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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

Preparing for the Unexpected and Unimagined

WHO WOULD HAVE EVER PREDICTED THAT A PHLEBOTOMIST would reuse needles? Just as surprising, who would have ever predicted that the phlebotomist would be working at a respected clinical laboratory like **SmithKline Beecham Clinical Laboratories** (SBCL)?

This shocking story *(see pages 7-11)* is a reminder that laboratory executives should never forget to anticipate *every* potential problem, no matter how outlandish. It is a reminder that the human element of unpredictability is always with us. No matter how rigorous the training, no matter how effective the management and supervision, individual employees are capable of doing unexpected, outlandish, and irrational things...usually at the most inopportune of moments.

You can appreciate the consequences to SBCL from the actions of this single "rogue" phlebotomist. One of healthcare's most respected and ethical corporations must now endure widespread negative publicity as well as the legitimate anger and anguish of affected patients and their referring physicians. It is a stain that does not easily disappear.

As you learn more about the facts surrounding this situation, you should ask yourself several questions. Could something similar to this happen within my laboratory? Is my laboratory prepared to deal with the publicity and consequences of such crises? More importantly, is my laboratory organized to prevent these types of events from happening?

Remember, laboratories handle things which affect the health of individual patients in a variety of ways. Just this month, television's *20/20 News* program profiled the "deficiencies" of nationally-prominent laboratories in diagnosing melanomas because they didn't use board-certified dermatopathology subspecialists. Whether the television journalists understand the medical science involved or not, laboratories they brand as "deficient" will find themselves undergoing unwanted public scrutiny.

Given the reality of today's society, laboratory executives should consider the episode of the Palo Alto phlebotomist who reused needles as a timely warning. It does pay to prepare for both the unanticipated and unexpected...no matter how outlandish the situation. Our good friend, Mark Smythe, has an apt term for this management responsibility. He describes it as "crisis anticipation-disaster avoidance." TDR

Our Pre-War College Industry Assessment

Labs Entering New Cycle Of Evolution and Change

By Robert Michel

CEO SUMMARY: As some of the nation's most astute and forward-looking lab executives prepare to gather in New Orleans for the fourth annual EXECUTIVE WAR COLLEGE, it is time to share our assessment of the laboratory and pathology industry. Recent events presage another profound shift in trends driving the evolution of laboratory services. This shift has positive ram-ifications for most laboratorians and pathologists.

Whenever the time for the *Executive War College* approaches, we like to take the opportunity to assess the laboratory and pathology industry.

Our role in gathering the management thought leaders of clinical laboratory and pathology for two days of debate, dialogue, and networking requires us to challenge conventional thinking. Those attending this year's *Executive War College* on May 11-12 consciously seek effective solutions to practical problems.

This requires our pre-*War College* lab industry assessment to be a critical look at real-world influences on the laboratory organization of today. It is one of our most closely scrutinized and intensely debated features in THE DARK REPORT.

This year we hope to be just as controversial. Travels to laboratories throughout the nation provide us a unique perspective on what works—and what doesn't. Regular conversations with diagnostics manufacturers, hospital administrators, and healthcare experts cue us about what's happening now and what's expected to happen in the next few years.

Of course, 100% of our predictions for the lab industry do not prove correct, but our consistent record for accuracy and timing is respected throughout the industry. THE DARK REPORT is now recognized as the leading source of accurate business intelli-

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gence for laboratory executives, pathologists, and even the financial community which funds laboratory organizations.

For 1999 and 2000, there is plenty of change ahead for the laboratory industry. But it will generally be positive change. This next market cycle is less about eliminating people and cutting costs and more about building the "right" kind of service menu.

FIRSTS FROM WAR COLLEGE '96

When the first EXECUTIVE WAR COLLEGE convened in Pittsburgh in 1996, it brought together laboratorians interested in what was then the hot trend of regional laboratory networking.

That meeting marked the first time leading regional lab network organizations made a public presentation to their management peers, with surprising results.

WAR COLLEGE '96 was the first discovery that regional laboratory networks would be one of the most difficult management projects to organize and operate. In the years since 1996, the truth of that discovery has been validated by the actual experience of regional laboratory networks in every area of the country.

To be more specific, since 1994, both the commercial laboratory segment and the hospital laboratory segment have undergone horrific restructuring. In many cases, rapidly-eroding finances forced lab organizations to take radical, wrenching steps to reduce costs and achieve stability of revenues and operating profits.

This was painful to all participants in laboratory medicine. Med techs and loyal employees bore the brunt of this, enduring waves of lay-offs, staffing cutbacks, and extra workloads. Surviving lab employees found themselves asked to do more work in exchange for less money.

But lab owners, pathologists, lab managers, and administrators suffered equally. The graveyard of defunct laboratories is littered with bodies: **Damon**, **Allied**, **Nichols**, **MetPath/Corning Clinical Labs**, **National Health**, **Physicians Clinical Labs**, **Meris**, and **Universal Standard** are among the best known. Each hit a financial brick wall that stopped them cold. Most morphed into a surviving organization which still operates today.

Hospital labs experienced their own brand of financial and consolidation mayhem. This activity predominated in 1995, 1996, 1997, and 1998.

In the commercial lab industry, the specific cycle of consolidation has passed. What is left can be described as a "mopping up" process. **Quest Diagnostics Incorporated's** impending acquisition of **SmithKline Beecham Clinical Laboratories** only represents a business move that **SmithKline Beecham, PLC** should have done several years ago, as did **Roche** and **Corning Corporation**.

Consolidation Now Ebbing

Among hospital labs, the tidal wave of lab consolidation is now ebbing. There will continue to be a significant amount of ongoing hospital lab consolidation projects. But these are latecomers attempting to catch up to their peers. For the most part, future consolidation projects will involve existing hospital systems that acquire new hospitals. The new hospital's laboratory will be consolidated and folded into the existing integrated system.

In both lab segments, these are clean-up events following the major

trend. This is why we declare the end to laboratory consolidation as a major industry trend. Granting the truth of this pronouncement, what do we identify as the next major lab industry trend?

Regionalization Is Next Trend

We believe the next trend is "regionalization." We define regionalization as the movement to create laboratory organizations which have extended service reach across a defined geographical area.

Unlike laboratory consolidation, which is an easy concept to define, laboratory regionalization will be an all-encompassing type of trend. It represents a variety of organizational models that can effectively and efficiently deliver laboratory testing services.

Despite this variety of organization models, each will have common characteristics that meet our definition of a regional laboratory system.

First, all participating laboratory sites are operated under a single administrative umbrella, regardless of who owns and operates the individual lab sites of the regional laboratory organization.

Second, the regional lab organization provides services to an easily-recognizable area of geography. In most cases, it will match the geography where the leading managed care plans have beneficiaries. This is consistent with healthcare's evolution toward both integrated clinical systems and integrated operational systems.

Third, regional laboratory organizations will generally utilize existing laboratory resources already operating in that city, regardless of who owns those lab resources. With declining reimbursement and laboratory overcapacity in most markets, there will seldom be the need nor the motive to construct new laboratory facilities.

Fourth, the regional laboratory organization will have responsibility for at least three key functions: 1) negotiating and servicing managed care contracts; 2) developing and managing a unified sales and marketing program; and 3) handling billing, collections, and utilization reporting.

FIRSTS FROM WAR COLLEGE '97

New Orleans was the site of WAR COLLEGE '97. The hot topic this year was hospital consolidation and a record crowd was on hand to learn from THE DARK REPORT's pick of the leading hospital laboratory consolidation projects.

WAR COLLEGE '97's "first" was the discovery that hospital laboratory consolidation was under way in virtually every major city in the United States. It was validation of the fact that a new model for laboratory organization was gaining dominance in the United States and Canada.

Using this checklist of four characteristics, there are a number of regional organizations operating today which already meet this criteria. Many have been profiled in THE DARK REPORT. Others appeared in recent years at the *War College* podium to profile their business strategy and experience in the marketplace.

One obvious category of regional laboratory organization is the network model. Early pioneers were **Reference**

Laboratory Alliance in Pittsburgh and **Bay Area Hospital Laboratory Network** in San Francisco. Launched in 1995, they found limited success and eventually collapsed into other forms of regional services.

A sampling of networks operating today are **Joint Venture Hospital Laboratories** in Detroit, **PacLab Laboratories** in Washington State, **Regional Laboratory Alliance** in Kansas City, and **LabNet of Middle Tennessee** of Nashville (a *War College '99* case study). There is also a pathology network, **Pathology Service Associates,** headquartered in Florence, South Carolina *(a War College '99 case study).*

FIRSTS FROM WAR COLLEGE '98

Case studies presented at WAR COLLEGE '98 revealed a fascinating surprise to both attendees and THE DARK REPORT alike.

It turned out that every laboratory case study at War College '98 shared something in common which no one had spotted. Each was a combination, in some manner, of a hospital lab venturing with a commercial lab. This was the first discov-ery that such joint ventures were increasing in number and influence.

More importantly, it was the first confirmation that financial pressures were causing hospital labs to reassess their traditional animosity to partnering with commercial labs. In today's managed healthcare world, financial benefits from specific part-nership arrangements are too com-pelling for hospital labs to ignore.

Of course, the national commercial laboratories operate regional laboratory organizations. Each of their regional mother ships in cities like Philadelphia and St. Louis acts as a core lab and anchors a network of stat labs, drawing sites and courier routes serving that particular metropolitan area.

Integrated healthcare systems operate regional laboratory organizations. **Penn State-Geisinger Health System** operates an integrated laboratory system which serves the system's hospitals, outreach clinics, and outpatient centers in a 30-county area of middle Pennsylvania.

Aurora Health Systems, based in Milwaukee, has a similar regional lab system which serves 17 hospitals located within a several hour drive of the metro area. Examples like **Presbyterian Laboratory Services** in Charlotte, North Carolina or **Health Midwest** in Kansas City illustrate that this model is already common.

Joint Venture Model

The other model of regional laboratory organizations is that of the commercial lab/hospital system joint venture. Newest of these is the joint venture with **MDS** and **Columbia/HCA** in Georgia. A new core lab was constructed in Atlanta. It does reference testing for Columbia's 18 hospitals in Georgia and solicits office-based testing from physicians in the Atlanta area.

Another similar model is **Dynacare-Hermann Hospital**. This is a joint venture between a commercial lab and a hospital lab that has been successful around its immediate hospital campus and is expanding its service area on a regular basis.

These examples are provided to make a point. Regionalization of laboratory services has been under way for several years already. As an industry

trend, its roots are already set deep. These earliest operational models of a regional laboratory organization will be copied by those to follow.

Dominant Influences

As in past years, this assessment offers our thinking and analysis about the dominant influences shaping laboratories and management decisions. We provide our reasons for developing these conclusions and invite comments and critiques from our clients and readers.

This annual assessment of the lab industry is an important statement. It is designed to provoke thoughtful conversation and debate at the upcoming *Executive War College* in New Orleans in just a few weeks.

Further, it is intended to help laboratory executives validate their own observations about marketplace developments in the lab industry. Good strategic planning requires an accurate, real-world assessment of events shaping our healthcare community.

A special word to pathologists. THE DARK REPORT is strongly convinced that pathology practice consolidation will be a trend that parallels, and follows behind, that of clinical laboratory consolidation.

The fortunes of both groups are closely linked. There is every sign in the marketplace that the number of pathology consolidation projects will increase during the next two years.

As these pathology practice consolidations occur, their natural evolution will lead to pathology regionalization. This will happen because of the same market forces which are now shaping the regionalization of clinical laboratory services.

Thus, pathologists have a demonstrated template to guide the strategic planning for their group practice. These trends are unstoppable. Attempts to deny change and maintain the status quo will have one result.

Those pathology practices which chose to "sit tight" and wait to see what happens next will discover an unpleasant fact. They will have ceded control over their destiny, their ability to diversify income, and their ability to chose the clinical methods and technologies they want to use in their practice of medicine.

PREDICTIONS ABOUT WAR COLLEGE '99

WAR COLLEGE '99 will convene at the New Orleans Sheraton Hotel on May 11-12. Several "firsts" will take place at this year's event.

With case studies from Canada and New Zealand to join American case studies at the podium, it will be the first international laboratory management program ever presented.

The laboratory and pathology sales and marketing edu-track at WAR COLLEGE '99 is the first-ever national gathering of lab sales managers and marketing directors.

A special one-day laboratory CEO SUMMIT is scheduled for Thursday, May 13. This will be the first national meeting exclusively for lab CEOs and senior hospital lab administrators. It's designed to be a strategic think tank for the lab industry's leading executives.

Laboratory executives and pathologists should realize that this regionalization trend will probably result in even greater change than that of laboratory consolidation. TDR

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

Discovery Shocks Public

SBCL Phlebotomist Found Reusing Needles in Calif.

Every lab manager's nightmare comes true as national news media headlines the story

CEO SUMMARY: News that a phlebotomist employed by SmithKline Beecham Clinical Laboratories (SBCL) was discovered to be washing and reusing needles got national media attention last week. During her 22-month employment at SBCL, this phlebotomist apparently reused butterfly nee-dles on "difficult to draw" patients. Ramifications of this dis-covery will affect not only SBCL, but the entire lab

ON APRIL 15, the *San Francisco Chronicle* broke a major story about the discovery by **SmithKline Beecham Clinical Laboratories** (SBCL) that one of its phlebotomists had washed and reused butterfly needles on "difficult to draw" patients.

Several thousand people were potentially exposed to HIV and hepatitis. The grisly news was immediately picked up by newspapers, radio stations, and television news programs throughout the United States. SmithKline, a company proud of its reputation for quality and patient care, found itself in an unwanted spotlight.

Joint Statement

On April 16, SmithKline Beecham responded to the *San Francisco Chronicle* story. SmithKline and the California **Department of Health Services** (DHS) issued a joint statement about the situation at a press conference in Berkeley, California.

According to SmithKline, a coworker had observed the SBCL phlebotomist reusing needles at the SBCL phlebotomy station in Palo Alto on March 22. When SBCL managers interviewed this phlebotomist later that day, she admitted to reusing needles.

State Health Investigators

She was suspended the same day and subsequently terminated. During interviews with state health investigators, she again admitted that she reused needles when drawing patients at the SBCL phlebotomy station.

The woman was identified by the press as Elaine Giorgi. She started work with SBCL on June 1, 1997. It is believed that she drew some 3,600 patients between that date and her suspension and subsequent termination.

Santa Clara County's health officer, Martin Fensterscheib, M.D. interviewed Ms. Giorgi and said that she told him she reused needles because "she was running out of butterfly needles and it was important that she not run out."

Although Giorgi claimed to have only done this for a short period of time, perhaps only two weeks in late February and early March, Dr. Fensterscheib was skeptical. He said he "found inconsistencies in her story...I can't believe that there was a very limited use."

SBCL responded to those comments. "Cost is not the consideration. Patient care is," said SBCL Public Information Officer Toby Dichter. "We don't go out and say 'Don't use too many butterfly needles.' (Phlebotomists) have absolutely unrestricted access to anything they need."

Many phlebotomists would take exception to Dichter's statements. Because of their cost relative to syringe needles, butterfly needles are widely recognized to be an item ever in "short supply" in hospital labs and commercial labs from coast to coast.

It is not uncommon in the lab industry for phlebotomists who use "too many" butterfly needles to find themselves evaluated negatively for the practice.

Washed Needles

Giorgi worked worked alone in an SBCL draw station located in a physicians' office tower next to the **Stanford University Medical Center**. She described to investigators a practice where she would wash used butterfly needles in a sink with water and diluted hydrogen peroxide. She then put the needles into clean needle containers to be used when drawing patients with difficult-to-pierce veins.

The woman completed her training as a phlebotomist in 1994. She worked at other laboratories before coming to SBCL in 1997. She further completed the SBCL phlebotomy certification before starting to draw blood on patients referred to SBCL. Officials stated that "it is not known when the woman began reusing needles, how often she reused them, or if she reused them at any other facility where she worked."

"Clearly we are shocked and baffled by this practice. It's a breach of medical care," stated Edward Kaufman, M.D., National Medical Director at SBCL at the joint news conference with DHS officials. "She can't explain why she did it."

First Lawsuit Filed As More Expected

Within days of the announcement that an SBCL phlebotomist had reused needles for blood draws, the first class action lawsuit against the laboratory was filed in Santa Clara County Superior Court by the law offices of Stephen Blick and Charles Hawkins.

Additional lawsuits are expected. Palo Alto is a wealthy suburban community. On the plus side for SBCL, it means that the incidence of hepatitis and HIV infections is very low. On the minus side, it means that most patients drawn by Giorgi are intelligent, aware, and have the financial capability to finance lawsuits.

There is also the possibility of criminal charges. Although no law in California prevents the reuse of needles for blood draws, a number of statutes can apply to the situation. The Santa Clara District Attorney's office and the Palo Alto Police are investigating the situation.

In addition to the possibility of civil claims and criminal charges, both SBCL and the phlebotomist are subject to regulatory scrutiny. A variety of government agencies can investigate the actions of SBCL and its phlebotomist to identify violations of regulations. If it is determined that regulations were not followed, appropriate fines, citations, and sanctions could be assessed.

Both health officials and SBCL executives agree that risk of infection was minimal, but possible. "Although we believe the risk is very low," stated Jon Rosenberg, M.D., a DHS specialist in disease transmission and control, "we can't assume that it's nonexistent or negligible."

Certified letters were mailed last week to the 3,600 patients who were drawn by Giorgi during her employment with SBCL, and to the patients' doctors. The letters notify the patients about the situation. A toll-free hotline was also established, and got 4,200 calls in its first day of operation.

Dr. Kaufman stated that SmithKline Beecham is "fully prepared to assume appropriate responsibility for costs associated with retesting, counseling, and treating patients who may have contracted a disease."

SmithKline Beecham, PLC now finds itself in the eye of a complex hurricane. Although the facts of this case are relatively simple, it is the consequences and ramifications that will prove complex and long-lasting.

SmithKline Beecham, PLC now finds itself in the eye of a complex hurricane. Although the facts of this case are relatively simple, it is the consequences and ramifications that will prove complex and long-lasting. It is the type of bad-news story that all clinical laboratories wish to avoid.

From that perspective, lab executives and pathologists should watch how SmithKline handles itself during this crises. There are several levels of management action involved in this case.

One, SmithKline must react to the patients placed at risk by the actions of its employee phlebotomist. This means identifying all individuals who were potentially affected and insuring that they get appropriate medical tests, counseling, and healthcare.

Two, SmithKline must deal with public relations disaster as it affects patients and physicians in the medical community, both in the San Francisco Bay Area and throughout the nation. It must reestablish confidence in the quality of its medical services.

Three, SmithKline has issues, and possible legal exposure, with public health agencies. It is certain that all government health regulators will want to be seen as "doing their jobs" and properly enforcing public health regulations. In this high profile case, it is easy for bureaucrats to characterize a corporation as the "bad guy."

Four, there is already a civil suit filed against SmithKline. More should be expected. SBCL's full exposure to civil suits cannot be evaluated until the health status of the affected patients is determined.

Five, this crises may lead to changes in the way SBCL manages its laboratory services, both clinically and operationally. As more is learned about why this phlebotomist became motivated to reuse butterfly needles, there may be changes in the way cost-cutting initiatives are allowed to control access to supplies required for the provision of clinical services.

Laboratory executives and pathologists should not underestimate the impact this crises will have on the entire laboratory industry. They should carefully follow this story and how it unfolds. What happens to SBCL, and how SBCL copes with this situation will teach valuable management lessons for other labs which may find themselves in a similar situation sometime in the future. TDR

Crises Management Plan Essential for Every Lab

Unexpected mishaps and rogue employees can put any lab in the same fix as SmithKline

CEO SUMMARY: "It can't happen here" is not good management. All clinical laboratories and pathology practices should anticipate the worst and develop their own internal controls to prevent the unthinkable and prepare for the unexpected. Rogue phlebotomists like the one at SmithKline Beecham Clinical Laboratories can appear anywhere, with similar destructive consequences.

WHAT'S HAPPENING TO **SmithKline Beecham Clinical Laboratories** (SBCL) in Palo Alto, California can happen to any laboratory in any city or town.

One rogue phlebotomist at SBCL, making a bad decision on her own, created a situation which threatened the health of 3,600 patients!

Imagine if this was your phlebotomist and it was your laboratory in the daily headlines. Would you and your management team be ready to cope with this situation? More importantly, is your laboratory organized to prevent such a situation from occurring in the first place?

"Prevention is a superior management plan for handling crises caused when employees do things that they are not supposed to," stated Richard Cooper, Partner with **McDonald, Hopkins, Burke & Haber** of Cleveland, Ohio. "Every lab should understand how suddenly it can find itself thrust into the public eye for the most unflattering situations."

"The managed care setting presents a different set of management risks and legal exposure than the fee-for-service setting," he said. "Quality of care issues become different. Most labs are familiar with the legal claim that the provider did not do everything that was appropriate for the patient. That is a common legal challenge in fee-for-service medicine."

New Legal Challenges

"Managed care introduces a new legal challenge," continued Cooper. "It stems from the risk that the provider assumes with capitated contracts. The laboratory could find itself facing legal claims that it reduced costs in a manner that exposed patients to risk or inferior care.

"Since employees are the source of a laboratory's strength and its weakness, lab administrators should implement five safeguards to insure that their employees and staff follow procedures, obey laws and regulations, and deliver an acceptable level of healthcare," he observed.

First on Cooper's list is a rigorous background check on every new hire. "You should thoroughly research the

past employment history of your prospective employees, subject to applicable employment laws" he said. "That way, you avoid hiring people with a known history of problems. You also help protect your lab should that employee later create a problem. You can demonstrate due diligence in hiring employees who provide reliable work histories.

Labs Have Liability On Several Grounds

Laboratories should understand their legal liability and exposure for damages extends across four basic areas.

1. ***PHYSICAL HARM***
   Did the laboratory cause a patient to suffer physically in any way?
2. ***PAIN & SUFFERING***
   Did the laboratory subject the patient to pain and suffering, whether physical harm was done or not?
3. ***PUNITIVE DAMAGES***
   How egregious and/or culpable was the laboratory and its employees in their actions?
4. ***REGULATORY & STATUTORY***
   Were regulations and laws violated by the laboratory?

"Second, continually review internal work rules and quality procedures to insure the lab's full compliance with all laws, regulations, and standards of good practice," Cooper said.

Notice that SmithKline's responses to many issues in the Palo Alto crises refers back to existing SBCL policies which forbid the very things the phlebotomist did. SBCL understands the importance of detailed and complete operating guidelines and quality standards of care.

"Third, audit regularly. Verify and document that your laboratory staff is following policies and procedures," he continued.

SBCL's responses to newspaper reporters' questions, consistently point out that their phlebotomy staff is regularly monitored by a group of managers. They want to make it clear that this one employee acted independently and hid her actions from those managers delegated to insure compliance.

"Fourth, when making decisions about reducing expenses and cutting costs, it is important for you to be sensitive to the quality of care your laboratory provides versus the cost of providing that care," noted Cooper. "It is smart practice to document that your changes to the cost of providing services are designed to continue supporting services that are of appropriate quality.

"Fifth, when problems are identified, provide training to your staff to teach them how to avoid or prevent those problems from reoccurring," he said. "This demonstrates your active and ongoing concern about quality and compliance. It provides further evidence that your laboratory is working to maintain a professional and fully compliant operation."

It is interesting to compare Richard Cooper's advice to laboratories with the actions of SmithKline Beecham in the Palo Alto phlebotomist episode. As a corporate entity, SmithKline is responding to each development with a consistent public face, based upon the same five principles elaborated above by Richard Cooper.

It this consistency holds up, then SmithKline may well survive this incident with a minimum amount of damage from civil litigation, regulatory sanctions, and possible criminal exposure. **TDR**

For further information, contact

Legislators May Repeal NY Lab Surcharge Tax

NY lab association's repeal efforts prove that labs can create public outcry for change

CEO SUMMARY: After two years of concerted effort, laboratories in New York are optimistic that state legislators will finally repeal an 8.18% surcharge tax on clinical laboratory tests. The significant insight behind this story is how laboratories educated patients about the surcharge. The response was a public deluge of phone calls and letters to elected officials, the governor, and regulatory agencies.

LABORATORIES IN NEW YORK are optimistic that the laboratory tax surcharge will be lifted from outpatient testing this year.

"From the governor's office and the assembly we are getting assurances that the 8.18% lab test surcharge will be dropped," said Thomas Rafalsky, President of the **New York State Clinical Laboratory Association** (NYSCLA). "The uncertainty about when the measure is actually voted upon comes from the shifting political battles between the Governor, the Assembly and the Senate on other legislative issues."

Hospital Funding Reform

Three years ago New York's state legislature passed a bill to reform the way hospitals in the state were funded. Called the *Health Care Reform Act for 1996* (HCRA), it became law on January 1, 1997. An 8.18% tax surcharge on outpatient laboratory testing became attached to the bill in its final days before passage, leaving insufficient time for clinical laboratories to get it deleted from the final bill.

"Clinical laboratories were never part of the prior hospital funding scheme," recalled Rafalsky. "Nor did they benefit from either the former funding arrangements or the reformed hospital funding plan."

"That is why NYSCLA was surprised to learn that, beginning January 1, 1997, all outpatient lab testing would be assessed an 8.18% tax surcharge," he explained. "This was definitely a financial hit to clinical laboratories.

"First, the labs had to collect and remit the surcharge payment from patients," noted Rafalsky. "Second, insurance plans and third party payers arbitrarily rammed reimbursement decreases onto the labs to recoup the amount of lab tax surcharge that they were responsible to pay.

"Further, if the patient did not pay the surcharge, the state **Department of Health** took the position that the laboratory was guarantor of the surcharge and responsible for its payment," noted Rafalsky. *(See TDRs, December*

16, 1996 and July 14, 1997.)

NYSCLA filed a lawsuit in late 1996 seeking injunctive relief from the surcharge. But the courts ruled that legislative action was the proper venue to redress this grievance, causing NYSCLA to change its strategy.

100,000 Patient Bills Daily

"Labs in New York send out 100,000 patient bills per day," observed Rafalsky. "So we had member labs begin stuffing flyers into their patient bills. These flyers educated patients about the lab test surcharge and asked them to contact their elected representative.

"This strategy worked far better than we had hoped," he continued. "More than 1,000 calls per day flooded the governor's office, the Department of Health and offices of individual senators and assemblymen. We definitely got their attention."

According to Rafalsky, lawmakers responded quickly with amendment bills to repeal the lab test tax surcharge. "At one point, all 35 Republican senators sponsored the Senate's bill, noted Rafalsky.

Here's where things got frustrating for NYSCLA's member labs. Political differences on other matters between the governor, the assembly, and the senate in late 1997 and into 1998 kept pushing the lab test surcharge onto the back burner.

"We've gotten repeated assurances from various individuals inside the governor's office and the assembly that the lab surcharge will not happen again," said Rafalsky. "HCRA sunsets at the end of this year. This makes it easier for the legislature to simply not include the lab test surcharge as they rewrite the next version of this law."

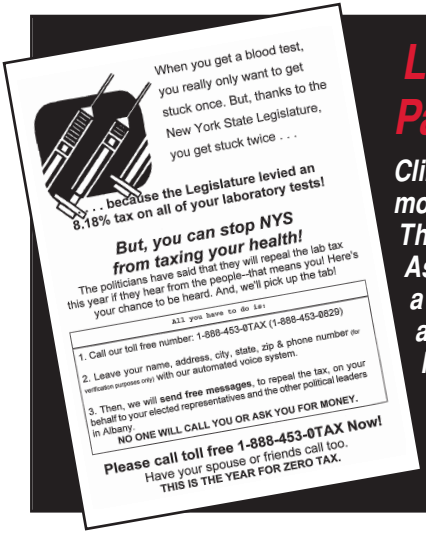
NYSCLA's impending success at getting a bad law changed demonstrates that clinical laboratories have the potential for substantial legislative success, but only if they work in concert.

Working Together

Recent progress on efforts in Congress to raise the amount of reimbursement by Medicare for Pap smear screening further demonstrates benefits that accrue when laboratories and pathologist work together.

Taken collectively, legislative initiatives by clinical laboratories in both New York's state legislature and the United States Congress indicate that the lab industry has sufficient clout to effect change. TDR

For further information, contact Tom Rafalsky at 212-664-7999.


When you get a blood test, you really only want to get stuck once. But, thanks to the New York State Legislature, you get stuck twice . . .

. . . because the Legislature levied an 8.18% tax on all of your laboratory tests!

But, you can stop NYS from taxing your health!

The politicians have said that they will repeal the lab tax this year if they hear from the people--that means you! Here's your chance to be heard. And, we'll pick up the tab!

All you have to do is:

1. Call our toll free number: 1-888-453-0TAX (1-888-453-0829)
2. Leave your name, address, city, state, zip & phone number (for verification purposes only) with our automated voice system.
3. Then, we will **send free messages**, to repeal the tax, on your behalf to your elected representatives and the other political leaders in Albany.

NO ONE WILL CALL YOU OR ASK YOU FOR MONEY.

Please call toll free 1-888-453-0TAX Now!

Have your spouse or friends call too.

THIS IS THE YEAR FOR ZERO TAX.

Labs in New York State Use Patient Bills as Lobbying Tool

Clinical laboratories in New York send out more than 100,000 bills to patients every day. The New York State Clinical Laboratory Association uses these billing statements as a way to communicate directly with patients about the laboratory test tax surcharge. At left is the current flyer that participating New York laboratories are putting in envelopes with the patients' bills. Patients support the surcharge repeal effort.

Lab Industry Update

Lab Contracts Priced Below Cost May be Defined as Inducement

PROBABLY THE MOST SERIOUS problem in the lab industry is one of its own making. "Below cost" contracting is a practice where clinical laboratories offer the managed care company a price which is less than its cost to provide the testing.

With laboratory overcapacity still abundant in many cities, "below cost" contract pricing remains common. Labs with unused capacity have an economic motive to bid for additional specimen volume using a marginal cost pricing formula.

Stop Destructive Lab Pricing

All laboratories recognize the self-destructive impact of this pricing phenomenon. How to stop it has been the quandry. Here's where the **New York State Clinical Laboratory Association** (NYSCLA) has a unique approach.

"Our members are very concerned about the effects of below cost pricing by managed care plans and laboratory providers," said Thomas Rafalsky, President of NYSCLA. "We recognize that if these types of pricing schemes continue, it will threaten the financial stability of the clinical laboratory industry. That is not good for patients, physicians, and healthcare in general."

NYSCLA has taken an unusual step to resolve the below cost pricing delimma. "In New York, there is a state statute which requires all providers to set healthcare fees at fair market value," noted Rafalsky. "Where such fees are not, it can be considered an inducement.

"We have written to the New York State **Department of Health**," he continued. "We are requesting it to provide an opinion as to whether the practice of offering laboratory fees which are below the actual cost of providing laboratory services represents an inducement."

This is a significant action by NYSCLA. Were the Department of Health to render an opinion that it is an inducement to offer prices for lab testing that are less than the full cost of testing, it could trigger major changes to contracting for laboratory testing in that state.

Even if the Department of Health were to issue such an opinion, there are a variety of economic and political interests which would try to intercede. They would use the courts and the legislature to soften the impact of such an opinion.

Below Cost Contracting

However, it must be acknowledged that NYSCLA's use of existing laws in New York state to address the problem of below cost contracting for laboratory services certainly has merit.

Whereas the vast body of law and regulations generally get used against clinical laboratories and pathologists, here is an instance where a trade association is attempting to use those same laws and regulations to the benefit of the lab industry. TDR

For more information, contact Tom Rafalsky at 212-664-7999.

Unilab Signs Agreement To Buy Bio-Cypher Labs

Sale of Bio-Cypher was long-predicted, Unilab to rapidly integrate its new purchase

CEO SUMMARY: Unilab's desire to purchase $60 million Bio-Cypher must be viewed against the impending acquisition by Quest Diagnostics of SmithKline Beecham Clinical Laboratories (SBCL). Whenever Quest takes control of SBCL's lab operations, it automatically becomes a significant competitor to Unilab in the Golden State. For Unilab, acquiring Bio-Cypher represents both an offensive and defensive strategy.

IT'S TAKEN A LONG TIME TO HAPPEN, but **Bio-Cypher Laboratories** (BCL) of Sacramento, California is finally on the sales block.

On April 6, **Unilab Corporation** announced a definitive agreement "to acquire substantially all of the assets (including the customer list) of **Physicians Clinical Laboratory** (doing business as Bio-Cypher Laboratories)."

BCL is estimated to have annual revenues approaching $60 million. Unilab is to pay about $36 million for BCL. Terms include $8 million in cash, 1 million shares of Unilab common stock, and a $25 million convertible note, with annual principal payments of $10 million. Unilab will also assume $4 million of BCL debt.

Unilab Is Optimistic

"Unilab is very optimistic about this acquisition," said Richard Michaelson, a Unilab Director and its former CFO. "Bio-Cypher's existing client base dovetails neatly into our statewide laboratory network. We believe that we can successfully integrate it's assets into our operation and generate meaningful increases to our operating profits and earnings."

Several potential buyers kicked Bio-Cypher's tires. Among them were **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, and **SmithKline Beecham Clinical Laboratories** (SBCL).

Well-Positioned Network

But no potential buyer could get as much benefit from BCL as Unilab. It already operates a major laboratory in Sacramento, across town from BCL's core lab. Its laboratory network throughout the state is well-positioned to service BCL's existing client base.

"Both the structure of the purchase and price to be paid for Bio-Cypher were appropriate to Unilab," stated Michaelson. "Probably no other lab in California can generate as much value from BCL's assets as Unilab."

Michaelson's comments reflect a truth about the California marketplace. As the marketplace eliminates excess laboratory capacity, those remaining

labs with low costs and high utilization of capacity will become stronger.

Unilab's acquisition of BCL represents both an offensive and defensive business strategy. It demonstrates how complex the California marketplace has become.

Leverage Lab Infrastructure

As an offensive strategy, buying BCL allows Unilab to leverage its existing laboratory infrastructure. BCL's specimen volume will soak up Unilab's excess capacity, particularly in its Sacramento and San Jose core labs. It also improves the productivity of Unilab's network of couriers and draw sites.

As a defensive strategy, Unilab's purchase of BCL blocks Quest Diagnostics. Quest Diagnostics is expected to complete its acquisition of SBCL this summer. SBCL's California business makes Quest a significant player in that state. BCL's $60 million client base would help Quest for many of the same reasons that it helps Unilab.

That is why Unilab's purchase of BCL is really part of a complex business strategy. It benefits Unilab in a variety of ways. However, Unilab faces several hurdles before it can declare this impending acquistion to be a success.

Bio-Cypher is a struggling company. Its problems are widely-known. Unilab's management team faces significant challenges in the upcoming integration. During the last year, there has been a steady exodus of capable lab managers from Bio-Cypher.

Insufficient Cash Flow

Its cash flow was insufficient to sustain regular operations. Billing and collections, in particular, have proved troublesome, further starving the company of much-needed cash.

But Unilab sees a strong, underlying foundation to BCL, one it believes has value. "For several years, Bio-Cypher had a rough time," noted Michaelson. "However, its client base has been relatively stable in the most recent period."

Michaelson is referring to the core of long-time, very loyal clients that continued to support BCL through its most difficult times. Unilab believes existing clients of BCL will stay with Unilab after the acquisition because of the additional services and financial stability offered by Unilab.

Unilab's recent purchase of **Meris Laboratories** in San Jose was similar. Meris had severe financial problems for several years. When Unilab purchased Meris last fall, it had great success retaining the client base of Meris. *(See TDR, November 8, 1998.)* Unilab has confidence that BCL's remaining core clientele will similarly opt to stay with its new owner.

Intensely Competitive

Clients and regular readers of THE DARK REPORT know that California has been the most intensely-competitive battleground for laboratory service in the United States. The fall of Bio-Cypher has been long predicted. The unanswered question was which of the major lab players would end up purchasing Bio-Cypher.

Bio-Cypher's removal from the marketplace eliminates the last obvious and sizable quantity of laboratory capacity from California. It will help efforts by remaining labs to improve contract pricing and reimbursement for laboratory testing in the state.

However, expect competition to be fierce for lab business in California. Michaelson explains why. "The numbers we see indicate that some $4 billion dollars of lab testing is done in California each year."

Unilab Corp. Versus the 800-Pound Gorilla: Will California Become Hotly Contested?

HUGE CHUNKS OF EXCESS LABORATORY CAPACITY have disappeared from California's lab marketplace. This means a new cycle of competition will soon begin in the Golden State.

The most obvious battle lines will be drawn between Unilab and Quest Diagnostics (after it acquires SmithKline Beecham Clinical Laboratories [SBCL]). The reason is simple.

Both will have the size to influence the market and service clients in every region of the state. Both will have an existing pool of managed care contracts with the largest HMOs. And both will have the capital resources to fund aggressive sales and marketing efforts.

"Unilab faces an interesting challenge," said one long-time industry executive in the state. "Will its acquisition of Bio-Cypher Labs wake the sleeping gorilla, Quest?

"In recent years, the competitive sales environment in California has been kind to Unilab," he continued. "After Quest acquires SBCL, that will probably change. Quest is capable of mounting a well-financed, professional sales campaign. I don't believe they will cede California, particularly with the strong revenue base that SBCL brings to them.

"I am familiar with Bio-Cypher and its extensive internal problems," mused the executive. "Unilab is paying a strong price for a troubled lab. I would surmise that one reason it is anxious to do this deal is to prevent Quest from buying Bio-Cypher.

"Should Quest decide to seriously compete for increased market share in that state," he concluded, "then Unilab's relatively easy ride in California will come to an end. There will be a real cat-

"Physicians' offices generate almost $2 billion in testing, and about half of that is performed by commercial labs," explained Michaelson. "There are still a lot of labs competing for this $1 billion of testing."

Michaelson's comments demonstrate that Unilab still recognizes that California remains an intensely competitive marketplace for laboratory testing. It knows that survival and prosperity depend on effective implementation of its business plan.

Disappear From The Market

The truth of this statement is reflected in the collapse of both Meris Labs and BCL during the last seven months. As these two labs disappear from the marketplace, almost $90 million per year of laboratory capacity and infrastructure disappears with them. That improves the competitive position of the remaining laboratories in California. But it also demonstrates that financial pressure on clinical laboratories continues to be intense.

For that reason, laboratory executives and pathologists will find the next market phase in California to be revealing. In this phase, Unilab, Quest Diagnostics, LabCorp and several other key competitors will be fighting under different ground rules.

California's next competitive cycle will be less about rock-bottom capitated rates and more about "value-added" laboratory services. Predicting winners and losers at this point is impossible. TDR

For further information, contact Richard Michaelson at 201-525-1000.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Think turnover among laboratory executives and administrators is high? Get a load of this! Among CEOs at the nation's 4,838 general, non-federal acute-care hospitals, the turnover rate was 16.9% during 1998. This was up from 12.1% in 1997. It means that one of every six hospitals got a new CEO last year, and three of ten hospitals got a new CEO during the last two years. The survey was performed by the **American College of Healthcare Executives** (ACHE). Hospital CEO turnover affects lab administrators and pathologists in several ways. It disrupts management planning for major laboratory initiatives, because the new CEO often arrives at the hospital with different criteria and priorities.

Accumed International was recently awarded a patent for a "Method and Apparatus for Automatically Detecting Malignancy-Associated Changes." The company is working on cytodiagnostic technology aimed at improving the early detection of several types of cancer, including lung cancer.

PROMOTIONS FOR PAST WAR COLLEGE FACULTY MEMBERS

Congratulations are in order for two former *War College* faculty members who recently earned promotions. Glen Fine, CEO of **MDS-Hudson Valley Laboratories** (MDS-HVL) of Poughkeepsie, New York, has been appointed Vice President of Operations for **MDS Laboratory Services** in the United States. Glen will move to Nashville in July and work from the MDS headquarters office there. Glen presented the MDS-HVL case study at the 1996 *Executive War College* in Pittsburgh.

Roman Szumski, M.D. is leaving **Calgary Laboratory Services** in Calgary, Alberta, where he was President and CEO. He will join **MDS, Inc.** of Canada full-time to develop diagnostics opportunities resulting from new advances in genomics, bioinformatics and microtechnologies. At the 1997 *Executive War College*, Roman presented the case study of the Calgary laboratory regionalization project. It created a single hospital/ commercial lab organization which lowered the region's lab costs by 30% while maintaining service levels.

FINAL ADD: ...PROMOTIONS

New President and CEO at Calgary Laboratory Services is Rosemary Pahl, M.D. Meanwhile, perceptive readers should take note that the CEO slot at MDS-HVL in Poughkeepsie is open. MDS-HVL is a partnership between two hospitals and MDS. It is an integrated regional laboratory with a core lab, effective outreach and a determined growth strategy.

Watch health insurance premiums zoom into double digits again for 2000. Yet, cost increases for hospitals and physicians remain at minimal levels. The **U.S. Labor Department's** Producer Price Index for acute care hospitals increased .01% in February and only 1.5% for the previous 12-month period. The physician segment increased by .04% and 2.4% for the comparable time periods. Clearly providers are not benefiting from higher premiums.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 17, 1999

THE DARK REPORT

UPCOMING...

- *EXECUTIVE WAR COLLEGE '99: First Report on Breakthroughs, Discoveries, and Insights.*
- *Texas Becomes a "Rough and Tumble" Market for Both Lab and Pathology Services.*
- *"Below Cost" Lab Contracts: Will New York Put a Stop to Widespread Practice?*
- *New Data Indicates Pathology Profession Shifting from Partnership Practice Models to Employee-Based Service.*