Volume IX, Number 11 Monday, August 5, 2002

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Attack on Clinical Path Professional Payments

MANY PATHOLOGISTS WITH AN ECONOMIC INTEREST in clinical pathology professional component reimbursement have yet to fully appreciate the impact of an unfavorable decision rendered by a Florida appeals court recently.

As you will read on page 5, an insurance company in Florida was actively sending letters to its patients and instructing them not to pay for clinical pathology professional services performed on lab tests ordered on their behalf. The **Florida Society of Pathologists** and two pathology group practices filed suit against the insurer, **Central States**, and won a court injunction requiring them to cease this activity in the summer of 2001. Central States appealed and, on July 12, the Fifth Court of Appeal issued a ruling which, according to plaintiff's counsel, seems to set certain requirements that a pathologist must follow to be paid for clinical pathology professional services.

For pathologists practicing in Florida, this ruling affects the way they bill for such services. It appears that judges, with little true understanding about clinical practices and long-standing reimbursement customs, have tried to fashion a solution which will please no one. From this point forward, there will be lots of frustration as payers, pathologists, and patients try to transact business under the ruling issued by the appeals court. Certainly those pathologists in Florida who bill for clinical pathology professional services will need to respond to this ruling and insure that their billing activities confirm to the appeals court's decision.

But I believe the Florida situation represents something greater. This appeals court ruling, assuming it is not reviewed and overturned by the state Supreme Court, establishes a precedent that supports the continued erosion of payment for clinical pathology professional services, both in Florida and throughout the nation. This is a disturbing development for those pathologists committed to excellence in the testing done by clinical laboratories. These are valuable clinical services and deserve appropriate reimbursement.

It might be time for clinical pathologists to use legislative solutions at the state and federal level to address the issue of fair compensation for clinical pathology services. That would be one way to counteract the short-sighted attitudes of private and government payers, who are willing to break apart the healthcare system in their attempt to squeeze out costs. TDR

Lab Testing to Boom During This Decade

Clinical labs, pathology groups, & diagnostic manufacturers poised for plenty of growth

CEO SUMMARY: Several recent acquisitions of lab test technology by billion-dollar diagnostics manufacturers reinforce a new reality in the healthcare marketplace: developing new diagnostic tests is faster, cheaper, and more profitable than developing new pharmaceutical products. This simple economic fact is driving an amazing expansion in the number of companies developing new lab test technology.

IT IS WIDELY-RECOGNIZED throughout the lab industry and pathology profession that research into the human genome will trigger a growing number of new diagnostic assays.

But less recognized within the lab industry is the comparative economic advantage that new diagnostic technology is gaining over new pharmaceutical technology. Simply stated, it is becoming cheaper, faster, and easier to develop new diagnostic assays and introduce them into clinical usage than it is to develop and market new prescription drugs.

For hospital laboratory administrators and pathologists, this developing marketplace dynamic warrants attention. The clear and speedy benefits that accrue from developing geneomic and proteomic discoveries into diagnostic assays is already a fact. A host of new and unknown companies are developing diagnostic assays and planning to introduce them into the clinical marketplace.

The compelling economics in favor of diagnostics over pharmaceuticals is best illustrated by the example offered by Jorge Leon, M.D., Ph.D. at the recent CLMA annual meeting in New Orleans. Dr. Leon is the Chief Genetic Officer at **Quest Diagnostics Incorporated**. During his presentation titled *The Post-Genomics Revolution: What's In It For The Lab Industry*, he noted that, on average, "it now takes between eight to ten years and one-half billion dollars to develop a new drug and bring it to market."

"In contrast," continued Dr. Leon, "a new diagnostic assay can be devel-

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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.)**

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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).

oped in 24 to 36 months for around $30-$40 million. Within a short time after market introduction, this new assay can generate as much as $70-$100 million in annual sales. At that sales level, these new assays are considered blockbuster successes."

Pharma Versus Diagnostics

THE DARK REPORT observes that this simple economic fact will alter the long-standing relationship that has existed between diagnostics and pharmaceuticals. Through most of the last century, the size, variety, and economic clout of the pharmaceutical industry was second to none in the healthcare marketplace.

But the regulatory and political climate is turning against the pharmaceutical industry. As investors and entrepreneurial scientists recognize that diagnostic lab tests can be developed at much less cost—and generate profits within a couple of years—then growing amounts of money will be shifted away from pharmaceutical research and development and into clinical diagnostics.

The earliest signs of this market evolution are already visible. On the pages of THE DARK REPORT, the relevance of new diagnostic players such as **Myriad Diagnostics**, **Exact Sciences**, and **Visible Genetics** has been presented. But for every company like these three, there are five or ten more with credible diagnostic technology working to get their products through the regulatory approval process and into the clinical marketplace.

Pharma Firms' Investments

More signs of the increased attention that diagnostics is getting are recent acquisitions of diagnostic technology by **Roche Holdings, Inc.** and **Bayer Corporation**. In the case of Roche, it purchased a portfolio of HPV patents from **Institute Pasteur**. Just 14 days ago, Bayer's diagnostics division announced its acquisition of **Visible Genetics, Inc.**, manufacturer of the TRUEGENE™ HIV-1 Genotyping Assay. As part of the acquisition, Bayer also gets hepatitis assays which Visible Genetics is developing. *(See sidebar on page 4.)*

Both Bayer and Roche are important pharmaceutical companies. But the improving economics of diagnostics motivated them to invest in acquiring relevant technology for their diagnostic divisions.

For strategic reasons, lab directors and pathologists should understand that the more attractive economics of diagnostic test development compared to new drug development will tug the laboratory industry into some new directions. As growing numbers of new diagnostic vendors enter the marketplace, the traditional distribution channel for new lab test technology will be altered in fundamental ways.

Pipeline Of New Assays

In the near future, possibly as soon as 24 to 36 months, laboratory professionals will find themselves confronted with a remarkably large number of new assays, assuming that the FDA approval process functions in an orderly manner.

These new vendors and their new diagnostic assays will trigger some interesting changes. THE DARK REPORT can identify at least four significant ways that both clinical laboratories and pathology group practices will be impacted:

- First, laboratory professionals will need to stay abreast of new diagnostic assays as they gain FDA approval. Home brew assays will also expand in number and clinical application.
- Second, labs will find themselves dealing with multiple new vendors,

since lots of start-up companies are entering the diagnostics field. This will complicate both the buying process and how the lab organizes itself to perform the tests.

- Third, new assays will probably not come through the traditional distribution pipeline, i.e.: in a kit form that labs can purchase and set up whenever clinical demand or volume warrants. In fact, tests may be referred to either the vendor's own lab to be tested, or to specific "licensed" labs which hold an exclusive contract with the vendor to perform such testing.
- Fourth, most of these new diagnostic assays will have a degree of clinical sophistication that requires a greater expertise within the laboratory offering and performing the test. Pathologists will find themselves taking a greater role in helping clinicians order these tests and evaluate the results, thus creating an opportunity for the lab to add value from clinical pathology professional services.

Other Consequences

As the evolving economics make clinical diagnostics more attractive relative to pharmaceuticals, there will be another interesting consequence. Clinical labs and pathology group practices will be the targets of increased sales and marketing attention from this host of new diagnostic companies.

Laboratory professionals remain the essential link between new diagnostic technology and clinicians. For these companies to launch their products successfully, they will need to gain the attention—and the help—of local laboratories. Thus, some of the same type of marketing largess that has traditionally been showered upon physicians by the pharmaceutical companies will undoubtedly soon be directed toward laboratory administrators and pathologists.

Although it may not lead to multiple vendors offering lucky pathologists courtside seats near Jack Nicholson at the Lakers' basketball games, it will certainly expose laboratory decision makers to a more intense level of marketing attention than they have received in past years.

Finally, the "Big Ten" diagnostic vendors which have anchored the lab marketplace for decades will not let upstart companies slice into their market share unopposed. Look for lots of new technology and acquisitions by the entrenched diagnostics companies as part of their competitive response. TDR

Bayer Acquires HIV Genotyping Technology

TO FURTHER BOOST ITS PORTFOLIO of infectious disease testing products, Bayer Diagnostics will acquire Visible Genetics, Inc., maker of the TRUEGENE™ HIV-1 Genotyping Assay.

The acquisition was announced on July 23. Visible Genetics offers the only FDA-approved HIV resistance typing assay in the marketplace. *(See TDR, July 15, 2002.)* Visible Genetics had earlier disclosed that it was seeking a buyer.

In 2001, Visible Genetics lost $40.7 million on sales of $13.6 million. For second quarter 2002, it reported revenues of $4.7 million, an increase of 18% over the same quarter last year. It also reported that sales of its TRUEGENE test were up 77% from last year.

Bayer Diagnostics will pay $61.4 million to acquire Visible Genetics. This is the second major acquisition Bayer has used to build its infectious disease product portfolio. In 1998 it purchased **Chiron Diagnostics**.

Law & The Lab Industry

Florida Appeals Court Strikes Blow To Clinical Path Payment

LEGAL ARGUMENTS SUPPORTING payment for clinical pathology professional services were dealt a blow when Florida's Fifth District Court of Appeal issued an unfavorable ruling on July 12 in Daytona Beach, Florida.

"The import of the court's ruling seems to be that a pathologist in Florida cannot bill a patient for clinical pathology professional services unless the pathologist has: 1) disclosed in advance the nature of these services to the patient; and 2) has obtained, in advance, written agreement from the patient to pay for these services," stated Jack Bierig, Attorney at **Sidley & Austin**, a Chicago-based law firm representing the plaintiffs.

The **Florida Society of Pathologists** and two pathology groups had sued **Central States** to prevent it from communicating to patients that payments by patients for clinical pathology professional services were not appropriate. In August 2001, a Florida lower court ruled in favor of the plaintiffs. The defendants had then appealed this decision.

Reversed The Lower Court

"The District Court of Appeal's ruling did not reflect an understanding of the services that pathologists perform for patients in directing the clinical laboratory," stated Bierig, "At this stage, plaintiffs ask that the District Court of Appeal certify two items.

"First, that its decision conflicts with the prior decision of a Florida court. Second, that it involves a question of great public interest," he explained. "Ultimately, the Florida Society of Pathologists and the two other plaintiffs can ask the state Supreme Court to review the case. The likelihood that it accepts this case would increase if the District Court of Appeals makes either of the two certifications we are requesting."

Pathologists brought suit after Central States began to oppose clinical pathology professional component billing. Its opposition to the long-standing practice included sending letters to patients stating that: 1) such services were "unreasonable"; 2) that such payments were "double billing"; and 3) that no service to the patients was involved.

Path Money Under Attack

As THE DARK REPORT has noted regularly, clinical pathology professional component reimbursement is under attack in a variety of settings across the country. This trend is occurring even as the complexity of laboratory testing is growing, requiring clinicians to interact more frequently and in more depth with clinicians about the tests they order and how to best interpret the results.

Although it too early to judge the impact of this negative appeals court ruling, pathologists throughout the United States should pay close attention to this legal battle and lend their support. All trends in today's healthcare system are consistent with a more intense role for clinical pathology professional services. The pathology profession should not lose its legal right to be paid for such services. TDR

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Dade Behring Primed To Become Public Firm

Once-beleagured diagnostics giant initiates comprehensive financial restructuring plan

***CEO SUMMARY:** Dade Behring is executing an ambitious plan to restructure its finances and become a public company. To reduce its debt burden, Dade's three owners are giving up their stock. Banks and bondholders will swap a portion of their debt for shares of stock in Dade. Once the financial restructure is completed, Dade Behring intends to expand the menu of diagnostic products and assays it offers laboratory customers.*

FOLLOWING 20 MONTHS of intense negotiations with banks, bondholders, and shareholders, **Dade Behring Inc.** filed a pre-packaged Chapter 11 Bankruptcy action in Chicago last Thursday.

"This is a very important day for our company," stated Jim Reid-Anderson, President and CEO at Dade Behring. "This step triggers the execution of a comprehensive financial restructuring plan which has the agreement of all stakeholders."

Three Benefits To Dade

"We expect three major benefits from our financial reorganization," he continued. "First, we will emerge with 50% less debt. Second, this court filing preserves our ability to utilize substantial tax benefits. Third, by using a Chapter 11 filing, it enables Dade Behring to become a public company."

The laboratory industry has long heard rumors about the financial difficulties at Dade Behring. This financial restructuring resolves those problems and leaves Dade in a strong financial position. Because the use of bankruptcy is a strategic tool in the restructuring, Dade's sales and service teams visited lab customers to explain the details and replace rumors with facts.

Debt-For-Equity Swap

"The key element is a debt-for-equity swap in which Dade's three corporate owners, **Aventis SA**, **Bain Capital Inc.**, and **Goldman Sachs Co.** give up their equity ownership of Dade Behring," stated John Duffey, Chief Financial Officer at the company. "This equity will then be distributed to banks and bondholders in exchange for a reduction of existing debt by about half."

The story of Dade Behring's creation in 1995 explains the current need to restructure the company's finances. "Dade was literally created by Goldman Sachs and Bain. Starting in 1995, these companies acquired certain diagnostics divisions from **Baxter**, **DuPont**, and Aventis," explained Duffey. "Money to finance these acquisitions came from bank debt and bonds."

Dade's Restructure Eases Debt Burden

TO REDUCE ITS $1.5 BILLION DEBT BURDEN, Dade Behring's financial restructuring plan includes the following elements:

1. Banks and bondholders will trade approximately half their debt (about $750 million) for stock in Dade Behring.
2. Aventis, Goldman Sachs, and Bain Capital will give up their Dade stock.
3. A prepackaged Chapter 11 Bankruptcy action is being used to implement the debt-for-equity swap.
4. Use of the Chapter 11 filing allows Dade to carry over valuable tax benefits.
5. Use of the Chapter 11 filing allows Dade to have publicly tradable stock upon discharge of the bankruptcy
6. Customers and suppliers of Dade will see uninterrupted services and payments because this financial restructuring was agreed to in advance by all parties.

In fact, the creation of Dade Behring was part of the consolidation wave in diagnostics that lab administrators and pathologists saw through most of the 1990s. But, as a company built through acquisitions, Dade Behring was saddled with considerable debt. Against 2001 revenues of $1.2 billion, Dade had to pay $160 million in interest to service its $1.5 billion of debt.

As many laboratorians know, Dade Behring holds a solid share of the market in several diagnostic categories, such as chemistry/immunochemistry, hemostasis, plasma proteins, and microbiology, among others. Worldwide, it has more than 39,000 installed instrument systems.

"Over the past 18 months, we've undergone many changes as a company," noted Duffy. "Jim Reid-Anderson became our new CEO at the end of 2000. We realigned the company's strategy to focus on customer excellence and customer relationship management. We also reduced our work force and pruned costs, generating about $75 million per year in savings.

Recent Revenue Growth

"During these same 18 months, Dade's revenue grew 11% and operating profit moved into the black to over $120 million for the 12-month period ending June 2, 2002," he added. "Overall, our business is dynamic and thriving. But the huge debt burden prevents us from accomplishing more. Our success in the marketplace caused both our shareholders and creditors to recognize a common interest in reducing our overall debt burden."

"Because we've pre-packaged our Chapter 11 filing, we believe it will be discharged in less than 60 days," observed Reid-Anderson. "That's because all the banks, bondholders, and shareholders agreed to its terms in advance and have already voted upon this plan.

"Even as this pre-packaged Chapter 11 action is moving ahead, we are preparing to file registration for our stock," added Reid-Anderson. We will be a public company upon discharge of the Chapter 11 and expect to be a NASDAQ-listed stock by year's end."

Plans For Coming Years

"As part of our planning, Dade Behring has been in close communication with its suppliers and customers to help them understand that all of Dade's services will continue unchanged and unaffected during this financial restructuring," noted Duffey.

For laboratory executives and pathologists, Dade's financial restructure is an early sign of change. Once completed, Dade is planning to become

more aggressive in the marketplace. In particular, it wants to enter the high-volume chemistry instrument segment with a product it calls Epsilon.

In the 24 months following the discharge of Dade's Chapter 11 filing, laboratory customers can expect to see a more energized Dade Behring competing in the marketplace, both in sales efforts and in the launch of new diagnostic products. In fact, between 2001 and 2003, Dade is boosting spending on research and development by 31%.

Its three corporate stockholders—Bain Capital, Goldman Sachs, and Aventis—are losing their equity in order to "wipe out" $800 million of debt.

"In spite of our heavy debt load, Dade Behring has consistently performed well for six consecutive quarters. However, that has not stopped the competition from taking advantage of the situation," remarked Reid-Anderson. "Now we are cutting that debt by more than half, while maintaining full services to customers and suppliers. We are now serving notice to both our customers and our competitors: Dade Behring is financially sound; it is investing substantial amounts of money in research and development; and it is dedicated to improving the products and services it provides to its many laboratory customers throughout the United States and the World."

A "Put Together" Company

The unique fact about Dade Behring lies in its formation back in 1995. Unlike most diagnostic manufacturers, Dade Behring was assembled from divisions divested by corporate parents. It found itself in the unusual position of offering customers an established line of instrument systems and reagents, but having to focus internally on developing a common corporate culture from the business units formerly owned by Baxter, DuPont, and Aventis. The large debt burden, created when its institutional owners bought the pieces that created Dade Behring, never gave its executive team enough cash flow to service the debt and still have enough to invest in future products.

Built Through Consolidation

Lab executives and pathologists should also not overlook a key strategic business observation about Dade Behring and why it needed to do this unusual financial restructuring. THE DARK REPORT has frequently written in the past about the fact that many companies built through consolidation had a difficult time paying back the debt used to fund their acquisitions.

This is certainly the case at Dade Behring. Its three corporate stockholders—Bain Capital, Goldman Sachs, and Aventis—are losing their equity in order to "wipe out" $800 million of debt. For these stockholders, the acquisition strategy did not prove to be a long-term business success. It's another example of a "grow by acquisition" effort that failed for the original owners.

On the other hand, the fundamental business within Dade Behring's component parts was always sound. Now that the company is cutting its onerous debt burden in half, its management team will have the time to concentrate on building the business, and the cash flow necessary to support healthy growth.

Collectively, these business actions should make Dade an even tougher competitor than it has been in recent years. Certainly Dade CEO Jim Reid-Anderson won't allow any competitors to "pick on Dade Behring" any longer. TDR

Contact Jim Reid-Anderson and John Duffey at 847-267-5426.

NEWSMAKER INTERVIEW

"You will see a more tightly focused Specialty Labs. We won't try and do everything, rather we will do what is important for our customers."
—Douglas S. Harrington, M.D.

NEWSMAKER INTERVIEW

Specialty's New CEO Reveals How His Company is Changing

There's a surprising amount of optimism from a company that some were ready to count out

CEO SUMMARY: In recent months, several events roiled the market for hospital send-out testing. Not the least was the public disclosure of state and federal sanctions against Specialty Laboratories. Hospital labs throughout the country found themselves forced to evaluate the situation and develop an effective response. News that Specialty is again compliant with lab regulations introduces new competitive dynamics in the market for hospital send-out testing. To help hospital lab administrators and pathologists understand today's altered competitive landscape, THE DARK REPORT presents this exclusive interview with Douglas S. Harrington, M.D., CEO and Laboratory Director of Specialty Laboratories. He intends to aggressively grow and strengthen Specialty. Because he is armed with a $70 million war chest, Harrington has the financial capability to force a response from competing reference labs. As the comments below demonstrate, Specialty Laboratories is showing a positive face to the laboratory industry.

EDITOR: When you became the new Chief Executive Officer (CEO) of **Specialty Laboratories, Inc.** in April, you found yourself in a high-profile job at a time of high crisis for your company. What was your prior relationship to Specialty and what motivated you to take what many people described at the time as "the toughest job" in the laboratory business?

HARRINGTON: At the time these events unfolded, I had just stepped down as CEO of **Chromavision**, based in Irvine, California. I remain on Chromavision's board of directors. During the past six years, I've served on the board of directors of Specialty Laboratories. Prior to Chromavision, I was a corporate executive at **Nichols Institute** in San Juan Capistrano. So I have deep experience in the reference and esoteric testing marketplace. When Dr. Peter made the decision to resign as Chairman and CEO of Specialty in April, the board offered me the position.

EDITOR: Given the pressures on the company at that time, what caused you to say yes? There's certainly a fair amount of risk in becoming CEO of a lab company which has just been hit with extraordinary regulatory sanctions.

HARRINGTON: I saw that, despite the regulatory problems, Specialty Labs is a fundamentally sound company, although a company in transition. It possessed core strengths in science and medicine, strong customer relations, and one of the country's most sophisticated laboratory IT capabilities. In my view, the regulatory problems could be resolved quickly if Specialty took the appropriate management actions which I believe we did.

EDITOR: Across the country, the April news of sanctions levied against **Specialty Laboratories, Inc.** by state and federal regulators triggered serious concerns by lab administrators in hospitals doing business with Specialty. For many reasons, Specialty could not make public statements about details of the regulatory sanctions, leaving a vacuum of information in the marketplace. In June and July, both the **California Department of Health Services** (DHS) and the **Centers for Medicare and Medicaid Services** (CMS) determined that Specialty is back in compliance with lab regulations. How would you characterize the problems that occurred and what you've done to resolve them?

HARRINGTON: Robert, I was not in the lab during the time these problems were identified. I can best speak about the issues which I've addressed since April 22 when I became CEO and Laboratory Director. The primary issues centered around California licensing requirements for the personnel category of "Clinical Laboratory Scientists" (CLS). These California requirements are stricter than those of most states. Specialty, like many labs, had incorporated laboratory aides to assist in the lab testing process.

EDITOR: What type of corrective action was instituted?

HARRINGTON: We went above and beyond the letter of the law to staff all testing procedures with 100% CLS. Wherever we find a "grey zone" we err on the conservative side. We focused not only on quality improvement but process improvement as well, enhancing our regular QA/QC procedures.

EDITOR: Could you describe this?

HARRINGTON: Our regulatory deficiencies did not involve issues of quality at the laboratory but of personnel. It might seem counter-intuitive to consider that a Ph.D., after rigorous scientific training, and managing high complexity testing in specific ways for years, then crosses a state boundary only to find herself unqualified, from a regulatory perspective, to do that very same type of work. To reflect the specific requirements of California's regulatory code, we instituted a laboratory-wide education program. It has two goals. First, to make people aware of the regulations and why they exist. Second, to teach them to understand our lab's policies and how to conform to those regulations. To accomplish these goals requires both a strong quality program and a process improvement program.

EDITOR: Effectively, then, your revamped "quality and process improvement program" is teaching what I will characterize as "new" work habits to the highly-trained technical staff so they do work in compliance with California's stricter regulatory code.

HARRINGTON: Yes. That's why I am Laboratory Director in addition to my CEO role. The quality and process improvement program director reports directly to me. We are methodically institutionalizing the quality management program.

EDITOR: Does this impact the test protocols used at the bench?

HARRINGTON: That's one key element of our effort. When a test is validated, that becomes the legal procedure to be followed by technical staff at the bench. It is an integral part of our management system now to insure that the procedure used by individuals at the bench matches the legal practice. That's required us to inspect every test protocol in the lab and scrub it to bring it into full regulatory compliance.

EDITOR: That's a daunting job, given the huge number of assays offered by your lab. Could you describe how that is affecting your test menu?

HARRINGTON: This is the reason we took down certain tests and referred them temporarily to other sources. In cooperating with the regulators, we had to immediately concentrate on bringing internal lab processes into compliance with legal requirements. As we implement compliant procedures for specific assays, we are restoring those to our test menu.

EDITOR: What has been the reaction of the state and federal regulators to these efforts?

HARRINGTON: As you know, we announced that Specialty Laboratories is again in full compliance with DHS and CMS, based on their review of our lab's current operations. I'd like to go further and say that my dealings with officials from DHS and CMS were absolutely stellar. The individuals from both agencies were respectful and professional. Where regulations lacked precision, they worked earnestly to provide us with the clarity necessary to achieve compliance. I have only good things to say about my interactions with both groups of people

EDITOR: Doug, that's a revealing and useful explanation of how Specialty restored its regulatory standing. I'd like to next discuss client relationships. Once news of the sanctions affecting Specialty's standing with the Medicare and Medicaid program became public, many hospital labs had concerns about continuing a business relationship with your company. Although it's a sensitive subject, it's one of great interest. Could you candidly discuss the impact the sanctions have had on Specialty?

HARRINGTON: I can make three observations about this. First, we did see a decline in business since April. In our second quarter earnings release, we noted that number of accessions had declined 11% compared to first quarter. We also provided guidance that we expect a 17% reduction in accessions for third quarter compared to first quarter 2002. We attribute these changes to the reductions we made in our test menu as well as certain customers redirecting specimens to other sources.

EDITOR: Can you quantify the impact of each factor?

HARRINGTON: That's something I cannot break out for you. I can say, most emphatically, that the institution that Jim Peter created here generated a lot of customer loyalty. Throughout this episode we believe we have been successful at maintaining this loyalty by communicating constantly and candidly about the issues. I want to also note that, by no means is our sales force demoralized. They are energized and on the street focused on winning back our customers. Helping in this effort is our new Vice President of Sales, Mark Willig, who recently joined us.

EDITOR: And your second observation?

HARRINGTON: I see Specialty Laboratories as a company in transition. We have always been a science-driven company and did an outstanding job in that regard. Specialty has been good at customer service, but I would not put it in the "great" category. Using our core strength in science, we are now working to evolve into a market-driven company.

EDITOR: What will be different about the "market-driven" Specialty Labs?

"As most lab administrators know, organizational stress is often what triggers profound and positive change. Specialty is undergoing this process."

HARRINGTON: We are striving to provide measurable added value and set new industry standards for customer service. To accomplish this, we removed a layer of management to make the company more responsive to customers' needs. In scrubbing our work processes, when we spot an opportunity for improvement, we catalog it. This is generating a prioritized list of improvements that we will implement.

EDITOR: You've got a third observation about the impact that sanctions have had on Specialty Laboratories.

HARRINGTON: Post-sanctions, we have specific operational strategies that will make us a different company in the future.

EDITOR: Please explain.

HARRINGTON: As most lab administrators know, organizational challenges are often what triggers profound and positive change. Specialty is undergoing this process and it may be the silver lining to this compliance matter. As we assessed our company, its strengths and its standing in the laboratory testing marketplace, we also identified specific business strategies that we want to pursue. The key strategies will be science, customer service, and information technologies.

EDITOR: How are you repositioning the company to accommodate these goals?

HARRINGTON: To be a market-driven company, we have to be close to the customer. We must also be responsive to rapidly-changing technology. That's why we flattened our management structure. We intend to better align Specialty's scientific capabilities with the needs of our clients. We see real value in introducing assays likely to have significant and immediate clinical value and application for our clients.

EDITOR: What about the customer service objective?

HARRINGTON: Customer service encompasses a lot of areas in the laboratory. It starts at the point a specimen is drawn from the patient. If any lab makes a mistake, it influences the course of a patient's life. That's why all labs must strive for zero tolerance of mistakes and errors. We are emphasizing the primacy of patient care to our entire staff. Any aspect of our operation that touches a patient or customer is under review for improvement.

EDITOR: What tools are you using to measure improvement in this area?

HARRINGTON: As one would expect, there's a variety of internal metrics that we closely monitor. This is a long-standing practice and we've been exceptionally candid with this quality assessment data, publishing them on an annual basis for the past several years. We're now planning to benchmark ourselves against the industry to ensure we are, at a minimum, performing at parity. Going forward, our goal is to set the standard for service. I know that sounds ambitious

given our recent problems but we are well-prepared, motivated, and off to a good start.

EDITOR: The other strategy you mentioned is information technology.

HARRINGTON: Yes. We consider Specialty Laboratories to be ahead of the marketplace in its effective use of information technology (IT). This is a core competence. For example, we are electronically linked to over 70% of our customers. Because this is a potent core competency and keeps us close to our customers, we will invest more heavily in expansion of our IT capabilities.

EDITOR: All your comments in this interview have a consistently aggressive posture and describe a Specialty Laboratories that intends to compete intensely.

HARRINGTON: That's true. Competitors should understand this fact. I want hospital laboratories to recognize that Specialty Labs is an evolving company. Despite the regulatory issues which placed it in the spotlight, this company has always had high-quality employees and we intend to maintain that. We are basically building on the best and the past. I personally believe that change is good for a company as it matures. Today in our company we are not destroying good things from the past. We are building upon them.

EDITOR: In making those comments, Doug, you demonstrate a willingness to take a different public profile than founder and former CEO James B. Peter, M.D., Ph.D. What key differences in your management style will become noticeable to hospital lab administrators?

HARRINGTON: Robert, you are talking to a guy who likes to get out and pound the pavement with the sales force. I like to visit customers, to listen carefully, and to find out what is good and what is bad. I like to return to mission control and fix it or make it right.

EDITOR: You personally had a high profile at the CLMA annual meeting in New Orleans five weeks ago.

HARRINGTON: That's a sign of our increased aggressiveness in pursuing new customers. We sense a significant opportunity here. We've dealt with a very intense set of issues and emerged relatively unscathed in a rapid period of time. People will see Specialty Laboratories out there promoting itself, focusing on its service improvements, client responsiveness and other advantages. But it is only by executing in areas that meet and exceed our clients' expectations that we can expect to build and maintain strong, long-term relationships. This is our goal.

EDITOR: Getting back to your executive style, the assertive display of Specialty Laboratories at CLMA certainly surprised many people.

"Competitors should understand this fact. I want hospital laboratories to recognize that Specialty Labs is an evolving company."

HARRINGTON: That was intentional. We want the lab industry to clearly understand that we were confident that our regulatory problem would be satisfactorily resolved. We went to New Orleans to demonstrate that this was not a company defeated, but was a company that was ready to "rock and roll." In fact, that's why we chose the House of Blues for our coming out party. We thought a famous rock 'n roll venue was the right metaphor to reinforce that message.

EDITOR: If I ask you how customers responded, I will probably get the safe answer that it was "great."

HARRINGTON: Not true. At CLMA, I spent hours in the booth on the exhibit floor to get face-to-face with clients. I lis-

tened to the good and the bad. I made no excuses and I am listening. Robert, what I have always found valuable is to talk to customers directly because they usually tell you what you are doing right and what you are doing wrong. The feedback was not always "great" at CLMA, but this did not deter me from making sure clients understand that I'm personally available to listen to their concerns and identify areas of improvement.

EDITOR: You've probably gotten an earful from many sources.

HARRINGTON: From the day I assumed my duties, I have either been in front of, or on the phone with, customers. I personally dealt with customer problems. To ensure direct access, I set up a client hotline at extension 636, and I listen to it. I am listening to the customers and I am talking to them.

EDITOR: Doug, your enthusiasm is counter-intuitive, given the impact that state and federal sanctions had on Specialty Laboratories. In the months following the announcement of sanctions, hospital lab administrators had to deal with lots of messy legal issues surrounding licensure, ability to bill Medicare/Medicaid, and the integrity of operations within Specialty. There was the further blow that came when **Quest Diagnostics Incorporated** announced that it would acquire two of your lab's larger customers, **American Medical Laboratories, Inc.** (AML) and **Unilab Inc.**, earlier in the year. This would lead to a loss of specimens at such time that Quest Diagnostics began to direct those specimens to its own reference laboratories.

HARRINGTON: It would certainly be foolish of me to deny the serious problems that have beset Specialty Laboratories this year. No doubt, these have been trying times. But the measure of any individual, and any company, is how they respond to setbacks. To date, I believe Specialty is making a good accounting of itself.

EDITOR: Reference lab competitors report strong flows of new accounts. Along with your decline in accessions, these are specific signs in the market that clients have moved lab testing business away from Specialty. Historically, any lab that has lost significant market share has found it difficult, expensive, and time-consuming to regain that lost business. Why will it be different in your case?

HARRINGTON: I have two answers. First, our largest customers have been very loyal. We've maintained close communications with them and we believe that we have strong relationships that will continue. This stabilizes a significant part of our customer base. Second, as most of your readers know, it takes a number of months for large hospital clients to complete the RFP process and switch to a new primary reference laboratory. That allows us to judge the new business that we will be bringing on during the balance of the year. This type of new account activity provides us evidence that we remain competitive in the marketplace.

EDITOR: Your confidence in Specialty's future certainly is the dominant theme in this interview. However, competition remains brutal in the lab testing marketplace. Specialty will be closely watched to see if it delivers the changes you are promising.

HARRINGTON: That's a challenge I welcome. Within Specialty, dealing with the regulatory sanctions has allowed us to get everyone's attention and make deep, lasting changes that make this a better laboratory company. Competition for hospital reference testing has always been intense and we expect to do well defending our clients and expanding our share of the market . TDR

Contact Douglas S. Harrington, M.D. at 800-421-7110.

Managed Care Watch

Big Premium Increases Drive Higher Profits at Nation's HMOs

EVEN AS EMPLOYERS COMPLAIN about spiraling healthcare costs, the nation's biggest health insurers are enjoying robust profits.

That brings up the interesting question about whether providers, including laboratories, can get better pricing during the next year, since HMOs are again profitable.

Bellwether HMOs To Watch

Good bellwethers for the HMO industry's financial health are **Aetna, Inc.** and **Kaiser Permanente**. Both companies reported robust profits for the second quarter.

Clients of THE DARK REPORT are familiar with the financial woes that have dogged Aetna in recent years. However, those days seem to be ending. Aetna reported its second straight quarter with net operating earnings following a lengthy period of financial losses.

For second quarter, Aetna's operating earnings were $91.3 million. This is a significant increase over its net operating loss of $44.3 million in Q2 2001. Most notable was Aetna's reduction in its medical claims ratio. It was 84.1% in second quarter, compared to 91.3% in second quarter 2001.

Kaiser Permanente's financial performance over the last two years has improved significantly from the sizeable losses it posted at the end of the 1990s. For the first six months of 2002, its net income was $458 million. This was an increase of 54% from the net income of $296 million it earned in the first six months of 2001.

A survey of other big national health insurance companies reveals a similar pattern of profitability. **United Health Group** reported record second quarter net earnings per share. **Humana Inc.** enjoyed a 19% increase in earnings, generated by higher revenues and big boosts in membership.

Experienced laboratorians know that the health insurance industry lives through cycles of mediocre financial performance which leads HMOs to aggressively raise premiums in subsequent years. As these premiums generate high revenues, it makes the insurers profitable again...at least until the next down cycle begins.

For laboratory administrators and pathologists hoping to gain better pricing and terms at managed care contracting time, HMOs' improved profit margins are good news. It gives providers some extra leverage during negotiations at contract renewal time.

Reaction of Big Employers

What remains unknown is the reaction of big employers to the profits posted by health insurers. Although health premium increases in excess of 10% are again predicted for next year, certainly employers will not be happy about paying higher premiums at a time when health insurers are reporting ample profits.

However, if health insurers do succeed in pushing stiff premium increases on employers for 2003, then laboratories should have strong arguments in favor of improved pricing for lab testing services at contract renewal time. TDR

Dark Index

Unfolding Events at Unilab, Specialty Labs and Dynacare

Each laboratory company is dealing with changes in its business operations

RECENT WEEKS BROUGHT important developments to several public lab companies. Each development changes and alters the competitive marketplace for laboratory testing services.

It was big news at **Specialty Laboratories, Inc.** when the troubled lab company signed a Plan of Correction (POC) with the Centers for Medicare and Medicaid Services (CMS), thus lifting sanctions that affected Specialty Laboratories' CLIA-88 license.

Also big news was the continued silence over how the Federal Trade Commission (FTC) is going to rule on the proposed acquisition of **Unilab Inc.** by **Quest Diagnostics Incorporated**. Many Wall Street analysts speculate that the FTC may have reservations about allowing the deal to close as currently structured.

Debt-For-Equity Swap

Notwithstanding its reservations about the Unilab/Quest Diagnostics deal, the FTC took no objection to the acquisition of **Dynacare Inc.** by **Laboratory Corporation of America**. That deal closed on July 25, thereby ending Dynacare's short life as a United States-based public laboratory company.

In the case of Specialty Laboratories, agreement with federal lab regulators was announced on July 18. With this agreement, Specialty Labs is now in full regulatory compliance with both state and federal lab regulators. Under the POCs signed with each agency, Specialty Labs will be subject to certain conditions for the next couple of years. *(See pages 9-14.)*

Specialty Reports Earnings

On July 23, Specialty Laboratories also disclosed its second quarter earnings. Net revenue declined to $34.1 million, compared to $45.2 million for the same quarter 2001. This was a decline of 24%. Specialty Labs had an operating loss of $12.8 million for the quarter.

Accessions declined by 6% compared to second quarter 2001 and by 11% when compared to first quarter 2002. Company executives attribute these declines to a reduction in Specialty's extensive test menu and clients redirecting specimens to competing laboratory companies.

The other development at Specialty Laboratories was the hiring of a new Vice President, Sales. Mark R. Willig was recruited from **Myriad Genetics**, where he had been Vice President of Sales since 1997. Willig also has experience with **Orca Medical Systems** and **Abbott Diagnostics**.

Even as Specialty Labs got good news from federal regulators, Unilab and Quest Diagnostics continued to await the FTC's decision on their proposed merger. The acquisition, announ-

ced April 2, has been in suspense while the FTC conducts an antitrust review.

In the months since the acquisition was announced, the FTC has actively made calls to organizations in California involved in laboratory testing. It is known that the FTC placed calls to: 1) independent commercial laboratory companies in California that compete against Unilab and Quest Diagnostics; 2) independent physicians associations which contract for lab testing services; and 3) hospitals. The FTC is evaluating the impact this proposed merger might have on competition in the nation's largest market for laboratory testing.

One issue of concern is the amount of market share that Quest Diagnostics would control following its acquisition of Unilab. In conversations with Wall Street analysts, Quest Diagnostics and Unilab estimate California's total market for laboratory testing is about $4 billion per year.

Estimate Of Market Share

Assume that 50% of that number is hospital inpatient/outpatient testing. The remainder, about $2 billion, represents tests that originate in physicians' offices. Of that $2 billion, about half, or $1 billion, is done by physician office laboratories (POL). That leaves about $1 billion in testing which physicians' offices refer to commercial laboratories.

Unilab does about $390 million per year of lab testing in California, virtually all of which are tests referred from physicians' offices. In the same market segment, Quest Diagnostics has told Wall Street that it does about $90 million per year in California.

Combine those two businesses, and post-merger Quest Diagnostics would control at least 48% of the market for physicians' office referral testing in the Golden State. On one hand, that is certainly a concentration of market share that would trigger antitrust concerns. On the other hand, the FTC has no track record of opposing the acquisition of one clinical laboratory by another clinical lab company. That is why there is much speculation in the investment community about why the FTC is taking so long to make a determination about this proposed merger.

LabCorp Buys Dynacare

Even as the proposed deal between Unilab and Quest Diagnostics awaits the FTC's decision, LabCorp's purchase of Dyncare is already done. Following the FTC's announcement that it held no objection to the merger, Dynacare obtained shareholder approval and, within days of that action, LabCorp acquired Dynacare.

In acquiring Dynacare, LabCorp gets sizeable laboratory operations in Ontario and Alberta. This adds a new dimension to the management challenges of integrating Dynacare into the LabCorp family. Canada's single-payer health system has significant differences from the United States healthcare model.

As it integrates Dynacare into its existing laboratory infrastructure, LabCorp expects to harvest as much as $45 million in savings during the next 30 months. Since Dynacare's annual revenues are about $300 million, that means LabCorp believes it can squeeze out about 15% of Dynacare's cost structure.

Economies Of Scale

The savings will accrue from two sources. First, considerable savings will come from consolidation and integration of laboratory sites throughout the United States. Second, LabCorp's estimate reflects the lower purchasing costs for reagents and other items that come from LabCorp's buying power with vendors. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Malpractice insurance has become a major concern in a growing number of states. Carriers are withdrawing from some markets and premium increases are significant. Pathologists in Florida tell THE DARK REPORT that they are awaiting quotes for next year, but that insurance brokers have told them to expect premiums to double, from around $15-$17,000 per year per pathologist to over $30,000 per year per pathologist.

LIQUID PREP PAP WARS

Competition in the market for liquid prep Pap smear products continues to be intense. **Cytyc Corporation**, maker of ThinPrep® test, reported revenues of $43.2 million for second quarter, compared to revenues of $53.0 million Q2 2001, a decline of 18%. **TriPath Imaging, Inc.**, maker of SurePath™, had sales of $9.1 million in second quarter, an increase of 55% over the $6.1 million in revenues for same quarter last year.

JCAHO ESTABLISHES SIX PATIENT SAFETY MEASURES

Major American corporations are pressuring healthcare providers to reduce and eliminate medical errors, contributing to better outcomes and lower costs. Laboratorians will see evidence of this pressure in their own hospitals next year. **The Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) is instituting six evidence-based goals for improving patient safety, effective January 1, 2003. Five of these six national patient safety goals correlate with safe practices identified by the **National Quality Forum**. (NQF).

ADD TO: Health Quality

Hospital-based lab directors and pathologists will see further evidence of the move to measure the quality of healthcare services and make rankings of this performance available to consumers. A number of states are instituting surveys to measure patient satisfaction following their hospital stay. Even the **Centers for Medicare and Medicaid Services** (CMS) is getting in the act. It plans to conduct a national patient satisfaction survey and may require, by next year, hospitals to use this survey to rate their own patient satisfaction. The federal **Agency for Healthcare Research and Quality** (AHRQ) is developing the survey. Already the **California Healthcare Federation** has conducted patient satisfaction surveys and posted the results on its Web site *(www.chcf.org)* and is doing a follow-up survey at 157 hospitals.

Here's an interesting peek at some developing point-of-care (POC) diagnostic technology that's not quite ready for humans. **Synbiotics, Inc.**, based in San Diego, California, is now selling veterinarians a 15-minute blood test to check the immunity dogs have to two infectious diseases: canine parvovirus and distemper. It's the first test of its type to be approved by the **U.S Department of Agriculture**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 26, 2002.

THE DARK REPORT

UPCOMING...

- ***Big Push in Hospital Send-out Testing: Blood Brothers are Heading Your Way.***
- ***How Florida Appeal Court Decision Changes Business Practices For Clin Path Professional Component Billing in That State.***
- ***Point-of-Care Diagnostics Company Runs Out of Cash: Why Physicians' Offices DIDN'T Want to Enter the POCT Business.***

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