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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Heparin, China, Reagents, and Your Lab

MANY OF YOU HAVE HEARD THE NEWS about the contaminant that was found in the heparin manufactured and sold by **Baxter International, Inc.** Authorities, responding last fall to reports of hundreds of bad reactions and 19 deaths to the drug, quickly focused on the Chinese companies that supplied the ingredients used by Baxter to manufacture heparin.

In recent days, the FDA announced that the contaminant was over-sulfated chondroitin sulfate. Chondroitin sulfate is "abundant and cheap," according to an FDA official quoted in *The Wall Street Journal*. Chondroitin is frequently sourced from animal cartilage and, when sulfate is added, the compound clumps together with heparin in a fashion that makes the contaminant challenging to identify in regular quality control testing.

Further, authorities now say that the contaminate was added early in the supply chain in China. Thus, it was already in the raw heparin that **Scientific Protein Laboratories** (SPL) purchased in China which it then processed into the active pharmaceutical ingredient that SPL sold to Baxter.

This latest episode of flawed or dangerous Chinese products making their way to the United States reminds us that manufacturing in many countries across the globe lacks the rigorous oversight and quality control standards that we take for granted in the United States and Europe. It also leads to this question: How many *in vitro* diagnostics (IVD) manufacturers and vendors are sourcing reagents, chemicals, and similar compounds from companies in China? Is there a risk that poor quality reagents or other flawed products that American IVD suppliers could be purchasing in China might move undetected through distribution channels, eventually reaching clinical laboratories in this country?

This is a reasonable question for labs to ask their IVD suppliers. After all, just in the past year, we have seen pets die from contaminated pet food and the discovery of tainted toothpaste, seafood, vitamins, and food additives. The contamination of heparin, a prescription drug, is just the latest example. To my knowledge, no major IVD manufacturer has issued a press release declaring its status relative to its purchase in China of reagents, chemicals, and other compounds used in its products. That disclosure might be a smart, proactive business strategy by leading IVD manufacturers. Their laboratory customers deserve the right to know if, what, and how much of the products they buy and use contain components made in China. TDR

Bostwick Labs Prepares For Public Stock Offering

Noted uropathologist David G. Bostwick, M.D. is pathology's newest successful entrepreneur

CEO SUMMARY: In recent years, annual revenue at Bostwick Laboratories has skyrocketed, reaching $102.8 million in 2007. Now the company, known for its national uropathology expertise, has filed documents in preparation for an initial public stock offering (IPO). Bostwick Laboratories is the latest success story in anatomic pathology. It hopes to raise $100 million and is preparing to expand its diagnostic services into other anatomic pathology subspecialties.

EARLIER THIS MONTH, **Bostwick Laboratories, Inc.**, filed its registration statement for an initial public stock offering (IPO). The laboratory company hopes to raise $100 million.

Should Bostwick Laboratories successfully complete its IPO, it will be significant for several reasons. First, it will affirm that the pathology profession has produced its newest successful entrepreneur pathologist. Second, it will demonstrate that going public still remains a viable way for a growing laboratory company to raise capital. Third, the price investors prove willing to pay for Bostwick stock will indicate how Wall Street currently values a lab testing company.

There is another significant fact about Bostwick Laboratories, which has its headquarters in Glen Allen, Virginia. The company is disclosing spectacular growth. For 2007, it reports annual revenue of $102.8 million. Yet just four years earlier, in 2003, it posted only $10.7 million in revenue.

Founder, Chairman, President, CEO, and Chief Medical Officer David G. Bostwick, M.D., M.B.A., gets full credit for this performance. After building his reputation as an expert in urology at the **Mayo Clinic**, Bostwick left and launched his own laboratory business in 1999.

One important distinction sets Bostwick Laboratories apart from most of the fast-growing lab companies of the past 15 years. Bostwick did not accept investment capital from equity funds, private investors, or other Wall Street sources. Instead, Bostwick built his business in true bootstrap fashion. Bostwick used his own money and the lab's retained earnings,

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

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plus bank loans, to finance year-to-year growth. That has allowed him to retain control over his company. In fact, currently Bostwick owns 99.68% of the outstanding shares in Bostwick Laboratories.

Multi-Year Growth Pattern

Starting in 2003, Bostwick Laboratories began an unbroken four-year run of solid growth in specimen volume and revenue. It now has laboratories in six locations, including Virginia, Arizona, New York, Florida, Tennessee, and London, England. The London laboratory is primarily supporting a nascent clinical trials business.

Having seen how **UroCor, Inc.,** and **Dianon Systems, Inc.,** grew rapidly during the second half of the 1990s by offering uropathology services directly to office-based physicians, Bostwick jumped into the same market in 1999. Today, urology represents 86.8% of the company's revenues.

In recent years, however, Bostwick Labs has established other testing services. It is now organized around four divisions that offer anatomic pathology services in urology, gynecology, gastroenterology, and nephrology. Now, the company is preparing to enter the dermatology market as well. Bostwick Labs employs 30 pathologists and has more than 750 total employees.

100 Sales Reps At Bostwick

In keeping with Bostwick's careful study of the success of UroCor and Dianon during the 1990s, Bostwick Laboratories supports an aggressive and professional sales and marketing operation. It currently maintains 100 sales representatives in the field. The sales and marketing effort is led by Jed Fulk, who is Executive Vice President of Sales and Marketing and has been with Bostwick Labs since 2003.

Earlier in his career, Fulk held senior sales positions at UroCor. Also, Fulk is a graduate of the United States Military Academy at West Point. This point is noteworthy, because, in its heyday, the top-performing Dianon sales force was heavily populated with graduates of the military academies. Bostwick seems to have observed this fact and appreciated how it contributed to Dianon's remarkable rates of growth in specimen volume and revenue during its go-go growth years.

For 2007, Bostwick Labs reports that specimens totaled 291,000 and revenues were $102.8 million. That was an increase of 82.6% over the 159,000 specimens received in 2006, when revenues totaled $58.4 million. These numbers imply an average revenue per accession last year of about $353.26.

Pathologist As Entrepreneur

It should be recognized that the accomplishments of Bostwick Laboratories, Inc., are a direct result of the business and clinical leadership of David G. Bostwick, M.D. The fact that this pathologist owns 99.68% of a $100 million-per-year lab company is just the starting point.

Including Bostwick, the current executive team consists of four individuals. Only one, Fulk, was hired before 2007. This fact demonstrates how Bostwick has maintained direct control over the operations of the company and its expansion in recent years.

Further, a new board of directors was assembled in February of this year. Of the seven outside directors, none has direct experience in the clinical laboratory industry. That's a sign that Bostwick wants fresh thinking and a different mindset guiding the strategic development of his laboratory company.

Bostwick's hands-on management style is evocative of another well-known pathologist-entrepreneur. Pathologist James B. Peter, M.D., Ph.D., founded **Specialty Laboratories, Inc.,** in the 1980s and, also using a hands-on management style, built the steadily growing laboratory into one the nation's major reference and esoteric lab companies. Peter was also the last pathologist-entrepreneur to bring a laboratory company to the public markets. In December 2000, Peter guided

Bostwick Laboratories At-A-Glance

BOSTWICK LABORATORIES®

Founded in 1999, Bostwick Laboratories, Inc. has grown in spectacular fashion, achieving 2007 revenue of $102.8 million. Bostwick Labs now has laboratory testing centers in five locations around the United States, plus a laboratory in London, England.

Founded: 1999

Stock: NASDAQ:BOST

Laboratories:

Glen Allen, Virginia.....70,000 s.f.
Uniondale, New York ....75.000 s.f.
Tempe, Arizona.....75,000 s.f.
Nashville, Tennessee....41,000 s.f.
Orlando, Florida.....12,000 s.f.
London, England .....4,500 s.f.

Annual No. Specimens: 291,000

Pathologists: 30

Employees: 750

Sales Reps: 100

Annual Revenues (in 000's)

2003.....$10.7
2004.....$19.2
2005.....$30.3
2006.....$58.4
2007.....$102.8

Executive Team

Chairman, President, CEO, Chief Medical Officer: David Bostwick, M.D., MBA

CFO: Gary Levine, CPA, MBA

Executive Vice President, Sales and Marketing: Jed Fulk

General Counsel: Richard Bostwick, Esq.

Medical Directors

Urology: David Bostwick, M.D., Hillel Kahane, M.D.

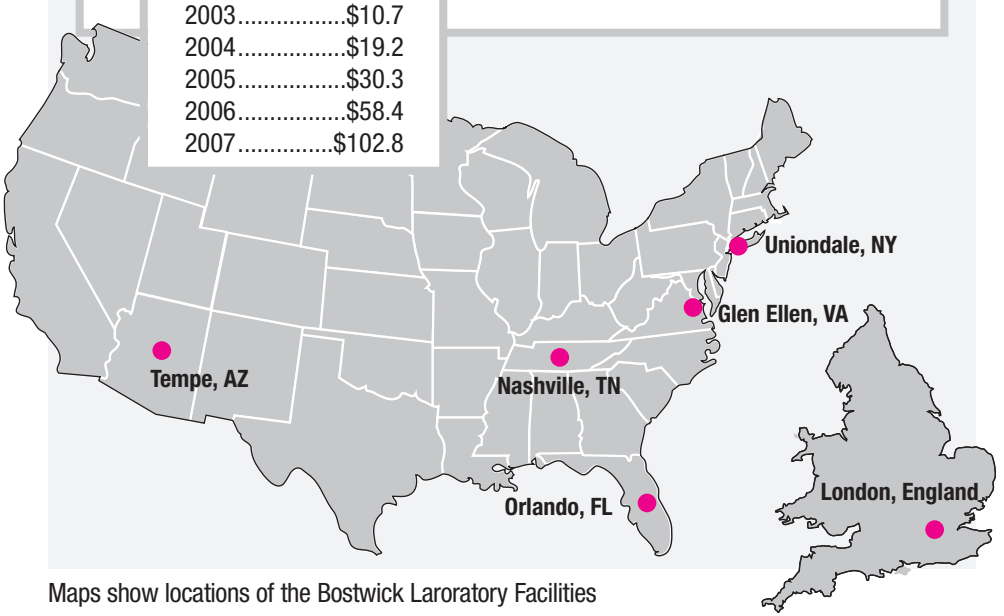
Gynecology: John Bishop, M.D.

Nephrology: WIlliam Glass, M.D., Ph.D.

Gastroenterology: Vito Santarsieri, M.D.

Biomarker Discovery: Jeff Ross, M.D.

Web Site: *www.bostwicklaboratories.com*



Maps show locations of the Bostwick Laroratory Facilities

Government's Heavy Hand Impedes Labs in California

GOVERNMENT REGULATIONS CAN DISTORT the healthcare marketplace and California provides a good example. In recent years, the state has refused to issue new laboratory licenses to serve MediCal, its Medicare program. The stated purpose is to control MediCal fraud by preventing fly-by-night operators from establishing lab companies that fraudulently bill the MediCal program for lab tests never performed or that are medically unnecessary.

But this same ban on new lab licenses affects Bostwick Laboratories, Inc., which is unable to gain a California state license. Bostwick addresses this issue in its public filing, stating that:

> Each of our laboratories is certified by CLIA, where such certification is required, and has all licenses required by the state in which it is located. However, many state licensure laws require a laboratory that solicits or tests specimens from individuals within that state to hold a license from that state, even if the testing occurs in another state. We currently accept testing from California, New York, Pennsylvania, Maryland, New Jersey, and Rhode Island, which require out-of-state laboratories to hold state licenses. However, we do not have licenses from California or Rhode Island. (TDR underline.) While we have applied for or are in the process of applying for licenses in these states, we have accepted specimens from such states in the past and are continuing to accept specimens from such states. For the year ended December 31, 2007, specimens from patients in California accounted for 4.9 percent of our revenues and specimens from patients in Rhode Island accounted for less than one percent of our revenues.
>
> We are in the process of implementing changes to the way we do business in California in order to bring our company into compliance with California law during the pendency of our California licensure application. However, our performance of clinical laboratory testing during the period in which we do not have a California license may subject us to sanctions...The government could also assert that a claim for payment from Medicare or another federal health care program for a test that was performed by a laboratory that was not properly licensed to perform the service was a false claim under the False Claims Act, providing for penalties of between $5,500 and $11,000 for each such claim.

As this example shows, California's ban on issuing state licenses to new laboratories has locked its lab marketplace into an arbitrary status quo. It denies California residents and physicians access to new laboratories which may offer better service or other innovations and new laboratory test technology that is not offered by labs currently holding California state licenses.

Specialty Laboratories, Inc. (with revenue of $153.2 million in 2000) to a successful IPO that raised $92 million.

Since founding his lab company in 1999, Bostwick's business strategy has been contrarian in one significant way. He has consistently refused to accept private equity investment capital during a time when most new lab company start-ups relied on private equity investors as the source of funding and management expertise to develop the business.

By not accepting private equity investment funds, Bostwick has accomplished two goals. One, he has retained total control of his enterprise. Two, he has not needed to refinance his company five to seven years down the road to raise the funds needed by private equity firms to repay their own investors.

The design of the initial public stock offering for Bostwick Laboratories will allow Bostwick to maintain control of his company while tapping a new source of capital that he can use to further expand his testing activities. It is likely that one element of this strategy is to position the company to operate independently for some time in the future. TDR

Hospital Lab Takes CMS To Court in CLIA Case

California Hospital takes CMS to federal court to fight revocation of its lab's CLIA certification

CEO SUMMARY: A California hospital challenged CMS in federal court over the threatened loss of its lab's CLIA certificate. CMS threatened to revoke the certificate in 2007 and stop paying the hospital's Medicare and Medi-Cal lab bills. In January, Victor Valley Community Hospital won a court injunction preventing CMS from revoking its CLIA certificate. Now the case is undergoing federal administrative review and CMS continues to press its case for revoking the lab's CLIA certification.

SINCE SEPTEMBER 2007, **Victor Valley Community Hospital** in Victorville, California, has operated under the threat that its laboratory could lose its CLIA certificate at any time.

That's the time when CMS (**Centers for Medicare & Medicaid**) served notice that it would revoke the laboratory's CLIA certificate as a result of the lab's violation of CLIA proficiency testing (PT) standards. If the hospital laboratory loses its license, it is likely the 115-bed nonprofit hospital would close, said lawyer Patric Hooper of **Hooper Lundy & Bookman** in Los Angeles. Hooper represents the hospital in a federal court action filed against CMS.

Whether or not Victor Valley Hospital's laboratory ends up losing its CLIA certificate, this federal court case represents an important legal challenge on behalf of laboratories hoping to get some relief from the Draconian enforcement measures levied by CMS when it determines that labs have violated PT standards. Hooper is optimistic that, when the case goes before a federal court judge, it will be resolved in favor of laboratories.

"CMS doesn't care about your intent and whether you sent a PT specimen to another lab inadvertently or not," Hooper said. "It doesn't care about this incident at Victor Valley in which a lab technician referred out a PT specimen because she thought she should treat PT specimens just like ordinary patient specimens. At the Victor Valley lab, these particular specimens are always referred out to **Quest Diagnostics**, and that's what this tech did.

The Will of Congress

"I think the regulatory staff at CMS believe their hands are tied," he continued. "They believe there is no other way to interpret the statute. But Congress could never have intended such a Draconian result simply because a laboratory worker was treating PT specimens the same as they regularly treat other specimens. So, in that sense, it's a good test case to bring before a federal judge.

"CMS recognizes its role in implementing the will of Congress and the law says an intentional referral of a PT specimen results in revocation of the lab's CLIA certificate," he added. "But at some point, a federal court is going to have to figure out what Congress

meant by 'an intentional referral.' What I think Congress meant by 'an intentional referral' is very different from what the staff at CMS believe.

"In January, the U.S. District Court for the Central District of California granted the hospital a preliminary injunction against CMS while lawyers for both sides argue the merits of CMS' action before an administrative law judge," explained Hooper. "The administrative law judge is expected to rule in favor of CMS. When that happens, the laboratory is likely to again face the immediate threat of losing its CLIA license.

Hearing Is Pending

"During the time the hearing on the CLIA revocation is pending before the administrative law judge, the revocation does not go into effect," Hooper said. "That means the hospital can operate as if nothing has happened. Based on case law that's been developed over the years, I am not optimistic about winning at the administrative hearing level. And, the government has filed a motion for summary judgment.

"But I do believe that when a federal judge looks at this, he or she will have a different viewpoint," Hooper explained. "That's where the case will go next—assuming the administrative law judge upholds what CMS has done, since they almost always rule in favor of CMS. Once that ruling is made, we must go to a departmental appeals board at the federal Department of Health & Human Services.

Revocation Still Possible

"That's the stage when it becomes a bit complicated," continued Hooper. "If the appeals board upholds CMS' decision, CMS will move to revoke the CLIA certificate again. So, we will need to go to the Ninth Circuit Court of Appeals in San Francisco and convince the circuit court to do what the district court has done—which is to keep the hospital operating while this action is pending.

"Essentially, what the district court did was issue an injunction stopping CMS from canceling Medicare and Medicaid payments for laboratory services," he said. "Victor Valley Community Hospital (VVCH) is a nonprofit hospital that is just barely getting by. If they lose their laboratory license, it will be difficult to survive."

When CMS learned of the PT violation, at the VVCH laboratory, it said it would withhold revoking the CLIA certificate if the hospital requested an administrative hearing. But CMS also said it would stop paying the hospital for Medicare and Medi-Cal clinical laboratory services.

VVCH is one of four hospitals in the High Desert about 100 miles north and west of Los Angeles. The hospital delivers about 2,000 babies annually, and its ER treats about 100 patients each day. Almost 60% of its patients are on Medicare or Medi-Cal. When issuing her injunction against CMS, U.S. District Court Judge Virginia A. Phillips said that, within four weeks of losing its ability to provide laboratory services, the hospital would need to lay off staff and the remaining hospitals in the region would have trouble providing care to all the patients in the area.

Is CMS Overreaching?

THE DARK REPORT observes that this case may provide a good test for laboratories hoping to see a stop to CMS' current CLIA enforcement policies. As Hooper observes, the lab tech at Victor Valley's laboratory sent the PT specimen to Quest Diagnostics Incorporated. Quest did as it is required by law and reported the PT violation to CMS. So this is also an example of how CMS is turning laboratories against each other because of their fear of CLIA enforcement. Expect other hospitals to file federal court actions in similar cases because of the extreme consequences of losing CLIA certification over an inadvertent PT violation. **TDR**

Contact Patric Hooper at 310-551-8111 or phooper@health-law.com.

Labs Should Prepare for Tighter CLIA Enforcement

CMS is stripping labs of their CLIA licenses for inadvertent violations of PT procedures

CEO SUMMARY: Lab directors and pathologists should take notice of disturbing new developments in enforcement of CLIA regulations. During the past year, CMS officials have revoked the CLIA certification of several hospital laboratories for what are, essentially, inadvertent violations of proficiency testing (PT) procedures. Revocation of lab's CLIA certification lasts for one year, and also includes a sanction that prevents the lab director and the lab owner from operating or owning a laboratory for two years.

IN RECENT MONTHS, federal officials have revoked the CLIA certification for a growing number of laboratories. These severe sanctions are generally linked to inadvertent violations involving proficiency testing.

In such cases, revocation of a laboratory's CLIA (Clinical Laboratory Improvement Admendments of 1988) certification lasts for one year. Further, when the **Centers for Medicare & Medicaid Services** (CMS) revokes a lab's CLIA certification for proficiency testing (PT) violations, it also forbids the laboratory director and the lab owner from operating or owning a clinical lab for two years.

The **College of American Pathologists** (CAP) is tracking this disturbing development. Although only a "handful" of labs have been affected, CMS sanctions are so severe that CAP has started an education program to alert pathologists and lab directors to this nationwide problem.

"CMS is being more vigilant in pursuing possible incidents of PT referral and intra-laboratory communication," explained R. Bruce Williams, M.D., FCAP. "Frequently, the sanctions are disproportionate to the level of noncompliance, especially when instances were unintentional. CAP is tracking a rise in unintentional incidents, and is finding cases of misunderstandings that have developed in the laboratory community. We are working to clear up that confusion." Williams chairs CAP's Commission on Laboratory Accreditation and is a pathologist with **The Delta Pathology Group** in Shreveport, La.

"Labs are required to have a CLIA license to perform human testing for diagnostic purposes" he said. "When the lab loses that license, it is basically out of business. It loses the ability to bill for Medicare and Medicaid and is prevented from performing tests and reporting results.

New Lab Director Needed

"When CLIA certification is lost, the hospital must arrange for its laboratory to be owned and operated under a license with a different owner and a different director," added Williams. "Small labs in rural hospitals have been shut down because the hospitals can't own those labs for two years, and because the pathologist can't direct the lab for two years. Basically, that

lab ceases to exist, creating unique patient care problems for the parent hospital.

"Even medium-sized hospital labs have been affected," Williams continued. "One hospital lab in a moderate size city lost CLIA certification and was shut down. Only after a new owner was found was that lab facility able to come back online.

"Sometimes, if the affected lab is part of a hospital chain, a sister hospital can step in and run the lab. Or, a hospital could work with a nearby hospital to have lab professionals come in and run the operation. Sometimes commercial labs come in and take over management and operation of the hospital lab in these situations. This problem is occurring not just to CAP accredited labs, but also to labs accredited by the **Joint Commission** and to CMS and state-inspected labs.

"One problem results from the way PT is conducted," explained Williams. "It is extremely easy to make a mistake and refer a PT test to another lab for confirmation. Those mistaken referrals are bringing harsh penalties.

CLIA Regs Require PT

"CLIA Regulations (section 493.801) say all laboratories must enroll in approved PT programs and that technologists must test PT samples in the same manner as the laboratory tests patient specimens. This regulation means that, if a lab runs a patient specimen only once, PT specimens also must be run only once. It also means that PT samples should be rotated among all staff that routinely perform the patient testing," he noted.

"In addition, each laboratory must report PT actually done at that laboratory," Williams said. "For example, if a laboratory performs HIV screening and routinely sends positive samples to another laboratory for confirmation, it is not allowed to do so for PT—as it would be considered *referral of PT*. Proficiency testing is meant to assess the testing done in one specific lab, *not* the testing done in another, outside facility. Although not entirely obvious, PT referral can occur unknowingly in the most practical lab situations," he added. *(See sidebar, "Common Situations Can Create Problems.")*

PT Handling Questions

"The penalties are severe and most of these situations are simply unintentional or inadvertent mistakes. Yet labs are being penalized heavily," Williams said. "These are not cases in which someone is trying to cheat on PT or get around the PT requirements. Having said that, let me add that the College is adamant that any person who purposefully cheats or tries to do something inappropriate on PT should be sanctioned harshly. We believe that PT cheating is inappropriate and not conducive to good patient care or good quality lab medicine.

"However, for lab professionals who have good intentions, there are many ways that labs can run afoul of these regulations inadvertently," Williams explained. "Let's say a main hospital laboratory has several different types of outlying labs such as a blood gas lab, a stat lab in the ER, and a lab in a physician's office that the hospital owns. For whatever reasons, a technologist in one of the outlying labs may have a PT result that would normally be reflexed to the main lab for confirmation. Lab techs know that they should treat PT samples as they would treat a patient sample. Given that, they would look at their own internal flow charts for what to do with the PT sample. Normally this result would be confirmed by the main lab and so they would send it over to the main lab. The main lab would run the test and report the result to the outlying lab.

"That situation happens frequently," Williams said. "Lab professionals believe they are handling the sample correctly because they are handling it as they would handle a patient sample. The caveat is that *you are not supposed to send PT samples outside of your CLIA or CAP lab walls!* In other words, you must keep all PT samples inside the lab and never refer any PT samples out. If you follow this one rule, you should be safe. But there is ample room for confusion.

"For instance, let's say you have a positive HIV test," he added. "You would normally send that out for confirmation. So, a lab tech doing PT might send out an HIV sample for confirmation. Or, you have a positive gram stain on a PT sample. Same thing: You would normally send that sample out for confirmation. Your lab might have limited microbiology testing in its lab and so you send off any positive results for confirmation and/or identification and sensitivity testing. Therefore, you might be inclined to do the same with PT samples for gram stains or microbiology. If you do, that would be inappropriate.

"Here's a less obvious example," Williams continued. "Let's say you have a hematology sample that involves Kodachromes. A technologist might normally handle that test at the bench and then show it to others. But you should definitely not show these PT samples to others in the lab and you shouldn't show it to a supervisor or a pathologist unless you would normally do that for a patient.

Confusion Reigns

"But this is where confusion arises if you have a case of an atypical cell that you would normally refer to a pathologist," Williams explained. "It would be okay to show that PT sample to the pathologist if the pathologist looks at the sample within the four walls of the laboratory.

"But say you are working in a small lab or a lab in a large system and the pathologist is not present in your lab at the time when you look at the PT slide," he said. "You would say to yourself, 'This normally goes to the pathologist.' So, you package up the PT slide and send it to the pathologist who is working at another CLIA lab site—even though the two labs are closely related and possibly are owned and operated by one hospital.

"In this example, that pathologist represents the lab where he or she is physically working—not the lab where the PT sample originated, even if the pathologist is the lab director," Williams said. "In this example, the right thing to do is for the technologist to wait until the pathologist comes to the technologist's lab. Then, it would be appropriate and legal to have the pathologist look at that PT slide. These are fine distinctions that are easy to miss for technologists and other lab professionals.

Common PT Situations Can Create CLIA Problems

SOME COMMON EXAMPLES in which laboratories may inadvertently "refer" Proficiency Testing (PT) include the following, according to the College of American Pathologists (CAP):

- **Reflex and confirmatory testing:** For a patient sample, if a laboratory does not perform the confirmatory or reflex portion of a test battery or other testing, the sample would typically be sent to a different lab for that testing. For a proficiency testing sample, a laboratory is prohibited from sending the proficiency testing sample outside of the participating laboratory. That laboratory must complete the proficiency testing result forms using the appropriate code.
- **If multiple CLIA numbers exist within the same institution** or ancillary laboratory, special caution must be taken when laboratories receive proficiency testing samples for laboratories with more than one CLIA/CAP number. If the specimen boxes are tested by the wrong area, this could lead to a perception of referral or "sharing" of PT. If both laboratories test the PT sample or if the wrong laboratory performs the testing and reports the results to the PT provider, it may be considered referral of PT.
- **Slides for pathologist review:** Certain patient slides, like abnormal differentials, involve patients and they require a pathologist's review. These slides may be sent to a site outside of the testing laboratory for this review. Proficiency testing slides, however, cannot be sent out. Rather, the pathologist must review the PT slide at the laboratory's physical address.

"Here's another situation to avoid, one that involves a hospital or facility that has multiple CLIA numbers within the same facility and those labs share the same computer system," Williams added. "If you put results for your PT samples into the computer and label them so it is possible for lab workers at any of the other CLIA labs to view the results, you could be penalized. So, don't label them as PT1 and PT2.

Recent Regulatory Emphasis

"These rules have been in existence since CLIA became effective in 1992," observed Williams. "However, CMS is stepping up its enforcement efforts, particularly to identify attempts to get around PT requirements. Because the penalties are so severe, it is important for all laboratories to be alert to these developments.

"We see a rise in the number of CLIA cases being reported to CMS, even though the number is small," he added. "Typically these violations come in pairs because two labs are affected at the same time: the referring lab and the receiving lab.

"Unfortunately, CMS has taken the position that it cannot see inside the minds of technologists who make these PT errors. Thus, it cannot determine if what happened was intentional or unintentional," said Williams. "CMS enforcement is predicated on the fact that any PT referral should be treated as an intentional referral. So any innocent mistake by a technologist who believes he or she is doing the right thing could lead to the harsh penalties enumerated previously.

"We asked CMS to differentiate between intentional and unintentional attempts to circumvent the PT rules and CMS officials declared that they must treat them all as intentional. That is their stance," stated Williams.

"Another problem for labs in this situation is that the appeal mechanism for these problems goes through an administrative law judge," he added. "To our knowledge, the administrative judge has upheld CMS' position on every appeal that has gone to a hearing.

"Recently, we learned that a non-CAP-accredited laboratory is taking CMS to court to challenge CMS's revocation of its CLIA certification. The lab's strategy seems to be that a court would be more amenable to understanding the difference between intentional and unintentional. After all, the courts address these issues every day. This court may recognize that the penalty may not fit the crime. That case has yet to be resolved.

"Another warning to lab directors may be helpful," continued Williams. "As CMS increased its CLIA enforcement, it is asking laboratories to report violations. This means that if a technologist refers a PT sample to another lab and that second lab reports the violation, then the second lab doesn't face the severe penalties. This factor may be one reason why we see an increase in the number of CLIA-related enforcement actions."

Education and Training

For labs seeking to avoid these severe sanctions, CAP advises education and training for staff. "Education always is the answer when trying to be in compliance," Williams said. "It's also important to have procedures to prevent unintentional PT referrals.

Williams' two other recommendations included: 1) don't put information about PT samples into your computer system where it would be easy to identify it, for example. 2) inform both the technologists and the send-out staff to not send out PT samples.

THE DARK REPORT observes that, once again, CMS is acting in a heavy-handed manner toward clinical laboratories. Punitive sanctions for inadvertent PT referrals affects patient care and disrupts the affected hospital when CMS revokes its lab's CLA certification for this cause. TDR

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Ascendium Consulting Is New Firm In Lab Market

Demand by labs for strategic and operational consulting services encourages new company

CEO SUMMARY: Growing numbers of laboratories are taking steps to reengineer work flow, evaluate automation solutions, and improve the operational performance of their laboratory. This is fueling a demand for laboratory consulting services and Ascendium Consulting is this newest healthcare and lab consulting company in this marketplace. It became operational on January 1, 2008, as a result of Roche Diagnostics, Inc.'s decision to divest its Healthcare Solutions business unit.

THERE'S A NEW NATIONAL CONSULTING FIRM in healthcare and the lab industry. On January 1, 2008, **Ascendium Consulting** launched operations.

Ascendium Consulting was created when **Roche Diagnostics, Inc.** divested its Healthcare Solutions consulting services division. Private investors joined together with executives from Healthcare Solutions to form the new company.

"All of the lab consultants and business development professionals from Healthcare Services joined us at Ascendium," said Trent Ritzenthaler, President and Managing Partner of Ascendium Consulting, based in Indianapolis, Indiana.

Offering Other Services

The birth of Ascendium Consulting shows some of the tension experienced by *in vitro* diagnostics (IVD) manufacturers as they develop different value added services to supplement their core business of instruments, reagents and consumables. These value added services are used to enhance ongoing relationships with lab customers.

THE DARK REPORT believes that Roche Diagnostics recognized that, by offering strategic management and operational consulting services to laboratory clients, it was encountering two issues. One, it wanted the consulting services division to generate incremental revenue for the organization through fee-based, objective consulting services.

Two, even though there was an arms-length relationship between the consulting division and the larger company, the consulting services could be viewed as biased towards Roche products. Healthcare Solutions was often involved in helping improve workflow, redesign physical space, and develop the entire infrastructure for newly formed diagnostic facilities. In that role, clients often sought direction on specific products, giving rise to a potential identity conflict.

Finally, the primary business at Roche Diagnostics is selling analyzers, instrument systems, reagents, and other consumables. Thus, it is likely that, on balance, Roche decided the added value generated by the laboratory consulting business unit was not enough to compensate for the different complications that accompany a consulting relationship with

a lab customer. Thus, the decision to divest the consulting services division.

For Ascendium Consulting, its status as an independent company means a new start and a new opportunity to sell its strategic, operational and information technology consulting services to a national healthcare market. "Because our professionals have an average of over 20 years experience in healthcare, and because all of our active clients agreed to stay with us, our new enterprise started fast and is already growing," observed Ritzenthaler.

Improving Lab Operations

According to Ritzenthaler, Ascendium sees strong interest by laboratories to improve operations in three areas. "There is much interest in Lean and Six Sigma and quality management methods," he explained. "Lab directors and pathologists are recognizing that laboratories operating from these principles are performing at a higher level than conventionally-managed laboratories.

"There are enough success stories in the public domain now that hospital lab directors have plenty of evidence and ammunition to take to their administration and demonstrate why introducing Lean and Six Sigma quality management methods into the laboratory will be a winning strategy," he continued.

Molecular Is A Growth Field

"Next, a number of our engagements have focused on molecular laboratory design and operation," stated Ritzenthaler. "Because this is both a new field in laboratory science and one that is growing exponentially, many laboratories must either create a brand new space in the lab to handle molecular testing—or these labs need to expand existing molecular lab space, facilities, and expertise.

"The third major trend we see in our consulting practice is the adoption and implementation of automation," he said. "This is not limited to the high volume chemistry and hematology core lab. Because of new instrument systems and automation solutions, it is now possible to automate other departments in the laboratory."

Ritzenthaler also identified another development that has caught the attention of pathologists and laboratory administrators. "A related trend involves the focus on measuring quality," he added. "Throughout healthcare, there is pressure to measure quality and be accountable for quality.

"In part, we're seeing this trend because payers are tying reimbursement to quality. Payers have seen that lab errors—such as when a pathology report is delivered to the wrong individual—can be very serious. Errors like these will be the target of lab efforts to improve the consistency and performance of individual work processes within the laboratory.

Labs Helping Providers

"Another dimension of the trend to measure quality is that the customers of diagnostic services—physicians, hospitals, and other providers—are paying attention to their outcomes and looking for ways to improve," he noted. "Smart lab managers and pathologists are recrafting their laboratory operations and performance to support the efforts of payers to reduce medical errors and improve patient outcomes."

Ritzenthaler's observations about the active steps laboratory leaders are taking to improve operations, streamline workflow, and deliver increased quality are consistent with what THE DARK REPORT observes across the laboratory industry. For that reason, Ascendium Consulting is entering the marketplace at an auspicious time.

Moreover, Ritzenthaler's comments about the booming interest in creating new molecular services or expanding existing molecular testing facilities hints at Ascendium's likely business strategy. It wants to emphasize this experience in tandem with its strategic and operational capabilities. TDR

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Legal Update

Medicare Competitive Bid Lawsuit Heads toward a Judge's Ruling

LOOK TO APRIL 7 FOR THE NEXT DEVELOPMENT in the federal court case filed by three San Diego-area laboratories challenging the Medicare Laboratory Competitive Bidding Demonstration Project. That's when the judge is expected to rule on the case.

The latest development was on March 14, when federal lawyers made a court filing. They argued that the position of the **Centers for Medicare & Medicaid Services** (CMS) is simple: laboratories should file any appeal of the Medicare Clinical Laboratory Competitive Bidding Demonstration Program through CMS' administrative review procedures.

Ruling Expected

Attorney Patric Hooper of **Hooper, Lundy & Bookman** in Los Angeles said last week that he expects the court to rule on the case by April 7. Hooper filed a challenge to CMS' claims, and the filing March 14 from CMS is a response to Hooper's challenge. Hooper represents **Sharp HealthCare**, **Scripps Health**, and **Internist Laboratory** which are in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) where CMS is conducting the demonstration project. *(See TDRs, March 3, 2008 and December 31, 2007.)*

On February 14, Federal District Court Judge Thomas J. Whelan issued an order denying the three labs' request for a temporary restraining order (TRO) to stop the demonstration project from going forward. In requesting the TRO, the labs challenged the procedural steps Health and Human Services (HHS) Secretary Michael Leavitt used to implement the project.

In its most recent court filing, lawyers for HHS argued that the labs failed to successfully challenge the procedural steps CMS used to establish the demonstration project. Therefore, the labs failed to show why the case should not be dismissed. In the March 14 court papers, CMS lawyers described three independent jurisdictional bars to the labs' challenge.

Three Bars To Lab Challenge

The first bar is the Medicare Act itself, which precludes all legal claims arising under the act and requires that such claims be presented to CMS. The act says the labs should exhaust all administrative remedies before filing a judicial review. Laboratories suing the government have said this administrative channeling requirement means they get no review of their claims, since CMS can pick winning labs and simply stop paying losing labs for lab services provided to Medicare patients.

Federal attorneys argued that the second jurisdictional bar is that, contrary to the labs' claims, federal law does apply to such challenges. The third jurisdictional bar on plaintiffs' claims derives from the speculative nature of the lab's alleged injury, CMS lawyers said. The labs could not claim injury, since CMS has yet to name the winning or losing bidders for the project.

When the judge ruled against the three labs on February 14, the Medicare lab competitive demonstration pilot went forward as announced. The next day, February 15, was the deadline for labs to submit bids if they were eligible labs under CMS' criteria and wanted to participate in the Medicare demonstration pilot. TDR

Digitization of Pathology Is Making Steady Progress

New technology and innovations contribute more capabilities to digitized pathology systems

CEO SUMMARY: Pathology digitization incorporates a greater scope of work-changing technologies than telepathology. It incorporates information technology, new diagnostic knowledge, and other engineering innovations to help pathologists move past glass and paper. Existing digital pathology systems are already helping pathologists reduce their travel from site to site by enabling them to view digitized images from a central location.

ONGOING ADVANCES IN DIGITIZATION AND PATHOLOGY INFORMATICS are providing pathologists with new tools that hold the potential to change the way pathologists work.

Pathology digitization was one of the trends identified and described in THE DARK REPORT'S biannual list of anatomic pathology macro trends. *(See TDR, February 11, 2008.)* Because digitization holds the promise of moving pathology away from paper, it is an important trend and one that complements the efforts across healthcare to move to fully electronic medical records (EMRs).

Changing Work Practices

In a more direct way, newly approved digital technology is already changing the way some pathologists work. Rather than having to be in the same room with specimens, this technology allows pathologists to work remotely. Further, in medical schools, the shift to digital images and away from glass slides means that newly-graduating pathologists enter the practice of pathology already comfortable and proficient with digital pathology images.

These developments have significant implications for the pathology profession, which is predicted to soon face a shortage of pathologists. That's because viewing digital images eliminates travel and saves shipping costs. "A pathologist who spends his morning at one hospital and then goes across town to read slides at another facility may not have to make that drive anymore," said Ole Eichhorn, Chief Technology Officer of **Aperio Technologies Inc.**, a company in Vista, California, that specializes in digital pathology.

"For example, this represents a dramatic change for pathologists who serve hospitals in rural areas," he observed. "Circuit-riding pathologists in rural areas—who literally spend every day of the week in a different location—don't have to do that anymore. Digitization of pathology images means they can perform the same work from a central location. By eliminating the time spent traveling, it makes the pathologist much more productive."

One of the features of new digital pathology technology is that digital images are stored on a server and can be viewed on a computer screen miles away.

"The system is designed to work much like Google maps in that you can pan and zoom over a large image," explained Eichhorn. "Just as you don't have to download the entire dataset of Google maps to find the nearest pizzeria, the same thing happens with a digitized pathology image. The pathologist doesn't need to see the whole image at high resolution. Rather, he/she pans through at lower resolution, zooming in to see features of interest, then zooming back out to continue studying the image.

"We don't view this technology as replacing eyeballs with automation," Eichhorn continued. "These digital images allow pathologists to find the things that are important more quickly, then use software tools to precisely quantify what they find. Thus, instead of estimating that something on the specimen is expressed at 70%, a pathologist would now be able to report that something is expressed at 68.234%, for example.

"It's doubtful that the day will come when computers replace pathologists," he added. "Instead, this new digital technology allows pathologists to quantify results more accurately, thus providing more specificity in the results reported to the referring physician.

Increasing Productivity

"Another benefit is that pathologists have always worked in the same physical location with their specimens," stated Eichhorn. "But digital pathology now allows pathologists to be in a different location from the physical specimens. This increases the flexibility and productivity of pathologists.

"Digitized images also make it easier to have subspecialist pathologists review specimens," he noted. "At the same time, use of digitized pathology images and systems allow pathologists to serve a wider community of hospitals and specialists while cutting down on travel and reducing the cost of shipping glass slides.

"Digitized pathology technology has important implications for a pathology profession struggling with a workforce shortage," observed Eichhorn. "Pathologists face increased pressure for a number of reasons. First, the absolute number of cases are increasing. Second, new diagnostic tests are introduced every week and pathologists must become proficient in using these new assays. Third, the number of pathologists is not increasing in proportion to increases in specimen volume. Thus, any technology that helps a pathologist become more productive is important.

"Digitized pathology technology has important implications for a pathology profession struggling with a workforce shortage," observed Eichhorn.

"Currently, there are few examples where a pathologist handles nothing but digital images throughout the day," said Eichhorn. "Rather, digital pathology applications are finding greater use in specific clinical activities, such as preparing for tumor boards, doing secondary consults, IHC quantification, use in medical education, or building up reference libraries. Like other areas of informatics and computers, as pathologists gain more personal experience with digital technology, they will be more comfortable in expanding its use in other areas of anatomic pathology and laboratory medicine."

Digital pathology systems are moving through the regulatory approval process. For example, in January, Aperio received clearance from the Food and Drug Administration (FDA) to market the manual read of digital HER2 slides from a computer monitor using its ScanScope digital slide scanning system. The FDA-cleared system is intended for use as an accessory to **Dako's** HercepTest to aid pathologists in the detection and meas-

urement of HER2 protein expression to assess breast cancer patients.

"This FDA clearance was an important milestone in pathology digitization," stated Eichhorn. "It is the first time the FDA has cleared any technology that demonstrates that what a pathologist views on a computer monitor is the same—for diagnostic purposes—as what the pathologists would view through a microscope.

"Previously, Aperio received clearance for an image analysis algorithm that quantifies HER2 by actually measuring the membrane staining of cells to show whether the protein is present," explained Eichhorn. "The software analyzes an image and produces a quantified result.

"Now that the FDA has cleared this technology for the manual read of a digital pathology image from a monitor," he added, "it means we can market the technology to the pathology community. It will permit pathologists to view the specimen image on a monitor in the same fashion as they would view a glass slide through a microscope."

Eichhorn thinks that the digital pathology technology will advance the quality and accuracy of diagnosis. "We believe this technology has the potential to reduce false negatives and false positives, but, we will be cautious about such claims and wait for the results of further clinical studies. Anecdotally, pathologists who have been early users of this system tell us they often find things in the digital pathology image that they might not have found otherwise."

➤Exclusive Worldwide License

Last fall, Aperio secured an exclusive worldwide license from **Los Alamos National Laboratory** (LANL) to LANL's Genetic Imagery Exploration (Genie Pro) image pattern recognition technology for digital pathology applications.

"This development is also significant," Eichhorn said. "The Genie Pro technology was developed for the military to identify rare events from satellite imagery. We have licensed it exclusively for pathology because it is very useful for looking for rare events in digital images. Pathologists spend a lot of time looking painstakingly through large samples to find something that's hard to find, such as metastasizing cancer cells in a lymph node, or bacilli in a lung sample infected with tuberculosis. This work is critical because if the pathologist misses something, you'll have a false negative, which affects patient treatment. So, in this way, the technology allows us to create products that will help pathologists do their jobs more efficiently and more effectively.

➤Four Elements In The System

"In our systems, there are four pieces," he explained. "First, there's the hardware to scan the slides and create digital images from the slides. Second, the technology allows the slides to be viewed. We give pathologists a viewing experience that allows them to zoom in and out and pan through large images. Third, there's image management, which includes workflow, access, security considerations, archiving, and other similar activities. Fourth, we have analysis tools that let pathologists measure things and find things in images.

"The software presents the 20 (or whatever number you choose) most likely instances of whatever you're seeking," Eichhorn added. "It saves the pathologist from having to pick through the entire haystack to find a needle. The software will do the work for them by identifying the 20 things that look most like a needle. And then the pathologist can decide whether each instance is a needle or not.

"We believe this technology has a lot of potential, but pathology is a conservative field," he said. "Although pathologists are not early adopters in general, they are starting to use this technology. As they do, others are becoming aware of it and we're starting to get a critical mass now—whereas a few years ago not many pathologists were aware of this technology." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Things are happening under new ownership and management at **DCL Medical Laboratories LLC.**, based in Indianapolis, Indiana. DCL announced a strategic partnership with **Third Wave Technologies Inc.**, a molecular diagnostics company in Madison, Wisconsin. In the partnership, DCL will serve as a product development and marketing partner for Third Wave for its emerging diagnostic technologies. DCL, with its existing base of client physicians and sales force, can introduce new diagnostic assays into the market. That can help Third Wave evaluate clinical acceptance for its new assays and other products.

BIO-REFERENCE POSTS STRONG REVENUE GROWTH

First quarter revenue grew 24% at **Bio-Reference Laboratories, Inc.** (BRLI), of Elmwood Park, New Jersey. The company had Q1 net revenue of $66.9 million, compared to $53.7 million it reported in Q1 2007. Patient volume was up significantly. For Q1 2008, BRLI served 962,000 patients, an increase of 15% over the Q1 2007 number of 836,000 patients. Average revenue per patient climbed to $68.83 in the current quarter, compared to $63.21 for the same quarter last year.

MORE ON: BRLI

Bio-Reference Laboratories has benefited from two business strategies. One, it is a tough regional competitor in the Greater New York City Metropolitan area and has clearly captured its share of new accounts as labs fight for **UnitedHealth's** lab testing business in the region. Two, it offers specific services in esoteric and reference testing that are marketed nationally. Because these tests are reimbursed at higher rates, BRLI is enjoying an increase in its average revenues per accession.

LAB OUTREACH AT STANFORD

According to an *East Bay Business Times* article on March 13, 2008, **Stanford Hospital & Clinics** of Palo Alto, California, is considering selling its laboratory outreach program. Gary Migdol, Director of Communications for Stanford Hospital & Clinics, was quoted as saying "There have been concerns about the financial viability of the outreach lab. There are a number of companies providing high-volume laboratory services at competitive costs nationally."

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 14, 2008.

Preview #4

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