical Laboratories had four hospital joint ventures with a total of eight hospitals

MARING: We would agree with that. However, a number of the ICL deals were actually lab management contracts. Notably, several of ICL’s true lab joint ventures continue to operate today, more than 20 years later. I don’t believe the four Damon joint ventures survived the expiration of the first five-year agreement.

TIFFANY: I would add that the longevity of these surviving ICL JVs demonstrates that it is possible to create a win-win business partnership between a hospital and an independent laboratory company.

EDITOR: If this is true, why don’t more laboratory joint ventures occur between a hospital and an independent laboratory company?

MARING: That’s a difficult question to answer, since every laboratory joint venture comes together for unique reasons.

EDITOR: Let’s tackle that question from another direction. Why has PAML suc-

ceeded in creating multiple laboratory joint ventures with hospitals and kept them going successfully, for as long as 12 years?

TIFFANY: It was a strategy born of necessity. PAML is based in Spokane, Washington, on the east side of the state. There are few large population centers outside the Seattle-Tacoma metropolitan area. To expand and develop our business in the mid-sized cities around the state, we needed a way to serve lab clients in those areas without having to build lots of infrastructure from scratch. We developed “Shared Testing Agreements” with community-based hospitals in these regions to assist the hospitals and compete with the national labs. These agreements evolved into our Joint Venture Agreements that we utilize today with major medical centers.

EDITOR: However, over the past decade, didn’t PAML acquire a number of regional laboratories in cities throughout Washington and Idaho?

TIFFANY: That is correct. Those acquisitions provided the foundation for developing a laboratory joint venture with local hospitals in those cities.

EDITOR: Please explain.

TIFFANY: One primary business strategy at PAML is to enter a new market by acquiring a local laboratory. We then look at opportunities to partner with selected hospitals to mutually build the outreach business.

EDITOR: That makes sense, particularly in the smaller cities found in Washington and Idaho. It allows your lab and the hospital to minimize the duplication of lab infrastructure. At the same time, by including inpatient test volume in the mix, it is easier to achieve economies of scale within that relatively small city.

MARING: Right on both counts. During the 1990s and into this decade, this approach allowed us to grow into the largest laboratory in the Northwest—and do it profitably.

TIFFANY: Another factor makes PAML unique. We are owned by a health system. Our core laboratory in Spokane is located across the street from one of its hospitals, the 623-bed **Sacred Heart Medical Center**. PAML and Sacred Heart have developed what we call a “virtual laboratory.” PAML’s core laboratory and the Sacred Heart Laboratory are highly integrated and are designed to operate as a single laboratory system. This minimizes duplication of testing, promotes increased economies of scale for both laboratories, and allows inpatients and outpatients to receive higher levels of service. This is the operational model we use in our joint ventures.

MARING: That distinction is important. Most of the larger laboratory companies in the United States are not as intimately involved in managing the complete inpatient testing needs for a sizeable hospital—who also happens to be the lab’s owner!

TIFFANY: Additionally PAML manages the inpatient laboratories at two hospitals in one of our joint ventures. In that regard, although PAML is an independent lab company, it is also a hospital laboratory. We have a sophisticated understanding of the needs and demands the hospital places on its laboratory.

EDITOR: From this perspective, you are describing PAML as a hospital-owned laboratory company that has a different relationship to the hospital industry than most other independent laboratory companies.

MARING: We would agree with that characterization. Because we are so intimately connected to the day-to-day issues at Sacred Heart Medical Center, our entire staff understands how to properly respond to inpatient testing issues while maintaining close relationships with outreach customers.

EDITOR: This is good background for my next question. Why Salt Lake City as the next market, and why MountainStar as a joint venture partner?

MARING: As we expanded our service area from Spokane, that led us to acquire and establish testing activities in Idaho. That's next door to Utah. As we studied the regional markets in Utah, we spotted an opportunity to enter Salt Lake City through acquisition.

EDITOR: In keeping with your strategy, the foothold into a new city is the acquisition of an existing laboratory, before looking for a hospital that would be a suitable laboratory joint venture partner.

MARING: That describes our entry into Salt Lake City. In November 2002, we purchased **Bio Labs**, which primarily served long term care facilities. In November 2003, we next acquired **Medical Drive Laboratory**, which served clients in a medical office building.



Thomas
Tiffany,
Ph.D.

➤ "...although PAML is an independent lab company, it is also a hospital lab. We understand, in great sophistication, the needs and demands the hospital places on its laboratory."

EDITOR: So these two labs provided you a base upon which to build outreach business.

MARING: Yes. Our sales efforts were directed to expanding test referrals from office-based physicians and we've seen steady growth in specimen volume and revenue in the Salt Lake City market.

EDITOR: So the next step in your strategy was to identify potential hospital partners for a laboratory joint venture based in Salt Lake City. What steps did you take?

MARING: There were several health systems that we considered prospects for a joint venture. However, MountainStar caught our attention. Its hospitals are well-managed and it has good leadership. HCA has created a management environment where the regional hospital administrators have a high degree of autonomy, even as standardization is emphasized in

specific areas. As an example, standardization in the laboratory means Meditech for the LIS. They have standardized buying groups too. It's an interesting mix, and it seems to be very effective.

EDITOR: When did the conversation start with the people from MountainStar?

MARING: In December 2003, I met with the CEO of **Lakeview Hospital**, one of the two MountainStar hospitals now involved in the joint venture. Administrators at Lakeview were already familiar with us, as our laboratory was located across the street from the hospital and our medical director was one of Lakeview Hospital's pathologists. At the CEO's direction, I began working with the CFO, who took us to a regional meeting of all the MountainStar CFOs. Lab managers were present at that meeting, where we presented the concept of a laboratory joint venture. One lab manager, Jane Newhall, recognized the value in a laboratory joint venture. She and the CFO at her hospital became champions for the joint venture and these two helped to carry this idea through to fruition.

EDITOR: With an expression of interest, what were the next steps?

MARING: We offered to produce a more detailed business plan of 80 to 90 pages within 60 days. When this was ready, we met again and presented this business plan.

EDITOR: Let's stop here for a moment. PAML has created a template for these joint ventures, hasn't it? Don't you propose a specific role for PAML and provide a range of services to the joint venture?

MARING: Yes to both questions. In our joint ventures, we act as the general manager. We are organized to provide all the pre-analytical and post-analytical services. That includes couriers, sales, marketing, setting up patient service centers, and accessioning. Under our agreement, we send them bar coded specimens that we can track appropriately and that are ready for them to accept and test with minimal additional lab

cost. The specimens can go right on their equipment and then, using a bidirectional interface, results are reported back to PAML where we are able to deliver the results to physicians through a variety of mechanisms (such as Web reporting and to EMRs) based on the needs of specific clients.

EDITOR: Would you say something about your use of information technology to support these laboratory joint ventures?

TIFFANY: PAML has invested heavily to create an integrated suite of software capabilities that allow us to track, in great detail, work in every area of our laboratory. This proprietary system is called "Outreach Advantage" and it is a key element in our laboratory joint ventures. At the heart of Outreach Advantage is a customer relationship management (CRM) engine built on Microsoft's CRM and highly-customized for our needs.



Noel Maring

➤ "Outreach programs need to be fast and efficient at building interfaces between the LIS and clients' EMRs."

EDITOR: Is this a paperless system?

TIFFANY: Yes, and more than that. It allows our staff to track specimens, claims, customer issues, and the entire spectrum of laboratory work processes, in great detail and in real time. We can spot patterns of service issues affecting individual clients—and fix them so that service to the client is close to flawless. One consequence of Outreach Advantage within PAML is that our service is extremely consistent, and client turnover due to service issues is almost zero.

MARING: The capabilities of Outreach Advantage were a big selling point for MountainStar. In particular, Jane Newhall, the lab manager I mentioned earlier, recognized very early that she

would be able to substantially increase volume in her lab without a corresponding need to add staff. Within the HCA system, her greater lab volume would qualify for the lowest supplier pricing discounts.

EDITOR: What were the reasons that MountainStar entered into this new laboratory joint venture?

MARING: They would be the best ones to provide you the full answer to that question. I know that one element in their decision was that they had recently completed their own analysis of the outreach market and determined that the capital costs to expand would be significant. For example, they did not have comparable electronic connectivity solutions to physicians' offices, which we already have. They would need to expand their customer service systems, which we could quickly provide by plugging Outreach Advantage into their systems. Moreover, they had concluded that, if they did not invest in connectivity and similar services, at best, their outreach volume would stay the same, if not decline over time.

EDITOR: How does the laboratory joint venture take advantage of the hospital lab's natural competitive advantages?

MARING: The hospital lab has two strong selling points to local physicians. First is the ability to provide inpatient, outpatient, and outreach lab test data to the referring physicians. National labs don't have both inpatient and outpatient lab test data. Second is that, for a number of routine and common reference tests, hospital labs can deliver results faster than out of town lab competitors.

EDITOR: Based on your experience in operating laboratory joint ventures with hospitals, what do you recommend to a hospital administrator or lab director who wants to energize and expand a laboratory outreach program?

MARING: They should factor in the new competitive trend of interconnectivity to the physicians' EMR. Outreach programs need to be fast and efficient at building

PAML Develops Business Strategy Based on Hospital Lab Joint Ventures



MountainStar Clinical Laboratories, LLC of Salt Lake City, Utah is the newest joint venture for Pathology Associates Medical Laboratories (PAML). During the past decade, PAML developed a strategy of opening up new markets by first acquiring a local laboratory company, then developing a laboratory outreach joint venture with one or more hospitals in the community. PAML generally assumes responsibility for pre-analytical and post-analytical functions and services, as well as handling reference testing for the JVs.

PAML's Joint Ventures with Hospital Labs

ALPHA MEDICAL LABORATORY, LLC

Coeur d'Alene, ID—Founded 1995
Kootenai Medical Center

TRI-CITIES LABORATORY, LLC

Kennewick, Pasco, Richland, WA—Founded 1997
Lourdes Health Network
Kennewick General Hospital
Kadlec Medical Center

TREASURE VALLEY LABORATORY

Boise, ID—Founded 1999
Saint Alphonsus Regional Medical Center

MOUNTAINSTAR CLINICAL LABS, LLC

Salt Lake City, UT—Founded 2007
St Marks Hospital
Lakeview Hospital

PACLAB NETWORK LABS, LLC

Olympia, Tacoma, Seattle, Everett, Bellevue, Kirkland, WA—Founded 1996

PAML (Bellevue, Seattle, Olympia)

Providence Health System—Washington

Providence Everett Medical Center

Providence Centralia Medical Center

Franciscan Health System

St Josephs Medical Center

St Francis Hospital

St Clare Hospital

Stevens Healthcare

Evergreen Healthcare

Overlake Hospital & Medical Center

interfaces between the LIS and clients' EMRs. This takes capital and resources that many hospitals are not willing to invest. Next to consider is the added cost of sales and marketing, along with the financial expertise to evaluate the profitability of individual accounts. Another consideration is accurate billing and collections and an effective customer service department. These all take staff resources and investment capital that may not be available.

NEWSMAKER
INTERVIEW

EDITOR: Those are useful recommendations. Thank you for helping us understand PAML's business strategy.

MARING: You're welcome.

TIFFANY: Yes, we appreciate the opportunity to explain why we believe in laboratory joint ventures, and how they can help hospitals develop more effective outreach programs.

TDR

Contact Thomas Tiffany, Ph.D., and Noel Maring at 509-755-8900 or nmaring@PAML.com.

Tiffany and Maring



Lab Market Trends

Medicare Demo Bidders' Meeting Reveals Many Problems Ahead

LAST WEDNESDAY IN SAN DIEGO, the Centers for Medicare & Medicaid (CMS) conducted an all-day information session for laboratories interested in submitting bids to participate in the Medicare Clinical Laboratory Services Competitive Demonstration Project.

It is estimated that a crowd of 100 showed up. More listened in, using a special telephone link to the Bidders' Conference. In what could be a portent of things to come, listeners reported that, not only did it take an hour or more into the conference before the telephone link was operational, but the sound quality was marginal and never improved.

► Portent Of What's To Come?

From this inauspicious start, the balance of the day revealed that implementation teams from CMS and **RTI International** (contracted to assist CMS in the design, implementation, and evaluation of the bidding demo project) have failed in one aspect of their mission: to design the framework of a bidding process that is relatively simple, understandable, objective, and transparent to the public at every step.

This assessment does not come from THE DARK REPORT, but directly from individuals who attended the bidders' conference and shared their impressions in the days following the conference. These individuals, without exception, expressed their disappointment at both the content of the conference and how it was conducted. Moreover, each attendee identified significant flaws in the bidding process, based on their study of the documents released by CMS and the explanations provided by representatives of CMS/RTI International over

the course of the bidders' conference. Often, CMS and RTI representatives could not answer questions which pointed out major gaps in their implementation plan.

None of this bodes well for the laboratory industry. The federal government is about to undertake a bidding auction process that is complex, lacks obvious logic, and alarms informed experts by its potential to roil the existing and quite functional distribution network of laboratory testing services in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area).

Lab directors and pathologists will have the opportunity to read plenty of information in other publications about the bidders' conference and how CMS plans to conduct the bidding process, select winning laboratories, and implement the demonstration project. Expect to read many criticisms, involving every aspect of the demonstration project—from its fundamental design to small details affecting implementation.

► Call To Action

THE DARK REPORT recommends that associations, trade groups, and industry leaders in laboratory medicine should seize the initiative to develop a sophisticated, informed criticism of the about-to-be-implemented bidding demonstration project. This policy "White Paper" should be distributed to local, state, and federal policymakers. Media contacts should be alerted, informed, and encouraged to report this story. Now that CMS and RTI have released their implementation plan, it is time for the laboratory industry to step up in a timely and professional way to deliver its message with a powerful punch!

Integrated In Vivo-In Vitro: Is It Pathology's Future?

➤ **Molecular pathologists and radiologists will share integration successes on February 5-6**

➤➤ **CEO SUMMARY:** *Across the globe, forward-thinking pathologists and radiologists are taking steps to use molecular technologies in ways that combine in vivo and in vitro testing. As this happens, traditional roles for pathology and radiology are likely to evolve toward a more integrated diagnostic service. To learn more about this trend, Molecular Summit 2008 is bringing together the first movers in molecular imaging and molecular diagnostics to share early successes and lessons learned.*

FOR THE PATHOLOGY PROFESSION, the abstract concept of integrating *in vivo* and *in vitro* diagnostics moved to a marketplace reality as a result of three developments during the past year.

The first event was the emergence of **Siemens AG** as the world's second largest *in vitro* diagnostics (IVD) company, following its rapid fire acquisitions of **Diagnostic Products Corp.** (DPC), **Bayer Diagnostics**, and **Dade Behring**.

The second was the effort, by **General Electric Corporation**, to acquire most of the diagnostics business of **Abbott Laboratories, Inc.** Although the deal was not completed, it put GE on record as being motivated to build its presence in IVD.

The third was the public statements by both Siemens and General Electric on their corporate strategies. In some form or fashion, both companies are stating that the future of diagnostic medicine lies in the effective integration of *in vivo* and *in vitro* diagnostics. These declarations have further credibility because both companies have demonstrated their readiness to spend billions of dollars to make their strategies a reality in the clinical marketplace.

Many pathologists reacted to these events with concern. That's because *in vivo* testing is currently the province of radiologists, while *in vitro* testing is the province of pathologists. Thus, any efforts to integrate *in vivo* and *in vitro* technologies into a single, integrated diagnostic continuum will require collaboration between radiology and pathology.

➤ **Radiologists & Pathologists**

In fact, it is in molecular medicine that early steps to integrate *in vivo* and *in vitro* diagnostics are occurring. These are definitely first mover efforts—not in the mainstream of pathology or radiology...yet. However, these early successes provide hard evidence of how pathologists and radiologists are likely to work together as molecular imaging and molecular diagnostics push their way into mainstream medicine.

To help pathologists and radiologists further understand these transformational developments, **THE DARK REPORT** is conducting *Molecular Summit 2008*, to be held in Philadelphia on February 5-6, 2008. The emphasis will be on molecular

imaging and molecular diagnostics. Presentations will be given by pathologists, radiologists, and informatics experts on how they are using molecular technologies in *in vivo* and *in vitro* testing.

➤ In Situ Assessment of Tissue

Several presentations involve ambitious efforts to apply core *in vitro* (pathology) technologies to *in vivo* (radiology) procedures. For example, at **The Methodist Medical Center** in Houston, Texas, the vision is to assess tissue *in situ* without the need for a biopsy. King Li, M.D., FRCP, Chairman, Department of Radiology, will discuss how he and his colleagues want to use tools such as PET or CT-PET to visualize events at the macroscopic level. If an abnormality is detected, a tiny fiber can be guided to the area and inject a stain that highlights a molecular probe.

Meanwhile, pathologists at the **University of Pittsburgh Medical Center**, are focused on oncology. They are working to create a seamless information flow. Michael J. Becich, M.D., Ph.D., Chairman, Department of Biomedical Informatics, will discuss progress in integrating molecular diagnostics data produced by *in vitro* testing with an integrated informatics platform that gives clinicians access to all the relevant data for individual patients.

➤ Integrated Reports for Docs

For a fascinating look at how pathology and radiology services can be integrated in ways that directly benefit physicians and patients, **Laboratorio Fleury** of São Paulo, Brazil, will present a case study. Jose Marcelo A. de Oliveira, M.D., Ph.D., Diagnostic Center Director, will discuss Fleury's strategy of providing "one stop" diagnostic services to patients.

In downtown São Paulo, Fleury's collection center draws 2,000 patients per day. The center also offers a complete line of imaging services, ranging from X-Ray and PETs to mammograms and sonograms. This equipment allows a patient

Molecular Summit 2008 Deals with Integration of In Vivo, In Vitro Testing

HOW WILL NEW MOLECULAR TECHNOLOGIES bring pathologists and radiologists into closer collaboration? **Molecular Summit 2008** has invited first mover and early adopter pathologists and radiologists to present their successes and lessons learned.

It will be the first global gathering to include both pathologists and radiologists using new technologies in molecular diagnostics and molecular imaging, respectively.

What: Molecular Summit 2008

When: February 5-6, 2008

Where: Sheraton Society Hill Hotel

Why: To explore early efforts to apply molecular technologies in ways that integrate molecular imaging and molecular diagnostics.

Info: www.molecular-summit.com for full details and to register.

to have several diagnostic procedures performed during one visit. Fleury then sends the physician a report that integrates clinical data, imaging, lab tests, and pathology.

Over the course of two days at the *Molecular Summit 2008*, advanced users of the newest molecular imaging and molecular diagnostics technologies will share the outcomes of these efforts. Several noted molecular strategists will provide detailed looks at how molecular medicine is expected to evolve in the coming years.

➤ In Vivo and In Vitro

Billions of dollars are flowing into molecular medicine and leading corporations such as Siemens are predicting integration for molecular imaging and molecular diagnostics. *Molecular Summit 2008* will provide a detailed look at how molecular's pioneers are working to make that vision a reality. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print,
too early to report



Last month, **Beckman Coulter, Inc.**, of Fullerton, California, announced that it will acquire the research flow cytometry instrumentation business of **Dako Denmark A/S**, of Glostrup, Denmark. The move strengthens Beckman's product line in the research market. Sale of Dako's flow cytometry division, which is based in Fort Collins, Colorado, is a step to concentrate efforts on molecular diagnostics. Patrik Dahlen, President and CEO of Dako, stated "This action reinforces our strategic intent to create a more focused business in anatomic pathology and tissue-based cancer diagnostics."

INVERNESS BUYS PARADIGMHEALTH

It's been a busy year for **Inverness Medical Innovation, Inc.**, of Waltham, Massachusetts. On November 26, it announced the purchase of **ParadigmHealth, Inc.**, of Upper Saddle River, New Jersey, in a deal valued at \$230 million. ParadigmHealth is a "provider and integrator of

care and disease management services for acutely ill and clinically complex patients, including neonatal intensive care and oncology patients." Inverness is pursuing a corporate strategy of "near-patient diagnosis, monitoring and health management. It has a growing portfolio of diagnostics products.

ADD TO: Inverness

Earlier this year, Inverness Medical outbid Beckman Coulter to acquire **Biosite, Inc.** for \$1.6 billion in a lengthy acquisition battle. (See TDR, June 4, 2007.) During 2007, Inverness also acquired **Alere Medical Inc.** (\$302 million—disease management and patient monitoring), **Matritech, Inc.**, (\$36 million—cancer testing), **HemoSense, Inc.**, (\$165 million—POCT blood coagulation), **Cholestech Corp.** (\$326 million—cholesterol testing), and **Quality Assured Services Inc.**, (\$25 million—home coagulation testing).

TRANSITIONS

- Longtime lab industry executive Frank Kearns, M.S., MBA, died on December 1, 2007. In recent years, Kearns had served as CEO of **Laboratory Alliance of Central New York, LLC**, in Syracuse, New York. He also held executive positions with **ARUP Laboratories, Inc.**, and **SmithKline Beecham Clinical Laboratories, Inc.**, in a career that started in Southern California.



DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...**Google** investing in **23andMe.com**, an online business that offers a \$999 genetic test to consumers, who purchase online, do the collection at home, and submit the specimen for testing.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, December 31, 2007.*

Announcing!

MOLECULAR SUMMIT 2008

Integration of In Vivo & In Vitro Diagnostics!

Sheraton Society Hill Hotel • Philadelphia • February 5-6, 2008

New molecular technologies are creating powerful ways to combine imaging, diagnostics, and informatics to give clinicians stunningly precise tools to diagnose and treat a growing number of diseases! To alert you to what's best—and what's not—this first-ever **MOLECULAR SUMMIT** has assembled national and global leaders in the areas of molecular diagnostics, molecular imaging, Join us to learn and master new opportunities for clinical and financial success!

*For full agenda and program details,
visit molecular-summit.com*

UPCOMING...

- **Medicare's Competitive Bid Demo: Bad News and Bear Traps for Unwary Lab Bidders.**
- **Assessing Best Strategies for Labs Preparing to Bid in San Diego Medicare Demo Project.**
- **Pathology Takes Big Financial Hit in 2008... and Few Are Prepared to Respond!**

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