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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

The Reality of Wide Scale Biological Attacks

MY TOPIC TODAY CONCERNS THE POTENTIAL FOR A BIOTERRORIST ATTACK to infect Americans on a vast scale. As most know, health authorities are struggling to explain new cases of pulmonary and cutaneous anthrax in victims with no obvious connections to contaminated mail or the post office. I consider this to be evidence that the infectious potential of biological agents like anthrax is not well understood and may be extraordinarily more potent than originally believed.

Let me add to this fact a story published in the October 22, 2001 issue of the *Wall Street Journal (WSJ)*. Found on page one and titled "The Military, Microbes, and Secret Tests Using the U.S. Public," it chronicles military experiments upon unknowing American citizens using biological agents. The most chilling test took place on September 20-27, 1948. Cruising in the Pacific Ocean, just off the city of San Francisco, a navy mine-layer with special equipment pumped an aerosol cocktail of *Serratia marcescems* and *Bacillus globigiin* into the foggy air. Military experimenters considered these bacteria to be harmless to humans. The bacteria were coated with fluorescent markers of zinc-cadmium-sulfide to help detect the results. The *WSJ* noted "based on results from monitoring equipment at 43 locations around the city, the Army determined that San Francisco had received enough of a dose for nearly all the city's 500,000 residents to inhale at least 5,000 of the particles."

Without commenting on other aspects of this particular Army experiment on unsuspecting American citizens, I would like to make two observations. First, in 1948, using technology considered crude by today's standards, our military was able to blanket the 49 square miles of San Francisco with enough infectious agent to expose virtually every resident! Second, in today's world, technology to create fine aerosols is highly advanced and small enough to fit inside a standard commercial helicopter or small pleasure craft. If I add these two facts together, it certainly seems that a well-planned bioterrorist attack has the potential to succeed on a scale heretofore undiscussed by our nation's leaders.

Conclusion? I believe the threat is immense and it's no coincidence that federal officials want to acquire 300 million doses of smallpox vaccine, enough for the entire population of the United States. My recommendation is that, because the nation's clinical labs will be first to see evidence of such attacks, they should take preparations for bioterrorist acts very seriously. TDR

Labs in NY & Wash, DC Get Anthrax Test Orders

Publicity about anthrax exposure generates test requests at local labs

CEO SUMMARY: In both New York City and Washington, DC, widespread publicity about exposure to anthrax generated a steady volume of test requests. Clinical labs in both cities adopted similar management strategies to deal with the sudden public interest in anthrax testing. One common step was to send detailed information about anthrax testing to physician clients, source of many anthrax test requests.

CLINICAL LABORATORIES in both New York and Washington, DC found themselves doing lots of anthrax tests in recent weeks.

"The first anthrax cases in Florida didn't cause much of a reaction around Washington, DC," said Jack Bergstrom, Executive Vice President at **American Medical Laboratories, Inc.** (AML), located in the Washington suburb of Chantilly, Virginia. "But that all changed following the discovery of anthrax in the letter mailed to Senator Thomas Daschle's office (D-South Dakota) on October 15.

"Beginning on that date, we began to see a regular flow of specimens with a request by the referring physicians to rule out anthrax," he continued. "There was also a noticeable increase in calls from the public requesting information about anthrax testing."

AML's experience mirrors that of most labs offering lab testing services in both Washington, DC and New York. Concerns about anthrax sparked three specific responses from the general population.

One, labs began to get a steady volume of phone calls from the public requesting information about screening tests for anthrax. Two, office-based physicians began referring specimens to labs accompanied by a request to rule out anthrax. Three, certain government agencies and private companies contacted labs to request that designated staff members be screened for anthrax.

"Inquiries and requests for anthrax testing picked up immediately after the

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news of the anthrax-infected NBC assistant," noted Elkin Simson, M.D., Medical Director of the Center for Clinical Laboratories at **Mt. Sinai Medical Hospital** in Manhattan. "In particular, a number of patients began showing up at our emergency department.

Lab Scheduled Extra Hours

"Our laboratory responded by extending the hours that we would do testing," he said. "In fact, our microbiology laboratory was temporarily staffed on a 24/7 basis during the initial phase of this concern.

"We sent information about anthrax to the clinical staff and it was posted on the Web sites of both the health system (*www.msnyuhealth.org*) and the medical school (*mssm.edu*)," continued Dr. Simson. "Specimens come to us from the emergency department, the hospital, and affiliated clinics. Clinical specimens come to our lab. Environmental specimens are referred to public health labs."

Although anthrax-contaminated sites were generally found in New York City and New Jersey, residents on Long Island also had concerns. "When the news broke about the discovery of anthrax in Tom Brokaw's office at NBC, the very next day we got cultures from doctors asking us to rule out anthrax," stated Pat Lanza, President of **Sunrise Medical Laboratories, Inc.** in Hauppauge, New York.

Meetings With Lab Staff

"The interesting thing that happened next was that some of our employees became concerned about potential exposure," she added. "We conducted a series of meetings with each department and reviewed the points about anthrax testing and safety procedures. We also discussed procedures for handling mail that appeared suspicious."

In the days following the initial disclosures about anthrax discoveries in New York and New Jersey, Sunrise fielded a call from an occupational medicine facility. "They inquired about the details of testing up to 500 employees of a local post office," noted Lanza. "Days later, that number was raised to 2,500 employees."

Even as more anthrax-contaminated sites were identified in New York and New Jersey, the nation's attention quickly shifted to Washington, DC. In recent weeks, the number of contaminated mail rooms and offices in government buildings climbed steadily. Residents in DC, already living in a high-profile target for terrorism, began keeping close tabs on the anthrax situation.

Steady Flow Of Phone Calls

"Because government buildings are likely targets for terrorists, our lab's proximity to the nation's capital puts us close to anything that happens," stated Chuck Krambuhl, AML's Executive Vice President of Employee and Client Relations. "Not only did we start getting a steady flow of phone calls from individuals with questions about anthrax testing, but patients were walking into our service centers and asking phlebotomists to educate them about anthrax testing. We also discovered that calls about anthrax were coming into different departments of the laboratory.

"Once we recognized this situation, our management strategy was to create an 'anthrax information center' and direct all requests to this newly-designated team," explained Krambuhl. "We changed the telephone prompt for callers to the lab, giving them an option to switch directly to our anthrax information resource center. Couriers and staff at the patient service centers referred questions to this phone resource. We also sent a special 'Lab Alert' to our clients, informing them of basic procedures for ordering anthrax tests."

In response to the anthrax contamination, some government agencies and private companies contacted AML to arrange anthrax screening for their staffs. "We've cooperated in these efforts," noted Bergstrom. "In some cases, several hundred people were screened.

"Normally, this is a category of lab testing which is typically quiet," added Bergstrom. "Operationally, our normal operating procedures allowed us to handle this unplanned increase in testing in a timely fashion."

Calls Come Into LabCorp

At **Laboratory Corporation of America, Inc.**, the situation has been similar. "We've certainly gotten inquiries and calls requesting information about anthrax," stated Pam Sherry, Senior Vice President of Investor and Public Relations at LabCorp.

"We sent detailed information to our clinician and staff about anthrax testing and employee safety. Like many other labs, we test only clinical specimens. Environmental specimens need to be sent directly to the appropriate public health laboratories," she noted. Sherry also confirmed that LabCorp has done screening programs for public and private organizations that had reasons to request such testing.

Community Resource

The bioterror attacks using anthrax reveal how quickly laboratories become an important resource for the affected communities. The experience of clinical laboratories in New York City and Washington, DC demonstrates that most labs already have in place the basic management procedures necessary to react effectively to this level of biological attack.

At the same time, the reality of this rather modest bioterror attack forces laboratories throughout the United States to contemplate a more fearful question: what happens if there is a wide-scale biological attack, affecting thousands of people? Can individual laboratories effectively respond? TDR

Contact Jack Bergstrom and Chuck Krambuhl at 800-336-3718; Elkin Simson, M.D. at 212-659-8181; Pat Lanza at 631-435-1515; and Pam Sherry at 336-436-4855.

Labs Beware: Coming Soon Home Tests for Anthrax

PREDICTIONS ARE THAT RETAIL STORES will have over-the-counter test kits for Anthrax as early as Thanksgiving.

These are non-invasive test kits to be used for determining whether anthrax is present in the environment, such as in a letter or in an air conditioning system. As a non-invasive test, these kits are exempt from most government regulation.

Vital Living Products, Inc. of Matthews, North Carolina may be first to market with such kits. Already, **Ace Hardware Corporation** has announced it will sell the $25 kit in its nationwide chain of 5,100 stores. Other national retailers are also expected to stock the kits.

Nationwide surveys indicate that as many as half the people polled would buy a home test kit for anthrax. Because these types of kits are designed to detect for the family of Bacillus bacteria (of which *Bacillus anthracis* is a member), some experts point out that a high number of false positives can be expected.

THE DARK REPORT advises that clinical laboratories should maintain a watchful eye on how consumers respond to the availability of home test kits for anthrax. Worried consumers, after using their home test kits, will definitely include clinical laboratories in their search for information and follow-up testing.

New Legal Trends Now Affecting Pathologists

Here are four developing legal trends that bear watching by pathology groups

CEO SUMMARY: During the past 36 months, quiet and significant changes have occurred to certain legal issues involving anatomic pathology services. The resulting new environment exposes pathology groups to different types of threats, particularly to their sources of income. This intelligence briefing launches a new series concerning the law and pathology.

WITHOUT MUCH ATTENTION or fanfare, specific legal issues affecting anatomic pathology services have evolved in new directions during the past 36 months.

THE DARK REPORT identifies four specific areas where the marketplace is in transition and pathologists may be at risk if they fail to recognize and respond appropriately. "Pathologists should be aware that a number of developments during recent years have created new risks for their group practices," stated Richard S. Cooper, Attorney and Partner at **McDonald, Hopkins, Burke & Haber** in Cleveland, Ohio.

"In some cases, it involves trends to reduce or even eliminate traditional sources of compensation for pathology services," he said. "In other cases, long-standing and accepted legal standards are changing and evolving in directions that create a different type of risk exposure for pathologists."

Four legal issues top Cooper's list of concerns. In future installments, THE DARK REPORT will provide more detailed assessments of each. As an introduction, Cooper categorizes these four trends in the following manner.

Attack On Clinical Fees

"Top threat on my list is the widespread action by hospitals and payers across the country to reduce or eliminate compensation for clinical pathology services," stated Cooper. "Obviously, this involves Medicare Part A agreements between pathology groups and hospitals. But it goes beyond that.

"There is sustained pressure by all classes of payers to eliminate the professional component for clinical pathology services," he continued. "This despite successful lawsuits which did affirm the validity of these professional medical services and the right of pathologists to bill for them.

"The second trend involves payer's actions that limit the number of pathology and laboratory providers for outreach medical services. This principally occurs in two ways," explained

Cooper. "One way is to limit the panel of pathology and lab providers. Another way is to offer reimbursement at levels that only larger labs are able to accept. Smaller anatomic pathology (AP) groups won't pursue contracts offering minimum reimbursement for AP specimens. In my opinion, this represents a sustained threat to the long-standing access pathology groups have had to patients in their community.

> ***"Pathology groups should recognize that the longer they delay before taking active steps to comply with HIPAA requirements, the greater the risk."***

"My third important issue is HIPAA compliance," noted Cooper. "Right now, payers are ahead of the industry in their compliance efforts. Next would be hospitals and health systems. Smaller labs and anatomic pathology groups are lagging. Pathology groups should recognize that the longer they delay before taking active steps to comply with HIPAA requirements, the greater the risk.

Pressure To Consolidate

"Fourth on my list of key legal issues is pressure by hospitals and integrated delivery networks (IDN) to drive consolidation among pathology group practices affiliated with individual hospitals in the IDN," he said.

"This pressure and interference has many forms," continued Cooper. "It can range from pressuring independent groups to consolidate to actually dictating how the consolidation should be accomplished and which individual pathologists should be retained in leadership positions."

Cooper's list of high-priority issues is rooted in the experience he and his colleague gain in advising their pathologist-clients. "Geographically, we work with pathology groups from almost every region of the United States," noted Cooper. "That gives us first-hand insights into which legal issues are regional in nature and which have national implications."

Business Strategies

THE DARK REPORT recommends that pathology groups take time to understand these trends and develop effective business strategies to counter them. In upcoming issues, THE DARK REPORT will address each of the four legal trends identified by Cooper in more detail.

These briefings will identify the factors defining the trend and explain how legal practices have changed. Also, effective responses and strategies already in use by top-performing pathology groups to deal effectively with these threats will be discussed, along with their pros and cons.

Preparation is one strategy that Cooper recommends. "At a minimum, I see lots of pathologists leaving lots of money on the table," he declared. "One reason is because the opposition is well-prepared and holds the money. But the other reason is that many pathologists do not prepare themselves effectively before entering into these types of negotiations. They are not good advocates for themselves." **TDR**

Contact Richard S. Cooper at 216-348-5438.

UPCOMING

To provide in-depth analysis on these important legal trends in anatomic pathology, **THE DARK REPORT** is launching an ongoing series. The next installment will address the trend of eliminating reimbursement for clinical pathology professional services.

Lab Industry Briefs

ROCHE DIAGNOSTICS POSITIONED TO SERVE PUBLIC HEALTH LABS

HEIGHTENED CONCERNS over bioterrorist attacks have accelerated plans within the public health lab sector to acquire state-of-the art diagnostic technology in DNA typing and enzyme immunoassay.

Roche Diagnostics has instrument systems well-suited for both testing categories. Its DNA analyzers will compete with systems from **Applied Biosystems** and **Cepheid**. Major competitors in the immunoassay field will be **PerkinElmer** and Applied Biosystems.

The **Center for Disease Control and Prevention** (CDC), along with state and local public health labs, is accelerating long-standing plans to incorporate speedier methods of detecting bioterrorist attacks. The goal is to replace conventional testing methods for such organisms as anthrax and plague with molecular and DNA-based technologies that are faster and offer increased sensitivity.

The CDC is currently working to validate molecular DNA and antibody tests for organisms and molecules most likely to be used in bioterrorist attacks. Its goal is to supply state public health labs with identical kits of reagents necessary to identify bioagents. This would allow faster and more accurate analysis to be done. It would also create common capabilities so that, if needed, results can be verified at other labs.

DIGENE CONTINUES TO BORROW FROM CYTYC'S MARKETING PLAYBOOK

EFFORTS TO ESTABLISH HPV TESTING as an accepted part of clinical protocols for cervical cancer detection continue at **Digene Corporation**.

As noted in past issues of THE DARK REPORT, Digene has studied the marketing methods used by **Cytyc Corporation** to successfully introduce thin-layer Pap tests into the healthcare community. One technique used by Cytyc was to position its thin-layer product as enhancing women's health.

Digene is following that same path. In Belgium's Parliament, the Chamber of Representatives has "approved unanimously a resolution calling for the introduction of human papillomavirus (HPV) testing within a national cervical cancer screening program."

Digene is hoping that this resolution, and similar pronouncements by authoritative organizations, will help create public pressure for health systems to incorporate HPV testing into their accepted clinical procedures.

CENTREX CLINICAL LABS SELECTS LABTEST.COM FOR WEB ORDERS, RESULTS

THROUGHOUT THE SUMMER, lab portal companies competed intensely to win the contract to implement browser-based lab test ordering and results reporting at **Centrex Clinical Laboratories, Inc.** of New Hartford, New York.

In September, Centrex awarded the contract to **Labtest.com**. Implementation of the new system is already under way. Some of the first sites are already live.

Centrex has a reputation for being an early adopter. Just two years ago, it became one of **Abaton.com's** first customers and one of the first hospital-owned commercial lab companies to implement browser-based lab test ordering and results reporting. *(See TDR,*

February 14, 2000.) However, **McKesson** now only supports Abaton.com for use as part of its integrated information product suite designed for multi-hospital health systems. This forced Centrex to look for another vendor, which turned out to be Labtest.com.

Among the emerging lab portal companies, Labtest.com has begun to establish its credibility. Earlier this year, **Diagnostic Laboratories, Inc.** of Honolulu, Hawaii and **PathLab, Inc.** of Portsmouth, New Hampshire (now owned and operated by **Laboratory Corporation of America**) selected Labtest.com for browser-based lab test ordering and reporting.

Sources also tell THE DARK REPORT that Labtest.com has the inside track to sell its browser-based ASP system to one of the major health system labs in New York City. It's a signal that more laboratories believe the physicians' office marketplace is becoming comfortable with the concept of browser-based lab test ordering and reporting.

SPECIALTY LABS REPORTS INCREASES IN SPECIMENS AND REVENUE FOR Q-4

ALTHOUGH SEPTEMBER was a turbulent month for the entire laboratory industry, **Specialty Laboratories, Inc.** seems to have taken it in stride.

For third quarter, it reported total accessions had increased 16% over the same quarter last year. Net revenue for the quarter was $42.8%, an increase of 8.3% and net income was $2.9 million, up by 22.4%.

This strong increase in specimen volume indicates that, despite economic doldrums in other sectors of the economy, demand for esoteric and reference testing remains strong. Clinicians continue to order sophisticated tests as an integral part of their practice.

Because of disruptions in the national air transport system following the events of September 11, it might be expected that national esoteric labs like Specialty would have experienced a flat or declining volume of accessions. Since that was not the case, the logistics response by Specialty's managment team seems to have sustained the incoming flow of specimens.

In fact, at 1:30 a.m. on Thursday morning of that tragic week, Specialty's Lifeguard flight, a **FedEx** charter, was the first plane to land at Los Angeles International Airport (LAX) since its closure at 9:00 a.m. on September 11. Specialty told THE DARK REPORT that, for the entire week, specimen volume was only down 15%.

TRIPATH IMAGING GAINS FDA CLEARANCE FOR THIN-LAYER PREP & SCREEN

AFTER A LENGTHY EFFORT, **TriPath Imaging, Inc.** finally obtained clearance from the **Food and Drug Administration** (FDA) to market its automated thin-layer preparation system and automated Pap screening system as an integrated product.

The FDA's clearance, announced October 8, makes TriPath Imaging the first company to offer a totally-automated solution for preparing, then screening, thin-layer Pap tests. Just nine days later, **MDS Laboratory Services** of Canada signed an agreement to acquire and use TriPath's automated Pap test system. MDS does about 500,000 of Canada's four million Pap smears yearly.

TriPath Imaging was formed from the merger of **AutoCyte, Inc.** and **NeoPath, Inc.** in the summer of 1999. *(See TDR, July 19, 1999.)* It has worked continuously since the merger to obtain clearance from the FDA to marry its automated PREP® system with AutoPap®, its automated screening system. **TDR**

Secrets For Negotiating Win-Win Agreements

Pricing Models and RFP Terms For Web Orders and Results

CEO SUMMARY: Browser-based systems for lab test ordering and results reporting are now offered by a growing number of vendors. Early adopter labs are successfully acquiring these systems and offering them to their physician-clients. In this third installment of our special series, Cory Fishkin explains how to develop effective RFPs (Request For Proposals). He also explains the three common pricing models offered by vendors, along with their benefits and disadvantages. With an insider's perspective and experience, Fishkin offers valuable information on how to negotiate for the right browser-based system at the right price.

PART THREE OF A SERIES

EDITOR'S NOTE: In the first two installments of this series, Cory Fishkin, President of Mostly Medical, Inc. of New York, identified and explained the operational requirements for an effective browser-based lab test results reporting system, followed by the same for browser-based lab test ordering. (See TDRs, July 23, 2001 and September 4, 2001, respectively.)

COMPARED TO PURCHASING traditional LIS software, the acquisition of a browser-based lab test ordering and results reporting system has unique differences which should be incorporated into the request for proposal (RFP).

"The concept of ASP (application service provider) systems requires a different relationship between the lab customer and its vendor of choice," stated Cory Fishkin, President of **Mostly Medical, Inc.** of New York. "Whether the lab hosts its own server or allows the vendor to do the hosting, the nature of the day-to-day business relationship has changed between the two.

"The success of this new type of business relationship starts with the RFP," he explained. "Moreover, a well-prepared RFP is key to negotiating the most effective price. Vendors see lots of RFPs. They recognize the good ones from the bad ones."

Fishkin believes a lab enjoys two benefits from a well-structured RFP. "One, the RFP communicates to the vendor whether or not the laboratory will be a good customer with which to work," he stated. "Two, the better the RFP, the more likely it is that the lab will negotiate favorable terms and prices.

Secrets Of The Good RFP

"That's why it is important that the lab understand how to craft a detailed RFP," continued Fishkin. "It forms the basis for developing a win-win relationship with the chosen vendor.

"This installment will first address the essential elements of an effective RFP," noted Fishkin. "Then I'll discuss the three common pricing models used to sell browser-based lab test ordering and reporting systems.

"Writing an effective RFP for a browser-based lab testing ordering and results reporting system is actually a fairly simple process," he said. "The first secret is *not* to create the RFP from scratch. Review RFPs your lab has used in the past to purchase LIS software. Organize your RFP in much the same way and borrow sections as appropriate.

"Your RFP should query the vendor about its past experience with the specific LIS software products used by your lab," observed Fishkin. "You want the vendor to provide a list of customers with the same LIS for which the vendor has created an interface. Be particular about which LIS versions have been interfaced successfully, because interfacing to different versions of the same LIS software can require radically different resources.

Critical Success Factor

"Next, it's equally important for the lab to identify the most significant practice management systems (PMS) used by its physician-clients," added Fishkin. "A good interface between the physician's PMS and the browser-based order entry module is a critical success factor.

"This requires the lab to survey its clients to determine the most prevalent PMS products used in the community," he said. "As part of the RFP, vendors should identify the specific PMS systems to which they have written interfaces and list their experiences with these systems.

"Requirements for training and installation in physicians' offices must also be addressed in the RFP," Fishkin stated. "Can these functions be outsourced to the vendor? Does the vendor have the resources to do this properly? This can be

Three Pricing Models For Browser Systems

ALONG WITH the introduction of browser-based systems for lab test ordering and results reporting came a new pricing model, the per-transaction model. Cory Fishkin, President of Mostly Medical, Inc. of New York explains the three common pricing models now found in the lab industry.

1 TRANSACTION MODEL:
This model charges a fee for every transaction between the lab and its clinician-clients. Pioneered by claims vendors, this pay-as-you-go model is suited for use with the introduction of application service provider (ASP) software offered on a remote host basis.

2 PER-USER MODEL:
In this pricing arrangement, the laboratory pays either a monthly, yearly, or one-time fee for each individual licensed to use the browser-based lab test ordering and results reporting system.

3 SITE LICENSE MODEL:
Probably the most familiar software pricing model, the vendor charges a flat fee to the laboratory, and is paid an annual support fee in the range of 18% of the site license cost.

an issue for hospital laboratory outreach programs.

"Frequently, there is only one individual responsible for marketing, customer service, trouble-shooting, and the like," he added. "Asking this same person to also install and train physician-clients in how to use the test ordering and results reporting system may overload them. That is why it might make good business sense to outsource these responsibilities."

Fishkin also recommends developing an RFP which is "vendor-friendly." "Too often, labs issue RFPs which require the vendors to repeat, in text, information which is already available in marketing and collateral literature," he commented. "Or, the RFP may pose broad questions, like 'explain your implementation procedures.' In both cases, vendors must spend more time and energy providing detailed written responses on topics for which better documentation already exists.

Use Checklists In RFP

"It's a much better strategy to use checklists," recommended Fishkin. "Ask the vendor to check items or services they provide which are relevant to the lab's needs. Alternatively, the RFP can invite the vendor to use attachments. That permits the vendor to attach documentation concerning implementation procedures and other functions.

"In both cases, your vendor can probably provide better information than if it must write narrative answers to broad questions," he noted. "As well, these basic guidelines insure that the RFP gives the lab a fair basis to evaluate competing vendors.

Earlier Interfaces

"Next, it is particularly important to identify how the vendor has interfaced its other clients to the same LIS and PMS systems in use by your lab and your clients,' commented Fishkin. "This is a key point and the lab should definitely contact those customers the vendor provides as references. Writing the interface and implementing it are critical success items as you move to introduce browser-based services across your laboratory organization.

"Another critical success factor is the vendor's ability to install the system and implement the solution with maximum success," he added. "During the RFP process, you should insist on meeting the staff and the

managers who will be responsible for implementation," stated Fishkin. "Frequently, it is only the sales people who work with the RFP. After signing the agreement, the lab then must implement the system working with an implementation team they've never met. It's a shrewd business step to meet the vendor's implementation staff during the RFP process. It gives you the opportunity to evaluate their capabilities and whether they can meet your laboratory's unique needs."

It's a shrewd business step to meet the vendor's implementation staff during the RFP process. It gives you the opportunity to evaluate their capabilities and whether they can meet your laboratory's unique needs."

Pricing is the next subject. "As vendors respond to the initial RFP, they have three basic pricing models to offer," he said. "These are: 1) the transaction model; 2) per user license model; and 3) site license model. Each has different advantages and disadvantages for laboratory customers."

According to Fishkin, the transaction model is the newest pricing model to emerge as part of the ASP remote-host business concept. "Transaction pricing involves charging the lab for each electronic transaction. This can be done by charging either a fee for a single patient's test order and results—commonly called a 'round trip'—or charging individually for test orders and reports.

"Under this pricing model, higher volumes of transactions will earn lower prices per transaction," he said. "Also, vendors have up-front fees. Each interface that needs to be written might cost between $10,000 and $75,000. Training and project implementation fees can run as high as $25,000. However, some vendors are willing to offset these up-front costs and recover those monies from slightly higher transaction fees during the life of the contract.

Price Per Transaction

"Typically, the price per transaction will range from 25¢ to $1.00. The exact amount is determined by transaction volume and whether the vendor's front-end fees were deferred and will be recouped from transaction fee revenues over the life of the contract," explained Fishkin.

The lab's sales strategy will influence the type of transaction pricing it selects. "Some labs want to emphasize browser-based lab test results reporting as the main service. They want to get as many doctors as possible to begin accessing lab test results by browser. To support this strategy, I recommend that labs ask their vendor for a two-tier pricing arrangement, with results reporting charged at a lesser sum than test ordering.

Economic Benefits

"Typically, test order transactions should be priced higher than lab results transactions," continued Fishkin. "This is sensible. It is less complex to report results. Also, the economic benefits to the lab from an accurate and complete electronic test order justify a higher price per transaction.

"Some vendors are amenable to this pricing arrangement," he stated. "They know that the more frequently a physician's office uses electronic test reporting, the more likely they are to subsequently adopt electronic test ordering. That benefits both the lab and its vendor.

"A couple of caveats about the transaction pricing model. First, make sure that support fees, generally

around 18% to 20%, are not assessed on implementation fees," advised Fishkin. "Such fees would include project planning, project management, training, administrative, set-up—anything relating to installation.

36-Month Estimate

"Second, the best way to determine your total cost and compare proposals from competing vendors is to add the up-front charges to your projected volume of transaction fees over the first 36 months of the contract," he added. "This is precisely what the vendor does to insure it recovers all its costs.

"Such a calculation allows the lab to understand how the pricing for individual services in the contract affect the total price paid over the life of the contract," observed Fishkin. "Equally important, it allows the lab to accurately compare its true costs between all vendors and any of the three pricing models that might be used."

Next is the per user license fee pricing model. "This can be described as 'pay-as-you-go'," said Fishkin. "For every clinician using the system, including M.D., P.A., and N.P., the lab pays a license fee to the vendor. This fee can either be a one-time payment or a monthly charge. It is based upon the number of individual users.

Popular Pricing Module

"Currently, this is the most popular pricing model in the lab marketplace," observed Fishkin. "It's easy to set up and manage. Monthly fees will range from $20 to $70 per user. One-time fees go from as low as $100 to as much as $1,500 per user. Again, if there is not a separate implementation fee, license fees should include implementation, including installation of the server, establishing a database, loading the lab's test catalog and ordering rules, and validating interfaces with the LIS.

"A word of caution about this pricing model," warned Fishkin. "Exercise care in how the agreement defines a user. Be sure to know whether it includes staff in the physicians' office or only clinicians. Further, make sure you can recycle the user license if individual physicians leave the client practice.

"It's been my experience that the laboratory's marketing strategy and client composition determines the economic justification for the per user license pricing model," observed Fishkin. "For example, if the lab serves lots of smaller physician group practices, per-user arrangements can be quite cost effective.

More Economical Options

"However, in larger groups and clinics where per-user fees could be assessed on 20 or more clinicians, it may be more economical for the lab to either switch to another pricing model or install a thick client, depending on the needs of the practice. Another option is for the vendor to carve out these types of clients and price them differently for the lab."

The third pricing model is the familiar "site license" arrangement, used for decades to acquire LIS software. It involves a flat cost to operate the system. "Conceptually, the lab pays once for use of the system and fees are not linked to either the volume of transactions or the number of clinicians using the system," explained Fishkin. "Annual support costs generally run between 18% and 20% of the license fee.

"The actual price of the system will vary according to the features selected by the lab and the number of users it expects to use it," he continued. "To negotiate the most favorable agreement, the lab should do detailed estimates of the number of physicians' offices which can be expected to move toward browser-based lab test ordering

and results reporting during the life of the contract. This is the customer mix which must be supported by the thin client ASP software.

"One benefit of the site license pricing model is that the fixed cost arrangement allows a laboratory to accurately budget its costs over a multi-year period. The downside is that the lab may be paying for the complete menu of functions such as orders, reporting, and queries, but only using certain services or for physician licenses you may never need."

Contract Terms

Fishkin notes that most site license agreements have a clause that allows the contract to be renegotiated if the lab's parent hospital or health system is involved in a merger or acquisition. "This is a reasonable response to major changes in the client's operations and transaction volume," he observed.

Fishkin notes that, regardless of the pricing model used, laboratories should be careful to establish the right kind of support for their needs. "If your lab provides services to emergency departments, urgent care centers, and physician's offices that offer weekend hours, you may need a 24/7 service arrangement," he said. "Also, you want a vendor whose support infrastructure is capable of notifying you if the system is down. That avoids the unpleasant surprise that occurs when a client calls and says they can't use the system.

"I'd also recommend that laboratories build an 'up-time' incentive into the agreement," he added. "In situations where the system might be down for hours or days, vendors should provide a credit to the laboratory. This credit is a motivation for them to maintain service continuity and fix problems fast!"

Inducement Issues May Need To Be Considered

"WHEN INSTALLING these browser-based systems in physicians' offices, it's important to remember that inducement issues must be considered," advised Cory Fishkin, President of Mostly Medical, Inc. of New York.

"For example, if the lab provides a PC to the physician's office which hosts the browser used to order lab tests and access results, the browser should point only to the lab's Web site," noted Fishkin. "If the physician is using the PC for other, non-lab related tasks, he should pay 'fair market' for these functions. Each situation may vary, so it's wise to consult your legal counsel about compliance and other legal issues."

Fishkin's advice and recommendations on RFPs and pricing models is based on several years of hands-on experience with the earliest generations of browser-based systems built on the ASP concept. THE DARK REPORT believes this experience can help laboratories acquiring such services to negotiate the best possible terms and prices.

Better Performance

Each new generation of browser-based lab test ordering and results reporting products offers a better combination of performance and price. Most likely, the pace of acceptance by physicians' offices will track the rate at which they acquire broadband Internet access in their offices.

The entire American healthcare system is moving toward more effective use of Internet-based services. Laboratories and pathology groups would be well-served to position their organizations to benefit from this trend. **TDR**

Contact Cory Fishkin at 888-391-6260 or email: cfishkin@optonline.net.

Legislative Update

Certain Medicare Lab Reforms May Make It Through Congress

ONE CONSEQUENCE of the terrorist attacks on September 11 is that proposed reforms to Medicare lab reimbursement policies have assumed a lesser priority with the current Congress.

Despite that fact, Congress must still address the day-to-day requirements of managing government functions. Thus, there is still activity under way to develop and pass bills affecting funding and policy issues for the Medicare and Medicaid programs.

"There is a measured degree of optimism that certain reforms involving lab testing may yet be passed by this Congress," stated David N. Sundwall, M.D., Executive Director for the **American Clinical Laboratory Association** (ACLA), based in Washington, DC.

"We are hopeful that action will be taken to bring about a national fee schedule for lab testing services," he noted. "That will benefit labs in several ways. However, given recent events, it is now unlikely that overall funding for lab testing will be increased."

Specific Reform Proposals

Dr. Sundwall noted that one reform measure that has promising prospects for enactment would allow labs to choose a single Medicare carrier. "There are some very tangible proposals to reform the way Medicare contracts for lab testing services," he indicated. "One element would allow labs to select and work with a single Medicare carrier. Another would bring more transparency to Medicare contracting procedures. For example, CMS (**Centers for Medicare and Medicaid Services**) would be more open to input and comments from laboratories during reviews of new testing technology and similar issues."

Recently CMS Director Thomas Sculley disclosed that reimbursement for the physician professional component would be reduced 4% in the next fiscal year. "This will certainly impact pathology professional fees," noted Dr. Sundwall. "When Medicare does cut physician fees by 4% across the board, it will be the first-ever reduction in the RBRVS schedule. This action demonstrates how priorities are shifting within the Medicare program."

Earlier this year, two bills were introduced into the House and Senate. Numbered as H.R. 1798 and S. 1066, the Medicare Patient Access to Preventive and Diagnostic Tests Act was designed to implement a number of the reforms to Medicare lab reimbursement policy recommended by the **Institute of Medicine** (IOM).

"We never expected to see the IOM's complete list of reforms passed. But there was enough Congressional support to give us hope that key reforms, along with additional funding, might be possible," explained Sundwall. "Despite recent events, the lab industry has garnered important attention to see at least a few long-overdue reforms enacted." TDR

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Dark Index

Quest Buys New Jersey Lab, Lab Investors Cash In Stock

Major shareholders of AmeriPath, Unilab, and Dynacare offer their stock to public

THERE'S LOTS OF BUYING and selling taking place among the public laboratory companies.

On one side of the spectrum, **Quest Diagnostics Incorporated** announced the acquisition of C**linical Diagnostic Services, Inc.**, a private laboratory company based in Englewood, New Jersey.

Clinical Diagnostic Services (CDS) was one of the largest independent lab companies remaining in the United States, with annual revenues of approximately $80 million. In recent years, majority owner Guy Seay had entertained offers from many buyers, but had always said no. Some were surprised by the decision to sell to Quest Diagnostics, but it makes sense for many reasons.

Savings From Integration

First, most clients of CDS are located in the New York metropolitan area. This is also prime geography for Quest Diagnostics. Thus, savings from operational integration should be significant.

Second, Quest Diagnostics holds many of the major managed care contracts in this region. This may help it generate more specimens from the physician offices served by CDS. That would provide additional revenues to Quest Diagnostics as a result of the CDS acquisition.

Third, CDS has a pool of talented medical technologists which, in light of the nationwide shortage of med techs, Quest Diagnostics can readily use. Quest's main laboratory in Teterboro currently has about 250 job openings. It's expected that current CDS employees will fill many of those open positions.

Secondary Stock Sales

Even as Quest Diagnostics was acquiring a major regional competitor, other public lab companies were busy. At **AmeriPath, Inc.**, **Dynacare, Inc.**, and **Unilab Corp.**, primary shareholders decided it was an auspicious time to sell blocks of their shares to the public in secondary offerings.

AmeriPath filed its secondary offering on September 17. Three major investors sold 4,125,000 of their AmeriPath shares for $107.25 million. The offering was priced on October 23. These shares represented 14.06% of Ameripath's 29.3 million outstanding shares.

Unilab Tests The Market

Next was Unilab, which filed on October 3. Investors connected with **Kelso & Company**, the private equity firm which acquired Unilab in 1999, offered 8 million shares. The secondary offering was priced on October 18 at $20.50 per share, representing a total of $164 million. However, the participating shareholders decided the price was not sufficient and the offering was not closed.

Just last week, on October 26, Dynacare filed for a secondary offering.

The company will sell 2.7 million shares. Stockholders, including the private equity investment firm **Golder, Thoma, Rauner, and Cressy** (GTCR) and several senior Dynacare executives, want to sell 2.3 million shares. Total value of the offering would be about $79 million at current prices. This would be about 25% of Dynacare's total outstanding shares. As of press time, this offering was neither priced nor closed.

Stock Sales By Equity Firms

Both Kelso and GTCR have moved to sell shares and recover their original investment, and subsequent profits, in Unilab and Dynacare, respectively. If the financial markets continue to be viewed as auspicious, the logical next lab company to make a public offering would be **American Medical Laboratories** (AML) of Chantilly, Virginia.

GTCR is a major investor in this lab company and wants to create a public market for AML's shares. In fact, this was attempted last fall. AML filed for an initial public offering (IPO) on September 29, 2000. *(See TDR, October 23, 2000.)* This occurred at about the same time that **Specialty Laboratories, Inc.** and Dynacare were also filing their own IPOs.

However, although Specialty and Dynacare did complete their IPOs, AML did not follow through with its own offering. Logically, American Medical Laboratories would be the next lab company to tap the financial markets.

Good News For Lab Owners

For those pathologists who continue to own and operate independent clinical laboratories, these recent events are a good sign. The financial fortunes of the public lab sector are strong. At a time when the general stock market is dragging, investors like the opportunities for profits and growth in lab testing.

This translates into higher prices when private laboratories are available for sale. Although terms of the sale of Clinical Diagnostic Services to Quest Diagnostics were not disclosed, knowledgeable sources believe that CDS was profitable and Quest Diagnostics paid a strong price to acquire the lab.

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Like LabCorp's acquisition of profitable **PathLabs, Inc.** of Portsmouth, New Hampshire last fall, these sales of profitable private labs stand in stark contrast to most of the lab acquisitions done in the second half of the 1990s. Those were private labs, either bankrupt or at the courthouse door. Public labs acquired these money-losing operations for little more than the value of core assets.

Opportunity For Pathologists

There's another important insight to be gained from these recent deals by public lab companies. The professional investment community is ready to commit significant dollars to those laboratory ventures they see as promising. THE DARK REPORT observes that pathologists with good management skills and a strong core business can readily attract financial backers.

Pathologists with entrepreneurial ambitions should take advantage of this market opportunity. The keen interest by professional investors in molecular and genetic testing means there is a ready ear for pathologists with a good business plan. The sustained revenue growth in the quarterly financial reports of public lab companies confirms that the laboratory test business is enjoying a time of prosperity. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's a milestone in the Pap smear testing marketplace. **Cytyc Corporation**, in its third quarter financial report, now claims its ThinPrep® product has 51% of the national market for Pap testing. Estimates are that 55 million Pap tests are done annually in the United States. A 51% market share translates into 28 million ThinPrep tests yearly.

Tenet & HCA

Public laboratory companies are not the only healthcare firms benefiting from keen interest by Wall Street. For-profit hospital corporations are also on a roll. Last week **Tenet Healthcare Corp.** went to market to sell $1 billion of debt securities. Response from the investment community was so strong, it decided to sell another $1 billion in bonds! Meanwhile, **HCA,** after reporting a 12% in-crease in third quarter earnings, announced that it will spend $250 million to repurchase shares.

VISIBLE GENETICS & GLAXOSMITHKLINE TO TEAM IN CLIN TRIAL

Many consider HIV typing and viral load testing to be the cutting edge of pharmacogenomics—the concept of using lab tests to guide therapeutic decisions. If true, the collaboration between **Visible Genetics, Inc.** (VGI) and **GlaxoSmithKline** (GSK) bears watching. Glaxo will use VGI's TRUGENE™ HIV-1 Genotyping King and OpenGene™ DNA sequencing system for a large scale Phase III clinical trial of a new HIV drug. This is the second GSK trial to use VGI's products.

ADD TO: VISIBLE GENETICS

Last month Visible Genetics received FDA clearance to market its TRUGENE kit and DNA typing system for routine clinical use. This is the first test kit for HIV resistance testing to receive clearance. In the testing continuum from esoteric to routing, some consider this an evolutionary step that will eventually make it possible for larger numbers of clinical labs to do such testing on site, instead of referring it to esoteric labs.

Kudos Are In Order

Maybe they should be called the "hardest working duo" in the lab business. For the third year in a row, CEO Larry Siedlick and President Pat Lanza have guided **Sunrise Medical Laboratories** to recognition as one of Long Island's "25 Fastest-Growing Firms" for 2001. Sunrise was also honored as one of Long Island's "Top 50 Private Firms" in the annual awards sponsored by **KPMG LLP**, **Hofstra University**, and *Long Island Business News*. Few companies are recognized in multiple years and even fewer are recognized in both categories the same year.

Here's an illustration of how the rapidly evolving technology of genomics will have practical impact on diagnostics and therapeutics. The **National Science Foundation** awarded an emergency grant of $200,000 to the **Institute of Genomic Research** to map the entire genome of *Bacillus anthracis,* using the strain found in Florida. The work is expected to take a few weeks and will initially be used to support forensic investigation of the case.

That's all the insider intelligence for this report. Look for the next briefing on Monday November 26, 2001.

News About The Next War

Mark Your Calendar:

MAY 7-8, 2002

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UPCOMING...

- ***A DARK REPORT Exclusive: Beckman Coulter Chair & President John Wareham Discusses Developing Trends In Diagnostic Technology.***
- ***How And Why Some Hospital Lab Outreach Programs Continue Growing Steadily.***
- ***Inside Look At New Management Approaches To Automating Lab Processes.***