

From the Desk of R. Lewis Dark...

THE **RD**ARK **REPORT**

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



Consumers are Ripe, Low-hanging Fruit!

ONE OF THE GREAT THINGS ABOUT MY JOB as publisher emeritus of THE DARK REPORT is that I get time to think about the global implications of new developments in the laboratory industry. Unlike most of you, harried by the never-ending demands of your work day, I am at the tail end of my useful business career. That means few distractions and plenty of time to reflect upon how the business intelligence presented by THE DARK REPORT can help you change your laboratory for the better.

With that introduction, I want to call your attention to the interview with **Caresoft, Inc.** President and CEO Jagjot (JJ) Singh, found on pages 9-14. His company is first to offer a credible, secure source for patients to access and view their personal laboratory test results. **Quest Diagnostics Incorporated** is the first major lab company to use Caresoft's Web site, called *mydailyapple.com*, as the communication vehicle between it and its patients. This accomplishment alone is a significant and important event for the entire laboratory industry. It opens the door to a new era of laboratory-patient relationships.

But what I consider particularly significant is the findings of three credible Internet surveys, reported by our editor on page 13. Simply said, consumers ranked Web access to their personal lab test results as about the single most valuable health service they could get on the Internet, by a margin of as much as 80%! However, the next fact is what excited me. One of these Internet surveys reports that 25% of the people responding would be "willing to pay \$5 per month to access their personal lab test results on the Internet." Wow! That means labs can have a brand new profit center, if they will invest some time and effort to establish the services that their patients tell pollsters they want.

Talk about ripe and low-hanging fruit! Our lab test consumers have an unfilled demand (and increased expectations) that most laboratories continue to ignore. Public lab companies will be first to seize this opportunity and devote resources to the public. Hospital and private labs will follow after the fact, ceding competitive advantage and recognition for innovation to their more proactive peers. But one thing is certain. Today there exists an unserved, yet growing group of consumers who are ready to do business with a clinical laboratory that pays attention to their unique needs and wants.

Two Labs Complete IPOs, AML May be Next in Line

Recent difficulties in the stock market proved challenging for new lab stocks

CEO SUMMARY: *During the year 2000, investors liked the performance of clinical labs. When stock market woes surfaced this fall, it was not enough to dampen investor interest in Dynacare and Specialty Laboratories. Both companies funded their initial public stock offering in a difficult market. Still on deck is American Medical Laboratories. It has yet to schedule a closing date for its initial public offering (IPO).*

DURING THE PAST 60 DAYS, both **Dynacare, Inc.** and **Specialty Laboratories, Inc.** successfully funded their respective IPOs (initial public offering).

With the expiration of the SEC-mandated "quiet period," executives from both laboratories and their underwriters can now comment publicly. As it turned out, the timing of the two lab IPOs coincided with a troubled and declining stock market.

"In recent months, the stock market became an unfriendly environment for many companies hoping to place an IPO," stated Financial Analyst William B. (Bill) Bonello of **USBancorp Piper Jaffray**. Bonello's firm participated in the underwriting of both stock offerings. Bonello is a spe-

cialist in the clinical laboratory and diagnostic testing market segments.

"It is one measure of success that Dynacare and Specialty Labs were able to fund their offerings despite the troubled financial markets," explained Bonello. "There were quite a few companies which attempted an IPO during the same period and were forced to withdraw their offering because of lack of investor interest.

"From that perspective, the financial community looked favorably at both lab companies," he added. "That's not surprising, since clinical laboratory stocks were hot during most of 2000."

However, the market did not give the two lab companies carte blanche. Dynacare had hoped to raise as much

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as \$89 million, selling shares at \$13. Instead, it raised \$50 million by selling five million shares at \$10. Specialty Laboratories did better. It raised \$92 million, against its target of \$86.3 million. It sold 5.75 million shares at a price of \$16 per share.

There is definite excitement in the professional investment community about the future of esoteric and genetic testing.

"There's a number of reasons why the market responded somewhat differently to the two lab companies," Bonello noted. "First, investors found the business niche at Specialty Labs to be much more compelling. Esoteric and genetic testing is a hot topic on Wall Street. You could say that investor excitement about the as yet unproven, but highly anticipated future for esoteric testing worked in favor of Specialty Laboratories.

"Second, Dynacare is in a 'show me' situation with investors. Its routine testing yields a lower revenue per accession than an esoteric laboratory. Investors want to see Dynacare's management team deliver the revenue growth and operating profits promised in its business plan," said Bonello.

AML May Be Next

Now that Dynacare and Specialty Laboratories have completed their IPOs, only **American Medical Laboratories (AML)** remains "in the queue." It filed its registration statement in September. But no closing date has been scheduled. Company officials and underwriters involved in the AML offering are under "quiet period" rules and cannot comment publicly.

However, indications are that AML intends to proceed with its IPO. It has posted strong growth in

revenues in recent years, which is always a plus with investors. Some investment professionals speculate that AML may be responding to specific points raised by regulators at the SEC. Once these regulatory hurdles are addressed, it can proceed with its IPO.

In researching this story, THE DARK REPORT made an interesting conclusion. There is definite excitement in the professional investment community about the future of esoteric and genetic testing. That accounts for the stronger interest shown in Specialty Lab's stock offering as compared to Dynacare's stock offering.

In fact, as the following story reveals, executives at Dynacare apparently made this same observation during their "road show" with the investment community. Dynacare's activities in esoteric and reference testing generated the strongest interest from professional investors. For that reason, Dynacare's strategic business plan now places a strong emphasis on expanding its esoteric and reference testing services.

Strong Revenue Growth

This should be no surprise to laboratorians. The promise and profit potential of pharmacogenomics is getting lots of hype with the professional investment community. Any lab company with a credible business plan involving esoteric and/or genetic testing will find a warm reception on Wall Street.

Meanwhile, both Dynacare and Specialty Laboratories have successfully funded their respective war chests. Each company will be spending money to expand its presence in the lab testing marketplace. This will certainly intensify competition among the growing number of national reference laboratories.

TDR

Contact William Bonello at 612-303-5532.

Dynacare's Business Plan Includes New Direction

Company wants to expand and emphasize services in esoteric and reference testing

CEO SUMMARY: Look for Dynacare, Inc. to undergo a significant transformation. Although it will not abandon its efforts to partner with hospital laboratories, Dynacare has made a renewed commitment to expand and market itself as a provider of esoteric and reference testing. These changes are a result of the extensive strategic planning required to prepare for its successful initial public offering (IPO).

IT WAS A MAJOR BUSINESS MILESTONE when **Dynacare, Inc.** successfully raised \$50 million in its initial public stock offering.

But the Dynacare of 1999 and 2000 will not be the Dynacare of the future. THE DARK REPORT believes the extensive strategic business planning required to organize and successfully place a public stock offering has caused Dynacare to rethink its basic business plan.

The "old Dynacare" was a Canadian lab company seeking to build revenues in the United States by partnering with hospitals and acquiring regional laboratories. The "new Dynacare" will be an American-based company strongly committed to growth from reference and esoteric testing.

Change Becomes Apparent

This change becomes apparent when Dynacare executives talk about the company's future. "We're glad to have this IPO behind us," stated Osama Sherif, Executive Vice President and COO of Dynacare. "It required lots of

work and attention by our management team. Now we can concentrate on investing the funds we raised and building our business."

Sherif's statements indicate that a reinvigorated Dynacare will raise its profile in the United States laboratory marketplace. The most visible change will come from its entry into reference and esoteric testing. "During the last six months, we formed a business division called **Dynagene**. It is our genetics and esoteric testing company," explained Sherif.

"We are developing Dynagene into a company-wide center of excellence," he added. "It will also become the foundation for a number of partnerships with academic and tertiary hospitals. These partnerships will be organized to take sophisticated esoteric testing technology developed in the research labs of our partners and package it for clinical use across the United States and Canada."

Along with its planned expansion into esoteric and reference testing,

Dynacare is also reshaping its management team. During the past year, it has reorganized its executive line-up and some new additions are expected.

"We're adding management talent in sales and materials management in the coming weeks," stated Sherif. "Dynacare intends to be a tightly-managed company. We want to streamline our work flows, control costs, and become ever-tougher in our sales and marketing capabilities. Going forward, these will be attributes which will set us apart from our competition."

One major change stimulated by the successful stock offering is the move of company headquarters from Toronto, Canada to Dallas, Texas. "Dynacare's corporate headquarters is now located in Dallas and the senior executive team now works from these offices," explained Sherif.

Management Initiatives

Dynacare's hospital partnerships in the United States attracted lots of attention during recent years, but the company has quietly moved forward on a variety of sophisticated management initiatives. One such initiative involves enhanced lab test ordering and results reporting services utilizing Internet technology.

"In Seattle, we are connecting to physicians' offices with Web-based, ASP (application service provider) products," said Sherif. "We are moving deliberately and learning a great deal about the advantages and obstacles of a Web-based system for ordering tests and reporting results."

According to Sherif, Dynacare is using information products from **Atlas Development Corp.** and **LabWorks**. "In theory, such systems should carve out a lot of costs," noted Sherif. "After all, Web-based, ASP products eliminate the dedicated telephone lines to individual doctors' offices, as well as line printers and PCs. However, our project

is still too new for us to quantify the specific cost reductions we've seen from these new information services."

New Strategic Emphasis

Taken collectively, the business initiatives discussed by Sherif demonstrate that Dynacare is in the midst of fundamental change. These changes will become visible over time.

Until the IPO, the company's business strategy was clearly organized around two themes: 1) build revenue by developing laboratory partnerships with selected hospitals around the United States; and 2) build revenue by selectively acquiring regional laboratories, then using sales to expand specimen volume.

Dynacare's change in direction is based on its decision to emphasize esoteric and reference testing as an engine of revenue and profit growth. It becomes the third leg of a three-prong business strategy.

THE DARK REPORT believes that two things will result from this shift in business direction, supported by the \$50 million in new investment capital. First, Dynacare's esoteric and reference testing business will get first priority. Second, Dynacare will pour more money and more sophisticated management talent into developing new hospital partnerships and lab acquisitions.

Marketplace Influence

If Dynacare's management team can execute these business strategies in an effective manner, it may well increase its influence upon the national marketplace for laboratory testing services. In the meantime, just the fact that Dynacare has an ample war chest to fund its business activities means that it will become much more visible to lab executives and pathologists throughout North America. **TDR**

Contact Osama Sherif at 972-387-3200.

Dynagene Outlines Plans to be Newest Source for Esoteric Testing

IT'S ANOTHER MARKET VALIDATION of the important role that esoteric testing and molecular genetics will play within the clinical laboratory industry.

Dynacare's strategic business decision to make a big play in esoteric and reference testing led it to create a new business unit last year. It is called **Dynagene, Inc.**, and operates laboratories in Houston, Texas and Seattle, Washington.

"Dynacare purchased **Laboratories for Genetic Services** in late 1999," stated DynaGene President Kevin Pishkar. "Its founder and Medical Director, C. Thomas Caskey, M.D. is now Dynagene's Medical Director. Dr. Caskey and his lab enjoyed a solid reputation for cytogenetic testing, particularly the areas of prenatal diagnosis and cancer cytogenetics.

Dynagene starts with some respectable assets. It has five M.D.s and Ph.D.s. The Houston lab has a staff of 65 and the Seattle lab has a staff of 25. The Seattle esoteric lab was acquired about three years ago. Also, Dynagene has recently formed an alliance with **Identigene, Inc.**, also based in Houston. "Identigene offers services in paternity testing," explained Pishkar. "We see mutual strengths between the two companies, particularly in testing experience and capabilities.

"For 2001, Dynagene plans to introduce new technologies in molecular genetics testing," continued Pishkar. "We want to be involved in cancer diagnostics, particularly the areas of leukemia and lymphoma, prostate cancer, and breast cancer.

"The existing Dynacare system of regional laboratories generates a considerable volume of reference and esoteric testing from our existing laboratory operations," stated Osama Sherif, EVP and

COO of Dynacare. "This gives Dynagene a solid foundation upon which to expand.

"From that perspective, you can say that Dynagene's first big client is Dynacare," explained Pishkar. "Each time Dynagene sets up a new esoteric assay, Dynacare regional labs will refer those specimens to us instead of their existing send out labs.

"Dynagene is also relying on the Dynacare sales force to represent our esoteric and reference testing services," he continued. "Dynacare's national sales force was trained in Dynagene's product lines last year and is already selling to potential customers.

Research and development will be a key business strategy at Dynagene. "It was Dr. Nichols at **Nichols Institute** and Dr. Peter at **Specialty Laboratories** that paved the way for this type of business model," commented Pishkar. "They've established the template for how to collaborate in developing new esoteric assays, then successfully introducing them into clinical use.

"Dynagene wants to emulate this business model. We are funding internal research and also creating working relationships with a number of academic centers of excellence. As viable esoteric assays result from these efforts, we are prepared to bring them to market," said Pishkar.

Dynagene's business plan is based upon using the existing resources within Dynacare. It will be supplemented by selected acquisitions of specialty testing labs and internal development of specific esoteric testing capabilities. The interesting question is whether the laboratory testing marketplace is ready for another competitor. There is already intense competition for the limited volumes of esoteric specimens.

Contact Kevin Pishkar at 713-798-9500.

Number of Hospital Deals Declines Again in 2000

*44 hospitals were closed during the year,
the largest number of closures since 1992*

CEO SUMMARY: *Probably the single biggest contributing factor to consolidation of hospital laboratories is when new owners or new healthcare systems take control of a hospital. For 2000, merger and acquisition activity in the hospital industry declined in 2000 by 40%. A total of 318 hospitals were involved in the 129 deals. This decline in hospital transactions is causing a decline in new hospital lab consolidation projects.*

JUST-RELEASED DATA INDICATES that the 1990s' boom in hospital mergers, acquisitions, joint ventures, and partnerships has slowed to a crawl.

Throughout 2000, only 318 hospitals were involved in 129 individual deals. This is a decline of 40% from 1999, when 530 hospitals were part of 142 deals.

These numbers were tallied by *Modern Healthcare*, the weekly publication tracking the hospital industry. It is the seventh year that *Modern Healthcare* has done this survey. Its tabulation includes mergers, acquisitions, joint ventures, long-term leases, and other partnerships in which a change in control or equity stake occurred. The survey excludes management contracts and simple affiliations.

Important Lab Trend

Statistics about hospital deals are important for tracking one important laboratory industry trend: the number of new hospital laboratory consolidation projects initiated each year. There is a close correlation between the change in own-

ership of a hospital and subsequent consolidation of laboratory services.

THE DARK REPORT carefully tracks these numbers. Two bar charts are presented on the next page. One chart shows the six-year change in the numbers of hospitals involved in "ownership" transactions. The other chart shows the number of total transactions for each year. Now that a clear trend is visible, several observations and conclusions can be made.

OBSERVATION #1: Deal activity during the four years 1995-1998 involved no less than 627 individual hospitals per year. This means about 12% to 15% of the nation's hospitals saw a change in ownership in each year.

OBSERVATION #2: During these same four years, a cumulative total of 2,817 hospitals were involved in some type of owners/management change. This is 56% of the nation's 5,000 hospitals.

OBSERVATION #3: For the most recent six years, the cumulative total is 3,365 hospitals, or 67% of all the hospitals in the United States.

CONCLUSION #4: During the past six years, as many as two-thirds of the nation's hospitals have been involved in some form of ownership or management change. Most of these deals were health systems acquiring independent hospitals.

CONCLUSION #5: The peak deal years began in 1995. Hospital lab consolidation became a widespread phenomena by 1997. Thus, lab consolidation seems to lag ownership changes by about 18-24 months.

CONCLUSION #6: In both 1999 and 2000, the number of hospitals and the number of deals declined significantly. This is evidence that few "choice" hospital acquisition opportunities remain. Accordingly, hospital lab consolidation will be less of an industry-wide issue.

New Lab Directions

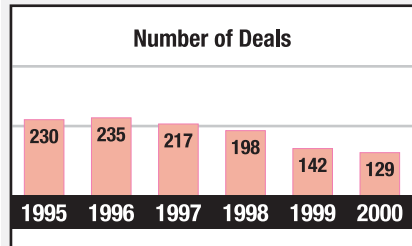
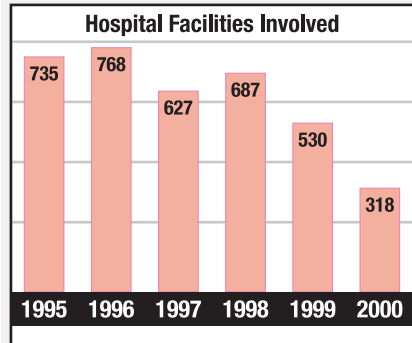
This data supports an overall conclusion that consolidation of hospital labs will diminish in importance as an industry-wide trend. THE DARK REPORT believes the strategic business emphasis for hospital laboratories is already evolving in several new directions.

The main pressures on hospital lab administrators will be to harvest year-to-year reductions in the costs associated with lab testing while simultaneously boosting the added value of lab tests. But since obvious cost savings have already been harvested (consolidation, greater purchasing volume, etc.), this will have to be achieved by more rigorous management of people and equipment, and the shrewd acquisition of new technology that boosts lab productivity.

"Shared Lab Systems"

THE DARK REPORT also stands by its prediction that there will be an increase in the number of health systems which form "shared laboratory organizations." Ever-greater volumes of specimens still reduce the average

1990s Boom in Hospital Deals Starting to Decline



Note: Includes deals completed and pending in 2000, includes mergers, acquisitions, joint ventures, long-term leases and other partnerships.
Source: *Modern Healthcare*

cost per test. Once a health system consolidates its internal hospital lab organization, its senior administrators will begin to view consolidation of several health system labs within the region to be both beneficial and desirable. Examples of this can already be found across the United States. (See *TDR*, April 17, 2000.)

It is for these reasons that the next generation of hospital laboratory administrators will be as equally skilled in management as they are in the science of laboratory medicine. Subtle pressures for sustained increases in lab productivity will reward those administrators who possess the knowledge and the skills to deliver those important gains.

TDR

Contact Robert Michel at 503-699-0616.

CEO SUMMARY: *Two recent Internet surveys revealed that consumers rank access to their personal lab test results as the number one most wanted feature in healthcare services. This is an early warning for laboratories and pathology group practices. Today's consumers have changing expectations about the types of services they want their clinical laboratory to provide. Caresoft, Inc. is one of several companies that want to capitalize on this consumer trend.*

PATIENTS WANT MORE CONTROL

Consumers Taking Active Role In Their Laboratory Testing

HEALTHCARE E-COMMERCE will have far-reaching impact on the organization of clinical laboratories and the way they deliver testing services to physicians, patients, hospitals, and payers.

There is a simple reason why this is true. The majority of information in the individual patient record which retains long-term clinical value to doctors is a patient's laboratory test data. Any company which intends to use the Internet to offer healthcare services quickly finds out that, to be successful, it must somehow include laboratory test data in its product mix.

This was certainly the case at **Caresoft, Inc.**, one of the first Internet health companies to establish a credible national presence. Earlier this year, **Quest Diagnostics Incorporated** began to allow its patients to use Caresoft's web site, *mydailyapple.com*, to access and view their laboratory test results.

THE DARK REPORT believes that Caresoft offers laboratory executives and pathologists early insights into two important trends. One trend is the arrival of companies that want to improve healthcare services through Internet-based products and services. The second trend is consumer involvement in all

aspects of their healthcare, particularly laboratory testing.

Because of its relationship with Quest Diagnostics, Caresoft is now offering "online retrieval of personal lab test results" to a potential pool of as many as 80 million people across the United States. This gives Caresoft (and Quest Diagnostics) daily experience with changing consumer needs and expectations.

"Caresoft was founded four years ago," stated Jagjot (JJ) Singh, President and CEO at the San Jose-based company. "From the start, our mission has been simple. We want to strengthen the bond between patients and their physi-

cian/patient Web sites. These were launched in April 1997 at several locations around the country, including **Massachusetts General Hospital** and the **Joselyn Diabetes Center**.

"This was a real eye-opener for us," noted Singh. "It was immediately obvious that several things were not working to the doctors' advantage. We found that physicians were open to on-line sharing of clinical information amongst themselves, one-on-one. But the two major barriers for expanding this activity are legal restrictions governing the practice of medicine across state lines and the lack of reimbursement for on-line medical services.

cian providers. In our view, it is information which 'glues' together the various pieces of the healthcare community.

"We recognized what most people in clinical laboratories already know—there are big gaps in how information is collected and flows between providers, patients, and payers," observed Singh. "Because our focus is specifically on the patient-physician relationship, we chose to emphasize services dealing with clinical information, such as lab test results."

Caresoft's interest in clinical information, and lab test results in particular, came as a direct result of its first physi-

"Those are two big reasons why most doctors are unwilling to spend time each day e-mailing their patients," he continued. "But these early experiences helped us to identify some particularly useful benefits we could contribute to the doctor-patient relationship.

"We realized that there was a way for an intermediary to become a trusted agent for both parties. The objective is to share information at the right level with the right people. And it was very obvious that the number one place to start was with clinical laboratory data. Patients not only want to know immediately when their lab test results are available to discuss with

E-Commerce Companies Recruit Lab Executives

WHEN HEALTHCARE E-COMMERCE COMPANIES decide to offer services involving clinical laboratory test data, they frequently recruit executives from the clinical laboratory industry.

At Caresoft, the position of Chief Operating Officer (COO) went to Ed Gallo. Gallo is a veteran of the clinical laboratory industry. He was Vice President of Healthcare Informatics at **SmithKline Beecham, PLC**. Prior to that, he was an executive with **Corning Medical Informatics** and **MetPath, Inc.**

Caresoft President and CEO Jagjot (JJ) Singh has a background in information management and systems integration in healthcare. Prior to Caresoft, he was General Manager of **Teknekron Healthlink Systems**, a healthcare data warehousing company.

their physician, but growing numbers of patients want to see their test report and understand what the lab test numbers mean in relation to their particular health situation," observed Singh.

Building from its experience with these early patient/physician Web sites, Caresoft decided to concentrate on improving the way clinical information was distributed and accessed by physicians, patients, and other relevant parties. Clinical lab tests were the obvious starting point because of the huge volumes of tests ordered daily.

"Quest Diagnostics was observing the same shift in consumers' needs and expectations," recalled Singh. "Working with them, we developed a way for patients to access and view their laboratory test results through the *mydailyapple.com* Web site, beginning in April 2000.

"We plan to expand the types of clinical information we handle for physicians and patients during 2001. This will include pharmacy in addition to lab test results," he added.

When implementing its lab test reporting service, Caresoft was forced to deal with two obstacles. The first involved state laws governing the ordering and reporting of medical lab tests. The second involved ethical and related issues from certain types of diagnostic tests.

State Laws Restrict Access

"It won't surprise anyone in the clinical lab world that some states have laws restricting the access patients have to their own laboratory test results," Singh commented. "These laws have a significant effect on us. Probably 14 to 16 states do not allow patients to access their test results through any mechanism other than a personal visit to their physician.

"Another serious issue involves lab tests for highly sensitive medical issues, such as cancer tests, pregnancy tests, and sexually-transmitted diseases," he noted. "Certainly these are situations where the test results are best shared in an appropriate physician/patient setting.

Complicated Issues

"In both cases, these are serious and complicated issues that need resolution," continued Singh. "More than one year has been spent working with lawyers at the state and national level to insure that both Caresoft and Quest Diagnostics handle lab test results in a manner which is highly ethical and absolutely legal.

"We have invested considerable resources into the areas of security, privacy, and confidentiality," he said. "Each is a separate challenge. We have upwards of ten specific security elements built into every aspect of our com-

pany. These include everything from user authentication to digital encryption.

"Also, to my knowledge, we are the only company in the industry to retain an outside company to do a privacy audit. **PricewaterhouseCoopers** is doing quarterly privacy audits and we post the results on our Website," added Singh.

In launching this consumer-focused service, both Quest Diagnostics and Caresoft were navigating unexplored waters. No laboratory had ever tried to offer such large numbers of consumers the opportunity to access their personal lab test results. Moreover, consumers were unaware that it might even be possible to gain direct access to their lab test results.

Concept Is Validated

"Even we were surprised at how readily patients responded to the opportunity to view their own test results," marveled Singh. "Internet polling and consumer focus groups had validated this concept, but the reality certainly outpaced our expectations.

In fact, Singh brings up a point which should be of high interest to both laboratory executives and pathologists. "Even as recently as nine months ago, consumers did not know that a service like this was even feasible. When many Internet polls asked 'What healthcare services do you want on-line?', it would list ten items, none of which included lab test results.

"About four months ago, three different surveys were conducted and each asked this question 'Do you want lab test results?'," added Singh. "In two of the three surveys, access to personal lab test results ranked #1 with consumers. It ranked #3 in the remaining survey.

"Moreover, in one poll, consumers ranked getting lab test results higher than getting e-mail from their doctor,"

he noted. "Moreover, 25% of the population said they were willing to pay to have access to their personal lab test results! This is certainly compelling evidence that consumers' expectations are changing in a big way."

Physician Communications

Making lab test results available to patients is only part of the implementation project. The way Caresoft communicates with physicians is equally important. "As we launched this service, we did pilot projects in a number of regions to study and understand how consumers and physicians would react to this service," said Singh. "We've learned that it is equally important to involve the doctors and keep them in the loop.

"Our research during these pilot studies indicated that as many as 70% of the doctors wanted to offer this type of service to their patients," noted Singh. "Doctors could see two benefits. First, it would save time in their offices because it would reduce the number of incoming and outgoing calls to find out whether lab test results were back and what they were. Second, it established a stronger bond with the patient and demonstrated that the physician was providing more services to the patient."

Acceptance By Physicians

According to Singh, both consumers and physicians have embraced the concept of direct access to personal lab test results because of evolving expectations in the marketplace. "Nationally, we see consumers shifting from a traditional position as a reactive and passive patient. Increasing numbers of patients are becoming proactive. They are taking an active role in their personal healthcare and that of their family members. The weapon they are using is information. It's just that simple.

Recent Internet Surveys Show Consumers Have High Interest in Seeing Their Personal Lab Results

CONDUCTED SINCE THE MIDDLE OF LAST YEAR, three individual Internet surveys provide surprising insights into consumers' readiness to access their personal laboratory test results through the Internet.

On October 17, 2000, **Harris Interactive** (a division of the **Harris Poll**) and **ARiA Marketing** released the results of a "Healthcare Satisfaction Study" done at the request of **iMcKesson LLC**.

When asked what Internet-based tools they would like to manage their healthcare, the answers were as follows:

- 83% of respondents want their lab test results to be available online.
- 84% want their doctors to send them electronic alerts (e.g., time for a flu shot).
- 80% want to receive personalized medical information from their physician after an office visit.
- 69% want online charts for monitoring chronic conditions.

An Internet study released May 2, 2000 by **Gomez Advisors, Inc.** listed "look up my lab results" as the third most requested Internet service, trailing only "e-mail my own doctor" and "e-mail national medical experts."

Source: Cyber Dialogue, 2000 Health Portal Study

"We are in the early stages of a profound shift in healthcare practices," noted Singh. "Traditionally, the healthcare system reacted to elementary data. This is no longer adequate. The need is for 'value-added' information which empowers patient and physician alike. Laboratories, as 'data-producing factories,' must react to this shift if they are to succeed.

"More specifically, it will no longer be adequate to print a numeric value of, say 240, on a test result report and

A third study was done by **Cybercitizen Health** and announced last fall. Two charts from this study are reproduced below. Table one shows that 63% of consumers participating in the survey want online "lab results with an explanation of findings." Table two shows an even more interesting fact. 25% of these consumers are willing to pay \$5 per month for "lab results with explanation of findings."

Table 1: Percent of Intensive Online Users

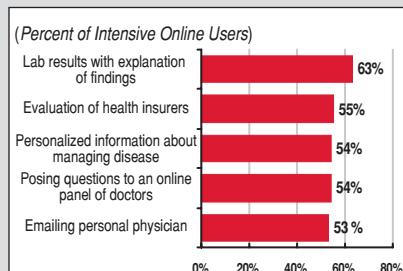
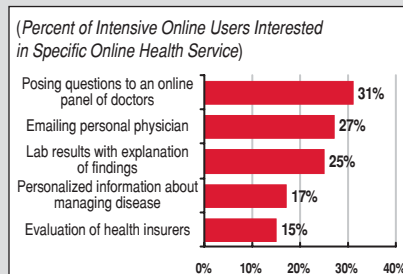


Table 2: Willing to Pay \$5 per Month for...



leave it to the doctor and the patient to determine what that means and how to respond to it," predicted Singh. "The market will soon want another six or seven layers of value added to that raw data to make it an easy-to-use service for consumers. Our role is to help laboratories and physicians boost the value of lab test information to increase the way it benefits their patients."

It is important to understand that lab test result reporting is only one service that Caresoft is developing. The

company is actively moving forward with services involving pharmacy, clinical trials, payer-provider-patient communications, and biotechnology. This is consistent with its mission of enhancing the patient-provider bond.

More Lab Relationships

Now that Caresoft has demonstrated the viability of its laboratory test results reporting service targeted at patients, it is developing business relationships with more clinical laboratories. "We wanted to spend the time to make sure we understood every part of the value chain and the business model with a partner such as Quest Diagnostics, but it is our intent to offer this service to any and all clinical laboratories," declared Singh.

"Agreements with other laboratories are in various stages of negotiation," he added. "As agreements are finalized we have the capability to swiftly get our new laboratory customers on-line with their physicians and patients. It requires two things.

"First, we need to connect our technology to the laboratory so the data can be transferred in a secure manner. Second, the lab simply needs to announce to its physicians and patients that the service is available," explained Singh. "We can accomplish both items in a matter of weeks and we intend to replicate it across other sites."

Evolving Pricing Model

Caresoft currently has sales reps in the field calling on potential laboratory clients. The pricing model is evolving and closely tied to volume. "We've driven the cost down to a very low level because we want it to add value for the laboratory and its patients and physicians. Labs who understand the value chain and how to use this to strengthen their relationships with doctors and consumers will be fastest to adapt this to their strategic business plan."

Caresoft and similar healthcare e-commerce companies represent both an opportunity and a threat for the laboratory industry. As an opportunity, such companies represent business tools for progressive lab executives to use to increase the added-value benefits of the raw lab test data they generate in the laboratories.

As a threat, these companies represent the competitive market forces which will create new groups of winners and losers from today's existing laboratory organizations. Labs that respond to the healthcare system's demand for enhanced laboratory test information products and services will prosper. Labs which are slowest to react will find themselves at a competitive disadvantage.

Another Wild Card

This is occurring because consumers (as patients) and physicians are changing. As users of laboratory testing, they are changing their beliefs about what constitutes a high-quality, high-service clinical laboratory. As lab users come to expect higher levels of services, laboratories must respond with services that meet and exceed the higher expectations of their patients and physicians.

The arrival of Caresoft and similar healthcare e-commerce companies is evidence that the marketplace is receptive to enhanced lab testing services, and willing to pay for them if necessary! **TDR**

Contact JJ Singh at 408-990-4718.

JJ Singh Scheduled to Speak at the EXECUTIVE WAR COLLEGE

JJ Singh will discuss the growing role of the consumer in laboratory testing at this year's EXECUTIVE WAR COLLEGE, scheduled for Tuesday-Wednesday, May 8-9, 2001 at the Hyatt Regency Hotel in Cincinnati. Call 800-560-6363 for information or to register.

HIPAA Hits Radar Screen, Expected to be Expensive

Hospitals may spend up to \$22.5 billion to comply with HIPAA in next five years

CEO SUMMARY: *HIPAA is beginning to generate controversy as implementation dates are announced. The American Hospital Association is painting a black picture, despite protestations of certain experts. Meanwhile, managed care companies are finding it difficult to come together and form a unified lobbying effort. All the signs point to a rancorous public debate on important healthcare issues.*

EXPECT LOTS OF TURMOIL and debate in the coming months to surround the implementation of HIPAA (Health Insurance Portability and Accountability Act of 1996).

On the hospital front, a study done by **First Consulting Group** of Long Beach, California estimates it will cost the nation's hospitals as much as \$22.5 billion to comply with HIPAA requirements during the next five years. The **American Hospital Association** (AHA) paid for this study.

Even as the AHA released the findings of its study and triggered a wave of criticism, two of the nation's biggest health insurance groups disclosed that merger plans were off. The **Health Insurance Association of America** (HIAA) and the **American Association of Health Plans** (AAHP) had hoped to join forces.

The combination of the two associations would have created a powerhouse lobbying group. With a budget of \$45 million and 200 people, the combined organization would have

been quite influential in shaping HIPAA guidelines, as well as federal legislation dealing with prescription drugs, patients' rights, and similar healthcare issues.

HIPAA Implementation

Pressures to implement HIPAA requirements will intensify as the months pass. Laboratory executives and pathologists will increasingly devote more time to HIPAA-related issues.

Events surrounding the AHA study and the collapse of the HIAA/AAHP merger demonstrate what little consensus exists within the healthcare industry. Critics of the AHA study, for example, believe it overstates the true cost of compliance. They believe HIPAA is an opportunity to improve the information services segment of healthcare and so should be viewed as an opportunity to enhance productivity, not as a "dead" cost of compliance.

In any event, HIPAA implementation deadlines will now place ever-growing pressure on labs and other providers.

Lab Industry Briefs

DNA DIAGNOSTICS MARKET GROWTH TO BE DOMINATED BY PCR TECHNOLOGY

FOR THE YEAR 2000, total DNA diagnostic technology sales were estimated to be \$517 million. By 2005, this number should increase to \$771 million, a growth rate of 8.4% per year.

This is the conclusion of Laura Roth, author of "The DNA Diagnostics Market," a study recently released by **Business Communications Company**. The sales figures represent revenues generated by manufacturers of DNA-based diagnostic tests.

For laboratory executives and pathologists tracking the development of diagnostic tests based on DNA technologies, this study provides some revealing insights. Roth points out that PCR-based diagnostics currently comprise \$394 million of year 2000 sales. With a 76% market share, PCR technology is dominant.

The remaining 24% of the market is split primarily among fluorescence in-situ hybridization (FISH), hybrid capture, line probe assays (Inno-LiPA™), RFLP, and sequencing. Molecular and cytogenetic testing for various diseases totaled \$66.3 million in 2000 and will grow by 10.3% per year, reaching \$103 million by 2005.

Roth believes that the brightest future for DNA diagnostics is the area of SNP (single-nucleotide polymorphism) analysis. SNP testing will make it possible to look at genetic variations within individuals to determine their affect on cancer, disease, and therapeutic options. She links SNP testing to the evolving concept of "personalized medicine."

The practice of personalized medicine will require advanced microarray

technologies that permit genetic analysis, for example, of individual tumors, even down to individual cancer cells.

But test microarrays are currently priced in the range of \$45 to \$90 per unit. Roth believes such price levels limit the market. She predicts that, when unit prices fall below \$10 per unit, the market will expand rapidly.

Roth also made an observation on a segment of medicine often overlooked by laboratory administrators. Roth points out that the demand for genetic counseling services grew 32.8% between 1996 and 1999. She stated, "The increase in the number of genetic counselors may reflect the increase in demand for people educated and trained to discuss risk assessment and genetic testing results."

Finally, Roth notes that research and development efforts in DNA diagnostics technology are widespread and well-funded. There are at least 50 to 60 companies, mostly in the United States, which are developing DNA diagnostics products.

KAISER RENEWS AUTOPAP CONTRACT AFTER TWO YEARS OF DELAY

IT'S BEEN MORE THAN TWO YEARS since **Kaiser Permanente** first inked a national agreement to acquire and use the automated Pap smear screening technology of **Tri-Path Imaging, Inc.** (formerly **Neopath, Inc.**).

Last month it was announced that Kaiser Permanente had "renewed its national pricing agreement" and was accepting delivery of four AutoPap® Systems in its Northern California Laboratory.

This is a major milestone for TriPath Imaging. In the fall of 1998, two nationally-respected Medical Directors, after evaluating the AutoPap System, declared they were ready to install AutoPap Systems throughout their national laboratory organizations.

Within weeks of each other, both Edward A. Kaufman, M.D., National Medical Director for **SmithKline Beecham Clinical Laboratories** (SBCL) and Gene A. Pawlick, M.D., Director, Regional Laboratory for Kaiser Permanente Northern California, decided to incorporate AutoPap Systems into their national Pap smear screening programs. (*See TDR, November 9, 1998.*)

In total, the two companies performed about 6.4 million Pap smears annually. This represented about 12.5% of the 55 million Pap smears done annually in the United States. It was an auspicious moment for Tri-Path Imaging and its economic future.

However, the hoped-for success never materialized. Within 90 days, **Quest Diagnostics Incorporated** announced that it would purchase SBCL. Medical Directors at Quest Diagnostics decided to emphasize **Cytoc Corporation's** ThinPrep® technology. Consequently, SBCL never became a TriPath customer.

At Kaiser Permanente, it was a different story. TriPath Imaging actually delivered AutoPap Systems to Kaiser. But the instruments were turned back at the loading dock. Few details have been disclosed about the situation, but apparently internal corporate agendas above the laboratory level blocked the move to AutoPap technology.

This situation has been one of the more interesting "unwritten" stories in the laboratory industry. In 1998, TriPath Imaging was poised to place its automated Pap smear screening sys-

tems in two of the most respected laboratory organizations in the United States. At that same time, Cytoc was struggling to gain market acceptance for its ThinPrep technology.

Now, just 24 months later, Cytoc Corporation has captured a sizeable share of the Pap smear testing market. It is arguably the "big dog" in the cytology marketplace. In contrast, TriPath Imaging has only a small portion of the market and is the company in the "come from behind" position.

MODEL CORPORATE CITIZEN PLEADS GUILTY TO CRIMINAL CHARGES

ON DECEMBER 18, 2000, **LifeScan Inc.**, a division of **Johnson & Johnson**, pled guilty to federal criminal charges related to the marketing of its SURESTEP® Blood Glucose Monitor.

The instrument is a home testing device used by diabetes patients to self-monitor blood sugar levels. A version called SURESTEP PRO is used in hospitals. Lifescan will pay a fine of \$29.4 million and additional restitution of \$30.6 million to the government.

There were two separate problems with the SURESTEP instrument systems which could generate error messages or false low results in certain situations. The government's case was that LifeScan, which introduced the device in 1996, knew of these defects in advance of applying to the FDA for marketing approval, but that it failed to disclose them in submissions and did not inform customers of the problems.

It is known that at least 61 patients suffered injury associated with the device, including some hospitalizations. The plea bargain agreement does not mention any deaths. LifeScan fixed both problems by early 1998 and offered free replacements to all affected customers.

INTELLIGENCE

LATE & LATENT
Items too late to print,
too early to report



In Cincinnati, the CHIN (community healthcare information network) effort of the mid-1990s has evolved into **HealthBridge**, a “secure, private Intranet that provides physician access to hospital clinical records, insurance eligibility, e-mail, and on-line medical reference material.” Three of the larger health systems in Cincinnati, representing 20 hospitals, are participating. In recent months, the first hospitals went live with their connections to the HealthBridge Intranet. Clinical laboratory results, radiology, and transcriptions are the first three clinical segments offered by HealthBridge.

ADD TO: HEALTHBRIDGE

When the *Executive War College* convenes in Cincinnati on May 8-9, 2001, clinical pathologists and executives working on the HealthBridge project will be on hand to tell how the system works and how local doctors are using it to access lab test data. HealthBridge has the capability to supplant many traditional lab functions in test results reporting, data storage, and data access.

MAYO CLINIC DROPS AETNA CONTRACT DUE TO PAY PROBLEMS

Here's another sign that providers are regaining some degree of power against managed care companies. On Friday, December 1, 2000, **Mayo Clinic** sent a letter to its patients stating that it was dropping **Aetna USHealthcare**, effective January 1, 2001. In the letter, Mayo Clinic said Aetna was neither paying claims accurately nor on time. Only about 2,000 of the 300,000 patients seen yearly at the Mayo Clinic will be affected by this decision. But the action by Mayo is seen as a further setback for Aetna, the nation's largest, and maybe the most beleaguered, health insurance company.

MORE ON: MAYO & AETNA

Aetna's reputation among healthcare providers is now a critical business problem. The company developed a reputation as a hard-nosed negotiator when contracting with physicians and hospitals. To change this reputa-

tion, it spent much of the last year mending fences. This has included removing many arbitrary restrictions affecting the freedom of physicians to refuse to participate in specific Aetna insurance plans. Within the clinical lab segment, there has been no observable change yet in Aetna's clinical laboratory contracting practices.

HOSPITAL PRICES CLIMB FASTEST SINCE 1995

Hospitals must have been anticipating the increased funding for Medicare passed by Congress last month. Wholesale prices at acute care hospitals are climbing at their fastest rate in five years. The price increase was .07% for November, matching the .07% increase in October. This is the biggest jump since October 1995, when the index climbed 1% for the month. The Producer Price Index is calculated by the **U.S. Labor Department**.

***That's all the insider intelligence for this report.
Look for the next briefing on Monday, February 5, 2001.***



UPCOMING...

- ***Operational Excellence: Secrets of Increased Productivity in Hospital Labs.***
- ***Diagnostics Companies Grapple with the Internet: Some Surprising Facts.***
- ***Why Industry Is Hiring Growing Numbers of Anatomic Pathologists.***