Volume XI, Number 9 Monday, June 28, 2004

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

Lawyers Attack Charity Hospitals: Labs Beware!

HOSPITAL-BASED LABORATORIES FACE A NEW THREAT—from an unexpected source! On June 17, 2004, a group of lawyers filed federal class action suits against 11 health systems or hospitals in eight states. These lawyers claim the hospitals named are in violation of their charitable or not-for-profit charters because they overcharge uninsured patients and use extreme collection tactics against poor patients.

Lead attorney in the group is Richard Scruggs. That's bad news for the hospital industry. He is the Mississippi attorney credited with engineering the tobacco industry settlement of 1998. In that case, the major tobacco companies agreed to pay $206 billion over 25 years. This money would compensate the money spent by 46 states to treat Medicaid patients for cigarette-related illnesses. I would like to point out that the settlement calls for 300 lawyers from 86 firms to pocket as much as $30 billion during the 25-year pay-out period. Scruggs' law firm, in Pascagoula, Mississippi, will receive $1.4 billion!

Now you know why I think this class action suit against charity hospitals is a threat. These lawyers have an incredibly rich war chest. They can afford to go fish for another whale. That describes the hospital industry. Remember the numbers: healthcare spending represents about 14% of our economy, estimated at about $1.4 trillion last year. The nation's 5,000 hospitals account for about half of that spending, or $700 billion.

So it should be no mystery why Scruggs and his cronies now want to target the nation's hospital industry. A successful class action suit has the potential to generate, with no exaggeration, billions of dollars in lawyers' fees. Most pathologists would agree that aggressive lawyers have destroyed medical malpractice insurance as a viable method of compensating legitimately injured patients and protecting the physicians who treated them in good faith.

It now appears that Scruggs and his gang want to shake down the hospital industry. I believe this will impact hospital laboratories in two ways. First, it will require hospitals named in the lawsuit to divert management time and money into their legal defense. That will squeeze the budgets for clinical services, like laboratories. Second, if these lawyers can win this case, the amount of money hospitals will be forced to pay will definitely squeeze all services. It's another potential blow to the long-term financial stability of hospital-based laboratories. TDR

Esoterix & UnitedHealth Sign National Test Pact

Esoterix earns a place as the third national laboratory for United's Docs

CEO SUMMARY: Just when it is assumed that the two blood brothers have a lock on national lab testing contracts with the nation's biggest payers, Esoterix inks an agreement with UnitedHealth Group. This now positions Esoterix to offer its higher-end reference and esoteric testing to hospitals and physicians providing care to more than 22 million Americans. It also triggers a question: will other payers follow suit?

IN AN UNEXPECTED DEVELOPMENT, **UnitedHealth Group, Inc.**, the nation's largest health insurer, added **Esoterix, Inc.** to its panel of national lab test providers under a contract that became effective June 1, 2004.

The decision to add a third laboratory company is a surprise. In recent years, the two blood brothers have enjoyed a virtual lock on national contracts with this country's largest health insurers. UnitedHealth's willingness to expand its national panel of laboratory test providers can be interpreted to mean it is seeking benefits beyond those currently provided by its existing network of lab test providers.

"This is a major business milestone for us," stated Esoterix President and CEO, James McClintic. "It demonstrates the progress Esoterix has made in recent years to establish itself as a respected source of specialized lab tests nationwide."

UnitedHealth Group currently provides health benefits to 21.7 million people. According to McClintic, UnitedHealth was motivated to add Esoterix to its national lab provider panel for two primary reasons. "One, physicians would have greater choice about where to direct their specimens for laboratory testing. Two, UnitedHealth believes that Esoterix can help it control leakage, particularly in the types of reference and esoteric tests that are our company's primary focus," he explained.

During a site visit by THE DARK REPORT to Esoterix's headquarters in Austin, Texas last week, McClintic

provided detailed information about the company's business strategy and how it played a role in snaring a contract with UnitedHealth.

"The story starts about two years ago," he said. "As hospital labs reacted to regulatory problems at one of the national reference labs, Esoterix decided it was an opportune time to intensify our sales and marketing to hospital labs.

"To service this market, we needed to broaden our existing test menu," continued McClintic. "So we added 500 tests, bringing our total menu up to 2,500 tests. For six months, we responded to plenty of RFPs and we won our share. However, the test mix for many of these RFPs was weighted significantly toward routine tests, which are reimbursed at very low rates.

Reassess Their Strategy

"That caused us to step back and reassess the outcome of this particular business strategy. Esoterix has always been a prime source for high-end, esoteric testing. We wanted to move back and emphasize marketing to hospitals and other customers who are intensive users of these tests," observed McClintic.

"In the market segment for sophisticated reference and esoteric tests, we give nothing away to any laboratory," he said. "That's because even the two blood brothers have to fly most of these types of tests to a selected number of national testing centers. That allows us to compete on quality, service, and turnaround time.

"In support of this re-emphasis on high-end, esoteric testing, Esoterix developed contracting opportunities with GPOs, IPAs, and payers. We found them to be most receptive, for an interesting reason: leakage," he added.

"The most painful leakage to a payer is not routine chemistry and CBCs. It is reference and esoteric tests," noted McClintic. "The reason becomes obvious when you ask physicians about the service they get from their labs. They don't discuss chem screens and CBCs. They talk about reference and esoteric tests. If service is bad, that affects their medical practice. If service is good, physicians consider the added value from that laboratory to be invaluable to helping them improve patient outcomes.

"Out Of Network" Tests

"Thus, there are two primary reasons why a physician will continually send lab tests 'out of network.' One, she is loyal to a certain lab providing specialty tests; or, two, she is angry about ongoing service failures by network labs. She sends tests out of network because she seeks a more reliable source for those lab tests which are 'mission critical' to her medical practice," he stated.

"Esoterix offers payers a way to solve these problems," explained McClintic. "We believe UnitedHealth Group recognized this. Leakage of high-end tests is expensive to any payer. UnitedHealth's national contract gives Esoterix the opportunity to demonstrate that it can give physicians the level of service which motivates them to stay 'in network.' As we achieve that, it's a win for Esoterix and a win for the payer."

Time To Deliver

The newly-signed national contract between Esoterix and UnitedHealth Group is only the first chapter in this story. Esoterix must now prepare to market its services to the thousands of physicians in the UnitedHealth network. That will take time and money. Then it must deliver services equal to or better than its in-network laboratory competitors. That may stimulate an interesting marketing free-for-all, one that will be instructive to watch as it unfolds. TDR

Contact James McClintic at 512-225-1100.

UnitedHealth's Decision Reveals Lab Market Shift

UnitedHealth uses new Esoterix contract to expand doctor choice and control leakage

CEO SUMMARY: News that UnitedHealth Group, Inc. added Esoterix, Inc. to its national laboratory services contract is a big story. UnitedHealth's decision to expand the laboratory panel demonstrates that factors other than lowest price played an important role. The move to supplement its two national labs with a third laboratory option indicates that UnitedHealth's existing lab panel was failing to meet specific expectations.

MANAGED CARE CONTRACTS for laboratory testing services in the 1990s were primarily negotiated on the basis of lowest price and a lab's ability to provide coverage throughout a designated region.

However, the new national lab services contract between **UnitedHealth Group, Inc.** and **Esoterix. Inc.** was negotiated around different objectives. As noted in the lead story on pages 2-3, UnitedHealth has at least two different goals for this pact.

First, by adding Esoterix to the national lab test provider panel, it expands the choices available to its physicians. Second, UnitedHealth expects the Esoterix contract to help reduce leakage.

Goals Can Reveal Problems

Business goals are often intended to resolve business problems. From that perspective, we can reasonably conclude that UnitedHealth is having at least two problems with its existing panel of national lab test providers. One problem must involve physicians' dissatisfaction with the laboratory services offered them (thus the need to expand their laboratory choices).

The second problem must be leakage that results from two sources: 1) physician unhappiness over poor lab service options; and/or, 2) the desire of physicians to refer their reference and esoteric lab tests to academic centers and other non-contract laboratories. These preferences may range from a physician's unique lab service needs to his/her long-standing relationships that often began in medical school.

UnitedHealth's decision to use the Esoterix contract as a way to reduce leakage connotes at least two probable facts. First, the most serious source of lab test leakage within UnitedHealth's national lab contract arrangements must be specialty testing. Esoterix is not a "chem screen/CBC" laboratory. It offers reference and esoteric tests.

By selecting Esoterix as the third national laboratory provider, UnitedHealth indicates it is not as concerned about the leakage of routine tests as it

is about leakage of high-value reference and esoteric tests. Such tests are reimbursed at much higher rates than chemistry panels and CBCs. Effectively, this leakage is much more expensive for UnitedHealth.

Dictating To Physicians

The action to improve physician choice probably means physicians are chafing at what they consider to be arbitrary limits on their ability to direct specimens to the laboratory of their choice. It is a well-demonstrated fact that physicians do not like to be told what to do by payers. It is highly likely that UnitedHealth has heard a significant number of complaints from physicians about the limited options for laboratory testing. Expanding the panel is one way to respond to those complaints.

Moreover, UnitedHealth's expansion of the lab services panel also implies that the laboratory services delivered by the existing two national laboratories fail to meet the expectations of some physicians. If UnitedHealth was fielding a regular barrage of complaints from physicians about lab test service deficiencies, that would certainly be motivation for it to take the unexpected step of adding a third lab provider to its national panel.

Major Business Decision

One interesting question raised by the UnitedHealth/Esoterix contract is this: did general physician dislike of the two blood brothers play a role in UnitedHealth's decision to expand its national laboratory panel?

In many regions of the United States, local lab competitors to the two oligopoly laboratory companies firmly believe that a significant number of physicians in their market harbor an outright distaste for either or both of these two companies. That distaste may date back years, when physicians watched a public lab company come into town, acquire the high-service local laboratory, then consolidate its testing into a faraway regional lab center. These physicians were then forced to endure lots of service breakdowns and other operational changes that displeased them.

Did a combination of this lingering discomfort and a natural inclination to rebel against a payer's limited panel of laboratory options play a significant role in UnitedHealth's assessment of why it needed to expand its lab panel? That question will be answered by whether or not Esoterix rapidly captures testing from UnitedHealth's physicians.

Letting The Market Decide

The market will tell us. If Esoterix executes well and builds a steadily growing share of lab test volume, it will be one reasonable sign that service issues were a problem; or that physicians were waiting for an option that would allow them to switch away from either of the two blood brothers.

One fact should not be overlooked. This is not a casual business decision. UnitedHealth will devote considerable resources in money and management time to implement the decision to add a third laboratory to its national contract. That fact also reinforces the conclusion that physician dissatisfaction and the actual level of leakage, combined, are a significant problem within UnitedHealth Group.

For laboratory administrators and pathologists, the fact the UnitedHealth Group is willing to expand its laboratory provider panel is an important event. It could be an early sign that the dual strategies of economies of scale and a "one stop shop" contract approach preferred by many payers fails to meet the unique laboratory testing needs of physicians in their network. TDR

National AP Firms Target Gastroenterology Groups

In competition against local AP groups, national firms steadily build market share

CEO SUMMARY: ***It's a trend as yet invisible to the radar screens of most pathology groups. A new crop of specialty AP companies is targeting gastroenterology. In the past 36 months, several have posted phenomenal growth in both specimen volume and revenue. The heightened competition for GI biopsies mirrors that seen last decade for urology biopsies. It confirms that national specialty labs are here to stay.***

IT'S A MARKET SHARE BATTLE that's received little recognition within the pathology profession. National anatomic pathology (AP) companies are steadily capturing business from the nation's gastroenterology (GI) clinics.

With this intelligence briefing, THE DARK REPORT is first to recognize this trend and describe its characteristics. In every battle for market share, there are winners and losers. To date, the winners are a handful of specialty AP companies. Collectively, the losers are local pathology group practices. It is their long-time GI clients who are opting to use a national AP laboratory.

As Goes Urology, So Goes GI

The story behind this development is instructive. In many ways, competitive changes now unfolding in the GI biopsy market mirror changes that occurred to the urology biopsy marketplace during the 1990s.

The theme is similar. National AP companies develop an enriched menu of lab tests and customer services to differentiate themselves from local anatomic pathology groups. Specialty physicians, whether urologists or gastroenterologists, are then visited repeatedly by sales reps from the national AP companies. Before long, these physicians decide to switch their business from the local pathology group to the national AP lab.

That decision to switch is made easier by the fact that most local pathology groups are either "asleep at the switch"—oblivious to the impending loss of a client—or because they refuse to invest to match the "better" services offered by the sales reps of the national lab company.

Who are the primary national competitors for gastroenterology business? Certainly **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** (with its **DIANON Systems** subsidiary), are big players. As well, **AmeriPath, Inc.** has a large presence. However, **CBL Path, Inc.**, based in Mamaroneck, New York and Ocala, Florida, and **Pathology Partners, Inc.** of Dallas, Texas are making steady inroads in the gastroenterology market-

place. In San Diego, **Prometheus Laboratories, Inc.** also offers GI testing services nationally.

One attribute shared by all these companies is a willingness to invest substantial resources into a professional sales and marketing campaign. That is how local GI clinics learn that there are other lab testing options besides the local pathology group practice to which they've referred specimens for many years.

More National Competition

National competition for GI biopsy business is following the same path of market evolution in the 1990s that unfolded with urology biopsy business. During that decade, **Urocor, Inc.** and **DIANON Systems, Inc.** were the first national lab companies specifically organized to market anatomic pathology services to office-based urologists.

By 1999, UroCor alone claimed to be doing business with more than 50% of the nation's board-certified urologists. In competing for the biopsy business generated by urologists, it was local pathology groups which lost market share.

In gastroenterology, national AP labs are using another customer benefit to raise the competitive bar.

These national companies differentiated themselves from local pathology groups by offering enhanced services. Remember a past debate within the pathology profession? It centered around whether or not color pictures of the relevant tissue on the pathology report did add value to the referring physician. UroCor and DIANON made millions on that simple feature—and stimulated growing numbers of local pathology groups to add similar photos to their own reports.

That's how the competitive bar is raised. In gastroenterology, national AP labs are using another customer benefit to raise the competitive bar. They differentiate themselves from local pathology groups by offering integrated informatics capability to GI clients.

The market shift to informatics integration is best illustrated by relationships many national AP labs have with a company called **gMED Corporation**, based in Weston, Florida. gMed sells "an advanced electronic medical record and procedure reporting application" to gastroenterology groups.

In less than two years, gMed has signed contracts with a number of AP lab companies and pathology group practices. Among them are: Ameripath (October, 2002), CBLPath (January 2004), Pathology Partners (January 2004), and **Palm Beach Pathology** of Palm Beach, Florida (June 2004).

"To remain competitive in our market, we saw the affiliation with gMed as a necessary step," stated Gary Onofry, Practice Administrator at Palm Beach Pathology. "For GI clinics and endoscopy centers, gMed offers a report writer and a tracking log feature. Gastroenterologists like it because it eliminates dictation and transcription. It also replaces their handwritten case tracking logs with an electronic case tracking capability.

IT Interface With Clients

"By building an interface between our pathology group's software system and gMed, the GI can electronically complete and transmit test requisitions. Our pathology reports transmit electronically into the patient EMR at the GI's office," explained Onofry.

Another major GI information systems is ProVation™ MD, offered by

ProVation Medical Systems, Inc. (formerly **cMore Medical Solutions**), of Minneapolis, Minnesota. But it is gMed which successfully entered into strategic relationshipswith several national AP firms focused on the GI biopsy market.

Reading The Tea Leaves

THE DARK REPORT considers the competitive evolution of the GI biopsy marketplace to be a significant event. During the 1990s, urologists were wooed by the first generation of AP-based national lab companies, including **UroCor, Inc.** and **DIANON Systems, Inc.** *(See sidebar at right.)* These companies forever changed the expectations, and lab testing relationships, for most of the nation's urologists.

The interest of national AP companies in forming strategic alliances with gMed is a good indication that the long-standing status quo between gastroenterologists and local pathology group practices is about to undergo a similar transformation. Several years from now, it will probably take a more complete menu of laboratory tests and enhanced services to win—and keep—the lab testing business of gastroenterologists.

Local Path Groups

For local pathology group practices, this is not a welcome development. They are already beleaguered, under siege on a variety of fronts. Now local pathology groups will have to devote resources and time into protecting their best gastroenterology customers from the national AP companies.

The intensified competition for GI biopsies must also be viewed in a greater context. It is one more sign that the entire healthcare system is increasingly willing to consider a non-local solution to meet its needs. Local pathology groups need to craft a strategy to cope with this change. **TDR**

Contact Gary Onofry at 561-820-0770.

UroCor Pointed the Way To Specialty AP Firms

MOST PEOPLE IN THE PATHOLOGY PROFESSION under-appreciate the strategic business lessons to be learned from **UroCor, Inc.**, the urology-based specialty laboratory company that once operated throughout the 1990s in Oklahoma City, Oklahoma.

It was 1997 when THE DARK REPORT visited UroCor. In the proceeding seven years, UroCor had grown from annual revenues of less than $1 million to $36 million. It had a multi-year ranking on *Inc. Magazine's* "Fastest Growing Companies" list. It billed itself as a "disease management company" focused on urology. But its primary revenues came from anatomic pathology services, supplemented by clinical lab testing.

At the time of THE DARK REPORT'S site visit, UroCor was literally an unknown company within the clinical laboratory industry. That changed following our intelligence briefing on June 23, 1997. We recognized that UroCor was successfully selling anatomic pathology services to one group of office-based physicians: Urologists.

It was our assessment that specialty physicians liked the concept of a national laboratory organized specifically to provide them the full menu of laboratory tests tailored to their practice needs. We used the headline "Future Laboratory Model Found in Oklahoma City" to indicate that this business model was likely to be copied.

Although UroCor was later acquired by **DIANON Systems, Inc.** in 2000 (and DIANON itself acquired by **Laboratory Corporation of America** in 2002), the idea of a national anatomic pathology company organized to serve a single medical specialty caught on. For example, **Prometheus Laboratories, Inc.** in San Diego was formed by some UroCor alumni to target gastroenterology.

NEWSMAKER INTERVIEW

Sysmex Anticipates Major Shifts In Laboratory Testing Market

"Innovating from our core technologies will lead Sysmex into very different areas of laboratory testing."

—John Kershaw

CEO SUMMARY: Sysmex America, Inc. surprised many this year when it hired its own sales and service team and begin distributing its products directly to laboratories in the United States. In this exclusive interview, COO John Kershaw explains why Sysmex moved away from its successful distribution agreement with Roche Diagnostics. He also reveals some surprising new products in the Sysmex R&D pipeline. In this wide-ranging interview, Kershaw discusses the American healthcare system, strategic drivers he believes will reshape the laboratory testing market, and how Sysmex will respond to these threats and opportunities. This interview was conducted by THE DARK REPORT'S Editor-In-Chief, Robert L. Michel

EDITOR: Let's explore three themes during this interview. First is the American healthcare system and your views about how and why it's changing. Second, what strategic drivers will reshape the laboratory testing marketplace during the next couple of years? Third, what new products and services will **Sysmex Corporation** offer in response to these trends?

KERSHAW: That's a good progression. We can start with the macro view, then drill down to very specific topics.

EDITOR: Agreed. Here is the first question. When Sysmex looks at the American healthcare system, what issues and trends does it consider to be most significant?

KERSHAW: We see the increased cost of healthcare as the single most alarming issue. In each of the past four years, there's been a double-digit increase in the cost of healthcare benefits. Many companies have had between 15 to 20% cost increases in their healthcare benefits.

EDITOR: That's a huge cost increase.

KERSHAW: Yes, and it's a cycle which must be broken. But no one has yet demonstrated an ability to control healthcare costs.

EDITOR: What may break this cycle?

KERSHAW: There are two contributing factors which must be resolved. First, we think most of the increased health costs stem from inefficiencies within the system, not from higher rates of utilization. Second, we believe the "profit motives" inherent in our healthcare system significantly contribute to higher costs.

EDITOR: What can affect this?

KERSHAW: Healthcare costs will be most affected by a shift in emphasis to preventative medicine and testing. Acute response medicine costs infinitely more in dollar terms than a good preventative program does.

EDITOR: What about other change agents in the U.S. healthcare system?

KERSHAW: The aging population is one obvious trend. But the United States will differ from other industrialized societies because of high rates of obesity. This is not mirrored by other countries. In tandem, the two trends of aging and obesity will cause a different mix of diseases in the United States. For example, obese elderly individuals will suffer from bone and joint problems not seen in other developed countries.

EDITOR: The combined impact of aging and obesity on the U.S. population has been neither widely recognized nor discussed with much detail.

KERSHAW: That's because this is a new phenomenon and healthcare researchers are seeing new health issues which were unimagined a decade ago.

EDITOR: Please provide some examples.

KERSHAW: Adult onset diabetes is affecting entirely new groups of people here in the United States. In recent years, the incidence of 30- and 40-year olds diagnosed with this disease has increased dramatically. This surprised researchers, with worse news to come. In the last year or so, a disturbing number of juveniles have surfaced with either full-blown Type II diabetes or pre-diabetes symptoms. These developments are so new that policy makers have yet to fully grasp the scope of the problem or how to respond to it.

EDITOR: How does Sysmex expect the healthcare system to respond to such disturbing trends?

KERSHAW: In our healthcare system, change is driven by money. The greatest cost savings and efficiencies will come from preventative treatment and early detection. Sysmex believes that both private and government payers will begin to shift a higher proportion of healthcare funding into prevention and early detection. One dynamic which will support and accelerate this development is the steady increase in the number of technologies which support more accurate diagnosis and therapy.

EDITOR: Are you hinting that a golden age of clinical diagnostics may be approaching?

KERSHAW: That might be a stretch. We expect new diagnostic technologies will contribute incremental improvements in the system. But let's go back to the theme of money as healthcare's change agent. Today, reimbursement emphasis in the U.S. is weighted to reward acute and episodic care. However, that is the most expensive way to treat anyone's health problems.

EDITOR: You are referring to the traditional argument about it being cheaper to treat an individual's high blood pressure than it is to later deal with that patient's acute cardiac event.

KERSHAW: Yes. Personally, I think the examples of Germany and the United Kingdom are instructive. In Germany, the emphasis is shifting to primary care. In the United Kingdom, budget dollars are moving away from hospitals and over to clinics. Both countries recognize the need to emphasize prevention, early detection, and early intervention relative to acute and episodic care. That has yet to happen fully in this country.

EDITOR: These are fascinating insights. Let's focus now on how these trends will affect laboratory testing and *in vitro* diagnostics.

KERSHAW: Sysmex began looking at these issues six years ago. The aging trend has been a problem in Japan—where Sysmex Corporation has its headquarters—for at least 15 years. We've tracked disease types and began monitoring their impact. Of course, lifestyle differences between Japanese and Americans make a direct comparison difficult. However, the health system's response to the aging Japanese population has given us insights on how we should prepare for aging of the population in the United States.

EDITOR: What emerged from these strategic studies?

KERSHAW: Not what you'd expect. A review of the literature about genomic and proteomic research and technologies led us to conclude that most biotech companies, including some of the biggest IVD firms, are taking a scattergun approach, as an industry.

EDITOR: Explain that, please.

KERSHAW: There's a lack of central focus in the collective R&D efforts of the biotech industry. Individual companies are pursuing very defined opportunities. Some of healthcare's giants seem to be opportunistically waiting. If a technology begins to show clinical promise, they are ready to step in and acquire or joint venture to gain access to that technology.

EDITOR: Has Sysmex decided on a different strategy?

KERSHAW: That's the right question. It strikes to the heart of our company, which is led by executives greatly influenced by many Japanese cultural traits.

EDITOR: I bet you're about to say something about continuous improvement, that concept of *Kaizen*.

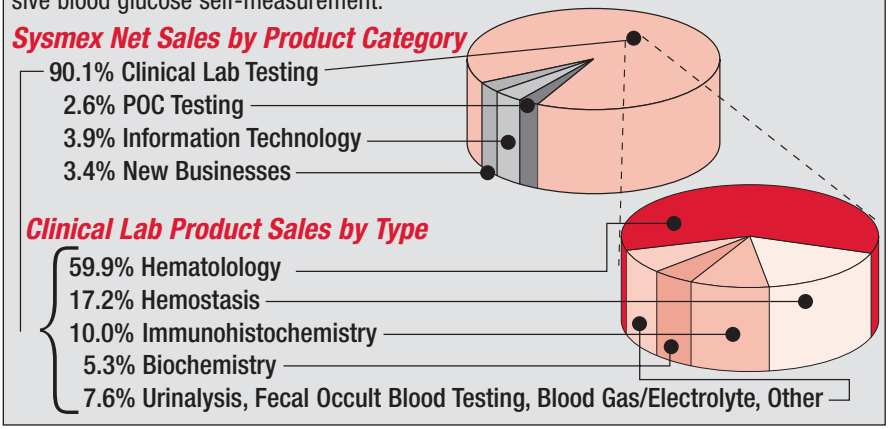
KERSHAW: That's a good guess. We've settled on a strategy of emphasizing and building upon our core technologies. Sysmex believes it is a world leader in as many as 17 unique core technologies. It wants to use its engineering strengths to continuously de-

Sysmex Preparing New Products For Lab Areas Outside Hematology

SYSMEX CORPORATION is a Japanese company with worldwide sales projected at U.S.$720 million in 2004. It is ranked among the top ten largest IVD manufacturers in the world. Globally, it holds a 20% market share of hematology.

The two pie graphs at right show how sales break down by product category. Clinical laboratory products comprise 90.1% of the company's revenue.

Although known primarily for its line of hematology analyzers and products, the company is putting significant R&D dollars into such areas as cervical cancer screening, tests to determine the effectiveness of anti-cancer drugs, and a product for "minimally invasive blood glucose self-measurement."



velop these core technologies, which include flow cytometry and the chemistry of cellular events, among others.

EDITOR: Do you have an example?

KERSHAW: Cervical cancer screening illustrates how we want to combine a core technology we possess with new technology that may have been developed elsewhere. We took our flow cytometry expertise and, with another reagent company, are developing a methodology with a goal to create an efficient first-line screening test for the detection of cancerous cervical epithelial cells by flow cytometry.

EDITOR: As a company well-known for its expertise in hematology, this type of product will probably surprise many in the lab industry.

KERSHAW: We've got a lot more surprises like that one. Another development project involves molecular diagnostic instrumentation for the intra-operative detection of metastatic carcinoma in lymph nodes. The first application is in breast cancer. Existing laboratory practices involve the use of manual tissue sectioning and microscopy, with or without the use of staining procedures. These methods are time-consuming and need to be performed by highly skilled personnel (i.e., pathologists). Because of the time constraints, intra-operative lymph node assessment is not as comprehensive as the formal microscopic lymph node assessment, which still needs to be conducted post-operatively.

EDITOR: How does Sysmex want to improve this current situation?

KERSHAW: Our solution is an automated instrument, which does not require the same level of expertise to

operate. LAMP (Loop-mediated isothermal amplification—**Eiken Chemical Co., Ltd.**) is the principle method used. It is a one-step isothermal method that does not require nucleic acid extraction prior to amplification. The result is enhanced diagnostic performance within a 30-minute time frame, without the need for highly skilled intervention. Sysmex is working on this project with a leading cancer center in the U.S.

EDITOR: How soon might this instrument system be available?

KERSHAW: It is currently undergoing clinical trials in Japan and the early results are promising. Sysmex projects an introduction into the United States by 2006.

EDITOR: Are there other examples of this core technology/new technology marriage within Sysmex?

KERSHAW: In Japan, Sysmex offers a fully-automated fecal occult blood testing instrument. The measurement principle is latex immuno-nephelometry, with a lower limit of detection and enhanced analytical sensitivity when compared to traditional methods of detecting blood in stool. The method is highly specific for human hemoglobin and is fully automated. Not only does it incorporate a better process—which is med tech friendly—for specimen collection and prep, but we think the economics of this test will support its use in an early detection mode. Another area of development involves the predictive qualities of certain markers for pharmacogenomics applications. This takes a core technology found in our hematology products and applies it outside hematology.

EDITOR: None of these new applications are in hematology.

KERSHAW: This product development is in addition to our continued development in hematology. Hematology will remain our primary focus for utilizing our core technologies. However, Sysmex today is a different company than it was just ten years ago. It has taken inspiration from **Sony Corporation**. Sony has a reputation as a pure innovator. It starting by taking existing technologies and creating something innovative. The Walkman—a miniature stereo system—is an example. Revenues generated by those successes were used by Sony to create products based on its own breakthrough technology innovations.

EDITOR: Are you saying, then, that a key attribute within the Sysmex corporate culture is innovation?

KERSHAW: Yes. This process started a decade ago and is beginning to bear fruit. We have several interesting and innovative diagnostic products to introduce in coming years.

John Kershaw

The MOLIS acquisition was a direct result of our effort to seek out "preventative care" opportunities.

EDITOR: How does laboratory information fit into the Sysmex strategy. In 1998, your company bought MOLIS, a laboratory information software system.

KERSHAW: The MOLIS acquisition was a direct result of our effort to seek out "preventative care" opportunities, particularly those that would be useful in the Japanese healthcare system. As we all know, laboratory test data plays a key role in prevention and early detection.

EDITOR: True, but most IVD companies have been slow to address opportunities in laboratory information. What stirred Sysmex to act?

KERSHAW: There were two pieces to our analysis. First, acute and episodic care is generally treated in hospitals. If you move out of that environment, you

must serve patients who are in doctors' offices, health clubs, and similar settings. As an example, if an analysis is done on an individual in a health club, it won't do much good to report a set of numerical results. Rather, you will want to say to that patient "your hematogram fits the profile of a long-distance runner." That type of report is one that a layman can understand.

EDITOR: So the first part of this strategy is tied to the ability to deliver laboratory test information to any location, in or outside of a healthcare facility. Further, your software allows you to analyze the lab test data, compare that to known profiles, and offer the individual a sophisticated analysis.

KERSHAW: That's right. It allows us to move out to the patient. The second piece involves clinical laboratories. Today, medical technologists review all laboratory tests to identify results which are abnormal. A lab software system has rules to help the med tech. However, about 98% of all lab test results are normal. The opportunity is to help the med tech, and the clinical pathologist, with those 2% of the test results which are abnormal. The shortage of med techs heightens the opportunity for us to provide a useful solution.

EDITOR: But why an LIS system?

KERSHAW: We went outside Sysmex because we wanted to buy an information solution which was designed and built upon a strong foundation of current generation technologies. The MOLIS acquisition infused a broad range of IT knowledge into our company.

EDITOR: What plans do you have for your LIS?

KERSHAW: Today, MOLIS is a separate business, with separate market characteristics. We believe it will evolve into a much closer relationship with the diagnostic testing process.

EDITOR: I find it interesting that some of the other major IVD companies are announcing ventures and collaborations with healthcare IT companies. That seems to affirm your strategic analysis of where the marketplace will end up.

KERSHAW: Maybe so. But we expect a major change. Today, clinical information systems sit between the lab testing instrument and the traditional laboratory information system (LIS). We predict that laboratory customers want a single, integrated IT solution which can collect lab test data, compare it to a patient's cumulative data, and then predict, analyze, and support diagnosis and treatment.

EDITOR: That's a tough vision to convert into reality.

KERSHAW: In the United States, the LIS business is a challenge for Sysmex. We face large competitors with lots of control over their customers. A "me-to" product will not survive in this environment.

EDITOR: Could we now shift gears and talk about the changes that occurred to Sysmex America during the past year? Specifically, why the decision to move away from the distribution agreement with **Roche** and establish your own sales and service team in this country?

KERSHAW: This was a difficult decision and fraught with significant risk. On one hand, the Sysmex–Roche relationship was always successful. On the other hand, Sysmex found that, to build market share in the United States, a distribution-only business model was not ideal.

EDITOR: Why is that true?

KERSHAW: In this country, Sysmex found itself facing two fundamental disadvantages. One, it did not manufacture in the United States. Two, it did not distribute directly in the United States. Each situation erodes the nor-

mal pricing margins enjoyed by any IVD company which manufactures here and directly distributes their own products. Recent healthcare trends in America further exacerbated this financial consequence.

EDITOR: What else contributed to this major strategic change?

KERSHAW: There were two contributing factors. First, Sysmex has a pattern of going to direct distribution and enjoying substantial success. When we went direct in Germany, we had the lowest market share. Ten years later, Sysmex held the top market position. It was a similar story in the United Kingdom when we went direct.

EDITOR: And the second factor?

KERSHAW: Today we have substantially more financial resources. In 1999, international revenues at Sysmex totaled $300 million. This year, Sysmex will post revenues of $720 million. This allows us to do a more effective job to support our customers in the United States, currently the world's single largest healthcare market. Sysmex has evolved into a customer-concentric company and direct distribution supports this attribute.

EDITOR: Does "close to the customer" reflect, like continuous improvement, a Japanese cultural trait that underpins this business strategy.

KERSHAW: Yes. Customer expectations are a key part of defining our quality. They also point us to product enhancements which add value.

EDITOR: We spoke about the Sysmex–Roche relationship. Will anything change in your business relationship with **Dade Behring Corporation**?

KERSHAW: No. If anything, it will become tighter. Our two companies engage in joint manufacturing and joint development of new coagulation analyzers and reagents. Our product lines are complementary and the existing structure works extremely well.

EDITOR: John, you've shared valuable insights about the healthcare system and diagnostic testing trends. You've also talked about the research and new products under development at Sysmex. Now that Sysmex is building a new sales and service team in the United States, there will inevitably be differences in the public face of Sysmex. How can you help our readers understand what you believe will differentiate Sysmex from other IVD companies during the next few years?

KERSHAW: Think "best of breed!"

EDITOR: That's an easy phrase to remember, but how does it relate to the new Sysmex business strategy?

KERSHAW: In today's marketplace, there's a competitive strategy we can describe as the "total supplier business model." These IVD companies want to convince a laboratory to buy all its instruments and reagents from a single source.

EDITOR: So what makes "best of breed" an effective answer to that competitive approach?

KERSHAW: Sysmex strongly believes that laboratories want a solution which incorporates the best demonstrated technology and delivers the highest possible level of clinical accuracy and quality. As I mentioned earlier, Sysmex has world-class excellence in 17 technologies. These are our springboards to further innovation which supports higher clinical outcomes on an operationally-robust platform. In the long run, we think "best of breed" wins out over the "total supplier business model." In hematology, for example, our research indicates that Sysmex' core technologies can make substantial contributions to advance the capabilities of medicine. TDR

Contact John Kershaw at 847-996-4500.

Lab Industry Briefs

DIGENE ENJOYS GROWTH OF 39% IN RECENT MONTHS

FUELED BY RECOGNITION that HPV plays a key role in causing cervical cancer, demand for **Digene Corporation's** hc2 High-Risk HPV DNA test is increasing at impressive rates.

For fiscal third quarter 2004, Digene reported revenue growth of 39% over the same quarter last year. Its revenues climbed from $17.0 million to $23.6 million. For the full nine months of fiscal year 2004, Digene's revenues topped $64.2 million. This was a growth rate of 46% over the previous year.

In response to the new cervical cancer screening guidelines, insurance companies have acted swiftly to accept and cover Digene's DNAwithPap™ test. In early January, Digene disclosed that it had agreements with payers representing 100 million lives. By mid-April, additional payer contracts raised that number to 150 million lives.

This is a remarkable accomplishment. FDA approval of the DNA with Pap test was granted in March, 2003. It took Digene only 13 months to achieve the payer contract milestone of 150 million covered lives!

Lab managers and pathologists should interpret these events as a sign of how swiftly the clinical marketplace can move to incorporate new clinical guidelines. It is also an opportunity for laboratories that want to be seen as the lab test innovator in their service region. They can be first in two ways. One, to provide educational programs to both physicians and women about the the new cervical cancers screening guidelines. Two, they can be first to provide appropriate laboratory tests and clinical pathology services needed to support this testing.

One example of an early adopter in cervical cancer screening is **Kaiser Permanente Northern California**. Last year, Kaiser decided to implement the new cervical cancer screening guidelines. In California, Kaiser serves 6.2 million beneficiaries. One consequence of that decision is that Kaiser's regional laboratory in Northern California is gearing up to perform 400,000 HPV tests this year, compared to only 5,000 HPV tests last year.

The new cervical cancer screening guidelines, their impact HPV test utilization, and the rapid coverage decisions by payers in this country sends another message to the laboratory industry. Swift acceptance of the clinical relevance of such molecular-based testing demonstrates how rapidly other new molecular tests can sweep across healthcare. However, that will only be true if such tests demonstrate clear and unambiguous clinical benefit, at a reasonable cost.

CONGRATULATIONS! ARUP LABORATORIES HAS ITS 20TH BIRTHDAY

JUNE 15 MARKED THE 20TH BIRTHDAY of **ARUP Laboratories, Inc.**, based in Salt Lake City, Utah. The day was marked by festivities which included a bluegrass band, rodeo riders, and "mechanical roping."

THE DARK REPORT extends its congratulations to ARUP Laboratories. The success of ARUP Labs is one of the lab industry's more remarkable stories.

It was back in 1994 when the Department of Pathology at the **University of Utah's School of Medicine** turned entrepreneurial. At that time, the Department of Pathology assumed ownership and operational responsibil-

ity for the clinical laboratories of the **University Hospital**.

That was a bold business move for academic pathologists—a move unmatched by any other academic pathology group during the past two decades. However, executive leadership at ARUP was up to the challenge. The laboratory has enjoyed double digit growth in specimen volume for each of the past 20 years. Its annual revenues are well past $100 million and climbing steadily toward $200 million.

It would be a positive boost for the entire profession of laboratory medicine if more academic pathology groups borrowed a page or two from ARUP's entrepreneurial playbook and started their own specialized laboratory company.

CLINICAL LAB INDUSTRY FORTUNES IMPROVE, BRLI GROWS BY 29%

TODAY'S CLINICAL LABORATORY INDUSTRY might be, metaphorically speaking, diagnosed as having a bipolar disorder.

The swings to feelings of depression are triggered by steadily declining reimbursement, proposals to reinstitute the Medicare 20% co-pay, and a host of threats to the status quo—some real and some perceived. When the emotional meter moves to exhilaration, it is usually the result of exceptional gains in market share, specimen volume, and profits by individual lab companies and hospital laboratory outreach programs.

One example of the positive mood swing is **Bio-Reference Laboratories, Inc.** (BRLI), based in Elmwood Park, New Jersey. For second quarter of its fiscal year 2004 (ending October 31, 2004), it reported revenue growth of 29%, compared to Q2 FY2003. BRLI's revenues jumped from $25.9 million to $33.6 million during this same period. Also during this time, BRLI's net income and earnings per share (EPS) increased by 29% and 25% respectively.

BRLI competes in one of the nation's toughest markets for lab services. It is New York City metro, which reaches into New Jersey and Connecticut. As a public laboratory company, BRLI must report its numbers. That makes it a useful gauge of the ongoing competitive wars between the two blood brothers and their regional competitors.

Around New York City, regional independent lab companies include **Enzo Clinical Laboratory**, **Quentin Medical Laboratories**, and **Sunrise Medical Laboratories,** among others. There is a group of nascent hospital laboratory outreach programs. Individually, these laboratories tell THE DARK REPORT that they are showing regular growth and enjoy a predictable level of profit.

Of course, this optimism is tempered by the lab industry's bipolar opposite: never-ending fears that even a single significant change in the healthcare marketplace may cause a smaller laboratory organization to collapse. Regional laboratories recognize that, for them, it is a tenuous thread which separates financial viability from financial disaster. That is one reason why the strong growth and financial performance of many smaller labs throughout the United States goes unrecognized.

THREE NEW DIRECTORS AT SPECIALTY LABS

MORE CHANGES AT THE LEADERSHIP LEVEL of **Specialty Laboratories, Inc.**, located in Santa Monica, California. Its three new directors are: Hubbard C. Howe, a retired investment banker, Michael T. DeFreece, Chairman and Chief Administrative Officer of **MarketSphere Consulting**, and David R. Schreiber, known in the lab industry for his role as Chief Financial Officer of **DIANON Systems, Inc.** prior to its acquisition by **Laboratory Corporation of America.** TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

There's early evidence that health benefit costs for 2005 may only increase by a single digit percentage. **Hewitt Associates** is gathering data from 160 large companies for its annual healthcare cost survey. It reports that an average increase of 13.7% appears likely, compared to a 17.5% increase in 2004. But when employers factor in the effect of health plan changes, which can include higher employee deductibles or co-pays, employers can reduce the overall net increase by as much as 4%.

Just ten days ago, Leo Serrano resigned his position as Executive Director of Laboratory Services at **West Tennessee Healthcare**. This is an six-hospital health system in Jackson, Tennessee. As one of the nation's first three major health system laboratories to apply Lean and Six Sigma techniques during 2003, Serrano has some unique experience that is fast coming into high demand.

MORE AND MORE GENETIC CANCER TESTS REPORTED AT ASCO

In late May, the **American Society of Clinical Oncology** (ASCO) held its annual meeting in New Orleans. Based on the topics presented at this year's event compared to 2003, THE DARK REPORT can make an important conclusion for the laboratory industry. First, there was a notable increase in the number or cancer therapies based on genetic and proteomic technologies. Second, there was a significant increase in the number of presentations dealing with genetic tests that predict: a) whether a patient is likely to contract cancer; or, b) whether the patient's cancer will be particularly aggressive; and/or, c) whether the patient's cancer will respond to a specific therapy.

ADD TO: Cancer Tests

Collectively, this increase in the number of presentations on genetic-based therapies and predictive tests for cancer is significant. It demonstrates that a number of promising technologies are about to emerge from the research laboratory and begin rigorous clinical study. Upon completion of those studies, some technologists will then find their way into clinical therapies and laboratory tests.

• It may be an early sign that the retirement wave of baby boomers is ready to hit. Paul J. Mountain, Senior Vice President of Science and Technology at **MDS Diagnostics Services**, has announced his retirement, effective at the end of this month. Mountain, a past president of the **Clinical Laboratory Management Association** (CLMA) intends to continue with his involvement in CLMA and NCCLS.

• **A f**ormer President and COO of **IMPATH, Inc.** served a short tour of duty for a start-up laboratory company which failed to become operational. Earlier this year, Richard Adelson joined the executive ranks of **Cantata Laboratories Inc.**, based in Cambridge, Massachusetts. Cantata was attempting to develop a metabolic profiling technology. But the technology did not perform and venture capitalists recently decided to pull the plug on the fledgling laboratory company.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 19, 2004.

THE DARK REPORT

UPCOMING...

- ***Exclusive Inside Story:*** ***Who's Behind Pathology "Doc-in-Box Condo Labs!"***
- ***Why Urology and Gastroenterology Groups Are Motivated to In-Source Pathology or to Use the Condo Lab Concept.***
- ***Understanding Essential Legal Arguments That Support Pathology Condo Labs—as Well as Inducement and Anti-Kickback Risks.***

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