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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

Welcome Back, Consumers!

DURING 2003, THERE WAS SURPRISING PROGRESS IN THE MOVEMENT to improve patient safety. Closely-connected to the patient safety trend are efforts to measure and make public the healthcare outcomes achieved by hospitals, physicians, laboratories, and other providers.

One reason why this movement is important is that it begins the process of restoring the consumer as the major decision-maker. Employers and payers want consumers to have ready access to information which shows which hospitals and physicians get better outcomes. As our clients and regular readers know, one big trend in health benefits is the move to consumer-directed health plans, with larger deductibles and out-of-pocket requirements.

I would think laboratory administrators and pathologists would welcome this development. For most of the 1990s, they had to deal with the gatekeeper HMO, which denied both the physician and the patient the ability to choose which clinical laboratory would serve them. Restoring consumer choice in laboratory services is a positive step for the laboratory industry.

So watch out for consumers! They will be back. Slowly at first, but in growing numbers as each year passes. Aging baby boomers are well-educated, like to control their healthcare decisions, and have plenty of money to spend for healthcare which they perceive best meets their needs.

What makes this consumer-driven powerful is that it has the support of the nation's largest employers. Many were sued by their employees when gatekeeper HMOs denied access to care. To avoid this legal liability, and to maintain a neutral role in providing health benefits, major employers are designing health benefit programs which give consumers more choice than at any time when fee-for-service medicine dominated the American healthcare scene.

Laboratories and pathology group practices should keep a close eye on the patient-choice trend and direct-access testing (DAT). Along with requirements to document improvements in patient safety and outcomes will come the need to provide consumers with laboratory testing services customized to their needs. I think labs will do much better when patients (and physicians) are encouraged to shop for laboratories and make their own decisions about who does their laboratory testing. TDR

2003's Big Lab Stories Reflect Health Trends

During the past year, healthcare trends were the major agents of change

CEO SUMMARY: At a minimum, 2003 proved to be a year of relative stability for the laboratory industry, as demonstrated by THE DARK REPORT's "Ten Biggest Lab Stories of 2003." The year was free of industry-wide crises and scandals. That allowed most laboratory administrators and pathologists to concentrate on improvements to their laboratory operations and service menus.

ONCE AGAIN, our list of the "Ten Biggest Lab Stories of 2003" provides revealing insights into issues actively shaping the management strategies of clinical laboratories and pathology group practices.

Just as we have in past years, THE DARK REPORT has identified ten of the most significant stories that surfaced during 2003. Each of these stories, in its own way, illustrates how the laboratory industry is reacting to evolutionary and revolutionary changes within the American healthcare system.

Mostly the news is good. Across all segments of the laboratory industry, individual lab organizations and pathology groups are enjoying an environment of relative calm. Reimbursement is stable, operations are predictable, and there is no "universal" outside threat comparable to the financial turmoil instigated by HMOs during the last decade.

However, this calm environment masks some potent forces for change. Within most large hospital laboratories and in all independent commercial laboratories, intense efforts to improve the status quo are under way. Simply put, smart lab administrators and pathologists are pushing their lab organizations to be more productive. They want to squeeze out more cost savings. There is also an ongoing need to acquire and deploy new lab technology that furthers the mission of their parent health system.

It is this management emphasis on improving operational performance

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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that has innovators and early-adopter laboratories turning to quality management systems like ISO-9000, Six Sigma, and Lean. For that reason, THE DARK REPORT believes the single most significant story of 2003 is the validation of quality management systems in transforming laboratory operations.

A "Feet First" Leap

The evidence comes from the experience that four large health system laboratories had when they decided to jump, feet first, into adopting quality management systems like ISO, Six Sigma, and Lean to make over their high volume core laboratories.

As first and exclusively reported in different issues of THE DARK REPORT, these four large health system laboratories were able to slash average turnaround times for inpatient testing by factors of 40%, 50%, and 60% following a 16-week implementation project. Of equal importance, productivity gains exceeding 50% were common, with comparable improvements in quality and service levels.

These accomplishments are remarkable and will not go unnoticed by other laboratory directors and pathologists. Inspired by the example of these four pioneering laboratories, THE DARK REPORT predicts that a steadily growing number of hospital laboratories will opt to introduce the management methods of Six Sigma and Lean into their labs during the next 24 months.

There is further progress on another significant laboratory industry trend that THE DARK REPORT was first to identify. That trend is the patient safety movement, which carries along with it several other key trends, such as improving healthcare outcomes, measuring and publishing provider performance, and paying financial incentives to hospitals, physicians, and other providers which achieve high outcomes.

Visible signs of this trend are the rapid-fire introduction of: 1) new standards by accrediting bodies that directly measure outcomes connected to patient safety; 2) the first outcomes-linked financial incentives by major insurance companies; and, 3) Medicare's efforts to collect data and measure the performance of hospitals. Not surprisingly, hospital administrators are beginning to ask their laboratories to make contributions to clinical improvements that serve these new objectives.

Anatomic pathology is affected by both of these top ten stories, but will follow the lead of clinical laboratories. However, anatomic pathology won't lag by much. THE DARK REPORT is already collecting incredible stories about early-adopter pathology groups which are actually doing "real-time" pathology for a growing percentage of their case volume.

Rounding Out The "Top Ten"

The eight other stories in our "Top Ten" for 2003 include recognition of laboratory medicine's role in suppressing the SARS outbreak, changes in how payers relate to laboratory providers, uneven Medicare compliance policies and similar trends of influence on today's laboratories and pathology group practices.

As in past years, THE DARK REPORT recommends that lab directors and pathologists use this list of big stories as the basis for a strategic planning session. Feedback from clients and regular readers tells us this has been a useful tool in aligning a laboratory's vision and strategic focus with the changing realities in the American healthcare system.

Further, expect to see additional intelligence briefings on these subjects during 2004. That's because they will have continued influence on the laboratory industry.

2003's Big Lab Story #1

ISO, Six Sigma, Lean Principles Are Validated in Core Lab Projects

PREPARE FOR A CYCLE OF DEEP CHANGE in how the nation's clinical laboratories are organized and operated. During 2003, several prominent hospital laboratories boldly took quality management methods used outside healthcare, applied them to laboratory operations, and harvested major benefits.

In Portland, Oregon, **Kaiser Permanente Northwest Laboratories** used ISO-9000 principles to design a new core laboratory facility and reengineer work processes. Productivity soared, quality increased, and gains in service levels were obvious to the lab's physician clients. *(See TDRs, July 28 and August 18, 2003.)*

Using a combination of Lean and Six Sigma management techniques, three major health system laboratories redid their high-volume core chemistry and hematology work cells. In projects lasting less than 16 weeks, TAT for inpatient testing was cut by an average of 50%, with comparable gains in productivity, overall costs, and lab service levels.

DSI Laboratories of Fort Meyer, Florida, **Fairview Health Services** of Minneapolis, Minnesota, and **West Tennessee Healthcare** of Jackson, Tennessee deserve recognition for these accomplishments. *(See TDR, September 8, 2003.)*

More importantly, it can be expected that other clinical laboratories will not be able to ignore improvements of this magnitude. Expect more labs to embrace ISO, Six Sigma, and Lean techniques.

2003's Big Lab Story #2

Patient Safety Initiatives Driving Deep Changes to Healthcare System

IF ANY QUESTIONS REMAINED about the importance of improving patient safety, the events of 2003 certainly dispelled them.

Throughout the year, various healthcare accrediting bodies announced changes and additions to their accrediting criteria specifically to improve patient safety. Probably the most prominent example is the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO). It is swiftly shifting its emphasis toward specific goals which enhance patient safety.

Employers are taking an assertive role through groups like the **Midwest Employers Group on Health** and the **Leapfrog Group**. Officials at the **Centers for Medicare and Medicaid Services** (CMS) are actively working with hospitals groups and other provider associations to develop and implement programs which reward improvements in clinical outcomes and patient safety.

Big news for the laboratory profession is the formation of a laboratory Quality Institute by the **Centers for Disease Control** (CDC). The effort was launched with a two-day meeting in Atlanta last April. This Quality Institute is chartered to develop national measures for laboratory quality. These measures will be collected and reported annually. The goal is to introduce these measures by the fall of 2004.

2003's Big Lab Story #3

Lab Industry Lobbies Congress: One Big Win, But Also a Setback

SUCCESSFUL OPPOSITION to the proposals to reinstitute the 20% co-pay for Part B Medicare lab testing services is a milestone victory for the laboratory industry.

This victory stands in stark contrast to a lackluster track record in lobbying Congress. Since the mid-1980s, the lab industry has endured regular cutbacks to funding for lab testing services. Because of unique politics, this year's effort by some within Congress to reinstitute the 20% lab test co-pay was considered to be a serious threat.

Thus, the successful effort to beat it back is an exceptional event. One major reason for this achievement is that a different cast of characters became involved and did a different type of lobbying campaign. It started with the **American Association of Bio-Analysts** (AABA), which, among other things, encouraged its member laboratories to go directly to seniors and educate them about this proposal.

It included individuals like the CEOs from cross-town competitors **Bio-Reference Laboratories, Inc.** and **Sunrise Medical Laboratories**, both located in metropolitan New York. The CEOs from both companies raised money, raised consciousness, and invested lots of personal time to educate key policymakers in Congress. Although the 20% co-pay was defeated, the Medicare bill which passed did include a provision freezing CPI updates for lab testing for several years. Thus, the need for more effective lobbying remains.

2003's Big Lab Story #4

Molecular Diagnostics Makes Important Inroads in Clinical Use

LABORATORY TESTS BASED on molecular technologies still represent a small portion of the total volume of tests performed annually in the United States. But that status quo is changing at a steady rate.

Most lab directors and pathologists are familiar with the key role molecular diagnostics now plays in treating HIV patients. Molecular technologies are finding diagnostic applications in other infectious diseases. Most prominent during 2003 was the recommendation by professional associations that cervical cancer screening guidelines now include HPV testing for women meeting specific criteria.

In oncology, the use of various molecular-based tests is gaining wider acceptance. An early example of pharmacogenomics is the use of the Her2/neu test with breast cancer patients to justify Herceptin® as an appropriate therapeutic option.

Another example of this trend is the marketing campaigns launched this year by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** to introduce their choice of molecular-based assays for colon cancer screening. Both national lab companies are using their extensive sales and marketing network to educate physicians and payers about these tests. As new molecular assays continue to reach the market, these types of marketing efforts will be used to introduce them and insure that adequate reimbursement is established.

2003's Big Lab Story #5

Evidence Accumulates of Uneven Medicare Compliance Practices

THIS IS A STORY WHICH IS STILL EVOLVING. Evidence is accumulating that uneven Medicare compliance practices are becoming a growing problem within the competitive market for lab tests referred from physicians' offices.

During 2003, a significant number of laboratory administrators and pathologists began to include uneven Medicare compliance practices in their service markets as one of their significant management challenges. This is a change from the last half of the 1990s, when newly-instituted laboratory compliance requirements for Medicare fraud and abuse caused many labs to act cautiously.

The issues revolve primarily around how lab competitors handle ABNs, how labs assess charge-backs to client bill accounts which did not provide the information necessary to successfully bill Medicare, and how labs use the "free testing" strategy described in an OIG fraud alert.

Anecdotally, most lab directors and pathologists have stories about egregious compliance practices by lab competitors in their area which have been willing to adopt aggressive interpretations of Medicare compliance guidelines and statutes. Just a few years ago, it was uncommon to hear these types of stories.

Using "chatter" on this topic as a guide, it is reasonable to conclude that there is a lack of uniformity in Medicare compliance practices across the lab industry. If this proves true, it could eventually trigger some type of action by the OIG.

2003's Big Lab Story #6

Robust Job Market for Pathologists And All Laboratory Professionals

FOLLOWING A DECADE of lab consolidation, when layoffs of medical technologists were common, the 2000s has seen a robust job market for med techs, pathologists, and all categories of advanced laboratory skills.

The inadequate supply of med techs has been well-documented on these and other pages. Less recognized is the already-acute shortage of histotechnologists. However, what is often overlooked is that the year-to-year increase in the volume of specimens tested creates a growing demand for skilled laboratory professionals.

This is a trend which has significant implications for clinical laboratories and anatomic pathology group practices. Continued growth in the volume of testing requires more trained labor, along with advanced technology that automates many labor-intensive steps.

The market is already responding to increase the supply of technical professionals. The number of med tech training programs is increasing. The number of distance learning opportunities is growing. It's a similar story in the pathology profession. Pathologists with sub-specialty skills are often getting multiple offers for positions or private practice partnerships. There is still a demographic "gap" that affects every category of laboratory professional skills. But there are positive signs that the supply of trained lab professionals will be increasing.

2003's Big Lab Story #7

SARS Outbreaks Reveal Strengths And Vulnerabilities of Laboratories

LEAVE IT TO THE REAL WORLD to provide SARS as a timely example of the strengths and vulnerabilities of our nation's laboratories.

On the plus side, the SARS outbreak demonstrated how modern diagnostic technology can speed up the process of recognizing new diseases and controlling outbreaks of these diseases. Researchers were able to quickly map the genetic structure of the SARS virus and identify its likely point of origin.

For a number of developed countries, the speedy recognition of this new disease allowed public health officials to take effective steps to identify travelers coming from affected regions and minimize or prevent the introduction of SARS into their country.

On the minus side, SARS showed gaps in how healthcare systems are prepared to deal with what may be primarily an airborne infectious agent. In Toronto, SARS patients in two hospitals exposed large numbers of hospital workers to the disease, forcing the workers into quarantine.

Laboratorians in Toronto learned important lessons about unidentified weaknesses in laboratory procedures. It was recognized that lab workers are potentially vulnerable to SARS exposure in patient service centers, from courier visits to physicians offices, and from interaction with infection control teams. However, just as during the anthrax episodes of 2001, good laboratory practices minimized risk.

2003's Big Lab Story #8

Good Times for Regional Labs And Hospital Lab Outreach Programs

EVENTS IN 2003 DEMONSTRATED that independent regional laboratories and professionally-managed hospital laboratory outreach programs are enjoying vigorous and profitable growth.

Although the number of independent commercial laboratories remains small, most are enjoying a relative time of prosperity. The largest of these firms is **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas. It has launched an expansion program which takes it outside of its traditional market of Texas. In California, smaller independent labs like **WestCliff Medical Laboratories** of Newport Beach are ramping up sales efforts and enjoying substantial increases in laboratory testing volumes.

Hospital lab outreach programs have similar success stories. **PacLab Network** in Washington State is growing at a steady rate, as are any number of hospital laboratory outreach programs.

Two primary reasons lie behind this rosy environment. First, in most cities, the primary competitor is one or both of the two blood brothers. Yet many physicians still prefer to use a local laboratory where that option exists. This favors regional labs.

Second, most local labs have adjusted to the fact that they may not be a contract provider for many health plans in their area. In recent years, they have learned how to capture the non-contract lab testing business which still exists in their marketplace.

2003's Big Lab Story #9

Payers Look for Different Benefits When Selecting Laboratory Providers

IN THE 1990S, many smaller regional laboratories lost access to managed care contracts. Public lab companies were aggressive in their willingness to accept contracts with capitated reimbursement and utilization risk as a way to gain exclusive access to patients.

However, healthcare trends and changing expectations of employers (who "buy" health plans for their employees) are causing health insurers to rethink aspects of their operations.

One factor in this change is consumer rejection of the closed panel, gatekeeper-model HMO. THE DARK REPORT was first to identify this shift back in 1998. Since that time, enrollment in PPO, POS, and other types of health plans which allow consumer choice has increased substantially. Insurers and employers had to respond to this major shift in consumer expectations.

In addition, the drive to improve patient safety and the trend to measure provider outcomes gives insurers an incentive to select laboratory providers on different criteria than the lowest price for high-volume routine lab tests.

This trend is creating opportunities for local lab providers that didn't exist in the 1990s. Compared to past years,the ability to provide inpatient and outpatient lab test data to physicians and payers and specialized testing services uniquely suited to a region's needs now have more value to some payers.

2003's Big Lab Story #10

Public Anatomic Path Companies "Hit the Wall" During a Tough Year

AFTER A MULTI-YEAR RUN of great gains in specimen volume and revenues, the nation's three largest public anatomic pathology companies "hit the wall" in 2003.

DIANON Systems, Inc. was acquired by **Laboratory Corporation of America** in January 2003. **AmeriPath, Inc.** sold itself to **Welsh, Carson, Anderson & Stowe** and became a private company early in 2003. **IMPATH, Inc.** filed chapter 11 bankruptcy in August 2003 and still seeks a buyer.

Although the management teams at all three companies lost their independence, that doesn't mean that the market opportunities to sell anatomic pathology services directly to physicians has disappeared. To the contrary, these three anatomic pathology firms demonstrated that the traditional model of anatomic pathology—a group practice serving one or more community hospitals—is no longer the only viable business model.

The problems in each of the three large public companies that led to sales or bankruptcy have less to do with a change in market demand and more to do with failings of the management teams within these firms to respond to rapid growth rates and other business challenges. *(See TDR, September 29, 2003.)*

With these three companies now distracted by internal issues, the time is opportune for competing pathologists to expand their businesses.

Letters To The Editor

LabOne Speaks Out About Use of "Free Testing"

DEAR EDITOR,

In the August 26, 2002 issue of THE DARK REPORT, an article appeared entitled, "Two Blood Brothers Use 'Free Testing' Strategy."

In markets that we are "in-network" with various payers, this tactic of providing free testing is increasingly prevalent. While the competitive injury inflicted on other providers by this questionable practice is obvious, the damage to payers also is substantial yet more insidious. Statistical data provided to payers from authorized in-network providers becomes skewed, thereby challenging the completeness of HEDIS reporting, utilization monitoring and outcomes measurements.

Further damage is caused to payers in such markets where the "Blood Brothers" are in network, such as Medicare, which are paying for laboratory testing while other payers are seemingly getting a "free ride." Such practices also serve to validate Medicare's concern that it is paying too much for laboratory testing in comparison to payments by other payers and provides a justification to drive policies like the proposed "usual charges" regulation.

As a laboratory concerned about such questionable practices, we have avoided them. However, as the marketplace is distorted by national laboratories that have the apparent economic capability to offer such "free testing," we are becoming increasingly concerned. Please advise us whether you have had any further discussions with the Centers for Medicare and Medicaid Services (CMS), about this competitive strategy, or if you have additional information concerning its legality.

Cordially,

John McCarty
Chief Financial Officer
LabOne, Inc.
Lenexa, Kansas

Mr. McCarty is describing the marketing strategy that involves use of the "Waiver of Charges to Managed Care Patients" method as outlined in a December 1994 fraud alert issued by the Office of the Investigator General (OIG).

Use of the "free testing" strategy in Tennessee was covered in the previous issue of THE DARK REPORT (December 1, 2003). Attorneys who specialize in Medicare compliance issues affecting laboratories and pathology group practices state that little detailed guidance on the subject of "free testing" has been issued by the OIG. If the "free testing" strategy becomes more common, it may spur the OIG to issue more guidance–Ed.

"New" Legal Landmines For Clinical Laboratories

Ongoing changes in liability, malpractice and legal risk require attention from labs

CEO SUMMARY: HIPAA is a big "new" source of legal exposure for laboratories and other healthcare providers. Also, recent court decisions and changes in clinical practices are adding to the legal risk for labs. Attorney Richard S. Cooper offers insights on how laboratories can better protect themselves, along with specific strategies to use in negotiating better terms with managed care companies.

June G. Smart, PhD

IT MAY BE TIMELY TO DO A LEGAL AUDIT within your laboratory to identify evolving legal landmines that might possibly prove troublesome, if not downright dangerous.

Has your laboratory recently changed the complexity of its test menu? Did your lab expand the geographic area where it provides laboratory testing services? Answer yes to either of these questions and your laboratory may have additional legal exposure.

Do you know that a lab that has failed to properly update its insurance coverage and liability plan is more likely to have exposure from liability issues than it is to have problems with either fraud and abuse or HIPAA violations? These questions represent a sample of the legal landmines waiting to explode, usually at the most troublesome time.

Legal Landmine #1: New Lab Service Lines and Liability

"It is smart for every laboratory to notify its legal advisors whenever it takes on a significant new service line (particularly one involving new technologies), establishes new laboratory operations or services in a new location, or opens a new draw station," stated Richard S. Cooper, Partner and manager of the health law department at **McDonald Hopkins, LPA**.

"Each one of these business actions can change the laboratory's potential liability profile and create new legal exposure," he noted. "Every laboratory should make it standard practice to consult with their legal advisor whenever it adds significant new services, expands into a new location, or opens additional patient service centers.

"The first step in reducing your potential liability is to review the contracts which cover new tests, services, or facilities," he added. "It is essential that you understand, fully and completely, the terms and consequences of these contracts. Next, review your insurance coverage with your legal department to see if you are adequately protected on these new activities. Coverage limits, exclusions, and

limitations are all relevant and should be reviewed.

"It is best to do this review *before* entering into new contract agreements," advised Cooper. "That allows you to reshape contracts so as to minimize your laboratory's potential liability and other forms of legal exposure," stated Cooper."

Legal Review

"This same type of legal review should be done when entering into agreements with clients such as physicians' offices, nursing homes, hospitals, and the like," Cooper said. "Often such contracts can contain language which may void or limit your current insurance coverage, or may inappropriately shift risk to your laboratory.

"Hospital laboratories must also coordinate their activities with existing hospital-wide legal policies and management programs," recommended Cooper. "This insures that the laboratory's operational activities do not trigger unexpected and unpleasant financial repercussions for the parent hospital or health systems.

"Liability can derive from unexpected sources. As laboratory medicine becomes more complex, it creates new exposure. Technology and changes in laboratory services, coupled with evolving regulatory environments, can change both the liability and malpractice status quo—often in ways that work against laboratories," counseled Cooper.

"With rapid changes expected in the fields of genomics, proteomics and pharmacogenomics, every lab's exposure to liability or malpractice deepens," he observed. "That is why lab directors and pathologists should consider it prudent and reasonable to discuss such issues with their legal advisors whenever the lab takes active steps to introduce new technology and new services."

Undertaking these legal reviews is only a first step. In today's litigious environment, it is necessary for laboratories to demonstrate that they are taking regular and proactive steps to minimize and eliminate liability. "Does your laboratory have adequate plans in place to cover each area of liability? Are your managers and staff trained to respond properly to an event which triggers liability?" asked Cooper.

"Without a clear plan of action, people may do things unintentionally, possibly triggering significant financial exposure," said Cooper. "Every laboratory should train all employees in the formal process for reporting liability risk concerns and liability events. However, don't establish a rule that is not consistently followed, as this will create more liability problems for your laboratory."

Legal Landmine #2:
Reducing Risk From Managed Care Contracts

When negotiating managed care contracts, risk exposure is a key element. Careful negotiations by laboratories at contract time can prevent potentially heavy financial losses in the future.

"Laboratories should view two contracting areas with concern," advised Cooper. "The first involves "most favored nation" (MFN) clauses. The second involves medical necessity.

"The MFN clause typically states that your laboratory must give the health plan your best prices," he explained. "Avoid MFNs. At the least, work to limit them. Should your laboratory sign a contract for a lower fee with another managed care plan, then your original contract with the first health plan will be paid at a lower rate.

"In this scenario, your laboratory has played into the hands of the managed care company. You have reduced

their plan costs and provided them with a marketing advantage. They can lower their rates and charge lower premiums, 'using' your money!"

If an MFN clause must be included, Cooper has additional advice. "The MFN clause should only be triggered with respect to 'like' plans: same payment type (e.g. HMO-HMO), comparable patient mix, same capitation arrangement, same demographics, same size plan, and same specimen volume," he said.

"Next, be aware of the patient populations and geographic locations included in the managed care contract," he said. "There may be different cost structures and usage levels at play. HMOs use actuaries to determine rates based on geographic location and population size; the larger the insured population, the lower the risk to the HMO. Your laboratory should negotiate a contract to address differentials in the risk and cost to serve the plan's beneficiaries.

"In cases where a laboratory does have a managed care contract with the "most favored nation" clause, it should also have a plan in place to monitor for events that might trigger the MFN," noted Cooper. "The goal here is to avoid unintentional violations of the contract.

Include Contract Provisions

"One additional way to protect against MFN clause violations is to include provisions in the contract which allows an independent auditor to review your managed care book of business and preserves your laboratory's right to challenge any findings. Collectively, these can prevent your laboratory from significant penalties."

Cooper next discussed medical necessity. "Negotiate a provision in your lab's managed care contracts that effectively gets the payer to agree that it will not deny reimbursement for services provided by the laboratory based upon determinations that the services were not medically necessary or that pre-authorization was not obtained," he said.

"This is a reasonable provision. Laboratories are not usually in the position to determine medical necessity and the payer retains the discretion to determine medical necessity," explained Cooper. "Similarly, your laboratory should attempt to negotiate out claim denials due to lack of an ABN, because the laboratory does not provide service directly to the patient and often cannot obtain an ABN."

Legal Landmine #3:
Misuse of Business Associate Agreements

With the arrival of HIPAA comes a new legal issue, centered around "Business Associate Agreements" (BAA). "In the case where a laboratory is simply referring a specimen to a reference laboratory, it is not necessary to execute a BAA," he explained. Similarly, if a laboratory merely receives referrals from another laboratory, it is not required to sign a BAA.

"It is important to understand the contractual responsibilities that result from a BBA," added Cooper. "For that reason, unless a laboratory is actually a business associate of the referring laboratory, it probably doesn't need to sign a BBA."

Legal Landmine #4:
Legal Education For Diagnosis Codes

Obtaining diagnosis codes from physician offices is an ongoing problem for almost all laboratories. One way to reduce the laboratory's potential exposure to fraud and abuse charges is to establish a proactive and ongoing education program for physician-clients.

"Most well-run laboratories handle this issue in a consistent manner,"

observed Cooper. "They conduct regular education programs for their clients. They also include language in their service contract with clients that requires physicians to properly complete diagnosis information. This makes the physician legally and contractually obligated to provide that information. It also documents that the laboratory is following a consistent policy with all its client-physicians concerning diagnosis information.

Physician Cooperation

"Such contract language is just the first step, however. When physicians don't follow the contract and fail to provide the diagnosis information, laboratories need to 'stick to their guns'," advised Cooper. "This is business that you don't want. Accepting specimens from a physician without diagnosis codes creates a legal land mine for the laboratory. In a situation like this, where the laboratory accepts specimens and assumes significant non-reimbursement due to lack of diagnosis codes, it faces possible exposure to fraud and abuse claims.

"When physicians don't follow the contract and fail to provide the diagnosis information, laboratories need to 'stick to their guns'..."

"Laboratories should not overlook developing good relationships with client physicians," added Cooper. "Studies have repeatedly shown that good relationships play a key role in minimizing legal risk. Laboratories should help physicians understand that a good working relationship works to the best interests of all parties. In the case of diagnosis codes, proper compliance is one way of precluding legal action which could embroil the physicians as well as the laboratory."

Cooper has good advice for another aspect of the diagnosis code problem. "Some managed care firms require diagnostic codes," he explained. "Laboratories should not assume responsibility for obtaining diagnosis information for patients under managed care contracts, because laboratories have no control over the physicians when it comes to capturing this information. In fact, we recommend that laboratories work with health insurers to have them include language in their contracts with physicians that makes it a requirement of the physician to provide the diagnostic information to the lab.

Summary

The insights and recommendations Cooper offers here cover a range of legal topics. Collectively, these topics demonstrate the significant and ongoing changes that affect a laboratory's exposure to liability, malpractice claims, and other legal risks.

However, Cooper is optimistic that every laboratory has the ability to tighten its legal defenses. "The most successful laboratories in my law practice have a common trait. They recognize that establishing a good legal foundation to their operations is essential to protecting the operational and financial integrity of the laboratory.

This is particularly true of hospital laboratories, which must operate outreach testing programs in a way that stays within the hospital's existing framework of liability coverage, managed care contracts, and legal policies. The continuing evolution in legal risk and and liability exposure means that every laboratory should regularly revisit these topics and update the laboratory's policies and procedures as appropriate. **TDR**

Contact Rick Cooper at 216-348-5438.

Abbott Acquires I-Stat, Resolves FDA Problems

Last week's announcements at Abbott Labs represent major milestones in its diagnostic unit

CEO SUMMARY: On December 15, Abbott revealed that it would pay $392 million to acquire I-Stat. Days later, on December 18, Abbott disclosed that the FDA had deemed its Lake County, Illinois diagnostic manufacturing plant to be "in substantial conformity" with the Quality System Regulation. Abbott can now restart manufacturing and sales of test kits that had be taken off the market in 1999.

IT WAS GOOD HOLIDAY NEWS for the diagnostics division at **Abbott Laboratories** last week. In separate announcements, the company disclosed its acquisition of **I-Stat Corporation** and its resolution of long-standing problems with the **Food and Drug Administration** (FDA).

Both developments will have some type of impact on many laboratories across the country. I-Stat's point-of-care instruments are widely used in hospitals. The FDA's action means that Abbott can begin to manufacture and sell some of the 125 diagnostic test kits which the FDA had pulled from the market in 1999.

The FDA issued a determination letter that described Abbott's Lake County, Illinois diagnostic manufacturing facility to be "in substantial conformity with the Quality System Regulation (QSR)." This finding is related to the consent decree that exists between Abbott and the FDA. The new finding specifies certain follow-up actions that Abbott must take and the consent decree will remain in force for another five years.

Abbott executives state that it will take several months to reinstitute manufacturing for the affected test kits. The company intends to reintroduce products on a rolling basis during the next 12 months. However, even as these test kits become available, Abbott faces another daunting task.

Rebuilding Customer Trust

Abbott must convince its laboratory customers to switch back to its brand of test kits. But these customers remember the turmoil, pain, and significant costs involved when the FDA required Abbott to pull those tests kits from the market in 1999. For many laboratories, considerable effort was required to locate, install, and validate substitute test kits.

Not only did many laboratory directors and pathologists work urgently to make this switch without disruptions in patient care, but they ended up feeling like Abbott had not dealt forthrightly with them during the crises. Abbott knows it has a tough sales and marketing challenge ahead. It must rebuild trust among many lab customers before

it can successfully obtain orders for the test kits now about to be offered again for the first time in four years.

The financial consequences of Abbott's fight with the FDA are also considerable. When Abbott paid the $100 million fine to the FDA in 1999, it was the largest such fine ever levied by the FDA. Since that date, Abbott has lost about $250 million per year in sales from those products pulled off the market and has been unable to introduce additional assays built around new technologies. It has also spent considerable money in attempts to rectify the deficiencies identified by the FDA.

Interest In POC Market

Abbott's acquisition of I-Stat reveals several interesting developments within the point-of-care (POC) testing marketplace. It will pay approximately $392 million to acquire the 90% of I-Stat's stock which it currently does not own. The price it is paying is a 20% premium over I-Stat's share price the day before the acquisition was announced.

In 1998, I-Stat and Abbott entered into a marketing, distribution, and stock-purchase agreement with Abbott. There were also research, development, and licensing arrangements for additional diagnostic products.

In recent years, I-Stat disagreed with Abbott on certain aspects of this relationship, including allocation of manufacturing cost savings. In the summer of 2002, I-Stat had announced it would terminate the distribution agreement with Abbott on December 31, 2003. It incurred a $52 million charge during 2002 to accomplish this goal. For 2004, I-Stat was forecasting a profit.

"Abbott was a disappointment as a distribution partner by any measurement," observed Al Kildani, Analyst at **C.E. Unterberg Towbin**. "I-Stat wanted to walk away from the agreement, take back control and regain the distribution, build a sales force, and become profitable for the first time ever. And that would have happened in the next quarter for the first time."

Below I-Stat's Expectations

As I-Stat's exclusive distributor, Kildani believes that Abbott had not performed to the expectation of I-Stat in building sales volume and revenue. Sales of I-Stat's Portable Clinical Analyzer represent about 15% of company sales. Disposable cartridge sales used in the instrument are 75% of I-Stat's sales.

Point-of-care testing is a hot market, compared to routine testing done in core laboratories, which explains Abbott's interest in acquiring I-Stat. Christy Wistar, Director of Investor Relations for Abbott, states that Abbott's sale of I-Stat products brings in $75 million a year. She estimates the market for POC testing is currently $500 million and will double to $1 billion in five years. "Since much of that growth would come at the expense of traditional labs, such as Abbott's clinical business," noted Wistar, "Abbott's investment in I-Stat's point-of-care products now makes sense.

Abbott Makes Its Move

"The original distribution deal was very favorable to Abbott," Wistar stated. "I-Stat wanted to terminate it, and it did. We saw this as an opportunity to secure access to the platform and solidify our presence in the point-of-care segment. We expect this business to grow in the double-digits: about 20% to 25% a year. We expect sales of $100 million next year."

Having resolved its major problem with the FDA and taken steps to acquire I-Stat, Abbott Laboratories is poised to become a different force in the laboratory marketplace. It remains to be seen how lab directors and pathologists respond to these developments. TDR

Who's Buying Labs? Activity Shifts Down

Remaining independent labs doing well, few sales of anatomic pathology practices

CEO SUMMARY: As the number of independent clinical laboratories dwindles, most remaining owners seem content to continue building their business—at least until a buyer makes them an offer "they can't refuse." Acquisitions of pathology group practices were also few in number during 2003. However, the reduced number of labs in the United States is causing some local pathologists to consider starting up new labs.

HAVING BOUGHT UP their largest remaining competitors in 2002, few obvious acquisition opportunities remain for the two national laboratory companies.

However, the deal-making market for laboratory transactions is anything but quiet. Behind the scenes, the two blood brothers continue to actively approach any laboratory organization that they see as a useful fit for their company to discuss a potential sale.

Other Laboratory Buyers

Quest Diagnostics Incorporated and **Laboratory Corporation of America** are not the only interested buyers. **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas has begun to move outside its historical market area to do acquisitions in such faraway states as Virginia and Ohio in recent months.

The deal-making environment is different this year in several ways. First, most lab acquisitions now involve small laboratories. In some cases, these acquisitions involve laboratories which basically serve a single large medical office building. These types of acquisitions are not disclosed by the public laboratory companies because they do not consider such purchases to be "material" changes to their financial performance.

In other cases, hospitals and health systems which own successful laboratory outreach programs have shopped their laboratories for potential sale. The most prominent example is the ongoing sales process involving **Health Alliance** in Cincinnati and its attempts to sell the physicians' office segment of its laboratory testing business. **Lab*One*, Inc.** of Lenexa, Kansas has announced that it is negotiating with Health Alliance to finalize an arrangement where Health Alliance would maintain ownership of its six hospital laboratories and purchase testing from Lab*One*.

Another laboratory owned by multiple hospitals and health systems that has been shopped for possible sale is **Spectrum Laboratory Network** of Greensboro, North Carolina. For a number of months, its owners have entertained offers for the laboratory.

In the case of both Health Alliance Laboratories and Spectrum Laboratory Network, the motive behind a possible sale is the desire of the hospital/health system owners to raise capital. Selling the outreach laboratory business is one way to realize the capital value of those outreach programs.

Changes In The Market

Given the national oligopoly that now exists in the physicians' office testing segment by the two national laboratories, the range of laboratory acquisitions known to have closed during 2003 point to some interesting characteristics in the laboratory services marketplace.

Thus, the interesting market trend which may emerge during the next 30 months is the formation of new, locally-focused laboratories in smaller cities around the United States.

First, most remaining independent commercial laboratories (defined as having no hospital/health system equity ownership) with revenues of more than $20 million per year continue to maintain their independence. Across the United States, only a handful of these types of laboratory companies remain. In general, these companies are posting strong growth and are not financially distressed.

Second, the majority of laboratories that have some hospital equity ownership are similarly doing well. There seems to be little motive for most of these lab companies to sell. There are exceptions, such as the two laboratories mentioned above.

Third, the interest by the two national laboratories to acquire small laboratories, including some that serve only a single medical office building or do specialty testing, is a new phenomenon. Over the last 20 years, these types of acquisitions were done by public laboratory companies, but they were not as common as what has been seen in 2003.

Fourth, the acquisitions of anatomic pathology practices remains limited to a handful of deals each year. Not surprisingly, **AmeriPath, Inc.** is the major buyer. It would be a significant development if either of the two blood brothers began to acquire pathology group practices in certain cities as a way to add capacity and build market share in anatomic pathology specimens. To date, there is no pattern of such acquisitions.

New Labs To Be Formed?

There may be another reaction to the market dominance of the two multi-billon-dollar national laboratory companies. In smaller cities around the United States, growing numbers of pathologists are beginning to seriously evaluate the opportunity to establish a new laboratory company.

In many cases, these are pathologists who had operated an independent company and sold it to one of the public lab companies sometime in the past 15 years. Observing the service deficiencies of the laboratories serving their communities—and with non-compete agreements that expired years ago—these pathologists recognize a clear need for a local laboratory that features the same high levels of service they provided prior to selling their laboratory.

Thus, the interesting market trend which may emerge during the next 30 months is the formation of new, locally-focused laboratories in smaller cities around the United States. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Two more not-for-profit hospitals received the Malcolm Baldridge National Quality Award last month. **St. Luke's Hospital** in Kansas City, Missouri and **Baptist Hospital** in Pensacola, Florida become the second and third hospitals to receive this award for quality achievement. Last year, **SSM Health**, a 21-hospital health system in St. Louis, Missouri became the first healthcare organization to win the award in a newly-created category for healthcare. There were 19 healthcare organizations which applied for the Baldridge Award this year.

MEDTOX EARNS ISO

There's another ISO-certified laboratory in the United States. **MEDTOX Scientific, Inc.**, based in St. Paul, Minnesota announced that it had earned certification in ISO 9001-2000 at the end of November. The company, which specializes in drugs of abuse testing, is actively introducing Six Sigma and Lean methods into its laboratory operations.

BUSY SURGEONS DETERMINED TO BE GOOD FOR PATIENTS

Last month the *New England Journal of Medicine* published a study that concludes that "patients can often improve their chances of survival substantially, even at high-volume hospitals, by selecting surgeons who perform the operations frequently." Researchers studied a nationwide sample of 475,000 Medicare patients. Based on 1998 and 1999 data for eight cancer and cardiovascular procedures, it was concluded that even when in hospitals with high volumes of procedures, mortality rates vary greatly among surgeons. As an example, for patients of surgeons who performed 22 or fewer aortic valve replacements, the mortality rate averaged 10.2%. It averaged only 6.1% for surgeons who performed 42 or more such procedures annually.

ADD TO: Busy Surgeons

The lead researcher was John Birkmeyer, M.D., Chief of General Surgery at **Dartmouth-Hitchcock Medical Center** in Lebanon, New Hampshire. Birkmeyer is a paid consultant for the **Leapfrog Group**. This study may have implications for the pathology profession. It may encourage researchers to investigate whether pathology subspecialists provide a higher level of expertise compared to pathology generalists, and, if true, whether that difference plays a significant role in patient care.

One sign of a possible slowing in the double-digit increase of annual healthcare costs comes from the **Center for Studying Health System Change** (CSHSC), a Washington-based policy research group. A study of the underlying costs that drive health insurance premiums, which include physician charges, hospital charges, and prescription drugs, rose by only 8.5% during the first six months of 2003. This is down from 10% in the final six months of 2002. CSHSC says that's the biggest percentage point drop since the early 1990s and may signal lessening in the annual rate of increase for healthcare premiums.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, January 12, 2004

PREVIEW #1

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Full program details available soon!
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UPCOMING...

- ***THE DARK REPORT'S Predictions for Anatomic Pathology's Biggest Trends During 2004.***
- ***Hospital Laboratory Outreach: Emerging New Threats and Opportunities.***
- ***Web-Based Lab Test Ordering and Resulting: A Surprise Home Run for Progressive Laboratories.***

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