Volume XXII, Number 13 Monday, September 14, 2015

How a Handful of Lab Companies Used Cardiology Tests to Scam $1 Billion from Government and Private Players!

PLUS... Meet the Richest Lab Sales Reps in the Lab Industry

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

Why Medicare Fraud Hurts Entire Lab Industry

IT'S THE $1 BILLION LAB FRAUD that no one realized had grown that big! In this special issue of THE DARK REPORT, you'll read about how the next chapter of the federal whistleblower lawsuit against three specialty cardiology labs and certain individuals has pulled the curtain open on what we think is the biggest case of laboratory fraud and abuse in the past 30 years.

Simply said, federal prosecutors allege in court documents that, between 2010 and 2014, the defendants paid illegal inducements to physicians totaling $80 million in exchange for lab test referrals. Court documents say that the labs filed false claims and were paid $500 million by the federal Medicare and Tricare programs!

If these allegations hold up in court, this is the biggest single case of lab fraud and abuse in the last 30 years. Plus, you can double that $500 million and make it a $1 billion fraud case. That's because, if these labs were offering inducements for Medicare patient referrals, they may have done the same for private patients. In fact, in this issue, you'll learn that two insurers have sued one of the lab companies and both insurers stopped paying claims submitted by this lab.

Also in this issue, we will also introduce you to the two richest sales reps in the lab industry. During the 2010 to 2014 period, they took distributions of $116 million from the company they founded that provided sales services to the labs named in the whistleblower lawsuits.

This is important news for all, particularly lab managers and pathologists who work in hospitals and health systems. Lawyers in these institutions are diligent in complying with federal and state anti-kickback laws. So their labs follow a conservative compliance policy.

But that is not the case with the handful of private lab companies that are always too willing to play fast and loose with compliance. Since they seldom are criminally prosecuted, they are willing to offer inducements to generate lots of revenue and the worst they think will happen is that, if the feds come after them, a civil settlement will result and they will pay back just a portion of the profits that resulted from their loose compliance practices.

Thus, if you would like to see the feds crack down on these aggressive business practices, it would be timely to let the Department of Justice know that you'd like to see swifter enforcement of federal law, along with tougher penalties. TDR

New Developments in $1 Billion Lab Fraud Case

Federal whistleblower case reveals details about what appears to be biggest-ever lab fraud

CEO SUMMARY: Court documents filed last month in the federal* qui tam *case against Health Diagnostic Laboratory, Singulex, Berkeley Heart Lab, BlueWave Healthcare Consultants, and several lab executives allege that the defendants used illegal inducements and kickbacks to file false claims and generate payments of $500 million from Medicare and Tricare. This money was paid in just 60 months, from 2010 through 2014. Add up payments to the defendants from private insurers—two of whom are suing HDL—and the total could be as much as $1.2 billion.

WOULD IT BE NATIONAL NEWS if only three healthcare providers used illegal physician inducements to generate more than $1 billion in payments from Medicare and private health insurers in just 60 months?

Of course it would! And if some of the same miscreants responsible for this billion-dollar healthcare fraud were involved in launching a new provider company that already generates criticism from competitors about its non-compliant sales and marketing practices, wouldn't that also be important news?

We think the answer to both questions is: Yes! In this special issue of THE DARK REPORT, you will read the nation's first comprehensive news coverage to explain how, between 2010 and 2014, three lab companies were able to take in between $1 billion and $1.2 billion from claims submitted to Medicare and private insurers that the federal government alleges were generated by offering thousands of physicians illegal inducements and kickbacks.

You will also learn the fascinating story of how two lab sales reps created a lab sales company that was paid $242.8 million during 2010 to 2014, and how that company distributed $116 million to those two individuals during the same period, making them the richest sales reps in the clinical lab industry.

This remarkable story does not stop there. You'll learn about evidence now surfacing in news stories that hints at how

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

some of the individuals accused of this wrongdoing—apparently having no fear of criminal prosecution from the federal government—may be involved in a brand-new lab company that specializes in the same cardiology tests that were at the heart of a still-unfolding whistle-blower case.

Big Whistleblower Case

The foundation to this story is the federal *qui tam* case that was filed by multiple whistleblowers and includes the following as defendants: **Health Diagnostic Laboratories, Inc.**, of Richmond, Virginia; Tonya Mallory, HDL's former CEO; **Singulex, Inc.**, of Alameda, California; **BlueWave Healthcare Consultants, Inc.**, of Hanceville, Alabama (the sales consulting company that marketed the testing services of HDL and Singulex), BlueWave's cofounders Floyd Calhoun Dent, III, of Columbia, South Carolina, and Robert Bradford Johnson of Hanceville, Alabama; and **Berkeley HeartLab** (no longer in business).

In September 2014, *The Wall Street Journal* used a front-page story to break the news about the federal investigation into those lab companies. Additional news coverage of ongoing developments means that many pathologists and lab administrators are aware that HDL and Singulex entered into settlement agreements with the federal government in April. Both companies denied guilt and agreed to upfront payments of $47 million and $1.5 million respectively, along with additional payments under certain conditions. *(See TDR, April 20, 2015.)*

Some Optimism At HDL

Following that settlement with the federal government, reports from inside HDL—which, at its revenue peak, dwarfed Singulex—indicated that the executive team there thought that they had weathered the storm. The belief was that, given the modest size of the settlement, HDL could survive financially.

But HDL was not prepared for what happened next. Following publication of the *WJS* story last Fall, HDL was sued by **Cigna Corporation** for $84 million. Now, within weeks of the settlement with the Department of Justice, HDL found itself being sued by **Aetna, Inc.**, for "tens of millions of dollars." Further, in court documents filed with HDL's Chapter 11 bankruptcy case in early July, it was reported that **UnitedHealthcare** had stopped paying HDL's claims.

Federal prosecutors claim that the three labs paid $80 million to physicians in the form of inducements, kickbacks, and other forms of illegal remuneration.

Outsiders then realized that HDL was in dire financial straits. Three of its largest payers had ceased to issue payment for HDL's lab claims. However, this financial stress was the result of HDL's own business actions.

The next chapter in the HDL story came on August 7. That's when the DOJ filed a whistleblower lawsuit against the defendants named above. Federal attorneys want a jury trial to recover money paid to HDL by the Medicare program, along with treble damages. At this time, there is no indication that the DOJ intends to press criminal charges against the individual executives named in this case.

The court documents reveal, for the first time, exactly how big the alleged fraud is. In the stories which follow in this issue of THE DARK REPORT, you'll learn that Medicare and Tricare paid $500 million to HDL, Singulex, and Berkeley, most of it in the years 2010 through 2014. In the lawsuit, the Department of Justices claims that the three labs paid $80 million to physicians in the form of inducements, kickbacks, and other forms of illegal remuneration in exchange for these lab test referrals.

THE DARK REPORT is the first national news source to understand and publish the ramifications of these disclosures. Assume that Medicare was 40% of HDL's business, for instance. That's a generous estimate. Medicare revenue is less than 20% of the payer mix for the national labs.

If HDL/Singulex/Berkeley were paid $500 million by the federal government, then it is probable that the three lab companies were paid $500 million to $700 million by private payers.

Add the two numbers up: It means the three labs were paid a total of between $1 billion and $1.2 billion by government and private payers—and most of that was during the 60 months beginning in 2010! Based on the allegations in the whistleblower lawsuit, this would be the single largest case of lab fraud in the past 30 years.

But the amazing news doesn't stop there. On pages 12-13, you'll read about the two richest sales reps in the lab industry. The federal lawsuit says that, between 2010 and 2014, HDL and Singulex paid BlueWave a total of $242.8 million for its sales consulting services. Dent and Johnson, the two owners, personally accepted $116 million in distributions from BlueWave during this same time!

Big Case Of Healthcare Fraud

In the simplest analysis, the defendants named in this *qui tam* lawsuit appear to have committed one of the biggest healthcare frauds in history, in one of the shortest time periods on record.

All of this matters to every pathologist and clinical laboratory profession in the United States. One of the biggest challenges in the lab industry today is getting payers—both government and private—to issue coverage guidelines and set reasonable reimbursement for new clinical laboratory tests.

Can the administrators of the nation's healthcare programs be blamed for acting slowly in their approval of new lab tests, when they see a handful of lab companies marketing tests in an abusive and fraudulent manner? A small number of bad players can give the entire profession of laboratory medicine a black eye.

The numbers do tell the story. There are 5,000 hospitals with labs in the United States. There are 3,200 anatomic pathology groups, most associated with a community hospital. Seldom are any of these laboratory organizations accused of fraud and abuse. One reason why is that the attorneys at their parent hospitals take a conservative approach to compliance with laws governing kickbacks and inducements.

Over the past 25 years, it has typically been lab companies funded by investors that have crossed the compliance line and found themselves facing enforcement action by a federal agency. However, as THE DARK REPORT has pointed out regularly over the years, both federal regulators and federal prosecutors have been both slow to take enforcement action and reluctant to bring criminal charges against the individual executives and physicians of lab companies widely-viewed by competitors as engaged in illegal sales and marketing practices.

HDL and Singulex paid BlueWave a total of $242.8 milion for its sales consulting services. Dent and Johnson, the two owners, personally accepted $116 million in distributions from BlueWave during this same time!

More details and analysis of this whistleblower case and associated developments are covered in the stories that follow. Lab professionals with insights and information about these companies and these matters are encouraged to contact our editor in confidence. TDR

True Health To Buy HDL Pending Court Approval

Lawyers representing whistleblowers say links between HDL and True Health may be inappropriate

CEO SUMMARY: This will be an interesting week in the ongoing saga of Health Diagnostic Laboratory. The judge in the bankruptcy case must review the sales auction and the winning bid of $37.1 million that True Health Diagnostics submitted. At least two lawyers representing whistleblowers in the federal case against HDL suggest that questions should be asked, given the public disclosure that True Health has relationships with one or more individuals involved in the federal government's case that alleges fraud by HDL and BlueWave Consultants.

IT WAS NO SURPRISE TO THOSE following the Chapter 11 bankruptcy action of **Health Diagnostic Laboratory, Inc.**, that the winning bidder in last week's auction to sell the lab company was **True Health Diagnostics LLC**, of Frisco, Texas.

On September 4, during the first phase of the auction, True Health was the initial low bidder, offering $32 million for "substantially all business assets of HDL," HDL said. At the time, HDL called True Health a "stalking horse bidder," because its bid was a floor for other bidders.

By the time bidding closed on September 10, sources told THE DARK REPORT that one more bidder stepped forward to force True Health to bid $37.1 million. The proposed sale is subject to the approval of U.S. Bankruptcy Court Judge Kevin R. Huennekens who will review the proposal this week.

The question remaining is whether the court will approve the sale given that some observers have said ties exist between **True Health** and HDL and individuals who have worked for HDL's former sales consulting firm, **BlueWave Healthcare Consultants Inc.** *(See the story that follows on pages 8-11.)*

HDL entered bankruptcy in June following a $100 million settlement in April with the U.S. Department of Justice, based on allegations that it had violated the Anti-Kickback Statute and the False Claims Act between 2010 and 2014. The DOJ was acting on reports from three whistleblowers who had knowledge of HDL's practices.

Insurers Bring Suits

After the DOJ settlement, one of the nation's largest health insurers—**Aetna, Inc.**—filed a suit against HDL, charging the lab company with fraud. Aetna stopped paying HDL's claims. HDL also got into a billing dispute with the nation's largest health insurer—**UnitedHealthcare**—and United stopped paying HDL's claims. Facing this drop in revenue, HDL filed for bankruptcy.

While HDL's current executive team wants the True Health sale to go forward, lawyers for two of the whistleblowers in the case said last week they would watch closely to see how the court reviews the ties between HDL and True Health.

"Regarding the purchase of HDL by True Health, I find it bizarre and troubling," said Niall McCarthy of **Crotchett, Pitre and McCarthy**. "I do not think it is appropriate that an entity with contacts to the defendants in a false claims case is allowed to purchase HDL, another defendant in the same false claims case." McCarthy represents Chris Reidel, former CEO of **Hunter Laboratories**, and a whistleblower in the HDL case.

Another lawyer who represents a whistleblower is Peter Chatfield of the law firm of **Phillips & Cohen LLP** of Washington, D.C. "The relationship between all of these companies involved with (True Health) will be something that could be challenged if it looks suspicious," said Chatfield who represents Michael Mayes, MD, an internal medicine specialist in Hilton Head Island, S.C. "This challenge could come either in the bankruptcy proceeding or if the government feels that a fraud is being committed through other means.

'People Are Watching'

"There are people watching to make sure that all the transactions involved in this case are as legitimate as possible," added Chatfield.

As noted in the story that follows on pages 8-11, court documents and news stories have identified that several individuals involved with HDL over the years are now associated with True Health. For example, The *Richmond Times-Dispatch* reported on September 4 that, in a deposition conducted by attorneys for HDL, it was determined that Jeffrey "Boomer" Cornwell, "who is identified in court filings as an 'agent and corporate officer' of True Health" was "formerly part of **BlueWave's** sales force" and a sales consultant for HDL.

Further, *Richmond Times-Dispatch* writer John Reid Blackwell reported last week that court documents show that True Health may have relied on sales personnel who once worked for BlueWave Healthcare Consultants, HDL's former sales consultant. HDL ended its relationship with BlueWave in January. HDL has said it believed a BlueWave executive recruited BlueWave salespeople to work for True Health, Blackwell wrote.

True Health's Investors?

An additional twist to this story is that there are rumors, as yet unconfirmed, that Cornwell or one of the principals in BlueWave may have invested in True Health or hold equity in the young lab company.

If true, this fact raises another interesting question. Since HDL has a $100 million lawsuit pending against BlueWave (whose countersuit against HDL for $200 million was dismissed), are Cornwell and BlueWave in a position to benefit if True Health was to become the owner of HDL? After the sale closes, would HDL withdraw its lawsuit against BlueWave?

It is also important for pathologists and lab administrators to understand that some aspects of the federal whistleblower case against HDL are still active. On August 7, 2015, the Department of Justice took the next step in the HDL case and officially intervened in the three separate whistleblower lawsuits. Court documents named Tonya Mallory, founder and former CEO of HDL; BlueWave Healthcare Consultants, including its two founders and owners, who are Floyd Calhoun Dent, III, and Robert Bradford Johnson; and **Berkeley HeartLab**.

These aspects to the HDL case present HDL's bankruptcy court judge with interesting issues to consider when he reviews the proposed sale of HDL to True Health this week. TDR

—Joseph Burns

Winning Bidder for HDL Connected to BlueWave

Cast of characters assembling at True Health has an interesting history with federal regulators

CEO SUMMARY: Events within the bankruptcy proceedings of Health Diagnostic Laboratory could be interpreted as setting the stage for the emergence of a laboratory company operated by executives—and marketed by a sales consultant—known to have had leadership roles in other lab companies accused by whistleblowers and the federal government of making illegal payments to induce physicians to refer lab tests to their respective lab companies. In that regard, some in the lab industry may consider this an example of history about to repeat itself.

IN WHAT MAY BE THE MOST BRAZEN GRAB of clinical laboratory assets in several decades, a small young Texas lab company with a 10,000 square foot lab facility is poised to purchase most of the assets of **Health Diagnostic Laboratory, Inc.**, of Richmond, Virginia, through an auction conducted by HDL and supervised by the U.S. Bankruptcy Court.

On Friday, the *Richmond-Times Dispatch* reported that, following the court-supervised auction, HDL had agreed to sell itself to **True Health Diagnostics, LLC**, of Frisco, Texas. To acquire "substantially all of the business assets of HDL," True Health will pay $37.1 million. *(See pages 6-7 for details of this sale.)*

This part of the HDL story has a surprise twist. A few colorful characters associated with HDL since its founding have been publicly linked to True Health. A company owned by at least one of these individuals has been sued by HDL in cases claiming damages of $80 million. Further, some of these people were named in the federal whistleblower case against HDL that alleged widespread fraud involving payment of inducements and kickbacks to physicians. And further, certain of these individuals were again named in a federal action that was filed on August 15, 2015, in a federal district court in Richmond.

HDL Sold To True Health

Thus, in an ironic development, HDL may be acquired by a small lab company that would thus be in a position to unwind the outstanding lawsuits against at least one of these individuals. Knowledgeable observers have stated that, because True Health appears to be associated with former associates of HDL, they would not be surprised to see True Health market its specialty cardiology tests to physicians using similar schemes that were alleged and described in the federal whistleblower case against HDL and **Singulex**.

If that were to occur, it would not be an unusual occurrence. Over the past two decades, at a handful of lab companies, certain executives willing to push compliance with federal and state laws have operated with little fear of criminal prosecution. It remains to be seen, however, if True Health Diagnostics will be operated in a manner that competing labs deem to be non-compliant with laws governing inducements, kickbacks, and medical necessity.

This story has two angles that pathologists and lab administrators should follow. The first angle involves the ongoing viability of HDL as an independent company under new ownership as it emerges from its Chapter 11 bankruptcy action.

It is uncertain how, given the pending sale of HDL, which of its liabilities it will be able to shed. Among those questions is whether the federal government will be paid the full amount of its civil settlement HDL signed earlier this year. The amount owed by HDL could be as much as $100 million.

HDL Sued by Aetna, Cigna

As if the federal case wasn't enough bad news, because of the federal investigation, HDL was hit with lawsuits from health insurance companies **Aetna** and **Cigna**. In their respective cases, both companies alleged that HDL waived patients' copayments, thus causing both health insurers to lose money and their ability to manage the costs of care patients receive.

In the lawsuits, Cigna seeks $84 million and Aetna seeks an unnamed sum (believed to also be in the tens of millions of dollars). While the suits are pending, it is believed that both companies have refused to pay claims submitted by HDL.

HDL also is having a dispute with the nation's largest health insurer, **UnitedHealthcare**. As a consequence, UnitedHealthcare has withheld millions of dollars in payment for blood-testing services, the *Times-Dispatch* reported.

In fact, some HDL employees have commented to lab industry colleagues that the first $47 million of the settlement to be paid to the federal government was an amount that HDL could handle. What put the lab company into bankruptcy court was when Aetna, Cigna, and UnitedHealthcare stopped paying HDL's claims. That put HDL in a cash-flow bind that is believed to be ongoing.

Further, HDL has substantial liabilities and financial obligations and it is still unclear how these will be resolved as part of the bankruptcy case. No one who has seen the bid documents for the auction has discussed this aspect of the sales process. It thus remains an open question as to how HDL will be operated following its probable sale to True Health.

The second angle involves the allegations that True Wave has relationships with the principals and ex-employees of HDL's former sales consultant company, **BlueWave Healthcare Consultants**. In January 2015, HDL terminated its business relationship with BlueWave, then sued the lab sales company. BlueWaves' countersuit against HDL for $200 million was dismissed. It then apparently began competing against HDL.

The *Times-Dispatch* obtained documents from the HDL lawsuit that appear to connect BlueWave's owners with True Health. In a story published September 4, the newspaper wrote that:

> *True Health has links to HDL's former contract sales provider, Alabama-based BlueWave Healthcare Consultants, and it has employed former sales representatives for BlueWave. HDL got the court's permission to conduct depositions of Robert Bradford Johnson, one of the co-founders of BlueWave, and Jeffrey "Boomer" Cornwell, who is identified in court filings as an "agent and corporate officer" of True Health and formerly part of BlueWave's sales force.*
>
> *HDL terminated its contract with BlueWave in January, prompting BlueWave to sue HDL for what it claimed was millions of dollars in unpaid sales commissions. BlueWave and its co-founders are now being sued*

by the federal government for the firm's alleged role in the kickback scheme, in which physicians were paid fees to send blood samples to HDL's labs. Tonya Mallory, HDL's co-founder and former chief executive officer, also is being sued.

HDL said in court filings that it believed True Health and Cornwell may have interfered with its business relationships with physicians and with a supplier for one of its blood tests.

According to the filing, Cornwell offered employment to other members of BlueWave's sales force, who had been representing HDL, to sell lab tests on behalf of True Health. "These individuals had access to the debtor's (HDL's) confidential and proprietary information," according to the court filing.

HDL said in its court filing that it had reason to believe that Cornwell had been "spreading misinformation to physicians and physician practices who have established relationships with the debtors (HDL) that such [medical] practices should order testing services through True Health because the debtors will be out of business within a few months.

HDL also said it believed Johnson [Robert Bradford Johnson, a co-founder of BlueWave] participated in a trade show as a representative of True Health in violation of a consent agreement with HDL.

Collaboration with Lab Buyer

These news reports seem to confirm that individuals with some sort of past or current association with BlueWave are collaborating with True Health, the lab company now positioned to purchase HDL.

Even physicians who were formerly clients of HDL and allegedly paid consulting fees by HDL are popping up in this story. For example, Sam Fillingane, DO, is a physician who has referred patient specimens to HDL and provided paid consulting services to HDL. He is listed as the Chairman and Director of Medical Education at True Health Diagnostics. He to owns and operates the **Fillingane Medical Clinic**, a "cardiovascular risk reduction clinic" in Flowood, Mississippi.

Fillingane's LinkedIn profile shows that he previously worked at HDL and Singulex. In April, HDL and Singulex reached settlement agreements with the federal Department of Justice involving alleged violations of the Anti-Kickback Statute and the False Claim Act. They both agreed to pay money to the federal government but admitted no guilt.

Last year, *The Wall Street Journal* reported that Fillingane was the highest-paid doctor on HDL's list of doctors receiving money from Medicare as a result of referring patients' specimens to HDL.

Third Angle To Watch

If there is a third angle to watch in this case, it is whether any of the principals named in the case involving HDL and BlueWave will face criminal prosecution and possible jail time. That remains an open question. On August 7, the federal government filed court documents and officially intervened in the three separate whistleblower cases that were the basis of the civil settlements last spring involving HDL and Singulex.

In court documents, federal prosecutors named as defendants: Tonya Mallory, founder and former CEO of HDL; BlueWave Healthcare Consultants, along with its founders and owners, Floyd Calhoun Dent, III, and Robert Bradford Johnson; and **Berkeley HeartLab**.

The federal government is not pursuing criminal charges against the defendants. Rather, the government is asking for a jury trial and wants to recover the funds paid by Medicare and Tricare, along with treble damages.

The attorneys from the Department of Justice who have been involved in this case are: From Charleston, South Carolina, Assistant U.S. Attorneys James C. Leventis Jr., and Jennifer J. Aldrich.

From the Civil Division of the DOJ in Washington are Attorneys Michael D. Granston, Patricia L. Hanower, Elizabeth Strawn, Mary Chris Dobbie, and Michael Edmund Shaheen.

Medicare False Claims

The scale of the alleged fraud is staggering. In the court documents, federal prosecutors described the allegations and said that, "These kickbacks resulted in false claims submitted to Medicare and Tricare which caused the federal government to pay more than $500 million ($500,000,000) to Berkeley HeartLab, HDL, and **Singulex**."

In the past 25 years, pathologists and lab administrators have heard many stories about fraud and abuse. But for just three lab companies to suck $500 million from the two federal health programs in the five- to seven-year period described in the court documents is unprecedented.

Further, for the majority of clinical labs in the United States, Medicare business typically makes up no more than 20% to 40% of annual revenue. Thus, it can be estimated that private insurers paid another $500 to $700 million to these three lab companies during those same years. The scale of this alleged lab fraud makes it easy to understand why Aetna and Cigna have filed lawsuits against HDL.

The huge size of this case makes it all the more curious why the federal prosecutors seem reluctant to pursue criminal charges against the defendants. After all, U.S. Attorney Paul J. Fishman in New Jersey prosecuted the **Biodiagnostic Laboratory Services** case and got criminal guilty pleas from 34 lab managers and doctors who accepted the lab's inducements. To bring criminal charges against this group of defendants and the physicians who accepted the money would send a strong message to the entire lab industry and all physicians across the nation. **TDR**

—Joseph Burns

True Health Is New Lab With Links to Ameritox

VETERAN LAB INDUSTRY EXECUTIVES are asking questions about True Health Diagnostics, LLC, of Frisco, Texas, now that it has surfaced as a buyer prepared to pay $37.1 million for Health Diagnostics Laboratory.

True Health is a new lab company and launched clinical testing services in the fall of 2014. Its CEO is Chris Grottenthaler, who was the Vice President of Finance at **Ameritox** between May 2006 and December 2011. The Senior Vice President of Sales and Marketing is Carol Nellis. She also worked at Ameritox, from August 2006 through April 2013.

In a federal whistleblower lawsuit against Ameritox, The Department of Health and Human Services wrote that Ameritox "paid kickbacks to induce its physician clientele to refer drug testing services to the lab that were reimbursable by Medicare... the settlement resolves allegations that the Baltimore-based company made cash payments to physician clients to induce referrals from January 1, 2003, through December 31, 2006, and that the laboratory testing service offered collector personnel at no cost to the lab's physician clients in order to induce referrals from January 1, 2003, through June 30, 2010." To settle the case, in 2010 Ameritox paid $16.3 million and did not admit guilt.

This means that Grottenthaler and Nellis both worked at Ameritox during the years when the toxicology company is alleged to have paid illegal inducements to physicians. Further, these two lab executives, now at True Health, are, according to news stories, doing business with Jeffery "Boomer" Cornwell and possibly also the BlueWave sales consulting company. Court documents allege that Cornwell and BlueWave participated in HDL's schemes to illegally induce physicians to refer tests to HDL.

These facts are why some in the lab industry are asking if these "fellow travelers" have come together at True Health with the intent to use a variety of inducements to win lab test referrals from physicians.

Meet Richest Sales Reps In Lab Testing Industry

Believe it or not! Feds say BlueWave was paid $242.8 million by HDL and Singulex

CEO SUMMARY: Without much fanfare, two individuals who had been sales representatives at Berkeley HeartLab as late as 2009, took distributions of $58 million each between 2010 and 2014 for their sales consulting services at BlueWave Healthcare Consultants, according to allegations in the federal lawsuit that was filed against BlueWave and three heart testing lab companies on August 7. If true, that makes Floyd Dent, III, and Robert Johnson the richest sales reps in the lab business.

IT'S TIME TO MEET THE TWO RICHEST SALES REPS in the clinical laboratory industry. The estimate of their wealth does not come from the list of the *Forbes* Richest 400. Rather, it comes from the **U.S. Department of Justice**.

The two individuals are Floyd Calhoun Dent, III, of Columbia, South Carolina, and Robert Bradford Johnson of Hanceville, Alabama. They are the cofounders of **BlueWave Healthcare Consulting, Inc.**, based in Hanceville.

Dent, Johnson, and BlueWave also are defendants in the federal *qui tam* (whistleblower) lawsuit that is continuing in Richmond, Virginia. Other defendants are **Health Diagnostic Laboratory** and its CEO, Tonya Mallory, **Singulex**, and **Berkeley Heart Lab** (no longer in business). *(See pages 15-22 for details of lawsuit.)*

Dent and Johnson contracted with HDL and Singulex to provide laboratory sales services through BlueWave. In the federal lawsuit, prosecutors claim that the defendants paid illegal inducements to encourage physicians to order medically unnecessary tests. The lawsuit said that during the years 2010 through 2014, HDL and Singulex paid BlueWave $242.8 million. ($223 million from HDL and $18.6 million from Singulex).

The court documents also say that, during this same period, BlueWave distributed "at least" $116 million to Dent and Johnson. Each individual received $58 million for the 60-month period ending in 2014! *(See sidebar on next page.)*

Fast-track To Riches

What makes this story intriguing is that, at the end of 2009, both Dent and Johnson were simply journeyman sales reps at Berkeley Heart Lab (a defendant in the federal lawsuit, but no longer in existence). Thus, the tale of how these two generated a quarter of a billion dollars in revenue at BlueWave Healthcare—and kept half for themselves—hints at the unimagined size of the fraud that is alleged in the federal whistleblower lawsuit.

Not much is known about Dent and Johnson. They and BlueWave have been under federal investigation for at least two years and there is not much personal information about them that exists in the public domain or on the Internet.

THE DARK REPORT has learned some facts about the careers of Dent and Johnson, however. Dent is a graduate of the **U.S. Naval Academy**. He worked in sales at **Pfizer**, **Aventis**, and **Sanofi-Synthelabo**. Around 2005, he joined Berkeley HeartLab as a sales representative. He worked there until the end of 2009, when he left to found BlueWave with Johnson.

Johnson is a graduate of **Auburn University**. He held sales positions at **Merck** and **Takeda Pharmaceuticals** through the 1990s. In 2001, he began working as a sales representative for Berkeley HeartLab, a position he held until leaving at the end of 2009. That's when Johnson and Dent cofounded BlueWave.

Biggest Lab Fraud Ever?

The magnitude of the fraud described in the whistleblower lawsuit has no precedent in the clinical laboratory industry. Federal prosecutors say that HDL, Singulex, and Berkeley were paid $500 million by the Medicare and Tricare health programs, most of it coming between 2009 and 2014.

There is another significant point to emphasize about the $116 million that went to Dent and Johnson. Even the after-tax amount that remains gives them ample financial capability to finance their own way back into the lab business. With such big profits to be made from their sales schemes, why wouldn't they?

This is also why there are ongoing rumors that individuals associated with BlueWave Healthcare Consultants are the source of the funding that launched True Health Diagnostics during the past 18 months. These rumors are unconfirmed, but the Richmond newspaper has published information that identifies Johnson as some type of marketing agent for True Health. Also, onetime employee of BlueWave, Jeffrey "Boomer" Cornwell, has been identified as "an agent and officer of True Health." TDR

BlueWave Paid $242 M, Owners Took $116 M

DOCUMENTS FILED ON AUGUST 7 as part of the federal whistleblower lawsuit have specific details about remuneration paid to the defendants. For the years 2010 through 2014, the U.S. attorneys claim the following about the payments to BlueWave Healthcare Consultants and its two owners, Floyd Calhoun Dent, III, and Robert Bradford Johnson:

> *Furthermore, BlueWave, Johnson, and Dent knowingly and willfully **solicited and received remuneration, totaling more than $223 million**, that was meant to induce them to arrange for or to recommend the purchasing or ordering of HDL's tests that might be paid for in full or in part by federal health care programs.*
>
> *From 2009 through July 2014, HDL collected approximately $333 million from Medicare and Tricare related to claims that were tainted by the processing and handling fees. Mallory's salary and bonuses were directly tied to HDL's profits, and she personally collected at least $26 million in salaries, bonuses, and stock distributions between 2009 and 2014. Between 2010 and 2014, **BlueWave received commission payments from HDL totaling more than $223 million**. Between 2010 and 2013, **BlueWave received commission payments from Singulex totaling more than $18.8 million**.* [Boldface by THE DARK REPORT.]
>
> *As joint owners of BlueWave, Johnson and Dent each received 50% of all net profits generated from BlueWave's improper contracts with HDL and Singulex. Upon information and belief, **the government estimates that Johnson and Dent <u>each</u> received at least $58 million from BlueWave distributions**.*

Regulatory Update

Isn't It Time for More Criminal Prosecutions of Lawbreakers?

Too many civil settlements without criminal charges leave some lab executives without fear of consequences

WILL FEDERAL PROSECUTORS BE PLAYING ANOTHER ROUND of the game "whack a mole" with some of the same principals and clients of **Health Diagnostic Laboratory** and **Bluewave Healthcare Consultants?** These are individuals who figured prominently in the ongoing federal whistleblower cases alleging fraud, kickbacks, and unnecessary testing at the lab company based in Richmond, Virginia.

What raises this issue is the possibility that certain of these individuals may be involved in a complicated scheme to regain control of HDL—now in Chapter 11 bankruptcy—through a sales auction being conducted by the bankruptcy court handling HDL's case. *(See pages 6-7 and 8-11.)*

This development will be of interest to those lab professionals who have been frustrated by the lack of effective enforcement of anti-kickback and fraud statutes by federal and state prosecutors over the past two decades. In the absence of firm enforcement of these laws, certain lab companies willing to push compliance limits have captured large volumes of specimens and generated unmatched amounts of profit.

This double standard could only exist because federal healthcare officials seem reluctant to regularly bring cases against certain lab companies widely viewed by most lab professionals as systematically violating federal laws governing inducement, kickbacks, and medically unnecessary testing.

As a result, inconsistent federal enforcement gave these same lab companies confidence that they could operate in this fashion. The principals running these lab companies had little to fear from the government. Seldom were criminal or civil cases originated by federal prosecutors in past years. Thus, these individuals saw little risk in operating as they did.

Why So Few Criminal Cases?

In those cases where a whistleblower had the federal government join his or her case, the Department of Justice typically has been willing to accept a civil settlement where the offending lab company—without acknowledging guilt or innocence—agrees to stop the alleged fraudulent activity. The disappointing aspect to these civil agreements is that the amount paid by the defendant lab was frequently much less than the total profits earned from the alleged fraudulent schemes!

Having observed this lack of strict enforcement of federal and state laws, these individuals are willing to push their inducements to physicians to the extreme. How else could a lab firm founded in 2008, grow to almost $380 million in annual revenue by 2013, while paying out what federal prosecutors claim was $80 million in illegal payments to physicians for lab test referrals? Maybe it is time to put fear of jail time back into the minds of those lab executives willing to bend the law past its breaking point. TDR

Feds Show How Labs Took $500 Million from Medicare

In addition, private health insurers are estimated to have paid three labs another $500 to $700 million

CEO SUMMARY: In this second phase of the whistleblower case against three cardiology testing labs and a sales consulting company, federal prosecutors are requesting a jury trial against the individuals named in the court documents filed August 7. Federal investigators alleged that executives at one lab began a fraud scheme in 1999 and then expanded that scheme to other labs over 15 years. The suit claims that the labs made improper payments to referring physicians.

FEDERAL PROSECUTORS HAVE PROVIDED A DETAILED LOOK at how three lab companies managed to defraud two federal healthcare programs out of $500 million in just a few years.

A half-billion-dollar lab scam is huge, but that amount is just half the story! These same three companies were paid $500 million to $700 million more by private health insurance companies during these same years. Add the Medicare and private insurer payments together, and that's a fraud totaling $1 billion to $1.2 billion!

$80 Million Paid To Doctors

Federal prosecutors allege that the three defendant lab companies paid $80 million in various forms, such as handling and processing fees, to physicians to generate the $500 million in payments from Medicare and Tricare payments.

But there's something more startling to this story. In addition to those payments to physicians, court documents say that the labs paid an amazing $223 million to their sales consultants, **BlueWave Healthcare Consulting**!

THE DARK REPORT is first to report the additional aspects of this federal investigation into the activities of **Health Diagnostic Laboratories**, **Singulex**, and **Berkeley HeartLab** (no longer in operation). In settlements to date, HDL and Singulex have both denied guilt and signed agreements that include some repayment to the federal government.

The huge dollars involved in these schemes is unprecedented for the clinical lab industry. Pathologists and lab administrators should understand what these three lab companies did for an important reason. Lab fraud on this scale is what causes payers to react with restrictive coverage guidelines.

As this happens, honest labs are handcuffed and find it impossible to provide a wide range of medical laboratory tests that improve patient care and are clinically useful. As a consequence, the lab industry's handful of scoundrels not only cheat the government and private health insurers, but they also negatively affect patient's access to many useful clinical laboratory tests.

To help lab executives understand the key details of the inducements, kickbacks, and other schemes alleged in the court documents filed by federal prosecutors, THE DARK REPORT is providing the following analysis of the case.

Overview Of The Case

This information comes from the lawsuit filed on August 7, 2015, in the United States District Court of South Carolina–Beaufort Division. Federal prosecutors are asking for a jury trial to recover funds, including treble damages, from these defendants: Berkeley HeartLab, Inc., BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, Robert Bradford Johnson, and Tonya Mallory. BlueWave is the sales consulting firm, and Dent and Johnson are the owners of BlueWave.

Mallory is the former president of Health Diagnostic Laboratories. The Medicare and Tricare programs paid the $500 million to Berkeley, HDL, and Singulex. Berkeley is no longer in business. (It was acquired by **Quest Diagnostics** and was closed.) HDL and Singulex have settled with the DOJ.

Payments To Physicians

Federal court records show that by offering or paying $80 million in improper processing and handling fees, the defendants in lab-billing schemes from 1999 through last year netted false claims totaling $500 million that the Medicare and Tricare programs paid. The federal Department of Justice explained in detail the extensive case it built against two blood-testing labs, two sales consultants, and a lab executive.

In the 48-page complaint, the DOJ explained how the sales consultants and the lab executive worked with the two labs to offer kickbacks to referring physicians in violation of the Anti-Kickback Statute and to generate false claims to the Medicare and Tricare programs in violation of the False Claims Act.

What follows are details taken word for word from the federal complaint. These have been lightly edited only for style and clarity.

Sham Processing Fees

Processing and handling fees were part of the scheme, described as follows:

From January 2010 through July 2014, Defendants BlueWave, Johnson, Dent, and Mallory conspired to offer, arrange for, and provide remuneration to physicians to induce referrals of blood testing to HDL and Singulex, including testing that was reimbursed by Medicare and Tricare. As with Berkeley, the remuneration was in the form of sham processing and handling fees and the waiver of Tricare copays and deductibles.

Berkeley, HDL, and Singulex are clinical laboratories that specialize in cardiovascular health and advanced lipid testing. Advanced lipid tests are generally more expensive than basic cholesterol and blood tests and often result in significantly higher profit margins for the laboratories that provide such tests. For instance, Medicare pays HDL well over $1,000 when physicians refer a patient for HDL's Initial Comprehensive CVD Baseline Assessment panel. Further, Medicare pays HDL over $600 for every CVD/Metabolic Follow-Up Profile that is referred—a panel that many HDL customers [physicians] ordered four times a year for each of their patients who received such testing.

Lipid Test Panel Profits

The following statements from the court documents describe how the profit margins on lipid panels played a role in the lab's marketing schemes:

Partly because the profit margins on advanced lipid testing are so substantial and also because these specialized tests have such limited clinical utility and would normally only be ordered for a small percentage of the population, competing laboratories like Berkeley, HDL, and Singulex resorted to illegal kickback *schemes to poach customers from their rivals and to induce referrals from a substantially larger portion of the population than medically necessary.*

No later than 1999, Berkeley implemented a nationwide scheme to pay physicians and physician groups a kickback disguised as a draw fee for every sample referred to Berkeley's laboratories. Between 1999 and 2005, Berkeley induced referrals by paying physicians and physician groups a "draw fee" of up to $20 for every sample referred to Berkeley—a sum that far exceeded the $3 draw fee permitted by CMS.

Between 2005 and January 2012, Berkeley continued offering and paying processing and handling fees, albeit at the reduced rate of $7.50, with a few accounts receiving as much $11.50. The payment of processing and handling fees had the intended effect.

Physicians who received P&H fees from Berkeley made substantial referrals to Berkeley. For instance, in 2010, Berkeley paid Dr. Bodo Brauer tens of thousands of dollars in processing and handling fees in exchange for approximately $570,843 worth of referrals. Also in 2010, Berkeley paid Dr. Jeffrey Gladden tens of thousands of dollars in processing and handling fees in exchange for approximately $556,825 worth of referrals.

In 2009, Berkeley paid Dr. Rex Butler tens of thousands of dollars in processing and handling fees in exchange for approximately $384,366 worth of referrals.

Between 2005 and 2011, Berkeley paid approximately $6 million in processing and handling fees to physicians and physician groups nationwide in exchange for referrals yielding roughly $96 million in Medicare and Tricare reimbursement.

Illegal Sales Agreement

The design of the sales agreements was described in the court documents:

Furthermore, BlueWave, Johnson, and Dent knowingly and willfully solicited and received remuneration, totaling more than $223 million, that

Federal Prosecutors Summarize the Case

IN THE WHISTLEBLOWER LAWSUIT FILED ON AUGUST 7, 2015, FEDERAL PROSECUTORS succinctly presented a broad summary of the case against the defendants:

Between 2008 and 2010, Defendants Mallory, Johnson, and Dent—all of whom had worked for Berkeley—left that company and initiated their own kickback scheme. Mallory founded HDL, a specialty laboratory that offered the same or similar testing services as Berkeley. Johnson and Dent created BlueWave, which provided an outside sales force dedicated to marketing and selling HDL's tests and test panels. Later, BlueWave also became the outside sales force for another specialty lab, Singulex, which offered tests that were similar to those offered by Berkeley and HDL.

From 1999 through January 2012, Berkeley provided remuneration to physicians and physician groups to induce the referral of federal beneficiaries to Berkeley. Such remuneration was in the form of sham processing and handling fees and the waiver of Tricare copays and deductibles.

Berkeley provided this remuneration with the intent to induce physician referrals of blood testing for which Berkeley sought reimbursement through two federal health care programs, Medicare and Tricare, in violation of the AKS. Berkeley knew it was not entitled to reimbursement for claims arising out of this illegal scheme, and therefore submitted or caused to be submitted claims in violation of the FCA as well.

By paying kickbacks to physicians, Berkeley also induced physicians to order large panels of tests that included a significant number of medically unnecessary tests.

was meant to induce them to arrange for or to recommend the purchasing or ordering of HDL's tests that might be paid for in full or in part by federal health care programs.

On June 1, 2010, two months after entering into the HDL Sales Agreement, BlueWave, Johnson, and Dent executed a very similar sales agreement with Singulex. This agreement named BlueWave as Singulex's outside sales force. Mallory approved of the terms in the Singulex Sales Agreement. Pursuant to the Singulex Sales Agreement, BlueWave was paid a monthly commission of 24% of Singulex's revenue collected from sales generated by BlueWave as BlueWave's fee for arranging for or recommending to doctors that they refer patients' blood testing to Singulex.

The Kickback Scheme

How Singulex paid BlueWave Healthcare Consultants is described this way:

In return for the samples being referred, Singulex paid BlueWave approximately $153,883 in commissions in 2010. In return for the samples being referred, Singulex paid BlueWave approximately $3.1 million in commissions in 2011. In return for the samples being referred, Singulex paid BlueWave approximately $7 million in commissions in 2012. In return for the samples being referred, Singulex paid BlueWave approximately $8.2 million in commissions in 2013.

Touting Processing Fees

The court filing explained the arrangement for these labs to pay physicians for their lab test referrals:

In their sales pitches, BlueWave sales representatives touted how much more HDL paid in processing and handling fees than competitor laboratories were paying. For example, Leonard Blasko, an independent contractor working with BlueWave, met with a physician on January 27, 2012. During that meeting, Blasko not only went into great detail about the benefits of the $20 processing and handling fees, he also called up another BlueWave sales representative, Charles Maimone, who mentioned to the physician that he could get an additional $13 if he ordered a Singulex panel in addition to an HDL panel. The processing and handling fees took into account the volume and value of the business generated by the physician.

More Test Volume, More Pay

The labs were aggressive in using sales reps to build specimen referrals, described in the court documents in this way:

The more specimens the physician sent to HDL, the more money HDL paid the physician. Similarly, the more specimens the physician sent to Singulex, the more money Singulex paid the physician. BlueWave, Johnson, Dent, and Mallory promoted processing and handling fees to referring physicians as a revenue generator.

For instance, on June 16, 2010, a BlueWave sales representative emailed a potential client and explained: your "practice has the potential to draw close to 100 panels a week if we were to include all other insurances we were not able to include previously.

"Therefore, 100 panels a week would result in a revenue stream for the office of $2,000 (100 x 20 panels) per week. He added, "this would far outweigh any rent money an outside laboratory could legitimately compensate the office to assist in collecting blood specimens." For some physician practices, processing and handling payments totaled over $100,000 a year. For instance, from 2011 through 2012, HDL paid $234,740 to the Colorado Springs Family Practice in exchange for $1.7 million in Medicare referrals. In 2012, HDL paid $107,660 to Dr. Lawrence A. May in exchange for $1.1 million in Medicare referrals. From 2011 through 2012, HDL paid $185,840 to the Family Physicians of the Spartanburg practice in South Carolina in exchange for $4.7 million in Medicare referrals. From 2011

In Sales Agreement, BlueWave Sales Consultants Got Monthly Fee Plus Up to 19.8% of Revenue

BLUEWAVE HEALTHCARE CONSULTANTS HAD AN EXTREMELY LUCRATIVE SALES AGREEMENT with the two defendant lab companies. The lawsuit provided details of how this agreement benefited BlueWave and its owners, Floyd Dent and Robert Johnson, as follows

In April 2010, Mallory, on behalf of HDL, and Johnson and Dent, on behalf of BlueWave, executed a sales agreement, which was dated January 4, 2010, wherein BlueWave would serve as HDL's exclusive outside sales force in certain enumerated states: Alabama, South Carolina, Mississippi, Tennessee, Georgia, Florida, North Carolina, Louisiana, and Texas.

Also pursuant to the HDL Sales Agreement, HDL paid BlueWave a monthly base fee, plus a "commission equal to... 13.8% of the revenue collected by HDL from sales" in BlueWave's territory. For the 18 months beginning after September 30, 2011, BlueWave was to be paid an "Increased Commission" that was "equal to… 19.8% of the revenue collected by [HDL] from sales" in the same territory. For the remaining time, HDL paid BlueWave "a commission equal to 16.8% of the revenue collected by [HDL]." The Agreement also conveyed shares in HDL to Dent and Johnson as individuals.

Between January 2010 and January 2015, BlueWave and HDL performed under the HDL Sales Agreement, and, by January 2015, BlueWave served as a large, independent sales and marketing force for HDL in 47 states and the District of Columbia.

Indeed, BlueWave arranged for physicians to order 753,062 samples in 2012 and 868,381 samples from HDL in 2013. In return for the samples being referred, HDL paid BlueWave approximately $6.9 million in commissions in 2010. In return for the samples being referred, HDL paid BlueWave approximately $21.1 million in commissions in 2011.

In return for the samples being referred, HDL paid BlueWave approximately $74.4 million in commissions in 2012. In return for the samples being referred, HDL paid BlueWave approximately $67.1 million in commissions in 2013. In return for the samples being referred, HDL paid BlueWave approximately $54.1 million in commissions in 2014.

In other words, the more HDL tests that BlueWave, Johnson, and Dent's customers referred, the more money BlueWave, Johnson, and Dent would make. Between October 2009 and July 2014, Medicare and Tricare paid HDL approximately $333 million for tests referred by physicians who received processing and handling fees.

through 2012, HDL paid $189,237 to the Keowee Primary Care & Internal Medicine practice in South Carolina in exchange for $3.5 million in Medicare referrals.

Between 2010 and 2014, BlueWave, on behalf of Mallory and HDL, paid physicians and physician groups roughly $68 million in processing and handling fees. BlueWave, Johnson, Dent, and Mallory could afford to offer such high processing and handling fees because the defendants promoted the ordering of large panels of tests, many of which were medically unnecessary, [and] which generated substantially more revenue than ordering only those tests that were medically necessary for each patient. HDL promoted baseline and follow-up panels as well as panels customized for a specific doctor.

BlueWave, Johnson, Dent, and Mallory promoted HDL's "baseline" and "follow up" panels. In South Carolina the baseline panel included as many as 20 or more individual blood tests, including a *number of one-time genetic tests. The "follow up" panel was smaller and omitted the genetic tests, but still included as many as 15 or more tests. Depending on the patient, many of the tests ordered in the baseline panel and the follow-up panel were medically unnecessary.*

Large Panels Encouraged

Physicians were encouraged to order panels costing several thousand dollars, which the federal prosecutors described as:

In South Carolina, HDL billed federal health care providers as much as $3,000 to $4,000 per panel. Mallory, Johnson, Dent, and BlueWave encouraged physicians to order a follow-up baseline panel every three months. For the customized panels, BlueWave sales representatives met directly with the ordering physician and presented the physicians with "recommended custom panels" consisting of dozens of tests that would be ordered on every sample submitted to HDL.

BlueWave, Johnson, and Dent sent out periodic reminders to BlueWave sales representatives with instructions to "make a concerted effort" to add additional tests "to each of your customers panels," or with directives to push newer and more expensive tests such as the CYP2C19 test. Physicians were required to order multiple tests in order to get the processing and handling fees.

Patient CoPayments Waived

An essential part of the scheme was that the labs never charged patient copays, which is described as follows in the court documents:

For instance, in the aforementioned January 27, 2012, meeting between Blasko and a potential customer physician, the physician was specifically told that he could get the processing and handling fees only if he ordered the full panel. As another inducement, Mallory, Johnson, Dent, and BlueWave advertised HDL's waiver of copayments and deductibles for all patients, including Tricare patients. Defendants waived Tricare copayments and deductibles to induce Tricare patients to agree to testing by HDL and Singulex. The combined effects of the processing and handling kickbacks and the waiver of copays and deductibles kickbacks worked to generate millions of referrals and HDL's profits soared.

For example, HDL starting testing in the fall of 2009 and by April 2011 it was receiving approximately 7,000 blood samples a week. By November 2012, HDL was receiving over 28,000 samples a week. By 2013, hundreds of thousands of blood samples from physicians' offices across the country were arriving on a weekly basis.

There were so many blood samples coming in that HDL got its own Federal Express mailing code. See Richmond Times-Dispatch *article, 2/6/12. In February 2012, Mallory told the* Richmond Times-Dispatch*, "[w]e run about 60,000 tests a day. We have been growing at a rate of about 5% a week for the last 23 months." The scheme was so effective that HDL was able to poach at least 75 high-referring physicians from Berkeley within 12 months of implementing the scheme. Those 75 physicians referred $28 million in Medicare reimbursements to HDL in 2011 and 2012 alone. Mallory, Johnson, and Dent directly profited from the kickback scheme they instituted.*

From 2009 through July 2014, HDL collected approximately $333 million from Medicare and Tricare related to claims that were tainted by the processing and handling fees. Mallory's salary and bonuses were directly tied to HDL's profits, and she personally collected at least $26 million in salaries, bonuses, and stock distributions between 2009 and 2014. Between 2010 and 2014, BlueWave received commission payments from HDL totaling more than $223 million. Between 2010 and 2013, BlueWave received commission payments from Singulex totaling more than $18.8 million.

Physicians Paid On Volume

The result of encouraging doctors to order panels that included medically

HDL, BlueWave Encouraged Physicians to Order Large Numbers of Medically-Unnecessary Tests

IN THE COURT DOCUMENTS, defendants are alleged to have no reservations or concerns about inducing physicians to order medically-unnecessary tests. These actions were described as follows:

BlueWave, Johnson, Dent, and Mallory promoted that physicians run unnecessary genetic testing on all patient blood samples held by HDL in storage, which Mallory said "alone could result in almost a million extra for us." In one instance, Mallory wanted the CYP2C19 genetic test to be run on all of the stored blood from patients for a South Carolina physician "by the end of July so that the reimbursement will hit us in September when we will need it to pay our next settlement fees to [Berkeley]." BlueWave, Johnson, Dent, and Mallory also successfully encouraged physicians to include the CYP2C19 genetic test on the standard and custom panels that doctors submitted to HDL.

As a result, the CYP2C19 test was unnecessarily performed on thousands of patients despite the fact that its sole utility is detecting whether a patient has an extremely rare gene that makes the drug Plavix ineffective. The CYP2C19 test was performed on thousands of patients who were not and would not be taking Plavix.

Berkeley, BlueWave, Johnson, Dent, and Mallory knew of the remuneration, and at times directly and personally authorized the payment of remuneration in exchange for referrals of tests. Mallory approved, on a case-by-case basis, HDL's payment of a higher processing and handling fee for certain physicians in order to get them to switch to HDL from competitors. For example, Mallory approved a request from an HDL Account Manager to pay an increased processing and handling fee to a physician who requested to be paid more after speaking with a colleague who was also paid more than the established rate. According to the HDL Account Manager, the physician's colleague "was a prime example of a doctor who cranked it out when offered the higher [processing and handling fees]." Defendants knowingly attempted to disguise the illegal remuneration by calling it a "processing and handling" or "P&H" fee and encouraging the use of these phrases.

Johnson at one point told Mallory and Dent, "I want to refocus that this is an [sic] ph [processing and handling] *fee not a draw fee. One word makes it legal the other illegal." Defendants received emails from physician practices and their attorneys asserting that the processing and handling fees were kickbacks. Even though Defendants claimed that the processing and handling payments were just meant to reimburse the practice for the time spent processing and handling the blood samples, Mallory authorized and HDL paid some physicians directly rather than the physicians' practices. HDL also mailed checks directly to a physician's house rather than to his practice.*

unnecessary tests is described as follows:

As joint owners of BlueWave, Johnson and Dent each received 50% of all net profits generated from BlueWave's improper contracts with HDL and Singulex. Upon information and belief, the government estimates that Johnson and Dent each received at least $58 million from BlueWave distributions.

Defendants' kickback scheme induced physicians to order more tests than were medically necessary because the amount of the physician's remuneration was tied to the volume or value of business generated by the physician. For example, Berkeley encouraged Dr. Mayes *to order tests in pre-packaged "panels" rather than specifically choosing individual tests to run on each patient. These panels included genetic tests like the CYP2C19 "Plavix" test, ApoE, and KIF-6, and the hormone test NTproBNP, that are not appropriate for most patients.*

Processing Fee Incentives

An interesting element in the processing fee scheme is that multiple tests needed to be ordered for the physician to get the maximum "processing and handling" payment, explained in the lawsuit as:

BlueWave sales representatives, trained by Johnson and Dent, marketed processing and handling fees to physicians as an additional revenue stream. For example, a BlueWave sales representative in Maryland told a practice that it would receive "$20 per patient per draw" called a "process and handling agreement," which was "significantly higher than the typical $2.76 reimbursement." The sales representative explained further that "[a]s long as two or more tests are ordered" HDL would pay the practice $20 and so "[w]ith two offices and 10 providers you can see how much revenue this could create" for the practice. The BlueWave representative later forwarded this email to Mallory. BlueWave sales representatives in Nevada and Washington encouraged physicians to order more tests by putting together charts calculating how much "P&H Missed Potential" revenue a practice had. For one practice the missed projected revenue was $145,000 per year.

BlueWave sales representatives also promoted the additional revenue physicians could generate for follow-up office visits. They recommended follow up visits to review the test results for which the physician could "bill one level to two levels higher for the office visit… generating an additional $60 to $85 per patient… $546,000 per year." At the instruction of Johnson, Dent, and Mallory, BlueWave sales representatives sold potential clients by hyping the additional revenue stream those clients would reap from the processing and handling fees. BlueWave sales representatives even went so far as to provide mathematical equations showing how much extra a doctor would make each month by ordering certain numbers of tests. Berkeley, BlueWave, and Johnson encouraged sales representatives to target physicians that were "money hungry doctors." If a physician was not satisfied with just the processing and handling fee from HDL, BlueWave, Johnson, and Dent encouraged sales representatives to offer to send blood to multiple labs in order for the physician to get paid multiple processing and handling fees. For example, when one physician asked if HDL would pay him more fees per test, the BlueWave representative told the doctor that the doctor could get an additional $13 if he also ordered tests from Singulex, without even explaining the Singulex testing to him. Mallory, Johnson, and Dent were personally aware of this practice and encouraged the sales representatives to do it.

Lawsuit Provides Insights

The contents of the federal whistleblower lawsuit filed on August 7 provide a rare opportunity for those pathologists and clinical lab managers who find themselves competing against labs like HDL, Singulex, and Berkeley HeartLab. The excerpts from the lawsuit reproduced in this story allow pathologists and lab administrators to better understand how such lab companies develop and use different forms of inducements and kickbacks to persuade physicians to refer lab specimens.

In addition, the information provided by these court documents demonstrates how much money can change hands when a lab company decides to offer inducements that it probably recognizes may cross the compliance line into dangerous territory. The lab considers that the reward outweighs the risk of federal enforcement action. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is a new national group that has the goal of addressing diagnostic errors in medicine. It is called the **Coalition to Improve Diagnosis** and became operational last month. The new group was organized by the **Society to Improve Diagnosis in Medicine** (SIDM). Eleven organizations are already part of the coalition along with two government partners, which are the **Agency for Healthcare Research and Quality** (AHRQ) and the **Centers for Disease Control and Prevention** (CDC).

CLEVELAND HEART, CLEVELAND CLINIC, PROCTER & GAMBLE IN DEAL FOR TEST

Last month, a new business venture was announced. A collaboration involving the **Cleveland Clinic**, **Cleveland HeartLab**, and **Procter & Gamble** will work together to develop and commercialize a biomarker developed at Cleveland Clinic that can be used for diagnosis and management of heart disease. The role of Cleveland HeartLab will be to develop a diagnostic test that measures the level of TMAO (Trimethylamine-N-oxide) in the blood. TMAO is produced by gut bacteria and has been linked to heart disease.

MORE ON: *Heart Test*

Separately, Cleveland Clinic and Procter & Gamble are working together to develop an over-the-counter product designed to help manage TMAO levels. These relationships show how the trend of consumer-focused health services is gathering momentum.

TRANSITIONS

- Don Howard, MD, PhD, will resign as Chairman and CEO of **CellNetix**, based in Seattle, Washington, to pursue other interests. His resignation is effective on December 31. Howard joined **Washington Pathology Associates**, the precursor group to CellNetix, in 1986.

- **WaveSense** of Irvine, California, appointed William W. Curtis as CEO. Curtis held executive positions at **MedVentures**, **Strategicon**, and **CBLPath**.

- Sami S. Abbasi is the new President and CEO for **PhyMed Healthcare Group**, of Nashville, Tennesse. Abbasi previously worked at **American Pathology Partners**, **National Surgical Care**, **Radiologix**, **Stephens & Company**, and **Citicorp**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 5, 2015.

It's New!

Lab Quality Confab

and Process Improvement Institute

November 3-4, 2015 • Sheraton Hotel • New Orleans, LA

Bill Baker, CIO, TriCore Reference Laboratories:

Using Clinical Analytics to Optimize Lab Operations in Real Time

Innovative labs like TriCore are beginning to combine clinical analytics and sophisticated software to allow real-time analysis of lab operations. In this exciting session, you'll learn how adding clinical analytics into the mix creates new insights on ways to improve lab workflow, with the added benefit of also contributing to improved patient care. For example, TriCore now has the ability to assess incoming lab orders in real time and use that information to adjust staffing levels in advance of surges or declines in the volumes of specimens needing

Plan to be with us and guarantee your place by registering today.

For updates and program details, visit www.labqualityconfab.com

UPCOMING...

- ***Can Lab Testing Be Managed Like Pharmacy? New Blue Cross Program Will Test the Concept.***
- ***Tracking Down Systemic Sources of Errors: One Lab Engages Nursing and Gets Big Payoff.***
- ***First Reports of How Labs Are Handling the Long-Awaited Transition to ICD-10.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends