Volume XXV, Number 2 Monday, January 22, 2018

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

Pulling Aside the Curtain on Alleged Lab Fraud

IN RECENT YEARS, MANY CLINICAL LAB ADMINISTRATORS AND PATHOLOGISTS have looked with dismay at the increased fraud associated with the laboratory test referrals of office-based physicians. High-profile federal cases involving lab companies accused of fraud garner national headlines.

Small companies sending sales reps into physicians' offices, however, have changed the landscape in 2018 versus that of 1998 by offering myriad inducements for lab test referrals. Today, office-based physicians are inundated with visits from sales reps representing many different lab companies. A significant number of these lab companies are willing to offer doctors different inducements that labs with more rigorous compliance policies would view as violations of the anti-kickback statute and the Stark Law. Unfortunately, there are large numbers of doctors who are willing to accept these inducements or kickbacks. And, a significant number of physicians are motivated to inflate the amount of inducements they receive by ordering large numbers of medically unnecessary tests for their patients!

Given the hundreds—probably thousands—of small lab entities that now play in this sector of healthcare, it is a daunting challenge to investigate all the suspected cases of fraud, let alone initiate successful actions to shut these labs down or hold their owners and officers accountable for their actions.

Both federal healthcare prosecutors and private health insurers face this challenge every year. Federal cases have a high bar to meet to prosecute and convict criminal wrong-doing. Civil actions also must overcome serious challenges when private companies accuse labs of wrong-doing. For their part, private payers find themselves playing "whack-a-mole" with lab entities they believe are engaged in wrongful business practices. They can revoke billing privileges for one lab company and, days later, the same owners and officers are submitting claims under a newly-incorporated and newly-named lab entity.

To help lab administrators and pathologists understand this problem, we've spent more than a year researching just one lawsuit involving a national health insurer and a group of related healthcare companies, including numerous labs, named as defendants in multiple lawsuits. On pages 12 through 22, we have published the first results of this investigation. It is a complex story that deserves a careful reading. TDR

Former HDL CEO Mallory Sues Richmond Law Firm

Facing $1 billion in claims, Mallory seeks $150 million from legal adviser LeClairRyan

CEO SUMMARY: It's a case of the client turning on the law firm. The former CEO of Health Diagnostic Laboratory is suing the law firm that advised her and her lab company on major legal matters. LeClairRyan of Richmond, Va., previously settled certain allegations with HDL's bankruptcy trustee for $20.375 million. Now Mallory hopes to win $150 million by suing LeClairRyan. Many lab executives and lawyers will be watching to see if new legal precedents emerge from this case.

For a law firm in Richmond, Va., the new year brought unwelcome news. On Dec. 27, Tonya H. Mallory, the co-founder and former CEO of **Health Diagnostic Laboratory** in Richmond, filed a lawsuit in the civil division of the Richmond City Circuit court. Mallory is suing **LeClairRyan**, HDL's former law firm, for malpractice.

In the lawsuit, she accused the firm of giving bad legal advice that contributed to HDL's downfall, according to reporting by John Reid Blackwell, who has covered the cases for the *Richmond Times-Dispatch*.

Mallory seeks at least $150 million in damages. Founded in 1988, LeClairRyan has 320 attorneys in 27 offices in 16 states and describes itself as an entrepreneurial law firm that provides business counsel and client representation in matters of corporate law and high-stakes litigation. Its largest office is in Richmond.

One reason for the lawsuit appears to be Mallory's concern that she faces "multiple lawsuits seeking damages in excess of $1 billion," Blackwell reported.

Blackwell interviewed Mallory about the lawsuit. In the interview, she told Blackwell that the $1 billion includes potential claims she faces from the bankruptcy estate of HDL and from a federal lawsuit.

In her lawsuit, Mallory claimed she received "incorrect legal advice given to her by several LeClairRyan lawyers over a several year period of time from 2008 through 2013," Blackwell wrote. (See our special issue of The Dark Report, Sept. 14, 2015, for details the federal government provided in court filings against

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 $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

HDL and other laboratories, "Feds Show How Labs Took $500 Million from Medicare.")

In 2008, Mallory co-founded HDL as a clinical lab company focused on doing blood sample tests for early signs of heart disease and diabetes, Blackwell explained. As CEO she drove the company to expand in Richmond, hiring hundreds of employees and building a new office and clinical lab. Within six years, however, she resigned as federal fraud investigators looked into the company's practices of paying fees to physicians for collecting patients' blood samples and sending them to HDL.

In her lawsuit, Mallory charged that legal advice from LeClairRyan "led to catastrophic results," including leaving Mallory potentially liable for staggering amounts owed as a result of the lab's business practices, Blackwell wrote. He added that a lawsuit federal investigators are bringing against Mallory is about to go to trial in South Carolina. That case was scheduled to start in December but has now been moved to a later date.

Law Firm's Response

For its part, LeClairRyan responded to a request for comment by saying the lawsuit was, "nothing more than an attempt by (Tonya) Mallory to avoid taking responsibility for the actions that she took on her own at HDL," Blackwell reported.

"We are disappointed that she elected to proceed in this fashion, and we flatly reject any notion that our firm is responsible to Ms. Mallory for her decisions," the law firm added. "We stand by the legal counsel that we gave to our client, HDL, and we have already resolved all matters relating to HDL with the bankruptcy trustee of HDL."

In the lawsuit, Mallory's attorney described a relationship between his client and LeClairRyan that began "back in the 2000s." At the time, the law firm's co-founder, Dennis Ryan, advised Mallory on the establishment of HDL. Also, LeClairRyan defended Mallory when her former employer, **Berkeley Heartlab**, sued her to prevent HDL from soliciting business from Berkeley's customers, Blackwell wrote.

One charge central to the federal government's case against HDL was the payments the lab company made to physicians to process and handle patients' specimens when sending those specimens to HDL. The federal government has made it clear that paying processing and handling fees to physicians is not allowed and may violate federal anti-kickback law.

'Process and Handling Fees'

"The lawsuit claims that after HDL was formed, LeClairRyan repeatedly advised the company that it legally could pay 'process and handling' fees, or P&H fees, to medical practices as reimbursement for the cost of collecting blood samples from patients to be sent to HDL's Richmond lab for testing," Blackwell wrote. "Those fee-paying practices ultimately led to several whistleblower complaints and a federal investigation into whether HDL violated anti-kickback laws by paying doctors as an inducement to order HDL's tests."

Soon after HDL was founded, Mallory asked LeClairRyan for advice on whether paying fees to physicians for collecting blood samples at their medical practices could be a violation of anti-kickback laws, Blackwell reported. The lawsuit shows that in 2009 and 2012, LeClairRyan advised Mallory that HDL's reimbursement practices met the requirements of the law, he added.

LeClairRyan's Legal Opinion

"Specifically, the lawsuit claims that on April 27, 2012, LeClairRyan gave HDL a legal opinion that the company's payment practices would fall under the 'safe harbor exceptions' of the anti-kickback statutes and the False Claims Act," Blackwell wrote. Not all members of the firm agreed with that assessment, however, he added.

In April 2015, HDL agreed to pay $47 million to settle charges the federal government brought against HDL. At the time,

Richmond Federal Judge Sides with HDL's Cofounders, Saying They Could Sue Law Firm

IN JULY, NEWSPAPERS IN RICHMOND, VA., reported that a judge in the Health Diagnostic Laboratory case ruled that it was possible for the former executives of HDL to sue its former law firm, LeClairRyan. The national firm with offices in Richmond had provided legal advice to HDL since the blood-testing lab was founded in 2008.

The judge, John A. Gibney Jr., filed his opinion on July 14 in Richmond federal court as a result of an appeal filed by HDL's founders Russell Warnick and Tonya Mallory, Michael Schwartz reported for *Richmond Biz Sense*. Warnick and Mallory sought to preserve their ability to pursue legal claims of their own against LeClairRyan related to its past representation of HDL insiders individually, he wrote.

Previously, the court handling HDL's bankruptcy filing approved a $20 million settlement that LeClairRyan agreed to pay to HDL's bankruptcy estate. Warnick and Mallory were concerned that the language in the agreement could be interpreted as preventing them from being able to individually deflect blame for the company's downfall from themselves to the law firm, Schwartz reported.

Gibney ruled that the agreement to pay HDL's bankruptcy estate doesn't read that way, he added. "The ruling also affirmed the prior approval of that $20 million settlement, which had already been signed off on by HDL and LeClairRyan and the bankruptcy court, but was held up by Mallory and Warnick's appeal," Schwartz reported.

HDL did not admit any wrongdoing. In June 2015, HDL filed for bankruptcy protection, he added.

The end result of the bankruptcy filing was that HDL sold its assets and laid off hundreds of staff members, Blackwell reported. *(See TDR, Sept. 26, 2016.)*

In September 2016, LeClairRyan agreed to pay $20.375 million to settle with HDL's bankruptcy estate, Blackwell wrote. Six months later, in March 2017, Dennis Ryan and two former HDL executives—Joseph McConnell and Satyanarian Rangarajan—agreed to pay $28.8 million to HDL's bankruptcy estate, while not admitting any wrongdoing, he added. Of that amount, Dennis Ryan agreed to pay $5 million, he reported, while noting that Dennis Ryan left the law firm in 2012 to work as HDL's executive vice president.

Mallory has since co-founded **Creo Wellness LLC**, a Henrico County-based corporate wellness firm, and said she lacks the financial resources to settle the claims against her, Blackwell wrote.

There may be something noteworthy that emerges as a consequence of the collapse of Health Diagnostic Laboratory, along with its federal settlement, the ongoing federal civil case against individuals involved with HDL, and the actions of the HDL bankruptcy trustee.

A Noteworthy Development?

That noteworthy development might be that law firms are now at increased risk if they write legal opinions for client laboratory companies that do not reflect a conservative interpretation of the federal anti-kickback and Stark self-referral laws as well as other statutes.

There are laboratory companies today providing physicians with legal opinions that conclude certain forms of inducements offered by the lab do not violate federal and state laws. It may be that the precedents of the HDL case and its associated lawsuits will put such law firms at greater risk of unwelcome litigation. TDR

—Joseph Burns

Market Update

Alberta Health to Build New Lab to Serve Edmonton, Province

AHS selects site for multi-million lab facility expected to perform 80% of testing in Edmonton region

FOLLOWING YEARS OF CONTROVERSY associated with different plans to build a large new laboratory facility to serve Edmonton and the surrounding region, **Alberta Health Services** (AHS) will finance and build the new lab with its own resources.

Last month, the Alberta government announced that it will develop a new central laboratory that will process 80% of the clinical laboratory tests in the Edmonton region and become the central lab for a new system from Alberta Health Services to process lab tests in the province.

Currently, the province of Alberta has six different organizations providing clinical lab services, reported Keith Gerein for the *Edmonton Journal*. Having so many organizations involved in lab services results in a needlessly complex and fragmented system, said Alberta Health Minister Sarah Hoffman.

The decision to build the new lab ends uncertainty over lab services in the province that started in 2015, when Alberta Health Services was planning to sign a deal for $3 billion in Canadian dollars ($2.4 billion in U.S. dollars) to have a private company build a new lab and manage almost all clinical lab testing in the Edmonton region, Gerein wrote.

Instead, Hoffman nixed the deal and set out to form a single, publicly-run lab services system for Alberta. As part of the plan, Alberta Health Services said it will assume control of the lab operations by 2022 from **DynaLife**, a private company that currently runs the province's largest lab.

In 2016, Alberta Health Services agreed to pay $50 million in Canadian dollars ($40 million in U.S. dollars) to acquire DynaLife's assets. In addition, AHS will become the new employer of DynaLife's 1,200 clinical lab staff and management personnel.

Training and Research

In an article for the *Edmonton Journal*, Keith Gerein reported in December that a parcel of land near the **University of Alberta** was chosen as the site for the new lab. The facility is scheduled to open in 2022. In addition to processing most of the tests in the Edmonton area, it will also serve as a training and research center for innovations in diagnostics, Gerein wrote.

Officials with Alberta Health Services estimated the cost of the facility will be about $325 million in Canadian or $260 million in U.S. dollars. To date, the provincial government has committed $20 million Canadian ($16 million in U.S. dollars) for planning, design, and site work over the next two years, Gerein reported. Construction is expected to start next year.

Millions of patients' specimens will be collected from throughout Edmonton and northern Alberta and brought to the new facility, said Michael Mengel, MD, the health service's Clinical Department Head of Laboratory Services for Edmonton. TDR

—Joseph Burns

To Grow Nationally, NY Lab Buys Tox Labs

ACM Global Labs buys DrugScan, a tox lab, and DSI Medical Services, a testing company

CEO SUMMARY: It is unusual when a regional health system's clinical lab company acquires a commercial lab company outside its geographic home. But that's what happened in December when Rochester Regional Health System's subsidiary, ACM Global Laboratories, acquired a toxicology testing lab and a pre-employment drug-screening company, both in Horsham, Pa., more than 300 miles from Rochester. One toxicology testing expert predicted further consolidation in this sector of the lab industry.

ROCHESTER, N.Y.-BASED **ACM Global Laboratories** acquired **DrugScan** and **DSI Medical Services** of Horsham, Pa., last week in an effort to expand its toxicology testing business nationwide.

A full-service clinical and pathology lab, ACM Global is affiliated with the **Rochester Regional Health System** in Upstate New York. Rochester Regional Health is an integrated healthcare system with $2.2 billion in annual revenue and 17,000 employees.

The health system's ACM Global Laboratories do 20 million tests annually and operate in more than 65 countries. Most of its international business centers provide testing for clinical trials, said John Foley, ACM Global's president.

In an interview with THE DARK REPORT, Foley said the acquisition of DrugScan, a toxicology lab outside Philadelphia that has operations in 23 states, will help ACM Global meet the growing demand for toxicology testing and help physicians and other providers manage patients with complex medication needs.

ACM Global completed the acquisition of DrugScan and DSI Medical Services on Dec. 31. Terms were not announced but ACM Global said it would retain DrugScan and DSI Medical Services' leadership, operations in Horsham, and its brand names. ACM Global acquired the two companies from **Eureka Growth Capital**, a private equity company that formed **Toxicology Holding Corporation** (ToxCo) to manage DrugScan and DSI Medical Services. Eureka sold ToxCo to ACM Global.

Great Reputation And Brand

"This acquisition expands our presence in the toxicology testing marketplace for both addiction treatment and pain management," Foley said. "DrugScan has a great reputation and brand name. Its toxicology testing operation runs 9.5 million tests annually.

"The reason for purchasing DrugScan and DSI Medical Services is we're making a commitment to grow ACM both organically and through acquisition," he added. "Before this, we focused on organic growth. Now, we want to accelerate our

growth, particularly in the toxicology and clinical trial markets.

Wants To Buy Tox Labs

"To do that, we will continue with further acquisitions in both of those areas," Foley said. "Now that the word is out, perhaps some labs will get the message and let us know of their interest to be acquired.

"We saw DrugScan and DSI Medical Services as a platform for us to grow the toxicology business for several reasons," he said. "One reason is they have a much broader geographic footprint than we do.

"For the most part, we cover New York and Connecticut," he added. ACM Global has a core lab in Rochester and a second lab in Norwalk, Conn. "But DrugScan has pain management operations in 23 states and through DSI Medical, it has a workplace screening presence in 47 states. In addition, DrugScan has sales people as far away as California," he added.

Contracts With Health Plans

"Another important reason for this deal is that DrugScan has contracts with 114 health plans, which is four times the number of health insurance contracts that we have," Foley added. "So, for all these reasons, the acquisition is an expansion strategy more than anything else.

"To be clear, we think of ACM Global Labs as three different businesses," he added. "One is a global business to support clinical trials for pharmaceutical sponsors and contract research organizations. For that business, we have four labs around the globe and offices in seven countries.

"The second business is a national toxicology testing operation, and the third is a regional business which is the normal medical diagnostics for hospitals and health systems," Foley explained. "We just opened the lab in Connecticut to serve the Medicaid program there." TDR

—Joseph Burns

Contact John Foley at 866-405-0400 or info@acmgloballab.com.

Small Tox Labs Will Be Acquisition Targets

TOXICOLOGY TESTING COMPANIES ARE likely to be acquisition targets in the coming months and years, said Mark McSally, COO and General Counsel for **Dominion Diagnostics**, based in North Kingston, R.I.

The acquisition by ACM Global Laboratories in Rochester, N.Y., of two toxicology lab companies in Horsham, Pa., is a typical example, he added. "The purchase by ACM Global is consistent with our thinking the last couple of years that there will be consolidation among toxicology companies," he explained. "Those consolidations will come either from larger labs and larger toxicology companies or from investment companies or from large health systems and maybe even from some large hospitals as well.

"Of course, there will be some closures, which we have already seen, and there will be some rolling up of smaller labs into larger organizations," he added.

"This is all due to the cuts in what Medicare and other payers are paying," McSally said. "We're in year three of reimbursement reductions in what Medicare pays for toxicology testing. When Medicare lowers test prices, Medicaid programs and many commercial payers will follow with their own price reductions for toxicology testing.

"In addition, there has been a significant tightening of medical policies from the private payers in terms of frequency limits on testing," he added. "One change payers have made is to put limits on when it's appropriate to do definitive testing. A lot of the payers will reimburse only to confirm a follow-up on a positive initial preliminary test for a prescribed medication. When payers put limits on definitive testing, that has an impact on a lot of labs where their model was to do a large panel of definitive testing."

Lab Regulatory News

After Two Decades, CMS Wants to Update CLIA Lab Regulations

IN THE FIRST EFFORT OF ITS KIND in more than two decades, the federal **Centers for Medicare and Medicaid Services** has published a request for information (RFI) in the *Federal Register* as a first step to revise the CLIA rules it promulgated in 1992.

Over the years, CMS has made some minor changes to the rules issued under the Clinical Laboratory Improvement Amendments of 1988. However, it appears CMS is ready to consider significant revisions to personnel regulations, proficiency testing (PT) referral, histocompatibility regulations, and fees that labs pay to keep the CLIA program running.

Clinical laboratory executives welcomed the RFI that was published on Jan. 9, saying the rules were outdated long ago. But they also said that some sections of the RFI were confusing and that, in other sections, the request does not go far enough.

Comments from clinical lab directors and pathologists are due by March 8. To view the eight-page RFI published in the *Federal Register* on Jan. 9, follow this link: *https://tinyurl.com/ydcve85k*.

The following is a short synopsis of the request for information. THE DARK REPORT will have a more detailed analysis of the RFI in the next issue (Feb. 12).

PT Referral Questions

On the issue of proficiency testing referral, CMS is seeking comments on applying discretion for situations in which it determines that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own; and under what circumstances it should use its discretion. CMS gained discretion in issuing sanctions in cases of intentional PT referral under the Taking Essential Steps for Testing Act of 2012 (the TEST Act). In some cases, that discretion may replace the automatic revocation of the lab's CLIA certificate and subsequent imposition of the two-year ban of the lab's owner or operator, the RFI said.

Under the RFI, CMS is seeking comments on what discretion it would have for the most egregious violation (called a Category violation), encompassing cases of repeat PT referral, regardless of circumstances; and cases in which a lab reports another lab's PT results as its own.

Significant Penalties

In a Category 1 violation, CMS can revoke the laboratory's CLIA certificate for at least a year; ban the owner and operator from owning or operating a CLIA-certified laboratory for at least one year; and may impose a civil money penalty.

Also, CMS seeks comments on alternative sanctions it could issue for proficiency testing referral by laboratories with a Certificate of Waiver (CoW) that have participated in PT referral. Currently, CoW laboratories that participate in PT are not exempt from the ban against proficiency test referral.

The RFI said, "Therefore, our only recourse in cases of proficiency testing referral found at CoW laboratories are principal sanctions (that is, revocation, suspension, or limitation)."

CMS requested comments on whether to use alternative sanctions to create parity for all types of labs involved in PT referral.

Among Clinical Labs' Most Pressing Issues: an Urgent Need for Flexibility in Hiring Lab Techs

For lab directors and administrators, the personnel requirements under CLIA may be the most troubling because labs need flexibility to hire and retain clinical laboratory scientists and technicians with a variety of skills and degrees.

If new rules prohibit the hiring of individuals who lack the proper credentials, labs may be unable to find adequate staff to fill jobs, given that most of the nation's aging lab workforce is approaching retirement age.

Under the personnel requirements section in the CMS request for information (RFI), the agency asks for comments on CLIA revisions that address issues related to nursing and physical science, along with staff competency. Current rules say a bachelor's degree in nursing is equivalent to a bachelor's degree in biological science for moderate- and high-complexity testing personnel. CMS is considering whether a nursing degree should be considered a separate qualifying degree to run moderate- and high-complexity tests.

At the same time, the RFI said, the term "physical science degree" is difficult to define because physical science is a broad discipline involving non-living systems that have nothing to do with lab testing. CMS seeks comment on whether any physical science degree should be considered appropriate for qualifying to meet the CLIA education requirements.

On personnel competency, the RFI said qualifications for general supervisors may be less stringent than those for technical consultants. The difference in degree requirements to qualify to assess competency presents staffing challenges in labs, the RFI said.

As a result, the RFI requested comments on whether general supervisors with associates' degrees should perform competency assessment for moderate complexity testing personnel in labs that do moderate- and high-complexity tests.

The RFI also requested comments on what should be considered appropriate laboratory training, experience, and skills when determining the qualifications for personnel to meet CLIA requirements, and what comprises appropriate documentation to verify training, experience, and skills.

CMS is considering revisions to the CLIA histocompatibility requirements that would reflect current knowledge, changes in transplant medicine, and advancements in laboratory testing, including the use of virtual crossmatching instead of a physical crossmatch to determine compatibility between an organ donor and recipient. A physical crossmatch (also referred to as a serologic crossmatch) is a mixing of specimens from donor and recipient to check for compatibility. Clinicians in transplantation medicine view CMS' current regulations on crossmatching to be a barrier to modernized decision-making on organ acceptability based on risk assessment, the RFI said.

Now that virtual crossmatching is a viable alternative to physical crossmatching, the RFI is seeking comments on what criteria and decision-making algorithms for virtual crossmatching would be an appropriate substitute for physical crossmatching.

➤CLIA Compliance Fees

The RFI also is seeking comments on CLIA compliance fees for laboratories holding a Certificate of Compliance (CoC), fees for laboratories holding a Certificate of Accreditation (CoA), fees for revised certificates, follow-up visits, complaint investigations, and activities related to the imposition of sanctions. TDR

—Joseph Burns

International Update

After Court Decision, India Faces Shortage of Lab Professionals

Supreme Court of India limits professionals who can sign out clinical laboratory reports

THERE IS ALREADY A SHORTAGE of competent professionals available to sign off on medical laboratory reports in India. Now a recent Supreme Court decision may exacerbate this problem.

On Jan. 11, the *Hindu Business Line*, a newspaper, reported that medical labs across India could face a significant shortage of competent professionals to sign lab reports after a recent Supreme Court decision, according to Girdhar Gyani, Director General with the **Association of Healthcare Providers** (India).

"His concern arises from a recent Supreme Court directive that allows only medical practitioners with a postgraduate qualification in pathology to countersign a medical lab report, a view held by the **Medical Council of India** (MCI)," the *Business Line* reported. Note that in India, the term "pathology" refers to the clinical laboratory.

The court's decision had the effect of reducing the number of people who can sign lab reports from 36,000 to 5,500, Gyani told *Business Line*. There was concern that such staff shortages would loom over the 300,000 clinical labs in India. "Patient safety can be hit," Gyani warned.

Business Line explained that, before the court decision, professionals who reviewed and signed lab reports were MD pathology, MD microbiology, MD biochemistry, MSc or PhD in microbiology and biochemistry. This protocol changed in June when the MCI debarred those having an MSc or PhD in biochemistry and microbiology from signing test reports. After pathology lab professionals challenged the order in court, the case went to the Supreme Court. Last month, the Supreme Court endorsed the MCI's position, Gyani told *Business Line*.

Assessing MScs and PhDs

"Those with an MSc and PhD qualification are no less competent than any doctor as they already have an analytical bent of mind and are part of the teaching staff," Gyani explains. In addition, these professionals were not seeing or treating patients.

The **Indian Medical Association** (IMA) weighed in on the controversy, saying that basic lab reports can be counter-signed only by registered medical practitioners and advanced lab reports by a registered medical practitioner with a post-graduate qualification in pathology, *Business Line* reported.

"Lab reports need interpretation with clinical findings and previous reports and these reports are often a decision maker in clinical treatment and hence require signature of at least an MBBS doctor. Any report without an interpretation may be incomplete," the IMA said.

India already has a shortage of doctors across the country, Gyani commented. Given the relatively small number of available qualified doctors versus the much larger number of clinical labs, the doctors will be overworked, he said. TDR

—Joseph Burns

CEO SUMMARY: UnitedHealth made national news when it filed a $100 million lawsuit against Next Health and other defendants in Dallas in January 2017. The insurer alleged fraud involving clinical laboratory tests. That lawsuit is just the latest chapter in an almost decade-long string of legal proceedings involving the healthcare businesses some of the defendants have organized. Following months of investigation, The Dark Report explains the serial nature of other lawsuits, federal indictments, and whistleblower cases involving some of these same defendants over the years.

Dissecting the UnitedHealthcare vs. Next Health lawsuit

Allegations of Lab Test Fraud Involve Multiple Defendants

When a major health insurer filed a lawsuit alleging healthcare fraud involving $100 million of clinical laboratory test claims in Dallas in 2017, it became national news. In court documents, **UnitedHealthcare** alleged fraud against **Next Health, LLC**, and multiple defendants involving how these defendants submitted claims for healthcare services, including clinical laboratory tests. UnitedHealth seeks $100 million in damages. *(See TDR, Feb. 21, 2017.)*

UnitedHealthcare (UHC) filed this lawsuit on January 26, 2017, but this case is just one chapter in a highly-complex story involving several of the defendants named in this lawsuit. Prior to this lawsuit, certain of the defendant companies and their owners or officers were involved in other lawsuits that alleged fraudulent behavior. Also, certain of these defendants were named in earlier actions federal regulators and federal healthcare prosecutors initiated.

Thus, the UnitedHealthcare vs. Next Health lawsuit is one significant event in a series of lawsuits and regulatory actions insurers, government officials, and whistleblowers have initiated in Texas over multiple years.

In its investigation of the UHC lawsuit, The Dark Report has learned that, since 2010, certain companies and individuals in Texas have repeatedly been the subject of lawsuits, criminal investigations, and regulatory actions. Allegations of fraud are a common theme in some of these lawsuits and criminal investigations.

The UnitedHealthcare lawsuit is the visible tip of a large iceberg; that iceberg being how certain individuals and their various companies are alleged to have repeatedly developed different ways to scam health insurers.

Stated differently, the allegations in the multiple civil lawsuits and federal indictments cumulatively portray these individuals as serial fraudsters. The documents filed in these cases claim to show evidence of numerous cases of fraud involving multiple companies over many years.

As one group of healthcare companies they operate becomes enmeshed in lawsuits and regulatory actions, these individuals seem to be able to create a new group of cross-linked healthcare companies to continue inducing referrals from physicians, thereby allowing them to submit bills to federal and private payers for what are often described in lawsuits and federal indictments as "over-priced" and "medically-unnecessary" procedures.

These schemes frequently include clinical laboratory tests, particularly in toxicology and pain management. But various court records describe these individuals as ready to provide other clinical services they see as lucrative.

The influence these types of allegedly-fraudulent arrangements have in the clinical laboratory testing market makes this a story worth telling in detail. For example, long-established medical laboratories are forced to compete against ever-greater numbers of newly-created lab companies organized to offer pharmacogenomic, pain management, and toxicology testing.

Competition from these allegedly fraudulent arrangements often frustrates established, well-run, and honest labs. In an effort to win lab test referrals, disreputable labs may offer their client physicians benefits and inducements that might possibly violate state and federal laws.

Since UnitedHealthcare filed its lawsuit in 2017, new chapters in this particular story about alleged fraud have been written. For example, in July 2017, Next Health and several of the other defendants in the UnitedHealthcare case were sued in Dallas by the insurance company that sold them executive liability policies. The insurer asked the court to void those policies, among other remedies.

Lawsuit Against HHS

Just a month later, on August 18, 2017, Next Health and one of the toxicology lab companies (Medicus Laboratories) named as a

defendant in the UnitedHealth case filed their own lawsuit against the federal **Secretary of Health and Human Services**. The defendants challenged pending regulatory actions that would revoke the CLIA license of one of the toxicology lab subsidiaries.

Next Health's Countersuit

The next interesting chapter in this story happened on Oct. 5, 2017, when Next Health and other defendants countersued UnitedHealthcare. In coverage of Next Health's countersuit, *Dallas Morning News* reporter Kevin Krause wrote:

> *Insurance giant UnitedHealthcare alleges that Next Health, a Dallas lab testing company, paid bribes and kickbacks to doctors and other providers between 2011 and 2016 for ordering overpriced and unnecessary drug and genetic tests under the guise of a wellness study.*
>
> *Next Health has now struck back with its own allegations, calling the [UHC] lawsuit a "shakedown" and a "corporate bullying tactic" by United to get out of paying for legitimate lab tests.*
>
> *Next Health also said United is trying to put it out of business, and the lab company noted various large sums United has paid to the government over the years for allegedly defrauding health care providers. Next Health has not been accused of any criminal wrongdoing.*
>
> *United responded by asking a judge to strike Next Health's filing, which it said is full of "immaterial, impertinent and scandalous allegations" intended to "smear" the insurance company.*

The best starting point for describing a pattern of alleged fraud and abuse in the Dallas area that goes back almost 10 years is to understand the claims that **UnitedHealthcare Services** made in a lawsuit filed in January 2017 against multiple defendants in the U.S. District Court for the Northern District of Texas.

Named as defendants in the case are:

- **Next Health, LLC**, and its subsidiaries:
  - **United Toxicology, LLC,**
  - **Medicus Laboratories, LLC**,
  - **US Toxicology, LLC**, and,
  - **American Laboratories Group, LLC**
- Erik Bugen
- Kirk Zajac

Multiple Defendants

The lawsuit collectively refers to these lab entities as "Next Health Labs," which will be used in this story.

In the lawsuit, UnitedHealth alleged that Next Health and its subsidiaries "engaged in unlawful conduct and inappropriate business practices. These included:

a) "payment of bribes and kickbacks to test referral sources, including physicians, sober homes, and sales consultants, in exchange for [lab] test orders;
b) "inappropriate utilization of standing test protocols;
c) "performance and billing for testing services not ordered by physicians;
d) "improper billing for services they did not perform; and,
e) "routinely ignoring patients' payment responsibilities in order to avoid drawing attention to their scheme."

Multiple Counts In Lawsuit

Specific counts in the lawsuit included fraud, conspiracy to commit fraud, sham to perpetrate fraud, theft, and unjust enrichment.

In Count 11 of the complaint, UnitedHealth alleged that Next Health and its subsidiary United Toxicology intentionally used a name for the subsidiary that was confusingly similar to the insurer's. In court papers, the plaintiffs said the purpose was to mislead UHC plan members into thinking that documents—such as explanations of benefits reflecting United Toxicology's "grossly over-priced and unnecessary services"—were associated with the insurance company.

How Next Health's U.S. Toxicology Division Filed Claims for Tox, PGx Tests with UnitedHealth

HOW DOES A REGIONAL COMPANY like Next Health of Dallas generate clinical laboratory test claims totaling $400 million over six years (2011 through 2016) to just one health insurer—UnitedHealthcare?

In the lawsuit filed by UnitedHealthcare against Next Health and Next Health Labs, the health insurer provides specific examples of how it alleges the defendant companies billed it for "unnecessary drug and PG testing, pursuant to blanket, non-specific testing profiles."

Reproduced below is a section of the UHC lawsuit. It shows how the defendants billed $18,400.89 for testing provided on three dates of service for each of three different patients, as noted below.

Excerpt from page 48 of the UnitedHealthcare vs. Next Health Lawsuit

The medical providers justify this battery of testing by using cloned statements that do not specify any particular test or any medical rationale underlying the testing.

180. Below are a few examples of the claims submitted to United by US Toxicology for the performance of unnecessary drug and PG testing, pursuant to blanket, nonspecific testing profiles. Each of the claims associated with each member arise from the same patient encounter.

Member	Date Submitted	Claim	Amount Charged	Amount Paid
#1	4/27/2016	5933444118	$10,125.99	$6,022.89
	5/5/2016	5933444119	$1,818.00	$1,636.20
	5/10/2016	5952668964	$6,456.90	$4,519.83
Total:			**$18,400.89**	**$12,178.92**
#2	5/22/2016	5968075771	$1,818.00	$1,818.00
	6/2/2016	5977016992	$6,456.90	$6,456.90
	6/2/2016	5980715033	$10,125.99	$10,125.99
Total:			**$18,400.89**	**$18,400.89**
#3	5/20/2016	5977017066	$1,818.00	$1,454.40
	5/20/2016	5977017067	$6,456.90	$5,197.16
	6/2/2016	5993090263	$10,125.99	$10,125.99
Total:			**$18,400.89**	**$18,400.89**

In the lawsuit, after this table, UnitedHealthcare wrote, "181. Utilizing 'custom' profiles to justify the performance of unnecessary drug testing is not a new concept. The Office of the Inspector General warned about the potential for fraud posed by custom profiles almost 20 years ago: 'customized profile[s] may result in the ordering of tests which are not covered, reasonable, or necessary and... the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal, and administrative law.' See Dept. of Health and Human Servs., Office of Inspector General, Compliance Program Guidance for Clinical Laboratories, reprinted in 63 Fed. Reg. 163 (Aug. 1998)."

Court papers describe the relief UHC sought: including enjoining defendants from submitting fraudulent claims based on unlawful conduct and inappropriate business practices; an award of actual, consequential, and exemplary damages; and attorneys' fees and court costs.

The lawsuit described substantial damages. In court documents, UnitedHealthcare stated that between

2011 and mid-2016, Next Health and its subsidiaries submitted claims to the insurer totaling more than $400 million for out-of-network drug and pharmacogenetic laboratory testing services. In the lawsuit, UnitedHealthcare said it made payments totaling $101.5 million to Next Health Labs, as follows:

- United Toxicology: $54.7 million
- US Toxicology: $23.9 million
- American Lab Group: $14.3 million
- Medicus Laboratories: $ 8.6 million

Federal Criminal Case

One important fact is that Semyon Narosov and Andrew Jonathan Hillman—principals of defendant companies in the UnitedHealthcare lawsuit—were named as defendants in a criminal healthcare fraud case filed on Nov. 16, 2016, in Dallas by U.S. attorney John R. Parker. In its complaint against Next Health, UHC described what it saw as the connections and similarities between the schemes of which it accuses Next Health and the Next Health labs and the alleged illegal kickback conspiracy at **Forest Park Medical Center** in Dallas (FPMC), as described in the federal criminal case.

The FPMC scheme resulted in the November 2016 federal indictment of 21 individuals, including executives, surgeons, physicians, sales and marketing consultants, and others. To date, four defendants in the FPMC case pled guilty to criminal felonies, including one physician. A trial involving 17 defendants is ongoing.

'Illegal Scheme'

According to UHC's lawsuit, two of those indicted in the FPMC case—Semyon Narosov and Andrew Jonathan Hillman—are also key figures in the Next Health network of companies.

In its lawsuit, UnitedHealthcare described how—in the FPMC federal indictment—the two men are alleged to have collectively controlled a hospital consulting company and "received bribe and kickback payments in exchange for referring patients to FPMC or to surgeons who performed medical procedures at the hospital."

Key Figures

"Narosov and Hillman held (and may still hold) ownership and/or management positions with Next Health and/or one or more of its subsidiaries," stated UHC in its complaint. "Through those ownership and management positions, Narosov and Hillman made sure that Next Health and its subsidiaries employed an illegal scheme that was similar to the one in place at Forrest [sic] Park."

Statements in both the federal indictment and in the UHC lawsuit describe how the defendants allegedly engaged in serial fraud by creating a series of companies and business groups. UnitedHealthcare stated that Next Health was a "rebrand" of **U.S. Health Group Inc.**

Name Reserved In 2004

According to records at the Texas Secretary of State, a New Jersey corporate services company filed a name reservation certificate in 2004 in Texas for "U.S. Health Group, Inc. "

Also, on May 17, 2010, Texas Secretary of State records show that **Pioneer Laboratories, LLC**, was formed in Texas, with Jeffrey L. Wasserman, MD, listed as its registered agent. Public records show that Wasserman is an anesthesiologist at **Pinnacle Partners In Medicine** in Dallas.

Three months later, on August 23, 2010, Medicus Laboratories, LLC (a defendant in the UnitedHealthcare suit), was formed as a Texas corporation, with Jeffrey Wasserman, MD, shown as its organizer. Its governing persons were listed as Pioneer Laboratories, LLC (Wasserman's company), and **Hospital Business Concepts, Inc**. Texas Secretary of State records show this company was formed in 2006 and list Andrew Hillman,

Timeline of Companies, Individuals Named in UnitedHealthcare vs. Next Health Lawsuit

IT IS DIFFICULT AND COMPLEX to investigate the business activities of the companies and individuals named or associated with the multiple defendants identified in the *UnitedHealthcare vs. Next Health, et al* lawsuit filed in Dallas in January, 2017.

The timeline that follows was developed from public information that includes lawsuits filed in federal and state courts, press releases by the Department of Justice and certain companies involved in these matters, and newspaper/media news stories.

To confirm the accuracy of this information, THE DARK REPORT has attempted to contact the attorneys representing parties named in the lawsuits, as well as the companies and individuals named in lawsuits, press releases, and news stories. We were not able to locate contact information for some parties and received no responses from others.

- **2004:** New Jersey company files name reservation certificate in Texas for "U.S. Health Group, Inc."
- **2006 Oct. 4:** Hospital Business Concepts, Inc., formed in Texas. Public records show Andrew Hillman, Semyon Narosov, and Yan Narosov as officers/directors.
- **2010 May 1:** Pioneer Laboratories formed in Texas; anesthesiologist Jeffrey Wasserman, MD, is registered agent.
- **2010 Aug. 23:** Medicus Laboratories formed in Texas involving Dr. Wasserman and Andrew Jonathan Hillman.
- **2011 to mid-2016:** Next Health/subsidiaries submit $400+ million in claims to UHC per UHC v NH et al.
- **2011 Oct. 13:** U.S. Health Group, Inc. formed in Wyoming. In its 2012 annual report filing, Semyon Narsov signs as president.
- **2012 Aug.:** HHS OIG sends letter to Medicus Laboratories, LLC (owned by Next Health) advising possible liability under federal law.
- **2012 Dec. 21:** U.S. Health Group, Inc. registers as foreign corporation in Texas. Address: 13601 Preston Road (an address associated with Hillman and Semyon Narosov).
- **2013 Feb. 12:** Whistleblower suit against U.S. Health Group and 38 subsidiaries, including defendants: Semyon Narosov, Andrew Hillman, Mike Austin, Jeffrey Wasserman, MD, Nick Oberheiden, Esq.
- **2014 Feb. 20:** Medicus settles with OIG for $5 million, 5-year Corporate Integrity Agreement, admits no guilt.
- **2014 Jun. 23:** Next Health LLC formed in Texas. Mike Austin, Narosov, and Hillman. Registered agent: Oberheiden Law Group.
- **2015 and 2016:** Narosov and Hillman still associated with U.S. Health Group (Public Information Reports, Texas Secretary of State).
- **2016 Nov.:** U.S. Attorney indicts Semyon Narosov and Andrew Jonathan Hillman in the case involving Forest Park Medical Center and an alleged kickback scheme.
- **2017 Jan. 26:** UnitedHealthcare sues Next Health, LLC, et al.
- **2017 Mar. 24:** Next Health files Certificate of Assumed Business Name as "**Total Life Sciences**."
- **2017 Apr. 25:** The Oberheiden Law Group resigns as registered agent for Next Health and several subsidiaries.
- **2017 Jul. 13:** Berkley Insurance Co. sues Next Health and Next Health Labs, Hillman, Narosov, Mike Austin to revoke officers and directors errors & omissions insurance policies, and alleging misrepresentations on the insurance applications.
- **2017 Aug. 18:** Next Health and Medicus sue state/federal officials/agencies to stop suspension/revocation of CLIA lab licenses.
- **2017 Nov. 13:** Court dismisses Next Health/Medicus suit against state/feds to stop suspension or revocation of laboratory license(s).

Semyon Narosov, and Yan Narosov as officers or directors.

The federal indictment in the Forest Park Medical Center case of November 2016 identifies Andrew Hillman and Semyon Narosov as defendants, and states, "Andrew Jonathan Hillman and Semyon Narosov—who collectively controlled a hospital consulting company—received bribe and kickback payments in exchange for referring patients to FPMC or to surgeons who performed medical procedures, including surgeries, at the hospital."

The federal indictment further describes the alleged fraud, stating that, "As a result of the bribes, kickbacks, and other inducements, FPMC *billed patients' insurance plans and programs well over half-billion dollars and collected over two hundred million dollars in paid claims* between approximately 2009 to 2013." (Italics by THE DARK REPORT.)

Officers In Several Firms

Court and Texas Secretary of State records link Andrew Jonathan Hillman and Semyon Narsov as officers or directors in businesses named in the FPMC indictment and also in the UnitedHealth vs. Next Health lawsuit.

The next court case involving these businesses was filed on July 13, 2017. On that date, Connecticut-based **Berkley Insurance Company** filed a lawsuit in Dallas. Berkley is the company that provided E&O insurance to the defendant companies. It brought suit against:

- Next Health, LLC,
- United Toxicology, LLC,
- Medicus Laboratories, LLC,
- U.S. Toxicology, LLC,
- American Laboratories Group, LLC, and,
- various other Next Health entities.

In this lawsuit, Berkley named these individual as defendants:

- Andrew Hillman,
- Semyon Narosov, and,
- Michael Austin.

Berkley's court case was brought to resolve controversy among the parties with respect to three insurance contracts (covering time periods 2014-2015, 2015-2016, and 2016-2017) and specific underlying lawsuits. Berkley said it seeks to rescind certain executive liability policies based on claims of material misrepresentations in the applications because of the failure to reveal the existence of the underlying lawsuits.

Court Declaration Sought

Court documents also say Berkley seeks a court declaration that the policies do not provide coverage for various lawsuits the defendants are involved in, including the FPMC criminal proceedings, a previous *qui tam* suit, the lawsuit brought by UnitedHealthcare, and others.

Notably, in addition to the allegations Berkley asserts, its court documents describe a regulatory problem some of the defendants have with the federal government. Berkley alleges that in August 2012, the **Office of Inspector General of the federal Department of Health and Human Services** (OIG) sent a letter to Medicus Laboratories—a named defendant in the UHC vs. Next Health et al lawsuit—advising that it may be "liable for civil monetary penalties and assessments under the Civil Monetary Penalties Law.

THE DARK REPORT'S research into Medicus Laboratories uncovered several developments possibly related to the OIG's notice of pending regulatory action. First, only four months after this OIG notice, on December 21, 2012, **U.S. Health Group, Inc.**, registered with the Texas Secretary of State as a foreign (Wyoming) corporation. It showed its address as 13601 Preston Road (one of the addresses associated with the Next Health organization, Hillman, and Narosov), Suite 220E, Dallas, Texas 75240.

However, Wyoming public records show that this U.S. Health Group, Inc., corporate entity was itself incorporated in Wyoming only as a domestic (Wyoming) company just 14 months earlier, on Oct. 13, 2011. On Aug. 24, 2012, Semyon Narasov signed this company's annual report as the company's president.

The qui tam suit alleged that the defendants set up a business scheme that provided illegal kickbacks and profit-sharing arrangements with referring physicians for them to refer patients who use products and services provided through companies the defendants and physicians owned.

Multiple Business Entities

An attorney familiar with these types of legal cases in healthcare and the clinical laboratory industry, commenting generally, suggested that this sequence of events is common in which individuals involved in healthcare fraud need to establish multiple business entities to facilitate their conduct.

The next legal action involved Medicus Laboratories and 46 other defendants. It was a whistleblower case filed in Texas Northern District Court on Feb. 12, 2013, by unnamed relators (plaintiffs).

Whistleblower Lawsuit

The case was United States of America et al v. U.S. Health Group, Inc et al; 3:13-cv-00701. This *qui tam,* or whistleblower, suit named U.S. Health Group, Inc., 38 of its subsidiary or related companies, and five individuals.

Among the corporate defendants were these companies:

- United Toxicology,
- U.S. Toxicology, and,
- Medicus Laboratories.

Among the individual defendants named in the *qui tam* lawsuit were:

- Semyon Narosov,
- Andrew Hillman,
- Mike Austin,
- Jeffrey Wasserman, MD, and,
- Nick Oberheiden, attorney and namesake of **The Oberheiden Law Group, PLLC**.

The relators claimed that U.S. Health Group, Inc. is "a parent company owned and controlled by…Hillman and others or entities that [they] own or control."

Multiple Allegations

The *qui tam* suit alleged that the defendants set up a business scheme that provided illegal kickbacks and profit-sharing arrangements with referring physicians for them to refer patients who use products and services provided through companies the defendants and physicians owned.

It is important to call attention the specific allegation of the use of "companies the defendants and physicians owned" as a vehicle for "profit-sharing" to be paid to referring physicians. Pathologists and clinical laboratory managers need to know about these arrangements. The whistleblower lawsuit appears to describe "medical service organizations (MSOs)."

In simplest terms, the MSO organizers sell stock in an MSO—typically registered with the state as a limited liability corporation (LLC)—to physicians. The stockholder-physicians are then paid revenue-sharing or dividends proportional to the revenue generated from their patient referrals.

It is common for the MSO organizers to create multiple MSOs and limit the

number of stockholding physicians in each MSO to just 10 to 25. In recent years, MSOs have become ubiquitous in Texas and many other states.

The risk to the organizers and the stockholding-physicians in an MSO is that the arrangement might be challenged by federal prosecutors as a violation of the Stark Law and the Anti-kickback statute.

The *qui tam* suit claimed the defendants used various business practices and billing, management, and administrative service companies owned by the same defendants to conceal their scheme. That may be why the number of defendants named in the lawsuit totaled 38, of which 33 were business entities.

The scheme resulted in the submission of millions of dollars of claims to federal healthcare plans in violation of the federal Anti-Kickback Statute, Stark Law, and state and federal false claims acts, the relators claimed.

Qui Tam Lawsuit Dismissed

This *qui tam* lawsuit was dismissed on Jan. 26, 2015. THE DARK REPORT has been unable to determine why this case was dismissed nor whether the settlement with Medicus Laboratories mentioned below is related to the *qui tam* case.

For Medicus Laboratories, the next chapter in its story happened on Feb. 20, 2014. On that date, the OIG announced that Medicus Laboratories, LLC, had agreed to pay $5 million and had entered into a five-year Corporate Integrity Agreement.

The DOJ stated that this settlement with Medicus Laboratories reflected efforts to combat fraud in the urine drug testing industry through a "unique combination of audits, investigations, and legal remedies." In accepting the settlement, Medicus denied any liability and no judgment or finding of liability was made against it.

In the midst of these developments, Next Health, LLC, was formed as a Texas corporation on June 23, 2014. That is just 120 days after the settlement between Medicus and the DOJ.

Public records for Next Health, LLC, list Michael A. Austin, 5710 LBJ Freeway, Suite 300, Dallas, Texas 75240, as its "governing person." (The Berkley suit alleges that Next Health was formed by Mike Austin and co-defendants Hillman and Narosov.) Next Health's initial registered agent was The Oberheiden Law Group, PLLC, also located at 5710 LBJ Freeway, Dallas, Texas 75240, in suite 120.

The primary addresses associated with Next Health or its subsidiaries are:

- 5710 LBJ Freeway, Suite 300, Dallas, Texas 75240;
- 13601 Preston Road, Dallas, Texas 75240; and,
- P. O. Box 797604, Dallas, TX 75379.

According to the UnitedHealthcare complaint, Next Health is the "hub of more than 160 entities registered as doing business out of 5710 LBJ Freeway, Suite 300, Dallas, Texas 75240, which overlap to create a complicated and opaque web of ancillary service providers."

Public records filed in Texas by U.S. Health Group, Inc., for 2015 and 2016 showed Narosov and Hillman as being associated with that company.

New Filings With The State

Since the filing of the UnitedHealth lawsuit against Next Health and the Next Health labs, the company made changes in its filings. According to Texas Secretary of State records, on March 24, 2017, Next Health filed a Certificate of Assumed Business Name, indicating "**Total Life Sciences**" as the name under which the business is, or is to be, operated.

On April 25, 2017, public records show that The Oberheiden Law Group resigned as registered agent of Next Health and a number of its subsidiaries. *(See sidebar on page 21 for comments made by Nick Oberheiden to THE DARK REPORT.)*

Contacting Defendants and Their Attorneys For Comments on UHC and Other Lawsuits

TO PROVIDE THE DEFENDANTS in these lawsuits and the companies involved in regulatory actions the opportunity to respond to the allegations that appear in the lawsuits, press releases, and news accounts presented in this story, THE DARK REPORT contacted the individual defendants and their attorneys. THE DARK REPORT was not able to locate contact information for some and received no responses from others. Below is a description of:

Attorney James S. Bell (James S. Bell PC); currently or formerly representing Next Health, LLC: Mr. Bell was contacted and made no comment, but provided copies of court documents in connection with the Next Health et al. counterclaim against UnitedHealthcare. Information from the counterclaim will be presented in a future issue of THE DARK REPORT. *(Also, see page 14.)*

Attorney Nick Oberheiden (Oberheiden and McMurrey LLP; formerly The Oberheiden Law Group, The Oberheiden Law Firm PLLC, which served as registered agent for various Next Health-related companies; named defendant in 2013 *qui tam* case against US Health Group et al). When reached, Mr. Oberheiden declined to comment, except to say that he failed to see the relevance of the *qui tam* suit that was federally dismissed with prejudice many years ago. *(According to uslegal.com, a "…dismissal with prejudice is dismissal of a case on merits after adjudication. The plaintiff is barred from bringing an action on the same claim. Dismissal with prejudice is a final judgment and the case becomes res judicata on the claims that were or could have been brought in it.")*

Attorneys Erica Bright and Noah Nadler (Wick Phillips Gould & Martin LLP); currently or formerly representing Advanced Total Management, American Laboratories Group LLC, Athena Surgical Products LLC, L2 Surgical LLC, Medicus Laboratories LLC, Next Health LLC, Ortho InMotion LLC, Principal Spine LLC, Total Surgical Management LLC, US Toxicology LLC, United Toxicology LLC, Vertelogic LLC, Andrew Hillman, Michael Austin, Semyon Narosov). No response was received from Ms. Bright or Mr. Nadler.

Attorneys Lisa Henderson and L. Kimberly Steele (Sedgwick LLP); currently or formerly representing Berkley Insurance Company). No response was received from Ms. Henderson or Ms. Steele.

Attorneys Andrew G. Jubinsky and Raymond Earl Walker (Figari & Davenport LLP); currently or formerly representing United Healthcare Services Inc. and UnitedHealthcare Insurance Company). No response was received from Mr. Jubinsky or Mr. Walker.

Attorneys Ernest Martin, Jr., Christopher A. Rogers, Micah Ethan Skidmore, Nicole Summerville (Haynes & Boone LLP); currently or formerly representing American Laboratories Group LLC, Medicus Laboratories LLC, Next Health LLC, US Toxicology LLC, United Toxicology LLC). Mr. Martin was reached by telephone and deferred any comments to Mr. James S. Bell for any comments. No comments were received from Mr. Rogers, Mr. Skidmore, or Ms. Summerville.

No response from:

Attorneys Stephen W. Mooney and Adam Joseph Sinton (Weinberg, Wheeler, Hudgins, Gunn & Dial); currently or formerly representing United Healthcare Services, Inc. and UnitedHealthcare Insurance Company, UnitedHealth Group, Inc.).

Jeffrey Wasserman, MD, of Dallas, Texas: Messages were left at his current listed medical practice.

Eric Bugen: Messages were left at a phone number that public records list in his name.

Kirk Zajac: Messages were left at a phone number that public records list in his name.

Semyon Narosov: Messages were left at a phone number that public records list in his name.

Andrew Jonathan Hillman: Messages were left at a phone number that public records list in his name.

Public records indicate that, despite its 2014 settlement with the OIG, Medicus Laboratories had additional and different regulatory or compliance issues. On Aug. 8, 2017, Next Health and Medicus Laboratories filed suit in Dallas against state and federal officials and agencies. In its lawsuit, the plaintiffs said they sought to stop these government agencies "from suspending or revoking their federal laboratory licenses."

In a news story about the lawsuit, the *Dallas News* wrote that the plaintiffs claimed that such a move—loss of the lab's CLIA certification—would effectively put them out of business.

The court dismissed the Next Health and Medicus Laboratories lawsuit against state and federal regulators on Nov. 13, 2017. A recent search for the Medicus Laboratories website at *www.medicus-labs.com* shows that this URL is currently not active.

Similarly, Next Health's website, when searched in November 2017, stated that the account had been suspended. There is an active LinkedIn page for "Next Health USA" of Dallas Texas. Also, as of late November 2017, U.S. Health Group, Inc. was listed in the Texas Secretary of State records as still active.

At this time, it is not known if there are other lawsuits, whistleblower cases, or government regulatory actions that involve the defendant companies and the owners and officers of those companies named in the UnitedHealthcare vs. Next Health, LLC and Next Health Labs lawsuit.

Complex Schemes

What is significant about the information and the timeline presented in this story is that it provides clinical lab managers and pathologists with a fuller understanding of how complex and sophisticated these healthcare schemes and business activities can be.

This information also documents an almost 10-year pattern of actions by selected individuals that have caught the attention of health insurers, government healthcare prosecutors, and whistleblowers. During this time—and in different lawsuits and regulatory actions during these same years—these individuals are alleged to have committed different types of healthcare fraud and abuse.

THE DARK REPORT has contacted the attorneys of record for the defendants in these cases to ask for comment. The outcomes from these efforts are reported on the sidebar on page 21. As additional comments are provided by these sources to tell their side of the story, that information will be presented to update this report.

Doctors' Role Is Untold

What remains untold about the events of the past decade in Dallas is the role of office-based physicians in sustaining the schemes alleged and described in various lawsuits. For example, it takes a huge number of lab test referrals from physicians to allow Next Health—as alleged by UnitedHealthcare in court documents—to submit $400 million in lab test claims.

Another insight from the activities of the defendants in the UnitedHealthcare lawsuit is the complexity of the business relationships they establish. In the court documents, UHC said, "Next Health is the hub of more than 160 entities registered as doing business out of 5710 LBJ Freeway, Suite 300, Dallas, Texas 75240, which overlap to create a complicated and opaque web of ancillary service providers."

Finally, this is but one example in one city of an alleged healthcare fraud involving lab testing that caused a health insurer to file a civil lawsuit. Across the United States, there are federal cases and payer lawsuits alleging similar fraud, typically involving tens of millions or hundreds of millions of dollars in lab test claims.

The large scale of this fraud and abuse involving lab testing has another consequence. As payers put in strict guidelines to curb different forms of fraud, it hurts those clinical labs that operate honestly. **TDR**

—Pamela Scherer McLeod

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In a first for Australia, a pathology lab was given authorization to use patient-collected cervical specimens from eligible women for cervical cancer screening purposes. **VCS Pathology** of Melbourne, Victoria, was given this authorization by Australia's **National Association of Testing Authorities** (NATA). Other pathology labs in Australia are expected to be granted similar authorization in coming months. It is believed that self-collection will encourage more women to participate in cervical cancer screening programs.

MAYO CLINIC, WUXI APPTEC FORM JV IN CHINA

Earlier this month, **Mayo Clinic** and **WuXi AppTec Group** of Shanghai, China, announced a joint venture "to develop and deliver clinical diagnostics in China."

HOSPITAL C-SUITE SALARIES TO BE TAXED AT NEW RATE

There's an interesting twist in the new tax reform law. Tax-exempt hospitals will now need to pay a 20% excise tax on compensation that exceeds $1 million per year that is paid to their five highest-paid employees (but not on compensation from the direct provision of medical services).

TRANSITIONS

- **Aeon Global Health** announced that pathologist Armando Moncada, MD, FCAP, was appointed as its new Chief Medical Officer. Moncada formerly served at **PCG Molecular**, **Lea Regional Medical Center**, and **Baylor College of Medicine**.

- **Precipio, Inc.,** of New Haven, Conn., selected Douglas Sites to be its new Vice President of Sales. Sites previously held sales and marketing positions at **Rosetta Genomics**, **Asuragen**, and **Plus Diagnostics**.

- Last month, attorney and Senior Counsel Peter Kazon retired from **Alston and Bird**, the Washington, DC-based law firm to "pursue new interests." Among his clients was the **American Clinical Laboratory Association** (ACLA).

- **Immucor's** new CEO and President is Avi Pelossof. His previous executive positions were at **Alere**, **Chembio Diagnostics Systems**, **IMS Group**, and **Citibank**.

- **Clinical Genomics** of Bridgewater, N.J., announced that Tadd S. Lazarus, MD, was named its Chief Medical Officer. Lazarus previously served as CMO or MO at **Luminex Corporation**, **Quiagen**, **Gen-Probe**, and **Roche Diagnostics**.

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...

...why many researcher teams are working in the field of nano-scale diagnostics to go beyond "lab-on-a-chip" and create "lab-on-skin" testing devices capable of monitoring many biomarkers used in clinical laboratory testing.

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, February 12, 2018.

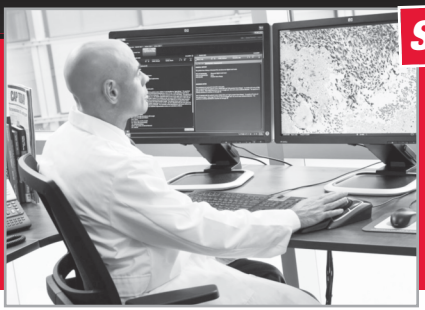

photo copyright GE Healthcare

SPECIAL SESSION!

Full-Day Summit on: Using Digital Pathology for Primary Diagnosis: What All Pathology Labs Need to Know!

Achieve excellence in clinical and financial performance: Learn about DP Technology, Workflow Impact, Clinical Quality

It was big news last year when the FDA cleared the first digital pathology system for use in the primary diagnosis of most types of biopsies. Now all pathology groups must decide when to take the plunge and invest in digital pathology.

To help you, we've organized a full-day digital pathology summit on May 3, following the two-day *Executive War College* on May 1-2. The event starts with a reception and digital product exhibition on the evening of May 2. This allows you to meet the summit speakers, see the digital pathology products, and get a head start on the summit itself.

Be ready for a full day of learning on May 3 about everything you and your pathology group needs to know about digital pathology. You'll hear clinical, operational, and financial case studies from innovative pathology labs using digital pathology. They will teach you the do's and don'ts, how to gain clinical advantage, plus effective ways to win new clients and develop new streams of revenue. You'll see all the leading digital pathology systems. Register today!

www.executivewarcollege.com

23 YEARS

Now in Our 23rd Year!

EXECUTIVE WAR COLLEGE

Conference On Laboratory & Pathology Management

May 1-2, 2018 • Sheraton Hotel • New Orleans

UPCOMING...

- ***Exclusive Newsmaker Interview with Sysmex CEO: What's Changing in Healthcare and with Labs.***
- ***New Compliance Challenge for Labs, Path Groups: Issues Associated with Third-Party Lab Sales Reps.***
- ***Another Molecular Lab Company Shuts Its Doors: Why Getting Paid Was Not the Major Issue.***

Visit: www.DarkReport.com