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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

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R. Lewis Dark

Founder & Publisher

Time to Change Bad Medicare Lab Policies

BYZANTINE MEDICARE REGULATIONS AND BELTWAY POLITICS are uncommon topics for THE DARK REPORT. There are any number of other sources out there that provide ample details about laboratory compliance, the complexities of billing and coding, and whether Senator Smootly will or won't vote for reinstating the 20% lab co-pay.

However, I believe the subject of long-overdue reforms to Medicare laboratory payment policies should be a top priority for every laboratory administrator and pathologist in the United States. You don't need me to remind you that, for virtually every year since 1987, Medicare funds have been taken off the lab industry table. That's right! Fourteen consecutive years of funding haircuts that no other class of healthcare provider has been asked to endure.

There is only one reason this situation occurred: the clinical laboratory industry has never spoken to Congress, the President, and HCFA with one united and persistent voice. We all know the reasons why. Over the years, commercial labs had one agenda, pathologists had another, and hospital labs primarily get paid under Part A, so they really didn't care what happened to Part B lab payment policies.

It's time to change that situation. As you will read on pages 9-14, the **Institute of Medicine** recently studied Medicare laboratory payment policies and issued 12 recommendations for reform. This is a significant development and gives the clinical lab industry an unprecedented opportunity for change. At the upcoming *Executive War College* in Cincinnati, IOM committee member John Matsen, M.D. will speak to the Lab CEO SUMMIT about how the IOM committee developed these recommendations, and his view on how the lab industry can work with the government to turn these recommendations into tangible reforms that benefit the entire lab testing community.

Attending the Lab CEO SUMMIT on May 10 will be a number of leaders from large lab organizations and several lab professional associations. Editor Michel hopes this group can bridge traditional differences and lay the groundwork for a truly broad coalition of lab industry interests that are willing to work together to insure speedy and vigorous enactment of the IOM's recommendations. I would encourage any of you interested in supporting this effort to contact us at THE DARK REPORT so you can be briefed and included in future activities. TDR

New England's Path Lab Is Acquired by LabCorp

Another venerable independent lab sells itself to a national lab company

CEO SUMMARY: With growing regularity, owners of larger independent clinical laboratories are opting to sell to one of the public lab companies. This time it's New Hampshire-based Path Lab, which agreed to be acquired by Laboratory Corporation of America. One intriguing aspect of this acquisition is LabCorp's interest in learning more about PathLab's successful joint venture arrangements with hospital labs.

WITH STUNNING SWIFTNESS, **Laboratory Corporation of America** will become the new owner of **Path Lab Holdings, Inc.**, based in Portsmouth, New Hampshire.

The deal was publicly announced on March 26 and both parties expect the deal to close by the end of April. Path Lab's sale to LabCorp ends the independence of a nationally-respected regional laboratory company.

Since its founding in 1971, Path Lab has succeeded in building a profitable business from long-lasting cooperative testing arrangements with hospitals. Currently, it provides lab testing services to six hospitals in New Hampshire and Massachusetts.

For LabCorp, Path Lab offers two key attractions. "First, Path Lab is located in areas where LabCorp has only a limited presence," stated Bradford T. Smith, Executive Vice President at LabCorp. "PathLab is particularly strong in the corridor extending from New Hampshire south into Boston, Massachusetts and Providence, Rhode Island.

"Second, the type of lab testing business Path Lab does is complementary with LabCorp's primary strengths," he continued. "This is particularly true of Path Lab's hospital lab business, which uses more esoteric testing.

"Tom Hirsch [Path Lab's President] and his management team have pioneered a number of innovations in hospital laboratory management which they can teach us," noted Smith.

"The longevity of Path Lab's hospital testing relationships demonstrates

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that this lab has been close to its customers and knows how to meet their needs. LabCorp would like to draw upon that experience and expertise," observed Smith.

Once the Path Lab sale is completed, LabCorp also intends to do something unusual in the way it operates Path Lab. "After closing, Path Lab will retain its name and identity," Smith said. "It will continue operations under its existing management system and executive team.

Path Lab's sale to LabCorp surprised many in the lab industry. It was considered one of the financially-strongest independent regional laboratories still operating in the United States.

"Existing LabCorp testing business in Path Lab's service area will be folded into Path Lab," explained Smith. "Since Path Lab has demonstrated the success of its business model, we want to retain Path Lab's resources and give it the freedom to serve the market as appropriate.

"This will include retaining existing information systems at Path Lab," noted Smith. "These information systems have unique capabilities and are an integral part of the service infrastructure used to support the cooperative testing with Path Lab's hospital partners.

Valuable People Skills

"LabCorp also considers Path Lab's people skills to be just as valuable as any other asset owned by the lab," added Smith. "This sale has been structured to leave all the people in place and provide them with the capital and support they need to grow and enhance their lab testing services."

Smith's enthusiasm is mirrored by P. Thomas Hirsch, President of Path Lab. "Our executive team wanted to stay together and continue building this laboratory organization," he said. "Also, Path Lab has never laid off employees and we were concerned about providing a secure future for our staff.

"The arrangement with LabCorp means our management team can continue working together," added Hirsch. "It also means a good future for all the people now working at Path Lab."

Hirsch was also willing to discuss some of the management qualities he believes contributed to Path Lab's sustained growth and financial success, despite the turmoil in healthcare during the 1990s. "Compared to many labs in the United States, we fully understood the economics of the business from a pricing and cost perspective," he said. "That helped us stay focused on key business factors.

Good Management Reports

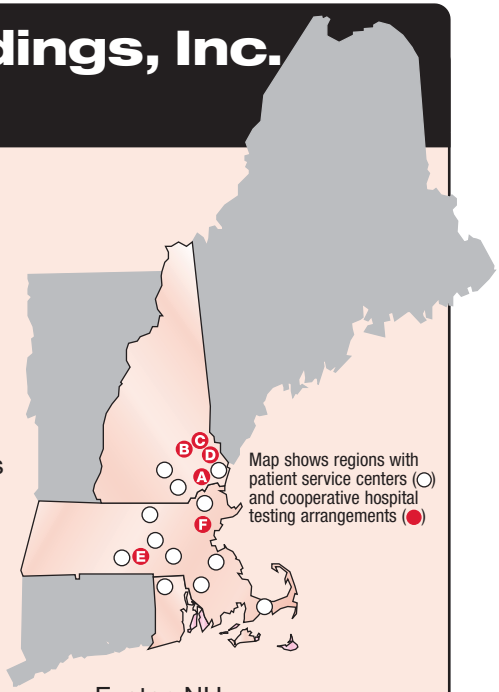
"Because we were originally owned by hospitals, and most recently by a private investment group, we had more financial and other reporting discipline than many labs our size," continued Hirsch. "We aggressively leveraged our information systems to help us manage the business. Consequently, we had better information to monitor performance, push down accountability, and properly evaluate new business opportunities.

"I've always found it interesting that laboratorians require accurate and complete data to make clinical decisions and report test results, but these same laboratorians, as lab managers, will work for years in a lab that lacks the detailed business data required to help them make sound management and financial decisions," observed Hirsch.

"We firmly believe that it's important to manage to results," he added. "If

Path Lab Holdings, Inc.
At-A-Glance

- **Founded:** 1971
- **Annual Revenues:** $50+ million
- **Main Lab:** Portsmouth, NH
- **Two Rapid Response Labs**
- **Patient Service Centers:** 38
- **Staff:** 780 employees, 560 FTEs
- **Clients:** 500 physician offices, 150 nursing homes
- **Cooperative lab testing arrangements with:**



A	Exeter Hospital	Exeter, NH
B	Frisbie Memorial Hospital	Rochester, NH
C	Portsmouth Regional Hospital	Portsmouth, NH
D	Wentworth-Douglass Hospital	Dover, NH
E	Worcester Medical Center	Worcester, MA
F	Fallon Clinic	Multiple locations in MA

you can't readily measure and track the effectiveness and quality of outcomes, your ability to produce 'above average' operating results is seriously compromised. That's why we try to give our managers both accurate information and the resources they need to make good decisions."

Path Lab's Sale Is A Surprise

Path Lab's sale to LabCorp surprised many in the laboratory industry. With revenues in excess of $40 million per year, it was considered one of the financially-strongest independent regional lab companies still operating in the United States. It was a fiercely-independent laboratory. That may be partly rooted in New Hampshire attitudes, best typified by the state's license plate motto of "Live Free or Die!"

However, unknown to many was the fact that, about six years ago, **Madison Dearborne Partners**, an investment fund linked to **First National Bank of Chicago**, had acquired a significant equity stake in Path Labs. In recent years, Madison Dearborne decided it was time to convert its equity investment in Path Labs into cash.

However, Hirsch and his executive team wanted to stay together and continue to operate and expand Path Labs. The solution was to look for a buyer willing to acquire Path Labs, and, as

part of the sale, allow the management team to continue running the lab under the existing business model.

Neither LabCorp nor Path Lab will comment on this situation. But it is known that, for a number of months, Path Lab's owners discreetly shopped for either a new equity investor or a buyer.

Presentation In New York

This included a presentation to professional investors by Path Lab at the **U.S. Bancorp Piper Jaffray** Investment Conference on Diagnostic Companies, held in New York City in September 2000. Among the prospective buyers who looked at Path Labs was **Quest Diagnostics Incorporated**, but no deal ever resulted from those talks.

LabCorp, which has only a modest market presence in the geographical areas served by Path Lab, has a keen interest in developing lab testing arrangements with hospitals. As noted by Smith, LabCorp viewed the Path Lab's acquisition as an opportunity to build its presence in a new market while simultaneously gaining access to lab executives skilled at developing and maintaining cooperative lab testing arrangements with hospitals.

Intrinsic Advantages

THE DARK REPORT believes it is significant that LabCorp has announced that it will allow Path Lab to continue operating as a regional division with its existing name, marketing identity, and management team.

This is a sign that LabCorp recognizes the intrinsic advantages a well-run independent laboratory has in its local service area over national lab competitors. LabCorp intends to maintain its local advantage by retaining Path Lab's identity in that regional market.

If LabCorp has the discipline to maintain Path Lab's local identify and unique business structure, it may be one of the rare times in the past 15 years that the acquisition of a regional lab by a national lab company did not result in a reduction of service and mass layoffs, but rather, contributed new resources into the local market that benefited lab and clients alike. TDR

Contact Brad Smith at 336-584-5171 and Tom Hirsch at 603-431-2310.

Path Lab Offers Web Test Orders & Results

BEGINNING IN JANUARY THIS YEAR, Path Lab began offering Web-accessed lab test ordering and results reporting to its physician office clients.

Path Lab is using the test ordering and reporting system of **Labtest.com**, based in Midland Park, New Jersey. "We've been selectively introducing this service to our existing clients," said Tom Hirsch, President of Path Lab. "It's not been a casual process. Few physicians' offices have broadband Internet access and it does take time and effort to educate the doctors and their staff about how to use this system to order lab tests and access results.

"So far this type of service has not reduced our costs," he continued. "We are still maintaining dedicated phone lines and printers in the physicians' offices. However, we recognize that it's important for our lab to develop this capability, along with the expertise to work with Internet-based technologies.

"We can see changes occurring to the way hospitals and physicians' offices handle clinical information," added Hirsch. "As these providers become accustomed to using the Internet for clinical and administrative purposes, it is important for Path Lab to provide state-of-the-art lab testing services.

"The way physicians use the Internet is like a moving target," Hirsch said. "They may not be ready today to fully embrace Web-accessed lab test ordering and results reporting, but the transition will happen."

Bigger Labs Have Always Coveted Hospital Testing

LabCorp's PathLab acquisition opens new chapter in efforts to woo hospitals

***CEO SUMMARY:** For almost two decades, the nation's largest laboratory companies have, for all intents and purposes, been "locked out" of the market of hospital inpatient lab testing. Executives at commercial labs have long viewed hospital inpatient lab testing as an untapped market. PathLab was successful at operating collaborative lab ventures with hospitals and LabCorp hopes to build upon this expertise.*

COMMERCIAL LABS have long coveted the testing done by hospital laboratories for inpatient services.

The reason is simple. More than half of the $35+ billion of diagnostic lab testing done annually in the United States is performed on hospital inpatients and outpatients. Yet commercial lab companies are involved in only a small percentage of this testing.

From the perspective of large commercial laboratories, hospital inpatient testing is the "untapped mother lode," a lucrative and untouched market ripe for harvesting. Commercial lab execs consider the hospital inpatient market particularly appealing for another reason: their regional labs are located in close proximity to many large hospitals. To them, it seems only natural that a portion of hospital lab tests could be economically consolidated into their regional laboratory centers.

Certainly this is not news to hospital lab administrators and commercial lab executives. During the past two decades, both groups have participated in many discussions about joint ventures, outsourcing, and other shared testing proposals.

Though the 1980s and 1990s, the larger commercial lab companies invested millions of dollars in sales efforts to convince hospitals that there was merit to various forms of shared testing relationships. Despite that considerable effort and expense, in 2001 only a relative handful of operational partnerships exist between commercial laboratories and hospitals.

Heightens The Interest

It is this fact which heightens the interest of THE DARK REPORT in **Laboratory Corporation of America's** impending acquisition of **Path Lab Holdings, Inc.** of Portsmouth, New Hampshire. *(See story on pages 2-5.)*

Because so few have succeeded in the past, many lab industry veterans would characterize LabCorp's goal of assimilating Path Lab's expertise and success in cooperative hospital lab testing as a daunting challenge.

They would observe that Path Lab's success in this type of hospital lab/commercial lab partnership is probably due, in large part, to the talents and personalities of specific individuals, in combination with circumstances unique to the local healthcare markets served by Path Lab.

It certainly seems the cautious attitude by hospitals toward collaborative testing arrangements between hospitals and commercial labs has changed little over the last 15 years.

During the past 15 years, attempts by national lab companies to clone specific types of unique local business models and lab joint ventures with hospitals in order to export them to other regions of the United States have generally proved unproductive and disappointing.

Partnering Arrangements

At the *Executive War College*s held in 1998 and 1999, there were several hospital lab management case studies that included some type of partnering arrangement with commercial labs. This was seen as favorable evidence that the number of collaborations between hospital laboratories and commercial lab companies were likely to increase in succeeding years.

However, this did not occur. One reason may be the easing of the negative financial impact that the 1996 Balanced Budget Act had on hospitals. During the financial squeeze of 1997 and 1998, hospitals had a motivation to collaborate with commercial labs. As financial pressures eased in 1999 and 2000, hospitals lost their motivation to consider this business strategy.

It was also during 1998 that **Premier, Inc.** and **Quest Diagnostics Incorporated** announced their agreement to offer Premier's 1,700 hospital members a unique brand of laboratory consulting expertise. Despite the hoopla and publicity surrounding this new service, few hospitals have stepped to the table and engaged the Premier/Quest partners in a comprehensive laboratory project.

Actively Seeking Deals

Two other major laboratory companies actively seeking collaborative lab partnerships with hospitals are **Dynacare, Inc.** and **MDS Laboratory Services**. In spite of sustained sales efforts, during the past 12 months these two companies have only been able to announce a meager number of new collaborative lab testing agreements with hospitals or hospital systems.

It certainly seems the cautious attitude by hospitals toward collaborative testing arrangements between hospitals and commercial labs has changed little over the last 15 years. Hospital administrators want direct control over their laboratory operations and are reluctant to trust their inpatient testing activities to an outside partner.

Viewed from this perspective, Path Lab's ability to sustain long-term cooperative testing arrangements with multiple hospitals in New England is an extraordinary accomplishment. Not surprisingly, LabCorp recognizes this fact.

Strong Revenue Growth

But it remains to be seen whether the market strategies and business model used by Path Lab to maintain its hospital testing arrangements in New England can be exported by LabCorp to other areas of the country. On the other hand, the Path Lab business model may prove attractive for smaller hospitals that are not part of big healthcare systems. TDR

Trends In Pathology

Wall Street Journal Addresses Error Rates by Pathologists

MEDICAL ERRORS HAVE TAKEN center stage in the public eye, and recently the *Wall Street Journal* (WSJ) printed a prominent story about errors made by the pathology profession.

On Friday, April 13, the WSJ's "Health Journal" column on the front page of section two tackled the topic of pathology errors and how patients should protect themselves from pathologists who don't get it right.

Under the headline "Risk of Error May Justify Second Opinion On Pathology Reports," columnist Tara Parer-Pope laid out an interesting argument as to why pathologists don't always make the right diagnosis, followed by recommendations on ways that patients can obtain a second pathology opinion.

The story quoted a study by **Johns Hopkins University** which determined that "about 1.4% of pathology cases involve serious errors, such as diagnosing cancer when a tumor is actually benign, giving a patient a clean bill of health when the problem actually is cancer, or diagnosing the wrong type of cancer."

Mistakes On 20% of Cases

Pathologists at Johns Hopkins also see higher rates of pathology mistakes for certain diseases. For example, of the 6,000 prostate cancer cases referred to Johns Hopkins yearly, Johns Hopkins pathologists find that as many as 20% of these cases have mistakes in grading and staging, which tell a doctor how aggressive or advanced the cancer is.

Pathologists should consider this prominent story in the *Wall Street Journal* as an important development. It's tangible evidence that the trend of consumer involvement in their healthcare continues to gather momentum.

Story On Pathology Errors

The purpose of the WSJ story was to educate consumers about two things. First, that pathologists get it wrong in a significant number of cases. Second, to teach different ways to request a second pathology opinion and effective methods to get around hurdles in the healthcare system that might prevent a second pathology opinion.

This WSJ story on pathology errors brings the pathology profession closer to the day when the cumulative caseload of opinions generated by individual pathologists will be "graded" or "scored," then published. This will permit referring physicians, patients, and payers to identify top-performing pathologists from those of only average talent.

For the pathology profession, the *Wall Street Journal* story on pathology error rates is another warning sign in the marketplace. At some point, individual pathology group practices will need to respond to the growing consumer demand for better education about their disease, quality rankings of individual pathologists, and improved consumer access to pathology subspecialists.

Consumers' concerns over pathology errors may turn out to be one lever that payers, physicians, and patients use to improve how the existing healthcare system uses pathology services. TDR

CEO SUMMARY: Since 1987, the clinical lab industry has endured almost non-stop cuts in the absolute level of Medicare reimbursement for lab testing. But the time may be ripe for laboratories to work together to effect far-reaching reforms to Medicare laboratory payment policies. Just as the Institute of Medicine issued its 12 recommendations for reforming Medicare lab payment policies, the country gained a new President, a new Congress, and a new HCFA administrator.

RECOMMENDATIONS FOR IMPROVEMENT

Institute of Medicine Calls For 12 Medicare Lab Reforms

MANY LABORATORIANS HAVE rightly categorized the clinical laboratory industry as the apparent "whipping boy" of the nation's Medicare program.

Their belief stems from an incontrovertible fact: every year since 1987, the effective level of funding for laboratory services under the Medicare Part B schedule has been reduced! That's 14 years of ongoing reductions to the effective amount of reimbursement paid for clinical lab services.

Of course, there are other intractable problems with the Medicare program that frustrate the clinical lab industry. Most lab administrators and pathologists are familiar with those issues.

But what many laboratorians currently overlook is an emerging opportunity for the clinical laboratory industry to effect beneficial changes to the way Medicare Part B treats laboratory testing.

IOM's Lab Recommendations

That opportunity derives from the **Institute of Medicine's** (IOM) recent report that makes 12 recommendations for reforming Medicare laboratory payment policies. Issued last fall, it has attracted some notice in the lab industry press, but has generated little widespread action by laboratorians to date.

THE DARK REPORT believes the clinical lab industry has an unmatched opportunity to effect positive reforms, using the IOM's 12 recommendations as the lever.

The timing is also extraordinary. The IOM report is fresh, having been issued only months ago. There is a *new* HCFA administrator, a *new* Congress, and a *new* President. The conjunction of these four events is unusual. It provides the perfect opportunity to present a compelling case that immediate and significant reforms must be made to Medicare Part B laboratory reimbursement policies.

Unfortunately, the laboratory industry may not be up to the challenge. The industry is fragmented and argumentative among itself. There is no precedent for creating a united effort to push Congress, the President, and HCFA to enact much needed-reforms to Medicare laboratory reimbursement policies. This is disappointing, since the benefits of specific fundamental reforms are certainly in the best interest of all clinical laboratories.

The story of how and why the IOM was chartered to study reforms to Medicare laboratory payment policies indicates that the lab industry already has a few friends in high places. Certain individuals in Congress were successful at including a mandate in the Balanced Budget Act of 1997 (BBA–Public Law105-33). This mandate directed the **Department of Health and Human Services** (DHHS) to examine the laboratory industry and make recommendations on improving the existing system.

Committee of 12 Experts

To accomplish this, DHHS arranged for the Institute of Medicine to create a committee of 12 experts, including three laboratorians, as well as physicians, economists, health care administrators, and health policy analysts. It was called the "Committee on Medicare Payment Methodology for Clinical Laboratory Services."

During 2000, the committee conducted studies and held five meetings. Not surprisingly, the committee found "limited data" about the national laboratory testing industry. It could not identify accurate financial data about different testing segments served by clinical labs. Nor could it find detailed data about the cost of performing lab tests and how current Medicare payment amounts compare to the cost of testing and to payments by other purchasers.

Despite the lack of comprehensive data about clinical lab testing in the United States, the 12 members of the IOM committee ended up sharing a common opinion: important reforms are long overdue to the

Institute of Medicine Created to Serve Congress

*IT WAS 1863 WHEN CONGRESS GRANTED a charter to the **National Academy of Sciences** as a "private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research..."*

As part of this charter, the National Academy of Sciences is required to advise the federal government on scientific and technical matters. The Institute of Medicine (IOM) was founded by the National Academy in 1970 specifically to advise the federal government on issues of "policy matters pertaining to the health of the public."

Not surprisingly, the Institute of Medicine was created only four years after the Medicare program was launched. Healthcare had become a major issue for Congress and federal policy makers. The need for an objective source of study and analysis on national healthcare issues was recognized and the IOM was formed to meet that need.

existing policies Medicare uses to reimburse for clinical laboratory services.

The committee issued 12 recommendations. *(See sidebar on pages 13-14.)* The first six recommendations focus specifically on payment methodology. The second six recommendations deal with problems in the current system and can be implemented independently or concurrently with the first six recommendations.

Three of the twelve committee members were laboratorians. They were: John Matsen, M.D., Professor Emeritus of Pathology and Pediatrics at the **University of Utah**, and formerly Board Chair of **Associated Research University Pathologists (ARUP)**; J. Stephen Kroger, M.D., Chief Executive Officer of **COLA** (formerly the Commission on Office Laboratory Accreditation); and David T. Smalley, Ph.D., Professor of Pathology at the **University of Tennessee Health Sciences Center** in Memphis, TN.

Solutions To Basic Problems

Taken collectively, the committee's 12 recommendations represent solutions to basic problems in the existing system for Medicare reimbursement for clinical lab testing services covered under Part B. Any clinical laboratory providing lab services to patients referred by physicians' offices would gain immediate and sizeable benefit if these recommendations were enacted in a swift and orderly manner.

Therein lies the challenge. Across the spectrum of the clinical laboratory industry, there has never been common agreement and united effort to lobby Congress on issues affecting clinical laboratory services.

This should not be surprising. Each of the lab industry's professional associations has a different purpose. For example, the **College of American Pathology** (CAP) exists to support the issues involving professional pathology services. The **American Clinical Laboratory Association** (ACLA) represents larger lab companies, including **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. Its lobbying efforts are generally directed to issues which directly impact its member labs.

Hospital Lab Emphasis

The majority of members of the **American Association of Clinical Chemistry** (AACC) and the **Clinical Laboratory Management Association** (CLMA) work in hospital-based laboratories. Since most funding for hospital laboratories is covered under Medicare

Part A policies, these associations stress a different set of Medicare lab testing issues than the commercial laboratory segment of the industry.

One of healthcare's lobbying giants, the **American Hospital Association**, has traditionally devoted little, if any, resources to lobby for Part B clinical laboratory reforms. That was because, during the 1980s and early 1990s, most hospitals did little or no testing testing that was covered under Medicare Part B reimbursement.

However, hospital consolidation in the second half of the 1990s has changed this situation. An increasing number of AHA member hospitals and health systems operate viable lab outreach testing programs that serve physicians' offices. Thus, within the AHA, there should be a greater incentive to invest resources in lobbying for Medicare Part B lab reimbursement policy reforms.

Diverse Lab Interests

Historically, then, fragmentation of interests within the clinical laboratory industry has resulted in an ineffective lobbying effort. Not surprisingly, that is why Congressional budget cutters found it easy to cut funding for Part B laboratory services through the past 15 years. Unlike other types of healthcare providers, budget recommendations that reduced the funding for lab testing encountered minor, often insignificant political opposition.

THE DARK REPORT believes that the time is ripe to change this situation. Unlike past years, there is now a general consensus among laboratories of all types that reforms to Medicare Part B laboratory payment policies are long overdue. There is also consensus that it is time for HCFA to undertake a comprehensive review of procedures used to establish laboratory test prices update them as appropriate.

At this year's *Executive War College* in Cincinnati on May 8-10, Lab CEOs will hear a presentation by IOM committee member Dr. John Matsen. In attendance will be individuals representing a number of lab industry professional associations, as well as independent laboratory owners.

Advance Agreement

Participants in this special program have agreed, in advance, to launch discussions on how to create an ad hoc lobbying effort that involves all segments of the lab industry. THE DARK REPORT believes that, for probably the first time ever, the compelling need for Part B lab pricing policy reforms can encourage an unlikely coalition of players to work together under a common lobbying "umbrella."

Ideally this would include independent laboratory owners, whether large or small, all the laboratory professional associations, the American Hospital Association, diagnostic vendors, information system companies, and even possibly group purchasing organizations. Each of these entities has a strong economic motive to support the enactment of overdue reforms to Part B laboratory pricing policies.

Failed Lobbying Strategy

It is time to end fragmented lobbying by the lab industry. As a business strategy, it has failed. The evidence is a virtually unbroken 14-year string of Medicare cutbacks in lab funding. Sensible business executives, when they see a business strategy fail, know it's time to try something new.

For the clinical lab industry, 2001 is the year for the entire industry to gather around a common strategy for enacting Medicare reforms. After 14 years of financial pain, it is certainly time that Congress and HCFA give the laboratory industry a higher level of respect. TDR

IOM's Study Committee Recommends Reforms To Medicare Laboratory Payment Policies

HERE ARE THE INSTITUTE OF MEDICINE'S 12 RECOMMENDATIONS for reforming Medicare laboratory payment policies. The first six recommendations deal exclusively with payment methodology, such as "how to establish the relative value of one test versus another and how to determine the relative resource use of different tests." The second six recommendations involve solutions to such problems as "the structure of claims processing contractors and how to improve payment-related administrative procedures."

RECOMMENDATION 1: Medicare payments for outpatient clinical laboratory services should be based on a single, rational, national fee schedule.

RECOMMENDATION 2: On an interim basis, relative payments for Medicare outpatient clinical laboratory services should be based on the current National Limitation Amounts.

RECOMMENDATION 3: A data-driven consensus process for refining the new Medicare national fee schedule for outpatient clinical laboratory services should be developed. HCFA should explore alternative methods for gathering data to be used in the process.

RECOMMENDATION 4: Medicare national fees for outpatient clinical laboratory services should be adjusted for geographic location. HCFA should also evaluate the need to adjust for certain other circumstances, particularly those likely to affect beneficiary access and make recommendations to Congress.

RECOMMENDATION 5: Processes should be put in place to refine and periodically update the fee schedule for Medicare outpatient clinical laboratory services.

RECOMMENDATION 6: To incorporate new tests into the Medicare laboratory fee schedule, there should be an open, timely, and accessible process that is subject to challenge. The process and fees produced should not impede clinical decision-making that is essential to providing appropriate care.

RECOMMENDATION 7: HCFA should review alternatives to the current system for doing outpatient clinical laboratory services for claims processing. More accurate, open, and timely coding process for new technologies as well as test and services should be sought.

RECOMMENDATION 8: The current policy of not requiring beneficiary cost sharing for Medicare outpatient clinical laboratory services should continue. Cost sharing is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program depending on its design.

RECOMMENDATION 9: HCFA should discontinue use of International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes as the basis for determining the medical necessity of clinical laboratory tests. HCFA should assess the need for any approach to evaluating the medical necessity of individual laboratory tests prior to payment of a claim. In addition, HCFA should evaluate alternative approaches for identifying and reducing unnecessary or inappropriate laboratory testing.

RECOMMENDATION 10: In its policy formulation processes, HCFA should provide opportunities for stakeholder input and develop better communication with contractors and other stakeholders when policies are being developed and once they are adopted.

RECOMMENDATION 11: HCFA should move promptly to consolidate the number of contractors processing all Medicare outpatient clinical laboratory claims, including claims from physician office laboratories (POLs) and hospital-based laboratories. The design of this consolidation should ensure that claims processing by regional laboratory carriers will not require major new billing procedures for POLs or hospital-based laboratories. Efforts should be made to strengthen local provider services and relations between carriers and laboratories.

RECOMMENDATION 12: HCFA should collect the data needed to effectively manage the performance of the Medicare outpatient clinical laboratory payment system.

Source: Medicare Laboratory Payment Policy—Now and in the Future, Institute of Medicine, Wolman, Kalfoglou, and LeRoy, Editors, National Academy Press, Washington, DC, 2000

Luminex Test Technology Entering Clinical Usage

Growing number of labs now generating patient test results from LabMAP™ system

CEO SUMMARY: Multi-analyte diagnostic testing is moving closer to widespread clinical usage. During the past 12 months, several of the nation's largest laboratory companies have begun to use Luminex Corporation's LabMAP™ system to generate patient test results. At the same time, the first diagnostic test kits based on LabMAP technology have been submitted to the FDA for review.

EARLY-ADOPTER clinical laboratories are rolling out the first versions of multiplex test assays using **Luminex Corporation's** LabMAP™ system.

"Large clinical laboratories are now generating patient results on a regular basis with our diagnostic test system," stated Randel S. Marfin, Vice President of Business Development at Luminex, based in Austin, Texas. "This is an important milestone for our technology, because it demonstrates that the LabMAP system is effective in clinical settings."

Growing Sales Of LabMAP

Laboratory executives and pathologists should keep a close watch on Luminex Corporation and its multi-analyte profiling (MAP) technology. As of March 31, 2001, Luminex had sold more than 500 LabMAP systems to customers in the biomedical research, clinical diagnostics and pharmaceutical markets.

More telling, of the 27 strategic partnerships Luminex has developed, 17 are with companies primarily involved in clinical diagnostics. This is evidence that diagnostic vendors consider Luminex's technology to be credible and want to incorporate LabMap into the diagnostic products they offer their clinical lab customers.

The most recent strategic partnership announced by Luminex involves **ARUP Laboratories** of Salt Lake City. "ARUP is developing a variety of immunoassay and molecular diagnostic tests that will run on the LabMAP system," said Marfin. "These assays incorporate the multi-analyte capabilities of the LabMAP system."

Luminex has similar strategic partnerships with **Specialty Laboratories, Inc.** and **Dynacare's** esoteric division, **Dynagene**. The company has also sold LabMAP systems to most of the largest lab companies in the United States, including **Laboratory Corporation of America**.

Other strategic partners are developing diagnostic kits which use the LabMAP system. "**Zeus Scientific** has

submitted an application for diagnostic test kits to the FDA," noted Marfin. "**One Lambda, Inc.** and **Lifecodes, Corporation** have both released human leukocyte antigen (HLA) tissue typing kits for clinical use."

Revolutionary Technology

THE DARK REPORT was the first in the lab industry to call attention to Luminex and its revolutionary bioassay technology. *(See TDR, December 21, 1998; copies available to existing TDR clients by request.)* Because of the relatively modest cost of the complete LabMAP instrument suite, called the Luminex 100 Integrated System (Luminex 100 IS, with a retail price of around $45,000), THE DARK REPORT believes a large number of clinical laboratories will be able to acquire this technology and benefit from it.

The transformational aspects of LabMAP derive from these facts:

1) the total cost, including a royalty fee to Luminex, is lower for each analyte than conventional diagnostic testing methods;

2) the current technology can support up to 100 assays per sample and Luminex is developing the capability to do 1,000 assays per sample;

3) each sample (with 100 assays) can be tested in just a few seconds;

4) the sample size can be as small as 50 microliters, or about the size of a capillary tube draw; and,

5) the LabMap instrument is compact and requires just a few square feet of counter space.

These five attributes illustrate why Luminex's technology is considered to be a paradigm-shifting breakthrough in diagnostic testing and other bioassay applications in pharmaceutical, bioagricultural, and biomedical research.

Now that clinical laboratories are beginning to use LabMAP to generate patient test results on a daily basis, it is important for lab executives and pathologists to understand the market dynamics currently pushing LabMAP forward.

For diagnostic applications, Luminex has followed a two-pronged business strategy. It actively encouraged two types of customers to acquire LabMAP systems and adopt them for diagnostic purposes.

One class of customers includes the nation's 10 to 20 largest clinical laboratories. Although Luminex will not disclose names of its lab customers, it is reasonable to assume that several of the large public lab companies own LabMAPs, along with the national reference labs which provide reference and esoteric testing to hospitals and other labs.

These five attributes illustrate why Luminex's technology is considered to be a paradigm-shifting breakthrough in diagnostic testing...

Beginning in 1999, Luminex began selling LabMAP systems to the biggest laboratories. Luminex represented that these labs could use LabMAP technology in two ways. First, they could use LabMAP to "home brew" existing assays. Typically, "home brew" assays are performed because cost-effective kits are not available or the assay is proprietary to the clinical laboratory. Because only a modest effort and expense is required to set up a home brew assay, labs could quickly benefit from this business strategy.

Develop New Assays

Second, labs with the Luminex 100 IS could develop new assays for proprietary use and commercial sale. This is a longer-term business strategy that has huge profit potential.

For a high-volume laboratory, the "home brew" approach offers immediate and substantial benefits. Although LabMAP is designed to be a multi-analyte testing system, it can also be economically used to perform single assays from single specimens. That's because it requires only minute amounts of both reagent and microspheres, resulting in a lower cost per test.

The economics are compelling. If a lab does 10,000 tests per year, with a kit cost of $20, and can do the same test on the LabMAP system on a "home brew" methodology at, say $5 per test (assuming marginal costs and the Luminex royalty), the lab would realize savings of $150,000 per year.

Luminex believes labs that follow this strategy would gain competitive advantage. These same labs, if they develop new diagnostic tests designed to run on the LabMAP system, could then market their proprietary tests, creating new revenue streams.

Different Business Strategy

With diagnostic vendors, Luminex has a different business strategy. It wants to license LabMAP as an open technology platform, leaving vendors free to create proprietary tests which run on that instrument.

"In November 2000, we submitted a device master file with information about the Luminex 100 IS (Integrated System) to the FDA," stated Marfin. "Our strategic partners can reference the device master file in their premarket submissions of diagnostic kits. This permits the FDA to consider the Luminex 100 IS instrument as a component of the diagnostic kit."

Zeus Scientific is using this process with the diagnostic test kits it has submitted to the FDA for review. It is the same process which ARUP, Dynagene, and Specialty Labs will use as they prepare to bring proprietary tests to market.

Bio-Rad Laboratories, Inc. was one of the first diagnostic companies to form a strategic alliance with Luminex. Bio-Rad, after learning more about the LabMAP technology, recently expanded its strategic partnership with Luminex to include drug discovery applications.

Bio-Rad's New Product

Bio-Rad has announced a product built upon LabMAP technology. It is called the "Bio-Plex™ Protein Array System" and is designed to enable drug researchers to extract more data from smaller samples.

THE DARK REPORT believes that Bio-Rad is preparing a version of this product for diagnostic applications. The company is tight-lipped about its diagnostic plans. But if it developed a way to use the Bio-Plex system to do many existing diagnostic tests using much smaller specimen samples, that would certainly give it competitive advantage.

Taken collectively, during the past 24 months, Luminex has chalked up some impressive accomplishments. It has strategic partnerships with 27 companies, including 17 diagnostic firms. It has placed 500 LabMAP systems in a variety of labs and other companies. Its vendor-partners have diagnostic test kits now either undergoing FDA review or available for sale.

Compelling Economics

This rapid progress is a signal to early adopter labs. A new era of inexpensive, accurate, multiplex testing is almost here. Early-adopter labs are now generating patient tests results with the LabMAP system. As they accumulate knowledge and experience, it is only logical that these labs will find new ways to use LabMAP technology to improve the quality of clinical lab testing. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It seems some companies serving the laboratory industry have learned the importance of having a better understanding of the inner workings of Washington, DC. Both **Cerner Corporation** and **Specialty Laboratories, Inc.** will add Nancy-Ann DeParle to their respective Boards of Directors. DeParle was Administrator of the **Health Care Financing Administration** (HCFA) from 1997 until October 2000. She is currently a fellow of the Institute of Politics and the Interfaculty Health Policy Forum at **Harvard University**, her alma mater.

STRONG REVENUE GROWTH AT DIANON

Anatomic pathology remains a growth business for some lab companies. **DIANON Systems, Inc.** announced first quarter earnings. Revenues grew by 21.1% over the same quarter last year, from $22.1 million to $26.8 million. Net income rose by 63% over the same period, from $1.3 million to $2.1 million.

BLOOD SUBSTITUTE CLEARED FOR USE BY SOUTH AFRICA

Blood bankers will be interested in this recent development. The **Medicines Control Council of South Africa** earlier this month issued regulatory approval for **BioPure Corp.'s** Hemopure® blood substitute to be used "in the treatment of acute anemia and avoidance of red blood cells in adult surgery patients." This is the first product cleared for human use in a new category of intravenously administered pharmaceuticals called "oxygen therapeutics." Designed to deliver oxygen to the body's tissues, these products are a sterile alternative to red blood cell transfusion.

MORE ON: HEMOPURE

Hemopure is derived from red blood cells extracted from cows. The product doesn't require refrigeration, which makes it suitable for use in remote parts of South Africa where clinics lack refrigeration. Hemorrhage during childbirth is a leading cause of death in Africa. The marketing application in South Africa was based on data from 20 human clinical trials conducted in Europe, Canada, the United States, and South Africa during the last 20 years.

EXPRESS SCRIPTS ADDS MCMAHON TO BOARD

LabCorp Chair and CEO Thomas McMahon will become a director at **Express Scripts, Inc.**, based in St. Louis. Express Scripts is a pharmacy benefit manager (PBM) serving 43.5 million members nationwide. THE DARK REPORT has observed that all healthcare e-commerce companies will have to handle lab data to be successful. After all, 70% of the permanent patient health record is made up of clinical lab results. Express Scripts' interest in having a lab company executive on their Board of Directors illustrates its recognition that lab test data will be important in the future success of the company.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 21, 2001.

THE DARK REPORT

UPCOMING...

- ***Best of the Executive War College: First News of Emerging Lab Trends.***
- ***Hospital System Lab Expands POCT Testing and Dramatically Slashes Costs.***
- ***Why Many Managed Care Lab Contracts Are Shifting Away From Capitation.***
- ***ISO-9000 Meets the Clinical Laboratory World: Changing Labs for the Better.***