



*From the Desk of R. Lewis Dark...*

# THE **RD** DARK REPORT

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

*R. Lewis Dark:*

Low Lab Test Prices and Uninsured Patients.....Page 2

Program Helps Uninsured Access  
Affordable Lab Tests.....Page 3

How One Akron Physician  
Helped Uninsured Patients .....Page 6

Pennsylvania Laboratory Earns  
ISO 15189 Accreditation.....Page 9

Continuing Uncertainty about Low Pricing  
For California Laboratory Firms .....Page 11

*Lab Update:* Judge Rules Against FTC  
In Westcliff Laboratory Case.....Page 15

Seeking Market Clout,  
Labs Form Networks .....Page 16

Intelligence: Late-Breaking Lab News.....Page 19

## COMMENTARY & OPINION by...

*R. Lewis Dark*  
Founder & Publisher



### Low Lab Test Prices and Uninsured Patients

LOW PRICES FOR CLINICAL LABORATORY TESTS ARE CAUSING PROBLEMS for labs in California and Ohio. In this issue of THE DARK REPORT, you will learn about both situations. The California situation has gotten lots of play, but the Ohio situation is breaking news.

In California, both the California Attorney General and the Department of Health Care Services (DHCS) have an interpretation of the state law on the pricing of healthcare services to Medi-Cal that they want to enforce. Each state agency is taking steps to enforce this interpretation. As many as 300 licensed laboratories in the state have been drawn into one or both of these enforcement activities. (See pages 11-14.)

In Ohio, a primary care doctor and his county medical society created a partnership that helped uninsured and underinsured patients access affordably-priced laboratory tests. Patients could visit the medical society's website and click through to an Internet-based lab test company to order tests priced at about the level of Medicare fees. In turn, the Internet-based laboratory company had a contract with one of the two blood brothers to use its network of patient service centers (PSC) and to perform testing at a discounted price. (See pages 3-8.)

What you will learn is that the Ohio arrangement is about to end. That's because after CNN gave this uninsured lab test program positive news coverage last December, the national lab company terminated its contract with the Internet-based laboratory company. As a consequence, uninsured patients in the Akron area will lose access to affordably-priced tests that they have enjoyed for the two years that this program has operated.

I find it ironic that, in California, these national laboratory companies are mounting a strong legal defense of their long-standing practice of offering deeply-discounted prices to selected clients even as they submitted claims for the same types of tests to the Medi-Cal program for reimbursement at its higher fee schedule. But in Ohio, in an arrangement that involves less than 1,000 patients per month and is used primarily by uninsured and underinsured patients, one of these national labs wants to pull the plug and end a successful program that is valued by doctors in that community. Given the economics of the marginal costs to perform such tests, it is disappointing that so few laboratories are willing to serve the uninsured—even as a simple public service. ■■■

# Helping Uninsured Access Affordable Lab Tests

➤ **County Medical Society and Internet lab test firm collaborate to help uninsured and underinsured**

➤➤ **CEO SUMMARY: Here's an innovative way to help uninsured and underinsured patients gain access to affordably priced laboratory tests. In Akron, Ohio, physicians organized a partnership between the Summit Country Medical Society and PrePaidLab, LLC, to offer laboratory tests at prices that are comparable to Medicare. Everything worked well until CNN broadcast a laudatory story in December on the arrangement and how it helped uninsured patients. Soon after, the national lab company terminated its low-price lab test contract with PrePaidLab.**

**S**EEKING A NEW WAY TO OFFER affordable and low-cost laboratory tests to uninsured and underinsured patients, a county medical society and an Internet-based lab test company got together and created an innovative arrangement that was immediately praised by physicians and patients alike.

Normally such a success story would end with “and they all lived happily ever after!” But, following a national news story last December during which CNN interviewed grateful patients and reported on the enthusiasm of doctors for this low-cost lab testing service, the Internet-based lab company was sent a notice of termination by the national lab company that provided it with lab testing at wholesale prices!

Caught by surprise, the Internet-based lab test company filed a Temporary

Restraining Order so it could dispute this action in court. And it would not be in the courtroom alone. Faced with the loss of their source of low-cost laboratory tests used to help uninsured and underinsured patients, physicians in the community also prepared to go to court in support of the Internet-based lab company.

This story centers around three principal players. The story continues to unfold even as this issue of THE DARK REPORT goes to press. The key players are:

- **PrePaidLab, LLC**, of Avon Lake, Ohio. This is the Internet-based discount lab test company. ([www.prepaidlab.com](http://www.prepaidlab.com))
- **Summit County Medical Society (SCMS)** of Akron, Ohio. It collaborates with PrePaidLab in the arrangement to provide low-cost lab tests to uninsured and underinsured patients. ([www.scmsoc.org](http://www.scmsoc.org))

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- **Laboratory Corporation of America**, of Burlington, North Carolina. PrePaidLab contracted with LabCorp to get its patients' specimens tested at discounted prices. PrePaidLab also pays LabCorp to use its patient service centers (PSC) to collect patient specimens.

### ► **Helping Uninsured Patients**

Since 2009, PrePaidLab and the Summit County Medical Society have collaborated in an arrangement specifically designed to help uninsured and underinsured patients access laboratory tests at an affordable price. On its website, the Summit County Medical Society allows patients to order the laboratory tests requested by their physicians and PrePaidLab receives these test orders.

Upon receiving such an order, PrePaidLab does two things. It transmits a laboratory test request to the patient that the patient prints out and gives to the phlebotomist. It also directs the patient to a nearby LabCorp PSC through a "Find a Lab Feature" on the website. LabCorp collects these specimens and performs the tests. PrePaidLab uses a secure email to send the test results to the patient and faxes the results to the patient's physician.

By all accounts, physicians in the Akron area place a high value on this arrangement. It gives them an effective way to help uninsured patients get access to much-needed laboratory tests at an affordable price.

### ► **CNN Airls A News Report**

In fact, it was broad support by both physicians and members of the community for this uncommon low-cost lab test service that caught the attention of CNN, the cable news network. In December, 2010, CNN ran a news story titled "Doctors Slash Patients' Lab-Test Costs."

The CNN reporter told the story about how Akron family physician Doug Lefton, M.D., organized a way to help uninsured patients access necessary laboratory tests at

an affordable price. "It's a little heartbreaking when you have someone in your office and they need a blood test and they won't do it [the lab test] because they can't afford it," stated Lefton to the CNN reporter.

Lefton took action to change this situation. On his own initiative, Lefton worked with PrePaidLab and the Summit County Medical Society to create an arrangement that made it possible for uninsured patients to get lab tests at a very low price. With PrePaidLab prepared to provide lab testing services at discounted prices, the new service went live on the SCMS website in January 2009.

PrePaidLab CEO Tom Patton told CNN that Lefton's uninsured patients who "would ordinarily not be able to afford lab work are paying almost identical the amount the government pays for Medicare."

The CNN news story gave the example of a lipid panel. It said that, in the Akron area, an uninsured person will pay as much as \$148. That patient can order the same test on the PrePaidLab website at a cost of \$18.

### ► **Available In 47 States**

CNN explained the role of Lefton, the Summit County Medical Society, and PrePaidLab. CNN noted that LabCorp performed the tests for PrePaidLab and that LabCorp PSCs in all states except New York, New Jersey, and Rhode Island participated in this program.

To give this innovative low-cost test service a human face, CNN reported on the experience of Akron resident Jeff Hughey, who is a 50-year-old information systems technician. Hughey needed a comprehensive metabolic profile, a lipid panel and a hemoglobin A1c test for blood sugar.

He was told that, despite having health insurance, the three laboratory tests would cost him \$400 or more. Although he had health insurance, the high deductible was a problem. "Insurance doesn't kick in until you have paid \$2,000

out of pocket,” stated Hughey “...I just couldn’t afford over \$400 for three simple tests.”

### ➤ **Purchase Lab Tests On Web**

His physician, Dr. Lefton, had told him about the low-cost lab test service on the SCMS website. “I got online with PrePaidLab, registered with them, checked the pricing, and the final total was \$50.45, including the \$9.50 service fee,” said Hughey to the CNN reporter.

CNN’s positive coverage of this story had two consequences. One was favorable and the other was not. After CNN aired this story in December, the number of patient specimens increased as consumers learned about the availability of a low-cost source of laboratory tests.

However, the unfavorable consequence is that, within a few weeks of the CNN news story, LabCorp sent notice to PrePaidLab that it was terminating its contracts to provide low-cost lab tests to PrePaidLab.

***...within a few weeks of the CNN news story, LabCorp sent notice to PrePaidLab that it was terminating its contract to provide low-cost lab tests to PrePaidLab.***

The *Akron Beacon Journal* reported, on February 11, 2011, that “in a letter to PrePaid [Lab, LLC], an attorney for LabCorp said the discount pricing program with the medical society breaches the terms of their contract.”

*Beacon Journal* reporter Cheryl Powell also wrote “In her letter to Patton, LabCorp Senior Vice President and General Counsel Sandra D. van der Vaart said Patton ‘personally publicly made false and misleading representations and statements regarding LabCorp’s relationship with Prepaid Lab to a reporter at CNN.”

Further, the CNN web page that carries the December story about this arrangement now has a correction: “The Summit County Medical Society and Dr. Doug Lefton’s arrangement for the low-cost laboratory test program was made with PrePaidLab LLC, not Laboratory Corporation of America (LabCorp). PrePaidLab CEO Tom Patton’s statements represented only his own views, not those of LabCorp.”

### ➤ **Temporary Restraining Order**

In response to this notice, PrePaidLab prepared to go to court and obtain a temporary restraining order to require LabCorp to continue testing per the existing contract while negotiations took place. Also preparing to go to court in support of PrePaidLab was the Summit County Medical Society.

However, as of this date, the parties have not yet been in a courtroom. Patton told THE DARK REPORT that his attorney is in contact with attorneys representing LabCorp. Inquiries to LabCorp about this matter by THE DARK REPORT had not been returned as of the time that this issue went to press.

As of press time, the two sides were still talking and PrePaidLab’s customers continue to use LabCorp PSCs to have their blood drawn and other specimens taken. Patton said that LabCorp continues to process the specimens and send out the test results.

### ➤ **Resolution To This Dispute**

It is not possible to predict how PrePaidLab, SCMS, and LabCorp may decide to resolve this issue. However it is not a surprise that the use of deeply-discounted lab test pricing for some customers and not others is causing is causing disruption in the lab testing marketplace. In this case, it is uninsured patients who are likely to lose access to affordably-priced lab tests.

**TDR**

—Joe Burns

# How One Akron Physician Helped Uninsured Patients

► **Goal was to find a clinical lab willing to deliver lab tests to uninsured patients at Medicare prices**

►► **CEO SUMMARY: For one primary care physician, treating uninsured and underinsured patients was challenging, since these patients could not afford to pay for the lab tests necessary for their healthcare. This physician enlisted the help of his local county medical society and eventually found an Internet-based lab test company and a physician office laboratory (POL) that would provide lab testing to uninsured and underinsured patients at affordable prices—prices usually just pennies above the Medicare lab test fee schedule.**

IN FAIRLAWN, OHIO, A SUBURB OF AKRON, family physician Doug Lefton, M.D., was frustrated and wanted to do more for his patients. Uninsured patients in his practice could not afford to get their lab testing done and that made it more difficult for him to properly manage their care.

That situation worsened as the economic recession of 2008 and 2009 deepened. Lefton decided to solve the problem of making affordable lab tests available to his uninsured and underinsured patients.

This is the starting point for an unusual story that has many implications for the future of clinical laboratory testing in this country. Among other issues blocking his way is the established pricing policies for lab testing and other healthcare services that often cause uninsured patients to pay the highest effective price, compared to government health programs and patients with private health insurance coverage.

A natural ally in this effort was the **Summit County Medical Society** (SCMS). Together, they began a study of laboratory test prices in the Akron metropolitan

market. “Our first step was to speak with local hospitals and laboratories in the Akron area,” Lefton said in an interview with THE DARK REPORT. “We asked how much they charged for various lab tests. This survey was conducted in early 2009.

On April 27, 2009, the *Akron Beacon Journal* did a Page One story about the high cost of clinical laboratory testing. The headline read “High Lab Costs Plague the Uninsured, Summit County Medical Society Wants Lower Prices for Patients Stuck with Bills.”

► **No Help From Local Labs**

The newspaper called attention to the work of Lefton and the medical society. Reporter Cheryl Powell wrote that “The Summit County Medical Society recently launched an effort to persuade Akron’s three hospital systems and labs in the area to discount bills for uninsured patients.”

Powell detailed how the Summit County Medical Society asked Akron’s three hospital systems and labs in the area to offer discounts to uninsured patients. “By law, medical institutions must charge

everyone the same rate for services,” she reported. “But most bills then are steeply discounted for patients covered by government and private health-insurance plans. Medicare, for example, ends up paying \$18.57 in Ohio for a cholesterol test for which labs in this area charge \$96 to \$147.75 to provide.”

### ➤ Prices At Medicare Fees

Reporter Powell also noted that Lefton was “leading the medical society’s campaign to get labs in the county to accept payments from uninsured patients that are similar to the amount Medicare pays.”

The *Akron Beacon Journal* presented the figures it had collected on what six different labs would charge an individual for five basic clinical laboratory tests. The price range for a basic metabolic panel was \$22.60 to \$175, the paper reported, and the Medicare reimbursement to the lab for this test was \$10.71.

“When the *Akron Beacon Journal*’s page one story showed the incredible disparity in lab rates depending on where you got the lab work done, that story helped our effort,” said Lefton. “That’s when Tom Patton, the CEO of **PrePaidLab, LLC**, learned of our efforts and called with an offer to help.

### ➤ Serving Patients In Akron

“Our original goal was to create an affordable lab test price program for the Akron area,” noted Lefton. “But we recognized that PrePaidLab, as an Internet marketer, would allow us to provide this lab test service to other areas around the United States.

“We created a way for patients to go to the Summit County Medical Society’s website and order these affordably-priced laboratory tests,” he added. “The medical society’s website links to PrePaidLab and allows patients to select their lab tests.”

Currently, SCMS’s home page at [www.scmsoc.org](http://www.scmsoc.org) prominently features this arrangement. “The medical society doesn’t make a dime from this endeavor and

## PrePaidLab Reaches Patients via Website

**S**TARTED AS A WAY FOR PATIENTS to order their own laboratory tests at affordable prices using a website, PrePaidLab, LLC, of Avon Lake, Ohio, also provides some employee benefits through a preferred provider network for self-insured employers.

“In our program with the Summit County Medical Society, these prices barely cover our cost to provide the lab tests,” stated Tom Patton, Founder, President, and CEO of PrePaidLab, LLC. “We recognized the need to make affordable prices available to uninsured and underinsured individuals.

“Akron is a market that has seen job losses as the rubber industry moved out,” he continued. “That means many individuals in this community don’t have health insurance, yet the doctors keep treating them. That is why it is important to give these patients access to lab tests at a price they can afford to pay—and which is about the same price paid by the Medicare program.”

“We did this work for the uninsured in conjunction with the **Heinz Family Philanthropies** in Washington, DC,” stated Patton. “This charity has done a number of programs for the uninsured. They advised our lab to not charge a price for these lab tests that would be less than the Medicare fees. So we strive to set these prices at a few pennies above the Medicare lab test price schedule.”

PrePaidLab has cut its margin as well,” emphasized Lefton.

“If you’re uninsured, you go onto the medical society website and you choose the test your doctor wants you to get,” he noted. “The link takes you directly to the PrePaidLab website,” explained Lefton, one of four physicians in the Fairlawn Family Practice, in Fairlawn. “You can see how much the test costs, which is very close to Medicare rates.

“The patient makes a payment via credit card and then gets a lab order to take to one of the draw sites,” he added. “PrePaidLab has contracted with **Laboratory Corporation of America** to use its patient service centers to draw blood and collect specimens.

► **Reporting Lab Test Results**

“After the test is performed by LabCorp, the test results are faxed to the patient’s physician,” said Lefton. “At the same time, the test results are also sent in a secure email to the patient.”

Lefton says the affordable lab test price program has succeeded in helping uninsured and underinsured patients improve their healthcare. “Previously, these people were not getting any lab work done because they couldn’t afford to pay for the lab tests. In turn, that made it more difficult for me to do my job as a doctor.

“Even for common medical problems, most patients must get blood tests,” Lefton continued. “For high blood pressure, for high cholesterol, for diabetes—each of these conditions requires the patient to get blood work done so that the physician can accurately diagnose and care for the patient.”

► **Serving The Target Market**

Test volumes indicate that the program is probably serving the uninsured and underinsured patients that were the target for this service. When PrePaidLab first offered lab test orders online in January 2009, it did fewer than 100 patients per month. When the medical society program began in February 2010, PrePaidLab was processing orders for fewer than 300 patients per month. After the CNN story was posted online on December 8, 2010, volume rose to more than 600 patients per month. Lefton believes patients in the Akron area represent about 100 of all the patients who are tested each month. **TDR**  
 Contact Tom Patton at 440-328-8890 or [tjpatton@prepaidlab.com](mailto:tjpatton@prepaidlab.com); Doug Lefton, M.D. at [douglefton@hotmail.com](mailto:douglefton@hotmail.com) or 330-836-9721.

—Joe Burns

**Akron Primary Care Group Also Offers Low Test Prices**

**D**URING 2009, ONE GROUP OF PHYSICIANS in Akron, Ohio, offered to use their own physicians office laboratory (POL) to provide affordably-priced lab tests to uninsured patients.

**Pioneer Physicians Network** (PPN) is comprised of 25 physicians and providers practicing from 10 locations around Akron. It issued a press release stating that “When a patient is given orders for lab work by his doctor, many times those lab orders are ignored because lab fees are, frankly, unaffordable if the patient has no insurance.

“...Pioneer Physicians Network has stepped forward and met the challenge to help those in our community. Beginning August 3, 2009, lab services will be available at PPN Lab Sites at rates which will be much more affordable for those without health insurance.”

The terms are simple. PPN requires the patient to pay at the time of service with cash, check, or credit card. PPN will then collect the specimen, perform the test, and deliver the results to the patient’s physician.

Here are some of the lab test fees charged by the Pioneer Physicians Network:

Lipid Panel	\$24.00
CBC	\$15.00
Basic Metabolic Panel	\$14.00
Comp. Metabolic Panel	\$20.00
Hepatic Function Panel	\$12.00
TSH	\$32.00
Direct LDL	\$18.00
HgbA1c	\$18.00
PSA	\$35.00
Prothrombin Time	\$10.00



# Pennsylvania Lab Earns ISO 15189 Accreditation

➤ **NMS Labs is now harvesting several benefits from adopting the ISO quality management system**

➤➤ **CEO SUMMARY: Clinical laboratories often promote themselves as being able to deliver quality results. But simply saying so is not the same as having an outside organization audit the laboratory to accredit its analytical processes and its other operational activities. NMS Labs in Willow Grove, Pennsylvania, pursued accreditation to ISO 15189 Medical Laboratories to gain this outside recognition as well as to benefit from implementation of the ISO quality management system (QMS).**

**W**HEN THE DECISION WAS MADE to pursue accreditation to ISO 15189 Medical Laboratories, leaders at **NMS Labs** of Willow Grove, Pennsylvania, wanted to put down a marker that would differentiate their laboratory from competitors.

“For us, the most important reason to earn accreditation to ISO 15189 was that it certifies that our laboratory delivers quality results consistently in a manner that is recognized immediately by anyone who understands ISO certification and accreditation,” commented Robert A. Middleberg, Ph.D., who serves as Vice President, Quality Assurance, and as Laboratory Director and Forensic Toxicologist for NMS Labs.

“The inspection of our laboratory and its work processes by outside auditors is quite rigorous,” noted Middleberg. “Every laboratory can claim quality, but having a credible ISO accreditation team come into your organization and validate the quality of your processes is a major benefit for us. It definitely helps our laboratory to stand out in the competitive marketplace.”

NMS earned its ISO 15189 accreditation late in 2010 and used the **College of American Pathologists** (CAP) as the accreditation organization. One major benefit to the laboratory came with the adoption of the quality management system (QMS) that is embedded in the ISO 15189 standards.

## ➤ **Benefit Of QMS Adoption**

“What sets accreditation to ISO 15189 apart from the existing laboratory certification, licensure, and accreditation programs in the United States is how it requires the lab to implement a QMS,” noted Middleberg. “We knew we were a good laboratory, but we had never integrated our management systems to the degree required by ISO 15189.

“Let me explain,” he continued. “As we mapped our existing management and operational procedures to the requirements of ISO 15189, we realized that adopting the quality management system of ISO 15189 would require us to bring more consistency to all our work processes, ranging from courier, acces-

sioning, and analytical to accounting, IT, purchasing, and maintenance.

“ISO and its QMS involves a review of each process in the laboratory, along with the documentation for that process,” said Middleberg. “Prior to adopting ISO 15189, we never had to integrate all the activities that make up our laboratory organization.

### ► Effect On Patient Care

“But the standards of ISO 15189 require that we look at how everything affects our operation,” he added. “Most importantly, each of these areas must be considered as to how it can adversely affect patient care.”

NMS Labs was founded in 1970. “Our lab has a staff of 205 and no pathologists,” noted Middleberg. “We offer about 3,500 different tests.

“Each year, we process about 300,000 to 400,000 requisitions for the clinical lab marketplace and about 50,000 requisitions for the forensics market,” he said. “However, because each forensics requisition requires many more tests than a clinical requisition, the number of forensic tests we perform annually is about equal to the number of clinical tests,” he explained.

“What makes NMS Labs unique is that, not only do we provide clinical testing for many reference laboratories, but we also have a big role in serving the justice system, both civil and criminal,” stated Middleberg.

### ► Demonstrating High Quality

“Earning our ISO 15189 accreditation is part of our goal to raise the public profile of NMS Labs while also demonstrating the high quality of its testing services,” he added. “ISO 15189 accreditation is recognized internationally and we see that as a benefit for our laboratory as it continues to expand into new markets.”

NMS Labs had earlier established a Lean program and its lab team was regularly implementing process improvement projects. “This knowledge base came in

handy when we made the decision to pursue ISO 15189 accreditation,” stated Middleberg.

“Our first step was to assemble a team that was built around eight individuals with experience in Lean methods,” he continued. “It was their job to spread the knowledge of ISO, its QMS, and other requirements throughout the laboratory staff.

“The team used kaizen events and worked hard to provide information to every staff member,” noted Middleberg. “This is important because, when the ISO auditors come in during their inspection, they will interact with each individual in the company.

“Further, one important aspect of ISO 15189 is that it does require buy-in and compliance from everyone in the company,” he continued. “ISO 15189’s quality management system instills a strong consistency in how every staff member executes their daily duties.”

### ► Gaining Recognition

“The only way any clinical laboratory can actually prove to the world that it is a quality lab is through its accreditations and certifications, along with having laboratory scientists who are credentialed and certified,” observed Middleberg. “For NMS Labs, we consider our ISO 15189 accreditation to be one way our laboratory company can gain recognition as a high-quality laboratory.

“At the same time, our ISO 15189 accreditation process has given us a very different perspective on our laboratory organization and what is required to deliver top quality on every test every day,” he continued. “Our work flow is more consistent and we can see how the QMS has helped us achieve a tighter integration of all the various functions and activities that happen every day and on every shift in our laboratory.”

**TDR**

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# Continuing Uncertainty For California Lab Firms

➤ **Small and mid-sized family-owned labs are concerned about pending settlement talks**

➤➤ **CEO SUMMARY:** *In its ongoing initiative to determine if clinical labs in California have violated the lowest-price regulation, the California Department of Health Care Services is preparing to send out revised letters to as many as 300 laboratory companies in the state. The letters will ask the labs to conduct a self-audit and send the results to state officials. Meanwhile, widespread uncertainty continues over the legal exposure of laboratories large and small that operate in California, pending further guidance by state officials.*

IN CALIFORNIA, UP TO 300 CLINICAL LABORATORY COMPANIES are in a regulatory limbo. At issue is the California Department of Health Care Services' (DHCS) interpretation of the state law that spells out how providers, including laboratories, should price the services they provide to Medi-Cal beneficiaries.

Last fall, DHCS sent these 300 laboratories a letter instructing them to conduct a self-audit to determine their compliance with California Code of Regulations (CCR), Title 22, section 51501(a). This is a state law that covers how providers should price services they bill to Medi-Cal. However, since sending those letters, DHCS bureaucrats have "gone silent" and have not provided additional guidance or explanation about how these self-audits should be conducted and reported to DHCS. (See TDR, December 28, 2010.)

DHCS has declined requests by THE DARK REPORT for comment. As a matter of policy, it does not comment publicly on matters involving an investigation or regulatory action against specific laboratory companies.

Many laboratories that received these self-audit letters are confused and uncertain how to go about complying with the DHCS self-audit request. Further, lab owners state that they do not fully know the legal consequences that would result from any self-audit reports that their lab might submit to DHCS.

## ➤ **Information Vacuum**

To help fill this information vacuum, THE DARK REPORT spoke to a number of individuals who have interacted with DHCS officials over this matter. The following intelligence assessment of this situation was compiled from a variety of these sources, each of whom asked to not be identified.

This story is made up of four distinct regulatory events. The first event was the press conference conducted in April 2009, by then-California Attorney General Jerry Brown. He announced that the state had joined the whistleblower lawsuit filed by **Hunter Laboratories** and Chris Riedel in 2005. Brown accused the seven laboratories named in the *qui tam* action of having

overcharged the Medi-Cal program by hundreds of millions of dollars.

The second event involves the response of DHCS following the unsealing of this whistleblower lawsuit. Between April 2009 and the spring of 2010, it conducted audits of as many as 30 laboratory companies in the state.

### ► Stop Medi-Cal Payments

The results of these audits then triggered the third event. Sometime in June and July, 2010, DHCS sent letters to the audited laboratories, charging them with having violated state law concerning the prices they billed the Medi-Cal program. The letter announced that DHCS was suspending their Medi-Cal payments and within 14 days, would “temporarily suspend and deactivate” the laboratory’s Medi-Cal provider number and National Provider Identifier (NPI) number.

It quickly became obvious that DHCS had overreached in this effort. It was singling some labs out for aggressive enforcement while leaving other labs free to use the low prices that DHCS alleges violate its interpretation of state law to win business away from the audited labs. Additionally, it was clear to outside observers that the DHCS actions were likely to conflict with efforts by the state attorney general to prosecute the whistleblower case.

### ► Request That Labs Self-Audit

The fourth event happened in September and October, 2010. DHCS sent letters to 300 laboratories and directed them to conduct a self-audit of their Medi-Cal claims. Since that time, DHCS has not responded to the requests of lab companies to provide further details and guidance in these matters.

Over the course of these four events, DHCS officials have interacted with many laboratory owners, executives, and their attorneys. Now some of these individuals have provided THE DARK REPORT with additional facts and their beliefs about how and why these events occurred.

“Here in California, this pricing case has been front and center for everyone in the lab business for months now,” observed one source. “What’s most upsetting to these lab companies is that—no matter who they ask—there has been no guidance from the California Department of Health Care Services whatsoever.

“Labs have no idea what to charge,” continued this source. “The DHCS people have said, ‘Trust us; it will get resolved,’ but so far, nothing has been resolved.”

An attorney representing a laboratory in these matters noted that DHCS sent self-audit letters to some physicians who performed lab tests in their offices. “When DHCS sent letters to 300 labs last fall, some of the labs were in physicians’ offices,” recalled the attorney. “Their labs do routine in-office lab tests, such as pregnancy testing and urine analysis, for example.

### ► Second Letter May Be Sent

“It turns out that DHCS realized it should not have sent the self-audit letters to any physicians,” explained the attorney. “To rectify this error, DHCS officials are preparing a second letter that has been drafted and may be mailed within the next few weeks. We all believe that about 300 labs in California will be sent these letters.

“At issue is how much the labs charge Medi-Cal versus what they charge other payers,” another lawyer representing a laboratory told THE DARK REPORT. “We know that state officials are negotiating with **Quest Diagnostics Incorporated** to come up with an agreement that settles the charges in the whistleblower lawsuit and also the charges made by DHCS after its audit of the Quest labs last year.

“Similarly, **Laboratory Corporation of America** is believed to be negotiating with state officials to resolve the whistleblower lawsuit and the DHCS charges placed against it following its audit by the departments last year,” continued the lawyer. “Don’t forget the other 30+ laboratory companies that got suspension let-

## Only One Lab Settlement in *Qui Tam* Case, Other Labs Have “Tolling Agreements” with the State

**I**T IS NECESSARY TO CORRECT INFORMATION presented in earlier issues of **THE DARK REPORT** concerning the fact of settlements between the California Attorney General and some of the defendant laboratories in the whistleblower lawsuit.

Only one of the laboratory defendants in the *qui tam* lawsuit is known to have settled with the California Attorney General. That is **Westcliff Medical Laboratories, Inc.**, and its settlement agreement was made public in May 2010, as part of its bankruptcy action. (See *TDR*, June 1, 2010.)

At the time that the Westcliff settlement became public knowledge, several sources were indicating that more than one of the smaller laboratories had also settled their role in the lawsuit with the California Attorney General. **THE DARK REPORT** thus published information stating that one or more other lab defendants had also settled with the California Attorney General and that fact was inaccurate.

To the degree that principals have since discussed this point off the record with **THE DARK REPORT**, their information on the matter indicates that the smaller laboratories in this action have entered into “tolling agreements” with the California Attorney General.

“A tolling agreement is a tool that parties in litigation use when a statute of limitations could run out,” said one source. “The tolling agreement essentially means you can extend that statute of limitations for a certain period. So, some of the defendant laboratories decided to take tolling agreements and let the two biggest labs—Quest Diagnostics and LabCorp—fight the issues first.”

For legal purposes, this means that the smaller laboratory defendants are taking the risk that, should the California AG either gain a settlement or win in court against the two national lab companies, the final terms will be better for the smaller labs than having negotiated with the AG using their own legal counsel.

ters last summer. Despite settlement talks and draft agreements with at least a few of these labs, DHCS has not finalized any of these arrangements, to my knowledge.

“Meantime, state officials are trying to determine exactly how each lab charges Medi-Cal versus what they charge other payers,” stated the attorney. “DHCS officials insist that the state law mandates that Medi-Cal should be charged the lowest amount that a lab charges any other provider for that lab test.

“Several colleagues and I think that one reason why nothing has been resolved is because Quest Diagnostics has yet to settle with California,” offered a third

attorney. “We believe that state officials hoped they could settle the Quest case by the end of the year.

“Having obtained this settlement, the domino effect would follow,” he continued. “The state figured it could next get LabCorp to settle and then settlements with other laboratory companies would fall into place.

### ► **Awaiting First Settlement**

“We anticipate that, having established a pattern and precedent with all these settlements, DHCS would then issue some guidance or some administrative action,” noted this attorney. “As it is now, DHCS has not

reached a settlement with Quest case, which makes it difficult for DHCS to give labs any real direction with certainty.”

“There are numerous small and mid-sized family-owned labs caught up in this case,” noted one source. “These labs have annual revenue of \$5 million to more than \$30 million. They are very worried about the potential loss they could face—depending on how a judge could rule in these cases. The numbers are potentially quite big.

### ► Hints Of Settlement Terms

“For example, last month, Quest Diagnostics issued a press release stating that it was in ongoing settlement talks with state officials and the figure of \$241 million was mentioned as a possible settlement amount,” explained this source. “Quest Diagnostics also stated that it had not billed the Medi-Cal program since September—even though it continues to provide lab test services to Medi-Cal beneficiaries. It noted that this situation was producing losses that Quest estimated at between \$25 million to \$33 million.

“If Quest Diagnostics was to end up paying as much as \$241 million in a final settlement with California officials, then the smaller labs are worried about what they may need to pay,” continued this individual. “It’s just my guess, but one can understand why Medi-Cal officials would look at the state budget and interpret the state law such that the Medi-Cal program should get the best price a provider extends to any other provider. I’ll bet, that in all these settlement negotiations, state officials are refusing to agree to any exceptions to their interpretation of the California pricing statute.”

### ► Consequences Of Settlement

There is another issue which complicates a potential settlement formula that could be universally applied across the entire clinical laboratory testing industry in California. It involves Federally Qualified Health Centers (FQHC). These health

centers are eligible for Federal Section 330 grants and provide care to individuals without health benefits, or who lack access to quality healthcare.

It has been common practice among a number of lab companies operating in California to extend very low laboratory test prices to FQHCs, since these lab companies want to support the FQHC mission of serving the underinsured and uninsured. However, because these low prices are less than the Medi-Cal lab test fee schedule, such pricing arrangements with FQHCs would violate the DHCS’s interpretation of 51501(a).

This is a serious problem for California officials. THE DARK REPORT was first to publish precise figures about FQHCs that were provided by the **California Primary Care Association (CPCA)**. There are 478 FQHC clinic sites in California and these clinics serve 2.9 million patients. This is a significant number of patients. (See *TDR*, December 27, 2010.)

### ► Complex Issues To Settle

The insights shared by knowledgeable individuals and presented here demonstrate just a few of the complexities that face both the California Attorney General and officials at the Department of Health Care Services as they attempt to interpret and enforce state laws governing how providers price services to the Medi-Cal program.

Of equal interest is the belief of some attorneys representing smaller lab companies in these matters that the national lab companies could end up negotiating a settlement that—in resolving state claims—includes terms which give them a competitive advantage over smaller independent lab companies in the Golden State.

Should that to happen, it may end up being a rather cheap price for either national lab company to pay to obtain a state-blessed market advantage over smaller lab companies in California. **TDR**



# Judge Rules Against FTC In Westcliff Laboratory Case

*LabCorp now can proceed to integrate Westcliff even as FTC files motion to appeal judge's decision*

**I**N A COURT RULING THAT WENT AGAINST the **Federal Trade Commission** (FTC) last week, **Laboratory Corporation of America** may have moved one step closer to completing its acquisition of **Westcliff Medical Laboratories, Inc.**, of Santa Ana, California.

On February 22, 2011, Judge Andrew Guilford of the U.S. District Court for Central California, denied the FTC's request for a preliminary injunction to prevent LabCorp from consolidating Westcliff's testing activities into its national testing network. The judge also dissolved the temporary restraining order, thereby allowing LabCorp to proceed to integrate Westcliff's assets.

The next day, on February 23, the FTC returned to Guilford's courtroom and filed a motion to appeal the decision and another request to prevent LabCorp and Westcliff from closing the transaction until this appeal is decided. For its part, LabCorp says it "vigorously will defend the merger in the hearing before an FTC administrative law judge, due to begin May 2."

## ► Acquisition Happened in May

This acquisition deal was inked back in May 2010. That month, Westcliff filed for bankruptcy protection and said in a court filing that it was planning to sell its assets to LabCorp. LabCorp was the highest bidder and it offered to pay \$57.5 million for Westcliff. (See *TDR*, June 1, 2010.)

Shortly after that, in June, LabCorp entered into an agreement with the FTC to hold the Westcliff assets separate until December 3, 2010. The FTC requested additional time to review the acquisition and how it might alter the lab testing marketplace in the nation's most populous state.

It was November 30, 2010, when the FTC announced its opposition to the acquisition. It stated that the merger of the two companies could harm competition in Southern California's market for laboratory testing. The FTC went to court seeking an extension of its agreement with LabCorp, pending a ruling in the administrative adjudicative proceeding on anti-trust matters scheduled for May 2, 2011.

## ► FTC's Market Analysis

The FTC has said LabCorp and Westcliff are two of only three vendors of clinical laboratory testing services for most physician groups in Southern California. The third is **Quest Diagnostics Incorporated**, the FTC said. The acquisition would result in higher prices and inferior service for physician groups, the FTC added. (*TDR*, Dec. 6, 2010.)

The FTC defined the Southern California market to include all counties south of, and including: San Luis Obispo, Kern, and San Bernardino. The FTC believes the transaction would leave LabCorp and Quest Diagnostics in control of about 89% of this lab test market. **TDR**

—Joe Burns

# Seeking Market Clout, Labs Form Networks

► Shared testing networks are spontaneously emerging in several cities across the nation

►► **CEO SUMMARY: Meet “Test Exchange Networks!”** *These are shared laboratory testing networks that have spontaneously appeared in different communities across the nation. Typically two or more local laboratories come together and begin to collaborate by sharing any number of resources. These collaborative networks can include community hospital laboratories, local pathology group practices, and even physicians’ offices. One observer says that financial survival often motivates cross-town competitors to work together.*

**L**OCAL CLINICAL LABORATORIES and pathology group practices are finding it advantageous to work together in ways unseen in past decades. One sign of this trend is the growth in shared lab testing networks.

Formation of shared laboratory testing networks is a way that local lab testing providers can collaboratively challenge the sales and marketing efforts mounted in their local communities by national laboratory companies. Shared lab testing networks mark another significant change in the lab testing marketplace.

## ► New Trend With Momentum

“This trend is relatively new and continues to pick up momentum,” stated Lisa-Jean Clifford, CEO of **Psyche Systems Corporation**, a laboratory information systems (LIS) software provider in Milford, Massachusetts. “We became aware of it when clients in several different communities independently came to us and asked us to add features to our LIS that would support the specific way that several local clinical laboratories and

pathology groups in their cities wanted to share resources.

“In many communities, there is a new attitude today among the various local labs serving that region,” explained Clifford. “Some of the old barriers are breaking down. In the past, it was common for labs in a community to consistently maintain their independence. Local labs regularly declined to participate in a shared competitive response to national labs entering their market.

“That is not the case today,” she added. “The lab testing marketplace is such that independent labs will take unusual steps to survive, to remain competitive, and to find ways to grow.

“Simply said, we see a number of cities where local labs—both clinical laboratories and pathology group practices—are willing to collaborate and share resources,” Clifford noted. “They will do this rather than let national lab companies move unchallenged into their markets.”

Clifford says there is another interesting dimension to these shared laboratory testing networks. Not only will the lab test



network include, say, local hospital labs and community hospital-based anatomic pathology groups, but it is increasingly common for office-based physicians to participate in such networks. For a hospital-based pathology group, the network approach is one way its pathologists can continue to provide either or both technical component (TC) and professional component (PC) services to local physicians.

### ► Filling a Market Need

For Psyche Systems, this fledgling movement in laboratory medicine is viewed as a desirable business opportunity. It sees a way to serve these shared testing networks by providing the customized services necessary to support test sharing across multiple laboratory organizations.

“We filed a trademark on the name ‘Test Exchange Network’ (TEN) to describe this functionality and menu of services,” Clifford said. “In essence, we use our connections and the informatics platform we’ve built over 34 years to help community-based hospitals respond when national pathology lab companies want to move into a market. This is an effective way for the small labs to come together and better compete against larger labs.

“We believe this trend of shared testing services developed spontaneously,” she continued. “It first came to our notice when selected customers approached us and we developed informatics solutions to support their particular shared testing arrangements.

### ► Leveraging Lab Resources

“Now we regularly learn of other independent laboratories or health system laboratories which are looking to do something similar, typically by leveraging information technology investments, resources, or a geographic footprint,” noted Clifford. “And when I say ‘resources’ that would be anything at all, including monetary, human resources, instruments, or even facilities.”

## Some Testing Networks Want to Share the LIS

“WHEN LABORATORIES involved in a test exchange network (TEN) want to share an LIS, that’s where we can play a role,” stated Lisa-Jean Clifford, CEO of Psyche Systems Corporation. “For example, one of our LIS customers decided it made sense to pay for several smaller laboratories in its network to use our LIS.

“In turn, that gave these smaller labs a way to access the unified database of lab test results,” Clifford commented. “Importantly, this unified database allows smaller labs to handle any type of test result data—whether it’s clinical, molecular, pathology, cytology, surgical, or Pap smears.”

Psyche Systems takes steps to restrict access to patient data in the unified LIS database. “Our IT staff installs the proper security rights for each lab to ensure full compliance with federal privacy laws,” noted Clifford. “It means that each lab is able to see its own tests, its own results, and its own patient information. But one lab can’t see data from any of the other labs in this shared testing arrangement.

“In our experience, the clinical laboratories and pathology groups involved in a Test Exchange Network deal with the license issues of the unified LIS in one of two ways,” she explained. “In one approach, each lab purchases a license to use the LIS. In the other approach, we’ve seen a larger laboratory actually purchase and support the licenses for other labs in the network to access our LIS.”

Clifford says that these test exchange networks are quick to organize and regularly prove to be nimble competitors in the marketplace. “The concept works for two reasons,” said Clifford. “First, the shared services are kept to a basic and simple level. Second, it involves as few as two labs willing to work together.”

“The motivation to collaborate and work together is generally survival,” she continued. “For example, participating labs may want to counter a national laboratory company that is moving into their territory. Or the labs may see collaboration as a way each participant can overcome budget cuts or budgetary constraints.

### ► Motivation Can Be Survival

“Regardless of the specific reason, the primary goal of each lab in these sharing arrangements is to survive,” she declared. “Once they start talking to each other they usually find ways to work together and serve a specific area by leveraging each others’ resources.

“For instance, one lab might offer a certain test menu that the other lab wants and doesn’t have,” Clifford continued. “Or there could be some overlap in their geography but less overlap in their test menus. There also could be overlap in the test menus and less overlap in the geography.

“It may be that one lab has a significant cost advantage when running certain tests due to its investment in equipment that allows that lab to produce results at a much lower cost than the second lab can,” she said. “By working together, the first lab can help the second lab meet a market demand quickly and effectively.

“In shared arrangements like these, the patient is generally free to visit a patient service center (PSC) operated by any of network labs to get blood drawn or a specimen taken,” Clifford said. “It is the lab with the equipment that runs the test.

### ► Helping Labs Serve Patients

“For the patient, what goes on behind the scenes doesn’t matter,” she observed. “But the lab that doesn’t have the equipment will get the test results and it will send those results to that patient’s physician.

“For the two labs and for the patient, it’s just as if the patient’s laboratory used a reference lab for the patient’s tests,” she said. “The only difference is the two labs

work together in an *ad hoc* manner. In this sense, they have formed their own little network. They commonly share or leverage their respective laboratory information systems as well.”

THE DARK REPORT considers it significant that Psyche Systems is regularly fielding requests for help in linking together two or more local laboratories in the same community as a way to meet their goal of sharing services and resources. This is an early marketplace sign that local laboratories are becoming more creative in how they counter the sales campaigns of national lab companies coming into their communities.

At the same time, this nascent trend may also be a sign that long-standing barriers to regional collaboration may be falling. As noted earlier by Clifford, survival is often the major motive behind efforts to form formal and informal lab test sharing networks in different cities across the country.

### ► New Interest In Lab Networks

Whatever the reason, this trend toward shared testing and service networks is a clear change from the past two decades. During the 1990s and 2000s, hospital laboratories and local pathology groups steadfastly maintained their independence and rebuffed regular efforts to create collaborative networks—whether for the purposes of negotiating managed care contracts or to reduce the cost of providing laboratory tests.

In an upcoming issue of THE DARK REPORT, we will provide an intelligence briefing about one of the Test Exchange Networks supported by Psyche Systems. This network consists of clinical labs, anatomic pathology groups, and physicians’ offices. Also, Lisa-Jean Clifford will be speaking about the trend of Test Exchange Networks at the upcoming *Executive War College*, which will take place in New Orleans on May 3-4, 2011.

**TDR**

Contact Lisa-Jean Clifford at 508-473-1500 x357 or [lj@psychesystems.com](mailto:lj@psychesystems.com).

# INTELLIGENCE

**LATE & LATENT**  
 Items too late to print,  
 too early to report



In recent months, deficiencies in forensic pathology have made news in both the United States and Canada. In a story released February 5, 2011, on *CaliforniaWatch.com*, reporter Ryan Gabrielson wrote that “Coroners in Northern California are farming out thousands of cases each year to a private firm whose doctors have dissected the wrong body and have given inaccurate testimony that helped send an innocent person to jail.” He was referring to **Forensic Medical Group Inc.**, and noted that more than a dozen counties in Northern California rely on this private firm. *National Public Radio* (NPR) produced a series on these same problems, titled “Shortage Of Death Detectives To Perform Autopsies.”

## **MORE ON: Autopsies**

Similar media coverage in Canada is focusing on the problems in forensic pathology in that country. On February 6, 2011, the *Vancouver Sun* published an in-depth report “Training Standards for Forensic Pathologists Vary Across

Canada.” In the provinces of Ontario and Alberta, government reviews of forensic pathology are ongoing in response to public disclosures of errors and “botched” autopsies that may have wrongly influenced convictions in a number of high-profile criminal trials.

## **PATHOLOGIST IN NIGERIA RELEASED BY KIDNAPPERS**

All turned out well for kidnapped pathologist Dr. Memfin Ekpo of the **University of Uyo**, which is Nigeria’s most prestigious university. After 18 days of captivity, he was released unharmed. It is not known if a ransom was paid. As reported by **THE DARK REPORT** on February 7, Dr. Ekpo was abducted by gunman during a church service on January 16. A hefty ransom was demanded for his release.

## **TRANSITIONS**

• Paul R. Sohmer, M.D. is the new President and CEO for

**Viracor-IBT Laboratories** of Kansas City, Missouri. His executive experience includes companies such as **TriPath Imaging, Inc.; Genetrix, Inc.; Nichols Institute;** and **Chiron Reference Laboratory.**

• Earlier this month, **Halfpenny Technologies, Inc.**, of Blue Bell, Pennsylvania hired Jim Whitehurst to be its Vice President of Sales. Whitehurst had previously been Vice President of Sales and Marketing for **Seacoast Laboratory Data Systems, Inc.**



## **DARK DAILY UPDATE**

*Have you caught the latest e-briefings from DANK Daily? If so, then you’d know about...*

...how **Quest Diagnostics Incorporated** will pay \$740 million to purchase **Athena Diagnostics** from **Thermo Fisher**. It is the highest price for a laboratory company acquisition in 2011.

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***That’s all the insider intelligence for this report.  
 Look for the next briefing on Monday, February 28, 2011.***

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