Volume IX, Number 8 Monday, June 3, 2002

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Big Fight is Brewing Over Lab Test Reimbursement

BY NOW, MOST LAB EXECUTIVES AND PATHOLOGISTS AGREE that Medicare Part B fees and reimbursement guidelines for lab testing have just about become de facto national standards. That's because private payers increasingly use Medicare as the basis for building their own pricing and reimbursement guidelines.

If you agree with me that this is now a fact in our industry, then you would also have to agree that helping Congress and CMS (Centers for Medicare and Medicaid) establish rational pricing and reimbursement policies for laboratory tests is now a critical success factor for our industry. After all, it is impossible to run a financially-viable laboratory if reimbursement offered by both Medicare and private payers is inadequate to properly recover expenses and leave enough capital for the lab to invest in new diagnostic technology.

My next question for you is simple, and is based on the news that language in the next Medicare funding bill basically states that the existing five-year freeze on CPI price updates for lab testing will not expire at the end of 2002, as planned. Instead, language in this bill would extend the CPI update freeze until competitive bidding for Part B lab test services is implemented. As someone who understands the importance of lab testing to the American healthcare system, are you prepared to take an active role in fighting this proposal?

I ask this question because, since the late 1980s, the lab industry has been utterly ineffective at maintaining appropriate funding for lab tests done under Medicare Part B schedules. As you will read in this issue of THE DARK REPORT, laboratories have suffered a real cut in absolute dollars paid by Medicare. In 1992, Medicare paid $3.9 billion for laboratory test services. This number fell to $3.5 billion in 1998! Moreover, in 13 of the last 14 years, lab services failed to get a CPI price update which equaled the actual CPI index.

There's a pattern here which should be disturbing to every laboratorian, physician, and patient in the United States. Congress has found it easy to roll over the lab industry and deny it fair updates to price schedules. In response, the clinical lab industry has demonstrated an inability to shape or influence Congressional funding bills in any effective way. Perceptive lab administrators and pathologists should decide that this is the year to change that situation—and educate Congress about the importance of appropriate funding for Part B lab testing services. TDR

CPI Lab Fee Adjustment Threatened by New Bill

Proposal is to link annual CPI price updates for lab testing with start of competitive bidding

CEO SUMMARY: Once again, the laboratory testing industry has been singled out as a healthcare "whipping boy" by Congressional aides. In working to develop the next federal budget, legislators again propose to deny annual CPI price updates for laboratory tests. This won't be anything new, since only once in 14 years has Congress funded a lab test CPI price update that was at least equal to the actual CPI rate for that year!

IT'S ANOTHER Congressional sucker-punch for the clinical laboratory industry. The newest budget bill proposal maintains the existing CPI (consumer price index) adjustment freeze, due to expire this year, until competive bidding for Part B laboratory services is instituted.

Neither option is palatable for the lab industry. In 13 of the 14 past years, the lab industry failed to get an annual CPI price adjustment for laboratory testing that fully matched the actual CPI. As a result of these specific cuts in payments for lab testing services, Medicare now reimburses less money for lab testing than it did in 1992!

Competitive bidding is a concept that CMS (**Centers for Medicare and Medicaid**) has tried to implement in various healthcare specialties for many years. Providers ardently object to this concept. To date, efforts of providers to stymie this initiative have prevented CMS from launching even a demonstration project of competitive bidding.

Under current law, a five-year CPI freeze for laboratory test prices is set to expire at the end of 2002. 1997 was the last year the lab industry got a CPI price update on Part B laboratory services. Moreover, it was the only year since 1989 that the CPI price update equalled or exceeded the actual CPI rate.

Thus, language in the new draft bill calling for maintaining the freeze on CPI price updates for lab tests until competitive bidding is instituted represents a significant blow to the lab industry. Until now, lab industry

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. **(ISSN 1097-2919.)**

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

lobbyists had been optimistic that funding proposals for the next fiscal year would be favorable to the laboratory industry.

Only Itself To Blame

The clinical laboratory industry has only itself to blame for this situation. Compared to other categories of healthcare providers, lab testing has become a funding orphan every time Congress and CMS sit down to budget funding for Medicare and Medicaid.

The **American Association of Clinical Chemistry** (AACC) recently published numbers that dramatically illustrate the funding shortfall which the laboratory industry has tolerated. Assume a Medicare reimbursement of $10.00 per laboratory test in 1984. Today, 18 years later, Medicare reimburses that same test for $8.55, almost 15% less in real dollars. The AACC calculates that, if full CPI price updates had been granted each year, Medicare would be paying $16.57 per test in 2002 in real dollars.

However, the AACC example does not factor in the full effect of inflation during the past 18 years. In inflation-adjusted dollars, Medicare's funding of lab testing services has been cutback by a factor approaching 50%.

Industry At A Crossroads

THE DARK REPORT believes the laboratory testing industry is now at a crossroads. Survival will be increasingly difficult if this industry cannot reverse the well-established pattern of federal underfunding demonstrated during the past 14 years.

Because Medicare prices and reimbursement guidelines are increasingly used by private payers to establish their own lab testing reimbursement policies, inadequate funding at the Medicare level will drive inadequate funding at the private payer level. This will eventually precipitate a financial crisis within the lab industry, negatively affecting commercial laboratories, hospital laboratories, and pathology groups.

One reason for this current situation is the lack of unity that exists within the clinical laboratory industry. There are too many diverse interests for laboratorians to speak with one concentrated and powerful voice to Congress and CMS. For example, pathologists concentrate on anatomic pathology issues and professional component reimbursement.

In contrast, commercial laboratory companies closely watch Medicare Part B lab test prices and guidelines, but hospital labs, paid under Medicare Part A policies, tend to have less interest in Part B lab test pricing issues.

Professional Associations

Historically, professional associations have reflected their member's unique interests. Thus, the **American Hospital Association** (AHA), always a powerful lobbying force, has not devoted significant resources to lobbying for improved funding of Medicare Part B lab test services. Not enough hospital labs operate laboratory testing outreach programs for the AHA to invest time in lobbying for more appropriate funding from Medicare.

Some aspects of this disorganized lobbying situation are changing. In recent years, the **Clinical Laboratory Coalition** was formed and has steadily attracted more members. It currently represents at least 10 professional associations, all with direct involvement in diagnostics and clinical laboratory testing.

However, across the clinical laboratory industry, there is still lots of apathy by pathologists, laboratory executives and administrators, and lab industry vendors on the importance of more appropriate funding for Medicare Part B lab test services.

14 Years of Medicare Lab Price Adjustments Fail to Keep Pace with Ongoing Inflation

History of CPI & NLA Adjustments To Medicare Lab Fee Schedule

For 14 years, Congress and the Centers for Medicare and Medicaid (CMS) have been neither kind nor generous to the laboratory testing industry, as the table below demonstrates.

Years where the CPI (consumer price index) fee update for laboratory tests failed to equal the actual CPI are highlighted in red. Only once since 1988, in 1997, has the CPI fee update equalled or exceeded the actual rate of inflation.

This table also shows how Congress and CMS used the National Limitation Amount (NLA) to drop the ceiling price paid for individual tests from 115% of the median fee in 1984 (based on median fees for all regional carriers) to 74% in 2002.

Year	CPI Fee Update %	Actual CPI Update %	Used to Set NLA
1989	4.0	4.8	100
1990	CPI-U	5.4	93
1991	2.0	4.2	88
1992	2.0	3.0	88
1993	2.0	3.0	88
1994	0.0	2.6	84
1995	0.0	2.8	80
1996	2.9	3.0	76
1997	2.7	2.3	76
1998	0.0	1.7	74
1999	0.0	2.6	74
2000	0.0	2.7	74
2001	0.0	2.8	74
2002	0.0	2.8	74

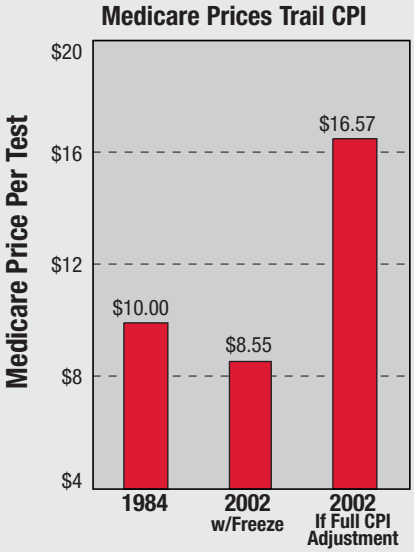
Source: American Association of Clinical Chemistry

Impact of Medicare CPI Pricing On Lab Tests From 1984-2002

Below is a bar chart which illustrates how Medicare has actually reduced the price per test paid in the past 18 years.

Assume a price per test of $10.00 in 1984. Medicare is now reimbursing that same test at $8.55 in 2002, a reduction of 14.5% in actual dollars during this same period.

As the third bar shows, had Medicare increased lab test prices annually by the full amount of the CPI adjustment, Medicare's test price of $10.00 in 1984 would be reimbursed at $16.57 in 2002.



Source: American Association of Clinical Chemistry

This apathy has contributed to one undeniable fact. During the past 14 years, the clinical laboratory industry has an almost unbroken record of Medicare funding failures. This relative decline in revenues realized from Medicare testing during this time period is one factor behind the collapse of the independent clinical laboratory industry.

Thus, it is imperative that individual lab executives and pathologists acknowledge that continued apathy at Medicare budgeting time will eventually lead to a further erosion in the capabilities of America's clinical laboratories to provide high-quality testing to patients of all socioeconomic levels. TDR

Contact Robert Michel at 503-699-0616.

Economics and Medicine

Vaccine Shortage Is Result Of Economic Disincentives

By Robert L. Michel

RECENT PUBLICITY about the nationwide shortage of vaccines makes it timely to remind laboratory executives and pathologists about the important role that economics plays in providing goods and services to the healthcare marketplace.

After all, good management strategy must incorporate an accurate assessment of market trends. Every laboratory's business plan must accurately anticipate the factors which affect its financial stability.

In the past few months, eight of 11 vaccines deemed critical for pediatric health are in short supply, including vaccines for whooping cough, diphtheria, and chicken pox. But the story doesn't stop there. Also in short supply are a number of adult vaccines, forcing waits upon patients who want to be immunized.

Source Of The Shortage

The remarkable shortage of vaccines in the United States provides an opportunity to illustrate how certain economic concepts can either bring consumers better quality products at ever-lower prices or create "artificial" shortages that reduce choice and increase costs. It all depends upon the way society and the government control or decontrol the marketplace.

Here's the set-up to the vaccine shortage. In 1967, there were 37 vaccine manufacturers in the United States, producing 380 licensed vaccines. By 2001, only ten manufacturers remained. The number of licensed vaccines fell to 52. This reduction in both suppliers and vaccines is counterintuitive. The explosive growth in medical technology during the past 20 years would lead one to expect an increase in the number of licensed vaccines over the 380 produced in 1967.

Inadequate Supply

Moreover, not only has the number of licensed vaccines fallen to an incredibly low number, but the supply is insufficient to meet patient demand. Why is this happening in United States? If there is strong demand, why won't companies provide the supply to meet this demand?

The answer is rooted in the economic disincentives that the government has fostered over the past 35 years. First, government regulations have become increasingly complex. This has raised the costs of companies willing to develop new vaccines, gain regulatory approval, and then sell these vaccines in the healthcare marketplace.

The second problem is the increasing risk of litigation, much of it frivolous. When the costs of anticipated legal costs are added to the sales price of individual vaccines, they become prohibitively expensive for consumers (patients).

But the third key factor is fascinating. It is the use of arbitrary buying power by a "monopoly buyer"—the government—to drive down the price it pays for vaccines. During the 1990s, the **Centers for Disease Control and**

Prevention (CDC), under a new government program instituted by the Clinton Administration, has become the purchaser of more than half of all vaccines used in this country. The CDC, backed by its clout and buying power, is paying less than half of what is paid by the private sector for many vaccines.

Factors Discourage Makers

The cumulative impact of these three factors has been to discourage vaccine manufacturers from investing in research to develop better vaccines. It also gave manufacturers a reason not to expand their capacity to produce greater quantities of vaccines to meet the growing demand within our healthcare system.

As a result, our healthcare system faces the visible dilemma today of inadequate supplies of licensed vaccines for children and adults. But it also faces the "invisible" dilemma of wonder-vaccines that might have been, but were never developed because of the economic disincentives in today's economy.

Here's an example. After a decade of development work, **Wyeth Corporation** last year brought a remarkable new children's vaccine to market for pneumonia and meningitis. When it established a price of $58 per dose, it was soundly criticized for price-gouging by the public health lobby. The CDC beat the price down, and currently pays $46 per dose.

Is A Fair Return Possible?

Not surprisingly, the triple-disincentives of complex regulations, unreasonable litigation costs, and heavy-fisted government purchasing philosophies (based on "social justice") have combined to make it nearly impossible for any company to earn a fair return from investments in vaccine development, manufacturing and distribution.

Still not convinced? I offer you the example of socialized economic systems in Europe and their impact on the pharmaceutical industry.

Many European nations force drug companies to sell their products at an artificially low price. In the short term, that saves money. But the long term effect is becoming visible. In recent years, a growing number of European pharmaceutical companies have shifted research and development activities out of Europe and into the United States.

In the United States, it is still possible for these companies to sell new drugs at a price that allows them to recover costs and earn a profit. But as we all know, in recent years the amount of money spent on prescriptions in the United States has increased rapidly. This is stimulating cries by politicians and consumer groups for regulation and price controls on drugs.

Same Trends In Drug Sector

If that happens, and there is much evidence that it may, will this be good for the American healthcare system? I offer the example of vaccines as an answer. In 35 years, the number of companies, the number of products, and even the supply of the remaining products, have all dwindled. It is likely the same thing will happen to pharmaceuticals.

I believe it is important for laboratory administrators and pathologists to understand the economic principles which create these situations. Used properly, they create incentives, better products, and lower costs. Used improperly, they create disincentives, reduce the quantity and quality of products, and increase costs.

Although I have used the examples of vaccines and pharmaceuticals in this story, laboratory testing can certainly be affected in the same way. Medicare's manipulation of routine test panels during the 1990s demonstrates how regulation and arbitrarily low reimbursement can stifle both innovation and the availability of quality lab tests. TDR

Business Buzz Saw Hits Anatomic Path Firms

Both IMPATH and US Labs cut loose CFOs as each deals with different types of problems

CEO SUMMARY: ***In recent years, both companies have enjoyed sustained and rapid growth in offering anatomic pathology (AP) services nationally. The departure of CFOs from both companies, each for different reasons, is a sign that such unbridled growth has created unique problems for each AP company. These problems are probably due to management decisions and not changes in the AP marketplace.***

TWO NATIONAL ANATOMIC pathology companies recently replaced their Chief Financial Officers (CFO), each for a different reason.

For any company, replacement of the CFO represents a significant event. It is often a sign that management is grappling with internal problems. Because anatomic pathology services have been a fast-growing segment of the lab testing industry, the shuffling of CFOs at **IMPATH, Inc.** and **US Labs, Inc.**, based in New York City and Irvine, California, respectively, are significant events.

Negative Cash Flow

In the case of US Labs, the departure of its CFO was unrelated to accounting practices. Apparently the fast-growing AP company has been outspending its revenues. The negative cash flow, also called the "burn rate" by investors, had precipitated a crisis of confidence in the executive leadership of US Labs.

To address the situation, in late April the Board moved Chairman and CEO Mike Danzi to Vice Chairman. It installed R. Judd Jessup as Chairman and CEO. Jessup was formerly President of **FHP International's** HMO division, which covered 1.8 million lives in 11 states.

Substantial restructuring is under way at US Labs to bring expenses in line with revenues. One sign of this activity is the transfer of its diagnostic cytology business to **Pathology, Inc.**, based in Torrance, California. This pathology practice has an ongoing business relationship with US Labs. The service change-over for diagnostic cytology services was effective on May 20, 2002.

Knowledgeable sources tell THE DARK REPORT that the investor groups which funded US Labs are looking at different exit strategies for the relatively young company. The negative cash flow is substantial and obtaining more money through another round of venture capital funding is not a desired option.

One interesting aspect to US Labs' business woes is a nearly parallel situation at **Specialty Laboratories, Inc.** *(See TDR, April 22, 2002 and May 13,*

2002.) Both companies are in a financial squeeze, but for different reasons. Credible rumors indicate that officials from both companies have looked at business scenarios that could possibly bring both companies together.

CFO Change At IMPATH

On May 16, IMPATH announced the resignation of CFO David J. Cammarata. In the careful language used by public companies in their press releases, Chairman and CEO Anu D. Saad, Ph.D. was quoted as saying "Dave has made valuable contributions during his eight years at IMPATH and we wish him well in his new endeavors."

Cammarata joined IMPATH in the years before its initial public offering. Thus, he was responsible for the difficult job of managing the finances of a rapidly-growing company. This included handling issues triggered by the frequent acquisitions that IMPATH used to build its revenue base.

...IMPATH has been under increased scrutiny by Wall Street analysts over its billing practices and how it reports revenues, accounts receivables, bad debt, and days sales outstanding (DSO).

Cammarata's exit from IMPATH is linked to recent events involving the company. Regular readers of THE DARK REPORT know that IMPATH has been under increased scrutiny by Wall Street analysts over its billing practices and how it reports revenues, accounts receivables, bad debt, and days sales outstanding (DSO).

These issues are related to certain IMPATH business practices which caught the attention of local pathology groups. In particular, this involved two elements. One was the way IMPATH billed insurance companies and balance-billed patients for the amount unreimbursed by insurers. The other involved its policies for coding and billing multiple markers on individual cancer cases.

In both instances, IMPATH instituted practices which were outside the norm for most anatomic pathology providers. Its activities have been considered aggressive by those pathologists who preferred very conservative coding and billing procedures. However, to date, IMPATH has only disclosed one settlement with Medicare, which involved allegations that it improperly billed Medicare for test controls run in parallel with certain types of assays.

Thus, IMPATH's replacement of its CFO at this time is a sign that increased interest by the professional investment community in its financial and accounting practices is causing significant changes to take place within the company. Some of these changes may involve reforms to certain of IMPATH's more aggressive billing and contracting practices. If so, those reforms should become visible in the marketplace once a new CFO has been hired.

Supported By Lab Industry

In recent years, THE DARK REPORT has noted the sustained growth in specimen volume and revenues posted by the handful of companies that offer anatomic pathology services to the national marketplace. This is an important trend which affects the profitability of local pathology groups.

However, it is also true that business success breeds its own unique problems. The recent turnover of CFOs in two national AP companies is a sign that such growth-related issues are now causing problems which need resolution. **TDR**

Contact Robert Michel at 503-699-0616.

Are These Joint Ventures A "Dying Breed"?

Commercial Lab JVs With Hospitals Are Declining In Number

CEO SUMMARY: There are many reasons why a properly-designed and well-managed laboratory test joint venture (JV) between a commercial lab company and a hospital should succeed. But no matter how strong such concepts look on paper, the real world has proven to be a harsh environment. A handful of promising JVs took root during the 1990s, but closures have thinned their ranks during the past two years. In fact, so many of these joint ventures have closed down in recent years that it might be accurate to declare commercial lab-hospital lab test joint ventures a "dying breed."

IT'S TIME TO RECOGNIZE THE FAILURE of the business model which paired a commercial lab company with a hospital in a laboratory testing joint venture.

In concept, the idea made sense. Most hospital labs have unused capacity during evening and early morning hours—prime time for testing specimens from physicians' offices. Commercial lab companies have expertise in sales, marketing, billing, collections, and other operational functions that complement the strengths of the hospital laboratory.

On paper, such a joint venture would seem well-positioned to profitably service the outreach market—those physicians who typically lease offices in the medical campus surrounding the hospital.

The merits of this business model were certainly obvious to the nation's large public laboratory companies. Throughout the 1990s, these lab companies openly declared they would like nothing better than to develop joint ventures with hospitals and integrated healthcare systems.

Looking For Hospital Partners

To find willing partners and develop these deals, lab companies invested lots of money in flying sales reps and executives all over the country to meet repeatedly with hospital administrators.

However, after more than ten years of intense efforts to develop these joint ventures, commercial lab companies were unable to develop more than a handful of projects. And frequently the actual financial performance of these joint ventures disappointed both partners, but for different reasons.

To justify their involvement in the JV, the commercial partner needed regular distribution of profits generated by the venture. However, this often conflicted with the financial goals of the hospital partner, whose goal was to have profits used to lower the hospital's cost for inpatient laboratory tests.

It was this inherent conflict over the use of profits, as well as the lackluster financial performance that caused a number of lab testing joint ventures between commercial laboratory and hospitals to unravel after a few short years. This usually occurred when the operating agreement came up for renewal.

End Of An Era

THE DARK REPORT believes that, if there ever was an era of the "commercial lab-hospital lab joint venture," it has certainly ended with the acquisition of **Dynacare, Inc.** by **Laboratory Corporation of America**. That's because Dynacare was most closely identified with these types of lab testing joint ventures.

Originally based in Canada, Dynacare entered the United States around 1994 with a specific goal: to build a profitable laboratory business based on doing laboratory testing joint ventures with hospitals. As most hospital lab administrators and pathologists can attest, during the balance of the 1990s, Dynacare sales people were frequent visitors to larger hospitals, always probing and trying to interest administrators in a laboratory joint venture.

Growth By Acquisition

One reason Dynacare decided to sell to LabCorp and cease operations as an independent company is because it was never able to develop enough profitable lab joint ventures with hospitals to generate the revenues needed to sustain its business operations. In fact, most of Dynacare's revenue growth in the United States was actually from its acquisition of small independent lab companies in various regions of the country.

Dynacare did develop some notable joint ventures with hospitals and health systems. But it should be noted that Dynacare spent an inordinate amount of money flying its people all over the country to identify likely partners and develop

Joint Venture Concept Like Mixing Oil & Water

WHENEVER THE SUBJECT of a joint venture between commercial lab companies and hospital labs comes up among hospital laboratory administrators, it stirs up lots of debate.

For whatever reason, putting hospital lab administrators together with commercial lab executives is like mixing oil and water. They have different business priorities that continually tug them in conflicting directions. This makes it difficult to find the common ground necessary to organize a lab testing venture that will be mutually profitable and long-lasting.

A well-conceived lab testing joint venture can provide many benefits to both partners. Through the years, THE DARK REPORT has toured a number of such JVs. It has observed, first-hand, significant achievements and happy partners. The mystery is why even some of the best-of-class JVs, after years of sustained success, are terminated by one or both lab partners.

deals from interested parties during the 1994-2001 period. If these marketing costs over seven years are tallied and divided into the handful of JVs which resulted from this marketing, Dynacare probably had a prohibitively expensive "marketing cost to acquire a new JV."

Similar Business Plan

But Dynacare's experience was not unique. Its sizeable marketing effort was mirrored by another Canadian company. **MDS Laboratory Services** entered the United States shortly after Dynacare with a similar goal: to develop collaborative lab testing ventures with hospitals and health systems.

MDS came to the joint venture concept differently. In the mid-1990s it had tried to sell its total laboratory automation (TLA) system to hospital labs in the United States and found no takers. Unable to sell its TLA system, MDS decided to create a collaborative business model where it would partner with a health system.

In this business model, MDS would build a state-of-the-art laboratory incorporating its automated equipment. MDS would manage the lab and, where possible, increase specimens into the JV's new lab through a laboratory outreach marketing program. The hospital partner would contribute trained technical staff, inpatient specimens and other resources. The two partners would split profits and costs according to a pre-agreed formula.

Limited Number Of JVs

Like Dynacare, during the remainder of the 1990s, executives and sales reps from MDS criss-crossed the country hoping to interest hospitals and health systems with their collaborative lab testing business model. As was true of Dynacare, MDS spent scads of money on travel and salaries over several years, but was only able to develop a limited number of collaborative projects with hospital partners.

It was a similar story at **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** during the 1990s. Each of the two blood brothers invested considerable sums of money attempting to develop joint ventures or collaborative lab testing agreements with hospitals and health systems.

In fact, in 1998, Quest Diagnostics signed a partnership agreement with **Premier, Inc.**, the nation's largest group purchasing organization. The objective of both partners was to develop partnerships with Premier member hospitals to improve their laboratory testing operations. *(See TDR, May 26, 1998.)* At the time, the news

generated lots of excitement in the lab marketplace, but THE DARK REPORT is not aware of a single Premier hospital that entered into a collaborative lab testing agreement with the Quest and Premier consortium.

Similar Business Plan

Each of these examples supports the contention of THE DARK REPORT that the era of the commercial lab-hospital lab joint venture, if there ever was one, ended with the sale of Dynacare to LabCorp. The four big lab companies mentioned above invested disproportionate money into developing only a limited number of actual joint ventures with certain hospitals.

That is certainly confirmation that hospitals are generally hostile to the idea of partnering with a commercial laboratory company. Further confirmation of this fact comes from an analysis of those lab testing joint ventures which did become operational.

Dynacare is a good place to start, since its entry into the United States was predicated on a strategy of emphasizing lab testing joint ventures with hospitals. Its first JV was with **Cedars Sinai Medical Center** in Los Angeles. This project disappointed both partners and was not renewed after the three-year contract expired in 1997.

Lab Outsourcing Contract

One big financial success for Dynacare was its acquisition of **Laboratory of Pathology** (LOP) in Seattle. Acquired in 1995, LOP was an independent commercial laboratory owned by pathologists. Although Dynacare-LOP is closely identified with **Swedish Hospital**, the business relationship is not a joint venture. Dynacare-LOP holds a contract to provide inpatient laboratory testing to Swedish Hospital.

Another big win for Dynacare was its joint venture with **Hermann Hospital** in Houston, Texas, launched in 1996. Despite some early mis-steps, the Dynacare-Hermann venture did quite well in the outreach market. However, several years later Hermann Hospital was acquired by **Memorial Health System**.

Memorial, with 12 hospitals, wanted to integrate Hermann Hospital's lab into its already-standardized regional lab division. First, it excluded Dynacare from participating in Hermann's inpatient lab testing. It then declined to renew its outreach testing agreement in 2001, thus terminating the last elements of the original lab testing JV.

Several JVs Launched

During these same years, Dynacare entered into lab testing JVs with Ellis Hospital in Schenectady, New York; **Froedtert Memorial Lutheran Hospital** in Milwaukee, Wisconsin; **University of Tennessee Medical Center** in Knoxville, Tennessee; and **Allegheny General Hospital** in Pittsburgh, Pennsylvania.

At the time Dynacare announced its sale to LabCorp, it also disclosed that it was terminating its contractual relationship with Ellis Hospital and Allegheny General Hospital. This leaves it with only two operational joint ventures after almost eight years of non-stop efforts to develop such joint ventures.

It's a similar picture at MDS. Since 1995, it developed two collaborative lab joint ventures with **HCA Corporation**, the for-profit hospital company. These are located in Atlanta, Georgia and Miami, Florida. It also has partnerships with **Baptist Memorial Hospital** in Memphis, Tennessee and a lab outreach JV with **Duke University Health System** in Durham, North Carolina. MDS also had a joint venture in Poughkeepsie, New York that was established with two hospitals back in 1988, known as **MDS-Hudson Valley Laboratories, Inc.**

For the marketing effort expended by MDS over the past seven years, this is not a large number of partnerships. One of these joint ventures was terminated. In 2001, the hospital partner of MDS-Hudson Valley Labs asked to cash out its partnership share and recast the relationship as an outsourcing contract.

Change In JV Status

MDS is thus the sole owner of MDS-Hudson Valley Labs and provides inpatient testing services on contract to **Vasser Brothers Hospital** and **Northern Duchess Hospital**. These hospitals were the two equity partners in the original MDS-Hudson Valley Labs venture organized back in 1988.

It should be noted that rumors regularly surface that the MDS-HCA relationship is strained due to the "disappointing" financial performance of the consolidated labs in Atlanta and Miami." But these are long-standing rumors and neither partner has publicly disclosed any changes or proposals to alter the original joint venture agreement.

For Quest Diagnostics, the failure of the Premier partnering agreement to generate joint ventures has been accompanied by a couple of other setbacks. It had announced a collaborative relationship with **Unity Health System** in St. Louis, Missouri. However, this relationship ended within a few years.

Collapse of Long-Lasting JV

Of more interest is the recent collapse of a long-standing joint venture with multiple hospitals that Quest Diagnostics had in Lincoln, Nebraska. **Clinical Laboratories of Lincoln, Inc.** (CLL) was formed in the late 1980s when pathologists from the major hospitals in Lincoln proposed forming a for-profit lab company to run an integrated lab services company.

From a central core lab, CLL managed all inpatient testing for its hospital owners and maintained a thriving lab outreach program. **Nichols Institute** purchased CLL in 1986 and CLL became a Quest Diagnostics lab when it acquired Nichols Institute in 1994.

In the last six months, Quest-CLL has been dismantled. Several of the hospitals served by Quest-CLL did a cost analysis of the inpatient testing services provided by Quest-CLL. In the case of one hospital, it was determined that savings of $6 million per year could be realized if that hospital reconstituted its inpatient laboratory and managed it directly.

Quest-CLL's hospital partners broke up the long-standing lab testing joint venture. Each hospital has pursued inpatient lab testing options it believes to be cheaper and more effective than what it received from Quest-CLL.

Disappointing Performance

In the late 1990s, **American Medical Laboratories, Inc.** (AML) developed a lab testing joint venture in Fairfax, Virginia with four hospital/health system partners. Called **Shared Laboratory Services, Inc.**, the venture built a core lab in the late 1990s and had high hopes. But service problems and dissatisfaction with the operational execution of the venture caused one health system partner to pull out in 2001. Another health system partner is preparing to leave SLS soon as well.

Another notable and long-standing lab testing joint venture existed in La Jolla, California. It was started in 1994 by **Scripps Healthcare** and **Pathologists Medical Laboratories, Inc.** (PML). Based on its sustained success, the partnership was expanded in 1996 to include operation of the labs in hospitals newly-acquired by Scripps. However, two years later, new admin-

International Clinical Labs Mastered Hospital JVs During Decade of 80s

MAYBE THE HIGHWATER MARK for lab testing joint ventures between commercial laboratories and hospital laboratories was the 1980s.

Laboratory executives with long memories recall that **International Clinical Laboratories, Inc.** (ICL) had a knack for developing lab testing joint ventures with hospitals. ICL had more than 40 active JVs with hospital laboratories prior to its acquisition by **SmithKline Beechman Clinical Laboratories** in 1988.

Because of its success in developing joint ventures with hospitals, ICL was much-admired by its commercial laboratory competitors. One of its earliest joint ventures continues today. **CompuNet Laboratories, Inc.** of Moraine, Ohio is a three-partner joint venture. Equity participants include **Miami Valley Hospital** and **Valley Pathologists**, the pathology group affiliated with the hospital, and **Quest Diagnostics Incorporated**.

CompuNet Laboratories was originally formed in 1987 by ICL. The first general manager for the joint venture was Bill Pesci, who is still in the lab business and is Executive Director of the **Carolina Laboratory Network** in Charlotte, North Carolina.

Over the past two decades, CompuNet survived a series of acquisitions involving its commercial laboratory partner. ICL was sold to SmithKline Beecham Clinical Laboratories. In 1999, Quest Diagnostics purchased SBCL and thus inherited SBCL's equity stake in the CompuNet joint venture.

istration at Scripps summarily ousted PML and brought in Dynacare to manage its labs on contract. PML's owner later won a multi-million dollar lawsuit against Scripps for its arbitrary actions in terminating the joint venture.

Two Important Points

This rather long litany of collapsed lab testing joint ventures in recent years makes two important points. First, despite the substantial money spent by commercial laboratory companies to market this concept to hospitals, there have been few takers.

Second, a high proportion of the joint ventures developed during the last decade did not survive. In most cases, the hospital partner moved to terminate the joint venture.

Based on these facts, THE DARK REPORT concludes that the concept of a lab testing joint venture between commercial labs and hospitals is impractical. Despite the obvious mutual benefits to both parties on paper, in the real world the needs of hospitals to lower costs and improve inpatient testing services seem to conflict with the needs of commercial lab companies to generate and distribute profits from the joint venture.

However, this is not the end of the story. There will always be a small slice of the hospital industry willing to experiment with commercial labs to find a business formula that works. These evolving experiments may guide the lab industry to a new lab testing joint venture business model that actually delivers substantial benefits to both hospitals and their commercial laboratory partners. **TDR**

Contact Robert Michel at 503-699-0616.

Healthcare E-Commerce

Pharmacy Web-Ordering Now A Physician Priority

STRONG PRESSURES ARE MOTIVATING office-based physicians to adopt electronic ordering for prescriptions. In part, this is because of the drive to eliminate unnecessary medical errors.

Estimates are that 6% of the nation's physicians now use an electronic method to order prescriptions for their patients. Consulting firms **Fulcrum Analytics, Inc.** and **Deloitte Research** predict that, within the next three years, more than 20% of physicians will be ordering prescriptions electronically.

This shift is moving physicians from a paper-based prescription ordering system to one that is electronic. It is comparable to how laboratories moved physicians' offices from paper-based lab test requisitions to computer-generated requisitions during the 1990s.

The next evolution for electronic laboratory test ordering is to move physicians' offices away from DOS-based computer systems and onto Web-browser-based systems. To achieve this will require software which is simpler and faster in operation, as well as more broadband connections in physicians' offices.

Parallel Trend With Lab

The trend toward electronic pharmacy ordering has many parallels with how the laboratory industry introduced DOS-based laboratory test ordering 12 years ago. Most pharmacies are not equipped to handle prescription and refill orders sent by physicians over the Internet. For this reason, most electronic pharmacy ordering systems convert the prescription into a fax which is then transmitted to the pharmacy. In some cases, physicians are ordering prescriptions through their computerized system, then handing the patient a print-out of the prescription to take to their pharmacy.

Still Using Fax Machines

At this time, pharmacies themselves are a barrier to greater adoption of electronic pharmacy ordering. That's because relatively few pharmacies in the United States are equipped to handle prescriptions transmitted via the Internet. Fax machines continue to be the most common method of receiving pharmacy orders.

This situation is expected to change rapidly. Growing numbers of pharmacies are actively investing to become Internet-capable. As this occurs, another barrier to wider use of electronic pharmacy ordering will be eliminated.

Lab executives and pathologists should track the growth of electronic pharmacy ordering in physicians' offices. As more physicians become comfortable with ordering prescriptions electronically, it is logical to assume that they will also become more comfortable using Web browser-based systems for lab test ordering and results reporting.

For this reason, the growth of electronic ordering for prescriptions may stimulate physicians to also begin using Web browser-based systems to order laboratory tests. TDR

Lab Industry Briefs

SIGMA-ALDRICH SELLS ITS EIA PRODUCT LINE TO IVAX DIAGNOSTICS

FOLLOWING ITS DECISION TO EXIT the clinical diagnostics market, **Sigma-Aldrich, Inc.** has sold its global enzyme immunoassay (EIA) product line to **Ivax Diagnostics, Inc.**, based in Miami, Florida.

The sale occurred on May 15. Sigma-Aldrich, through its Sigma Diagnostics division, was selling EIA instruments and reagents produced by Ivax, and "private-labeled" under the Sigma name. One consequence of this sale is that Ivax Diagnostics becomes the prime supplier for those lab customers who were using Sigma's EIA products.

Ivax Diagnostics is a relatively small manufacturer, with annual sales of about $10 million. Its business strategy is to offer a full menu of test kits for lower volume EIA assays. It sells an automated "walk-away" EIA instrument, called Mago®, that is an open system. Labs seeking to consolidate a variety of low-volume EIA assays on a single instrument platform will find several aspects of the Mago system to be appealing.

POINT-OF-CARE TESTING CONTINUES TO MAKE NEW INROADS IN HOSPITALS

THROUGHOUT THE 1990S, there was a running debate about the value of point-of-care testing (POCT) in hospital settings.

Advocates of core lab testing argue that there are advantages of lower cost, better supervision of testing activity, and higher quality of test results when tests are performed in a core laboratory.

Advocates of POCT argue the advantages of faster TAT, lower cost per healthcare encounter, and acceptable quality when POCT operators are properly trained. The core lab-POCT debate often turns intense, because each side has evidence to support their position.

However, it is always the marketplace which gets the final word. One bellwether for the growth of POCT testing is **i-STAT Corporation** of East Windsor, New Jersey. It was one of the earliest manufacturers of a viable POCT instrument.

The inroads i-STAT has made in POCT is revealed in its first quarter earnings report, which was made public last month. i-STAT now claims to have 27,000 analyzers in use worldwide. Its sales of cartridges for these analyzers totaled 2.69 million units during first quarter 2002.

This means that i-STAT analyzers are performing almost 11 million tests per year in the hospitals and healthcare settings where they are used. Sales of i-STAT analyzers, cartridges, and peripheral equipment should bring the company revenues of more than $59 million this year.

More intriguing is what lies ahead. i-STAT intends to introduce several new tests this year. These will be in the form of cartridges that are compatible with the i-STAT analyzer. A test for prothrombin time is heading to market. i-STAT is also preparing to introduce its first immunoassay test. It will be the cardiac marker troponin I.

The market acceptance of i-STAT shows how the healthcare community is steadily adapting to the concept of POCT. For lab administrators and pathologists, there are two key insights revealed by this situation.

First, as diagnostic instrument manufacturers develop POCT analyzers which are perceived to be easy to use, accurate, and cost-effective in clinical settings, healthcare providers will accept them. But these POCT instruments must truly deliver those benefits.

Second, i-STAT shows how rapidly the technology that enables random test-random specimen diagnostic instrument platforms is developing. Since its introduction early in the 1990s, i-STAT has steadily added new tests to the menu of cartridges that can be utilized with its analyzer. i-STAT's first immunoassay test opens the door to an even wider menu of tests.

i-STAT is only one example of how diagnostic manufacturers are making progress at reducing size of the instrument required to perform a test, as well as reducing the amount of reagent and specimen. It is this type of innovative technology which will encourage a growing number of tests to migrate out of the core lab and into point-of-care and near-patient settings.

FTC EXTENDS REVIEW OF QUEST DIAGNOSTICS' ACQUISITION OF UNILAB

It was a closely-watched deadline. As of Friday, May 24, **Quest Diagnostics Incorporated** released the news that the **Federal Trade Commission** (FTC) had requested additional information concerning the Quest Diagnostics' acquisition of **Unilab Corporation**. *(See TDR, April 22, 2002.)*

This surprised many in the lab industry. That's because, of the great number of lab acquisitions transacted over the years, the FTC's past pattern has been to allow mergers between commercial laboratory companies to proceed without additional delay. Generally, government concerns about potential antitrust issues triggered by specific mergers were not enough to trigger government action.

This situation may be changing, particularly after the remaining "middle-tier" public lab companies, **American Medical Laboratories**, **Unilab**, and **Dynacare**, have been acquired by Quest Diagnostics and **Laboratory Corporation of America** during the past four months.

This concentration of market share in the physicians' office lab testing segment by the two blood brothers seems to have caught the attention of government antitrust regulators. Unilab is already the dominant presence in the physicians' office segment of the California market. Post-merger, Quest Diagnostics would hold a commanding market share in California. That seems to have antitrust regulators concerned.

THE DARK REPORT has spoken to several owners of independent commercial laboratories in California. Each has gotten calls from individuals at the FTC. Different sources have told THE DARK REPORT that some independent physicians' associations (IPA) have complained to the FTC. They are unhappy with the prices and the quality of lab testing services provided to them in the state already. They are concerned that Quest Diagnostics' acquisition of Unilab, by creating a clear monopoly, would cause the current situation to further worsen.

The FTC also delayed its ruling on the acquisition of **Digene, Inc.** by **Cytyc Corporation.** *(See TDR, March 11, 2002.)* Twice the FTC has extended its period of study on this deal, apparently concerned about the antitrust issues related to Cytyc's ownership of Digene and its DNA-based HPV test technology.

Since the FTC's extension of time in the Quest Diagnostics-Unilab merger is unusual, lab industry experts are closely watching further developments. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Medicare fraud investigators may not be getting big headlines in recent years, but they are collecting ever-growing amounts of money from healthcare fraud settlements, judgements, and impositions. A record $1.36 billion was collected in 2001. During the year, federal investigators filed 445 criminal indictments and 188 healthcare fraud cases. Some observers believe fraud enforcement efforts may be lessened in the aftermath of 9/11 as federal agencies devote more resources to fighting terrorism.

FDA APPROVES HIV RESISTANCE SOFTWARE

In less than 30 days, **Visible Genetics Inc.** gained **Food & Drug Administration** review and clearance for its next generation of software for interpreting HIV drug resistance from results of its TRUGENE™ HIV-1 Genotyping test. Each update includes information about new drugs and mutating strains of HIV-1 that are developing resistance to specific drugs.

ORASURE GAINS FDA APPROVAL FOR QUICK HIV-1 TEST

Subject to the company meeting certain conditions, the **Food and Drug Administration** (FDA) has notified **OraSure, Inc.** that its OraQuick® Rapid HIV-1 Antibody test is approvable. This test uses a finger-stick sample of whole blood and will detect HIV-1 antibodies in ten minutes. OraSure is best known for its oral fluid test for HIV-1, which has met with ready acceptance in many prominent AIDS clinics in the United States. It is also used in life insurance testing. By developing a whole blood test for HIV-1 using its proprietary technology, OraSure hopes to open a wider market by enabling point-of-care screening for HIV-1.

HOSPITAL C.O.N.S

Look for certificates of need (CON) to become a hot issue in certain states as hospitals respond to increasing admissions rates with plans to expand their facilities. The CON approval process will attract opposition from competing hospitals seeking to block new competition. Large employers may also get involved. Testifying before a Michigan state panel last March, executives from **DaimlerChrysler AG** testified in favor of retaining the state's CON laws. DaimlerChrysler offered some interesting statistics. In Michigan and New York, it spends $1,839 and $1,331 per employee or family member per year on healthcare. These are states with CON laws. In Wisconsin and Indiana, Chrysler pays $3,519 and $2,741, respectively, per person for healthcare. These are states without CON laws.

"Better" Marker For Prostate Cancer?

Researchers at the **University of Michigan Medical School** discovered a new genetic marker for prostate cancer which they believe is more accurate than prostate specific antigen (PSA). The gene expresses a protein enzyme called a-methylacyl-CoA racemase (AMACR). It is present only in malignant cells and is visible when stained. Their study was published in the April 3 issue of the *JAMA*.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 24, 2002.

UPCOMING...

- ***Will Acquisitions of AML, Unilab, and Dynacare Change Competitive Balance in Physicians' Office Market Segment?***
- ***How Small Hospital Labs are Using Vendors to Get Big Gains in Productivity.***
- ***Pathology's Newest Opportunity: Cancer Diagnostics Becomes a Booming Field.***

For more information, visit:
www.darkreport.com