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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Executives Lose Big in Federal Jury Trial

RATHER THAN ENTER INTO A NEGOTIATED SETTLEMENT with federal prosecutors, the former executives of **Health Diagnostic Laboratory** (HDL) and **BlueWave Healthcare Consultants** decided to take their case to a jury in a federal court in South Carolina. The outcome has notable lessons for all lab managers and pathologists, as well as the attorneys who advise them.

As you will read on pages 3-7, the jury verdict was that former HDL CEO Tonya Mallory and BlueWave executives Floyd Calhoun Dent III and Robert Bradford Johnson were guilty of violating the federal False Claims Act. The three defendants were ordered to pay $16.6 million, which, under the penalty provisions of federal law, will be tripled to about $54 million.

Of course, there will be post-trial motions and negotiations, and the defendants may choose to appeal the verdict. So, the final outcome of this case might turn out differently. In the meantime, however, the verdict in this jury trial sends clear messages to the clinical lab profession and lawyers who advise them.

The first message is the increased risk of federal enforcement against the owners and managers of lab companies, if their lab operations and their sales and marketing programs to physicians are found to violate the federal False Claims Act or other statutes, particularly if the sales reps induced physicians with payments or other goods in exchange for the lab test referrals of Medicare patients.

The second message is that at least one federal judge and jury is ready to consider the quality of legal advice given to lab owners and managers about federal and state compliance issues. One question the court considered was the actual advice and opinions lawyers provided to HDL and BlueWave's executives. Did it come from credible attorneys with experience in healthcare litigation? Was it advice that might reasonably be viewed as imperfect or flawed?

The other question the court considered was how the defendants responded to the legal advice provided to them. This included advice from outside lawyers who questioned the legality of some of HDL and BlueWave's practices. Did the defendants ignore legal opinions that did not support their strategies that were generating millions in profit? The outcome of this trial should give all lab owners and managers—and their lawyers—a good reason to review their lab's compliance with federal and state law. TDR

Insights from Jury Verdict in HDL, BlueWave Case

Lawyer offers lessons for lab directors after jury orders CEO, sales execs to pay $54 million

CEO SUMMARY: After a two-week trial, the executives of Health Diagnostic Laboratories and BlueWave Healthcare Consultants were found guilty of violating the federal False Claims Act. Defendants Tonya Mallory, Floyd Calhoun Dent III, and Robert Bradford Johnson were ordered to pay the United States millions for causing HDL to submit more than 35,000 false claims to Medicare and Tricare. Also, Dent and Johnson were found liable to pay the US for certain Singulex lab test claims.

On Jan. 31, a jury in U.S. District Court for the District of South Carolina found Tonya Mallory, the founder and former CEO of **Health Diagnostic Laboratories** (HDL) of Richmond, Va., guilty of violating the federal False Claims Act (FCA). Also, the jury found Floyd Calhoun Dent III and Robert Bradford Johnson guilty of violating the FCA. Dent and Johnson had served as sales representatives for HDL while working for **BlueWave Healthcare Consultants**, HDL's former marketing partner.

In the jury verdict, the court ordered Mallory, Dent, and Johnson to pay $16,601,591, which, the jury found, was the value of filing 35,074 false claims for HDL's services, said attorney Peter W. Chatfield of **Phillips and Cohen** in Washington, D.C.

Under the treble-damages provisions of the FCA, the defendants' $16,601,591 liability will be tripled, said Chatfield. He followed the case closely because he represents Michael Mayes, MD, an internal medicine specialist in Hilton Head Island, S.C., who filed one of three whistleblower suits in the case. As a whistleblower, Mayes stands to collect an amount that is yet to be determined, Chatfield said.

The jury also found Dent and Johnson guilty of violating the FCA for paying $10 to $20 process-and-handling-fee kickbacks to doctors to induce them to order tests from **Singulex,** a specialty heart lab in Alameda, Calif., the law firm said. For the 3,813 claims filed in the Singulex portion of the case, the court ruled Dent and Johnson must pay $467,935, an amount that would be tripled as well, Chatfield said.

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Under the FCA, damages are automatically trebled to compensate the government for the costs it incurred in identifying and remedying fraud and to deter future fraud. In this case, that means the total combined liability of the defendants amounts to about $54 million, plus additional, mandatory penalties in an amount the court will determine, Phillips and Cohen said.

The government alleged that Mallory, Dent, and Johnson conspired to pay kickbacks in the form of blood draw and processing and handling fees that totaled $20 for each blood test referral to HDL. In finding the defendants liable for those false claims, the jury must have concluded that at least one purpose of the payments made with respect to those claims was to induce doctors to order cardiovascular blood tests for federally-insured patients from the former defendant labs that the doctors might otherwise have thought were not medically necessary, the firm added.

Additional Penalties

After the two-week trial in Charleston, the jury found the three defendants jointly and severally liable for 35,074 false claims that HDL submitted to the government, causing damages totaling $16.6 million. Under the FCA, the defendants face additional penalties of $5,500 to $11,000 for each false claim, said the law firm.

Katie O'Connor reported for the *Richmond Times-Dispatch* that Mallory would contest the decision by filing a post-trial motion and may file an appeal. The court scheduled a mediation hearing for March 7 for the parties to negotiate an end to litigation, Chatfield said.

"The defendants wanted a jury to decide whether or not they violated the anti-kickback statute and/or the False Claims Act," noted Chatfield. "The jury has now rendered its verdict based on a review of all the relevant facts. It is time for the defendants to get serious about accepting the consequences of their actions and to make full, appropriate restitution to taxpayers."

The case began in 2011 when Mayes and two other whistleblowers alleged that the defendants paid kickbacks to physicians to induce them to use HDL's blood-testing services. The **U.S. Department of Justice** joined the case in 2014.

HDL, Singulex Settlement

In April 2015, the DOJ announced that HDL and Singulex agreed to resolve allegations that they violated the FCA by paying remuneration to physicians in exchange for patient referrals and billing federal healthcare programs for medically unnecessary testing. Soon after the agreement was announced, HDL filed for bankruptcy and later was sold to **True Health Diagnostics** of Frisco, Texas. *(See TDRs, April 20 and Sept. 14, 2015.)*

For clinical lab directors and pathologists, one important take-away from the cases of Mallory, Dent, and Johnson is that all labs should ensure that they get good legal advice from lawyers who specialize in healthcare law, Chatfield cautioned.

"The first lesson is to recognize that, whenever you run businesses in healthcare, it is essential to get advice from people who specialize in healthcare law and understand the complex legal issues of financial arrangements," advised Chatfield.

"One big issue in the case was this: at what point did the unlawfulness of what was being done become clear to the lab directors and the marketers?" he asked. "Originally, the lab directors and marketers relied on legal advice that was based on a description of conduct that did not focus on the most relevant facts. "That's because the lab executives or the marketers or both didn't disclose to the attorneys the full details of how the lab (such as failing to alert the attorneys that tests were being marketed at least in part as a way for referring doctors to generate extra revenue for their practices) and the marketing programs were being conducted based on the incorrect assumption that the labs needed to pay doctors for work associated

with processing and handling blood samples that would be sent to the labs.

"That problem with the incorrectly framed questions was compounded by the fact that the attorneys being consulted were not specialists in healthcare and did not understand all the relevant issues," Chatfield explained.

Another major issue in the case was how much HDL paid physicians for sending patients' blood samples to the lab company. Those fees were paid to doctors for processing and handling lab specimens.

"HDL had been paying those fees to physicians before the **Inspector General of the federal Department of Health and Human Services** issued an advisory opinion in June 2014 that said the payment of P&H fees was illegal," stated Chatfield. The OIG issued its "Special Fraud Alert: Laboratory Payments to Referring Physicians," on June 25, 2014.

Confusion About Payments

Chatfield explained the issue, saying, "Medicare and Medicaid will not permit labs to pay processing and handling fees to referring doctors so that there is no economic incentive to refer specimens to a specific lab."

"But for HDL and BlueWave, there was confusion about these payments because they started paying those fees before the OIG opinion and they were paying P&H fees above the blood draw fee as a way to compensate physicians for preparing the lab samples for shipping to the lab," he added. "Their premise was that they could pay doctors to do this because otherwise the physicians were doing work for the lab [processing specimens] that was not compensated. That premise was factually and legally wrong.

"At this point, if HDL and BlueWave had a healthcare lawyer look at the CPT codes for how doctors are compensated, they would have discovered the CPT code for processing and handling shows a zero payment," Chatfield said. "The payment is zero for that work because physicians are already paid as part of a panoply of payments to doctors that compensate them for that work.

"Ultimately the defendants' lawyers argued that maybe the defendants had made a mistake and didn't understand the rules—at least at first," he explained. "But working against that argument was the fact that the OIG ruling came out in June 2014, and other advice was coming from outside lawyers who worked for various doctors who claimed that the defendants needed to stop paying those P&H fees

"In addition, there were internal healthcare lawyers that HDL hired directly who were telling HDL to stop paying those fees," added Chatfield. "These internal lawyers said that the OIG opinion was considered to be a red flag, meaning HDL needed to move away from paying these fees.

"At that point, the problem appears to have become that HDL and BlueWave

Health Diagnostics Lab, Singulex Settled in 2015

AN EARLIER LEGAL CASE against Health Diagnostic Laboratories and Singulex was settled in 2015. On April 9, 2015, the U.S. Department of Justice reported that Health Diagnostic Laboratory and Singulex, a heart lab in Alameda, Calif., agreed to resolve allegations that they violated the FCA by paying remuneration to physicians in exchange for patient referrals and billing federal healthcare programs for medically unnecessary testing.

Under the settlements, HDL agreed to pay $47 million and Singulex agreed to pay $1.5 million. In the lawsuits, the DOJ alleged that HDL and Singulex induced physicians to refer patients to them for blood tests by paying them processing and handling fees of between $10 and $17 per referral and by routinely waiving patient co-payment and deductibles.

were so wrapped up in how much money the strategy was generating for them, that they were reluctant to put the brakes on it," he stated. "They were especially reluctant because they thought other labs might continue to pay these fees to physicians.

"When the jury looked at the evidence, the issue seemed to be this: at what point did the records show that the strategy became more than a mere mistake? At what point did it become clear that the defendants knew that what they were doing was wrong?" Chatfield asked. "At what point did they know it was illegal and then just refused to quit?

"It appears from the verdict that the jury was hitting the defendants for the period when the record shows there was a meeting with BlueWave, HDL, and the lawyers to discuss this issue," he said. "In this big meeting, the lawyers told HDL and BlueWave to stop without saying specifically, 'You need to stop.'

"By that time, the lawyers were in this weird position where, on the one hand the companies were making $450 million in sales over the course of four or five years, and, on the other hand, the lawyers for HDL and BlueWave gave the defendants an absolutely clear statement from OIG that this particular pattern of conduct was likely illegal," he noted.

Warning Points

"The conduct meets all the normal warning points of being illegal because the conduct was volume-based—meaning the more times the physicians sent lab samples, the more money they made in payments from HDL," Chatfield said. "That's a problem, especially when they targeted money-hungry physicians, as they told their sales representatives to target. And also because they were telling the doctors to order lab tests that wouldn't normally be considered medically necessary.

"Remember, referring physicians were ordering tests from a specialty heart lab," he added. "That means a lot of tests were ordered that typically are not considered medically necessary for the general population. HDL's client physicians were using these tests more as screening tests in a general population.

Medical Necessity

"Physicians were being told to consider ordering these tests all the time because it might save a handful of patients' lives," commented Chatfield. "That's really the difference between screening and medical necessity—but as screening tests, these tests are very expensive.

"In addition, HDL was doing zero balance billing, which is generally not something labs should do as a marketing strategy," continued Chatfield. "HDL did this for all kinds of insurance—whether it was commercial, Tricare, Medicare, or Medicaid. For Medicare, zero balance billing is required of all insurers providing lab services, so the promise can be misleading in suggesting these labs were offering a special benefit. But with Tricare and many private payers, such offers violate program rules. Defendants made those claims broadly for the benefit of the physicians to avoid patients complaining to physicians about having to pay copayments for expensive tests. HDL decided not to charge any patients anything so that the physicians would not get such complaints.

"That's how the case fell into place," he said. "From my perspective, the jury did a fabulous job of listening to all the testimony and using common sense to recognize that the testimony showed there were improper sales pitches that occurred," he said. "I think the verdict shows that the jury bought the notion that the defendants had just sort of run amuck in their eagerness to make all this money.

"It was clear from the testimony that two lab salesmen—Dent and Johnson—were making almost $50 million in income over four or five years," he added. "And Mallory, the CEO of the lab, was making

Lawyer Explains Why Attorneys Might Equivocate When Millions Are at Stake

IF A QUESTIONABLE BUSINESS STRATEGY IS GENERATING millions in revenue, lawyers may give advice that seems less than perfectly clear, said Peter W. Chatfield, an attorney in a case involving Health Diagnostic Laboratories.

"In a civil suit, the defense can raise what's called an affirmative defense," he continued. "It can do so based on the use of advice of counsel, which is one of the legal strategies that the defendants used in this case. They argued that they made business decisions while relying on the advice of counsel. Therefore, they argued, they could not be liable for any kind of knowing misconduct.

"The challenge in arguing that you relied on advice of counsel is twofold," continued Chatfield. "First, in raising that defense, you automatically waive attorney-client privilege because you can't say you relied on advice of counsel unless the jury can hear everything that the attorneys told you, good or bad. The entirety of the case becomes about the reasonableness of relying on the attorney's advice under all relevant circumstances.

"Second, the advice you get from counsel is only as good as the information you give them," he added. "If you fail to give them all the information necessary for your lawyers to understand all the circumstances and the legality of what you're doing, you cannot establish the affirmative defense of advice of counsel.

"That's what happened in this case," Chatfield explained. "The defendants never disclosed certain elements of what was happening to the attorneys, including, in part, the purpose of the payments used to induce referrals.

"Also, relatively early in the process HDL got information from others who said the lab was wrong to offer payments for processing and handling," he added.

"In fact, a healthcare lawyer in Florida wrote and explained to HDL that paying the processing and handling fees was illegal and showed how physicians are already paid for processing and handling in the per-visit fee," he said. "Therefore, the lawyer wrote, paying a separate fee for P&H is a double payment, meaning there's no way it can be legal.

"In a case like this, it is easy to see that even an excellent healthcare lawyer who has a client making $100 million a year or more from a business strategy might struggle to give a clear and unequivocal answer if the CEO is asking that attorney to give an absolute 'yes-or-no' answer to a question about whether it's legal or not," he explained.

"Lawyers know there is always a small chance of a surprise verdict in a case or opinion from an administrative regulator," he said. "As a lawyer, you may be reluctant to tell clients they absolutely must stop immediately and give up all this money, if there is any chance that unexpected events will make the advice turn out to be wrong. Attorneys who incorrectly present a question as having an absolutely clear answer when even a little doubt remains can end up getting sued for malpractice if they ignore the slight chance of a surprise outcome or reversal of government position.

"Instead, the lawyer will say something like, 'It's not looking at all good for you' or 'All the signs point to the fact that you need to stop.' They won't come flat out and say, 'You need to stop,'" Chatfield said. "In law, it's difficult to have absolute answers. Then, the defendants will respond by saying, 'Well, if you won't tell us, then I don't care if the government says it's illegal. The government can be wrong and we're willing to do it until someone tells us it's absolutely illegal.'

"At some point, that decision becomes reckless, and that's what happened in this case involving HDL, Singulex, and BlueWave," concluded Chatfield.

$21 million. Clearly, the finances influenced the defendants' decisions about not wanting to heed the lawyers' warnings." TDR

—Joseph Burns

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Use of '1099 Marketers' and Lab Compliance Risk

Growing use by labs of third-party marketers to sell lab tests can generate serious problems

CEO SUMMARY: Experts in lab compliance predict that clinical laboratories and anatomic pathology groups must anticipate tougher enforcement of federal and state laws this year. One source of increased compliance risk for lab companies is the rising use of third-party marketing agreements. David Gee, an experienced lab industry attorney at Davis Wright Tremaine, said lab owners and executives need to understand all the compliance risks associated with use of "1099 marketers."

ONE CONSEQUENCE of the deep cuts to the Medicare Part B clinical laboratory fee schedule this year will be increased competition for lab specimens. To offset the decline in revenue, labs will want to increase specimen volume. That means more intense competition for referrals of office-based physicians.

To do so, some lab companies may boost their sales efforts by entering into third-party marketing agreements. In recent years, the number of third-parties that market clinical laboratory tests has grown substantially.

Yet the use of third-party marketers—also called "1099 marketers"—presents lab companies with serious compliance and regulatory risks. That's the opinion of attorney and Partner David Gee of **Davis Wright Tremaine, LLP**, of Seattle.

During a recent *Dark Daily* webinar, Gee selected third-party marketing arrangements as one of his three most significant lab compliance issues of 2018. The other two were the importance of effective regulatory compliance programs as the cornerstone of every lab's risk management strategy and the memo that Sally Q. Yates wrote in September 2015 while serving as Deputy Attorney General in the federal **Department of Justice**. Called the Yates Memo, this directive increased the liability risk of laboratory administrators, pathologists, and staff for compliance violations of federal laws.

Third Party Lab Marketing

Gee explained why one of his lab compliance priorities for 2018 involves liability and fraud risk for labs contracting with 1099 marketers—particularly when compensation is based on a percentage of the dollars collected from the lab test claims billed to payers and patients.

"Compared with past years, it is more common today to see labs using third-party consultants, companies, and medical services organizations (MSOs) to sell lab testing services," stated Gee. "The term '1099 marketers' is the slang to distinguish these independent contractors from the sales representatives who are employees of the labs they represent.

"The challenge with these third-party marketing arrangements is that they have the potential to expose the owners and

managers of a lab company to multiple and serious compliance risks," he added. "You need to look no further than the jury verdict in the current ongoing case of the federal government against **BlueWave Healthcare Consultants** and other defendants previously associated with **Health Diagnostic Laboratories**.

"A lab company's use of third-party sales representatives is central to this federal case and lab compliance officers and executives should be familiar with it," recommended Gee. "This case shows the potential risk that labs assume when dealing with third-party marketing entities.

"Currently, certain parties of the BlueWave and HDL cases have reached settlements with the federal government for a combined total of more than $54 million," he said. "Of the four remaining defendants, three are individuals.

Anti-Kickback Violation

"One compliance development from this case is that it demonstrates the long-standing position of federal enforcement authorities that percentage-based compensation for 1099 marketers violates the Anti-Kickback Statute and is a predicate for False Claims Act liability," Gee explained. "The case was decided in a jury trial in early January, and any verdict will create further legal precedent on this issue for laboratory companies." *(See "Mallory, Dent, Johnson Found Guilty in Trial," pages 3-7.)*

In describing the types of third-parties engaged in these arrangements, Gee said, "MSOs and other 1099 marketers are middlemen. The concerns that the government has with 1099 marketers—such as MSOs and other 'distributors'—apply equally to any kind of payment for services involving the 'recommending or arranging for' items and services that will be billed to Medicare or to Medicaid, including clinical laboratory tests."

"When lab companies use third-party marketers to sell their lab testing services, they expose themselves to other forms of

Feds Say Percentage-Based 1099 Marketing Is Illegal

DOCUMENTS FILED BY THE FEDERAL GOVERNMENT in its case against BlueWave Healthcare Consultants and other defendants previously associated with Health Diagnostic Laboratories state that the payment of percentage-based sales incentives violates federal law.

During his webinar presentation on lab compliance, attorney David Gee of Davis Wright Tremaine showed the following quotations, which were taken from United States' Application for Prejudgment Remedies Against Defendants BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson, filed Feb 5, 2016:

- *BlueWave Defendants entered into Sales Agreements which, by virtue of their compensation scheme, fall directly within the class of relationships prohibited by the Anti-Kickback Statute (AKS).*
- *[T]he Sales Agreements… and the ensuing performance under those Agreements was blatantly unlawful.*
- *The Sales Agreements are illegal and are not saved by the safe harbor regulations.*
- *[C]ourts as well as HHS OIG have repeatedly found commission-based sales agreements with independent contractors to violate the AKS. HHS OIG made a conscious choice to exclude such agreements from the AKS' safe harbors due to the potential for program abuse. Finally, the plain language of the AKS precludes such arrangements. The Sales Agreements are unlawful.*
- **Anti-Kickback Statute Language is "extremely broad."** *[P]rohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State healthcare programs.*

regulatory and compliance risk," Gee noted. "Please understand that the risks with MSOs and third-party marketing agents don't end at liability, they also carry financial risk and often undo the culture of compliance labs have worked to create and sustain," he said. "

Labs Vulnerable To Risk

Labs are particularly vulnerable to increased risk when an MSO or third-party group calls on a doctor's office and represents multiple interests, Gee explained. "They might use contact points for one lab company to sell other products for which they offer improper financial incentives to physicians, even if not tied directly to orders for lab testing. In this case, liability for the kickbacks could nevertheless fall on the laboratory.

"Labs sometimes fail to consider the significant economic risk that results from the lab's lack of meaningful contact with the customer," Gee said. "Third-party marketers often view those customers as their own. Should your lab's business relationship sour or cease with the 1099 marketer, the third-party's immediate recourse is to take your lab's customer roster with them and divert those customers to your competitors. Because your lab did not directly create goodwill with the customer, there is little incentive for customers to remain loyal to the lab and not follow the sales group to the next destination.

Exposure To Economic Lose

"Laboratories that use third-party marketing must consider the consequences from both a liability and a strategic standpoint," observed Gee. "Failure to do so can cause both economic loss and loss of reputation—each a critical aspect of today's competitive laboratory landscape."

During his presentation, Gee outlined six reasons that a lab company using a third-party marketing agreement could encounter problems. Some problems affect the lab's business. Other problems could increase the lab company's risk of violating federal and state laws.

"One, in these arrangements, your laboratory not only has no line-of-sight to 1099 marketers and their sales practices, but your lab also has no line-of-sight to its customers," noted Gee. "This makes it difficult, if not impossible, for your lab's compliance officer to have confidence that the third-party marketers are compliant in their sales practices.

"Two, 1099 marketers and other middlemen generally are not part of whatever compliance culture your lab company has invested to build and sustain," he explained. "Again, this increases compliance risk for the lab company.

'Patients Won't Get A Bill'

"Three, third-party marketers can disregard or subvert your lab's policies, without a great deal of oversight from you," noted Gee. "Take the common example of 1099 marketers telling your lab's client-physicians that their patients won't ever see a lab test bill and won't be charged for copayments and deductibles. In the case of BlueWave, the jury found the principals of that marketing company guilty in part for paying processing and handling fees to referring physicians.

"Four, 1099 marketers find it easy to consider your client physicians as 'their customers,'" stated Gee. "Their focus often is not on promoting customer loyalty to your lab company.

"Five, your lab company is exposed to higher compliance risk if 1099 marketers and their middlemen wear multiple hats," he continued. "If, in addition to your lab's testing, the 1099 marketers also sell pain creams and other clinical products or services, for example, any kickbacks (including free services or lavish entertainment) they might offer to physicians may be imputed to your lab company.

"Six, at the end of the day, a third-party marketing arrangement can erode how your laboratory business is valued in the event of a strategic transaction," added Gee. "How secure and sustainable is the goodwill your clinical laboratory has

In Texas, Feds Indict Third-Party Marketers for Kickbacks Paid to Induce Lab Testing

IN RECENT YEARS, a substantial number of lab testing companies have decided to engage third-party marketers to visit physicians' offices and sell lab testing services. While speaking during a Dark Daily webinar about lab compliance, attorney David Gee of Davis Wright Tremaine, LLP, discussed reasons why labs should be careful when considering third-party marketing agreements.

To illustrate how "1099 marketers" can violate state and federal laws, Gee referenced a federal case in Texas. The federal **Department of Justice** issued a press release on July 13, 2017, that announced indictments of four individuals who had generated "unnecessary" toxicology tests billed to federal health programs.

DOJ Announces Indictments

The DOJ stated, "As part of that enforcement, Erik Bugen, 42, Jody Sheffield, 43, Matthew Hawrylak, 41, and Britt Hawrylak, 38, were charged by information for their role in a $36 million fraud scheme involving unnecessary and improperly prescribed toxicology and DNA cancer screening tests which were billed to TRICARE, announced the United States Attorney's Office of the Northern District of Texas. Each defendant faces a maximum statutory penalty of five years in federal prison and a $250,000 fine."

Gee's slides summarized how the DOJ described the actions of the four indicted 1099 lab sales marketers as follows:

- May 2014 to July 2017, [four defendants] operated **ADAR Group** in Killeen, Texas.
- [Adar Group was] paid by **Xpress Laboratories** and **Progen Lab** for referring testing orders for TRICARE beneficiaries.
- Bugen and Sheffield gave Walmart gift cards in exchange for urine and saliva specimens that were mailed to Xpress Laboratories and Progen Lab for unnecessary toxicology and DNA cancer screening tests and billed to TRICARE by **Cockerell Dermatopathology** in Dallas.
- Bugen and Sheffield disguised the gift cards as a food assistance program for low-income beneficiaries.
- ADAR Group employees collected urine and saliva samples from up to 200 patients per day.
- Bugen and Sheffield paid doctors a flat fee per month to sign orders for toxicology and DNA cancer screening tests. The doctors never saw the patients and had no doctor-patient relationship with the patients. Beneficiaries did not receive the test results.
- ADAR employees obtained signature stamps from the doctors and stamped the doctors' signatures on testing orders before sending the forms to Xpress Laboratories and Progen Lab.
- ADAR Group employees also placed false diagnosis codes on TRICARE claim submissions to make it appear that the beneficiary needed the testing… to ensure that TRICARE would accept, and pay, the claim.

with referring physicians? Does the third-party marketing arrangement undermine the value of your laboratory company's intangible assets, such as your customer list?"

More on 1099 marketers will be in upcoming issues of THE DARK REPORT. TDR

—Jon Stone

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NEWSMAKER INTERVIEW

Healthcare's Transformation Now Bringing Changes to Lab Industry

"Today, patients want to get diagnosis and treatment faster with fewer visits to the doctor's office. They want speedier and more comprehensive delivery of clinical services, be it laboratory tests, imaging, or other procedures."

—Ralph Taylor, **President, Sysmex America, Inc.**

CEO Summary: To bring testing closer to patients, clinical laboratories will need to offer sophisticated point-of-care systems for two reasons. First, that's what patients want, and second, a shortage of applicants for lab tech jobs will force labs to use more senior staff to process abnormal test results, leaving lower-level staff to manage normal results. Abnormal results will be produced in the central laboratory, and normal results will be produced closer to patients. Therefore, hospital labs will become almost like referral labs for abnormal specimens while normal testing will migrate to near-patient settings. To make these changes, labs will need to work with companies developing automated systems that reduce staff hands-on time.

Since passage of the Affordable Care Act of 2010, almost every aspect of healthcare in the United States has changed significantly. Changes certainly are occurring in the clinical laboratory sector, and many lab directors expect Congress and the Trump administration will make still more changes.

To get an idea of how those changes have affected labs and to analyze how clinical labs can prepare for what's ahead in the coming years, The Dark Report interviewed Ralph Taylor, Chief Executive Officer of **Sysmex America** in Lincolnshire, Ill. Sysmex America serves clinical labs in North and South America with automated hematology and urinalysis analyzers and middleware information systems.

Taylor joined Sysmex as an Executive Vice President in 2007, and in March, Sysmex named Taylor CEO. He is responsible for management and strategy and continues to lead operations in Latin America while also growing the flow cytometry business.

In the interview, Taylor focused on three general themes:

1. How Sysmex views the way the healthcare system is transforming in the United States.
2. How Sysmex's executives believe clinical laboratories will respond to healthcare's transformation by changing how they are organized and deliver test results to physicians and patients.
3. How Sysmex and other companies serving labs are developing technologies, products, and services that will help medical labs meet the changing needs of hospitals, physicians, and payers.

EDITOR: Let's start with the changes happening to healthcare. What are the primary drivers of change that you see here in the United States, and, more broadly, across the globe?

TAYLOR: We are watching the trend in which healthcare is moving closer to the patient. Today, for example, patients seek fewer encounters with the healthcare system. They want to receive diagnosis and treatment faster with fewer visits to the doctor's office. They want faster and more comprehensive delivery of clinical services, be it laboratory tests, imaging, or other procedures.

EDITOR: Is this trend something younger generations, such as Generation X and the Millennials, are pushing?

TAYLOR: In part, yes. We see this trend happening among all patients. But it is particularly true with Millennials. This generation is more educated about healthcare. Compared with older generations, Millennials are savvier in how they select healthcare providers and in how they acquire the care they need.

EDITOR: What does this mean for providers?

TAYLOR: For providers, a greater proportion of their patients are now well-informed. They show up having researched their health conditions. They know the type of care and treatment they want.

EDITOR: How are physicians and hospitals responding to these informed patients?

TAYLOR: For informed patients, we see innovative providers adopting a consumer-based approach to delivering care. They recognize that growing numbers of patients now go on the Internet to rate healthcare providers on such factors as convenience, wait times, and the quality of care they receive.

EDITOR: How can medical technologists, pathologists, and other lab professionals respond to these consumers?

TAYLOR: When you see such changes occurring at the macro level, then we as lab professionals need to focus on how we can meet those demands by doing our jobs more efficiently. That means we need to deliver test results faster and provide more information about what those test results mean.

EDITOR: Do you see connections between this consumer-based emphasis and how payment models are changing as Medicare and private payers move away from fee-for-service and to payment arrangements that reward providers on patient outcomes and satisfaction?

Ralph Taylor

➤"Sysmex strongly believes that core labs will continue to anchor lab testing services in the communities they serve. What will change is the type of lab testing that makes up the largest volume of specimens tested in core labs."

TAYLOR: Yes, absolutely, there is a connection. Consumers are searching for service efficiencies in healthcare—just as they do when buying other products. They want more information about the care they receive. In particular, they want information about what forms of treatment are best. Providers need to respond to those demands for information.

EDITOR: Can these changes be seen in the health systems and hospitals where many lab professionals work?

TAYLOR: We do see this, particularly as payers evolve in how they reimburse hospitals. For example, we see some hospitals competing in terms of the way they provide services. More intense competition will drive improvements in efficiency throughout the healthcare system.

EDITOR: Given what you've said about how health systems need to have a more consumer-focused approach to care, do you foresee health systems, hospitals, physicians, and even insurers taking different approaches to meet this demand for consumer-facing care?

TAYLOR: We believe hospitals and insurers will soon be able to publish data on the results they've produced from pay-for-performance programs. As that happens, physicians and hospitals will become much more cognizant of how they're measured and how their performance compares with that of other physicians and hospitals.

EDITOR: Will this published data give better-performing providers a competitive advantage?

TAYLOR: All evidence to date says, yes, that will be true. With access to patient outcomes data and satisfaction scores, most patients will be able to select among the top performers and avoid poor performers.

EDITOR: What type of patients will use this information to shop for a hospital, a physician, or a lab?

TAYLOR: Only the more informed patients will bother to seek out that information. They will research all providers who deliver their care. That research will include each provider's background and prior experience. By contrast, the everyday healthcare consumer will not do that even though such information will be more readily available.

EDITOR: Can providers use outcomes data and patient satisfaction scores to their advantage?

TAYLOR: That is happening already. Many hospitals and insurers use existing

rankings and similar information in their marketing materials. In the future, more such marketing will be used to drive patients toward better-performing providers.

EDITOR: Now that we've covered that first theme about what changes are occurring, let's go one level deeper. Given the changes you've described in healthcare, will these changes affect how labs organize themselves to deliver testing services?

TAYLOR: My answer is consistent with the major changes we just discussed for the healthcare system at large. As providers shift their focus to patient-centric healthcare—delivered as close to the patient as possible—so also will clinical laboratory testing services move closer to patients.

EDITOR: Do you have examples that are already in the marketplace?

TAYLOR: Today, you can see health systems and hospitals trying to accommodate patients' schedules rather than requiring patients to show up according to the hospital's or the lab's schedule. Another example is how some clinical labs are establishing patient service centers in retail settings, including pharmacies and grocery stores.

EDITOR: THE DARK REPORT has written about this trend. Last year, **Laboratory Corporation of America** and **Quest Diagnostics** announced agreements with national grocery and pharmacy chains to put PSCs into retail stores.

TAYLOR: That strategy makes sense because it's patient friendly. It's time-consuming for patients to drive to the local hospital, find a parking place, and then get to the PSC in the hospital or the nearby physicians' office building. Conversely, it's much more convenient for patients to go from where they live to a grocery store or pharmacy to have their lab specimens collected. We expect that kind of accessibility will increase across the marketplace.

EDITOR: Is "faster and more convenient" a trend in lab test turnaround times, and, if so, are Sysmex's lab clients moving in this direction?

TAYLOR: That answer is a definite yes! We already have some labs making test results available to patients within the same day or—in some cases—by the next morning. Along with a faster TAT in reporting lab results, as appropriate, those results will include more commentary and guidance from labs about what those results mean. Many physicians already find this added value helps improve their medical practice productivity.

EDITOR: Given that you see early signs of labs shortening test turnaround times and adding clinically-useful commentary in lab test reports, how is this trend consistent with moving more lab testing closer to the patient? What is the future for core laboratory facilities versus point-of-care and near-patient testing?

TAYLOR: Sysmex strongly believes that core laboratories will continue to anchor lab testing services in the communities they serve. What will change is the type of lab testing that makes up the largest volume of specimens tested in core labs.

EDITOR: Would you explain that?

TAYLOR: Core laboratories have something unique and irreplaceable. This is where the expert knowledge of lab medicine resides in a community or region. In core labs, you have experienced clinical pathologists, chemists, and laboratory scientists working in close collaboration with each other and with referring physicians. The core lab of the future will be the center of sophisticated diagnostic expertise and capabilities.

EDITOR: Given that core labs will continue as the medical community's most sophisticated testing resource, what type of testing will be dispersed within the community and done closer to the patient than is currently done?

TAYLOR: As mentioned earlier, the trend is to serve patients in convenient settings, so that routine screening and

common tests will be pushed outside the core lab, meaning to point-of-care and near-patient settings.

EDITOR: Is this trend why specimen collection will shift into retail stores and similar settings?

TAYLOR: Yes, particularly for routine screening and other common tests, more specimens will be collected in such convenient settings as **CVS' Minute Clinics** and in PSCs in supermarkets and other retail stores. Quest, LabCorp, and other large lab companies are moving draw stations into pharmacies, such as **Walgreens**. If these pharmacies had the equipment to do the testing there, then they would do so. That's the next logical step in the evolution of moving care closer to patients.

EDITOR: Our readers will note your statement that lab tests in retail pharmacies is a next logical step in the move to bring lab tests closer to patients. What other disruptive trends do you see coming?

TAYLOR: How about the news that **CVS Health** will acquire **Aetna**? That creates the opportunity for CVS to establish an integrated health delivery system that includes the health insurer and can provide care in 9,600 CVS pharmacies nationwide.

EDITOR: What would you say about the trend of consolidation in the hospital sector and the way integrated health systems are establishing large spheres of influence? The **Aurora** and **Advocate** combination in Milwaukee and Chicago and **Northwell Health** in New York are examples of such big health systems. From your perspective, how do these big health systems change the landscape for clinical laboratories?

TAYLOR: There are two important ways that these systems affect labs. First, these systems have learned to adapt to the crisis that most other labs face because all labs have an aging population in the workplace and need to hire and retain skilled staff while facing a shortage of applicants to fill those lab-tech positions. One consequence of this crisis is that the labs in larger health systems are supplementing those workers with less-skilled staff who then run most of the analyzers and other lab systems.

EDITOR: What is the second way large health systems affect labs?

TAYLOR: The second way large health systems affect labs is that they are separating normal results from what we might call abnormal results. Normal lab test results will be produced closer to patients. However, abnormal results will be produced in the core laboratory.

EDITOR: By that, do you mean lab tests for generally-healthy patients will move closer to the point of care? And tests for patients with complex conditions or difficult-to-diagnose diseases, will be referred to core labs?

TAYLOR: Yes. Sysmex believes that specialized laboratory staff will handle the abnormal test results, meaning the skilled staff will be assigned to those samples. When that happens, the hospital lab will become almost like a referral lab for abnormal specimens within its community. Meanwhile, normal testing will migrate to near-patient settings.

EDITOR: This is consistent with your earlier prediction that core laboratories will be an essential resource in their service areas because they have the sophisticated expertise and experience to perform complex testing and to help physicians with difficult-to-diagnose patients. How will IVD manufacturers support this development?

TAYLOR: While these changes are happening, Sysmex and other IVD manufacturers will respond by developing automation for laboratories specifically designed to remove the hands-on time for each sample.

EDITOR: What areas of lab workflow will be the most difficult to automate in this way?

TAYLOR: Even with new automated systems that reduce staff hands-on time, the fact is that much testing must still go through accessioning, the one part of clinical labs where hands-on processes are still required. In their struggle to address this problem, labs and companies serving labs do not yet have an answer.

EDITOR: Now that we've connected how patients will drive change and how hospitals and health systems are responding to those changes, are there other transformative forces that will cause labs to operate differently over the next three to five years?

TAYLOR: Yes. Probably the most significant of these other transformative forces is the new Medicare 2018 Clinical Laboratory Fee Schedule. It substantially lowers the prices for many key lab tests and this will negatively change lab finances.

EDITOR: Many expect the Medicare fee cuts will cause some labs to shrink or close, but will there be other consequences from these price cuts?

TAYLOR: Those lower rates will drive labs to look for more efficiencies. And, when calculating a lab's total cost of testing, the manufacturer's costs may be one of the smallest components of total costs. Therefore, labs will need to drive efficiencies into the cost of each test. That will force them to be creative in rethinking current testing models. One obvious way to drive down testing costs is to reduce labor costs. Even though some staff are not highly paid, their salaries are a major element driving the cost of each test.

EDITOR: Now that we've covered the first two themes, we can address the third theme: How will Sysmex and other companies develop the products and services that labs will need in a transformed marketplace?

TAYLOR: I will repeat one theme central to our strategic thinking about healthcare and the lab testing marketplace. Sysmex and all companies serving clinical labs will need to look at how they can develop analyzers to move testing closer to the patient. For Sysmex, the XW-100 was the first entry in this new world of CLIA-waived CBC testing.

EDITOR: You surprised many IVD executives with the FDA clearance to sell a CLIA-waived hematology analyzer that can do routine CBCs in near-patient settings, including physician offices.

TAYLOR: That may be true. But your readers should understand the more significant aspect of FDA's clearance. Sysmex had to work in close communication with the FDA to develop a path to develop a CLIA-waived system for what is a CBC with three-part differential. The next step would be to develop a five-part differential with a CLIA-waived status. If we can do that, we would obviously be providing more useful information to clinicians and patients from a hematology perspective.

EDITOR: What other clinical lab tests do you want to develop for use in CLIA-waived systems?

TAYLOR: Sysmex intends to expand its portfolio of testing that is CLIA-waived. To accomplish that, we are exploring whether it is possible to create a CLIA-waived suite of analyzers and instruments that functions as a near-patient lab. For example, we are trying to determine if we can add the most commonly-requested immunohistochemistry tests.

EDITOR: That is an ambitious goal.

TAYLOR: Yes, it is, but it's not immediately achievable. If we can do all that, however, we would provide a greater form of intelligence to assist doctors who need diagnostic test results. What I'm describing is a type of mini-CLIA-waived lab suite. That's an area we are assessing and the CLIA-waived XW-100 is the first step in that direction.

EDITOR: Will this CLIA-waived suite of analyzers and instruments be developed in stages?

TAYLOR: Certainly, yes. We knew we could develop the first CLIA-waived CBC with three-part differential. But it was still a challenge to make that a reality. Now our task is to create a suite of products in the CLIA-waived space. The next step for us is to provide more relevant parameters to our XW-100 so it can handle abnormal testing. Another development challenge is to help laboratories manage those samples in specific ways that require the minimum amount of staff work. As we do that, we will help clinical labs reduce the amount of lab-staff intervention that is needed from laboratory technicians.

EDITOR: Do you have a guiding vision for all of these future analyzers and tests?

TAYLOR: My vision for the future is that one day the lab technician will not be someone who stands in front of a hematology, immunochemistry, or other analyzer. Instead, the future lab tech will sit at a terminal reviewing and acting on data coming from many different analyzers. The lab tech of the future will not be touching tubes and loading analyzers.

EDITOR: Are you hoping, therefore, to bring an end to the current era where highly-trained clinical laboratory scientists spend their time managing analyzers or a section of an automated line?

TAYLOR: Definitely. Our vision is that the lab systems of the future will be operated and managed by lab staff that have much less training than is true today. These new staff members basically will be machine minders. That is not the best term, but it describes what they will do.

EDITOR: In your view, will the highly-skilled clinical laboratory scientists continue to be essential to every laboratory because they will spend their time ensuring the quality of lab test results? If so, will they be the source of added value for labs in the future, meaning these clinical pathologists, chemists, and other lab scientists will collaborate with providers to help them make faster, more accurate diagnoses?

TAYLOR: Yes. Lesser-skilled staff will handle specimens, load and unload machines, and do similar tasks. The qualified lab staff will do all of the interpretive work, authorizations, and sample validation.

EDITOR: Does that mean lab professionals should expect to see Sysmex and other IVD manufacturers offer analyzers, instruments, and automated solutions designed to reduce hands-on labor?

TAYLOR: I believe that will be the case. Our strategy, and possibly the strategy of our competitors, will be on two levels. First, we will continue to drive forward with automation by working to minimize the level of manual intervention with each sample. Second, we will look at how we present lab test results—meaning the forms in which the data reside—so that we can provide greater information that allows faster and more specific data interpretation. That is the next logical evolutionary step given where we are now after developing the Sysmex XW-100.

Ralph Taylor

➤"...the future lab tech will sit at a terminal reviewing and acting on data coming from many different analyzers. The lab tech of the future will not be touching tubes and loading analyzers."

EDITOR: How does your CLIA-waived system fit with this strategy?

TAYLOR: The reason we started the XW-100 project was to fulfill the unmet need for CLIA-waived testing in doctors' offices. We aim to create a type of CLIA-waived mini-lab environment to offer key immunochemistry testing and also clinical chemistry testing along with urinalysis. If we could do that, we would be moving some core laboratory testing to a CLIA-waived environment.

EDITOR: Where else might this type of testing be performed?

TAYLOR: The next logical need to fill is for the patient who is at the pharmacy waiting to get clinical lab testing done there. If we can meet that need, it would be an extension of that philosophy.

EDITOR: Now that the XW-100 is on the market, do you worry that competitors will duplicate it or make something better?

TAYLOR: Yes, absolutely. In every industry, everyone wants to produce the next better mousetrap. If you go back five or six years, we showed that the FDA was reluctant to give certification to a CLIA-waived product in hematology. Our experience is that the FDA is open to this idea if you provide the right controls in terms of the result. So, in that way, we created a pathway for how it could be done for other CLIA-waived tests.

EDITOR: Does that mean other IVD companies are expected to launch similar instrument systems?

TAYLOR: Our competitors are likely to follow that path because there are about 70,000 CLIA-waived labs in the United States. There's a lot of people eyeing the hematology part of that market because it didn't have a CLIA-waived product.

EDITOR: This has been an enlightening conversation, Ralph. Any closing thoughts?

TAYLOR: I'd like to emphasize one point, and it is that—no matter in what setting the lab sample is collected—it will be experienced, trained clinical laboratory professionals who will oversee the network of labs and sites performing those tests. As medicine becomes more complex and personalized, the need for the expertise of pathologists, clinical chemists, and clinical laboratory scientists of all disciplines will be greater than ever before. TDR

—Joseph Burns

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Ralph Taylor

CLIA Waiver for XW-100 Supports Fast Results

IN NOVEMBER, the FDA cleared a complete blood cell count test from Sysmex and its XW-100 Automated Hematology Analyzer.

For this analyzer, the FDA granted a CLIA waiver, allowing it to be used in non-traditional laboratory sites, such as physicians' offices, clinics, or other facilities with a CLIA Certificate of Waiver. Also, a wide range of support staff can run the analyzer, allowing for fast availability of results, the FDA said. The XW-100 is the first, automated, CLIA-waived hematology analyzer to offer an accurate, same-visit CBC with differential and a sample-to-result time of three minutes, Sysmex said.

This technology provides healthcare professionals with a report of 12 parameters in the same patient visit to assist in establishing a diagnosis and treatment plan. The XW-100 is a quantitative, automated hematology analyzer intended for *in vitro* diagnostic use to classify and enumerate the following parameters for venous whole blood: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#.

It is not approved for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases or disorders, oncology patients, critically ill patients, or children under the age of 2.

GE Healthcare Sells Omnyx to Inspirata

CEO pursued GE/Omnyx since 2016, saying software was ideal complement for customers

CEO SUMMARY: Now that the FDA has cleared a digital pathology for use in primary diagnosis, interest in DP is building. Inspirata purchased Omnyx and its assets because the Omnyx Dynamyx digital pathology software has strong features that could be integrated into Inspirata's digital pathology solution. In this interview with THE DARK REPORT, Inspirata CEO Satish Sanan outlines the steps the company took to acquire Omnyx and how his company plans to support Omnyx's customers.

OVER MORE THAN A YEAR, THE CEO of **Inspirata** doggedly pursued GE Healthcare in his attempts to secure a deal to acquire **Omnyx LLC** of Pittsburgh. His efforts paid off when the acquisition was announced on Jan. 31. Terms of the sale were not disclosed.

In an interview with THE DARK REPORT, CEO Satish Sanan explained the strategy Inspirata, a digital pathology company in Tampa, used to acquire what Sanan called the jewel of the deal, Omnyx's digital pathology software, Dynamyx. *(See sidebar, page 21.)*

In 2008, the **University of Pittsburgh Medical Center** and **GE Healthcare** agreed to contribute $40 million each to form Omnyx LLC, a 50/50 joint venture that would develop a digital pathology system. *(See "GE, UPMC Create Company for Digital Path Imaging," TDR, June 16, 2008.)*

The partners predicted that Omnyx would capture 25%, or $500 million, of a market that at the time was estimated to grow to $2 billion. That dream died in December 2016 when GE Healthcare ended the partnership, saying regulatory uncertainty and variable global demand caused the company to cease pursuing new business opportunities for Omnyx and scale back to support its existing customers.

Inspirata now plans to sell Dynamyx, along with hardware from other scanner vendors, Sanan told THE DARK REPORT. "Dynamyx is CE-marked in Europe and it has a Health Canada license for use in *in vitro* diagnostics," he added.

An Integrated Solution

An early innovator in connecting pathology departments with its own whole slide image scanners and software, Omnyx had installed its digital pathology systems in Europe and Canada. In the past month, Sanan has visited with or spoken to the largest pathology groups using the Omnyx system, Sanan said.

"This acquisition is significant because it takes us the last mile to having a fully integrated, end-to-end digital pathology solution with a device- and application-agnostic whole slide image viewer and image management system," he added.

"By acquiring Omnyx, Inspirata can use the Dynamyx software—which is

Inspirata Sought Deal for Omnyx Because Its Goal Was to Blend Software Features

FOR INSPIRATA CEO SATISH SANAN, the announcement that his company had acquired Omnyx from GE Healthcare was the culmination of a more than 14-month-long pursuit for what he considered to be the ideal software partner.

"We wanted to do this deal in 2016 when GE first said it would get out of the business of developing software and hardware for pathologists," Sanan said.

"I called the people at GE and at Omnyx and met with the leadership teams," he added. "I wanted to buy whatever assets they would sell. But, they were already speaking with some larger companies and expressed concern about our lack of a global footprint."

Sanan did not give up, meeting with GE officials numerous times in the intervening months to explain why Inspirata valued Omnyx' assets. "I told them that scanners should not be the main goal," he said. "The goal should be the functionality, the workflow, and the software.

"Omnyx has the most advanced digital pathology software in the marketplace," he added. "I know that because we did our due diligence. They had pieces that we didn't have, such as histology functionality that is quite useful. They also have a strong and novel image-compressional algorithm that is a big differentiator.

"I told them we have features that Omnyx doesn't have," Sanan added. "And, our software is interoperable with other systems so that it can display images and reports from radiology, for example.

"For pathologists, we have a complete workflow," he explained. "Just in the past few months, we added features to manage molecular pathology and other diagnostic testing reports. The combined systems could become the Cadillac of digital pathology workflow software."

Met With Omnyx Leadership

Over the months, Sanan's arguments went unheeded. "Then in January 2017, I met with their top leadership again," he said. "Along with affirming Inspirata's continued interest in acquiring the company and its assets, I emphasized how Omnyx would be a strategic fit for us.

"Nothing happened at this time because GE was in discussions with two very large companies," he recounted. "But then, about March of last year, we began talking again.

"We quickly learned that Omnyx had done its due diligence on us and they were ready to hear our proposal," recalled Sanan. "Our talks led to a deal at the end of December and we made the announcement in January."

scanner-agnostic—to offer a fully-supported IVD device cleared for primary digital diagnosis in Europe and Canada," he noted. "At the same time, the addition of the Omnyx users expands our customer base and our geographic footprint."

Inspirata will retain Omnyx's employees and offices in Pittsburgh and establish a center of excellence for the development of digital pathology software in the Steel City.

In April 2017, **Philips** won approval from the FDA to market its Philips IntelliSite Pathology Solution (PIPS) for review and interpretation in the primary diagnosis of digital surgical pathology slides prepared from biopsied or other tissue.

At the time, Inspirata had partnered with Philips to use the company's scanners as part of what it calls its end-to-end workflow solution.

The FDA approval is important to

Inspirata's deal with Philips because PIPS is the first whole-slide imaging system granted such status.

Strengthened Partnerships

Now, Sanan said, he has a more potent message that his sales team can deliver worldwide. "Actually, I see Inspirata's partnership with Philips, **Leica**, and other scanner manufacturers strengthening because our Omnyx acquisition provides new opportunities for all of them to sell scanners through us to the Omnyx customer base that we've acquired in Canada and Europe," he noted. "Soon, we plan to replace the Omnyx VL120 scanners for those customers.

"In addition, we have new global opportunities, including in Europe and Canada, to expand our customer base," he added. "That will provide other scanner companies with sales opportunities in partnership with us."

For large pathology groups in the United States, the Inspirata-Omnyx deal is important because Inspirata works closely with Philips to offer the PIPS system to these groups.

FDA Approval

"In the United States, we remain the only partner for Philips for the digital pathology workflow," Sanan explained. "Right now, Philips is the sole scanner manufacturer with FDA approval for primary diagnosis, but I expect other scanner companies will gain FDA approval in the coming weeks or months."

Inspirata also plans to market its digital pathology solution to smaller pathology groups, Sanan said. "In the near future, we will offer a converged software-as-a-service solution (which combines the best of the Dynamyx software with our existing Digital Pathology Cockpit software) to small labs and groups of 10 to 15 pathologists at a low entry cost," he explained. "Those small pathology labs and smaller pathology groups will be able to use other low-cost, non-FDA approved scanners that they can self-validate for primary diagnosis.

"Once the Omnyx deal was done but before it was announced, I thought it was important for me to meet personally with Omnyx's largest customers in Canada and Europe," Sanan said.

"I asked each one of these customers about the Omnyx system. I wanted to know what they liked and what they didn't like," he continued. "I wanted to find out what the pain points were. I learned that they love the Dynamyx software and they want to continue using that software. I also learned that they want someone to honor their existing contracts and continue to deliver on the original promise.


Satish Sanan

➤"In the near future, we will offer a converged software-as-a-service solution... to small labs and groups of 10 to 15 pathologists at a low entry cost."

"These labs made a significant investment of millions of dollars in hardware and software and they didn't want that money to go to waste," he said. "Also, they didn't want to start over with a new digital pathology vendor. They wanted to retain the systems they were using.

Hardware-Agnostic

"It turns out, that their needs fit the Inspirata business model because we are hardware agnostic," he concluded. "Omnyx customers can keep their IT hardware and Dynamyx software, and we'll replace and sunset the Omynx VL120 scanners and support that investment going forward."

Inspirata was profiled in a story published in the July 13, 2015, issue of THE DARK REPORT. That story can be accessed at *www.darkreport.com*. TDR

—Joseph Burns

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Lab Market Update

Strategies to Offset Medicare Cuts to Be Shared at Exec. War College

Other sessions will focus on getting paid for more lab test claims, test utilization, and adding value

DEEP PRICE CUTS to the Medicare Part B Clinical Laboratory Fee Schedule was the big story of 2017. The big story of 2018 may be the widespread financial disruption to the clinical lab industry as labs see dramatic declines in their revenue from these Medicare fee cuts.

One early opportunity for lab administrators and pathologists to understand the full scope of these Medicare price cuts will happen in New Orleans on May 1-2. That's when the 23rd annual *Executive War College on Lab and Pathology Management* will bring together 100 speakers in more than 60 sessions.

Front and center at the *Executive War College* will be two aspects of the Medicare fee cuts. First will be reports from major lab organizations and the nation's largest lab billing and collection companies as to the precise declines in lab revenue they are tracking. This will be the first opportunity for the lab managers to assess the cumulative impact that Medicare price cuts have had nationally during the four months since they became effective.

Negative Financial Effect

Second will be sessions led by labs and lab billing companies to share which strategies are proving most effective at offsetting the negative financial impact of the Medicare fee cuts. This is essential knowledge that every lab can use, since the need to reduce costs by enough to offset the lost revenue from the Medicare price cuts is essential for labs to stay financially viable.

Other equally significant issues will be addressed this year. For example, multiple sessions will deal with effective ways to get paid for lab test claims. Contracting with insurers to win network status and the most effective ways to successfully appeal denied claims will be discussed. Other sessions will focus on responding to tougher payer audits.

Prior-Authorization Programs

Another major issue is the expanded use of prior-authorization programs by major insurers and the growing influence of laboratory benefit management companies. These subjects will be covered in several sessions and will be of particular interest to labs that perform molecular and genetic tests.

The positive opportunities for clinical labs and pathology groups to grow, improve profitability, and deliver more value will be discussed by multiple speakers. One aspect of this is how labs add value by working with physicians to improve the utilization of lab tests. There are exciting breakthroughs in this aspect of clinical laboratory operations.

Because space is limited, it is recommended that lab executives register early. Confirmed sessions and speakers are posted at *www.executivewarcollege.com.* TDR

NILA: CLIA Proposal Doesn't Address Flaws

Areas needing attention include the proliferation of waived tests, number of analytes for PT tests

CEO SUMMARY: For many years, NILA has urged the federal Centers for Medicare and Medicaid Services to make significant changes in CLIA regulations. Yet, in its recent request for information, CMS addressed five specific areas. But the federal agency left out the need for a comprehensive overhaul of the CLIA regulations in other areas, including adding more analytes requiring proficiency testing and the proliferation of waived tests, according to NILA Administrator Mark Birenbaum.

WHEN PREPARING COMMENTS ON PROPOSED changes to the CLIA regulations, per the recent request for information (RFI), clinical lab directors might want to mention that the proposed revisions do not go far enough, recommended Mark Birenbaum, PhD, Administrator of the **National Independent Laboratory Association.**

Comments are due to the federal **Centers for Medicare and Mediciad Services** by March 12. While CMS has made minor changes in the past 26 years, the RFI is the first time since 1992 that CMS has sought to revise the rules significantly. *(See "After Two Decades, CMS Wants to Update CLIA Lab Regulations," TDR, Jan. 22).*

Urged To Make Changes

For many years, NILA has urged CMS to make several significant changes in its CLIA regulations. Yet, when CMS issued proposed revisions in a request for information published in the *Federal Register* on Jan. 9, none of the changes that NILA requested were included, Birenbaum said in an interview with THE DARK REPORT.

"In this proposal, CMS will consider only five areas for revisions, and these five areas are not nearly as important as some other areas they don't even mention," Birenbaum said. "Lab directors should be aware that CMS is considering some changes to the CLIA regulations but not a comprehensive overhaul.

"The RFI does not address such issues as proficiency testing and the need to update and revise the list of analytes subject to CLIA's PT requirements," he added. "A second significant area of concern involves the proliferation of waived tests.

"I was on a CLIA steering committee before CMS drafted the 1992 CLIA regulations," he said. "When the 'waived, moderate complexity, high complexity system' was first considered, only eight tests were in the waived category. At the time, no one envisioned there would eventually be thousands of waived test systems."

In the RFI, CMS also is considering revisions to personnel regulations, proficiency testing referral, histocompatibility regulations, and fees that labs pay to keep the CLIA program running. About those

fees, Birenbaum urged lab directors to request that CMS publish annual financial reports for the CLIA program. These fees should not generate a significant surplus, he added. *(See sidebar on page 26.)*

Use this link to view the RFI: *https://tinyurl.com/ydcve85k*.

More Alternative Sanctions?

"One significant issue that CMS overlooked involves the consequences when one lab refers PT specimens to another lab," he explained. "Labs know they can't do that. If they do, they could lose their CLIA certificate.

"In 2012, CMS adopted alternative sanctions for moderate and high-complexity labs," he added. "In the RFI, CMS said it is considering alternative sanctions for certificate-of-waiver labs. That sounds reasonable, because CMS should be able to apply alternative sanctions to all labs. Under current CLIA regulations, however, most certificate-of-waiver labs aren't required to do PT. So, this seems to be a solution in search of a problem.

"What's more, CMS is overlooking the bigger issue regarding PT, which is that CMS has not updated the list of analytes covered by PT since 1992," noted Birenbaum. "Everyone knows the list of analytes most labs use has changed substantially in the past 26 years.

Additions To PT Analyte List

"The fact that the RFI left out the issue of updating and revising the list of analytes in the PT program is surprising because not long ago, CMS invited PT providers to a meeting about updating the analytes subject to CLIA-required proficiency testing," Birenbaum explained. "Along with other PT providers, we attended, but nothing happened, and this is not mentioned in the RFI. CMS needs to decide which additional analytes need to be included in PT requirements.

"Another area that needs updating is the proliferation of waived tests and the fact that the certificate-of-waiver labs don't have to do PT," he said. "PT is not required under CLIA for certificate-of-waiver labs, although a few states have laws requiring it. Thus, the great majority of certificate-of-waiver labs don't have to do PT.

"Why is this important today?" asked Birenbaum. "When CLIA regulations were issued in 1992, there were eight waived tests. Now, there are close to 200 waived analytes, and the number of waived test systems is in the thousands and growing.

"That means there is no PT data on these systems before they are waived," Birenbaum warned. "Time and again, we've advised CMS that it needs to gather data on how these devices and instruments work in the field before they are waived.

Many Proposals; No Results

"Many times, we've made proposals to CMS about how this could be done," he added. "We've suggested that CMS require two to three years of proficiency testing data. CMS would designate these instruments and systems as moderate complexity, at least initially. Moderate complexity tests require PT.

"Then, if the PT data is excellent, CMS could designate the instrument as waived," he said. "But if there's significant variation and the PT data isn't excellent, CMS could keep that instrument in the moderate complexity category and continue to gather PT data.

"That way CMS would have some idea about how those instruments and systems perform in the field. That's just common sense," he added.

"After gathering two to three years' worth of data on how these systems work as moderate complexity tests, CMS would have enough PT data," he explained. "With that amount of data, CMS would know whether to designate those instruments and systems as waived.

Lab Lawsuit Involving NY State Lab Fees Shows Reason for Increased Caution on CLIA Fees

BEFORE LAB DIRECTORS provide meaningful comments about CLIA fees, they need to know how the federal Centers for Medicare and Medicaid Services accounts for the fees it collects, stated Mark S. Birenbaum, PhD, Administrator of the National Independent Laboratory Association (NILA).

In a request for information CMS published last month, the agency asked for comments from lab directors and pathologists about the fees labs pay to keep the CLIA program running. Birenbaum suggests that labs should have information about the finances of the CLIA program before they submit comments in response to the RFI.

"CMS needs to publish the financial results from the CLIA program over the past few years. How much does it collect overall and how much is it spending?" he asked. "Is CMS making money or losing money on CLIA fees? If it's making money, how much is it making? If it's losing money, what activities are the most costly?

"Only when these details are known can lab directors comment on changes in fees," added Birenbaum.

In this argument, Birenbaum has the benefit of history. The RFI also seeks comments on CLIA compliance fees for laboratories holding a certificate of compliance or a certificate of accreditation, fees for revised certificates, follow-up visits, complaint investigations, and activities related to imposing sanctions.

In 2013, NILA won a multimillion-dollar refund for overpayment of fees charged to approximately 230 New York and out-of-state laboratories under the New York Department of Health's Clinical Laboratory Evaluation Program (CLEP).

"In New York, we sued the state Department of Health, which runs CLEP, three times and got $23 million back for our labs because New York overcharged on the CLEP program," he explained.

"The CLEP program was supposed to collect the money to run the inspection and certificate program in New York State but state officials had built up a surplus for which some of the expenses (at least $23 million) were not justified," he said. "The finances of the CLIA program should be much more transparent than New York's CLEP program was."

"Instead, as it stands today, the only performance data for these waived systems is primarily what the manufacturer supplies," Birenbaum said. "But manufacturers are producing that data under controlled conditions. Data from controlled conditions do not necessarily predict how that instrument or system will operate in the field in clinical settings.

"This proliferation of waived tests is a problem because it basically deregulates laboratory testing by allowing thousands of test systems to operate with no proficiency testing data at all," he commented.

"It's ironic that CMS says it now wants to make the penalties for certificate-of-waiver labs that refer PT specimens to other labs the same as the penalties for other labs, but CMS doesn't mention that most certificate-of-waiver labs are not required to participate in PT," he added.

"Here is why that is a big deal: CMS waived a **Theranos** test procedure before the surprise inspections at Theranos revealed problems there," stated Birenbaum. "To my knowledge, there was no PT data on the Theranos waived test before (or after) it was waived." **TDR**

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Because of the explosion in different payment systems, hospitals, physicians, and providers such as clinical laboratories are facing a new challenge: how to match a payment to a specific patient's service. *Modern Healthcare* writer Tara Bannow reports that, "back when most patients paid with cash or checks, most health systems relied solely on banks to handle their payment processing." Now, the proliferation of online and point-of-sale payments has complicated this process. When a provider doesn't properly apply the payment to a patient's account, it can create a credit issue for that patient.

MORE ON: *Payments*

Modern Healthcare said that, just between 2011 and 2014, online and point-of-sale payments grew from 2% of transactions to 11%. Merchant services firms like **Wind River Financials** of Madison, Wis., are resources that healthcare providers can use to process payments more quickly, accurately, and cheaply.

LACK OF FUNDING AT UK'S NATIONAL HEALTH SYSTEM?

In the United Kingdom, the **King's Fund**, an independent healthcare charity, says the **National Health Service** is more than halfway through its most austere decade ever. World Bank statistics reflect this: In 2009, the UK spent 9.8% of its GDP on healthcare; by 2014, it fell to 9.1%. A recent surge of flu patients has caused many UK hospitals to delay elective surgeries and wait times in emergency departments have lengthened significantly.

TRANSITIONS

- **Opko Health, Inc.**, announced that Gregory Henderson, MD, PhD, resigned as CEO of **BioReference Laboratories** in January. Prior to BRLI, Henderson had served at **Mount Sinai Health System**, **Pacific Pathology Partners**, **Harrison Medical Center**, **Ocshner Clinic Foundation**, and **Wilmington Pathology Associates**.

- Alberto Gutierrez, PhD, joined **NDA Partners** as an Expert Consultant. He previously served in numerous roles at the **Food and Drug Administration** during a 25-year career at the federal agency.

- Jonathan Sheldon is **Qaigen's** new Senior Vice President of Bioinformatics. Previously, he held executive positions at **Oracle**, **Translational Medicine**, **InfoSense, Confirmant**, and **Roche Products**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...how researchers at **Penn State Health Children's Hospital** have determined that microRNA in saliva could be used as biomarkers in point-of-care concussion testing during sports events. This is an example of how testing may move outside the core lab.

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

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 5, 2018.