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From the Desk of R. Lewis Dark...

THE DARK REPORT

Reliable Business Intelligence, Exclusively for Medical Lab CEOs / COOs / CFOs / Pathologists

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Healthcare, Free Markets, and Consumer Choice

ONCE AGAIN, WE ARE PROUD TO BE FIRST TO INFORM YOU ABOUT another major development in the healthcare industry. As you will read on pages 2-6, physician group practices in California are about to undergo a financial meltdown. The ramifications of this will touch healthcare providers in every city around the nation.

If there are widespread financial failures and bankruptcies among private group practices in California, it will not be a proud moment for healthcare. At THE DARK REPORT, our concern is that government will use the California crisis as an opportunity to do even more harm to our system. This will be a bad thing. Historically, free markets are faster and more efficient at providing win-win solutions than government legislators and bureaucrats.

Which leads me to make an important point to our clients and readers. We do not have a free market in healthcare in the United States. A reasonably pure free market exists in the computer industries. During the last 25 years, we have seen incredible leaps in the performance of computers, at rapidly declining costs. As consumers, it has made the Internet possible. I don't need to remind you how the Internet is transforming the daily routines of most middle class Americans. This is the free market at its best. We benefit from ever-improving products at ever-declining costs.

Healthcare could be the same way, if the free market was truly allowed to work its magic. But healthcare is saddled with government regulations. Over the years, vested interests have gotten the government to protect their part of the healthcare puzzle. HMOs have a federal exemption from patient lawsuits. Physicians have strict licensure requirements that now impede efforts at telemedicine. Attempts to reform aspects of healthcare regulation meet with resistance by those private enterprises whose vested interests would be harmed.

I believe that the right solution is to get government, and private vested interests, out of the way of those physicians and providers who can offer quality care at competitive prices. If consumers, through programs like Medical Savings Accounts (MSA), were given positive incentives to shop for their healthcare, they would make rational decisions and reward good physicians with their business. Of course, the free market does separate winners from losers rather quickly. But we all benefit from that by getting a better quality product at a lower price. For my nickel, I hope consumer choice is quickly restored to our system of healthcare. TDR

California's Physicians Face Financial Meltdown

Many docs already suffering financial woes; hospitals may not be far behind

CEO SUMMARY: It's a what-if scenario that may come true. Healthcare providers in the Golden State are going broke at an astounding rate. Physicians seem to be the hardest hit, but signs indicate that hospitals are also heading toward serious financial difficulties. In a nutshell, a decade of draconian cutbacks to provider reimbursement have left many of California's doctors literally at the point of bankruptcy.

CALIFORNIA'S EXPERIMENT in managed care continues to devastate physicians and other healthcare providers.

Clinical laboratories were the first to be upended by the managed care freight train in California during the mid-1990s. Now it appears that physicians are next on the hit list, with hospitals not far behind.

This is probably the most important under-reported story in American healthcare today. Physician group practices in the nation's most populous and wealthiest state now stand at the brink of widespread financial collapse. Yet this fact is ignored by the media and unknown to most people.

THE DARK REPORT predicts a financial meltdown of physician group practices in California will occur sometime during the next 12 to 24 months.

This will cut across all sizes of group practices and all types of physician specialties. It won't affect salaried physicians, such as those employed by **Kaiser Permanente** or the Los Angeles County healthcare system. But it will affect those physicians in private practice settings, including some pathologists.

Here is the bad news. A recent study by **PriceWaterhouseCoopers**, the national accounting firm, projects that one in ten physician groups in California holding capitated agreements from HMOs will close their doors during 1999!

Reports are, that by August of this year, at least 15 physician groups had

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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 $10.80 per week in the US, $11.40 per week in Canada, $12.45 per week elsewhere (billed semi-annually).

ceased to do business. Several practices are losing as much as $500,000 *per month!*

The bad news doesn't stop there. Since 1996, at least 115 of the state's physician groups and IPA's (independent physician associations) have also filed bankruptcy or ceased operations. PriceWaterhouse-Coopers reports that two out of three physician groups are losing money and that eight out of ten physician groups cannot meet four basic financial benchmarks.

Failure Of Managed Care

These facts certainly confirm that managed care, as it unfolded in California, failed to meet the needs of physicians as partners and providers to that state's healthcare system.

THE DARK REPORT believes this information also confirms another important fact. The managed care game in California is soon to hit financial bottom. When it does, state politicians will step in to resolve the mess that payers and providers created, but were unable to solve. Unfortunately, solutions enacted by politicians are seldom viable, particularly in the long run.

For lab executives and pathologists concerned about the future impact of managed care in their own marketplace, the California experience should be closely watched. There are increasing signs that the entire private healthcare system in the state is on the verge of a financial meltdown. Thus, any arbitrary political cures will surely be copied as other states encounter similar problems.

In many respects, the economic woes of physician practices in California are identical to the problems experienced by clinical laboratories in that state since 1994. Reimbursement is inadequate to fund services, capitated contracts push risk onto providers, and competitive pressures to access patients encourage providers to tolerate inadequate reimbursement.

There will be one difference in the way clinical labs and physicians get a resolution to these problems. Clinical laboratories chose not to respond with a collective effort. And, clinical laboratories lacked clout with employers, politicians, and payers.

Physicians have an existing framework for unified action. Through state and national medical associations, they already have vehicles for responding in a united fashion. Physicians also have clout. Their direct access to patients gives doctors influence with both citizens and politicians.

The seriousness of events in California should neither be underestimated nor overlooked. THE DARK REPORT recommends that laboratory executives and pathologists watch and learn from the experience of California.

"It's important to understand one thing about events in California," stated Michael Casey, Managed Care Analyst of **Medical Data International** in Santa Ana, California. "Its healthcare experience is unique compared to other states.

"This is because California and Minnesota are the 'trial and error' sites for managed care," he explained. "No other state has seen the kind of managed care experiments that happen in California and Minnesota."

Progressive Experiments

"Not only are these experiments very progressive, but many managed care initiatives have taken deep root, particularly in California," noted Casey. "In contrast, there are a whole lot of states where capitation has barely made an appearance."

Casey recognizes the financial difficulties facing physician practices. "The problem in California has been

California Medical Association Responding To Financial Threat

IT APPEARS THAT arbitrary reimbursement cramdowns may soon become a thing of the past in California.

"The California Medical Association (CMA) is pursuing solutions at two levels—the micro and the macro," said Hobart Swan, Associate Director of Communications for CMA.

"At the micro level, we are pushing state legislation," he explained. "One bill would require reimbursement paid by health insurers to be actuarially sound and sufficient to cover the cost of acceptable care. The other would address the problem of forcing physicians to accept pharmacy risk without actuarially sound reimbursement."

Negotiate As United Group

"At the macro level, CMA wants to give doctors the ability to negotiate as a united group," Swan noted. "We feel it's important to unify the House of Medicine. It will take concerted action and a common focus to accomplish the necessary reforms to our state's managed care system."

In reviewing activities by CMA, it is clear that one major thrust of the attack on California's managed care system will focus on the fact that the state's HMOs knowingly underfund physician reimbursement, while averaging 15% in profits and overhead.

*"It is important to recognize that current capitation rates do not reflect the cost of care," noted Swan. "For example, a **Towers Perrin** study for 1998 showed the cost of treating pediatric patients (0-21 years old) averages $47 per child per month in California. A 1998 CMA study revealed that pediatricians were only getting an average of $24.24 per child per month. Further, certain pediatricians surveyed reported that they got as little as $10 per child per month!*

"Not only do managed care companies offer underfunded contracts," Swan added, "but these contracts are unfair to physicians. They are forced to accept terms, such as pharmacy risk, or not get access to patients.

"This shows the market influence of the major managed care players in our state," noted Swan. "The six largest insurance plans cover 92% of the market. It creates a situation where large medical groups feel compelled to sign contracts in order to retain access to enough patients to support their practice."

Owed Millions Of Dollars

*"Fiscally-unsound reimbursement set up widespread financial problems," stated Swan. "Everything began exploding when **FPA**'s bankruptcy left California docs with $61 million in unpaid claims. Less than one year later, **MedPartners**' failure meant another $60 million.*

"The healthcare system in California is a shaky artifice, a Hollywood set that looks impressive from the street, but holds nothing behind it," offered Swan. "People in California remain unaware that the doctor treating them today may only be one week away from bankruptcy and the closure of his practice."

two-fold," he said. "One, managed care plans shifted risk onto physicians and other providers. Two, reimbursement levels are below the cost to provide care. This means providers have had to put out money to maintain healthcare services to their patients.

"The solution to these problems is a better balance of risk-sharing between managed care plans and doctors, combined with adequate levels of reimbursement for clinical services," noted Casey.

PHYSICIANS STRUGGLE WITH CARE VERSUS COST

ANECDOTAL STORIES ABOUND in California. They describe the dilemma between the need to provide patient care, and the fact that such care often goes unreimbursed.

Daniel Higgins, M.D., an emergency room physician in Los Angeles, testified in a state senate committee meeting last March about the financial problems of a colleague.

According to Dr. Higgins, the bankruptcy of FPA Medical Management caused an oncology colleague to go bankrupt. While waiting to get reimbursed from FPA, this oncologist continued to purchase chemotherapy drugs out of his own pocket for his cancer patients.

Few experts will dispute the fact that physicians in California were too willing to accept risk without possessing the management resources and expertise to manage that risk. But the subject of reimbursement exposes the managed care industry to some valid criticisms.

"Capitation rates fail to accurately reflect the cost of providing care," said Hobart Swan, Associate Director of Communications for the **California Medical Association** (CMA). "Numbers published in thePriceWaterhouseCoopers study demonstrate this fact.

Concern over this disastrous financial situation for physicians caused the California Medical Association to issue a public warning last month. CMA also convened a special meeting. At that gathering, Cherise Skeba, a senior manager at PriceWaterhouseCoopers, noted that the healthcare system in California is losing $1 billion per year.

Below National Average

According to Skeba, its average premium of $120 per member is $7 below the national average, and California is considered to have a high cost of living. This sets up an interesting contradiction. Because of these low premium payments, California's healthcare system averages $83 million per month less than the average state!

Skeba also noted that, during the six year period from 1993 to 1999, the amount that HMOs paid to physicians to care for their enrollees actually dropped from a high of $45 per patient per month to a low of $29. This number is 30% below the national average.

THE DARK REPORT observes that hospitals in California are another class of healthcare providers which have significant financial problems. THE DARK REPORT predicts that, from 1999 forward, an increasing number of hospitals in California will report financial losses.

Reimbursement Rates

If this comes to pass, it demonstrates that managed care, as practiced by HMOs in California, failed to incorporate providers into a winning formula of clinical excellence at reasonable rates of reimbursement.

What will be the consequences of these developments? THE DARK REPORT predicts a bevy of legislative remedies in the Golden State. Politicians always love to solve high-profile issues. But just as the

Medicare/Medicaid programs are turning rotten after 33 years of operation, so also will California's legislative palliatives prove to be worse than the current situation.

THE DARK REPORT believes that future events in California related to the financial woes of physician practices will trigger several responses.

One, physicians in private practice will mount a high profile campaign to educate Californians and their elected officials about the one-sided arrangements common in the managed care system that exists today.

Two, we may soon see the collapse of a managed care system built on providers assuming unlimited risk against capitated reimbursement. As reported in the last issue of THE DARK REPORT, California hospitals are already rejecting capitated arrangements. Certainly doctors are ready to act in a similar fashion.

Stronger Legislation

Three, we expect to see stronger legislation enacted, accompanied by vigorous enforcement. New laws will require managed care companies to pay reimbursement which is sufficient to cover the cost of care. Such reimbursement arrangements would have to be validated by independent actuaries.

Unfortunately, THE DARK REPORT expects that resolution to government funded healthcare programs in California, particularly MediCal and Medicare, will prove extraordinarily difficult. Progress in reforming managed care and developing the next generation of health delivery vehicles will instead come from the private sector.

Our predictions of an impending financial meltdown for physician group practices in California will actually strengthen the financial fortunes of clinical laboratories and pathology practices in other areas of the United States over the next few years.

Managed care plans need providers. They also want as few restrictions on their operations as possible. This is why there will be slow and begrudging progress toward mutually beneficial contracts between laboratories and HMOs.

Delayed Payments Earn HMOs big $'s Each Year

Every healthcare provider has the same problem: getting timely payment from the payer. The ***American Psychological Association*** *(APA) decided to calculate the amount of money insurers pick up by delaying or denying claims and forcing them into the appeals process.*

PriceWaterhouseCoopers did a study for the APA and results were released in August. If claims were delayed the maximum 377 days permitted under Senate Bill 1344, private health insurers would earn $280 million per year on interest from the "escrowed" funds.

PriceWaterhouseCoopers assumed an average rate of 6.15% per year on investments. It calculated year 2000 private sector healthcare expenditures at $440.1 billion, and assumed that only 1% of this would be delayed for the 377-day maximum.

Just delaying 1% of private healthcare expenditures allows private insurers to pick up $280 million in interest. Now you can better appreciate the economic incentives HMOs have to delay timely payments to providers!

This won't happen overnight. But the self-interest of HMO executives is strong. In the next few years it will be in their best interest to offer clinical laboratories, physicians and other healthcare providers an improved contract relationship. TDR

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Lab Venture in Houston To Include a New Partner

Pact with Memorial Hermann Healthcare will create expanded laboratory operation

CEO SUMMARY: For months, lab industry rumors said the Memorial-Hermann merger had killed the Dynacare-Hermann Hospital laboratory joint venture, despite its sustained profitability. Now comes news that the Memorial Hermann Healthcare System and Dynacare will expand the laboratory joint venture. It demonstrates that the economics of a successful laboratory joint venture can be compelling.

MANY NAYSAYERS WITHIN THE clinical laboratory industry will be surprised to learn that **Memorial Hermann Healthcare System** and **Dynacare, Inc.** will expand their Houston-based laboratory joint venture.

For months, rumors had one consistent theme—that the merger between the Memorial and Hermann systems meant the death of Dynacare-Hermann Laboratories.

"I am pleased to say that Memorial Hermann Healthcare System (MHHS) and Dynacare are forming a new business venture," said Osama Sherif, Executive Vice President of Dynacare U.S. "It will commence upon the operational start-up of our new laboratory facility in Houston."

Profitable From Day One

"The new partnership will build upon the success of the original venture between Hermann Hospital and Dynacare, started in 1995," Sherif noted. "This partnership was profitable since day one, and 1998 was a particularly profitable year for the enterprise. As hospital systems see the continual erosion of revenue from other sources, it makes a profitable laboratory venture more attractive."

According to Sherif, the original Dynacare Hermann Laboratory venture will continue to operate while a new, state-of-the-art, 60,000 square foot core laboratory is constructed.

50-50 Partnership Venture

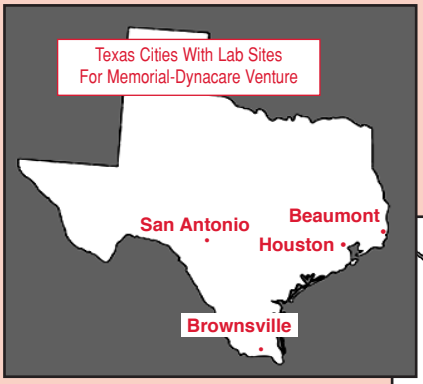
"The new partnership is a 50-50 venture between MHHS and Dynacare," he explained. "It will become operational when the new core lab facility is ready. That should be in the first quarter of 2000.

"Each of MHHS's 12 hospitals will continue to staff and manage their own on-site limited menu laboratory," continued Sherif. "Reference and esoteric testing from the hospitals will go to the core laboratory.

"This new core laboratory will also anchor the joint venture's expansion of outreach sales and marketing," added Sherif. "With the exception of the Dallas/Fort Worth market, Dynacare is contributing its existing Texas out-

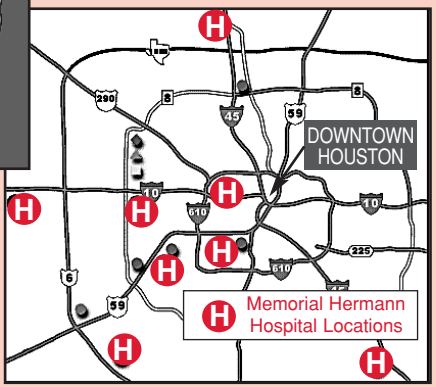
New Joint Venture Wants To Cover Texas

What gives any well-structured hospital lab/commercial lab joint venture a competitive edge for outreach testing is its well-positioned infrastructure. Hospital labs have great access points for phlebotomy, combined with good capability to do stat testing locally. These two maps show the existing lab resources available to the new Memorial Hermann-Dynacare venture.



Dynacare is contributing its existing out-reach testing to the expanded laboratory venture. Dynacare operates laboratories in Brownsville and San Antonio. MHHS has hospital labs in Houston and Beaumont.

Within the Houston metropolitan area, the nine MHHS hospitals provide an excellent base for marketing outreach testing ser-vices. It will make the lab joint venture a tough competitor within that city.



reach business into the new venture." (Dynacare already has a joint venture in Dallas with the **Baylor Healthcare System**.)

It appears that the new joint venture in Houston is designed to accomplish three primary objectives for its partners. One, to generate net profits for its equity owners. Two, to rationalize laboratory infrastructure among MHHS's twelve hospital laboratories. Three, to bring additional value-added laboratory services to the hospitals and physician offices around each MHHS hospital campus.

"The laboratory joint venture involving Hermann Hospital has been a fast-growth enterprise," stated Bill Pesci, Chief Operating Officer of Dynacare Hermann Laboratories. "Since its launch in September 1995, our growth rate in accessions has averaged 25% per year."

Sales And Marketing

"The partnership's sales and marketing program in Houston and other Texas cities is working well," he continued. "Total accessions were about 1,200 per night in 1995. Now they top 6,000 per night. This rapid growth has squeezed us for additional space in our existing core lab, currently located within Hermann Hospital.

"Construction of a new off-site core lab gives us the opportunity to expand our test menu," added Pesci. "For example, the new lab will allow us to create a NIDA-certified drugs of abuse

testing capability. We also expect to enhance our esoteric testing."

Dynacare Hermann Laboratories already acts as a national esoteric testing center for the other Dynacare regional laboratory operations in the United States. Pesci says that the plan is to increase the reference and esoteric capabilities of the new Houston core lab so that it can better serve the other Dynacare regional labs in the United States.

Enlarged Lab Venture

Within Houston, the enlarged laboratory joint venture should increase its competitive position for outreach business. This is because Memorial Hermann Healthcare System is in the process of buying three Houston hospitals from **Columbia/HCA Healthcare Corporation**. MHHS will then have eight hospitals strategically positioned throughout the Houston metro area.

Further, MHHS plans to add to its member hospitals by entering other Texas markets. As this occurs, the laboratory partnership will gain additional access points and local lab testing capabilities.

"There is another aspect to this expanded laboratory venture which is exciting," declared Sherif. "Memorial Herman Healthcare System has worked hard at clinical and operational integration. Compared to most IDNs, it is moving swiftly to develop the benefits of clinical integration.

"This integration creates the opportunities to use the laboratory in new ways," he continued. "For example, Memorial, Hermann, and Dynacare each use **Cerner** software. All partners want to exploit this common information system platform to link into physician offices and develop a two-flow of information."

As Osama Sherif's comments indicate, the revamped partnership between MHHS and Dynacare intends to move beyond a standard core lab/satellite lab business model that offers outreach testing. The partners want to use the clinical laboratory as a leverage point to support the more global needs of Memorial Hermann's integrated health network.

Nimble Competitor

This makes the future in Houston quite interesting. The remaining two blood brothers will have a nimble competitor to deal with. This new partnership has a good network of access points, lab infrastructure, and physician-hospital relationships. Its sales force has already proven that it can capture new testing business.

These market dynamics in Houston demonstrate that competition is alive and well, but there must be a rational business plan if hospital lab/commercial labs are to succeed. TDR

Contact Osama Sherif at 416-322-2318 and Bill Pesci at 713-704-1708.

Joint Venture Projects Average Five-Year Life

"I've been almost continuously involved in hospital lab/commercial lab joint ventures since 1985," stated Bill Pesci, Chief Operating Officer at Dynacare Hermann Labs.

"Whether at International Clinical Laboratories (ICL), Smith-Kline Beecham Clinical Labs, or Dynacare, it's been my experience these joint ventures have about a five-year life," Pesci observed. "Somewhere around the five-year point, the hospitals seem to want to either end the partnership or recast it in a fundamentally different way.

"The merger between Memorial and Hermann fell right into that pattern," he concluded. "The merger created an obvious need to evaluate and redefine this particular laboratory partnership."

Revamped Houston JV Validates Industry Trend

Hospital systems becoming more willing to participate in laboratory joint ventures

CEO SUMMARY: Change is notoriously slow in both the hospital and the clinical laboratory industry. The announcement of a revamped laboratory joint venture between Houston's Memorial Hermann Healthcare System and Dynacare demonstrates that market pressures continue to encourage the rationalization of laboratory services. It doesn't hurt that this joint venture also expects to post healthy profits.

IT IS SIGNIFICANT THAT the laboratory joint venture between **Hermann Hospital** and **Dynacare, Inc.** was revamped and continued by **Memorial Hermann Healthcare System**.

Hospital administrators traditionally have been hesitant to cede control over their clinical laboratory operations to an outside partner. This is why the commercial laboratory industry has only created a handful of these hospital lab/commercial lab joint ventures.

But deteriorating economics in the hospital industry will soon change this fact. THE DARK REPORT predicts that the pace at which new hospital/commercial lab joint ventures are announced will increase during the next 12 months.

What will surprise many observers, however, is that most of these announcements will not involve the two blood brothers, **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. Instead, most of these agreements will be with the two Canadian laboratory companies, Dynacare, Inc. and **MDS Laboratory Services.** The reason is that Dynacare and MDS offer hospital laboratories a different value proposition than Quest and LabCorp.

These two labs also do not have the emotional baggage that is a legacy of the commercial lab industry's past 15 years of mergers and acquisitions, which caused so many service breakdowns for their hospital laboratory customers.

Market Validation

Because the new deal between MHHS and Dynacare represents a market validation of the concept of laboratory regionalization, it is important to look at what motivated MHHS administrators to expand and continue the joint laboratory venture.

This decision was based on two primary factors. The first was the operating track record of the original **Dynacare-Hermann Laboratories** enterprise. During a four-year period, it delivered measurable results in terms of profit distributions, enhancements to lab services, and operational efficiency. That meant MHHS administrators were looking at a known quantity. It reduced the risk of the proposed new joint venture.

Second, both MHHS and Dynacare looked at the market potential of continuing into the future. Both parties recognized the opportunity to reap considerable profits, particularly given the experience of the past four years.

THE DARK REPORT believes that five worthwhile benefits were achieved by the original Dynacare Hermann Laboratories joint venture. These same benefits are attainable by any other hospital system that is open-minded enough to pursue them.

BENEFIT #1

Outreach testing generates net profits to the participating hospital partners.

No matter how many times THE DARK REPORT highlights similar success stories, hospital administrators seem to deny this indisputable fact. At a time when reimbursement for hospital services is declining, surely any worthwhile flow of real profits from laboratory outreach sources is worth pursuing.

BENEFIT #2

Increased specimen volume from outreach testing lowers the average cost per test for hospital inpatient lab tests.

This is another indisputable fact. Shrewd hospitals used this tool to consistently lower their laboratory costs over a multi-year basis. It also provides the added benefit of employment stability for loyal lab employees.

BENEFIT #3

Increased specimen volumes from outreach testing allows the lab to expand the in-house test menu and improve turnaround times for test results.

Impact of these two benefits upon the hospital are undeniable. Enhanced test menus and faster turnaround times contribute to reduced hospital costs. It improves inpatient care and contributing to faster patient discharges. These lab enhancements also improve doctor satisfaction with hospital services, which is also a desirable outcome.

BENEFIT #4

Having multiple laboratory partners in a joint venture permits the development of a core lab.

The more laboratory sites available for combining test volumes, the greater the resulting benefits for all participating laboratories. It provides the opportunity to reduce redundant lab resources and eliminate excess laboratory capacity while generating economics of scale from the expanded core laboratory.

BENEFIT #5

An effective outreach laboratory test program finances computer links between the hospital and physician offices.

This computer link can funnel other clinical data between hospital and physician. It further reinforces the service bond between hospital and physician. Case studies presented in THE DARK REPORT and at the *Executive War College* demonstrate how powerful this feature can be improving physician-hospital relationships.

Pathologists Also Win

It should be further noted that pathologists can also be winners in these hospital lab/commercial lab joint ventures. Whether pathologists are given an equity position or not, the pathology practice will generally see an increase in specimens and case referrals as the joint venture's sales force develops new client accounts.

This was precisely what pathologists associated with the Dynacare-Hermann Laboratory venture experienced. The increased volume and associated revenues helped offset general declines in pathology reimbursement and other sources of revenue erosion.

Thus, the expanded Houston joint venture is a reminder that good business opportunities still exist for perceptive hospital administrators. **TDR**

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FDA Wants Abbott Labs To Toe Regulatory Line

Diagnostics giant faces consent decree as regulators adopt "get tough" stance

CEO SUMMARY: In the short term, it's Abbott Laboratories which must deal with increasingly aggressive FDA regulators. But the real story behind the story is that the FDA is stepping up regulatory oversight of the entire diagnostics industry. Abbott faces serious consequences if it cannot resolve its disagreement with government regulators about quality issues in manufacturing reagents for its diagnostic instruments.

ON SEPTEMBER 28, **Abbott Laboratories, Inc.** disclosed that it had received notification by the **Food and Drug Administration** (FDA) of alleged noncompliance with FDA Quality System Regulations.

Potentially, the FDA's action could lead to a complaint for injunctive relief which would include "the cessation of manufacturing and sale for a period of time of a number of diagnostic products." Effectively, the FDA would seek to put Abbott out of the reagent business until it agreed to government terms.

Negotiations Continue

For its part, Abbott Laboratories continues to negotiate with the FDA. This process would probably lead to a consent decree, where the company would agree to fix problems without admitting any wrongdoing.

The alleged violations apparently involve the company's diagnostics division manufacturing plant in Lake County, Illinois. This plant produces as much as $1.5 billion per year of reagents and test kits used in Abbott's diagnostic instruments, including its TDx, TDx FLx, IMx, and AxSym products.

The FDA inspected this manufacturing plant during the fall of 1998. The inspection led to a warning letter, dated March 17, 1999, in which FDA inspectors cited problems with how Abbott monitored the quality of certain products, including reagents.

Further, the March 17 letter, which was made public through the FDA's Freedom of Information Act Office, also raised issues with Abbott's handling of software defects with its AxSym instruments.

The FDA letter states that the company knew about glitches with AxSym's software that might lead to incorrect test results for ten months before notifying customers of this situation. FDA inspectors also noted that Abbott retained no records supporting its decision to delay informing customers about this situation.

Abbott Laboratories finds itself in a no-win situation. Over the last year, it has apparently failed to show the

degree of responsiveness and cooperation sought by FDA regulators. Even if the FDA's allegations prove to have no merit, Abbott's actions now make it a high-profile target for regulators.

It means the company will now spend tens of millions of dollars over several years to regain a favorable standing with the FDA. This is capital and management time which could have been better invested in developing new technology for the laboratory marketplace.

More Aggressive Stance

Moreover, clients of THE DARK REPORT should know that we consider the FDA's enforcement actions against Abbott Laboratories as confirmation that the agency is taking a more aggressive stance in regulating the entire diagnostics industry.

On the day before the news broke about Abbott's troubles with the FDA, THE DARK REPORT was meeting with the CEO of another billion-dollar diagnostics giant. This CEO revealed that, only a year or so earlier, his company's manufacturing processes had come under similar FDA scrutiny.

They were slow to respond to FDA concerns, which caused regulators to escalate their warnings. As a result of that "near miss," this diagnostics vendor is spending $60 million over a three-year period to fully meet all FDA good manufacturing requirements.

Revamping Procedures

This means bringing documentation of its quality processes up-to-date, revamping audit procedures, and working with FDA inspectors to insure that its overall operations are in full compliance with FDA requirements.

THE DARK REPORT will not be surprised if, over the next 12 months, any major diagnostics company finds itself in the public eye as a result of FDA action. Clearly the enforcers are more aggressive. They want the diagnostics industry to pay more attention. This compliance effort can be seen as parallel trend with that of clinical laboratory compliance by HCFA and the OIG.

Ultimately, this will probably result in increased costs to the diagnostics vendors. It will make it more difficult for them to reduce product prices to their clinical laboratory customers.

Just as importantly, Abbott's current problems with FDA regulators provide a timely reminder that good relations with government enforcers is good business practice. **TDR**

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Abbott Laboratories, Inc.

At-A-Glance

Headquarters:	Lake Forest, IL
Founded:	1900
# of FTEs:	56,000
1998 Revenues:	$12.6 billion
1998 Net Earnings	$2.3 billion
NYSE Symbol:	ABT

Chairman of the Board & CEO:
Miles D. White

President & COO:
Robert L. Parkinson, Jr.

Product Lines:
Pharmaceutical Products
Diagnostic Products
Hospital Products
International Products
Chemical/Agricultural Products

Notes:
Abbott's diagnostics division had revenues of $2.79 billion in 1998. This represents about 22% of Abbott's total sales.

Pap Smear Marketplace Shifting into High Gear

Cytyc and TriPath prepare for combat as only survivors in the Pap smear wars

***CEO SUMMARY:** It took just four years to shake out the weakest competitors in the emerging field of automated cytology. Now only TriPath Imaging, Inc. and Cytyc Corporation remain in competition. Indications are that this will be a nasty battle. Pathologists and lab executives contemplating the purchase of either company's Pap smear products can expect the sales process to be intense.*

EXPECT THE NEXT PHASE of the Pap smear wars to be a battle royale between **Cytyc Corporation** and **TriPath Imaging, Inc.** of Burlington, North Carolina.

TriPath Imaging is the new name of the just-merged **AutoCyte, Inc.** and **NeoPath, Inc.**, finalized on September 30, 1999. *(See TDR, July 19, 1999.)* TriPath Imaging promises to be a tough competitor for Cytyc.

THE DARK REPORT has several reasons to predict that there will be nasty competition between Cytyc and TriPath. For better or worse, it will be laboratory administrators and pathologists who find themselves caught in the middle of this marketing war, because they make the buying decisions.

Marketing War

The first sign that it will be a no-holds-barred marketing war was Cytyc's decision to file a patent infringement lawsuit against AutoCyte on September 13. Cytyc Corporation claims that AutoCyte's CytoRich® preservative fluid infringes its patent for PreservCyt®.

A variety of sources tell THE DARK REPORT that the lawsuit seems to lack enough substance to prevail, and the timing of its filing coincided with proxy communications issued to Neopath stockholders prior to their vote to approve the merger with AutoCyte.

Patent Infringement Suit

It should be pointed out that the last automated cytology company to file a patent infringement lawsuit later found itself in bankruptcy. That was **Neuromedical Systems, Inc.**, maker of the PapNet system. It sued NeoPath for patent infringement in July 1996. That suit went nowhere, as did Neuromedical, which filed for bankruptcy in February of this year.

Both Cytyc and TriPath start the next round of battles with some interesting customer alignments. Recent events create the opportunity for these alignments to shift.

For example, **Quest Diagnostics Incorporated** has shown its preference for Cytyc's ThinPrep even as **SmithKline Beecham Clinical Laboratories** (SBCL) was adopting

TriPath's (NeoPath's) AutoPap® System for primary Pap smear screening. These decisions were made before TriPath's (AutoCyte's) automated monolayer PREP® System got FDA approval to hit the market.

Now that Quest has bought SBCL, it can be considered open season for Cytyc and TriPath to try and dislodge the other's products from the combined Quest laboratory company.

Another interesting aspect to this impending marketing struggle is the recent announcement that the **Johns Hopkins Outpatient Center Clinics** will use TriPath's PREP System for cervical cancer screening.

Alert readers will recall that Quest Diagnostics (which prefers ThinPrep), has a strategic alliance with Johns Hopkins (where the outpatient clinics will use PREP). So here is another clinical decision point that will require different medical directorships to sort out their preferences for competing cytology products

Combined Pap System

For laboratory executives and pathologists, this cytology marketing battle becomes even more fascinating to watch because TriPath is working to deliver a combined system which will automate Pap smear preparation with monolayer technology, then do an automated screen.

TriPath believes it can offer this combined automated prep/screen system at a price per Pap smear which is under the $9.75 retail price per ThinPrep offered by Cytyc. If this occurs, TriPath Imaging offers the clinical laboratory industry a value proposition which up to now has been unavailable in the marketplace.

Because THE DARK REPORT expects the marketing wars between Cytyc and TriPath to be intense on the upside, and possibly nasty on the downside, we recommend that potential buyers of these cytology systems do rigorous analysis of both the clinical and economic performance of these systems. It seems a sure bet that lots of sales horse puckey will be slung at potential buyers during the next 12 months! TDR

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Was Aetna's Decision Actually Meaningful?

MANY LABORATORIANS CONSIDERED it big news when **Aetna/U.S. Healthcare** announced last month that it would reimburse for both monolayer Pap smear technology (ThinPrep and PREP) and automated Pap smear screening (AutoPap), *(See TDR, September 20, 1999.)*

However, this may not be a major benefit. Laboratorians and even Wall Street financial analysts have overlooked one fact about Aetna's decision. Since Aetna has a very restricted panel of laboratory providers, it probably doesn't expect to see a lot of Pap smear tests that involve monolayer preparation or automated screening.

For one thing, SmithKline Beecham Clinical Laboratories (SBCL) is the sole source lab provider for Aetna/U.S. Healthcare in nine key states, and SBCL is not big on ThinPrep. Of course, now Quest holds that Aetna contract, but Quest is certainly bound by the existing terms–and pricing–of that contract. Plus, Quest will continue to provide testing to Aetna using the SBCL lab infrastructure for some time into the future.

Thus, the fact that Aetna/U.S. Healthcare has a restricted panel of laboratory providers means that its decision to reimburse for these cytology procedures gives it a good public relations boost with physicians, patients, and employers. But the reality of its lab testing contracts means it probably doesn't expect many of these tests to actually be submitted for reimbursement.

Lab Industry Briefs

UROCOR INKS PACT TO MATCH DIAGNOSTICS WITH THERAPEUTICS

HERE'S A PIONEERING EFFORT to more closely link diagnostics and therapeutics into a single product package.

UroCor, Inc. and **Mallinckrodt, Inc.** signed an agreement that allows Mallinckrodt to sell and distribute UroCor's new radiation treatment for prostate cancer.

UroCor's product, ProstaSeed I-125, is a radioactive pellet used in brachytherapy. This is a clinical procedure which uses ultrasound guidance to place the pellets in the patient's prostate to fight cancer. For early stage prostate cancer patients, this can preclude removal of the organ, which often leads to problems of impotence and incontinence.

With more than 200,000 prostate cancer cases diagnosed annually in the United States, UroCor believes that about 60% are potentially treatable by brachytherapy. Seeds for a single procedure cost about $4,000. The potential market in the U.S. for such seed implants is $150 million.

UroCor's strategic plan is to combine its specialized expertise in prostate cancer to differentiate its radiation seeds and work with Mallinckrodt's access to the hospital market. UroCor's primary business focus is to provide diagnostic, prognostic, and therapeutic services to urologists.

UroCor will put a dedicated sales force in the field to sell its diagnostic and therapeutic services to radiation oncologists and medical physicists. Mallinckrodt will stock the ProstaSeed I-125 in its 35 nuclear medicine pharmacies, along with 80 independent pharmacies. Mallinckrodt will also provide direct sales and will include UroCor's product in its hospital group purchasing agreements.

Mallinckrodt must meet minimum annual purchase levels. Sales revenues will be divided among the two companies according to an agreed-upon formula.

This relationship bears watching. UroCor's revenues have come primarily from offering diagnostic testing services to urologists. *(See TDR, June 23, 1997.)* But the company has always wanted to provide these same urologists with therapeutics.

This strategy has begun unfolding during the last year. UroCor beefed up the number of sales people and has begun to offer certain pharmaceutical products to its urologist customers.

UroCor's success in marrying diagnostic services with therapeutics will demonstrate the feasibility of this business strategy for other clinical labs that offer disease-specific testing services.

UNILAB MOVES A STEP CLOSER TO BUYOUT BY KELSO & COMPANY

CALIFORNIA'S DOMINANT COMMERCIAL laboratory placed $155 million in private notes in September. **Unilab Corporation** is refinancing existing obligations in preparation for its sale to **Kelso & Company**, the leverage buyout specialists. *(See TDR, June 7, 1999.)*

The transaction was a private placement. Apparently CEO David Weavil and rumored CEO-to-be Bob Whalen

toured the country together to do the financial dog and pony show for potential investors. The refinancing is a necessary step prior to Kelso's purchase of Unilab's outstanding stock. Kelso will pay approximately $420 million in cash and notes to acquire Unilab.

Commercial laboratory owners consider this a high price, since Unilab's annual revenues are in the range of $300 million. Because Unilab already has a big chunk of the California laboratory market, Kelso's strategy to grow the company after the acquisition will be watched with interest.

AMERIPATH ACQUIRES MORE PATHOLOGY GROUPS

MORE ACQUISITIONS WERE ANNOUNCED by **AmeriPath, Inc.** in September. The pathology-based physician practice management (PPM) company expanded its footholds in Wisconsin and Texas.

It acquired **Associated Laboratory Physician Services** of Wauwatosa, Wisconsin. This 18-physician practice serves the five hospitals of Milwaukee's **Covenant Healthcare System**.

Winston N. Hollister, M.D. will be Managing Director of that AmeriPath business unit. He's familiar to many pathologists as a recent past President of the **American Pathology Foundation**.

In Dallas, **Pathology Associates of Texas** has become an AmeriPath practice. This nine-physician group serves the two hospitals of the **Harris Methodist Healthcare System**. It also provides outreach services to several reference labs, including **Quest Diagnostics Incorporated**.

MEDPARTNERS IS DEAD! LONG LIVE CAREMARK Rx!

WHILE WE ARE ON THE SUBJECT of physician practice management companies, remember the PPM-behemoth known as **MedPartners, Inc.**?

The collapse of this $6.5 billion dollar giant caused the entire PPM industry to lose favor with Wall Street investors. It's failure in California has left doctors holding $100 million in unpaid claims and hospitals holding another $200 million in unpaid claims. *(See TDR, November 30, 1998.)*

MedPartners recently announced that only 12 physician practices remain to be sold before it has totally exited the PPM business. To sever its past connections with its financial debacle as a PPM, MedPartners is assuming a new name.

It will now be known as **Caremark Rx, Inc.**, and its major business service will be prescription benefit management. Once the New York Stock Exchange approves these arrangements, Caremark Rx will get a new trading symbol to replace the MDM it currently uses.

EPITOPE GETS NIH GRANT TO DEVELOP SALIVA-BASED SYPHILIS TEST

HOPING TO BROADEN THE USE of its patented oral fluid testing technology, **Epitope, Inc.** has obtained a $1.1 million Small Business Innovation Research Grant (SBIRG) from the **National Institutes of Health** (NIH).

The grant will fund development of a syphilis test using either blood or oral fluid samples. When successful, this saliva-based assay could affect testing volumes at clinical laboratories.

Currently there are 36 million syphilis tests done annually in the United States. That number is expected to increase as the **Centers for Disease Control and Prevention** (CDC) launches a nationwide program for the elimination of syphilis later this month.

Epitope wants to position itself in this market segment with its OraSure technology. Epitope's HIV-1 test is already used in many AIDS clinics. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's a hats-off to **Ortho-Clinical Diagnostics** (OCD). At a time when everything in the healthcare system seems to be taking things away from clinical laboratories, OCD has organized a worthwhile laboratory management best practices day for its most loyal customers. Started four years ago, this unique event is championed and nurtured by James Ellis, OCD's Director of Laboratory Consulting. Its quality and impact grows with each year, and that's reflected in the growing numbers of attendees who represent lab adminstrators from the leading hospitals and IDNs around the United States.

ADD TO...OCD

This year's event, held September 28-29 in Dallas, provided a fascinating look at the new President of Ortho-Clinical Diagnostics. Catherine Burzik gave a no-nonsense presentation about practical management techniques for getting results fast. She inspired the lab administrators in attendance with her "BAT" meetings—Business Action Teams are fast, short-lived, action-oriented teams organized to swiftly resolve a particular business issue. They meet weekly at 7 a.m., and include all personnel relevant to the issue at hand. Since the President (Ms. Burzik) chairs each meeting, action items get an immediate blessing for implementation. That's certainly one way to insure that things get done quickly!

AETNA GETTING INDIGESTION FROM ITS AQUISITION OF PRUDENTIAL

When **Aetna, Inc.** paid $1 billion for **Prudential Healthcare** earlier this year, it got a lot more problems than it bargained for. Aetna now acknowledges that losses from the Prudential business unit will be around $200 million for the year. This is twice the original estimated loss. Further, expectations are that the Prudential business will be lucky to hit break-even in 2000. With the addition of Prudential Healthcare, Aetna now insures about 10% of the American population. It has contracts with more than 400,000 of the nation's 600,000 physicians.

NEW SOLUTION FOR COLLECTING LAB FEES

Here's a possible solution for labs frustrated at the no-pay habits of patients. Reuters New Service reports that an Iranian hospital has set up a cell to detain patients who are unable to pay their medical bills. Sina, a state-run hospital in Tehran, created a cell in its orthopedic unit, with three guards. "To make sure patients will fulfill their financial obligations, we began detaining patients who fail to pay several months ago," said an unamed director of the hospital. The news report also said that the hospital had been forced to readmit two inmates for treatment because of injuries they suffered while attempting to escape!

Pathology Service Associates, LLC, (PSA) the national organization of state pathology networks, announced the appointment of Edward W. Catalano, M.D. as Co-Chairman. His home practice is **Richland Pathology** in Columbia, South Carolina. As Co-Chairman, he'll share duties with Louis D. Wright, Jr., M.D., PSA's other PSA Co-Chairman.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, November 1, 1999

UPCOMING...

- ***Expanded Regional Laboratory Network Hits Florida Marketplace.***
- ***Final Installment of the Ten Management Myths That Led the Clinical Lab Industry Astray***
- ***News From the Quest/SBCL Merger: A First Look at Post-Acquisition Strategies.***