Volume XII, Number 3 Monday, February 14, 2005

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

“Frankenstein the Tumor” is No More

HOW MANY OF YOU HEARD ABOUT THE TUMOR NAMED “FRANKENSTEIN”? This is a story which made national news in mid-January and again in early February.

The story line is simple. A nine-year old boy in Richmond, Virginia was diagnosed in May 2003 with embryonal rhabdomyosarcoma. A grapefruit-sized tumor was impinging on his optic nerves and carotid arteries, causing blindness and headaches. The boy named his tumor “Frankenstein,” or Frank for short. Chemotherapy and radiation treatments shrank it to the size of a peach pit, restoring his vision, but there were serious side-effects. For a while he couldn’t walk or eat and had to be fed through a tube, according to his mother.

Following chemotherapy, the problem was that the boy’s parents did not have the money required to pay for the biopsy necessary to determine if the remaining tissue in the tumor was malignant. To raise money to pay for the biopsy procedure, his parents had been auctioning, on **E-Bay**, a bumper sticker reading “Frank Must Die.” That’s how the story came to the attention of the national media.

Learning of the boy’s plight, Hrayr Shahinian, M.D. of the Skull Base Institute at **Cedars-Sinai Medical Center** in Los Angeles, California offered to perform the procedure at no charge. Using a minimally-invasive technique, the biopsy was conducted on February 2. The surgery was declared a success and the tissue was sent off for analysis.

As of press time, the family had not received the pathology report. They have scheduled a press conference for tomorrow, February 15, to announce the results. The press conference will be conducted at the Willard International Hotel in Washington, D.C. and Dr. Shahinian will be present to discuss the findings.

Certainly there are many heartwarming aspects to this story, particularly if David, the young boy, gets a pathology report which indicates he is cancer-free at this time. On the other hand, this story exposes gaps in how the American healthcare system responds to the needs of individuals who lack adequate financial resources. This tale also draws attention to the time required after the biopsy procedure before test results and the pathology diagnosis can be provided to the patient, his physician, and his parents. TDR

Five Lab Acquisitions Over the Past Ten Weeks

Smaller lab companies continue to be gobbled up by purchasers

CEO SUMMARY: Many lab executives and pathologists will be surprised to learn that five independent laboratory companies were acquired between December 1, 2004 and February 11, 2005. Only one acquisition was announced to the public. The other four were private sales and both buyers and sellers preferred to avoid any publicity associated with these acquisitions.

OVER THE PAST TEN WEEKS, at least five clinical laboratory acquisitions occurred. This flurry of acquisition activity attracted little attention, since four of the laboratory companies being acquired were relatively small and there was no public announcement of the sale by either buyer or seller.

The three smallest deals involved **Clinical Laboratories of Black Hills** (Rapid City, South Dakota), **Omega Medical Laboratories** (Allentown, Pennsylvania), and **Cytology Services of Maryland** (Laurel, Maryland). Each lab has estimated annual revenues of about $12 million or less.

Laboratory Corporation of America bought Black Hills Clinical Labs. **Quest Diagnostics Incorporated** purchased Omega Medical Labs, and **Adventist Health Corp.** was the buyer of Cytology Services of Maryland.

The biggest transaction was the $175 million sale of Irvine, California-based **US LABS** to LabCorp. Publicly announced in December, the sale was completed on February 3, 2005. US Labs has an estimated $75 million in annual revenue.

Probably the most interesting lab acquisition during this period was the sale of **Universal Diagnostic Laboratories** (UDL) in Brooklyn, New York to **National Laboratory Partners, LLC**. Estimates are that UDL has annual revenues of about $22 million. Most of its lab testing business originates from Brooklyn and and the surrounding boroughs of New York City.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.65 per week elsewhere (billed semi-annually).

National Laboratory Partners (NLP) is a new arrival in the laboratory industry. NLP's President and CEO is E. Craig Dawson and its General Manager and Chief Scientific Officer is Len Poikey, Ph.D. Both individuals have extensive lab management careers. They both worked together at **American Medical Laboratories** in Chantilly, Virginia. Dawson held executive positions at LabCorp and **National Health Laboratories**.

New Owners At Universal

NLP took title to Universal Diagnostic Labs on December 23, 2004. Universal's former owner, Marvin Numeroff, will consult with UDL during the transition to new ownership. During the past year, National Laboratory Partners has quietly negotiated for several laboratory acquisitions, particularly in the New York metropolitan area. It would like to acquire laboratories which meet its strategic business criteria.

Around New York City, laboratory competitors are still reacting to the news that an unknown group—National Laboratory Partners, LLC—now owns and operates Universal Diagnostic Laboratories. No operational or sales changes at UDL have been observed in the marketplace to date.

Significant Development

The sales of Universal, Black Hills, and Omega Medical are significant for several reasons. First, it demonstrates that consolidation in the independent commercial laboratory sector continues. Any laboratory with a critical mass of annual revenue continues to receive acquisition offers, whether solicited or not.

Second, in the case of LabCorp, over the past 24 months, it has quietly acquired a number of small lab companies. Under SEC guidelines, its purchase of small laboratories like Black Hills Clinical Laboratories is considered an immaterial event, so these are not announced to the public. However, string together enough $1 million to $10 million lab acquisitions and there are enough specimens and revenues to add a couple of points to LabCorp's year-over financial statements.

In contrast, Quest Diagnostics Incorporated does not seem to have the same appetite to acquire these types of small laboratory companies. Its purchase of Omega Medical Labs in Allentown, Pennsylvania is a rather exceptional occurrence.

Third, for owners of small laboratory businesses, these acquisitions demonstrate that buyers can still be found. Because the purchase prices of these recent sales were not disclosed, it is impossible to know whether the buyers were willing to pay a strong price, relative to EBITDA (earnings before interest, taxes, depreciation, and amortization).

Where Are Pathologists?

Fourth, the appearance of a new investor/operator group—National Laboratory Partners, LLC—is a sign that experienced lab executives continue to believe that owning a commercial laboratory company is a good business opportunity. That raises the question as to why there are no pathologists actively looking to acquire or to build commercial laboratory companies.

Pathologists who owned such laboratories and sold them to the national laboratory companies over the last two decades often "threaten" to re-enter the business and establish a new commercial laboratory in their city. This makes sense. They know the market and they have existing relationships with referring physicians in the area. However, no pathologists have yet taken tangible steps to seize this opportunity by establishing such a new lab company in their town. TDR

Review of 2004 Lab Sales Identifies Buyer Interest

There are new buyers for laboratories, but only if the selling lab meets certain criteria

CEO SUMMARY: Laboratory acquisition activity was surprisingly high during 2004. One reason is that new buyers appeared in the marketplace. However, all buyers have specific acquisition criteria. When a selling lab meets that criteria, it can expect multiple bidders and a strong purchase price. Here's a review of 2004's lab acquisition activity, with commentary about which types of labs are in high demand.

THREE NEW LABORATORY BUYERS appeared during 2004. At least two of these buyers are actively hunting additional acquisitions.

"Many pathologists and laboratory executives will be surprised to learn how much merger/acquisition activity took place during 2004," stated Chris Jahnle, Managing Director at **Haverford Healthcare Advisors**, located in Paoli, Pennsylvania. "We know of 13 laboratory acquisitions and it is likely that several more sales of smaller laboratories happened, but were never announced to the public."

"The biggest acquisition was **Genzyme Corporation's** purchase of **IMPATH, Inc.** last March," added Jahnle. "It paid $215 million for IMPATH. It also purchased **Alfigen, Inc.**, a specialty testing lab company in Pasadena, California for $47.6 million.

"The second biggest lab deal of 2004 was the sale of **US LABS, Inc.** to **Laboratory Corporation of America** for $175," he said. "Announced in December, this acquisition closed just 11 days ago."

If laboratories are selling, who is buying? This is a relevant question because it identifies new competitors in existing markets. The answer also helps determine how the laboratory testing marketplace is evolving.

Who is Buying Labs?

"A look at the buyer's side of our transaction summary *(see page 6)* shows how certain buyers were the most active during 2004," observed Jahnle. "**American Esoteric Laboratories, Inc.** and LabCorp each did three acquisitions during the year—four for LabCorp if you count the US LABS purchase that was announced in December 2004 and closed in February 2005.

"American Esoteric Laboratories (AEL) is a new lab company. It states that it wants to acquire specialty niche laboratories that support its menu of reference and esoteric testing," Jahnle said. "However, its purchase of **Memphis Pathology Laboratories** in September put it squarely in the physicians' office testing market, at least in the Memphis, Tennessee Metro area.

"The most active buyer of independent commercial laboratories seems to be LabCorp," he explained. "It has consistently been a bidder whenever larger laboratories came up for sale. But in contrast to Quest Diagnostics Incorporated, LabCorp seems to have a continuing interest in buying smaller independent laboratory companies.

Interest in Smaller Labs

"Two examples are LabCorp's purchases of **Redding Pathologists Laboratory** (Redding, California) and **Clinical Laboratories of Black Hills** (Rapid City, South Dakota) during 2004," continued Jahnle. "It is estimated that each of these lab companies had annual revenues in the range of $5 million to $15 million."

Lab*One*, Inc. purchased the laboratory assets of the **Health Alliance** in Cincinnati, Ohio early in 2004. It paid approximately $42.4 million for about $50 million per year in laboratory revenues. "During the past 24 months, Lab*One* has actively sought to acquire private lab companies," noted Jahnle. "Expect them to continue bidding, particularly if the transaction includes a laboratory providing both hospital inpatient and outreach testing services.

National Lab Partners, LLC

"One laboratory acquirer which surfaced at the end of the year is **National Laboratory Partners, LLC**," he said. "It purchased **Universal Diagnostic Laboratories** of Brooklyn, New York in December. This is a new company, made up of experienced laboratory executives who, over the years, have worked at some of the nation's largest public lab companies.

"National Laboratory Partners will continue to seek to grow by acquisition, whenever possible. Depending on its access to venture capital, it may be a bidder whenever larger laboratory companies are listed for sale," observed Jahnle.

"There is one buyer who didn't do a laboratory acquisition during 2004. That is **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas," he stated. "During 2003, CPL had acquired a laboratory in Virginia and another in Toledo, Ohio. I believe CPL remains an interested buyer for laboratory companies they see as a good strategic fit for their business plan."

Overall, Jahnle considers that the lab acquisition activity of 2004 demonstrates that laboratory consolidation will continue. "Existing buyers, such as LabCorp and Lab*One*, remain active bidders," he explained. "In addition, each year new buyers appear. In 2004, that was American Esoteric Labs and National Lab Partners.

Multiple Offers To Sellers

"This field of buyers means that laboratory sellers have a high degree of probability that more than one buyer will offer to purchase their lab company," continued Jahnle. "It is an outcome that was not expected just a couple of years ago, when, between themselves, the two national lab firms bought **American Medical Laboratories**, **Dynacare**, **Unilab**, and **DIANON Systems**. Each of these lab companies was an eager buyer of laboratories in their own right."

THE DARK REPORT can identify three distinct segments to the laboratory services market that attract the interest of potential buyers. They are: independent lab companies which offer routine testing services to office-based physicians, specialty testing/niche laboratories, and pathology group practices, particularly those with technical laboratories serving the outreach market. Jahnle concurs, and offered these insights about each.

"Commercial lab companies offering routine testing are truly a vanish-

Clinical Lab Acquisitions Continue At End of 2004 and Into Early 2005

AT LEAST FIVE CLINICAL LABORATORIES WERE acquired during December 2004 and the first six weeks of 2005. That is an unusual level of acquisition activity, since so few independent clinical laboratories remain in private hands in the United States.

This acquisition activity demonstrates that consolidation continues to reduce the number of independent commercial laboratories offering routine lab testing services to physicians' offices. Moreover, the size of the laboratories being acquired continues to shrink. Three of the five labs acquired in late 2004 and early 2005 had estimated annual revenues of $12 million or less. A fourth wasn't much larger than $22 million in annual revenues.

Tracking these acquisitions has become more difficult for another reason. Because the clinical lab companies being bought are so small, if their buyer is a public lab company, that company is generally not making a public statement announcing the acquisition.

Keep that fact in mind as you review the table below. Prepared by Haverford Healthcare Advisors of Paoli, Pennsylvania, it is believed to be reasonably complete. But the list of clinical laboratory acquisitions may not include all the clinical laboratory sales actually completed since January 2004.

Clinical Laboratory Transactions Summary

(Prepared by Haverford Healthcare Advisors)

Transactions for 2004:

Date	Buyer	Seller	Purchase Price*	Revenue of Target*	Purchase Price to Revenue
Jan-04	Lab*One*	Alliance Lab Services, Cincinnati	$42.4	$50.0	0.85
Jan-04	American Esoteric Labs	Thrombocare Laboratories	ND	ND	NA
Feb-04	Genzyme Corporation	Alfigen	$47.6	20.0	2.38
Mar-04	Lab*One*	Northwest Toxicology	$10.0	$11.0	0.91
Mar-04	Genzyme Corporation	IMPATH Physician Services Unit	$215.0	$153.0	1.41
Mar-04	LabCorp	MDS NY and Atlanta Lab Operations	ND	ND	NA
Mar-04	LabCorp	Redding Pathologists Lab	ND	ND	NA
Mar-04	Bio-Reference Labs	Metropolitan Diagnostic Med Lab	$0.5	ND	NA
Jul-04	Bio-Reference Labs	Cancer Genetics, Inc.'s Cytogenetics Lab	$2.5	ND	NA
Aug-04	American Esoteric Labs	Centron's Molecular Testing Business	ND	ND	NA
Sep-04	American Esoteric Labs	Memphis Pathology Laboratory	ND	ND	NA
Dec-04	LabCorp	Clinical Laboratories of Black Hills	ND	ND	NA
Dec 04	National Lab Partners, LLC	Universal Diagnostic Laboratories	ND	ND	NA

Transactions for 2005:

Date	Buyer	Seller	Purchase Price*	Revenue of Target*	Purchase Price to Revenue
Jan-05	Adventist Health Corp	Cytology Services of Maryland	ND	ND	NA
Feb 05	Quest Diagnostics	Omega Medical Labs	ND	ND	NA
Feb 05	LabCorp	US LABS	$175.0	$75.0	2.33

* In millions • ND is "not disclosed • NA is "not available"

ing breed," he said. "That supports a strong sales price in situations where a routine clinical lab company has significant market share in second-tier cities and rural markets.

"Because these types of labs are generally pathologist-owned and operated, they have a tight lock on their client base and market share," explained Jahnle. "That makes it tough for national labs to win new clients in such regions. As a result, such laboratories are in high demand by buyers.

"This is not true of most independent labs still operating in urban areas. Often their client base is heavily weighted to nursing homes, forensic toxicology, and other types of low-margin clients. Lacking access to managed care contracts, these types of commercial laboratories are much less desirable to buyers," he observed.

High Demand By Buyers

"In the specialty testing/niche laboratory segment, demand can be quite high for select sellers," noted Jahnle. "When there is a match between the buyer's strategic needs and the specific test menu of the seller, a transaction will result.

"If you look at the sales transaction summary, there are several examples of this," he continued. "Genyzme's purchase of Alfigen (cytogentics), AEL's purchase of **Thrombocare Laboratories** (coagulation), and **Bio-Reference Laboratory, Inc.'s** purchase of **Cancer Genetics'** cytogentics laboratory aptly validate this market trend.

"That brings us to anatomic pathology," declared Jahnle. "For anatomic pathology group practices, one expected buyer would be **AmeriPath, Inc.**, but only if the pathology group practice meets its acquisition criteria. We have not seen any other public laboratory companies actively seeking to acquire hospital-based pathology groups.

"However, it is a different situation for pathology sub-specialty laboratories, particularly in urology, gastroenterology and dermatology," he added. "Often these types of pathology laboratories exclusively serve an outreach market. There are multiple buyers whenever such pathology labs come up for sale.

Pathology Technical Labs

"In situations where a pathology group is based in a hospital, but owns a technical laboratory that serves the outreach market, I've seen strong buyer interest," observed Jahnle. "I believe this reflects a marketplace reality.

"The reason there is strong buyer demand for pathology laboratories serving primarily an outreach market is that buyers understand that hospital inpatient volumes continue to decline relative to outpatient and office-based services. They want pathology outreach labs which serve this fast-growing outreach market."

Jahnle's observations and opinions complement a long-standing prediction by THE DARK REPORT. Laboratory consolidation will continue. As it does, it will concentrate market share—and market power—in the hands of a select group of large laboratory companies.

If this pattern plays out, it means that new buyers entering the lab services market will build their laboratory companies to a certain size, then sell to the larger lab companies—who have good business reasons to offer a generous price.

It will take several more years to validate this prediction. Will lab companies, as they reach a revenue base of $100 million, choose to remain independent? Or, will they choose to sell to a larger laboratory company? **TDR**

Contact Chris Jahnle at 610-407-4024.

Barristers Offer Insights Into OIG Opinion 04-17

There's more compliance guidance to come on the subject of physician self-referrals

CEO SUMMARY: This is an intelligence briefing which tries to "read between the lines" and: 1) provide useful information about the OIG's "undeclared" views on physician self-referral issues, particularly as they relate to anatomic pathology condominiums; and, 2) how specialist physician groups and pathologists are reacting to such issues in the real world of the healthcare marketplace.

By Pamela Scherer McLeod

IT IS WIDELY-BELIEVED that the **Office of Inspector General's** (OIG) Advisory Opinion 04-17, made public on December 17, 2004, is government's initial response to the growing trend of specialist physician groups trying to capture ancillary service revenues that result from their own patient referrals. The question, however, is whether 04-17 is the last word we should expect to hear from the government on this issue.

Ancillary Revenue

A variety of business arrangements designed to allow physicians to capture ancillary revenue from their own referrals have recently appeared in the marketplace. That is how anatomic pathology (AP) laboratory condominiums came into existence. *(See TDRs, July 19 and August 9, 2004.)* And it is AP lab condominiums that are the subject of OIG Advisory Opinion 04-17.

To supplement coverage on this topic, THE DARK REPORT conducted its first-ever audio conference on January 26, 2005. The objective was to make two attorneys, each with unique insights on 04-17, available for discussion and specific questions by clients and regular readers. Several valuable nuggets of intelligence resulted during the 90-minute session.

Thomas Bartrum was the first attorney to speak. He is with *Waller Lansden Dortch & Davis*, located in Nashville, Tennessee. Bartrum has a national health care practice representing health care facilities and ancillary service providers. More significantly, he was part of the legal team that made the original request to the OIG for an advisory opinion on the basic concept of AP laboratory condominiums.

Over the course of 12 months, Bartrum served as the requestor's primary contact with the OIG. He thus participated in several conversations with the OIG as the OIG developed its position on the topic.

"During our conversations with the OIG, several interesting things occurred which bear directly on two points.

One, why the OIG chose to issue Advisory Opinion 04-17 and, two, how it crafted its response in that document," stated Bartrum. "When our client first requested an advisory opinion on its proposed business model for an AP lab condominium arrangement with referring physicians, the OIG told us right from the start that it would not issue a favorable advisory opinion on this business model."

"Armed with that knowledge, our client decided to proceed," he explained. "Because compliance law in areas like the Anti-Kickback Statute and the Stark Law is continually evolving, we wanted to find out precisely what the OIG's position was with respect to the AP laboratory condomium model, regardless of whether, in the final analysis, the OIG was unable to grant a favorable advisory opinion.

OIG Showed Keen Interest

"During these conversations, the OIG showed keen interest in the topic and indicated they had several concerns with the proposed AP lab condo model," said Bartrum, "while acknowledging that the model presented by our client was one of the more conservative models of which they were aware.

"Early in these conversations, the OIG expressed its concerns as to whether the Stark Law's in-office ancillary services exception was intended to protect such business arrangements as the AP laboratory condominium," he recalled. "Pathologists and specialty physician groups should take this as an indication that the OIG will not stand for attempts to do indirectly what the law will not allow them to do directly. "

In Advisory Opinion 04-17, the OIG specifically footnoted its concerns about the potential for an AP laboratory condo to violate the Stark Laws. "This is consistent with the discussions we had with the OIG during their investigation into this request for an opinion," observed Bartrum. "The OIG had raised the issue that, although this business model might look acceptable on paper, in actual operation there were obvious ways in which the arrangement could violate the Stark Law. It was also noted that such AP lab condo arrangements might lead to abuses such as inappropriate utilization and improper claim submissions."

> ***"During these conversations, the OIG showed keen interest in the topic and indicated they had several concerns with the proposed AP condo lab model..."***

As to the Anti-Kickback Statute, Bartrum stated "The OIG expressed a real concern over physicians capturing a portion of the revenue generated from their own referrals. In this regard, the OIG clearly takes the position that the Anti-Kickback Statute is potentially violated if a healthcare provider outsources the development and management of an ancillary service line to an established provider of that ancillary service line. The OIG dismissed our argument that such arrangements should be okay since clearly the physician could develop its own AP laboratory."

High Interest In Topic

"It was clear to our legal team that, within the OIG, the topic of AP laboratory condominiums was of interest at the highest levels," added Bartrum. "Such interest was evident by the relatively quick turn around of the opinion and that, during our conversations with the OIG, senior OIG staff participated and actively discussed points of interest to them.

"I take their keen interest and hands-on involvement to mean that we have not heard the last word from the OIG on physician attempts to capture a portion of the revenues generated from ancillary services deriving from their own patient referrals," he noted.

Contractual Joint Ventures

Bartrum also had a useful insight about why Advisory Opinion 04-17 was strongly based upon the OIG's Special Advisory Bulletin on "Contractual Joint Ventures," dated April 30, 2003. "Although the discussions our legal team had with the OIG covered a variety of compliance concerns under the Stark Law and the Anti-Kickback Statute, the OIG seems to have found it simpler to base their opinion on the points made in its Special Fraud Alert on Contractual Joint Ventures," he observed. "Not only was such an analysis the simplest way to deny a favorable advisory opinion on the model presented by our client, but appears to be an effort by the OIG to further elucidate its earlier published guidance. on contractual joint ventures."

More Guidance To Come

"However, because of the many different compliance issues the OIG identified during its investigation of our request, I think it would be a mistake to assume that the OIG would be fine with an arrangement that did not raise the contractual joint venture concerns," observed Bartrum. "Further, I believe we will see more from the government on both the topic of anatomic pathology laboratory condominiums specifically and physician attempts to capture ancillary revenue in general."

If Bartrum represents the opportunity for us to "eavesdrop" and learn something about how the OIG evolved its thinking as expressed in Advisory Opinion 04-17, then Richard Cooper gives us a window into the healthcare marketplace.

Cooper is a partner at **McDonald Hopkins**, headquartered in Cleveland, Ohio. McDonald Hopkins has a large national healthcare practice. It represents specialist medical groups and also has an extensive client list of pathology group practices and laboratory companies.

"Our legal advice to specialist groups and pathologists is consistent and identical" stated Cooper. "Any type of business arrangement which involves a physician gaining financial benefit as a result of his/her patient referrals will raise significant compliance issues.

"This makes it important to conduct extensive and intense due diligence," he added. "Unfortunately, there are physician groups which, in their desire to access the economic benefits of such arrangement, fail to conduct effective due diligence.

"Don't rely on a legal opinion from the promoter, or, even worse, just take their word for it that one exists," cautioned Cooper."

"Don't rely on a legal opinion from the promoter, or, even worse, just take their word for it that one exists," cautioned Cooper. "Insist on obtaining a copy of the promoter's legal opinion and get your own review by competent legal counsel."

Cooper says that OIG Advisory Opinion 04-17 has already made an impact. "We see a greater degree of caution by specialist groups interested in acquiring their own AP laboratory condominium," he observed. "There seems to be a pause in the marketplace while everyone tries to determine what might be the OIG's next action on this subject.

"The tenor of Advisory Opinion 04-17 and knowledge that the OIG's 2005 Work Plan includes a review of pathology services provided in physician group settings will probably curtail businesses that have already started," observed Cooper. "The conclusions and aggressive tone make it clear that the intent of the OIG is to prompt a behavior change."

> ***"The conclusions and aggressive tone make it clear that the intent of the OIG is to prompt a behavior change."***

Both Cooper and Bartrum believe that influential legislators, such as Senator Charles Grassley (R-Iowa) may also keep this issue on the OIG's front burner. Their consensus is that further guidance will be forthcoming on both AP laboratory condominiums and physician self-referral issues.

Both attorneys also believe that some state legislatures may take up either or both the issues of physician self-referrals and AP laboratory condominium arrangements. Were this to occur, such state laws would be enacted independent of any action taken by the OIG.

Unfavorable OIG Opinion

THE DARK REPORT believes it is important to recognize a key fact: in response to a provider's request, the resulting OIG Advisory Opinion 04-17 is unfavorable regarding the proposed AP lab condominium arrrangement. Yet few legal commentaries or news stories printed following the issuance of OIG 04-17 start with the obvious declaration that the OIG declined to provide a favorable opinion on the concept of the AP lab condominium business model described. It is also noteworthy that, according to Bartrum, the AP lab condo business arrangement described in the request letter sent by his client to the OIG was more conservative in design than some already operating in the marketplace.

Increasing Compliance Risk

Moreover, as Bartrum discussed during this audio conference, the OIG asked questions about several other compliance issues it considered to be of concern regarding the AP lab condominium arrangement. Since a number of these compliance concerns were not addressed in Advisory Opinion 04-17, that makes it likely that the 2005 OIG Work Plan item on pathology services in physicians' offices is a sign that the OIG wants to provide guidance or comments on those issues.

Given these circumstances, it is reasonable to interpret the issuance of Advisory Opinion 04-17 as the start of a process in which the OIG may steadily raise the compliance risk for arrangements, including anatomic pathology laboratory condominiums, that allow a physician to financially benefit from his/her own patient self-referrals. Also, with the OIG now on record as issuing an unfavorable opinion on a "conservative" AP laboratory condominium arrangement, it certainly should raise the discomfort level of those who continue to operate existing lab condos. TDR

Contact Thomas Bartrum at 615-726-5720 and Richard Cooper at 216-348-5438.

Doctor "Pay to Perform" Launched by Medicare

Laboratory testing plays a key role in guidelines measuring outcomes

CEO SUMMARY: Medicare's just-announced physician "pay-for-performance" program will be a positive development for laboratories and pathologists. One consequence is that physicians will be measured on how effectively they use recommended lab tests in certain areas of care. This will give physicians a motive to work with laboratories which offer added-value lab testing services.

HEALTHCARE'S 800-POUND GORILLA just barged into another crowded room. On January 31, 2005, Medicare announced its first "pay-for-performance" program for physicians.

The design of this program should be beneficial to clinical laboratories. At the same time, however, this pay-for-performance program is another step closer to the time when laboratories and pathologists will participate in their own pay-for-performance arrangements—both with Medicare and private payers.

Ten Large Medical Groups

The **Center for Medicare and Medicaid Services'** (CMS) new initiative is a demonstration program for physician group practices. Ten large medical groups are participating. Each group has at least 200 physicians. Collectively, these ten groups represent 5,000 physicians serving an estimated 200,000 Medicare beneficiaries.

Groups will continue to receive fee-for-service reimbursement for their Medicare patients. During a three-year period, performance payments from Medicare will be funded by the savings attributable to improved patient care.

These savings will be calculated by comparing the physician groups' improvement and comparing that to Medicare's average growth rate in spending for the region around that participating physician group. A bonus of up to 5% of the measured savings in the pool will be paid to the physician group. Calculated on this basis, Medicare's physician pay-for-performance plan is expected to be revenue neutral.

Officials at CMS hope the plan provides incentives for the medical groups to "use electronic records and other care management strategies that, based on clinical evidence and patient data, improve patient outcomes and lower total medical costs." The emphasis is on early detection and preventative care, to prevent chronic disease complications and avoidable hospitalizations while improving the overall quality of care.

The quality measures to be used in this program are listed in the table on page 14, opposite. There are 32 measures that address common chronic illnesses as well as preventative diseases. CMS developed these measures in concert with the **American Medical Association's** Physician Consortium for Performance Improvement, the **National Committee for Quality Assurance** (NCQA—the health insurance industry's accrediting body), and the **National Quality Forum**.

Ten Medical Groups

The ten medical groups participating in this program were selected on a competitive basis. The list is published in the sidebar opposite, on page 14. It reflects geographical diversity as well as medical groups functioning in a variety of healthcare settings, such as integrated delivery systems (**Geisinger Health System**, Danville, Pennsylvania), academic centers (**University of Michigan Faculty Group Practice**, Ann Arbor, Michigan), and stand-alone clinics (**The Everett Clinic**, Everett, Washington).

There is a key issue in Medicare's physician pay-for-performance program that will impact the laboratory industry. That issue involves the specific performance measures used to evaluate physician effectiveness. Many of these measures will require the physician to order the right test at the right time for his/her patients—then act appropriately based on the lab test data and other clinical indications.

THE DARK REPORT recommends that laboratory administrators and pathologists study this list of 32 quality measures. It is highly likely that these specific quality measures will eventually be embraced by private health insurance companies and employers funding health benefits.

Medicare, the AMA, the NCQA, and the National Quality Forum identified these 32 measures as having the best potential to achieve two goals: 1) to improve healthcare outcomes by a significant amount; while, 2) at the same time reducing the overall cost of care.

Thus, as Medicare's physician pay-for-performance program unfolds over the next three years, it will be closely monitored. Successes—and hopefully breakthroughs—in treating these common chronic illnesses will likely motivate Medicare, private payers, and employers to introduce these quality measures to other physician groups throughout the country.

For the laboratory industry, this is a beneficial development. Any number of these quality measures rely heavily on the proper use of testing and effective follow-up by the physician. In both subtle and overt ways, this provides a motive and an incentive for physicians to rely more heavily on the laboratory medicine expertise of pathologists, Ph.D.s, medical technologists, and other specialists in laboratory medicine.

THE DARK REPORT believes another upcoming event may have some links to this pay-for-performance program. On April 29-30, the **Institute for Quality in Laboratory Medicine** (IQLM) will publicly announce its national quality indicators for laboratory services. This will take place at a public meeting in Atlanta on those dates.

Lab Quality Indicators

The IQLM is an organization incubated by the **Centers for Disease Control and Prevention** (CDC). It is known that the IQLM development team developing the laboratory quality indicators will utilize a number of existing measures already tracked in the healthcare system.

Collectively, these initiatives demonstrate how swiftly the healthcare system is moving to give providers incentives to improve healthcare outcomes. TDR

Medicare's "Pay for Performance" Plan To Incentivize Physicians

PGP Demonstration Quality Measures

Diabetes Mellitus	Congestive Heart Failure	Coronary Artery Disease	Preventive Care
HbA1c Management	Left Ventricular Function Assessment	Antiplatelet Therapy	Blood Pressure Screening
HbA1c Control	Left Ventricular Ejection Fraction Testing	Drug Therapy for Lowering LDL Cholesterol	Blood Pressure Control
Blood Pressure Management	Weight Measurement	Beta-Blocker Therapy – Prior MI	Blood Pressure Control Plan of Care
Lipid Measurement	Blood Pressure Screening	Blood Pressure	Breast Cancer Screening
LDL Cholesterol Level	Patient Education	Lipid Profile	Colorectal Cancer Screening
Urine Protein Testing	Beta-Blocker Therapy	LDL Cholesterol Level	
Eye Exam	Ace Inhibitor Therapy	Ace Inhibitor Therapy	
Foot Exam	Warfarin Therapy for Patients HF		
Influenza Vaccination	Influenza Vaccination		
Pneumonia Vaccination	Pneumonia Vaccination		

Source: Centers for Medicare and Medicaid Services

MEDICARE'S ANNOUNCEMENT of a physician "Pay for Performance" demonstration program will involve ten medical groups, each with at least 200 physicians. It will last three years and offers the potential bonus of up to 5%, based on improvements in outcomes and several other measures. Medicare will fund the incentive payment from savings that accrue from improved healthcare outcomes.

Medicare's newest pay-for-performance program will impact the laboratory industry in two ways. First, it is one step closer to a Medicare pay-for-performance program for laboratories and pathologists.

Second, most of the areas of clinical measurement (listed in the table above) require laboratory tests to guide the physician in early detection, diagnosis, prognosis and patient monitoring. This will increase physicians' interest in working with laboratories and pathologists capable of adding value to the physicians' medical practice.

Ten Medical Groups In Medicare's Physician "Pay for Performance"

- **Dartmouth-Hitchcock Clinic**, Bedford, NH
- **Deaconess Billings Clinic**, Billings, MT
- **The Everett Clinic**, Everett, WA
- **Geisinger Health System**, Danville, PA
- **Middlesex Health System**, Middletown, CN
- **Marshfield Clinic**, Marshfield, WI
- **Forsyth Medical Group**, Winston-Salem, NC
- **Park Nicollet Health Services**, St. Louis Park, MN
- **St. John's Health System**, Springfield, MO
- **University of Michigan Faculty, Group Practice**, Ann Arbor, MI

Cytology Diagnostics

Evolution in Pap Marketplace Shows Impact of New Guidelines

Sales of Digene's HPV test grow rapidly, direct-to-consumer ads will start in March

NEW GUIDELINES for cervical cancer screening issued last year are fueling strong growth in the sales of **Digene Corporation's** HPV test.

For its fiscal second quarter that ended on December 31, 2004, Digene reported sales of $27.0 million. That's a 28% increase from Digene's sales of $21.1 million for its second quarter last year.

HPV test revenues are the major part of those sales. For this past quarter, Digene's worldwide HPV test sales totaled $22.3 million, compared to $17.1 million from the comparable quarter last year. That's a 30% increase.

In offering guidance to investors, Digene estimates that, for its full fiscal year ending June 30, 2005, it will see growth of 40% to 50% in HPV test revenues over the previous year. The majority of Digene's HPV test sales are coming from the United States.

Direct-To-Consumer Ads

Digene is expanding the sales team which calls on physicians and details them about the company's products. It is also preparing to launch a direct-to-consumer advertising campaign in March.

There was equally strong growth at **Cytyc Corporation**, which manufactures the liquid preparation ThinPrep® Pap Test. Revenues for the year ending December 31, 2004 were $393.6 million. This is 23% more than its $303.1 million in sales for 2003.

Cytyc disclosed that it has shipped 158 imaging systems to laboratories in the United States since it released this product. On February 9, 2005, Cytyc announced that it had acquired **Proxima Therapeutics, Inc.** in a transaction valued at $160 million.

Proxima manufactures a single-use device "for the treatment of breast cancer that positions radiation sources directly into the post-lumpectomy site to optimize radiation treatment while minimizing damage to surrounding tissue."

The operative words in Cytyc's acquisition of Proxima Therapeutics are "single-use device." Consumables are the most profitable part of the IVD business and Cytyc believes the Proxima business model—and its consumables—are complementary to Cytyc's core business model.

At **TriPath Imaging, Inc.**, full-year revenues totalled $68.5 million, a 27% increase over the $53.8 million it posted for 2003. The company's net income for 2004 was $605,000, compared to a loss of $8.5 million in 2003.

TriPath manufactures the liquid preparation SurePath™ Pap Test and the Focal Point™ imaging system. It is also developing molecular diagnostic tests for malignant melanoma and cancers of the cervix, breast, ovary, and prostate. TDR

Lab Industry Briefs

PFIZER AND GLAXO-SK TO USE RFID TAGS IN 2005, RFID TEST IN BLOOD BANK

RADIO FREQUENCY IDENTIFICATION (RFID is making swift progress in a variety of healthcare applications.

The **Food and Drug Administration** (FDA) wants to secure the nation's drug supply through widespread use of RFID tags by 2007. To counter drug counterfeiting, some pharmaceutical companies are moving faster.

Pfizer said it will have RFID tags on all bottles of Viagra by the end of 2005. **GlaxoSmithKline** announced that it would have RFID tags on its drug products most susceptible to counterfeiting by late 2005 or early 2006. **Purdue Pharma** will put RFID tags on bottles of OxyContin and possibly also Palladone.

In each of these cases, pharmaceutical manufacturers will label bottles shipped to pharmacies to ensure that drugs are authentic. RFID labels will also make it possible to track a bottle's pedigree as it passes through the system and to make it easier to manage product recalls.

At **Georgetown University Hospital** in Washington, DC, the blood bank is launching a pilot project to evaluate the effectiveness of RFID tags to track blood products. RFID tags are being placed on collection bags used by the local blood donor center.

RFID tags will be used within the donor center and the Georgetown University Hospital blood bank to track units of blood from time of collection through transfusion. The goal is to improve accuracy and allow better management of the blood products to maximize utilization.

Since March of 2004, Georgetown's blood bank has placed read-only RFID tags on the wristbands of patients in the blood infusion unit. The RFID tags have the patient's name and medical record number. The scanner reads both the bar code and the RFID and helps nurses ensure delivery of the correct blood type.

Gerald Sandler M.D., Director, Transfusion Medicine at the Georgetown University Hospital, will be at the *Executive War College* in New Orleans on May 3-4, 2005 to report on how RFID tags are performing within his laboratory.

NEWLY-PUBLISHED STUDIES SUPPORT WIDER USE OF HIV SCREENING TESTS

HIV SCREENING for the greater population is cost justified. That is the conclusion of two studies published in the *New England Journal of Medicine* (NEJM) on February 10, 2004.

One study was done by the **Yale School of Medicine**. The other was done by researchers at the **Duke Clinical Research Institute at Duke University** and the **Veterans Affairs Palo Alto Health Care System**.

Publication of these two studies may be the first salvo in an effort by advocates to build a case in favor of more HIV screening among the general population. Greater utilization of HIV screening tests would impact most clinical laboratories in the United States.

The Yale study used a mathematical model of HIV screening and treatment to predict the benefits of HIV counseling, testing, and referral. It was their determination that a program of "routine, voluntary HIV screening every three to five years is cost-effective by U.S. standards, in all but the lowest-risk populations."

The Duke/VA study team used a different model. It included variables for patient characteristics, the natural history of the disease, timing of testing and treatments, immunological status, outcomes, medical costs, and quality of life parameters. This model drew information from the latest clinical trial results and studies published in the scientific literature.

Their model targeted patients who were unaware of their HIV status when they entered the health care system, whether at a hospital, clinic, routine medical or emergency room visit. Calculations were then done to measure the incremental costs and benefits across the lifetime of typical patients. The analysis also assessed the cost-effectiveness with and without considering the benefits to the sexual partners of the patients.

It is estimated that 1 million people in the United States are infected with HIV. Of this number, about 280,000 are unaware of their HIV infection. Current HIV screening guidelines are inconsistent and many people are not diagnosed in the early phases of their disease.

MDS EXITS ITS DUKE DEAL, HCA LAB JOINT VENTURE IN FLORIDA WILL BE NEXT

WITH THE EXPIRATION of its laboratory management contract with **Duke University Health System**, **MDS Diagnostic Services** comes one step closer to resolving its business interests in the United States.

In March 2004, MDS sold its lab operations in Poughkeepsie, New York and Atlanta, Georgia to **Laboratory Corporation of America**. It was predicted at that time by THE DARK REPORT that MDS Diagnostic Services was in the process of unwinding all its laboratory service commitments in the United States. *(See TDR, April 5, 2004.)*

So it was no surprise when MDS announced on September 4, 2004 that it had sold its interest in **Memphis Pathology Laboratories** (MPL) to **American Esoteric Laboratories, Inc.** MDS timed that sale to coincide with the expiration of its contract with the other hospital owners of MPL. *(See TDR, October 11, 2004.)*

In concluding its management agreement with Duke, MDS Diagnostic Services is left with just one laboratory joint venture. That is **Integrated Regional Laboratories** (IRL). Based in Fort Lauderdale, Florida, it is a joint venture (JV) with **HCA Inc.**, the nation's largest for-profit hospital corporation. THE DARK REPORT expects that, when the joint venture contract expires between HCA and MDS, MDS will sell its interest in IRL, leaving it with no laboratory operations in the United States.

CIGNA MOVES AGAINST METABOLIC SYNDROME

CIGNA CORP. WILL ATTACK morbid obesity by proactively helping individuals diagnosed with metabolic syndrome.

Although 5% of the U.S. population is morbidly obese, 24% are believed to have metabolic syndrome. These are people with at least three of the five factors for metabolic disease. They are hypertension, high levels of cholesterol or triglycerides, abnormal blood sugar, and obesity concentrated in the abdomen.

Alert readers will note that most of these five risk factors require laboratory tests as part of the diagnosis. Thus, Cigna's proactive healthcare initiative will increase laboratory test utilization among the targeted population. It is estimated that 20% of all healthcare costs are spent on obesity-related conditions. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's a new leader at the **Clinical Laboratory Management Association** (CLMA). On February 7, 2005, CLMA President Judy Lien announced that the association's new Chief Executive Officer is Dana Procsal, Ph.D., a veteran laboratory industry executive. Most recently, Procsal was Vice President of Laboratory Improvement Programs at the **College of American Pathologists**, a position he held for ten years. His lab experience goes back to **BioScience Laboratories** in Van Nuys, California. It also includes positions with **SmithKline Beecham Clinical Laboratories**, where he was General Manager of the Chicago Laboratory.

MORE ON: *CLMA*

CLMA is embarked on a major "makeover," thus, its new executive director no longer has that title, but is now the association's CEO. CLMA's joint annual meeting with the **American Society of Clinical Pathology** (ASCP), scheduled for March 5-8, 2005 in Chicago, has its own new name: CLMA/ASCP "ThinkLab '05."

PATHOLOGY ERRORS ATTRACT NOTICE OF WALL STREET JOURNAL

Recently, *Wall Street Journal* Columnist Tara Parker-Pope, writing in a story about cancer care, noted that "pathology reports in cancer cases have errors of 1% to 20% of the time." That caused a reader to write and ask "Is this [pathology error rate] someone's best guess, or is it documented by research?" Last week, on February 8, Parker-Pope published the letter and responded by saying, "There is growing evidence that patients should always seek a second opinion on lab work when cancer is suspected or diagnosed, but I have been surprised by how many skeptical doctors have written me asking for the specific studies supporting this." She then referenced a "most-cited" research study from the **Johns Hopkins School of Medicine**.

ADD TO: *Pathology Errors*

Parker-Pope stated that the Johns Hopkins study concluded that about 1.4% of pathology cases involve serious errors. She also noted that the error rate varies depending on the body part and type of cancer. As to the higher rate of errors, Parker-Pope referenced the Hopkins study and wrote "In the case of prostate cancer, about 20% of the time mistakes had been made in staging and grading, which tell doctors how advanced or aggressive the cancer." In finishing her response to the letter-writer, Parker-Pope referenced similar studies on pathology errors by **Dana Farber Cancer Institute** (2004), **Northwestern University** (2002), and **St. James University Hospital** in the United Kingdom (2005). With publication of her response to the question of pathology errors, Parker-Pope will certainly be peppered with missives from peeved pathologists wanting to clarify the accuracy rate of pathology diagnoses.

Congratulations are extended to **American Esoteric Laboratories, Inc.**, which held a grand opening of its new laboratory facility in Dallas last month.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 7, 2005.

UPCOMING...

- ***Eliminating the LIS: How One Hospital Lab Feeds Data into the Hospital EMR and to Its Outreach Physicians.***

- ***Cytology Certification Requirements: Why There's Trouble Ahead for Regulators, Educators, and Laboratories.***

- ***"State of the Market" Update on Molecular Diagnostics in the United States.***

For more information, visit:
www.darkreport.com