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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Healthcare Buyers Move to Change System

ON PAGES 9-14 OF THIS ISSUE, you will read our Editor's cogent analysis of why healthcare buyers are taking active steps to measure the quality of services provided by hospitals and physicians, then make those measurements available to the public.

The **Leapfrog Group's** determination to survey hospitals and post the findings on its Web site is a milestone event. Those of us who've been in the healthcare industry for the last two or three decades remember all the battles against making public any type of rating of physicians and hospitals. Mostly this debate has centered around public access to disciplinary findings against "bad" doctors by licensing boards. In general, public access to data ranking provider performance has been successfully avoided.

It now looks like that is about to change. Editor-In-Chief Robert Michel makes a compelling argument that the Leapfrog Group's measurement initiative is not isolated. Comparable projects are unfolding at NCQA (for health plans) and in California (the insurer consortium that wants to measure medical group performance). This will certainly affect clinical laboratories and anatomic pathology groups, so, once again, THE DARK REPORT is first to alert our clients to intelligence and market insights of great value.

For my part, I would like to add the prediction that "consumer-concentric" healthcare will end up being the only effective solution to the renewed upward spiral in healthcare costs. However, I also predict that things will get worse before they improve, because of political ineptness in the handling of the nation's Medicare and Medicaid programs. Lab executives and pathologists should not overlook the major influence that government-funded health programs continue to exert on the entire healthcare system.

Unfortunately for all of us, the future will be bleak before it improves. First of all, Medicare bureaucrats cannot react to new technologies and social changes with innovative solutions. Their inept pricing and reimbursement policies have already damaged our healthcare system. By not allowing the free market to establish rational pricing, Medicare is distorting the true value relationship of healthcare services. Then comes the politicians, primarily Congress. Certainly our Congress is a reactive institution, unable to innovate. Thus, it remains to the private sector, both employers and consumers, to drive positive change in our healthcare system. TDR

FNA Clinic Business Becomes Part of Unilab

California will have nation's first chain of fine needle aspiration (FNA) clinics

CEO SUMMARY: Pathology has a new business model entering the marketplace. The goal of FNA Clinics of America, Inc. is to offer patients speedy access to the FNA procedure and provide referring physicians with a final diagnosis within hours of the FNA procedure. Unilab Corporation recognized the opportunity to support a value-added service and gain access to the follow-on testing.

ENTREPRENEUR RICK FERGUSON is about to find out if the health-care system is ready for the business concept of a fine needle aspiration (FNA) clinic.

Unilab, Inc., California's largest clinical laboratory, thinks enough of the concept that it purchased Ferguson's start-up company, **FNA Clinics of America, Inc.** (FNA) and will provide the capital needed to expand the business. Unilab will also provide any follow-up lab testing ordered on specimens collected by FNA.

"Each FNA clinic will be staffed by a board-certified cytopathologist and a medical technologist," stated Ferguson, who is President and CEO of FNA. "The cytopathologist will collect the specimen and also provide the diagnosis.

"Our goal is that patients have immediate access for FNA procedures in an outpatient setting that is pleasant and non-threatening," he continued. "In fact, since the opening of our first FNA clinic last year in San Diego, California, we've actually done 'walk-in' patients. Following the appointment with their physician where a visible lump was detected, they came directly to our FNA clinic to have the procedure performed.

"We believe immediate patient access will be a competitive advantage. In many cities, it frequently takes five days to several weeks to schedule and perform an FNA procedure," observed Ferguson.

"We expect speedy reporting to be another source of competitive advan-

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tage," noted Ferguson. "We have the capability to provide a copy of the final report by fax or e-mail within two hours of the procedure. We've done this in our San Diego clinic. Our experience in these situations is that both the referring physician and patient are impressed and pleased to get definitive news so quickly."

Enhanced Clinical Benefits

THE DARK REPORT has been following the development of Ferguson's concept of the FNA clinic for more than a year. It represents one new approach toward making pathology services more accessible to patients, while giving referring physicians enhanced clinical benefits.

The benefits of FNA over other procedures are known to most pathologists. First, an FNA procedure spares the patient the anesthesia, stitches, pain, and fear that accompany a surgical biopsy. Second, an FNA collection done by a board-certified cytopathologist increases the likelihood that a good specimen was collected. Third, the diagnostic accuracy rate on FNA specimens approaches 92%.

The potential market for FNA services is significant. Ferguson estimates that three million biopsies are done annually in the United States. As many as 750,000 of these biopsies could be done with the FNA technique.

More FNA Clinics To Open

Now that FNA Clinics of America has become part of Unilab, things are happening quickly at the young company. "The build-out of our second clinic in Beverly Hills is almost complete," stated Ferguson. "We are also selecting sites for clinics in Pasadena, Newport Beach, Rancho Mirage, and Scottsdale."

As both a new venture and a new business concept, there is plenty of risk. Neither Ferguson nor Unilab know if this business concept will attract enough patients to make it profitable. Nor do they know if the economics of operating the clinics will prove viable. Future decisions by Medicare and private payers about reimbursement might also work against the financial success of the FNA clinic.

However, Ferguson is taking proactive steps to demonstrate to California's managed care plans that fine needle aspiration procedures have both clinical and economic value. "We are about to launch a six-month study with a managed care plan located in Orange County," said Ferguson.

"The study's protocol will require that whenever a physician participating in the study detects a lump under the skin of the patient, he will refer the patient to the FNA clinic. The FNA procedure will be done before any radiology procedures," he explained.

Two Study Objectives

"This study has two basic objectives," added Ferguson. "First, what is the clinical accuracy of the FNA diagnosis and how does that compare to other methods? Second, what is the cost of the encounter of care that includes an FNA procedure virus one which incorporates radiology and other procedures?"

According to Ferguson, HMOs in Southern California are concerned about the spiraling costs of radiology services involved in diagnosing cancer. If a cancer diagnosis based upon an FNA procedure is more accurate, faster, and costs less money, they are interested in developing protocols that incorporate this knowledge.

It is noteworthy that an HMO has entered into a six-month study with FNA Clinics of America. It's willing to invest time and money on ways to use diagnostic testing to improve clinical outcomes while reducing the overall cost of the healthcare encounter.

The business plan of FNA Clinics of America also provides an example of how specialization will become increasingly important within the pathology profession. By advertising that only board-certified cytopathologists will do the FNA procedure and perform the diagnosis, it is expected that both clinicians and patients will recognize this benefit and select FNA over competing sources offering the same procedure.

Another element of FNA Clinics of America should not be overlooked. It intends to place a full-time sales representative in each clinical location. Since this sales rep will be paid on the volume of business he/she generates, this will be another competitive factor that will place pressure on hospitals, surgery centers, local pathology groups, and other physicians that offer FNA services.

Sign Of Change

THE DARK REPORT considers the business concept of FNA clinics to be an important sign of marketplace change. It represents the general move away from a small pathology group practice offering generalized services in favor of more specialization.

It also represents an attempt to offer referring physicians and patients a higher level of service than found in many existing markets. For patients, it is a less painful procedure done in a friendly setting—with a diagnosis that might come in just a couple of hours. For physicians, it allows them to accelerate appropriate treatment if necessary, thus improving the care they provide to their patients.

Pathologists should not discount the consumer appeal that "speed" has upon patients. If it was your wife or daughter with a suspicious lump, what would they prefer? A specimen collection in two days to a week, with a diagnosis 24 to 48 hours later? Or an FNA collection within hours of the physician detecting the lump, and the possibility of a definitive diagnosis that same day? A yes answer to the second scenario puts you in agreement with the entrepreneur and the investors who believe FNA Clinics of America can be successful.

Clinics In Seven Cities

Ultimately, it will be the healthcare marketplace which provides the definitive answers to those questions. By the end of 2002, FNA Clinics of America will be operating in at least seven cities. If the concept is working, then the continued expansion of FNA clinics will be the confirming sign. TDR

Contact Rick Ferguson at 714-427-5430.

Unilab Positioned To Get Reference Tests

IN EVALUATING THE REVENUE POTENTIAL of the business concept of an FNA clinic chain, Unilab recognized that there would be additional testing required for many of the FNA specimens.

"Typically, about three out of every five FNA specimens will require follow-on testing," explained Rick Ferguson., President and CEO of FNA Clinics of America. "These tests tend to have higher value because they include flow cytometry, molecular markers, and other types of sophisticated assays."

During the next few years, as FNA Clinics of America attains a critical mass of FNA procedures, a significant volume of reference testing will be generated. Unilab should get the lion's share of these tests. That's an attractive benefit and shows how a niche strategy has the potential to generate new flows of lab specimens.

Lab Industry Update

Court Orders Roche to Pay IGEN $505 Million in Damages

IT WAS A BIG COURT WIN for little **IGEN International**. On January 10, a jury in federal district court in Maryland decided that IGEN could terminate its licensing agreement with **Roche Holding AG**.

The jury also awarded IGEN a total of $505 million, $105 million in compensatory damages and $400 million in punitive damages. In 1992, Roche licensed biotechnology from IGEN for use in its Elecsys diagnostic product line. It its lawsuit, IGEN claimed that Roche had breached the licensing agreement in a number of ways, including "placing products based on IGEN's technology with customers other than hospitals, clinical reference laboratories, and blood banks, the only fields permitted by the agreement."

Laboratory customers using Roche's Elecsys® 1010, 2010, and E170 Systems will want to carefully track further developments in this case. The court victory gives IGEN the right to terminate the licensing agreement. Legal experts say that IGEN's case is strong and should hold up on appeal. Both Roche and IGEN state the licensing arrangement will continue until appeals have been heard. This process could take up to 18 months.

Court Loss

Officials at Roche were rather sanguine about the court loss. "It [immunodiagnostics] is not one of the most dynamic markets in diagnostics," stated Heino von Prondzynski, head of Roche Diagnostics in an interview with **Reuters**. "The growth potential is in other areas, such as genomics and proteomics. This is where we've invested heavily."

However, some financial analysts who closely track Roche Holdings were of a different opinion. "This is a huge win for IGEN and puts pressure on Roche to resolve this," stated Daniel Owczarski, an analyst at **Gruntal and Co.** "IGEN's technology is core to Roche's diagnostics business, and that is now at risk. I think we will see some serious discussion between them to come to some agreement."

Analyst Denise Anders at **Bank Julius Baer** believes that Roche diagnostic products using the IGEN patents generate between $250 and $300 million in annual sales. Contract cancellation rights were estimated to be worth as much as $2.0 billion.

Annual Sales at IGEN

In contrast, IGEN's annual sales total $31.5 million. The technology at issue is IGEN's Origen technology, which uses light to detect the targeted biological substance. Roche's major application of the Origen technology was in immunoassay analyzers.

In the short term, laboratory customers using Roche's Elecsys systems should see no changes. There is another 18 months of legal appeals ahead and both companies will engage in serious discussions on how to resolve this situation. However, it should not be overlooked that IGEN's decisive court victory gives it the upper hand as Roche looks for a solution. TDR

IMPATH Buys Tamtron In Surprise Decision

Further consolidation among providers of anatomic pathology software systems

CEO SUMMARY: In an unexpected announcement, IMPATH, Inc. announced it would purchase Tamtron Corp., the largest remaining independent vendor of anatomic pathology systems. It was just months earlier that Cerner Corporation acquired Dynamic Healthcare Technologies, Inc. and its CoPath™ product. IMPATH's goal is to implement Tamtron's PowerPath™ System throughout its network of pathology clients.

REMEMBER VICTOR KIAM? During the 1980s, he was that crazy guy seen in commercials saying "I liked the Remington electric shaver so much that I bought the company!"

It's the same story at **IMPATH, Inc.**, which announced on January 8, 2002 that it would purchase **Tamtron Corporation**. Tamtron was the largest remaining independent vendor of anatomic pathology software systems. Its PowerPath™ System is used in 350 sites throughout the United States.

"IMPATH was looking to upgrade its anatomic pathology software system and implement a single solution across all our facilities," stated Richard Adelson, IMPATH's President and COO. "The further we went into the RFP process, the more we liked the company, its people, and its products. There were compelling reasons why purchasing Tamtron was a good business decision for both our companies."

That Tamtron has been acquired is not a surprise. In recent years, larger healthcare information companies have regularly scooped up smaller companies with innovative products, but limited revenues. Tamtron fits that description and has long been seen as a likely takeover target.

What did surprise many in the lab industry was Tamtron's buyer: IMPATH. IMPATH's primary business is providing sophisticated diagnostic services to community hospital-based pathologists and oncologists. To acquire and operate a software vendor was an unexpected development.

"Within the laboratory industry, Tamtron has a good reputation," said Adelson. "That fits squarely in our strategy of enhancing patient care. As we learned about Tamtron, we could see that it had a solid base of pathology clients. Because of its size, it had limited access to the capital it needed for continued growth.

"As part of IMPATH, we can provide the resources Tamtron needs to expand its share of the market and add new features to its software products," he continued. "At the same time, PowerPath

will be implemented in all the pathology laboratories within IMPATH.

Tamtron President and CEO Steven Tablak confirmed these plans. "It was certainly unexpected that a potential PowerPath customer has become Tamtron's owner," he noted. "However, during the 'get-acquainted' process, both our companies recognized their mutual strengths and common interest in advancing the profession of anatomic pathology.

"More specifically, we both believe that pathologists must adapt and use increasingly sophisticated information management capabilities to remain effective clinical partners with the physicians they serve," declared Tablak. "This will be especially true as molecular diagnostics expands with advances in genomics and proteomics."

This statement is the key to understanding why IMPATH and Tamtron believe they make a good fit. As Tablak notes, "anatomic pathology is moving from a clinical model where the pathologist simply issues a report to the physician to one where the pathologist becomes a consultative resource to clinicians who are increasingly overwhelmed by the sheer volume of new diagnostic and therapeutic technologies. The pathology information system is the platform which will enable this shift to occur.

"That is why IMPATH's acquisition of Tamtron has synergy. Tamtron's pathology customers primarily perform pathology in support of general clinical surgery. IMPATH offers these pathologists the next level of case work-up after the referring pathology makes a primary diagnosis. These two segments are not competitive, but complementary," explained Tablak.

Adelson concurs. "Because IMPATH primarily provides diagnostic support to pathologists working in community hospitals, our strategic business need is to develop, over time, a better information bridge with our clients," he said. "We want to be able to seamlessly pass data back and forth. This would also support our services in clinical trials and tissue banking, which are currently under active development. These are logical extensions of our primary business relationship with these same pathologists and physicians.

Strong Development Team

"Here is where Tamtron gives us a unique business advantage," he continued. "They have a strong development and service team. In parallel with PowerPath's ongoing development, we want to tap these development resources to develop a sophisticated information network with our clients."

That is a long-term objective. In the short-term, IMPATH intends to operate Tamtron as a stand-alone business. After the expected closing of the sale, sometime in the next 45 days, Tamtron will continue to operate from its existing offices in San Jose, California.

IMPATH plans no major changes for Tamtron and its existing pathology customers. IMPATH will develop collaborative sales and marketing programs with Tamtron so that IMPATH sales reps can help identify and introduce prospective customers to Tamtron.

What will be most interesting to watch, however, is how IMPATH may possibly develop future capabilities that allow PowerPath to create a two-way flow of information between IMPATH and its referring pathology groups to support business activities in clinical trials and tissue banking. *(See sidebar on page 8.)* That would support additional revenues to IMPATH and its clients from those same activities. TDR

Contact Iris Daniels, Vice President, Investor Relations at 212-698-0300.

Clinical Trials and Tissue Banking Require Sophisticated Informatics

In certain areas of cancer testing, IMPATH might be described as a pathology "juggernaut." For example, in breast cancer, it's estimated that IMPATH currently holds a 30% share of the 194,000 new cases diagnosed annually in the United States.

As a business strategy, IMPATH wants to leverage its access to such high volumes of cancer cases and create additional services and products which have value to clinicians, drug companies, and biotech firms. Ways to do this include participating in clinical studies and establishing a tissue bank.

IMPATH's tissue bank is called GeneBank. The goal is to collect 50,000 tissue specimens which are linked to data about treatment protocols and outcomes. Here is where enhanced informatics and Tamtron's in-house team of developers, becomes a potential asset for IMPATH.

"As we get case referrals from our clients," stated Richard P. Adelson, IMPATH's President and COO, "we would like to have a fluid, seamless information link that would allow us to support these clients in identifying patients appropriate for clinical studies and tissue collection.

Informed Patient Consent

"Ideally, this information system would also simplify obtaining informed consent from the patient, hold relevant documents, track specimens and medical records, and provide support services necessary to participate in such activities," he explained.

With this mission, IMPATH joins the pursuit for the Holy Grail of many pathologists: the ability to get permission, then access downstream data about treatments and outcomes which can be matched with the pathology diagnosis and tissue. As blinded data, this information is expected to find ready buyers among pharmaceutical companies and biotech firms throughout the world.

There are any number of companies pursuing this Holy Grail. They range from the two blood brothers, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, to **AmeriPath**, **DIANON**, **IMPATH**, **USLabs**, and tissue banking start-ups, including **Genomics Collaborative, Aradis**, and **Tissue Informatics**. *(See TDR, April 9, 2001.)*

Strong Development Team

What gives IMPATH a strong hand in this poker game are two things: 1) the sheer volume of cancer cases it handles annually, and 2) the ongoing business relationship it has with hundreds of community hospitals. But to capitalize on these assets, IMPATH needs to develop an information management system that allows it to economically and effectively support these smaller hospitals in placing patients into clinical trials and providing tissue specimens.

If it can accomplish this, it helps itself and its clients make money through these activities. But to play the strong cards in its hand, it needs a viable informatics system which can tie these diverse data sets together and allow them to be easily managed.

Over time, IMPATH is working to create an integrated line of healthcare services which start with the advanced diagnostics performed on "difficult-to-diagnose" cancers and include clinical studies support, tissue banking activities, and a sizeable repository of data about cancer cases.

CEO SUMMARY: When 96 big corporations, employing 28 million people and spending $52 billion on healthcare, begin publishing hospital performance measurements so their employees can make informed choices, that's big news! THE DARK REPORT predicts this is a major step toward detailed measurement of the quality and cost performance of providers, including pathology groups and clinical laboratories. This trend will create new pressures for laboratories to improve their services.

EVEN HEALTH INSURERS WANT TO REWARD "QUALITY" DOCS

Provider Performance Ranking Now Hitting Healthcare System

By Robert L. Michel

FEW LABORATORY EXECUTIVES and pathologists know much about the **Leapfrog Group**. But that will probably change as a result of the Group's new initiative.

Beginning on Thursday, January 17, members of the Leapfrog Group began to show employees of their members how 241 hospitals in six regions measured up in three performance areas. The goal is to help employees make informed choices about hospitals which get better healthcare outcomes and have systems in place to reduce medical errors.

I consider this to be a significant event and urge lab executives and pathologists to follow this story. The Leapfrog Group has clout and influence. Its willingness to begin publishing data on hospital performance is an early effort to what I believe will be a major trend within the American healthcare system.

The Leapfrog Group was formed in 2000. It has 96 members which include some of America's largest corporations as well as some state and federal agencies. It was formed in 2000 because of concerns raised in the **Institute of Medicine's** (IOM) report on medical errors. The IOM estimated that errors in hospitals play a factor in between 44,000 and 98,000 deaths annually and produces more than $20 billion per year in additional costs. These findings received national media attention.

Leapfrog Group's 96 members—which include **General Motors**, **AT&T**, **General Electric**, **IBM**, and **Boeing**, among others—employ 28 million people and spend more than $52 billion on healthcare each year. To help control costs and improve the quality of care provided to its employees, the Leapfrog Group polled hospitals in six regions on three measures: 1) whether hospitals computerize doctors' orders; 2) whether specialized doctors are employed in intensive-care units; and 3) whether hospitals have extensive experience in certain clinical procedures. *(See sidebar on page 11.)*

Of the 500 hospitals offered the opportunity to participate, 241 provided information which is now available on the Web site *www.leapfroggroup.org*. Leapfrog's Web site also lists the 250 hospitals which declined to participate.

This development is remarkable. During the past ten years, attempts to place information about healthcare quality measures into the public domain has triggered rancorous and intense debate. Among the most strident opponents of such efforts have been certain hospital industry groups.

That is why laboratorians will be surprised to learn that the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) accepted an invitation by Leapfrog Group to become a formal partner one day before the public release of Leapfrog's hospital information. Maybe JCAHO was feeling the sting of a study published early this month in the journal *Quality Management in Healthcare*.

The findings of the study revealed that a hospital's accreditation status did not correlate to better quality and safety of patient care. The study specifically noted that hospitals with higher-than-average rates of deaths and complications often received favorable scores from JCAHO.

One observation by study co-author John R. Griffith, from the **University of Michigan School of Public Health**, is that the accreditation process relies almost exclusively on surveying the hospital's organizational structure and process. He noted that little weight is given to objective performance measures, such as the rates of death and unexpected complications, as well as whether the hospital is adaptable and incorporating the latest clinical procedures and new technologies.

LeapFrog Group Gathers Hospital Data

INFORMATION ABOUT THE 241 HOSPITALS that responded is now available on the Leapfrog Group's Web site. The information covers hospitals in Atlanta, Georgia; California; East Tennessee; Minnesota; Seattle/Tacoma/Everett, Washington; and St. Louis, Missouri.

During the next year, Leapfrog will collect information on up to 1,000 hospitals in another 15 regions. The effort has support from some credible organizations. "Do not send your parent to a hospital that is refusing to give this kind of information," stated John Rother, Director of Policy and Strategy for the **American Association of Retired Persons** (AARP). He added that his organization would "do everything we can to make sure that people know this information is available."

There is plenty of room for progress. Only 3% of participating hospitals have instituted computerized pharmacy ordering. About 10% have intensivists overseeing ICU care at least eight hours per day. For high-volume procedures, there was a wide range, with 31% meeting the annual requirement of 400 or more coronary angioplasties and 15% doing seven or more esophageal surgeries per year.

That is why JCAHO's willingness to partner with the Leapfrog Group is a significant event. The timing of JCAHO's announcement, one day before Leapfrog made its hospital data available to the public, demonstrates that it will become more responsive to the quality concerns of employers.

For laboratory executives and pathologists, this is a signal event in determining how the healthcare system will evolve in the next few years. I believe it is the first of what will become a major effort to identify, measure, and report on the quality performance of all categories of healthcare providers.

Pressure of Price Increases

The direct stimulus for measuring providers has been the news that healthcare prices increased during 2001 by the highest level in seven years. Data released by the **Department of Labor** show the Consumer Price Index for medical care increased 4.7% during 2001. Employer's health premium costs jumped by more than 12% last year and this fall's premium increases are predicted to be in the range of 15%.

Employers are concerned about the uncontrolled growth in healthcare costs. With the failure of the closed-panel HMO business model, neither employers nor health insurers know exactly what strategy will work best to control costs. But public pressure to reduce medical errors is fueling the interest in measuring provider quality and making those measurements public.

By no means is the Leapfrog Group's hospital "performance" database unique. I can find several other surprising and groundbreaking examples of the new focus on provider quality. In California, a consortium of the state's largest health insurers are preparing to offer a bonus to physicians who measurably improve the quality of the healthcare they provide.

Six Big California MCOs

The consortium is led by six major managed care players: **Aetna**, **Blue Cross of California**, **Blue Shield of California**, **Cigna**, **Health Net**, and **PacifiCare Health Systems**. The details of this incentive plan, called "Pay for Performance", are listed in the sidebar at right. The idea is to pay

participating physicians from a pool funded by 2% of the year-to-year increases in premiums. As part of this initiative, an independent organization would be hired to "evaluate how physician groups perform on measures using laboratory, pharmacy, administrative, and patient-survey data."

Another particularly intriguing example of measuring and publishing the quality of healthcare comes from the **National Committee for Quality Assurance** (NCQA). In November, it launched a program called the "Quality Dividend Calculator." The calculator is designed to provide employers and health plans with detailed estimates of how much money a company can save if it utilizes an accredited HMO.

The NCQA is matching epidemiological data, HEDIS scores, and cost information against research data on the costs of employee productivity and absenteeism. The result is an estimate of savings that can accrue to an employer when using an accredited HMO.

Compare Savings

Currently the "Quality Dividend Calculator" can only provide estimates of savings between an NCQA-accredited HMO and a non-accredited HMO. But later this year it expects to be able to allow employers to make direct comparisons between accredited plans.

From our studies here at THE DARK REPORT, all of these events have a common theme: to measure healthcare providers against certain quality criteria and make these measurements available to the public. Although in its infancy, this is a trend which will have significant impact on the way clinical laboratories organize themselves and deliver lab testing services.

I believe this is true for two reasons. First, on their own as a provider segment, clinical labs and pathology group practices will find themselves measured, and these measurements will be made public.

Second, clinical laboratory testing and anatomic pathology services are delivered in support of other segments of the healthcare system. If, for example, a primary care physician finds himself being measured on his diagnostic accuracy, he will begin to hold his chosen laboratory to a higher standard of accuracy, quality, and service.

California Insurers Create Provider Bonus

"PAY FOR PERFORMANCE" was announced in California earlier this month by the **Integrated Healthcare Association** (IHA), a managed care policy development group.

The objective is to create a pool of funds that would pay physicians that perform against a standardized set of healthcare measures. It would be funded by putting 2% of the increased premiums for capitated payments into the incentive pool. It is estimated that the fund could total between $100 and $150 million per year.

The IHA says "by design, this process will widen the gap between the best-performing and worst-performing groups, with the expectation that this will accelerate the consolidation or exit from the market of the worst-performing [medical] groups."

There are plenty of critics that point out that reimbursement for physicians in California is inadequate and that problem must be addressed first. But the effort to measure physician performance has already started at individual health plans. PacifiCare, for example, currently provides information to the public about how well each of its medical groups takes care of patients.

Certainly both marketplace dynamics will get the attention of lab administrators and pathologists. How long will it be before labs see this type of "customer pressure?" My guess is that direct evidence of it will become visible over the next 24 months. That's because clinical laboratories will not be the highest priority, since lab testing expenses are not the major component of healthcare spending.

How To Spot This Trend

However, for hospital laboratories in mid-sized and large hospitals, this trend will become visible as hospital administrators accelerate their efforts to acquire and implement electronic prescription ordering systems. There will also be increased efforts to hire board-certified specialists to staff critical care units.

I also think that this trend will play out in a similar way as the NCQA's accrediting of health plans. Just a few years ago, the NCQA began requiring health plans to simply report whether or not Pap smears had been performed on women. In another year, HgA1c testing was added for diabetic patients. But in subsequent years, the NCQA has increased the detail of the reporting, to actually capture test results and determine whether, for example, an individual with high HgA1c results received care appropriate for a diabetic.

Political And Social Forces

This incremental approach is how provider quality measurements will be implemented. Notice that each of the Leapfrog Group's three measurements are simply yes/no ratings. Does the hospital have an electronic prescription ordering arrangement? Does the hospital have intensivists in the critical care units? Does the hospital have a minimum volume of cases in technically complex procedures?

That is phase one. It will take a while to gather this data and get hospital administrators to build those resources into their institution. The next phase will be to measure the effectiveness of the electronic prescription ordering system, for example. It is a path that eventually leads to precise measurements of error rates and the quality of outcomes.

I posit that this trend to measure the quality of healthcare provider services is a direct result of the impact that quality management systems have had on the corporate world. The evolution from TQM and CQI to ISO-9000, Six Sigma, and Lean Management has taught corporate managers that it is: 1) possible to effectively measure all types of services; and 2) to use those measurements to improve the quality of the service while reducing its cost.

Healthcare "Buyers"

As buyers of healthcare, it is logical that corporate benefits managers want to buy healthcare services of a known quality (based on relevant measurements) and the ability to shop services based on the value package of quality at a specific cost. This means that purchasers of healthcare, including employers, payers, and patients, will be actively supporting efforts to measure the quality of care among different providers, and have these measurements ranked and made public.

It is important that laboratory executives and pathologists recognize this newly-emerging trend. A first step is to include this factor into the strategic planning process. The next step is to help everyone in the laboratory understand that measurement—and provider performance ranking—will play a growing role in healthcare purchasing decisions made by all classes of buyers of lab testing services. TDR

Contact Robert Michel at 503-699-0616.

Early-Adopter Employers Moving to "Defined Contribution" Plans

Some of America's largest corporations are offering a new type of health insurance coverage to their employees. Called "defined contribution", it puts the employee back in total control of his/her healthcare decisions and spending.

The defined contribution involves three levels of healthcare reimbursement. First, the employee receives a medical account from the employer, say, of $2,000 per year. This money is used to pay 100% of his medical bills during that year, until it is used up. Second, for the next $1,000 of medical spending in the year, the employee pays that out-of-pocket. Third, all medical expenses in excess of $3,000 during the year (in this example), are covered at 100% by the company if the patient stays in the network.

Defined Contribution Health Plan:
Key Elements

- **Each employee gets a medical account of $2,000 which can be spent on virtually any medical service.**
- **During the year, every medical and drug bill is deducted from the $2,000.**
- **Once the $2,000 medical account is spent, the employee pays 100% of the next $1,000 of health costs.**
- **After the employee has spent $1,000, the company pays 100% of all expenses, so long as the employee stays in the network.**
- **Any of the $2,000 medical account which is unspent at the end of the year is rolled into the next year.**

The employee can roll any unused portion of his $2,000 medical account into the following year. It is typical of these plans that preventative services, such as mammogram screening, are fully reimbursable and aren't counted against the employee's medical expenses.

No Deductibles And Co-Pays

Since there are no deductibles and co-pays common in fee-for-service plans and HMOs, this defined contribution health plan puts the consumer "at risk" for the full amount of the $3,000 he spends each year on medical care. It encourages employees to ask about medical fees and even shop around to minimize their costs.

Critics point out that this arrangement might encourage a patient to forego or skip certain clinical procedures in order to save money. So far, however, there is no evidence to support this claim. In fact, employers using defined contribution health plans are reporting increased employee satisfaction and decreased costs in certain areas of health services.

Last year, **Medtronic Inc.**, a maker of medical devices based in Indianapolis, Indiana, offered defined contribution plans to all of its 10,000 employees. About 1,300 signed up for the new plan. One year later, the company reports high satisfaction by employees enrolled in the defined contribution plan.

If the structure of the defined contribution plan sounds familiar, it's probably because the concept borrows liberally from the existing MSA (Medical Savings Account) model. That is another type of health coverage designed to put the consumer in control of his/her healthcare choices.

Should defined contribution health plans become popular, it will fulfill another prediction by THE DARK REPORT; that the healthcare system with the highest quality and the lowest cost will be one where consumers have responsibility to make their choices about care and spend "their" dollars directly with providers, including labs.

Lab Industry Briefs

MEDUNITE MOVES CLOSER TO ONLINE HEALTH TRANSACTION SERVICES

MEDUNITE INC.'S PLANS TO USE the Internet for claims activity and other transaction services is moving forward.

On January 17, it announced an agreement with **Bio-Reference Laboratories, Inc.** (BRLI) that will allow physician-subscribers of BRLI's *CareEvolve.com* Web portal to use MedUnite's transaction services. This includes claims submission, patient eligibility, and claims status inquiry.

Another lab industry vendor working with MedUnite is **XFin, Inc.**, a start-up company based in Carlsbad, California. X-Fin is developing an ASP-based (application service provider) software system for laboratory billing and collections. X-Fin is now implementing this product in its alpha development site, a laboratory in Southern California.

MedUnite survived the dot.com crash. It is a company founded by seven large health insurers, including **Aetna**, **Anthem**, **CIGNA**, **Health Net**, **Oxford**, **PacifiCare**, and **WellPoint Health Networks**. These companies wanted to protect the transaction-processing side of their business from companies like **WebMD** (formerly Healtheon).

SUNQUEST GETS ISO-9001 AND A NEW NAME: MISYS HEALTHCARE

IT'S NOT **Sunquest Information Systems** anymore. Effective on January 23, 2002, the company has a new name.

It's now called **Misys Healthcare Systems**. The "new" company was formed by combining Sunquest with **Medic Computer Systems** and **Home Care Information Systems**. **Misys PLC** is a British company which acquired Sunquest last year. *(See TDR, August 13, 2001.)*

Misys Information Systems also earned certification for ISO-9001 in January. This makes it one of the few healthcare information companies to have ISO certification. During 2001, **Siemens Medical Systems** of Malvern, Pennsylvania earned its ISO certification.

GENETICS RESEARCH GENERATING HUGE AMOUNTS OF DATA

IT'S OFTEN BEEN PREDICTED that the sheer volume of lab testing data expected in the future will overwhelm existing data storage capabilities of most labs.

Here's an insight into that problem. In the January issue of *Fast Company* magazine, drug researchers at **Roche Holdings**, the Swiss-based pharmaceutical and diagnostics giant, talked about the problems of managing lab data.

Each sample run on **Affymetrix Inc.'s** GeneChip generates 60 million bytes of raw data. To analyze that data requires 180 million bytes of data storage. Roche was running 1,000 GeneChip experiments each year in 1999 and 2000. According to Jiay Ding, a Roche researcher, "every six months the IT guys would come to us and say 'you've used up all your storage'."

It turns out that in Roche's Nutley, New Jersey facility, 10 researchers working with GeneChips were hogging 90% of the computer capacity designed to support the 300 researchers at that laboratory site! TDR

Cytyc versus TriPath: Pap Wars Will Intensify

Both companies are positioning themselves to compete more aggressively for market share

CEO SUMMARY: Earlier this month, Cytyc Corporation announced that it had filed Pre-Market Applications (PMA) for two new product lines to complement its ThinPrep® liquid preparation kit. This is a sign that competition between the two major vendors is about to heat up. If so, it will help lab customers negotiate better terms when they buy these products.

DURING THE NEXT 12 TO 24 MONTHS, clinical laboratories will have more choices for performing technology-enhanced Pap testing.

Armed with FDA approval for its integrated PREP® and AutoPap® System, **Tripath Imaging, Inc.** is building momentum in the Pap testing marketplace. On January 17, **Dynacare, Inc**. announced that it would implement the PREP/AutoPap solution for automating liquid preparation and computer screening of Pap smears.

Dynacare handles more than 1 million Pap smears annually in the United States and Canada, making this an important account for TriPath. It is a sign that TriPath is ready to be a credible competitor against **Cytyc Corporation**, with its ThinPrep® liquid preparation product. To date, Cytyc's dominance of liquid preparation Pap testing has been virtually unchallenged.

By Cytyc's calculation, it has now captured more than 50% of the 55 million Pap tests performed annually in the United States. In 2001, its revenues topped $153.2 million.

But Cytyc recognizes the need to move beyond its dependence on a single product, which is its liquid preparation Pap test. To diversify, it has launched three product initiatives.

Cytyc's FDA Filings

First, it acquired **Pro-Duct Health, Inc.** last fall in a $167.5 million transaction. Pro-Duct has an FDA-approved ductal lavage device used in breast cancer detection. Second, Cytyc has filed with the FDA for two products related to its ThinPrep liquid preparation test.

On January 7, 2002, Cytyc announced the filing of a Pre-Market Application (PMA) with the FDA for its new product, the ThinPrep Imaging System®. This is an interactive computer system linked to a microscope designed to "assist cytotechnologists in the primary screening and diagnosis of ThinPrep Pap Test slides." It also announced the filing of a PMA supplement to allow chlamydia and gonorrhea

testing directly from the liquid prep collection vial, using **Roche Diagnostics's** COBAS AMPLICOR system.

New Product Entry

Cytyc's interactive computer system to help with cytotech screening is aimed at countering TriPath's Automated AutoPap Screening system, which currently is the only device approved by the FDA to screen Pap slides and categorize a percentage of the reviewed slides as normal without human review (but with QA/QC).

According to Cytyc, its ThinPrep Imaging System "combines imaging technology to identify diagnostic fields of interest with automated microscope stage movements to facilitate screening these fields." However, the company has not commented on what type of sophisticated visual imaging capability may be part of this system. Since the cytology market has already rejected a microscope station with a computer-guided stage to insure the cytotech reviews the complete Pap slide, it will need to have some type of "diagnostic assist" capability to attract the interest of cytology laboratories.

Potential Patent Conflict

There is another other interesting aspect of the coming market battle between Cytyc and TriPath Imaging over "smart software" which captures a digital image of cells on a Pap slide and uses an algorithm to make a diagnosis. Because TriPath holds an extensive portfolio of patents developed by **AutoCyte**, **NeoPath**, and **Neuromedical Systems** in earlier years, some expert observers believe it would be difficult for any company to develop competing technology that would not infringe TriPath's patent estate.

THE DARK REPORT predicts that this will be a bitter fight between these two companies. Clinical labs considering one company over the other will find themselves under intense sales pressure by both companies. That competition may turn nasty in certain selling situations.

There is a precedent for this type of rancorous situation. The two companies have already sued each other in recent years over claims of patent infringement and the like. The suits were settled out of court, but there is no evidence that amicable relations exist between these two competitors.

More Choices

What will make this market cycle particularly interesting is that clinical laboratories will increasingly have choices about what "flavor" of liquid prep products and screening products they prefer. That's a sign of how the market for enhanced Pap technology is maturing. TDR

Guided-Stage Products Were Offered to Labs

DURING THE SECOND HALF of the 1990s, two companies offered products designed to help cytotechnologists screen Pap slides.

These products used a software program to help the cytotech scan the entire Pap slide and mark specific areas of the slide. The microscope stages were motorized and the software was designed to insure that the cytotech would review the entire slide.

One product line was offered by **Accumed** and was called Accel. The other was manufactured by **NeoPath** under the brand name of Pathfinder. Despite several years of sustained marketing to clinical labs, sales of "computer-guided" screening products were negligible. Both companies pulled the products from the market due to customers' lack of interest.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It may be a sign of change in how at least one national managed care company is willing to contract for laboratory services. During the last four weeks, **UnitedHealthcare** signed agreements with **Dynacare, Inc.** and **Bio-Reference Laboratories, Inc.** (BRLI). Dynacare operates labs in 21 states while BRLI's core market is Greater New York City. UnitedHealthcare is showing a willingness to expand its lab provider panels.

TRICORE LABS GETS NEW PRESIDENT

Russell W. Duke, Ph.D. is the new President and CEO of **TriCore Reference Laboratories** in Albuquerque, New Mexico. This is the laboratory joint venture owned by three IDNs and hospitals. For most of the 1990s, Duke was Director of Operations at **Sonora Quest Laboratories** in Phoenix, Arizona, which he left in 1998. Most recently Duke was President and Laboratory Director of **Kronos Science Laboratory** in Phoenix.

MALARIA PARASITE'S GENOME MAPPED BY CONSORTIUM

With 30 million letters of DNA code and 6,000 genes, it took five years and $30 million to map the genome of *Plasmodium falciparum*, the parasite responsible for malaria. A scientific team that included Britain's **Wellcome Trust**, the **Institute for Genome Research**, and **Stanford University** are preparing to publish the entire DNA sequence for this parasite. Each year this disease affects 300 million people worldwide and kills 1.5 million. By mapping the parasite's genome, researchers hope to identify vulnerabilities in the organism that could be attacked by new drugs.

MORE ON: MALARIA

THE DARK REPORT believes this achievement is another sign of how genetic technology is already changing the way different diseases are studied. Since malaria is not a significant problem in the United States, any new diagnostic and therapeutic products developed from the DNA sequence will not have much impact here. But the pattern of targeting a high-impact disease, mapping its DNA, then using this map to trigger research for diagnostic and therapeutic products is already being applied in research labs throughout the United States and the world. Expect to see more announcements about the successful DNA mapping other organisms known to cause disease.

AMERICAN HEALTH SPENDING ON THE RISE

Just-released data from the **Centers for Medicare and Medicaid Services** (CMS) show that overall spending on healthcare increased by 6.9%, to $1.3 trillion during 2000. Hospital costs rose by 5.1%, to $412 billion. This is the first percentage increase exceeding 4% since 1993. Private and public spending on healthcare averaged $4,637 per person in the United States for 2000.

Last minute add: Albert L. Nichols, M.D., founder of the famed **Nichols Institute** died in recent days. He was 67 years old and died in his Aspen, Colorado home. More in the next TDR.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 18, 2002.

PREVIEW #4

EXECUTIVE WAR COLLEGE

May 7-9, 2002 • Astor Crowne Plaza • New Orleans

Topic: Using Lab Data to Slash Hospital Pharmacy Costs and Improve Healthcare Outcomes

Once consolidation of Health Midwest s nine hospital labs was complete, the lab s strategy was to support improved clinical care, especially through better use of microbiology test data in prescription ordering. Working in concert with pharmacy and physician staff, the team achieved annual savings of $1 million in reduced pharmacy costs, along improved patient outcomes.

Full program details available soon call 800.560.6363
or visit darkreport.com

UPCOMING...

- ***Part two of The Dark Report's series "Pathology and the Law"—Potent Legal Strategies to Protect Part A Compensation***
- ***Rural Hospital Regional Lab Network Shows How Collaboration Makes a Difference.***
- ***Update on Consumers and Direct Access to Laboratory Testing.***
- ***Exclusive: How Albert L. Nichols, M.D. Influenced the Laboratory Industry.***

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