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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

Reading the Tea Leaves from 2010's Events

EACH YEAR WHEN WE PRESENT OUR "Top Ten Lab Stories" for the year, I am always surprised at which forces for change emerged during the prior 12 months. In presenting THE DARK REPORT'S "Top Ten Lab Stories for 2010," our editor has pointed out that four of these ten stories involved the federal government in some form or fashion.

That is an interesting observation. It implies that, particularly compared to earlier years, the laboratory testing industry and healthcare in general will feel immediate effects from federal government policies and regulation, as well as the reimbursement levels voted annually by Congress. In my view, this is a major difference from earlier years.

For example, in the second half of the 1990s and the first half of the 2000s, I would say that THE DARK REPORT'S list of "Top Ten Lab Stories" for each year was generally heavily influenced by the activities of the two blood brothers and the Wall Street investment community. Certainly, the way both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** regularly scooped up the second tier laboratory companies as they came to market has shaped and altered the competitive marketplace for laboratory testing services. That acquisition activity has diminished somewhat in recent years, primarily because this consolidation wave left few independent lab companies to be acquired.

However, I cannot recall a year prior to 2010 when federal government activities made up as many as four of THE DARK REPORT'S "Top Ten Lab Stories" list. Just in the past 12 months, the feds have passed a major health reform bill that will enact major changes in each of the next eight years, the "meaningful use" rules that will guide how 480,000 physicians adopt EMRs in the next few years were published, the FDA is prepared to regulate LDTs, and a federal judge has ruled against patents for gene isolation and/or purification. Collectively, these four developments have the potential to trigger significant changes in how clinical laboratories and pathology groups conduct their business and get reimbursed for their lab testing services.

It is a fact that state and federal budgets are under unprecedented stress—pressure probably not seen since World War II. That makes it easy to predict that our federal government will probably be the most influential change agent on the American healthcare system in the next few years. Whether this turns out favorably for pathology and lab testing remains to be seen. TDR

Our Top Ten Lab Stories Highlight Major Changes

During 2010, passage of the health reform bill overshadowed other important lab industry stories

CEO SUMMARY: What makes 2010 a watershed year for the laboratory testing industry is enactment of the 2,700-page Patient Protection and Affordable Care Act (PPACA). Even if parts of this bill are repealed, the remaining parts of the massive legislation will trigger major changes to the healthcare system as it operates today. Other stories in 2010 point to a promising future for the lab testing industry, particularly in the field of anatomic pathology and molecular diagnostics.

FEW WOULD CHALLENGE ENACTMENT of health reform legislation as the most important lab industry story for 2010. Signed into law in March, it will cause far-reaching changes to the healthcare system as we know it today.

For that reason, THE DARK REPORT has ranked it number one on our "Top Ten Lab Stories for 2010." However, the government's role in a top ten lab industry story is not restricted just to passage of the health reform bill. At least three other stories on our list involve government actions that have the potential to greatly influence or alter the laboratory testing marketplace.

For example, our story number two centers around the fact that 480,000 physicians are poised to begin EMR adoption starting in 2011. This is a direct result of federal financial incentives and disincentives slated to take effect between 2011 and 2015. *(See page 5.)*

Our story number eight recognizes the importance of the FDA's public statements that it is prepared to regulate laboratory-developed tests (LDTs). This summer, it began to hold public meetings to gather comment and input from the clinical laboratory testing industry and other interested parties. *(See page 8.)*

Similarly, story number 10 deals with the court ruling by a federal judge that invalidates seven of the BRCAI and BRCAII patents that underpin Myriad Genetic's proprietary molecular assay. The case now goes to the appeals court and experts believe that it may reach the Supreme Court. *(See page 9.)*

Thus, during 2010, the federal government actions represent four of the 10 stories in our list. Compared to the 11 years

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that THE DARK REPORT has compiled a lab industry "top ten stories" list, this is quite unusual. Since 1999, each year's list of top ten stories has seldom included more than two stories directly tied to an action or new policy by the federal government.

What else is new on this year's top ten story list? The answer to that question is "anatomic pathology." Four of the remaining 10 stories on the 2010 list involve major developments in the anatomic pathology sector of laboratory testing.

As you will read, pathologists at **Beth Israel Deaconess Medical Center** (BIDMC) in Boston have launched a research collaboration to sequence whole genomes of patient specimens, with the goal of identifying new ways to diagnose and treat cancer and other diseases. This story is ranked number 3. *(See page 6.)*

➤Big News In Anatomic Path

At number 5 is the news that **Roche Holdings** paid $100 million to acquire **BioImagene, Inc.**, the digital pathology company. *(See page 7.)* Following at number 6 is **General Electric's** acquisition of **Clarient, Inc.**, for the princely sum (particularly if you were a Clarient shareholder) of $587 million! Clarient is a national laboratory company that provides pathology testing services, including its own proprietary molecular assays. *(See page 7.)*

Rounding out the four anatomic pathology stories on our top ten list is story number 9, which is the news that several private pathology group practices decided not to sell themselves, but to instead bring in private equity investors and partner with them to further develop their pathology group practices.

The first two pathology groups out of the gate in January, 2010, with this strategy were **PathGroup, Inc.**, in Nashville, Tennessee, and **Pathology, Inc.**, in Torrance, California. Based on news reports, they raised $100 million and $25 million, respectively. *(See page 9.)*

That doesn't mean the clinical laboratory side of the lab testing industry was quiet in 2010. Our story number 7 is about the increased interest that hospital and health system CEOs are showing in building their laboratory outreach testing programs.

➤Hospital CEOs Take Action

Two news events that support this trend were the announcements this fall by **Providence Health & Services** of Burbank, California, and **Centura Health** of Denver, Colorado, that each would collaborate in a laboratory testing outreach joint venture with **Pathology Associates Medical Laboratories, Inc.**, of Spokane, Washington. The health systems operate six and 12 hospitals, respectively, in their primary service regions. *(See page 8.)*

It is noteworthy that there is steady growth in the number of hospital and health system CEOs who now recognize and acknowledge the value that a profitable and productive laboratory outreach testing program has to the institution. It means that more resources are likely to be channeled to various hospital laboratory outreach programs. In turn, that will make them stronger when competing for the lab test referrals of office-based physicians.

➤Strategic Planning

Collectively, THE DARK REPORT'S "Top Ten Lab Stories for 2010" provide a good road map for understanding the current state of the laboratory testing marketplace and how it is likely to evolve in coming months.

It is recommended that laboratory administrators and pathologist business leaders use this list of top lab stories in 2010 as the basis for a strategic planning session within their laboratory organizations. This can be a useful step in updating strategic business plans so they take into account the need to respond to changing government regulations as well as new developments in the competitive marketplace.

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TOP TEN OF 2010 STORY no.1

Passage of Health Reform Bill Sets U.S. Healthcare on Uncertain Course

REGARDLESS OF WHETHER YOU ARE FOR OR AGAINST the health reform bill called "Obamacare," its passage by Congress last spring is a watershed event in American healthcare.

With its enactment, the healthcare system in the United States was propelled into an uncertain future. That uncertainty exists for two reasons. First, the 2,700-page legislation spells out numerous significant changes and creates a host of new commissions with the charter to study and change specific areas of healthcare.

Second, the voter displeasure expressed last election day makes it possible that foes of the health reform legislation might actually be able to repeal significant parts of the bill.

What is certain to occur is a reduction in fees for laboratory testing. For the five years of 2011 through 2015, Medicare Part B laboratory testing fees will be reduced by 1.75% each year. *(See TDR, August 23, 2010.)* Labs are likely to also be hit by the 2.3% tax on medical devices. This tax takes effect on January 1, 2012. *(See TDR, March 29, 2010.)* Repeal of either the specified Medicare Part B fee cuts or the medical device tax is uncertain at this time.

Enactment of the Patient Protection and Affordable Care Act (PPACA) must be considered the single biggest news story for the lab testing industry during 2010. In each succeeding year, consumers, hospitals, physicians, and labs will learn more about how this legislation changes today's status quo.

TOP TEN OF 2010 STORY no.2

480,000 Physicians Poised to Adopt EMR Systems Starting Next Year

WIDESPREAD ADOPTION of electronic medical record (EMR) systems by virtually all the nation's office-based physicians will forever change the way clinical labs and pathology groups provide lab testing services.

This summer, federal officials released the final draft of "meaningful use" criteria. These spell out precisely how the physician must use an EMR to qualify for federal incentives that will be paid during 2011, 2012, 2013, and 2014. *(See TDR, August 2, 2010.)*

During this four-year period, an individual physician can earn as much as $30,000 in total federal incentives for demonstrating meaningful use of the EMR. Starting in 2015, any physician not using an EMR will be paid less by Medicare as a penalty. This combination of incentives and dis-incentives is expected to motivate more than 480,000 physicians to adopt EMRs during the next 48 months.

This is a story that most pathologists and clinical laboratory executives fail to fully acknowledge. First, all clinical laboratories and pathology groups will be required to spend lots of money and resources to arrange interfaces between their lab information systems (LISs) and their client physicians' EMRs. Failure to respond effectively means the lab could lose that physician's account.

Second, this is a "one-time" transition. By 2015, the mass adoption wave will be over. That is why labs must be prepared to help physicians adopt an EMR.

TOP TEN OF 2010 STORY no.3

Beth Israel Pathology Opens Door To Whole Human Genome Sequencing

THIS FALL, THE PATHOLOGY DEPARTMENT at **Beth Israel Deaconess Medical Center** (BIDMC) announced that it was launching a research project to use whole human genome sequences for the study of cancer and other diseases.

What makes this possible is the fact that the cost of sequencing an entire human genome has fallen to about $8,000—and is expected to continue a steady decline into the foreseeable future. *(See TDRs, October 15, 2010 and November 15, 2010.)*

By all measures, this is a milestone event for anatomic pathology and the laboratory medicine profession. It represents one of the earliest research efforts to take patient specimens, particularly of cancer, and sequence the entire human genome. The resulting information will be studied to identify better ways to diagnose disease and select the best therapies.

The Chair of Pathology at BIDMC, Jeffery Saffitz, M.D., Ph.D., told THE DARK REPORT that, as it becomes quite cheap to sequence an entire human genome, pathologists are likely to find themselves in a primary care role. As the whole genomes of well adults and newborns are analyzed, it will be possible for pathologists to help develop health maintenance plans and participate in lifelong efforts to optimize health.

Should this come to pass, it would give pathologists the same important role in wellness management that they currently have in diagnosing disease.

TOP TEN OF 2010 STORY no.4

ISO 15189 Makes Further Progress Among U.S. Clinical Laboratories

YOU CAN STILL COUNT THE NUMBER OF ISO 15189-ACCREDITED LABORATORIES in the United States on less than 10 fingers. But that won't be true by the end of 2011.

Over the course of 2010, a number of first-mover clinical laboratories achieved accreditation to ISO 15189:2007 Medical Laboratories. A larger number of clinical laboratories during the year began the process required to eventually earn accreditation to ISO 15189.

Probably the largest laboratory organization to earn ISO 15189 accreditation during 2010 was **Spectra Laboratories, Inc.**, of Rockleigh, New Jersey. A division of **Fresenius Medical Care North America**, Spectra typically handles 109,000 patient accessions weekly. *(See TDR, June 25, 2010.)*

ISO 15189 is gaining global favor as the quality management system (QMS) of choice for clinical laboratories. The ISO 15189-accredited laboratories in the United States report that adoption of a QMS has brought tangible benefits and positions them to deliver continuous improvements in quality and patient service.

This story makes THE DARK REPORT'S Top Ten for 2010 because it demonstrates how progressive laboratory organizations in the United States are working to raise the bar ever higher on patient quality and lab performance.

TOP TEN OF 2010 STORY no.5

Digital Pathology Gets Respect As BioImagene Sells for $100 Million

PROBABLY THE MOST SURPRISING ACQUISITION of an *in vitro* (IVD) manufacturer during 2010 was **Roche Holdings'** purchase of **BioImagene, Inc.**, for $100 million in August.

BioImagene is one of the early leaders in selling digital scanners and digital pathology systems. This is a field so new that probably less than 1,000 pathology laboratories worldwide own and operate a digital pathology system. *(See Dark Daily, August 24, 2010.)*

Thus, it is significant that Roche was willing to pay $100 million for a young firm selling products into an infant market. For pathology marketplace observers, this is an important confirmation that digital pathology has a bright future.

It should not be overlooked that another healthcare giant is also developing its own digital pathology solution. **Omnyx, LLC**, is **General Electric's** joint venture with the **UPMC Health System**. Unlike Roche, which has both a large pharmaceutical business and a large IVD business, GE is big in radiology and molecular imaging.

Pathologists can expect to see both multi-billion-dollar healthcare giants develop digital pathology solutions that advance the respective interests of each company. In the case of GE, digital pathology applications that are integrated with molecular imaging are a likely outcome. In the case of Roche, it will be to use digital pathology solutions to support decisions about use of therapeutic drugs.

TOP TEN OF 2010 STORY no.6

GE's $587 Million Purchase of Clarient Is Big Boost for Anatomic Pathology

WILL ANATOMIC PATHOLOGY and molecular diagnostics be a fast-growing source of profits in future years? **General Electric** just placed a $587 million bet that the answer to that question will be "yes!"

On October 22, GE announced an agreement to purchase **Clarient, Inc.**, for $587 million. Based in Alieso Viejo, California, Clarient offers a menu of specialized testing services, including proprietary molecular assays.

Wall Street investors were surprised at the strong price that GE was willing to pay for Clarient. That's because, for 2009, Clarient reported $91.6 million in revenue and posted a net loss of $6.1 million. Thus, GE's purchase price of $587 million represents one of the largest premiums paid by a buyer for a laboratory testing company during the past 10 years. *(See Dark Daily, October 22, 2010.)*

It should be noted that General Electric is staking out a strong position in molecular pathology. It is a partner in **Omnyx, LLC**, its digital pathology joint venture with **UPMC Health System**. Now it owns a national pathology company with sophisticated expertise in molecular diagnostics.

GE's acquisition of Clarient is a bold statement of its intent to become a major player in molecular diagnostics and anatomic pathology. It also hints at a strategy that GE may have of developing an integrated diagnostic product line that combines molecular imaging with molecular pathology.

TOP TEN OF 2010 STORY no.7

PAML's New Hospital Outreach JVs Reflect More Interest in Lab Testing

DURING 2010, THERE WAS COMPELLING EVIDENCE that more hospital and health system CEOs are waking up to the immense value that a successful laboratory outreach program can deliver to their institutions.

Pathology Associates Medical Laboratories, Inc. (PAML), is one direct beneficiary of the increased interest of hospital CEOs. PAML entered into hospital laboratory outreach joint ventures with two multi-billion-dollar health systems just weeks apart this fall. *(See TDR, September 13, 2010.)*

On August 31, PAML and **Providence Health & Services** of Burbank, California, announced a lab outreach joint venture that will operate in the San Fernando Valley. Providence owns six hospitals in California.

Next, on September 7, PAML and **Centura Health** of Denver, Colorado, disclosed their plans to operate a laboratory outreach joint venture. Centura owns 12 hospitals in the region and reported revenue of $1.8 billion for 2010.

Each of these new joint ventures are an important sign that hospital laboratory outreach programs are a trend which continues to grow. This is true in both the growth in the number of hospitals which operate such programs, and growth in the market share of physicians' office lab test referrals that are served by hospital laboratory outreach programs.

For pathologists who advocate that lab testing be performed near physicians and patients, this is a favorable trend.

TOP TEN OF 2010 STORY no.8

FDA Takes First Steps to Regulate Laboratory-Developed Tests (LDTs)

SEVERAL BREAKING NEWS STORIES during 2010 forced the FDA to put regulation of LDTs at the top of its action list.

Any potential FDA action that brings LDTs under direct FDA purview will directly touch every clinical laboratory and anatomic pathology group in the United States. That's because a wide range of commonly-ordered laboratory tests are LDTs and are performed daily in literally every lab in the nation.

Although the FDA has rattled sabers for years about its right to regulate LDTs, it had not taken definitive action. Then, in the spring of this year, news headlines trumpeted how **Walgreens Company** was ready to sell genetic testing kits to consumers in 6,000 of its retail pharmacies, beginning on May 14, 2010. The FDA swiftly responded. It also sent letters to a number of Web-based genetic testing companies that targeted consumers. *(See TDR, June 21, 2010.)*

Next, the FDA announced that it wanted to broadly regulate LDTs. It convened a public meeting on July 19, 2010, to solicit public comments on its plans. An overflow crowd of laboratory professionals packed the meeting to express their opinions on the FDA's intent to regulate LDTs. More meetings and public comment will take place in coming months.

Should the FDA decide to exercise tight regulatory control over all laboratory-developed tests, this will be a major development for the entire clinical laboratory testing industry.

TOP TEN OF 2010 STORY no.9

Anatomic Pathology Groups Tap Private Equity Funds for Capital

EARLY IN 2010, several of the nation's larger private anatomic pathology groups accepted tens of millions of dollars from private equity investors.

The year opened in January with **PathGroup, Inc.**, of Nashville, Tennessee, announcing a leveraged recapitalization which raised more than $100 million. Also in January, **Pathology, Inc.**, of Torrance, California, raised capital, reported by some sources to be $24.65 million. *(See TDR, January 25, 2010.)*

In each case, pathologist-owners of the existing private pathology practice decided not to sell the entire business. Rather, the pathologists sold an ownership share to private equity investors, while retaining substantial equity for themselves.

These two private equity deals, along with several other similar transactions involving private pathology groups during 2010, signal a shift in the business thinking of some larger pathology groups. Until 2010, it was more common to see a buyer purchase the entire pathology practice, including the technical laboratory and professional service group.

Instead, these pathology practices are choosing to keep a significant equity share in their business, while tapping private equity investors for capital that can be used to fund expanded sales and marketing programs, along with other improvements to the business activities of the group. As other pathology groups need to cash out retiring partners, there is likely to be more of these types of deals.

TOP TEN OF 2010 STORY no.10

Federal Court Ruling Against Myriad May Change Gene Patent Protection

MANY PATHOLOGISTS AND LABORATORY SCIENTISTS believe that genes should not be patented. At least one federal judge agrees with that position and ruled against **Myriad Genetics** in a court case that is now moving to the federal appeals court.

It was March 29 when a federal judge's ruling in New York invalidated seven patents related to the BRCAI and BRCAII genes. Now the action moves to the federal appeals court level and some legal experts believe the Supreme Court may end up accepting this case. *(See Dark Daily, March 31, 2010.)*

If true, it will be years before Myriad Genetics and the laboratory testing industry learn whether the federal court system will uphold patents on genes or overturn existing laws that support the patents Myriad uses to protect its proprietary molecular assays.

The twist in this story is that, in November, the Department of Justice (DOJ) filed an amicus brief with the appeals court. It argued that mere "isolation" or "purification" has never been enough for a patent. This position is contrary to earlier DOJ defenses of gene patents.

The stakes in this court battle are huge. Laboratory tests involving tens, hundreds, and thousands of genes are working their way toward clinical use. If labs had to pay patent licensing fees on every gene, this would be both expensive and time-consuming. It would hold back progress in genetic testing. TDR

FTC Opposes LabCorp's Acquisition of Westcliff

➤At issue is how the acquisition might reduce competition and lead to higher prices in So. Calif.

➤➤CEO SUMMARY: On November 30, FTC commissioners filed an administrative complaint opposing Laboratory Corporation of America's acquisition of Westcliff Medical Laboratories, Inc., on the grounds that it "violates antitrust laws and would lead to higher prices and lower quality in the Southern California market..." This is the first serious FTC challenge of a clinical lab acquisition since Quest Diagnostics Incorporated announced it would purchase Unilab Corporation in 2002. LabCorp is responding to the FTC's action.

In the past 15 years, it has been a rare event for the **Federal Trade Commission** (FTC) to oppose the acquisition of one clinical laboratory company by another laboratory company.

But that is exactly what occurred on November 30. That's the day when the FTC issued an administrative complaint against the acquisition of **Westcliff Medical Laboratories, Inc.**, by **Laboratory Corporation of America**.

➤"Violates Antitrust Laws"

In public documents, the FTC described the administrative complaint as "charging that LabCorp's acquisition of Westcliff, which was completed June 16, 2010, violates antitrust laws and would lead to higher prices and lower quality in the Southern California market for the sale of clinical laboratory testing services to physician groups."

The FTC has established May 2, 2011 as the date for an administrative law judge to commence a trial on this matter. The FTC said it will also take steps to obtain an injunction in federal court "to prevent LabCorp from integrating the Westcliff assets while the case is being tried in the administrative court."

For its part, LabCorp has gone to the federal bankruptcy court in Santa Ana which oversees Westcliff's Chapter 11 bankruptcy action. LabCorp filed documents with the bankruptcy court to "seek declaratory and injunctive relief to prevent the Federal Trade Commission from collaterally attacking the Court's June 9, 2010, Sale Order."

Thus, it appears that the FTC and LabCorp may be heading for the proverbial Mexican standoff concerning this matter. At issue is whether LabCorp's acquisition and integration of Westcliff Medical Laboratories into its Southern California operations will lessen competition in the region and thus have anti-competitive consequences for that lab testing marketplace.

Westcliff Medical Laboratories is based in Santa Ana, California. It primarly serves physician clients in Southern California. LabCorp had acquired Westcliff after the financially-struggling

lab company filed Chapter 11 bankruptcy last May. *(See TDR, June 1, 2010.)* LabCorp's acquisition of Westcliff was completed on June 16, 2010.

At that time, the FTC moved swiftly and directed that LabCorp not integrate Westcliff into its company, but operate it as an independent business until the FTC made a final decision about the anti-competitive issues relating to this acquisition. Nine days later, on June 25, LabCorp agreed to hold the Westcliff assets separate and apart while the FTC investigated the transaction.

Details Of The FTC Complaint

In its November 30, 2010, complaint, the FTC wrote: "LabCorp and Westcliff are two of only three vendors of clinical laboratory testing services for the vast majority of physician groups in Southern California, with the other being **Quest Diagnostics Incorporated**. By eliminating one of only three significant alternatives for most physician groups, the acquisition will result in higher prices and inferior service for physician groups… ."

For this complaint, the FTC defined Southern California as the counties south of and including San Luis Obispo, Kern, and San Bernardino. The FTC stated that the Westcliff acquisition "would leave LabCorp and Quest in control of approximately 89% of the market."

Effect On Competition

The FTC explained that, if it was determined that LabCorp violated the Clayton Act or the FTC Act, then the federal agency could mandate a variety of remedies. It could: order divestiture; prohibit LabCorp from doing business with Westcliff; require prior notice of any anticipated mergers, consolidations, or combinations of the two businesses; require the filing of periodic compliance reports; or, order any other appropriate relief.

The FTC staff, in researching the facts about the California laboratory testing marketplace and the events leading up to Westcliff's Chapter 11 bankruptcy, recognized how Westcliff's competitive marketing efforts had changed under new owners and new executive teams following its acquisition by **BioLabs, Inc.**, in 2006.

Repeatedly in the complaint, the FTC characterized Westcliff, under its new owners and managers, as willing to aggressively pursue capitated contracts with managed care companies and IPAs (independent practice associations). Westcliff was described as a "price-cutting maverick competitor."

It seems that the FTC considered the rapid growth of Westcliff from 2007 on—when it vigorously used discounted pricing and other differentiators to pursue capitated lab testing contracts—as evidence that Westcliff was a robust competitor during that period.

Westcliff's Sales Success

In fact, in the complaint, the FTC indicates that Westcliff was winning more managed care contracts than LabCorp during this time period. The FTC noted that: "LabCorp admits that Westcliff has been able to secure over [redacted number] physician group contracts in Southern California in just over three years and that in the same time frame, LabCorp has won [redacted number]. Westcliff's impressive success rate demonstrates that it has a much greater chance of winning upcoming business than would be implied by its current market share."

The FTC also wrote that "The Acquisition eliminates a price-cutting maverick. As an upstart competitor seeking to expand its share of physician group business, Westcliff had the incentive to win business by aggressively pricing managed care contracts and did so...

"Westcliff also extended capitated contracts to physician groups that LabCorp and Quest would only service on significantly higher fee-for-service terms. In contrast, both LabCorp and Quest were

seeking to increase prices and reduce services to physician groups in Southern California over the same time period."

The FTC noted that, in Southern California, Quest Diagnostics is the leading vendor and LabCorp is second. It also wrote that, prior to its acquisition by LabCorp, Westcliff was the third-largest provider of lab services in the region and Southern California was its primary market area. The FTC says that the acquisition has an anti-competitive effect because it eliminates "an aggressive competitor" and "a price-cutting maverick."

Public Documents Inform

The various public documents surfacing on this matter will reflect the different legal arguments that the FTC and LabCorp will put forth in support of their positions. These documents help laboratory executives and pathologists understand the regulatory implications of the FTC's decision to oppose LabCorp's acquisition of Westcliff.

One has to go back to 2002 to find a similar action by the FTC involving mergers and acquisitions of clinical laboratory companies. On April 2, 2002, Quest Diagnostics announced an agreement to acquire **Unilab Corporation** of Van Nuys, California. At this time, Unilab had revenue of $390 million and Quest agreed to pay a purchase price of about $1.1 billion. *(See TDR, April 22, 2002.)*

FTC Challenged Acquisition

The FTC decided to challenge this acquisition. It took many months for the FTC and Quest Diagnostics to agree on a resolution. Almost one year later, on February 21, 2003, a settlement agreement was announced.

Quest Diagnostics was allowed to acquire Unilab. However, to meet the FTC's concerns about maintaining competition in Northern California, Quest was required to divest to LabCorp the following: 46 patient service centers (PSCs); five rapid response laboratories; all of Quest's Northern California contracts with physicians; one Unilab contract with Northern California physicians; plus "all related assets necessary for the provision of clinical lab testing services to such groups, including customer lists and information." *(See TDR, March 3, 2003.)*

THE DARK REPORT believes that this current FTC challenge to LabCorp's acquisition of Westcliff is the first time since 2003 that the FTC has decided to challenge a laboratory acquisition that it views as potentially violating laws relating to anti-competitive business practices. Moreover, the fact that the acquisition involves the California lab testing marketplace may be relevant.

In California, IPAs play a major role in contracting for laboratory testing services. IPAs often prefer capitated prices for lab testing. Many of the same executives who led Unilab prior to its sale to Quest Diagnostics were also working at Westcliff during the years prior to its Chapter 11 bankruptcy.

Déjà Vu On Capitated Prices

At Unilab, this executive team became known for its willingness to offer very low capitated prices as a way to access the IPA physicians' fee-for-service pull-through business. A similar pricing strategy was instituted at Westcliff between 2007 and 2010.

Thus, it may be that the FTC received complaints from IPAs who—having experienced the higher prices that followed Quest Diagnostics' acquisition of Unilab since 2003—were wary of similar price increases they expected might follow after LabCorp acquired Westcliff Medical Laboratories.

Regardless of how this case is resolved, the bigger issue is whether the FTC has finally recognized how years of acquisition activity by the nation's largest lab companies changed the competitive balance in different regions across the country, particularly in the market segment of office-based physician lab test referrals. TDR

FTC's Complaint in the Westcliff/LabCorp Matter Argues that Westcliff Had Other Business Options

IN ITS ADMINISTRATIVE COMPLAINT issued November 30, 2010, against Laboratory Corporation of America, the Federal Trade Commission (FTC) addressed the issue of Westcliff Medical Laboratories, Inc.'s financial condition at the time of the Chapter 11 bankruptcy filing.

To address the issue of "failing firm" (referring to Westcliff's Chapter 11 bankruptcy), the FTC laid out its arguments, as follows:

FAILING FIRM

38. LabCorp's acquisition of Westcliff is not immunized by the "failing firm" doctrine. That affirmative defense places the burden firmly on defendants to demonstrate that:

(1) the allegedly failing firm faced the imminent prospect of business failure at the time of the acquisition;

(2) that the firm could not have been successfully restructured under Chapter 11; and

(3) that the firm seeking to acquire the failing firm is the only available purchaser. LabCorp cannot meet these strict criteria.

39. At the time of the Acquisition, Westcliff was generating profits from its operations and had [redacted number] in annualized revenue. Its financial difficulties stemmed primarily from approximately [redacted number] in debt generated by a 2006 private equity deal.

Despite that debt, Westcliff was an attractive business. It was the third-largest independent clinical laboratory in Southern California, and its revenues had increased [redacted number] percent over the preceding two calendar years. As a result, Westcliff had significant enterprise value, and other firms were willing to acquire Westcliff throughout the time that the LabCorp deal was being negotiated.

In these circumstances, LabCorp was not, as it would have to be, "the only available purchaser," and Westcliff cannot be said to have made, as required, "unsuccessful good-faith efforts to elicit reasonable offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger." Merger Guidelines §11.

40. The fact that Westcliff was in Chapter 11 bankruptcy at the time the Acquisition closed does not affect the failing firm analysis. The bankruptcy was not an indicator that Westcliff was failing; rather, it was a specific condition imposed by LabCorp as part of the acquisition.

Further, the fact that an auction was conducted after LabCorp was installed as the "stalking horse bidder" and that no bids were received shows nothing more than that there were no bidders willing to pay the stalking horse price of $60 million or more for Westcliff. Even at that late date, there were a number of firms willing to purchase Westcliff for a consideration above liquidation value.

41. Under these circumstances, it is unreasonable to conclude that Westcliff would have been liquidated. Westcliff had "minimal" liquidation value, and virtually all of its value was as a going concern. The secured creditors realized that they would not receive any return on their investments if Westcliff had been liquidated, and therefore believed that even if LabCorp did not purchase the company, Westcliff would have been sold to an alternative purchaser, albeit at a lower price.

Time for Labs to Use Web To Recruit Med Techs

Most labs have yet to recognize that the Web is now a very productive MT recruiting source

CEO SUMMARY: On the Web, clinical laboratories have a chance to identify potential new hires weeks or months in advance and to interact with potential job candidates in ways that were not possible in the past. An experienced lab recruiter explains how labs can benefit from these new methods of reaching potential staff. In Salt Lake City, ARUP Laboratories has already taken the opportunity to use the Web and social media to create conversations with medical technologists and other potential employees.

ACROSS THE NATION, large numbers of clinical laboratories struggle to recruit and retain enough medical technologists (MTs) and clinical laboratory scientists (CLSs). Now comes news of a more effective way to find and attract top MT and CLS talent.

"Many laboratories fail to meet their staff recruiting goals for a simple reason," stated Peggy McKee, the CEO for **PHC Consulting**, a recruiting firm in Celina, Texas, that specializes in finding staff for labs. "Their staff recruiting program relies almost exclusively on placing help wanted ads in newspapers and trade publications.

"This type of MT recruiting campaign overlooks the power of the Web and social media sites to attract qualified candidates for the entire range of positions in a clinical laboratory," emphasized McKee. "Simply said, clinical labs in a hiring mode should do a better job of using the Internet to put the word out about their job openings and career opportunities.

"Many lab managers still do not recognize how powerful trends have dramatically reshaped staff recruiting," she continued. "Today there are more niche job boards, more on-line aggregators, and growing use of social networks such as *Facebook* and *LinkedIn*.

"Laboratories now have new options for communicating their job openings and career opportunities via the Web," said McKee. "Labs can use blogs and electronic newsletters to get the word out.

"Both blogs and e-newsletters are ways that laboratories can maintain conversations with the target candidate pool," she noted. "Then, when there is a job opening, your lab is already a known quantity."

Internet Changes Everything

McKee's insights illustrate one important way that the Internet is changing staff recruitment. She recommends that a clinical lab develop a presence on the Web and use that presence to engage ongoing conversations with laboratory professionals. This creates a ready pool of qualified candidates for recruitment efforts.

"This is a new recruiting strategy," said McKee. "It's not the cold start of earlier days, when placing a newspaper help-

wanted ad would start the process. It's just the opposite—a warm start, because your lab has kept a conversation going for months and years with lab professionals who represent the wider recruiting pool.

Reading Your Lab's Blogs

"What makes this a doubly-effective recruiting and retention strategy is that you always have a surprisingly large number of people reading your blogs, postings, and e-letters who know your laboratory organization," added McKee. "They already know lots about your culture, your lab's goals, and what makes it a good place to work."

ARUP Laboratories of Salt Lake City, Utah, is one of the first laboratories to develop an ongoing social media program. In recent years, it created one of the lab industry's first full time positions to manage its social media program.

"ARUP's Web presence is designed to reach a variety of audiences," stated Kristen Deem, who holds the unique position of Web Editor and Social Media Specialist at ARUP Laboratories. "We recognize that, just as the lab itself needs to reach a variety of audiences, so too do the lab's websites.

"We serve many different audiences," continued Deem. "For example, we have a blood bank that provides blood for local hospitals. This activity is supported by our blood services website.

ARUP's Multiple Websites

"Of course, we have our main corporate website," she noted. "Another website is called ARUP Consult. It provides information on test selection and interpretation. ARUP Consult is designed to assist doctors as they order tests.

"In addition, we have the child diagnostic site, *www.childx.org*, which is a nonprofit group that's committed to research and development for pediatric laboratory medicine," Deem added. "We also have a scientific resource site that's affiliated with the **University of Utah's** academic research.

"Another important way we reach our audiences for recruitment is through an electronic newsletter that we started about 18 months ago," she said. "The electronic newsletter includes information about what's happening in the company, awards that ARUP has won, new lab testing departments that have been added, and information on scientific developments and new lab test technologies.

"One goal of this newsletter is to reach former employees who have left ARUP, but who may be eligible to return to jobs we have open," she said. "As we all know, it takes a lot less to retrain somebody who's already worked in your laboratory, versus someone who's brand new to your laboratory organization. We find that our electronic newsletter is a great way to keep in touch with these people.

Recruiting Former Employees

"One way we built the subscriber list is by having our recruiters contact a number of former employees," stated Deem. "We started with 54 former employees and through the sign-up box on our Careers page, this list has now grown to over 1,000 subscribers who have opted-in to receive our newsletter. From that, we've had four recruits who are former employees who wanted to come back to new positions.

"Our Careers page is designed to help anyone interested in working at ARUP Laboratories to find out more about our company," noted Deem. "For instance, we explain how to get hired here, our dress code, what life in Utah is like, and information on internships. We try to give them as much information as possible. We link to this Career page from our other websites and from other sources on the Internet."

THE DARK REPORT would like to hear from any clinical lab pathology group currently using social media and engaging the med tech community via its website. TDR

Contact Peggy McKee at 888-263-5688 x100 or peggy@phcconsulting.com; Kristen Deem at 801-583-2787 or deemk@aruplab.com.

10 Strategies to Boost Med Tech Recruiting

Besides developing a presence on the Web, labs can utilize 10 more recruiting strategies

CEO SUMMARY: Headhunters regularly see the best and worst of clinical laboratories in the areas of medical technologist recruiting and retention. Based on her experience, veteran recruiter Peggy McKee offers 10 proven strategies that every laboratory can use to improve both its recruitment of med techs, as well as retention of staff. These strategies reinforce each other and complement the expanded Web presence that McKee recommends be maintained by every lab.

TEN MORE EFFECTIVE STRATEGIES to improve medical technologist (MT) recruitment and retention were offered by Peggy McKee, CEO for **PHC Consulting** in Celina, Texas. These complement her advice for clinical laboratories and pathology groups to get on the Web and use social networking as a recruitment tool. *(See Pages 14-15.)*

STRATEGY NUMBER 1 ➤

Use Internships

"What makes the use of internships such a great strategy is the fact that you can try before you buy," noted McKee. "Internships also are called job shadowing.

"An intern can be a high school or college student," she said. "Don't overlook professionals with biology and chemistry degrees. Their participation as an intern is one way they can earn certification as a medical technologist. These people are hungry for the opportunity to experience the workplace and to work in your laboratory. And, it may not cost anything if it is an unpaid internship.

"Your lab's internship program can be for six to eight weeks or three months," continued McKee. "But also offer internships that may last for one to five days. This is a way for interns to rotate through different sections of the laboratory and see what happens within each of these sections during a real work day.

"Internships do not require a lot of structure," she added. "You can learn if each of the interns shows up on time, whether they can communicate intelligently, and if they ask questions that demonstrate that they would fit well in your laboratory. At the same time, the interns get to see what your staff is like. They can learn about the personality of the laboratory, as well as the positives and negatives of working there.

STRATEGY NUMBER 2 ➤

Recruit Overseas

"Next, consider hiring outside the United States," McKee said. "Every month, I get email requests from client companies who want to know if I will represent medical technologists from India or the Philippines in the United States. Some U.S. laboratories have a high number of these folks filling positions.

"Hiring outside of this country can be challenging," she added. "Not only are

there cultural issues to consider, but the paperwork and regulations can be complex. However, often these candidates are highly motivated and hard working. If you can find a laboratory doing this, have a conversation to see how it's working. Learn from that lab's successes and mistakes before attempting this on your own.

STRATEGY NUMBER 3

Better Job Descriptions

"Write better job descriptions!" advised McKee. "I am amazed at how dull some job descriptions are. It makes me wonder if the person who wrote such a unappealing job description would apply for that position. You'll reap great rewards by putting more time and thought into writing effective and thorough job descriptions.

"Some employers will pay more to sponsor jobs on job search sites. When they do, I recommend that they spend the time necessary to develop a job description that is specific, that 'sells' the opportunity, and that provides details about the compensation," she said. "You don't have to show the exact pay; a pay range is fine. If you match workers' 401(k) contributions, include that information too.

"In fact, it's best to overcommunicate with candidates so that they fully understand what you want from a candidate that applies for each job opening," McKee explained. "Qualified candidates are much more likely to apply for a job that is fully explained than one that isn't.

STRATEGY NUMBER 4

Advertise Continuously

"Your on-line presence is a tremendous opportunity and most laboratories fail to take advantage of it," observed McKee. "I recommend that every laboratory maintain a continuous job posting for medical technologists. Some human resources professionals may be uncomfortable with this idea, but candidates know that you will post jobs that may not always be available. If so, you can add, 'No current position, but anticipating growth in the future.'

"Once candidates apply on-line, then you have their name and contact information in your database," she noted. "These candidates should then begin to receive your electronic newsletter, which is my next suggested strategy.

STRATEGY NUMBER 5

Use E-Newsletters

"Your laboratory should produce an electronic newsletter at least once a month," McKee advised. "When I started work as a recruiter, I did an electronic newsletter once every six months, and then I moved to quarterly. Every time I send out the newsletter, great things happen. As a recruiter, I'm always looking for candidates, job orders, speaking engagements, and other opportunities. Recruiting is like fishing, and all these steps are like setting hooks. Every time I send out the newsletter, I get 10 or 15 responses back and someone says, 'Call me if you get this kind of a job.'

STRATEGY NUMBER 6

Recruit At Universities

"Your lab should regularly recruit at the university level," she continued. "Some labs can identify 10 colleges and universities in their service areas but not every lab can do so. Select the college training programs with which you want to work and develop an internship program with each one, if possible. With high visibility on these campuses, your laboratory will get more qualified candidates anytime you publicize a job opening.

STRATEGY NUMBER 7

Assess Your Talent

"Number seven is assess your talent with personality profiling tools," McKee said. "Labs that do this report a better rate of staff retention. Your lab's staff turnover drains resources and depletes your talent pool because you lose people who are trained on your equipment and who know your laboratory and your pathologists.

"That's why I recommend using personality assessments such as the DISC profile (which stands for dominance,

influential, steadiness, and conscientiousness)," she explained. "In my own business, I use DISC profiles for assessing personalities because there are certain personalities that don't work in my personal lab, if you will.

"For any laboratory that is experiencing unacceptable rates of staff turnover, I recommend that it conduct a baseline assessment of those folks: 1) who have recently exited; 2) who are coming into the organization; and, 3) who are among the top-performing individuals within your laboratory organization.

"Among medical technologists, typically, the most consistent performers will have high SC attributes (meaning steady and conscientious) and lower DI characteristics (meaning dominance and influence)," she said. "This translates into long term job satisfaction. Were your lab to hire someone with a high DI, he or she may be exceptional on the job, but the role of medical technologist is not likely to satisfy their personality. Unless you promote them into management within 18 months, they often leave.

"DISC and similar profiling tools are useful in retaining med techs," added McKee. "It's much less expensive to keep existing lab staff than to continuously hire new medical technologists.

STRATEGY NUMBER 8 ➤

Use a Mentor Program

"Another effective way to increase retention—and recruit top candidates—is to revive or initiate a mentor program," recommended McKee. "When staff members are mentored, they recognize that your lab is educating them and that they are being prepared for other opportunities. Mentoring challenges participating staff in positive ways. It also helps you identify staff who could become supervisors or lead techs.

STRATEGY NUMBER 9 ➤

Engage Their Intellect

"Making it possible to rotate around the laboratory is a useful strategy," McKee said. "Medical technologists often feel as if their job is like working in a factory, performing production-type work by moving tubes from here to there. Use work rotation to help them engage their scientific knowledge and experience to the benefit of the lab and patient care. This is a positive factor in staff retention and helps in recruiting solid performers.

"Be proactive about making special activities available to staff," noted McKee. "Engage your Web-savvy staff to assist with the lab's *Facebook* and *MySpace* accounts. Have them write articles and identify authors for blog articles. Your lab's most ambitious med techs will see these as ways to develop additional skills.

"Remember, they took this job because they have a deep interest in science," she added. "Therefore, get them involved in evaluating equipment or some other task that taps their scientific background.

STRATEGY NUMBER 10 ➤

Show Some Love

"Don't forget to show your staff some love," urged McKee. "What would a $5 gift card to a coffee shop or a book store do for your staff? What would be the effect of giving an hour off early? Or, lunch with a supervisor or with a pathologist? What could those things do to provide staff with a feeling of participation, involvement, and value? Keep in mind that this kind of staff enthusiasm must be communicated to new job candidates."

➤Opportunity To Improve

Collectively, McKee's 10 medical technologist recruiting strategies make an important point: effective staff recruiting and retention requires a comprehensive and sustained effort. Few laboratory organizations devote effort to all 10 strategies. However, that creates an opportunity for any lab to improve its med tech recruitment and retention by doing better at even just a couple more of these strategies. TDR

Contact Peggy McKee at 888-263-5688 x100 or peggy@phcconsulting.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

With its announcement last month of an agreement to acquire **US Oncology** for $2.16 billion, **McKesson Corporation** has greatly expanded its presence in oncology. US Oncology provides practice management services in support of 1,392 oncologists who work at 517 locations in 39 states. US Oncology is also a partner in the **med fusion** joint venture laboratory that opened in Dallas, Texas, this spring. US Oncology estimates that it serves 17% of all cancer patients in the United States. Wall Street analysts say that, when the US Oncology business is combined with McKesson's existing oncology business, McKesson will serve approximately 3,000 physicians and have a 25% market share of specialty pharmaceutical sales volume. It was 2007 when McKesson paid $575 million topurchase **Oncology Therapeutics Network**.

MORE ON: *McKesson*

Pathologists and lab administrators will recognize another name associated with US Oncology. It was owned by **Welsh, Carson, Anderson & Stowe**. This is the same private equity company that was a major shareholder at **LabOne, Inc.**, and was owner of **AmeriPath, Inc.**, which it sold to **Quest Diagnostics Incorporated** for almost $2 billion in 2007.

STERLING LABS RECOGNIZED AS "FAVORITE FIRM"

Tacoma, Washington-based **Sterling Reference Laboratories, Inc.**, recently earned a distinctive honor. In a public survey, it was voted by citizens as a "Favorite Pierce County Company." In a news story about its selection, Sterling's owners were recognized for their exceptional efforts to turn around the struggling lab company after they purchased it seven years ago. It was noted that, during a time when there was not enough money to pay bonuses, the owners washed employee's cars to make clear their appreciation. Now the company is hiring during the down economy and employs a staff of 85.

TRANSITIONS

• **Neogenomics, Inc.**, of Fort Myers, Florida, has appointed Kevin C. Johnson to its Board of Directors. Johnson served as Chairman, CEO, and President of **Dianon Systems, Inc.**, prior to and through its sale to **Laboratory Corporation of America** in early 2003. Johnson also held executive positions at **MetPath, Inc.**, **Corning Clinical Laboratories**, and **Quest Diagnostics Incorporated**.

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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the **U.S. Government Accountability Office's** (GAO) recently-released report on group purchasing organizations (GPOs) and whether they actually save money for member hospitals.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 27, 2010.

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