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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Marketplace Rewards Those Who Get It Right

INTELLIGENCE BRIEFINGS IN THIS ISSUE REVEAL INTERESTING DEVELOPMENTS in our industry. I would agree with our Editor's assessment that a new cycle of investment in laboratory companies is about to occur. There is also confirmation that laboratories which offer HMOs more than simple lab test data can get a leg up on their competitors.

On the East Coast, **DIANON Systems, Inc.** has inked a pact with **Aetna/U.S. Healthcare** and **SmithKline Beecham Clinical Laboratories** (SBCL) to provide anatomic pathology services across a number of states covered under SBCL's contract with Aetna. *(See pages 16-17.)* Attendees at our *Executive War College* in May 1998 heard Arthur Steinberg, M.D., the architect of DIANON's value-added information product (known as CarePath™), outline how and why this service was designed to meet the needs of patients, physicians and managed care plans.

One year later, DIANON Systems accomplished its business objective. CarePath is singled out by Aetna's Medical Director as one reason why the company was selected to be a sole source AP provider in three states, and a preferred AP provider with Aetna/U.S. Healthcare plans in other parts of the country.

On the West Coast, the purchase of **Unilab Corporation** by **Kelso & Company**, a respected LBO (leveraged buyout) firm, for almost one half billion dollars provides evidence that big money players on Wall Street believe the clinical laboratory industry is on the verge of a financial turnaround. *(See pages 1-4.)*

What these events, three thousand miles apart, tell us is that the marketplace is evolving. DIANON Systems is not sitting tight, doing the same things in 1999 that it did in 1996. Instead, it is investing in new services and paying sales people to educate their potential customers about the benefits of these services. As a result, this proactive management plan has harvested "sole source" arrangements with Aetna and Oxford Health Plans during the last six months.

Expect a similar story with Unilab. New owners are going to insist that this once-troubled laboratory proactively go into the marketplace with new products. As it does, the competitive market will change, for better or for worse. Along the way, the marketplace will reward those laboratories and pathology practices which got it right! TDR

Investors Coming Back To Clinical Lab Industry

Private LBO company pays $420 million in cash and debt to acquire Unilab Corp.

CEO SUMMARY: Wall Street money is beginning to flow back into the commercial laboratory industry. This time the beneficiary is Unilab Corporation of Tarzana, California. New York-based Kelso & Company signed an agreement to buy 93% of Unilab's shares. The common perception among financial ana-lysts and money managers is that commercial laboratories may again be a worthwhile investment.

COMMERCIAL LABORATORIES are again finding themselves attractive to investors. The latest deal is **Kelso & Company's** acquisition of **Unilab Corporation**.

Kelso & Company is a private investment company involved in LBOs (leveraged buyouts). On May 25, it announced an agreement to purchase 93% of Unilab's stock for $5.85 per share, paid in cash.

This was a 20% premium over Unilab's market price on that date. As a result of this transaction, Unilab will be merged into **UC Acquisition Sub, Inc.**, a wholly-owned subsidiary of Kelso & Company.

Unilab is the largest commercial laboratory in California, with revenues of $217 million in 1998. It does no testing outside that state. During the last six months, it acquired two major competitors, **Meris Laboratories** and **Bio-Cypher Laboratories** (formerly **Physicians Clinical Laboratories**). *See TDR, November 9, 1998 and April 26, 1999.)*

THE DARK REPORT considers this transaction to be a significant event for the clinical laboratory industry. During the next two years, it will impact laboratory activities in four ways.

One, a new cycle of investment in commercial laboratories by outside investors is about to begin.

Two, in California, the competitive battle for market share of laboratory specimens will intensify.

Three, existing independent commercial laboratories can view both Unilab and yet-to-be identified new investors as serious and qualified buyers.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $10.80 per week in the US, $11.40 per week in Canada, $12.45 per week elsewhere (billed semi-annually).

Four, there will be a heightened emphasis on sales and marketing by all public laboratories. However, this will not take place at the physicians' office level, it will occur at the level of HMOs, IPA, and similar global contract sources.

Each of these four dynamics will affect the continuing evolution of the laboratory industry in fundamental ways. Here's a closer look at how each dynamic can be expected to play out in the healthcare marketplace.

MARKET DYNAMIC ONE

New Cycle Of Investment

During 1999, nearly $2 billion will be spent on the acquisition of publicly-traded laboratories. Kelso & Company is paying $420 million for Unilab. **Quest Diagnostics Incorporated** will pay $1.27 billion to purchase **SmithKline Beecham Clinical Laboratories.**

Lenders and investors are willing to commit this money in 1999 because they have watched the success of **Golder, Thoma, Cressey, Rauner Inc.** (GTCR). During the last 30 months, GTCR made sizeable investments in both **Dynacare, Inc.** and **American Medical Laboratories**. *(See TDR, May 12, 1997.)*

Donald Edwards, a GTCR principal, told laboratory CEOs at last month's *Executive War College* in New Orleans that GTCR was pleased with the performance of both Dynacare and American Medical Laboratories. GTCR is a 50% owner of Dynacare, which it helped convert from a publicly-traded company into a private firm.

Wall Street analysts share a view, rightly or wrongly, that the finances of the commercial laboratory industry have hit rock bottom. They can only improve. "This is a company [Unilab] that's back from the dead in an industry that's back from the dead. It's a lower-risk strategy for management," said Nancy Weaver, financial analyst with **Stephens, Inc.** about the Unilab deal.

Weaver's opinion is shared by an increasing number of financial analysts and portfolio managers. They see the relatively depressed share prices of Unilab, Quest Diagnostics, and **Laboratory Corporation of America** as providing a good opportunity for market gains. They interpret the stabilizing finances of these companies as an early sign that the market for clinical laboratory services will improve during the next few years.

Given these facts, THE DARK REPORT predicts that other investments will be made in the commercial laboratory industry during the next 18 months. In cities where such investments occur, they will disturb the laboratory status quo.

MARKET DYNAMIC TWO

Increased Competition in California

As Unilab comes under control of new owners, it can be expected to develop a well-funded and focused sales and marketing program. Kelso wants Unilab to increase its profitability, which means Unilab must go out and build specimen volume.

Accordingly, competition for business in California can be expected to intensify. This will not be the financially-struggling, unfocused Unilab of 1996 and 1997. Competing labs can expect Unilab to show a new intensity in its pursuit for additional specimens and revenues.

Expect this intensified sales and marketing effort to concentrate on global contracts for laboratory testing. This emphasizes building contracting relationships at the level of

Public Lab Competitors in California Must Confront Unilab's Size and Clout

Acquisitions Make Unilab the "Big Dog"

Ranking of Public Laboratory Facilities in California–Routine & Common Tests

Rank	Lab	Accessions/Day	Annual Net $
1.	Unilab-Tarzana	25,000	$132 mil
2.	Unilab-Sacramento	15,000	$79 mil
3.	Unilab-San Jose	10,000	$53 mil
4.	SBCL-Van Nuys	9,000	$48 mil
5.	SBCL-Dublin	6,500	$34 mil
6.	LabCorp-La Jolla	6,300	$33 mil
7.	Quest-San Diego*	1,400	$15 mil

** Quest operates a national reference lab in San Juan Capistrano.*

(Note: These are estimates based on public sources and private information. The companies themselves have not validated these numbers. Assumes net revenue per accession of $22.)

Although California is the largest market for clinical laboratory testing in the United States, as the ranking at left demonstrates, none of the Three Blood Brothers have as large a presence in the state as Unilab Corporation. These numbers are estimates and have not been validated by the individual companies.

the HMO or IPA, rather than selling directly to physicians' offices.

MARKET DYNAMIC THREE

More Lab Acquisitions

If one accepts the assumption that new investors want to enter the commercial laboratory marketplace, then it becomes obvious that the pace of laboratory acquisitions will increase during the next few years.

THE DARK REPORT sees this occurring in two ways. First, public laboratories, including Unilab, Quest Diagnostics, and LabCorp, will selectively target and buy independent laboratories which offer them strategic benefits. Unlike the bidding frenzy of the early 1990s, these deals will be soberly negotiated, and based on their appropriateness to the acquiring laboratory.

Second, outside investors will use acquisitions as a way to buy into the commercial laboratory industry. This is what occurred to **American Medical Laboratories** of Chantilly, Virginia. Independent labs with size and regional market clout will be the most attractive candidates for investors.

Expect owners of these laboratories, many who regret not having sold their laboratory in the pre-1994 acquisition frenzy, to be willing sellers to this new class of buyers. As they sell, their laboratories will come under more aggressive management.

MARKET DYNAMIC FOUR

Intensified Sales & Marketing

One major consequence of this new investment money flowing into commercial laboratories will be increased intensity in sales and marketing for additional specimens.

This will be particularly devastating to any remaining smaller independent laboratories as well as hospital lab outreach programs that are run in a half-hearted manner. The reason is simple.

New owners of these acquired and "revamped" clinical laboratories will operate them under the principles of modern corporate management. Many of their competitors are laboratory managers still rooted in the old man-

agement models of the fee-for-service 1980s and early 1990s.

This management transition has parallels in other industries. When Japanese auto manufacturers entered the U.S. market in the 1970s, they used a different management philosophy to organize their companies. They designed, built, and sold cars under a different set of management precepts.

Management Philosophies

Not until the Big Three Detroit auto makers incorporated Japanese management philosophies into their business did they stabilize their market share. During the late 1970s and early 1980s, a similar process happened to manufacturers of business copiers and semiconductors.

THE DARK REPORT considers it important that both commercial laboratory executives and hospital-based laboratory administrators understand this point about new management principals. This transformation is already under way. American Medical Labs and Quest Diagnostics represent this new approach to management, marketing, sales, and service.

Managers Who Don't Deliver

New investors have influence in these companies. Managers who don't deliver will be replaced by those who can. This new class of managers will have an additional talent over today's crop of lab administrators. They will be capable of initiating and managing proactive change in the lab while simultaneously improving the science of laboratory testing.

This duality of management thinking has been slow to take root in the clinical laboratory industry, particularly among hospital lab administrators. THE DARK REPORT believes that new investors now arriving in the lab industry will be a catalyst. They will accelerate this evolution toward a new management philosophy.

Clients and regular readers of THE DARK REPORT should evaluate how these four market dynamics will alter competition in the regional markets served by their laboratories. The healthcare marketplace is evolving at a rapid pace. What was a good management strategy last year may be a ticket to bankruptcy next year.

For that reason, laboratory executives should keep closely attuned to developments at both the regional and national level. In coming months, THE DARK REPORT will write more about the impact of Quest Diagnostics' acquisition of SmithKline Beecham Clinical Laboratories. Like the Kelso purchase of Unilab, the Quest-SBCL merger will stimulate a number of far-reaching changes to the laboratory industry.

Hospital Labs Not Immune

As discussed earlier in this story, hospital laboratories should not consider themselves immune to the acquisition activity unfolding among commercial laboratories. Many independent laboratories believe that they can grow by capturing either hospital specimens, or gaining contracts to manage hospital labs. New investors, who don't understand the differences between hospital labs and commercial labs, will tend to direct their sales force to generate business from hospital sources.

Will the arrival of large amounts of new investment capital be good for the clinical laboratory industry? Only time will reveal the answer. In the meantime, one thing is certain...more change is ahead for both commercial labs and hospital laboratories. TDR

For further information, contact Robert Michel at 503-699-0616.

Palo Alto Needle Reuse Episode Widens in Scope

Former SBCL phlebotomist's career trail involves labs, hospitals, and doctor's offices

CEO SUMMARY: As many as 15,000 people have been offered free blood testing because they may have been drawn by this phlebotomist since 1994. Regulatory action, private lawsuits, and media coverage are subjecting laboratories to unwelcome, even unwarranted, scrutiny. As the ramifications of this phlebotomist's decision to reuse needles ripples through the healthcare system, lab administrators should heed the lessons to be learned.

NEWS THAT A PHLEBOTOMIST reused needles created shock waves in the San Francisco Bay Area. Since the public announcement on April 16, there have been ongoing disclosures.

To date, at least 15,000 people have been offered free blood testing because they had some chance, however slim, of being exposed to infection by phlebotomist Elaine Giorgi. This covers most sites and companies where she has worked since 1994.

Reused Butterfly Needles

The matter became public when **SmithKline Beecham Clinical Laboratories (SBCL)** and the California **Department of Health Services** (DHS) conducted a joint press conference to announce the discovery that a phlebotomist had reused butterfly needles on "difficult to draw" patients. *(See TDR, April 26, 1999.)*

The facts are simple. Elaine Giorgi, a phlebotomist working for SBCL in its Palo Alto patient service center, was terminated after a co-worker reported seeing her washing disposable needles in a sink on March 22.

She admitted to SBCL managers, and later to public health agency officials, that she had reused butterfly needles. "She believed she needed to reuse needles to conserve those needles," reported state health investigator John Rosenberg. "She recognized they are more expensive than the usual needles."

For clinical laboratory executives, the affair of the "Palo Alto Phlebotomist" provides invaluable insight as to the consequences of breaching the public's confidence in health services.

SmithKline Beecham Clinical Laboratories was the first laboratory in the hot seat. Although national media coverage died down relatively quickly, there remains high awareness of this matter throughout the San Francisco area. In the seven weeks since the news became public, past employers of Ms. Giorgi were identified and brought into the story.

Starting in 1994, it is known that Elaine Giorgi worked at **Unilab** (then called **PathLabs**), **Mills Peninsula Health Services**, and **Laurel Medical Group** before taking a position at SBCL in June 1997.

Unilab no longer has patient records for these sites and dates. It is estimated that about 350 patients will get offers of free testing from Mills and Laurel. SBCL offered 3,700 patients served at the Palo Alto draw site free testing and counseling. It has since offered another 11,700 patients free testing and counseling.

On May 14, Ms. Giorgi agreed to a preliminary court injunction requested by the state attorney general's office. It bars her from drawing blood, doing injections of any kind and, preparing labels or medical specimens pending further court action.

Risk of contracting one of the three most serious blood-borne diseases through transmission by dirty needles:
Hepatitis B: 20%-30%
Hepatitis C: 3%
HIV: 0.3%
Source: Calif. Dept. of Health Services

Lab executives familiar with this case have wondered what kind of exposure SBCL faces from claims by patients that they became infected with HIV or hepatitis as a result of the phlebotomist's actions. It didn't take long for that problem to surface.

In Santa Clara County Superior Court, "Jane Doe 7659" filed a lawsuit against Elaine Giorgi and SBCL on May 6. The plaintiff claims she was told by county health officials on October 29, 1997 that she tested positive for hepatitis C.

According to her attorney, Richard Alexander of **Alexander Hawes & Audet**, this woman had never tested positive before that date. The attorney said Jane Doe 7659 had blood drawn at SBCL's Palo Alto site in June, July, and September 1997.

Here's where laboratories will get a first-hand lesson on the legal system versus medical reality. Once the lawsuit was filed, health officials were quick to point out that linking any individual infection to this phlebotomist will be difficult.

Exposed To Hepatitis

"There is a certain percentage of the population that has been exposed to hepatitis and we would expect some people to test positive," said DHS spokesman Ken August. "We may never be able to ascertain definitively whether someone was exposed to a virus through unsafe medical practices or some other risk factor."

Besides shared needles, August was referring to transmission of hepatitis through sexual activity and other unidentified means. Most laboratorians are familiar with the incidence of HIV and hepatitis among the wider population.

Scott Morrow, M.D. Medical Officer for San Mateo County, stated that the incidence rate of hepatitis C is between 1.2% and 1.8% for the population of the United States.

Some Will Test Positive

Epidemiologists at DHS believe that, of the 1,500 patients already screened for infection as a result of this matter, as many as 20 will test positive for hepatitis C, with most learning about it for the first time. "Studies show that between 50% and 70% of people with hepatitis C don't know it," said Dr. Morrow.

What complicates any court determination of liability from hepatitis C infection is the fact that, in 20% of all cases diagnosed, no risk factor is ever identified. This is expected to be true for some individuals drawn by Ms. Giorgi and now undergoing precautionary blood testing.

Seven weeks after the public learned about this problem, SmithKline Beecham Clinical Laboratories continues to find itself in the headlines. The fears and emotional distress caused by this situation will not disappear overnight. For example, there are many people who still recall the *60 Minutes'* expose of the "Pap smear industry" during the mid 1980s...and that was almost 15 years ago!

SBCL's Unfortunate Luck

Laboratory executives in all parts of the country should consider SBCL's unfortunate luck as a warning. Every laboratory in the United States could experience a similar situation if any single employee took a rogue action like that of phlebotomist Elaine Giorgi.

It is evidence of the clinical laboratory industry's stellar record for safety and patient care that this is the first such case in decades to attract wide-spread public attention. Laboratories should be justifiably proud of this accomplishment.

On the other hand, Ms. Giorgi's actions, and the consequences to a well-respected laboratory company, demonstrate how easy it can be for one employee to erode an honorable company's goodwill with the public.

THE DARK REPORT recommends that laboratory executives and pathologists meet with their management team and evaluate existing policies, procedures and management oversight of phlebotomy and other lab operations which could compromise patient care.

Anticipating such crises costs a laboratory a lot less time and money than dealing with the disaster after it occurs. **TDR**

For further information, contact Robert Michel at 503-699-0616.

Timeline For SBCL Phlebotomist Affair

March 22—Co-worker observes phlebotomist Elaine Giorgi washing disposable needles in the sink at SBCL's Palo Alto service center. SBCL suspends Giorgi that day. She is later terminated.

April 15—*San Francisco Chronicle* discloses story about SBCL's phlebotomist reusing disposable needles.

April 16—SBCL and California Department of Health Services hold joint press conference to release details of the situation and offer blood testing to 3,700 patients affected by this situation.

April 23—First class action lawsuit filed against SBCL in Santa Clara County Superior Court. Palo Alto police begin investigation to determine if criminal actions occurred.

April 26—State Representative Carole Migdon introduces bill to increase certification requirements for phlebotomists, including 80 hours of training.

May 5—"Jane Doe 7659" files lawsuit in Santa Clara County Superior Court claiming her hepatitis C infection was caused by the phlebotomist's actions at the Palo Alto draw station.

May 7—Minor "Ryan K." files suit, claims he fears he may have contracted a disease from Giorgi, although the disease is undiagnosed.

May 8—UCSF Stanford Health Care officials disclose that several HIV-positive patients had blood drawn at the SBCL phlebotomy site in Palo Alto.

May 13—Giorgi accepts court injunction preventing her from drawing blood.

May 24—SBCL discloses all locations and dates where Giorgi worked. Offers free testing and counseling to 11,700 more people.

IMPATH Foresees Growth Opportunity...

Developing Technology Expected To Fuel Boom In Anatomic Pathology

CEO SUMMARY: Established demographic trends point to a coming boom in the demand for anatomic pathology services. Greater numbers of senior citizens, living longer lives, will raise the number of cancer cases diagnosed annually in the United States. New diagnostic technology will increase the value of the pathologist to clinicians. But before a pathology practice can benefit from this expected "bonanza," it will have to develop appropriate clinical and business strategies for partnering with clinicians, HMOs, and integrated healthcare systems.

FOLLOW-UP AND CONCLUSION TO OUR IMPATH PROFILE

MANY PATHOLOGISTS are intuitively aware of a premise we believe true about the future of anatomic pathology: early diagnosis and improved therapeutic options drive ever-growing volumes of business to anatomic pathologists.

Accept this premise, and the pathology profession has a bright future. The capability of detecting cancer earlier and with more accuracy, combined with targeted therapies that cure patients who meet criteria for that therapy, will result in a steady growth in demand for anatomic pathology services.

This premise should be equally true for clinical laboratories. Early detection of disease, supported by targeted therapeutic technologies, will generate increased volumes of specimens to clinical laboratories.

Profitable Company

Earlier this year, THE DARK REPORT profiled **IMPATH Inc.**, with major facilities in New York and Los Angeles. It's a fast-growing, profitable company which provides diagnostic and prognostic services primarily to community hospital–based pathologists throughout the United States. *(See TDR, February 1, 1999.)*

IMPATH is a company benefiting from the development of new diagnostic technology which supports specific therapeutic options. Its business plan is built around our premise: early detection of disease, matched with effective therapeutic options, generates more demand for clinical services.

In this follow-up story to our earlier coverage of IMPATH, we've asked its President and CEO, Anu Saad, Ph.D., to share her vision of pathology's future. As CEO of IMPATH, Dr. Saad interacts regularly with hospital-based pathologists, oncologists, academic center researchers, pharmaceutical firms, clinical trials companies, and managed care plans.

"Pathologists and laboratorians should look at the relationship between two dynamics in the healthcare marketplace," said Dr. Saad. "First is the market phenomenon where early detection of disease encourages the development of new therapies for that disease.

"Second is the fact that pathologists sit on a wealth of clinical data which has great value to clinicians, patients, and payers," continued Dr. Saad. "As integrated medicine becomes more widespread, pathologists who incorporate this clinical data into their services will have a competitive advantage over pathologists who don't."

Steady Growth In Testing

IMPATH, along with **UroCor, Inc.** and **DIANON SYSTEMS, Inc.**, are three public companies which benefited during the 1990s from the steady growth in testing for breast cancer and prostate cancer. Their sustained multi-year growth in revenues and earnings provide real-world validation of Dr. Saad's first market dynamic.

"Drug companies have the incentive to develop new cancer therapies only when diagnosis occurs early enough for intervention to be successful," commented Dr. Saad. "Compare, say, breast cancer with lung cancer. Right now, technology that supports early detection of lung cancer does not exist. As a result, therapeutic choices are limited."

Developing Specific Therapies

"Such is not the case with breast cancer," she continued. "First, it's now recognized that 'breast cancer' is actually a set of different cancers which occur at that site. Second, we can detect breast cancer at an early stage.

"Once diagnostic tools demonstrated the ability to detect different types of cancer at an early stage, drug companies responded by developing specific therapies to attack distinct types of breast cancer," Dr. Saad stated. "This technology curve of diagnostics and therapeutics for breast cancer is now occurring to prostate cancer," she added.

"PSA testing launched this process. Diagnosis of prostate cancer can occur earlier. Emerging technology is capable of

identifying different types of prostate cancer. In response, a number of new therapeutic drugs and techniques for prostate cancer are arriving in the clinical marketplace."

Decision About Therapy

"These things drive one another in the market," she noted. "As we understand more about the biology of prostate cancer, we provide more information to physicians about their patient's prostate cancer. Thus, the oncologist's decision about which therapy to select is more closely tied to the information received from pathologists."

According to Dr. Saad, lymphoma is a disease which perfectly illustrates this relationship between early detection, multiple therapeutic options, and improved recovery rates. "Only 20 years ago, lymphomas were a much worse disease than today," explained Dr. Saad. "Why? Because we could not distinguish between Hodgkin's, non-Hodgkin's, B-cell, T-cell and other types of lymphoma.

"Today, a lymphoma patient presents with biological specificity. Treatment is targeted to to that specific patient," Dr. Saad said. "Such is not the case with other types of cancer, such as lung cancer or pancreatic cancer. They are commonly diagnosed at a relatively late stage. By the time these cancers are visible, the patient is past the point of being just symptomatic."

Early Detection

Dr. Saad believes that, as new diagnostic technology makes early detection for lung cancers, stomach cancers, and other cancer types possible, pharmaceutical companies will invest more money to develop therapies which are effective when applied during earlier stages of these diseases.

"Early diagnosis and better therapeutic options drive more cancer business toward pathologists," she stated. "IMPATH recognizes this market dynamic and is prepared to grow with that coming increase in referrals. Pathologists should do likewise."

Here is where Dr. Saad believes the intersection of market dynamic one and market dynamic two provides great opportunity for the profession of anatomic pathology.

"Pathologists really need to empower themselves," she declared. "It is pathologists who collect and accumulate data about patients and their cancers. It is pathologists who can combine this information with other patient demographics to build a registry database. Oncologists must have this registry data before they can develop treatment protocols."

Here is where Dr. Saad makes a very sophisticated point about the healthcare community. "Probably the main source of treatment protocols today are clinical trials. The primary purpose of clinical trials is generally not to develop protocols, but to evaluate the effectiveness of new therapies and identify actual side effects."

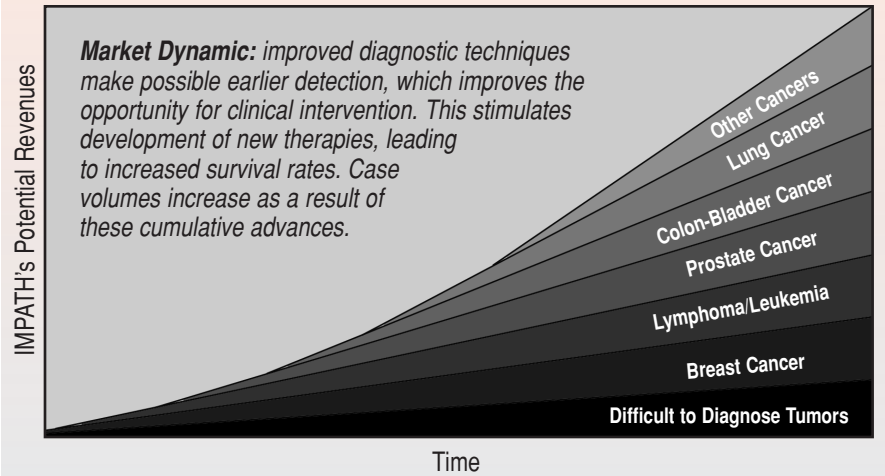
Demand For Protocols

"Yet, there is a genuine demand, by oncologists and managed care plans, for effective protocols to guide diagnosis, therapy, and follow-up," noted Dr. Saad. "Because pathologists sit atop this flow of data, they have the opportunity to convert simple data into information which adds clinical value."

THE DARK REPORT seized this opportunity to ask Dr. Saad to share her view on how anatomic pathology will evolve in the future. Her response was insightful.

"My sense of everything unfolding in healthcare tells me that pathology, as a profession, will not move toward greater consolidation. I don't believe there will be huge "companies" operating pathologists from coast to coast.

Market Dynamics Encourage More AP Cases



"Instead, pathologists will continue to function in local settings, probably doing more outpatient work, anchored near the hospital," said Dr. Saad. "Maybe there will be some regionalization of group practices, but the critical need will be for pathologists to access advanced technology and consult with centers of excellence, like IMPATH.

"The challenge for pathologists is to involve themselves more deeply into the treatment decision-making process," she continued. "That requires a fundamental shift in thinking. Pathologists should cease to say 'I diagnosed this cancer and that's the end of it' and begin to say 'how do I become an ongoing partner with the clinician to support the diagnosis, decide on the right therapy, and monitor the patient's progress.' Pathologists who answer the second question should have a secure future."

Potential For Pathology

Dr. Saad's conviction about the potential for pathology to be an integral partner with the clinician is unshakable. "Pathologists are very powerful. They hold the tissue. They hold the key to patient biology. The more information they can capture and present to oncologists, pharmaceutical companies, and managed care plans, the more important they become to the entire healthcare system."

Virtual Information Networks

"That is why I believe the more critical challenge to pathologists right now is not how to consolidate into big groups, but to link themselves with others to form virtual information-based networks, thereby empowering themselves to play a more critical role in the patient management process. That includes everything from diagnosis and treatment to the development of new drugs."

When asked why consolidation of pathology was less of an option, Dr. Saad replied, "when a patient goes in for a biopsy, the typical surgeon or oncologist doesn't want to send that specimen out-of-state. They prefer that a pathologist literally in the room next door use the microscope and advise them on whether they should proceed to surgery or stop and pursue another therapy."

This assumes a duality of pathology services. Dr. Saad's experience tells her that a clinician wants personal access to a locally-based pathologist. But it is the pathologist who will then

refer certain specimens to "centers of excellence" as necessary to insure an appropriate diagnosis is performed.

Supporting this prediction of a coming boom in the demand for anatomic pathology services are two demographic trends in the United States.

Supporting this prediction of a coming boom in the demand for anatomic pathology services are two demographic trends in the United States.

First, the absolute numbers of people reaching 60+ years old will climb steadily through the coming decades as Baby Boomers hit their retirement years.

Second, it is expected that senior citizens will live longer than earlier generations. This increases their odds of developing cancer.

As the sidebar on the opposite page demonstrates, one in two men, and one in three women, will contract cancer in their life times. The majority of these cancers appear after the age of 60.

Anatomic pathologists should carefully consider the implications of these demographic trends against the financial successes during the 1990s of IMPATH, DIANON, and UroCor.

Sophisticated Expertise

All three companies offer clinicians sophisticated expertise in the detection of certain types of cancer. Lab tests are supported by specialized anatomic pathology resources. Each company has a steadily-growing number of client physicians.

This is early evidence that this business strategy meets a need in the integrated clinical healthcare world toward which we are evolving.

More importantly, each of these three companies publicly states that their future success depends on their ability to convert today's test data into tommorrow's value-added clinical information.

Dr. Saad spoke to this issue. "IMPATH is investing considerable resources to develop information collection and management capability. Currently we have nearly 500,000 cancer cases in our data base.

"This is not simple data, like age, weight, and sex," she continued. "These are full biological profiles on almost 500,000 patients. We are starting to link this data with treatment decisions made about these patients, and their outcomes.

"As this develops, it permits us to participate in helping clinicians and managed care plans develop protocols. Oncologists are under increased pressure to show the value of what they do."

Better Patient Outcomes

"Our database, built around the original cases referred to us by local pathologists," noted Dr. Saad, "will play a key role in helping oncologists demonstrate they are achieving better patient outcomes and managing costs appropriately.

"This database and the information it generates has important value to pharmaceutical companies," continued Dr. Saad. "For example, we can help drug companies rapidly identify large numbers of patients who have the appropriate biological profile to participate in drug studies. This accelerates the collection of data necessary for FDA approval of the new drug."

"I should also point out the doctors are highly motivated to participate in clinical trials," added Dr. Saad. "Patients request it, drug firms solicit their participation, and it helps physicians stay current on new technology. IMPATH is creating the ability to help them identify patients for such clinical trials."

Dr. Saad's comments throughout this interview support the oft-stated belief of THE DARK REPORT that anatomic pathology has a bright future. But it is a future

LEADING SITES OF NEW CANCERS – 1999 ESTIMATES

Here are the leading sites of new cancers for males and females. Approximately 1.2 million new cases of cancer are diagnosed each year. As the table below demonstrates, technology has yet to be developed for early detection of many types of cancers. As this occurs, pathologists should expect to see an increase in diagnostic referrals, as well as the opportunity to take a more active role in helping the clinician use the diagnosis to determine therapy and monitor the patient's progress.

MALE		FEMALE	
Prostate	179,300	Breast	175,000
Lung and Bronchus	94,000	Lung and Bronchus	77,600
Colon and rectum	62,400	Colon and rectum	67,000
Urinary bladder	39,100	Endometrium (uterus)	37,400
Non-Hodgkin's lymphoma	32,600	Ovary	25,200
Melanoma of the skin	25,800	Non-Hodgkin's lymphoma	24,200
Oral cavity	20,000	Melanoma of the skin	18,400
Kidney	17,800	Urinary bladder	15,100
Leukemia	16,800	Pancreas	14,600
Pancreas	14,000	Thyroid	13,500
Other sites	122,000	Other sites	130,000
All sites	**623,800**	**All sites**	**598,000**

Source: American Cancer Society, Cancer Facts & Figures–1999.

PROBABILITY OF DEVELOPING INVASIVE CANCERS

Population demographics point to an increase in individuals diagnosed with cancer. First, an increasing number of individuals are reaching the age of 60 or older. Second, the Baby Boomer generation is expected to have extended life spans. Both demographic trends predict an increase in the number of cancer cases diagnosed each year in the United States.

All Sites*	Birth to 39	40 to 59	60 to 79	Birth to Death
Male	1 in 61	1 in 12	1 in 3	1 in 2
Female	1 in 51	1 in 11	1 in 5	1 in 3

**Excludes basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. Data are from 1993-1995.*

Source: American Cancer Society, Cancer Facts & Figures–1999.

which requires pathologists to embrace the value of information over basic test results.

It also requires pathologists to build ongoing clinical relationships with physicians. Eventually, like radiologists, pathologists can play a role in diagnosis, selection of therapies, and monitoring the patient's progress. TDR

For further information, contact IMPATH Inc. at 800-447-5816.

Public Laboratory Rankings

GENERAL REFERENCE LABORATORIES

Ranking By 1998 Annual Revenue

($s in millions)

Rank	Laboratory	1998 Revenue	% Change	1997 Revenue
1.	Laboratory Corporation of America	$1,612	+6.0%	$1,520
2.	SmithKline Beecham Clinical Laboratories	$1,550	+11.5%	$1,390
3.	Quest Diagnostics Incorporated	$1,498	-2.1%	$1,530
4.	Unilab, Inc.	$217	+1.4%	$214
5.	Lab*One*, Inc.	$102	+29.1%	$79
6.	DIANON Systems, Inc.	$62	+1.6%	$61
7.	Bio-Reference Laboratories, Inc.*	$47	+23.7%	$38
	Total: General Reference Laboratories	***$5,088***	***+5.3%***	***$4,832***

**Fiscal year ending 10/31/98*

Note: Universal Standard Healthcare sold its laboratory testing business to LabCorp, July 1998.

Comments on this Year's Ranking

Change continues to dominate the laboratory industry. Among general reference labs (above), Universal Standard Healthcare, ranked number 7 last year, sold its testing business.

Similarly, Laboratory Specialists of America was acquired by Kroll-O'Gara Associates (below), and so not ranked on this year's list of Boutique/Niche laboratories.

The table below highlights public companies pursuing specific niche markets for diagnostic testing. Their high growth rates reflect the opportunity that exists within emerging niche markets.

These rankings provide a handy reference for basic market trends affecting publicly-traded laboratory companies.

BOUTIQUE / NICHE LABORATORIES

Ranking By 1998 Annual Revenue

($s in millions)

Rank	Laboratory	1998 Revenue	% Change	1997 Revenue
1.	IMPATH Inc. *(oncology).*	$56.3	+51.7%	$37.1
2.	UroCor, Inc. *(urology)*	$47.6	+44.2%	$33.0
3.	PharmChem, Inc. *(substance abuse)*	$43.2	+10.2%	$39.2
4.	MedTox *(substance abuse)*	$29.6	+3.5%	$28.6
	Total: Boutique / Niche Laboratories	***$176.7***	***+44.7%***	***$122.1***

Note: Laboratory Specialists of America sold to Kroll-O'Gara Associates, December 1998.

DIANON Systems Nails Contract To Provide AP Services To Aetna

Success in earning provider status shows that pathologists can split AP from lab testing

Several years of intense marketing and sales efforts paid off for **DIANON Systems, Inc.** of Stratford, Connecticut. Last month the publicly-traded lab disclosed a new contract with **Aetna/U.S. Healthcare**.

The pact, signed with Aetna and **SmithKline Beecham Clinical Laboratories** (SBCL), allows DIANON Systems "to provide anatomic pathology services to specialists through SBCL's sole source arrangement with Aetna/U.S. Healthcare. The agreement initially covers Aetna members in HMO plans in three states: New York, New Jersey, and Pennsylvania." DIANON also becomes a preferred provider for PPOs and indemnity plans in all states where Aetna operates.

A Major Accomplishment

For DIANON, this is a major accomplishment. The company invested significant management resources and money in marketing its services to Aetna/U.S. Healthcare during the last three years. Gaining provider status with national managed care giants like Aetna is critical to DIANON's long term strategic business plan.

Although many local pathologists consider DIANON to be a competitor for biopsy business originating around their hospital campus, DIANON's successes in gaining anatomic pathology carve-outs may eventually benefit the entire pathology profession.

Until DIANON's success with **Oxford Health Plans, Inc.** *(See TDR, January 11, 1999.)* and Aetna, managed care plans and HMOs invariably lumped anatomic pathology with laboratory testing and awarded that contract to a commercial laboratory.

Educate Contract Managers

DIANON now demonstrates that it is possible to educate ancillary contract managers and medical directors of managed care plans about the specific benefits of anatomic pathology (AP). As these managed care executives understand the differences between AP and laboratory testing, they are willing to unbundle the two services and contract for them individually.

In that regard, DIANON's achievements with Oxford and Aetna make it easier for locally-based pathology practices to argue their case and gain a carve-out of anatomic pathology. But, for local pathologists to accomplish this goal, they will have to match one element crucial to DIANON's success.

Simply put, local pathology practices will need to invest in a sales and marketing capability that will spend the time necessary to educate managed care executives about anatomic pathology. These sales and marketing people must also build a relationship with the HMO contract staff. Then, as contracts come up for renewal, the pathology practice has good prospects for split-

ting the anatomic pathology apart from the contract for laboratory testing.

Another important element supporting DIANON's multi-year effort to gain provider status is its willingness to invest in converting raw lab test data into useful clinical and utilization information. DIANON's product is called CarePath™.

Designed To Be Value-Added

At the 1998 *Executive War College*, Arthur Steinberg, M.D., DIANON's Director of Medical Management, shared the workings of CarePath. It is designed to be a value-added benefit to physicians, patients, managed care plans, and even employers.

Aetna's Chief Medical Officer, Arthur Liebowitz, M.D., actually singled CarePath out for recognition. "DIANON's unique program includes [pathology sub-]specialists who are devoted to specific organ sites and Carepath, a highly enriched diagnostic information system which represents a valuable treatment tool for our member's physicians."

Dr. Liebowitz's statement should send a message to the anatomic pathology community, as well as commercial laboratories. Information has value and can make one provider candidate more desirable than another.

Creating Attractive Product

At a time when many hospital-based pathology practices are still in a tizzy over how to respond to national pathology providers which print color pictures of the gross and micro on patient reports, DIANON Systems should get credit for creating an information collection-presentation product that two national HMOs find attractive.

This is an example of how the clinical marketplace "raises the bar" for customer service. It changes customers' expectations about what is an acceptable level of service and what is not.

Clients and regular readers of THE DARK REPORT know that we are not afraid to take strong positions about where the clinical marketplace is headed. This story about DIANON's success with Aetna/U.S. Healthcare validates several predictions we've made, both on these pages and from podiums around the country.

First, managed care companies will separate anatomic pathology from the contract for laboratory testing...but only after pathologists have invested time in helping them understand what anatomic pathology is and how it can help the HMO improve patient care.

Information More Valuable

Second, information is more valuable than raw laboratory test data. UroCor and DIANON proved that clinicians prefer patient reports with color pictures of the gross and micro over those without. Now DIANON is demonstrating that information products that offer more than basic lab test data have value with managed care plans. Oxford and Aetna are examples of two recent "buyers."

Third, number one and number two just don't happen. It requires an investment of money, dedicated staff, and management commitment to take the time necessary to effect this change in the marketplace. DIANON, along with **AmeriPath** and **Pathology Service Associates**, are examples of pathology-based companies willing to put such money on the table.

As a result, it will be these types of companies which crowd local pathology practices out of the market, at least until local pathologists decide to make similar business investments in their own group practice. **TDR**

For more information, contact THE DARK REPORT at 503-699-0616.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another laboratorian has caught entrepreneur's fever. Paul Gotcher accepted a position in April as Vice President of Sales and Marketing for **Advanced Pathology Systems, Inc.** (PSI) of San Francisco. PSI is a start-up company developing enhanced microscopy techniques. Gotcher was most recently with **ARUP Laboratories** in Salt Lake City. Gotcher earlier served as President and CEO of **Sonora Laboratory Systems** of Phoenix, Arizona.

Longtime readers of THE DARK REPORT will remember Adam Koch. While with **Coulter Corporation**, he toured Japanese laboratories and the Japanese automation show and shared his experiences in our issue of March 18, 1996. Congratulations are in order, as Koch has accepted a position with **Labotix Automation Inc.** of Peterborough, Ontario, Canada. He will serve as Director of Sales and Marketing for Labotix activities in North America.

CLMA SURVEY INDICATES ONGOING CHANGES AMONG HOSPITAL LABS

From the **Clinical Laboratory Management Association** (CLMA) comes some useful information. A survey of 500 senior-level clinical laboratory managers indicates that restructuring of hospital laboratories is widespread and ongoing. Asked about activities covering the May 1997-May 1998 period, several business strategies were dominant. During that 12-month period, 39% reported joining a network, 19% reported implementing a core lab concept, and 36% reported introducing point-of-care testing. The complete report is available through CLMA by calling 610-995-9580.

ADD TO...CLMA SURVEY

Summaries of the survey seem to validate THE DARK REPORT's theme that laboratory regionalization will be the dominant organizational form in the near future. The proportion of hospital labs joining regional networks, combined with the expansion of point-of-care testing, indicate that labs within multi-hospital organizations are finding it necessary to integrate their operations internally within the healthcare system (POC) and externally in the local healthcare marketplace (networks).

Advertising promotions are finally reaching the staid laboratory world. A new mailing from *MLO Magazine* offers subscribers an opportunity to get an "MLO Platinum Plus MasterCard." It seems to be the first affinity credit card offered to the laboratory industry. Maybe we should wait to see if we can get a "*CAP Today* Platinum Plus Visa Card!"

Abbott Laboratories secured a major plum when it signed an agreement with **Novation** (the group purchasing combination of **VHA Inc.** and **University Healthsystem Consortium**, also called UHC). The contract makes Abbott the sole-source provider of immunoassay equipment and tests for Novation's members. Term of the agreement is three years.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 28, 1999

THE PARK REPORT

UPCOMING...

- *Point of Care Testing: How One Integrated Health System Laboratory Came to Grips With Rapidly-Changing Technology.*
- *Diagnostic Industry Profile: Looking at Market Leader Roche Diagnostics.*
- *GPOs Increasingly Proscribe Laboratory Purchasing Options: How Labs Are Coping.*
- *Pathology Profession's Undiscussed Secret: Acquiring Leverage Over Hospitals' Payment Of Part A Compensation.*