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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Steps Toward the Globalization of Lab Medicine

PATHOLOGISTS AND LABORATORY EXECUTIVES in this country generally don't pay much attention to what is happening to clinical laboratories and anatomic pathology services in other countries. That is understandable, since there is lots of change unfolding in the lab testing marketplace within this country.

On the other hand, if it is true that globalization of healthcare in general—and laboratory testing specifically—is an emerging trend, then there is strategic value in monitoring key developments in other developed countries. Today, I'd like to share a short list of unfolding events affecting lab testing services in several countries. At a minimum, it provides evidence and insight that the globalization of lab testing looms.

Let's start in the British Isles. THE DARK REPORT has briefed its clients and readers about the 100% outsourcing of Ireland's Pap testing to an American lab company. That was followed by the Irish government's announced plans to consolidate hospital testing into a handful of central labs, along with construction of two stand-alone lab facilities to serve office-based physicians.

In the United Kingdom, the new coalition government has announced the goal of reducing healthcare spending by £30 billion—a 20% reduction from the current level. For pathology and lab testing, the budget reduction is £750 million per year. At the same time, the **National Health Service** (NHS) is in active negotiations with private organizations and *in vitro* diagnostics (IVD) companies to explore and establish new models of integrated and consolidated regional laboratory organizations.

Canada's issues seem to center around the quality of anatomic pathology services. In recent weeks, news stories have covered the findings of commissions and review teams tasked with identifying why patients in some hospitals received inaccurate lab test results. Consolidation of lab testing services is also ongoing in several provinces.

In Australia, an American private equity company is poised to acquire a private hospital company that happens to own one of Australia's largest pathology companies. If the new owner were to decide to divest this pathology business, it is likely to roil the lab testing marketplace down under. Also during this time, the federal health program has instituted cuts in funding for lab testing services.

At some point, these restructuring and cost saving efforts will encourage a government health program to invite foreign lab companies into their country. That may be one likely path toward the globalization of laboratory testing. TDR

New "Meaningful Use" Rules Are Easier on Docs

Predictions are that some EMR systems will not be easy to integrate with the lab's LIS

CEO SUMMARY: The federal government will spend $20 billion over the next four years to encourage every physician to use an electronic medical record (EMR) system. For labs, this increase in connectivity represents a significant marketing opportunity. However, the new federal rules on meaningful use of EMRs released last month may complicate the situation for clinical labs and pathology groups. One EMR expert says that's because some EMR systems will do a poor job of interfacing lab test orders and lab test reporting with the lab's LIS.

LONG-AWAITED RULES for "meaningful use" of electronic medical record (EMR) systems by physicians were announced last month by federal officials. Clinical laboratories and pathology groups will want to be ready to help physicians with their EMR projects.

"For physicians, the new rules are less burdensome," observed Pat Wolfram, Vice President Marketing and Customer Services for **Ignis Systems Corporation**, in Portland, Oregon. "It had been proposed that physicians would need to meet 25 criteria relating to EMR use before they would be eligible for the federal incentives authorized under the HITECH Act of 2009."

Wolfram has been involved with EMR systems for more than 15 years. As a consultant to physicians and labs on EMR systems, Wolfram has extensive experience in helping to create interfaces that allow EMRs to handle lab test orders and accept electronic reporting of lab test results.

"The new rules published on July 13 won't be as favorable for labs because the requirement for computerized physician order entry (CPOE) of laboratory test orders has been removed," explained Wolfram. "Also, a requirement that the EMR accept the import of structured laboratory test results was trimmed from 50% to 40%.

"In practical terms, the new rules lower the bar for EMR functionality," he continued. "It allows EMR vendors to provide very limited lab integration capabilities, yet still pass the meaningful use

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criteria. That alone promises to be troublesome for the nation's clinical laboratories and pathology groups, for a very good reason.

"Physicians consider it important that their EMR system integrate well with their choice of a clinical laboratory," said Wolfram. "However, physicians often assume that the EMR system they intend to purchase works well in allowing full integration of laboratory test ordering and laboratory test results reporting. That is why physicians tend to not look closely at these functions during their EMR evaluation.

"In addition, as pathologists and lab directors know, orders to laboratories can be less complete or 'clean' from those EMRs that do not integrate well," he added. "It also means the EMR's ability to retrieve and display lab test results could be less than ideal."

Wolfram believes that the earlier draft of meaningful use criteria would have forced stronger integration capabilities on the EMRs. That is because the earlier draft required the meaningful use of an EMR system to include laboratory test ordering capabilities and a higher percentage of structured lab test result reporting.

➤ Certified EMRs Are Key

"Under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, eligible health care professionals and hospitals can qualify for $20 billion in Medicare and Medicaid incentive payments when they adopt certified EMRs," noted Wolfram.

"Starting in 2011 and going forward four years, physicians can be rewarded for adoption and use of qualified EMR systems," he explained. "In year five of this program, physicians not using a qualified EMR system will be paid less by the Medicare program than those physicians who do.

"The new meaningful use rules announced by DHHS on July 13 make up phase 1 of the federal program to reimburse physicians for investing in EMRs," observed Wolfram. "A revision to the meaningful use rules is expected as part of phase 2."

Federal incentives for physicians will be paid over several years. "Each physician who invests in an EMR system and follows the meaningful use rules can get up to $44,000 from Medicare," noted Wolfram.

➤ Incentives To Motivate Docs

"It is believed these incentives will motivate physicians to select an EMR system and begin using it during 2011," he stated. "As that happens, laboratories should be prepared to provide their referring physicians with as much guidance as possible to help them achieve effective integration of the lab test ordering and lab test reporting functions between their LIS and the referring physicians' EMR system."

The revised rules on meaningful use released on July 13 are a direct result of public comment that followed the publication of a draft of the meaningful use criteria earlier this year. It was this draft that listed 25 criteria. In response to the public comment, the EMR meaningful use requirements were reduced in number.

"After considering the feedback and public comment, the Office of the National Coordinator (ONC) looked at which criteria could be eliminated without watering down the effectiveness of the meaningful use rules," observed Wolfram. "The new rule established just 15 required criteria, along with a list of 10 more criteria, of which the physician can choose to defer five during the years 2011 and 2012.

➤ Incentives To Motivate Docs

"There are two criteria in the new meaningful use rule which deal specifically with ambulatory lab orders and laboratory test results," he added.

"That is a changed from the previous rules, which required 80% of all clinical orders to be electronically captured in the EMR," he said. "Under the former rules,

When Physicians Consider Purchasing an EMR, Labs Should Provide Their Own EMR Report Card

WITH TENS OF THOUSANDS OF PHYSICIANS about to implement an EMR system, the next few years will be very busy for clinical laboratories and pathology groups because of the need to build the integrated interfaces required to support lab test ordering from the EMR as well as reporting of lab test results.

"Laboratories have both an opportunity and a responsibility to explain the complex connectivity issues that physicians face with linking an electronic medical record (EMR) system to a laboratory," declared Pat Wolfram, Vice President Marketing and Customer Services for Ignis Systems Corporation, in Portland, Oregon. Ignis specializes in helping physicians and labs develop interfaces between EMRs and laboratory information systems (LISs).

"In my experience, one of the most effective things a laboratory can do when helping physicians during their EMR implementation is to produce a report card based on their own EMR integration experience," said Wolfram. "This report card should identify those EMR products with which your laboratory has already integrated. It should also state the specific order/result functionality that is expected of that EMR.

"Include two checklists on the report card," he continued. One checklist is for the user features that the physicians and nurses experience during everyday use. The second checklist is for the setup and maintenance of the lab ordering/resulting modules.

"If you can provide this report card and checklist during the time when the client physicians are evaluating different EMR products, it can help them understand which EMR products may best fit the specific needs of their medical practice," he added.

Goal of EMR Report Card

"Your goal is to encourage them to purchase and use a known EMR that handles lab test orders and lab test results with ease," added Wolfram. "Consider this report card to be a good complement to the EMR product's certification by CCHIT (Certification Commission for Health Information Technology).

"As the agency that certifies EMRs, CCHIT has certified over 70 different EMR vendors for physician use," he explained. "But the CCHIT certificate for a specific EMR product won't tell the whole story.

"No EMR vendor is going to tell a physician that its product does not efficiently handle laboratory test orders and lab test results," added Wolfram. "That is why it is helpful for a clinical laboratory to create its own EMR report card that details the strengths and weaknesses of different EMR products to which it has built the electronic interfaces on behalf of client physicians."

qualifying clinical orders was defined to include medications, lab tests, images such as radiology, and other diagnostic procedures. Each type of clinical order had to be documented within the EMR.

"The rules issued on July 13 now only require medication orders, and these only under certain circumstances," he noted. "Thus, one consequence of the new meaningful use rules is that physicians won't be required to change the way they order lab tests in order to qualify for the Medicare incentives related to EMR adoption and use.

"In such situations, under the new meaningful use rules, it is possible for a physician to set up an EMR and meet enough criteria to qualify for the Medicare financial incentives, while still using paper requisitions to order laboratory tests,"

stated Wolfram. "For this reason, it may not be until the phase 2 meaningful rules are issued in coming years that paper lab test requisitions finally disappear.

"The new meaningful use rules were also relaxed on the results side," Wolfram added. "It's still required that a percentage of laboratory test results must be structured and codified. But it used to be that 50% of the laboratory test results needed to be structured and now it's only 40%.

"Labs need to understand the definition of 'structured results'," he said. "Structured results allow the EMR to display trends, trigger protocols, and report across populations.

➤400% Growth In EMR Use

Wolfram predicts that there will be fourfold increase in the number of physicians using an EMR system between now and 2015. Currently there are 120,000 physicians using an EMR and that number may grow to 480,000 physicians by 2015.

If the rate of physician adoption and implementation reaches the level predicted by Wolfram and other experts, then double to quadruple the number of physicians will be in the market shopping for EMR systems, compared to past years. In turn, these same physicians will want their laboratory to step up and support integration of either or both lab test ordering and lab test results reporting.

That means laboratory administrators and pathologists should be preparing their laboratory organization to accommodate a much larger number of EMR–to–LIS integration projects. However, this added expense can produce a benefit.

Each time a laboratory develops an electronic interface for lab test orders and lab test reporting between the physician's EMR and the lab, this interface will act as an anchor that helps maintain both the clinical and business relationship with that office-based physician. TDR

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Meaningful Use Criteria Are in Two Categories

For the first round of Medicare and Medicaid EMR bonuses in 2011-12, physicians must meet 15 core objectives and at least five of 10 "menu set" items. Each objective has a measure to determine if an EMR was used to perform the function for an appropriate number of opportunities:

Core Set Criteria

(must meet all criteria)

- Record patient demographics
- Record vital signs/chart changes
- Maintain current and active diagnoses
- Maintain active medication list
- Maintain active allergy list
- Record adult smoking status
- Provide patient clinical summaries
- Provide electronic health information copy on demand
- Generate and transmit prescriptions electronically
- Use computerized physician order entry for drug orders
- Implement drug-drug/drug-allergy interaction checks
- Be capable of electronic clinical information exchange
- Implement one clinical decision support rule
- Protect patient data privacy and security
- Report clinical quality measures to CMS or states

Menu Set Criteria

(can defer up to five criteria for 2011-12)

- Implement drug formulary checks
- Incorporate clinical lab test results
- Generate patient lists by condition
- Identify patient-specific education resources
- Perform medication reconciliation between care settings
- Provide summary of care for transferred patients
- Submit electronic immunization data to registries
- Submit electronic epidemiology data to public health agencies
- Send care reminders to patients
- Provide timely patient electronic access to health information

Source: Centers for Medicare & Medicaid Services

Guest Opinion

Lab Industry Would Be Smart To Issue EMR Report Card

360,000 physicians are about to adopt EMRs, which means labs will need to build interfaces

Guest Opinion by:
Pat Wolfram

Editor's Note: For almost 20 years, Pat Wolfram has worked to develop electronic medical record systems at companies like MedicaLogic and GE Healthcare. His firm specializes in developing effective electronic interfaces that allow a physician's EMR system to handle lab test orders and lab test results with that physician's clinical laboratory provider.

IN THE NEXT FOUR YEARS, more than 360,000 physicians will take steps to implement and use an electronic medical record (EMR) system in their medical practice. Federal policy and incentive dollars will drive this tidal wave of EMR adoption.

This pace of EMR adoption by the nation's physicians is unprecedented. It also represents both a serious threat and a great market opportunity for all the clinical laboratories and anatomic pathology groups in this nation.

Report Card On EMRs

For that reason, I recommend that the laboratory testing industry in this country take the necessary steps to convene a working group and issue a report card on different EMR products. This report card would provide physicians with an objective, clear assessment of how each EMR system available for purchase in the United States is able to appropriately support the interfaces needed for accurate lab test ordering and lab test results reporting.

Such a report card would be welcomed by physicians. Currently, they have no credible source of information that helps them understand the strengths and weaknesses of the different EMR products currently offered for sale—particularly in regards to seamless lab test orders and lab test reporting. Thus, an objective EMR product report card issued by a representative clinical laboratory task force would give them the information they need to make an informed decision about the features and benefits of the EMR systems they are ready to purchase.

This same report card can help laboratories better deal with the challenge of widespread EMR adoption and use. As a threat, there are two issues soon to confront laboratories throughout this country.

First, any clinical lab which is unresponsive to the request of a client physician to build the electronic interfaces necessary to support lab test ordering and lab test results reporting between the physician's EMR and the lab's LIS is at risk of losing that account to a competing laboratory willing to spend the necessary money to achieve those goals.

Second, even where a laboratory wants to step up and help that physician with the lab orders/lab results interface, it requires plenty of money, lots of expertise, and a competency in healthcare information technology that will place great stress on

the budgets of most clinical labs and pathology groups. Simply put, the demand for EMR–LIS interfaces by many doctors—all at the same time—can overwhelm a laboratory organization.

Market Opportunity For Labs

As a market opportunity, this approaching tidal wave of EMR adoption by physicians is likely to mean that the first laboratory which helps them interface their EMR for lab test orders and lab test results reporting has an advantage in establishing a business relationship for years into the future.

After all, it will be expensive and time-consuming for a physician group to switch laboratories and create the necessary interfaces with the new lab provider needed for the EMR to handle lab test orders and results reporting.

These are the reasons why I encourage the laboratory testing industry to issue a report card on how the laboratory testing profession evaluates the different EMR systems. This report card will be in addition to the EMR meaningful use requirements put out by ONC.

Currently, what usually happens is the physician chooses an EMR based on a wide set of criteria, and lab integration is a "check in the box" not requiring much diligence. Only after the purchase does the physician approach the hospital or the lab with the request that it integrate the ordering and reporting functions to that EMR.

70 Different EMR Interfaces

Even if all 70 of the currently-certified EMR vendors are strong at handling lab integration, that's still 70 different integration projects which, in theory, the lab would have to tackle. It is the reason why labs and the lab industry need to get in front of this issue by offering an EMR report card and holding local town meetings to educate physicians on the strengths and weaknesses of the various EMRs.

There is very little downside to this strategy. For example, even if a physician didn't choose an EMR that handles laboratory data efficiently, he/she will appreciate the fact that the local laboratories stepped up with an objective EMR report card that was good advice at a time when the physician most needed that advice.

It would not be difficult to empanel a lab industry task force to gear up for this work. It would also not be complicated to define the EMR criteria relating to laboratory test orders and test reporting that physicians should use when evaluating the purchase of an EMR system.

Interfaces To Laboratories

Physicians need to know how easy each EMR product is to interface with laboratories. In working with hospitals, laboratories, and office-based physicians, my company has seen wide differences in how EMRs deal with laboratory tests.

There are some EMR products that are quite easy to automate for lab test ordering. These systems make it simple to deploy the ordering rules for each assay offered by the laboratory. And just as frequently, there are EMR products out there which are less adept in how they handle lab tests orders and accept lab test results. However, physicians have no credible, objective source of information to help them evaluate these capabilities.

Laboratories are the experts in how to interface EMRs with their LISs. It is eminently sensible for the laboratory industry to develop a useful EMR report card to inform and guide physicians as they prepare to purchase and deploy an EMR in their medical practice.

With 360,000 physicians about to act on the need to buy an EMR, there can be no more auspicious time for the lab industry to be proactive on this issue. Best of all, I think physicians would welcome a lab industry-endorsed EMR report card. TDR

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Actions of Ex-Employees Can Breach Lab Security

Theft of valuable lab assets is common and costly, but labs can easily protect themselves

CEO SUMMARY: Lab managers should take steps to protect patient data and proprietary information. This includes customer lists, payer contracts, customer-specific pricing, sales force compensation information, lab testing intellectual property, and protected health information. Technology now makes it easy for a departing employee to collect company data by moving it to a USB drive or even an iPod.

EVERY DAY, SOMEWHERE IN THE UNITED STATES, a departing employee at a clinical laboratory—before their last day on the job—furtively gathers confidential company information, including the customer list, to take with them to their next job, which is typically a position with a competing lab company.

"This can be devastating for a lab, or any company, on many levels," stated James Giszczak, Co-Chair of the Unfair Competition and Trade Secret practice team at **McDonald Hopkins LLC**, a national law firm with headquarters in Cleveland, Ohio. "The departing employee is often a long-serving and trusted employee who has given notice late in the afternoon, at the end of the week."

"By giving short notice on a Friday afternoon, the departing employee has intentionally left little time for the lab owner and human resource managers to secure company property and restrict the departing employee's access to confidential company information, client lists, and other valuable company assets," noted Giszczak.

"Typically, when a company has not taken the steps we recommend to protect their valuable business assets, we will get a call on a Friday evening, around 5 p.m. or 6 p.m. (or even in the middle of the night) from a panicked owner, a human resource manager, or a manager. They've just discovered that an employee has given his or her resignation," he continued. "It is now common for an employee to give notice by e-mail or voice mail.

Taking Company Records

"Once alerted to this resignation, the laboratory owner then audits the employee's accounts and the information the departing employee was known to have," commented Giszczak. "The laboratory owner discovers that the employee may have downloaded the entire database on the way out the door."

"Having not been proactive, the lab owner is now scrambling to protect the lab's assets," Giszczak added. "We immediately investigate and take all action necessary to protect the company, including going to court at a moment's notice.

"This is the moment of truth," he said. "Our ability to protect the company will dramatically depend on the planning, or lack thereof, for this contingency. Not surprisingly, it is critical that the lab owner have every available weapon in his/her arsenal when they need it."

Ounce Of Prevention

"Unfortunately, by the time the owner calls me, the resigning employee most likely has already used a flash drive, iPod, or similar device to misappropriate the lab's proprietary information and customer lists to take with them," stated Giszczak. "If the lab was even moderately proactive, having considered this scenario and taken protective measures, the damage to the lab can often be minimized. If not, the damage could be immeasurable."

Giszczak made these comments during a recent audio conference titled "Strategies to Protect the Key Assets of Clinical Laboratories and Pathology Groups," conducted last month by THE DARK REPORT. The focus was on protecting the most valuable business assets of a laboratory company or pathology group practice.

"When a laboratory or pathology group fails to properly protect its confidential business information, client lists, and other types of proprietary data," noted Giszczak, "it not only faces substantial loss of business if the departing employee uses that information to benefit a direct competitor, but it may also have significant exposure resulting from recent legislative changes and judicial decisions."

New Regulatory Risks

"There are many new regulatory risks about which lab owners must be aware," noted Giszczak. "Assume that someone takes information from your lab and triggers the notification requirement under the federal HITECH ACT or a state data breach statute. This may require your lab to: 1) bear the costs associated with the notification to the affected individuals; 2) bear the costs of providing credit monitoring to those individuals; and 3) bear the costs of dealing with all of the ancillary issues that accompany compliance with state and federal laws."

"What many pathologists and laboratory managers don't realize is that the financial exposure from this type of data loss can be staggering," he continued. "For example, the average cost of a security breach is roughly $4.6 million in loss of intellectual property. Another $600,000 is typically paid in associated costs by the lab or company that loses such data."

The recent recession represents another source of risk to laboratory owners, lab administrators, and HR managers that is overlooked when taking steps to secure the lab's confidential business information. "The economic downturn is a factor that laboratory owners and human resource managers must also take into consideration if they want to fully protect their most important business assets," commented Giszczak.

"Over the course of this recession, many of our clients and prospective clients needed to trim some of their workforce," he explained. "When these employees are terminated, they often continue to be a major threat for the laboratory.

Access To Company Data

"Pathologists and lab managers are often unaware that some ex-employees continue to have access to company data even after they were terminated," explained Giszczak. "When information technology decision makers were recently surveyed, 42% of respondents identified laid-off employees as the biggest IT security threat that was caused by the recession."

Giszczak next discussed some of the simple steps that clinical laboratories and pathology groups could take to protect their confidential and proprietary information, and other valuable business assets. "First, it is important to be proac-

Data Security Expert Explains How Technology Facilitates Information Theft from Laboratories

AN EMPLOYEE SEEKING TO STEAL the names of a lab's referring physicians can do so with relative ease today, said attorney James Giszczak, the Co-Chair of the Unfair Competition and Trade Secret practice team at McDonald Hopkins LLC, a national law firm. "Simply by downloading all of the data to a USB drive, the departing employee can walk out with the laboratory's most valuable proprietary data in his or her pocket," he said.

"Most laboratory owners underestimate the risk this poses to the value of their laboratory company," explained Giszczak. "Today, it is easy for anyone to purchase a 100-gigabyte USB drive at a price of about $100. This USB drive can hold an entire data base of customer information that belongs to a very large organization."

"That means any departing employee willing to buy such a 100 Gigabyte USB drive could download all the client account information of a laboratory, then walk out the door and take that client information over to a laboratory competitor."

"Recently, the device of choice that employees use to steal company information is the iPod," Giszczak continued. "These employees plug their iPods into their company's IT system, then download the information they want.

"Lab managers often overlook the fact that an iPod is a storage device," noted Giszczak. "Most people use it for legitimate purposes—music and videos—but it is increasingly common to see employees use their iPods to steal proprietary information from their employer."

tive. Your lab should act now to conduct an appropriate review and put the right protections, policies and procedures in place—before they are needed.

"Begin by conducting a review of your laboratory's business assets and the data it collects and stores," Giszczak noted. "These assets include data on the relationships that labs have with their referral sources for lab testing and other business activities. Don't forget that what should be included in this category will be the names and information about customers and prospects, payer contracts, sales force compensation information, customer-specific pricing, and testing intellectual property used by your laboratory."

"Other information kept by your laboratory has great value and should also be protected," he added. "That includes the lab's employee base, including its sales representatives, office managers, and the pathologists associated with the laboratory organization. All of these people are significant assets. Quite frankly, they are the main assets of the organization and are too often overlooked."

"In our legal practice, we like to talk directly with the key managers working at each of our laboratory clients," added Giszczak. "These managers know the specific information they keep that is essential and valuable to the success of the laboratory organization. These informa-

tion sources are critical assets and need to be identified and protected."

"Assess what preventive measures are already in place and explore what additional measures can and should be taken to protect these assets," Giszczak said. "Typically, a laboratory has agreements already in place, such as employment contracts with employees. These agreements will provide some protection to the laboratory, if drafted appropriately so that they are valid."

"These agreements should be reviewed to make certain that they contain the necessary provisions such as non-competition and non-solicitation provisions," he advised. "It is also critical to make certain that these provisions are valid in the state in which they would be enforced: not all states treat these provisions the same.

"You must be certain that the agreement is enforceable in the applicable state where the employee resides," noted Giszczak. "Similarly, the laboratory should have confidentiality agreements with every employee.

"This is especially important for any healthcare organization," he explained. "A laboratory handles sensitive patient information. It can be at risk if it doesn't have appropriate agreements with each employee as to how such patient information must be protected."

New Laws Increase Risk

"What makes these agreements particularly important now are the recent federal privacy laws that define 'protected health information' (PHI)," Giszczak said. "Because of this recent federal legislation, your laboratory's agreements need to specifically address these new requirements and describe the appropriate steps expected of the employee to protect that information."

"In the event of a data breach, these agreements may help minimize the damage, demonstrating that your lab has taken some steps to responsibly handle PHI. Keep in mind, this is only one piece of the protection puzzle."

"Also, it is important not to overlook the other documents executed by your laboratory staff," he stated. "Review the security measures taken in your laboratory organization. Pay particular attention as to who can access sensitive information. Most likely, you can minimize those that have access to paper files or computer data bases. This too reduces the likelihood of theft and is yet another indicator that you are taking steps to protect not only your confidential information, but also PHI."

Prevention Is Simple

"It is generally simple and inexpensive to put measures in place to protect this valuable information," noted Giszczak. "These same measures will have a dramatic effect on your lab's ability to responsibly protect its most valuable business assets."

"Every laboratory should also prepare appropriate checklists and have them in place," he advised. "They don't need to be elaborate, just a reference tool to make certain that all of the bases are covered when the fateful call comes in at 5 p.m. on Friday.

"Furthermore, each time an employee is terminated or resigns," continued Giszczak, "the responsible lab manager and/or human resource liaison will now have a roadmap to consistently collect all company property and take all the actons necessary to shut off that departing employee's access to all company computers, records, and other property."

"It is important that this be done in a timely fashion," Giszczak added. "No clinical laboratory or pathology group wants a terminated employee to go home and continue to access its laboratory information systems. This is a particularly sensitive area for laboratories because of the types of confidential patient and physician information that is handled by the lab on a daily basis."

"Second, work with an attorney who is experienced in this area of law," he stated.

"Our team has counseled clients in all 50 States and has litigated these matters in 38 States. In doing so, we have become familiar with all of the nuances in the various laws of these states.

State Laws Are All Different

"Such direct legal experience is critical, since—in addition to applicable federal laws—each state has its own statutes and relevant court decisions that can dramatically impact your likelihood of success," emphasized Giszczak. "Therefore, if your lab's attorney is not well-versed on these topics, your lab may not be fully protected—but you won't learn that until there is a problem and a judge rules against your laboratory and in favor of the ex-employee."

"The third step is to respond quickly when a threat is detected," commented Giszczak. "If you delay, not only are you giving the ex-employee an opportunity to do more damage, but the Court will not find your arguments that this is truly an emergency very credible. You must implement your action plan as soon as you know your lab's assets are at risk or when it is necessary to respond to threats to your laboratory's market share.

Prevention Is Simple

"It's inevitable in every organization that employees will come and go," he said. "Some of your lab's best staff will leave because people will always try to further themselves. And it's inevitable that, as those people go, some of your lab's assets will go with them."

"This is why it is important for your laboratory's leadership to do some advance planning," advised Giszczak. "Take time to anticipate these situations and to respond accordingly. A good example is that situation I mentioned earlier, when there is a voice mail resignation on Friday afternoon by a key employee.

"If that were to happen, how will your lab management team respond?" he asked. "It is not a matter of *if* this call will come! It's just a matter of *when*! This is why your laboratory should take the opportunity to develop an effective plan that puts your managers in the position to react appropriately whenever your lab's most valuable business assets are at risk of loss."

Giszczak's insights and recommendations about the need for laboratories to properly protect sensitive information and business assets is a timely reminder for pathologists and laboratory administrators. Changing times make it imperative to regularly assess risk and institute appropriate safeguards, especially now that even a low-level employee with an iPod can download large data bases belonging to the lab. TDR

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Protecting Lab Assets Starts With Easy Steps

SIMPLE AND EASY STEPS are all that is needed for a clinical laboratory or pathology group practice to protect its most valuable business assets. That's the advice of James J. Giszczak, Co-Chair, Unfair Competition and Trade Secret Practice Team at the law firm of McDonald Hopkins, LLC. Giszczak outlined these actions:

Reasonable Steps to Guard the Confidentiality of a Lab's Information

- Routine verification of confidentiality procedures.
- Routine employee reminders of confidentiality policy.
- Prohibiting removal of confidential information from company premises.
- Restricting copying of confidential information (numbering copies, etc.).
- Conducting exit interviews.
- Pursuit of departing employees with access to confidential information.

Dark Index

Specimen Volume Declines Reported By Quest Diagnostics and LabCorp

For second quarter, outside data indicates there were 5% fewer patient visits to doctors

IN REPORTING SECOND QUARTER EARNINGS, there was enough difference in the numbers announced by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** to catch the attention of financial analysts.

Revenue at LabCorp was up for the quarter while revenue at Quest Diagnostics was down for the quarter. But the devil is in the details. Financial analysts know that the financial performance of one quarter does not necessarily represent a trend.

On the other hand, for more than a decade, the quarterly financial reports of the two blood brothers have typically moved in a close relationship. With such large market shares of the physicians' office testing market, basic business trends typically have similar influences upon the finances of both companies.

So the fact that LabCorp's revenue during the quarter was up and Quests' revenue for the quarter was down caused financial analysts to explore possible reasons for this discrepancy in market performance.

LabCorp reported a 4.2% growth in revenue for Q2-2010 compared to the same quarter last year. By contrast, Quest Diagnostics reported a decrease in its Q2-2010 revenue of 1.4%, compared to the same quarter last year. However, LabCorp's 4.2% growth in revenue masked a 2% decline in the number of specimens. This was offset by a 4.2% increase in price.

At Quest Diagnostics, specimen volume declined by 1.3% for the quarter. It did not disclose a figure for its price increase or decrease for the quarter. But Quest Diagnostics did announce that revenue per requisition declined by 0.3%. LabCorp's revenue per requisition increased by 6.3% for second quarter.

In providing guidance to investors for the balance of 2010, Robert A. Hagemann, CFO at Quest Diagnostics, told analysts on the July 21 conference call that: "Based on our results through the first half, we've become more cautious in our outlook for the remainder of the year and now expect full year revenues to be approximately 1% below the prior year, due principally to our changing outlook for volume. Keep in mind our guidance excludes any acquisitions which may be completed in the second half [of 2010]."

LabCorp Raises Guidance

During LabCorp's second quarter conference call on the following day, its CFO, William Hayes, also updated his company's guidance for the financial community. "This morning, we updated our 2010 financial guidance. We expect revenue growth of 4.5% to 5.5% compared to previous guidance of 2.5% to 4.5%," stated Hayes.

This divergence in basic rates of growth between the nation's two laboratory testing behemoths has not been seen in recent years. Since both companies have multi-year track records as reliable cash-generating machines for shareholders, financial analysts want to understand the reasons for these differences in financial performance between Quest Diagnostics and LabCorp.

Slow Economy and Dominant Market Share Are Likely Factors in Quest, LabCorp Earnings

IT IS NOT OFTEN THAT THE QUARTERLY EARNINGS TRENDS DIVERGE BY MUCH between Quest Diagnostics Incorporated and Laboratory Corporation of America. Both laboratory companies reported declines in specimen volumes for the second quarter compared to same quarter 2009. But LabCorp showed a 4.2% increase in revenue during this period while Quest Diagnostics reported a decline in revenue of 1%.

By contrast, Sonic Healthcare issued an advisory following the two quarterly earnings calls of Quest Diagnostics and LabCorp. Sonic disclosed that, for the first six months of 2010 (January 1 through June 30), its lab operations in the United States posted organic revenue growth (excluding acquisitions) of 3.6.%. It said its organic growth in specimen volume was up 1.4% during this same six-month period.

Selected Information from Second Quarter 2010 Earnings

	Quest Diagnostics	LabCorp
Revenue	$1,875 billion	$1,238 billion
Revenue Growth %	-1%	4.2%
EBIDTA	$430 million	$320 million
EBIDTA %	22.9%	25.9%
EBIDTA Change %	5%	6%
Pre-Tax Income	$330 million	$260 milllion
Pre-Tax Income as % Revenue	17.6%	21.0%
Market Capitalization	$8.4 billion	$7.4 billion
Net Debt to Capitalization	44%	33%
Revenue Growth Guidance/2010	-1%	4.5% to 5.5%

One fact was discussed by both companies during their quarterly conference calls. Data collected by **IMS Health** of Norwalk, Connecticut, indicates that patient visits to physicians' offices declined by approximately 5% in the second quarter 2010, compared to the same quarter in 2009. Both Quest Diagnostics and LabCorp noted that their respective declines in specimen volume were less than the drop in patient visits to physicians' offices.

If there was an elephant in the room during both conference calls, it was the potential for either laboratory to acquire the assets of **Genzyme Corporation's** testing businesses in genetics and diagnostics. Genzyme announced in May that it intended to explore the sale, spin-off, or management buyout of its genetics and diagnostics divisions. These business lines together generated $538 million in revenue during 2009.

Financial analysts expect aggressive bidding for the Genzyme lab testing assets. Both Quest Diagnostics and LabCorp are expected to vigorously pursue this acquisition opportunity.

Business Strategy At Quest

On its conference call, Quest Diagnostics discussed a four-point business strategy with financial analysts, Surya N. Mohapatra, Chairman and CEO, characterized these as programs launched last quarter "to improve our self-effectiveness and get closer to our customers."

First is a program to upgrade the skills in its sales force. "We have targeted high potential sales reps from other healthcare fields, such as cancer diagnostics and car-

diovascular disease, many with specific expertise in key areas such as cancer diagnostics and cardiovascular disease," explained Mohapatra. "To make them effective sooner, we have enhanced our training programs and we are giving them advanced tools to better target sales leads."

Target Markets For Growth

Quest Diagnostics' second program is to target "specific geographies with the greatest opportunity for growth, including areas where [laboratory] competitors are challenged." The third program is, in selected markets, to beef up service by adding personnel, such as phlebotomists and service reps where appropriate and by opening more patient service centers (PSCs).

Quest Diagnostics' fourth program is to ramp up sales and marketing efforts on selected tests believed to have the greatest growth potential. Mentioned on the conference call were cancer diagnostics, cardiovascular testing, allergy testing, and tests for women's health.

At LabCorp, current business priorities center around four areas: lab acquisitions, expanding managed care contract access, introducing a new electronic gateway for physician clients, and improving internal operations—including new lab automation solutions.

LabCorp's Lab Acquisitions

In the area of lab acquisitions, LabCorp executives discussed the purchase of **DCL Medical Laboratories** of Indianapolis, Indiana, in June. The other acquisitions discussed was of **Westcliff Medical Laboratories** of Newport Beach, California. The FTC is reviewing this acquisition. *(See TDR, June 10, 2010.)*

LabCorp's second business initiative involves managed care contracts. It is now a provider for **Empire Blue Cross Blue Shield** of New York. This health plan serves 2.8 million beneficiaries and Quest Diagnostics had held an exclusive contract with Empire for most of the past decade.

The third business project is deployment of what the company calls LabCorp Beacon. LabCorp Chairman and CEO David King described this as "our new online gateway for client lab connectivity... accessible anywhere and at any time. LabCorp Beacon is an end-to-end solution that allows physicians to view, share, manage, and analyze lab results."

Internal operations is the fourth business initiative at LabCorp. King detailed its key elements, stating on the conference call that "Our **Protedyne** subsidiary continues to provide innovative solutions for automating and streamlining our operations.

"We are rolling out next-generation [phlebotomy] appointment scheduling," he continued, "and we continue to optimize the workflow at our patient service centers to improve the customer experience, as well as the overall efficiency of our business."

Sysmex Agreement

King called attention to a major agreement with **Sysmex America, Inc.**, explaining "we have fully automated hematology operations in our regional core laboratories throughout the United States. The Sysmex partnership allows us to increase throughput with less labor and to improve turnaround time for our customers. It is one of the largest laboratory automation projects ever undertaken."

Another point of particular interest to pathologists is that during both conference calls, analysts asked about specimen declines associated with anatomic pathology TC/PC arrangements by office-based physicians. Both of the national laboratory companies acknowledge that business retention is problematic in this sector of their business.

Assessing the range of topics discussed during this series of conference calls, financial analysts are closely monitoring two key areas. One is the quarterly increases or decreases in specimen volume. The second is the trend in managed care contract pricing. Each is a sign that growth opportunities are narrowing for the two blood brothers. TDR

Lab Law Update

AAB's Suit Prevails over NY State Following 11 Years of Litigation

SCORE A BIG WIN FOR THE GOOD GUYS! An appeals court in New York state has upheld a lower court ruling that the **New York State Department of Health** (NYSDOH) intentionally overcharged clinical laboratories for the costs of regulating clinical laboratories and blood banks, possibly going back decades.

On July 22, the Appellate Division, Third Department of the Supreme Court of New York, issued its ruling. One direct consequence of this decision is that NYSDOH will now need to recalculate the fees that should have been charged to member laboratories of the **American Association of Bioanalysts** (AAB), which was the plaintiff in the case.

NYSDOH has indicated that the restitution to AAB member laboratories may be as high as 75% of the money that these laboratories paid to the Department of Health between 1998 and 2006. In the future, the DOH will be required to issue bills to laboratories that conform to the Court decision.

11-Year Legal Battle

In its complaint, originally filed 11 years ago, the AAB had noted that the fees charged by the NYSDOH increased sevenfold during the period 1984 through 2010, raising from $2.4 million per year in 1984 to over $17 million per year today. According to state law, charges assessed upon laboratories were to be "limited to reimbursing the Department for the necessary costs of the regulation of clinical laboratories and blood banks."

Attorney Jeffrey Sherrin of the Albany, New York, law firm of **O'Connell & Aronowitz, PC**, served as general counsel for AAB. In response to the appellate court ruling, Sherrin wrote that "In today's ruling, the Court agreed with the lower court's finding that the fees charged to the labs were 'arbitrary and capricious,' and that the Department's 'bald estimates' of the actual costs of the laboratory regulation program could not support the fees charged when the Department failed to either keep accurate, contemporaneous financial records or even disclose those documents cited in support of the cost estimates."

The scale of the DOH's miscalculations appears to be substantial. Sherrin quoted Justice Robert S. Rose, who wrote for the Appeals Court that "The Department's intention to shift as many costs as possible onto the clinical laboratories was further revealed in the testimony that the Director had once boasted that he had been able to transfer 17% of the [NYSDOH] **Wadsworth Center's** budget to the clinical laboratories."

In a press release about the appellate court's ruling, Mark S. Birenbaum, the Administrator of AAB, stated that "Once again, a New York State Court has vindicated AAB's efforts to prevent the New York State Department of Health from covertly inflating the fees it charges clinical laboratories. In affirming the lower court's Decision, the Appellate Division has recognized that the New York State Department of Health clearly abused its authority for years at the expense of clinical laboratories."

The outcome of this long-running court battle is a reminder that the laboratory medicine profession can benefit by challenging state and federal health

programs in appropriate circumstances. It was a legal challenge by several laboratory organizations in San Diego, California, for example, that ended the Medicare Part B Competitive Bidding Demonstration Project in early 2008. *(See TDR, April 8, 2008.)*

Judges' Written Rulings

According to accounts of the testimony in the AAB lawsuit against the NYSDOH, as well as written rulings by judges involved in the case, the Department of Health wandered far afield from its statutory responsibilities and authorities.

Sherrin wrote that "Testimony at the trial showed that laboratories were being charged for things like $1,000 of baked goods for Health Department meetings [to which the laboratories were not even invited]; the costs of developing new assays for which DOH scientists held patents and [for which] the Department would receive royalties; research into environmental pollution; and many other activities amounting to millions of dollars that did not support clinical laboratory regulation."

There was similar commentary by one of the judges. Retired Supreme Court Justice Edward R. Sheridan was the Judicial Hearing Officer. He presided over the entire 30-day trial, which took place in 2008. In his decision, issued on September 28, 2008, Sheridan wrote "In effect, [NYSDOH] has turned the clinical laboratory reference system special revenue account into an unauthorized and unsupervised revenue stream that is limited only by the bounds of defendant's creativity..."

Unauthorized Spending

What originally triggered the lawsuit by AAB was its discovery that the DOH was taking money from clinical laboratory and blood bank fees and spending that money on salaries of individuals who did no work related to the regulation of New York licensed clinical laboratories. AAB even found instances where these funds were flowing to individuals who did not work for the NYSDOH. AAB also knew about instances where funds from laboratory fees financed trips to California and Europe, as well as cars for the New York Commissioner of Health.

Aspects of this legal case are worth considering. For example, this litigation was originated by the American Association of Bioanalysts and sustained by it over 11 years on behalf of its members, which are mostly smaller private laboratory companies.

Thus, it is interesting to consider whether larger laboratory associations and organizations declined to join this lawsuit over the years because of their fear that suing regulators would turn out badly for the largest of their laboratory members. After all, history is replete with examples of industry regulators, who, after losing an important challenge by a company under their regulation, intentionally turn the regulatory spotlight onto that company and exact revenge through what might be characterized as "micro-regulation" in a punitive fashion.

Overstepping Authority

Another informative insight is how a regulatory agency that lacks effective oversight can use its government powers to tax and assess fees in a manner that violates the law. But because the companies such an agency regulates do not have access to information about these collections and expenditures, it is almost impossible to accurately monitor the situation and identify activity that violates either or both the intent and the fact of the law.

At a minimum, Mark Birenbaum, the AAB, and its independent lab members should be recognized for standing up to a clear case of regulatory over-reach. This was an expensive and time-consuming law suit. But the final appellate court ruling confirms that—in this lawsuit—the defendants were not on the right side of the law. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It was a productive second quarter for **MEDTOX Scientific, Inc.**, of St. Paul, Minnesota. Total revenue climbed 18.1%, to $25.2 million, compared to $21.3 million for the same period in 2009. Operating income grew to $1.5 million, an increase of 176%. Known as a drugs of abuse testing company, MEDTOX saw revenue growth of 5.6% from this source during the quarter. Revenue grew from $21.3 million in Q2-09 to $25.2 million in Q2-10. This is a sign that the workforces of employers are stabilizing after the deep recession.

MORE ON: *MEDTOX*

There is more to the MEDTOX story than its ongoing role in the drugs of abuse testing market. In 2008, MEDTOX launched a clinical laboratory testing business that is concentrated in and around the Minneapolis-St. Paul Metro. This business has grown steadily. MEDTOX reported that revenues from this clinical laboratory business climbed 41% during second quarter 2010, reaching $7.6 million. By contrast, clinical lab revenues were only $5.4 million for Q2-09. In just 30 months, MEDTOX has built its clinical lab revenue to an annualized rate of about $30 million per year.

CLEVELAND CLINIC STARTS BUILDING $75 MILLION LAB

Last week, officials at the **Cleveland Clinic** broke ground on the long-delayed construction of a new laboratory building of 135,000 square feet. This laboratory facility is designed to support a major expansion of lab testing. The Cleveland Clinic intends to grow its laboratory outreach in the greater Cleveland metropolitan area. It also wants to increase its role as a national provider of reference and esoteric testing services. *(See TDR, March 16, 2009.)*

TRANSITIONS

• Ken Botta resigned his position as Chief Executive Officer of **SED Laboratories** in Albuquerque, New Mexico. Botta started at SED in 2007. He previously held executive positions at **AmeriPath, Inc.**; **Dynacare, Inc.**; and **Laboratory Corporation of America**.

• John Glaser will become CEO of **Siemens Health Services** on August 16. Glaser comes to Siemens after serving for 15 years as the Chief Information Officer for **Partners HealthCare System** in Boston, Massachusetts. Glaser was also an advisor to David Blumenthal, M.D., during the time when Blementhal headed up the Office of the National Coordinator for Health Information Technology.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 23, 2010.