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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

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Founder & Publisher

Go to a Football Game, Get a Free Genetic Test!

GENETIC TESTS REPLACED BOBBLEHEAD DOLLS AS THE GIVEAWAY at yesterday's Baltimore Ravens home game against the Cleveland Browns. That's a first in the world of professional sports!

Tens of thousands of football fans received a fee DNA test kit as they entered the stadium on Sunday. The event was sponsored by **Orig3n**, a genetic testing company based in Boston. Orig3n is offering a free test of four genes.

News reports said that one gene being tested is described by the company as helping to "predict an increased risk of low levels of Vitamin D." ACTN3 was the only other gene included in the test that was identified. It was described as "yielding information on whether a person 'is likely to have enhanced performance in power and sprint activities or is considered normal.'"

During the game, fans can use the collection kit to swab the inside of their cheeks. The samples can be left at collection bins inside the stadium and the consumer will then register online with Orig3n to obtain the results.

Critics were quick to point out the many problems that could result from such a free genetic testing effort. "There's nothing in this that I think is a good idea," stated Toni Pollin, MS, PhD, an associate professor at **University of Maryland School of Medicine**, in an interview with the *Baltimore Sun*. "The tests they are talking about are not going to be useful for a particular individual."

On the other hand, this could be a marketing coup for Orig3n, founded in 2014. Where the Ravens play, the **M&T Bank Stadium,** seats about 71,000 fans. In one afternoon, the gene testing company reaches tens of thousands of people with a free sample of its genetic test. It also benefits from the many news stories about this unique free genetic testing program.

What is most significant about this free genetic testing program at a professional football game is how it confirms that genetic testing is becoming almost commonplace. If a professional football team can allow free genetic tests for fans, what unorthodox setting will gene testing companies use next to get their tests out to the public?

I wonder if an analysis of one's genes would demonstrate the potential for enhanced performance in power and sprint activities? In my school days, my football and rugby coaches figured that out on their own, without the benefit of a genetic test. And their findings were reliable, reproducible, and accurate! TDR

Labs in Texas, California Deal With Fraud Charges

Allegations include fraud, illegal kickbacks, and medically unnecessary tests at two labs

CEO SUMMARY: Two toxicology lab companies accused of fraud are fighting to stay in business. In the case of Medicus Laboratories of Dallas, it is asking a federal judge to issue a temporary restraining order to prevent state and federal lab regulators from pulling its CLIA license. At Proove Biosciences of Irvine, Calif., following a series of news reports about ex-employees and others accusing Proove of illegal actions, the company went to bankruptcy court and put itself in receivership.

TWO LABORATORY COMPANIES WERE responding in different ways as a result of fraud charges in recent weeks. In one case, the charges came in a series of news articles that appear to have led to a bankruptcy filing. In the other case, the fraud charges stemmed from lawsuits by the government and from one of the nation's largest health insurers.

One laboratory company was **Proove Biosciences**, a genetic testing firm in Irvine, Calif., that was ordered into receivership for restructuring and asset sale, according to *Stat News*. *(See sidebar, page 5.)*

The other company was **Medicus Laboratories** of Dallas. On Aug. 18, Medicus and its majority owner, **Next Health**, sought a temporary restraining order in County Court of Law No. 3 in Dallas. The companies sought an injunction to stop the federal **Department of Health and Human Services** from suspending or revoking their federal laboratory licenses. Also named as defendants were Thomas Price, the DHHS Secretary, and Seema Verma, administrator of the federal **Centers for Medicare and Medicaid Services**.

The Dallas Morning News reported earlier this month that, in 2014, Medicus paid $5 million to settle a federal civil complaint that it defrauded Medicare over urine testing services. In its request for a restraining order, Next Health and Medicus charged that state and federal officials intend to shut down the lab.

In addition, the newspaper reported, "A team of state and federal inspectors arrived at Medicus' laboratory in April for

a five-day inspection, reportedly in response to an anonymous complaint, the lawsuit said. The team also inspected five other labs owned in part by Next Health, the lawsuit said."

Lab's 'Pervasive Problems'

In a letter from CMS dated May 10 to officials at Next Health and Medicus, CMS said of Medicus, "Your laboratory demonstrated systemic and pervasive problems throughout the laboratory which has led to the findings of immediate jeopardy," the newspaper reported. Such a finding means that CMS can suspend, limit, or revoke a laboratory's license to operate and do so without a hearing or a chance to challenge the allegations, the article added.

The Dallas newspaper also reported on the alleged, so-called "Whataburger scheme," saying, a former marketing contractor for Next Health was named in an unrelated criminal case involving alleged kickbacks for lab tests. In that case, prosecutors reported that a company called the **ADAR Group** gave out $50 gift cards to people in exchange for having them urinate in cups in restrooms at Whataburger restaurants, the newspaper reported, saying the tests were part of a wellness study.

In addition to the problems Next Health and Medicus face with CMS, *Becker's Hospital Review* reported Sept. 6 that two executives of Next Health, Andrew Hillman and Semyo Narosov, were facing federal kickback charges in connection with their relationship to **Forest Park Medical Center** in Dallas. Hillman, Narosov, and 19 others allegedly paid or received $40 million in bribes and kickbacks to physicians and other providers for overpriced and unnecessary drug and genetic tests, the website reported.

On Dec. 1, U.S. Attorney John Parker of the Northern District of Texas announced that FPMC's founders, investors, physicians, surgeons, and other executives were charged with various felony offenses stemming from their payment or receipt of approximately $40 million in bribes and kickbacks for referring certain patients to FPMC.

Next Health faces more legal trouble as a result of a lawsuit from one of the nation's largest health insurers, **UnitedHealthcare**. In January, UHC named Next Health and other affiliated labs in a lawsuit filed in U.S. District Court for the Northern District of Texas. In addition to Next Health, UHC named **United Toxicology**, Medicus Laboratories, **US Toxicology**, **American Laboratories Group**, Erik Bugen, and Kirk Zajac as defendants. The labs perform drug and genetic laboratory tests and Next Health describes itself as a leading ancillary service company, the lawsuit says.

'Unlawful Conduct' Cited

In the lawsuit, UHC says, "Next Health's rapid growth has been primarily, if not exclusively, driven by its unlawful conduct and inappropriate business practices. Specifically, Next Health and its subsidiary labs paid bribes and kickbacks to referral sources (physicians, sober homes, sales consultants, etc.) in exchange for test orders; they inappropriately utilized standing test protocols regardless of patients' medical histories, clinical conditions, or needs; they performed and billed for testing services that were not ordered by physicians; they improperly billed for services that they did not perform; and they routinely ignored patients' payment responsibilities to avoid drawing attention to the scheme."

UHC's lawsuit references the DOJ's actions in December, saying the DOJ indicted several executives, surgeons, physicians and others in connection with a similar illegal kickback conspiracy at Forest Park Medical Center.

"For years, Next Health and its subsidiaries succeeded in illegally billing commercial insurers for improper and unnecessary laboratory services," the

UHC lawsuit states. "Between 2011 and mid-2016, Next Health and its subsidiaries submitted thousands of claims to United, charging more than $400 million for out-of-network drug and pharmacogenetic laboratory testing services. United paid Next Health and its subsidiaries more than $100 million for these claims. Unbeknownst to United, all of the claims arose from the illegal and improper practices set forth herein."

Kickbacks and/or Bribes

Last year, UnitedHealth discovered the illegal operation, then launched an investigation into Next Health and its subsidiary labs. "The investigation revealed, among other things, that Next Health funneled kickbacks and/or bribes to providers in multiple geographic areas for drug and pharmaco-genetic test orders," said the court papers.

"One of these illicit arrangements involved Next Health's sales consultants paying people $50 to urinate in a cup in a Whataburger bathroom so that the urine could be portioned out and sent to Next Health for multiple unnecessary and expensive drug tests that were later billed to United and its customers. This one kickback scheme resulted in UnitedHealth paying Next Health subsidiaries more than $11.1 million in less than one year," said the lawsuit.

'Unlawful Conduct' Cited

One characteristic that Medicus Laboratories and Proove Biosciences have in common is that they specialize in testing for pain management and drugs of abuse. This sector of the clinical laboratory industry has a reputation for fraud and abuse on an unprecedented scale. Is the Medicus case—involving enforcement action by federal lab regulators and a lawsuit by a major health insurer—a first sign that federal prosecutors and private payers are ready to get tough with lab companies accused of illegal activities? TDR

—Joseph Burns

Troubled Proove Biosciences Forced Into Receivership

IN AUGUST, Proove Biosciences, a genetic testing company in Irvine, Calif., was ordered into receivership for restructuring and asset sale, according to *Stat News*. In a report by Stat's West Coast Editor Charles Piller, he wrote that, on Aug. 7, the court supervising the case appointed Michael Thatcher of **Glass Ratner Advisory & Capital Group** of Atlanta as receiver.

Since last December, Piller has written several critical stories about Proove. In his article on Aug. 31, Piller reported that Proove founder Brian Meshkin blamed the company's problems on Stat's reporting, specifically articles published in December and February. "Those articles quoted experts who expressed deep doubts about the company's scientific claims that it could predict a patient's likelihood of becoming addicted to opioids," Piller wrote. In his earlier reporting on Proove in December and February, Piller had written that one researcher said the company's claims about its tests linking a patients' genetic profile to addiction to be "hogwash."

"Stat's investigations also described business practices—including coercing patients to take unnecessary genetic tests—that former Proove employees and outside experts described as unethical and possibly illegal," Piller wrote.

FBI agents and representatives from the federal Department of Health and Human Services raided Proove's offices in June collecting documents in a criminal probe, Piller wrote. "According to legal experts, Proove and many of its affiliated doctors operated in ways that could violate federal and state anti-kickback laws, which are meant to prevent unneeded testing," he added.

In defending his company, Meshkin called the reporting on the company's practices to be "erroneous and damaging" and said they were based on false allegations from disgruntled employees.

Positive Patient ID System for Toxicology Testing

Texas lab company develops new solution to give physicians confidence with patient results

CEO SUMMARY: The urine drug testing industry is challenged every day to detect the large number of patients trying to cheat on their drug tests. GenoTox Laboratories of Austin, Texas, developed a DNA-authentication method for urine samples that allows the lab to detect when patients have used a substitute for urine when undergoing medication- and sobriety-monitoring. Called ToxProtect, the test authenticates samples and detects urine sample substitutions.

EVERY LABORATORY WANTS TO DIFFERENTIATE its lab testing services. The goal is to add value to the physicians and patients it serves while giving it a competitive advantage over other labs. A lab company in Austin, Texas, has developed a diagnostic service that it hopes will help it achieve both goals.

GenoTox Laboratories is a toxicology lab company that provides testing for medication monitoring in pain management and sobriety programs. It saw an opportunity to give its client physicians and other licensed providers a way to ensure that the urine specimen collected from a patient did, indeed, come from that patient.

Authenticity of Specimens

"Urine testing is the gold standard for monitoring for drug abuse and treatment compliance," stated Shawn Lunney, COO of GenoTox. "So, it becomes a significant problem when the authenticity of the specimen is in question. It can threaten the integrity of the therapeutic treatment plan and compromise the trust crucial in the physician-patient relationship.

"Addiction is a disease of the brain and not a moral failing," said anesthesiologist and board-certified pain specialist Matthew McCarty, MD, Founder and Chair of GenoTox. "By the time a patient is addicted, he or she will do anything to access the drug, including cheating on urine tests."

Every clinical laboratory performing drugs of abuse testing knows that patients commonly attempt to fool these tests. Synthetic urine and similar products intended to corrupt the testing are a billion-dollar business. Using warmed substitute urine often is touted online as a fool-proof way to cheat a drug test.

GenoTox saw the opportunity to improve the integrity of urine drug testing. It believed many physicians would take advantage of a service that would scientifically confirm—with 100% accuracy—that the urine specimen submitted to the lab was from the patient being tested.

To give physicians confidence that the lab results come from the patient, GenoTox developed an assay, called ToxProtect, that uses DNA-authentication

of urine samples. Company executives thought the test could revolutionize medication and sobriety monitoring. A patent is pending for this test.

"The test represents the first innovation in the science of urine testing in over a decade," Lunney told THE DARK REPORT. "It's disruptive technology aimed at significantly improving the value by overcoming the shortcomings of current validity testing in urine drug testing."

Next-Generation Drug Test

GenoTox calls ToxProtect a next-generation urine drug test (UDT) that authenticates samples, reveals mislabeling errors, and detects urine sample substitutions. The test involves adding a one-time cheek swab to the urine collection process.

When a physician has questions about a sample's authenticity or if there is a history of unexplained results in the presence of normal validity measures, a physician will order ToxProtect. GenoTox has used ToxProtect on more than 10,000 samples.

Based on its experience working with ToxProtect and clinical specimens, GenoTox learned that, each time ToxProtect reported a negative match (where the patient's urine specimen and the patient's DNA sample did not match), in 98% of these cases, the validity tests for the urine specimen had reported normal (that it was human urine). GenoTox concludes that these findings demonstrate how easily warmed substitute urine can fool validity testing methods.

GenoTox uses advanced technologies, such as **Agilent** 6460 liquid chromatography systems, for its urine testing. Its test detects more than 100 controlled substances and reveals the presence of synthetic or substitute human urine. Results are delivered via online physician portal, fax, or EMR interface, usually within 32 hours.

To develop the genetic ID with its ToxProtect assay, the lab uses genomic cross-verification to match a urine sample

Flagging Patients Who Cheat by Adulterating Their Samples

"WE HAVE MANY STORIES OF SUCCESS with our positive patient ID test," stated Michael Willoughby, Chief Commercial Officer of GenoTox. "One physician using ToxProtect had 12 patients who did not match the specimens. This test enabled him to identify sample-adulterating issues that would otherwise have gone unnoticed.

"At another clinic, ToxProtect revealed 13 substitutions in the first 200 confirmations," he added. "These physicians had the opportunity to consult with their patients who were substituting urine samples and place them on a revised treatment plan. They were able to discuss potentially life-threatening issues such as addiction and discontinue controlled substances or, by recognizing earlier relapse, recommend a higher level of addiction treatment.

"Another benefit to ToxProtect is that it doesn't take long for a physician's patients to learn about its ability to detect adulterated urine specimens," he continued. "We've had feedback that ToxProtect becomes a deterrent against cheating, resulting in open conversations about what is truly going on with the patients in their treatment plans.

"Our client physicians tell us that ToxProtect has helped many of their patients get back on track," explained Willoughby. "One doctor told us that a patient actually called in and admitted to submitting synthetic urine in a random test when faced with genetic matching. These are patients who previously slipped through the system without being detected."

Willoughby also pointed out that another benefit of ToxProtect is how patients no longer have to go to a collection center to provide a urine sample. "They can do it at home and ship the specimen to the lab overnight. "This convenience factor can help patients stay on track and provide a truly randomized sample collection."

to its donor. The matching has been accurate in 100% of the cases.

The need for a way to positively confirm the authenticity of a urine specimen and that it does come from the patient is recognized by other health organizations. For example, in June, the **American Medical Association** issued a CPT code (0007U) for ToxProtect. This code will be added to CMS' Clinical Laboratory Fee Schedule for 2018 as a proprietary laboratory assay.

In addition to CMS, other payers are interested as well. "GenoTox has been accepted as an in-network provider by **Amerigroup** and **Blue Cross**," stated Michael Willoughby, GenoTox' Chief Commercial Officer. "Insurers recognize that there is value in getting the earliest possible detection of illicit drug use.

"Discontinuing opioids when cheating occurs saves on future urine drug testing and other services," he explained. "Also, recognizing relapse in addiction earlier than conventional drug testing allows doctors to start more aggressive treatment, such as medication-assisted treatment."

Other laboratories have considered co-marketing the ToxProtect test. "We're in active discussions across the country," noted Willoughby. "We have 20 reps in various states and are looking at the possibility of strategic partnerships with larger labs that cover regions where we do not have reps and to partner with hospital outreach programs."

Developed to Fill A Need

It was an actual incident in his clinic that motivated McCarty to develop a solution to counter patients who cheat on their drug tests. McCarty, board-certified in pain medicine, recounted the story of an overheard conversation between a mother and daughter in the lobby of his clinic, which caught his attention. "I heard the mother say to her daughter, 'Make sure it's the right temperature,'" recalled McCarty. "I knew that synthetic urine kits often include methods for warming the solution to mimic an authentic specimen. This episode motivated me to find a fail-safe way to match urine drug test specimens and donors."

Recognizing the frustrations physicians have when prescribing pain medications because of all the "cheat on urine test" products for sale in the marketplace, McCarty asked his team at GenoTox if there was any way to match the specimen to the patient.

"It took us about two years to develop a method to accomplish this goal," stated Lunney. "It can be difficult to isolate DNA from urine."

Proliferation Of Tox Labs

Another factor supports the need for a solution that positively confirms the authenticity of a urine specimen. It is the explosive growth in opioid prescriptions and the associated need to use drug tests to monitor patients' compliance. That growth also brought with it a proliferation of new toxicology laboratories built around urine testing.

Many of these toxicology and pain management lab companies use questionable and even fraudulent business models and practices so as to quickly cash in on the profit boom of the confirmatory testing market.

"The toxicology world in general has built a reputation around urine drug testing that is less than credible," McCarty told THE DARK REPORT. "At the same time, the opioid epidemic presents complex challenges for all stakeholders.

"That includes what we call the four P's: patients, physicians, payers, and populations," he added. "Payers are faced with questionable claims. Communities across all demographics are being affected. Patients are at risk of not getting the safety and therapeutic benefits of their treatment plan. Physicians face uncertainty regarding the authenticity of urine specimens."

Lunney highlighted an associated industry which enables patients to cheat on their urine tests. "Today, hundreds of vendors are selling synthetic urine products designed to cheat the UDTs," he observed. "This is now a $1 billion-dollar-year industry in the United States!

500 Fake Urine Products

"For example, **Amazon.com** currently features almost 500 products intended to prevent accurate UDT results and just four years ago only 120 products were offered," observed Lunney. "Sadly, traditional validation measures—including pH, temperature, creatinine, and specific gravity—are not 100% reliable in uncovering this healthcare fraud

"Until now, there has been no solid authentication method capable of definitively matching the patient to the sample. That means that current estimates of drug diversion—12.8%—are likely low," he continued. "It becomes very challenging for doctors to simultaneously balance legitimate patient needs against reasonable vigilance measures, including UDTs, while maintaining effective therapeutic relationships with patients."

When asked how physicians were responding to the ToxProtect test, Willoughby was quick to respond. "Physicians tell us that ToxProtect is a valuable clinical tool in three primary areas," he said. "First, it helps them protect a patient's treatment plan by answering the nagging questions surrounding a particular sample's authenticity.

Cheating Patients Identified

"Second, it uncovers patients who are cheating, making it possible to discontinue use of controlled substances or uncovering relapse earlier," he added. "And, third, it protects both the physician and the medical practice from unnecessary liability."

Within the clinical laboratory industry, the toxicology and pain management sector is recognized to have widespread problems with patient compliance, along with fraud and abuse by numerous lab companies. In order to differentiate itself in the marketplace as a legitimate lab company while delivering a useful benefit to referring physicians, GenoTox took the high road by developing a DNA-based test that matches the urine sample to the patient with an extremely high level of confidence.

Lab administrators, pathologists, and PhDs should consider GenoTox and its ToxProtect assay as examples of how innovative thinking and willingness to invest in developing a useful solution can pay dividends. It is why, in this highly competitive market segment—often marked by abusive sales practices—GenoTox is winning the loyalty of a growing number of physicians because it is helping them achieve better outcomes with their patients. TDR

—Pamela Scherer McLeod

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Opioid Epidemic Fuels Need to Stop Drug Test Cheating

ACROSS THE NATION, OPIOID ADDICTION is now a major problem. The story of the opioid epidemic is steeped in tragedy, rooted in greed, and marked by a critical need for effective tools to address the problem.

The statistics of the opioid crisis are staggering—both in terms of the number of overdose deaths and the broader economic impact. According to the CDC's website, between 2000 to 2015, more than 500,000 people died from drug overdoses. Overall, federal officials estimate that opioid abuse drains nearly $80 billion a year from the American economy.

In July, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that the president declare the opioid-addiction crisis to be a national emergency priority.

CEO SUMMARY: In the latest chapter of an explosive case at the University of Kansas Medical Center that includes claims of a cancer misdiagnosis, an unnecessary surgery, and a cover-up that involves the former chair of pathology, the patient has sued for fraud, negligence, and civil conspiracy. After a whistleblowing pathologist filed an earlier lawsuit, Medicare did its own investigation and found deficiencies in care delivery that left patients at the University of Kansas Medical Center at risk.

Former pathology chair, surgeon, academic hospital named in lawsuit

Pathologist's Error, Cover-up Lead to CMS Investigation

AMONG MANY SIGNIFICANT DEVELOPMENTS in a case of misdiagnosis and a cover-up involving the now-former chair of pathology at **University of Kansas Medical Center** (KUMC), one of the most explosive is that the federal **Centers for Medicare and Medicaid Services** had done its own investigation in the case.

As a result of its investigation into this medical error and the actions of hospital staff following an unnecessary surgery, CMS stated that the actions of the pathologist, the surgeon, and other hospital staff were deficient and "placed all patients receiving services at [the] hospital at risk for receiving care that does not meet acceptable quality and standards."

The disclosure of CMS involvement comes one year after a pathologist, Lowell Tilzer, MD, filed a whistleblower lawsuit charging that the chair of the department of pathology at KUMC had misdiagnosed a patient's illness, causing a surgeon to remove the patient's organs unnecessarily. The lawsuit then said the pathology chair and the surgeon covered up the misdiagnosis.

The fact that CMS investigated the claims in Tilzer's lawsuit was disclosed in a lawsuit the patient, Wendy Ann Noon Berner, filed Aug. 1. Berner's lawsuit restated many of the statements in Tilzer's lawsuit, including the charges that after being notified of the diagnostic error and the patient's unnecessary surgery, "KUMC's and KU Hospital's administrators resisted [the whistleblower's] efforts to thoroughly investigate the matter and conduct a review known as a 'root cause analysis;' and KUMC and KU Hospital did not take corrective action." THE DARK REPORT covered these developments last year. *(See TDR, July 25 and Sept. 26, 2016.)*

For laboratory professionals, this case is a public example of how the healthcare system can harm a patient in a life-changing manner and then fail to be accountable to that patient.

In addition, this case highlights the flaws in the system of hospital and laboratory accreditation and regulation. If not for a single principled pathologist in the department who recognized the diagnostic error and how the patient was harmed—but who was not told about the error—then this flagrant cover-up might have succeeded.

Told post-surgery that she was cancer-free, Berner would not have learned that her life-changing surgery was unnecessary. But now she must live without essential organs, needlessly removed.

Also, if not for Tilzer and now Berner, this major medical error and the alleged cover-up by the diagnosing pathologist, the surgeon, and the hospital administration, would never have come to the attention of the hospital's accrediting bodies and government regulators. A patient choosing a hospital would be unaware of this diagnostic error and the actions of physicians and administrators to hide the error from the patient, regulators, and the public.

Using court documents, THE DARK REPORT provides an overview of the alleged original diagnostic error by the former chair of pathology at KUMC and the subsequent events as described in Berner's lawsuit.

On Aug. 1, Berner filed her lawsuit in Wyandotte County District Court, claiming fraud, negligence, and civil conspiracy. Named as defendants are the pathologist and former chair of the KUMC pathology department, Meenakshi Singh, MD; the surgeon, Timothy M. Schmitt, MD; **Kansas City Hospital Authority**, the University of Kansas Medical Center, and the **University of Kansas Physicians**. In addition to the misdiagnosis and needless surgery, the lawsuit alleged that Singh amended the patient's medical record to conceal the misdiagnosis. As a result of not informing Berner about the misdiagnosis, the patient got suspicious and started investigating the case, the lawsuit charges. That's when she read about the misdiagnosis in a Kansas City newspaper last summer.

After Tilzer filed a lawsuit on July 1, 2016, in which he outlined the steps that led to the alleged misdiagnosis, Singh, hospital CEO Bob Page, and others sought to cover up the misdiagnosis, court records show. Tilzer also alleged that Page reprimanded and attempted to intimidate him during a meeting in Page's office.

In his lawsuit, Tilzer charged that Singh, who at the time was the head of pathology at

KU Medical Center, misdiagnosed an unnamed patient as having cancer. That misdiagnosis led to the surgical removal of part of the patient's pancreas, records show.

That lawsuit raised troubling questions for the hospital because Tilzer was the former chair of pathology at the hospital, and he was challenging the misdiagnosis of Singh, who was the department chair when the patient was misdiagnosed as having pancreatic cancer. Tilzer later withdrew his lawsuit.

In the most recent lawsuit, Berner fills in the details in the case, explaining that Singh reviewed three fine needle aspirate samples from Berner's pancreas and "misdiagnosed one or more of the FNA samples as cancerous, including her primary misdiagnosis of pancreatic neuroendocrine tumor."

Based on that misdiagnosis, Berner, who was 44 at the time, was informed that this type of cancer is 94% lethal within five years of diagnosis, the lawsuit says, adding that Schmitt told her surgery was necessary for her survival.

Life-Altering Surgery

Schmitt explained that Berner needed a Whipple procedure but did not explain the possible complications, such as lifelong medical complications, the loss of some or all of the essential functions of her pancreas, temporary or permanent loss of digestive functions and enzyme production, the inability to produce insulin, the development of diabetes, and the need to take high-cost medications for life, the lawsuit charges.

On Sept. 1, 2015, Schmitt performed a modified Whipple procedure and open cholecystectomy and also removed her appendix, a portion of her small intestine, and her bile duct, the court records show. "The modified Whipple procedure is a major surgical operation involving the removal of the head of the pancreas, the duodenum, the proximal jejunum, gallbladder, and part of the stomach," the lawsuit says.

During a post-surgery examination of Berner's tissue samples, a board-certified pathologist established that the plaintiff's pancreas was not cancerous and was "essentially normal," the lawsuit says.

Tissue 'Essentially Normal'

"The 9/4/15 surgical pathology report concluded: "[n]egative for tumor in the entirely submitted specimen. After the post-surgery examination determined that Plaintiff's pancreas was not cancerous, the pre-surgery tissue sample was re-examined by the same board-certified pathologist. The post-surgery re-examination of the pre-surgery tissue sample established that the pre-surgery sample was not cancerous, and that Dr. Singh misdiagnosed the pre-surgery tissue sample. The removed portion of plaintiff's pancreas was normal. The entire Whipple procedure on 9/1/15 was unnecessary," court documents show.

After learning the results of the post-surgery examination, Singh told Schmitt the results of the FNA that she used as the basis for diagnosis of neuroendocrine tumor of the pancreas was inaccurate.

In his whistleblower complaint last year, Tilzer alleged that Singh did not recognize the difference between acinar cells and islet cells. She then covered up her misdiagnosis by placing an addendum to her original report stating the original cancer diagnosis and the normal removed organ matched, thereby concealing her original misdiagnosis and perpetuating Berner's mistaken belief that her pancreas was cancerous, the lawsuit explains.

After being hospitalized for eight days, Berner was discharged on Sept. 9, 2015, five days after the post-surgery examination. At this time, she was not yet informed of the misdiagnosis and still had a diagnosis of primary pancreatic neuroendocrine tumor, the lawsuit charges.

On Sept. 18, nine days after Berner's discharge, Singh added an addendum to the medical record, say court documents.

In Case of Pathologist's Misdiagnosis at KUMC, Timeline of Events Begins in September 2015

THE FOLLOWING IS A TIMELINE OF EVENTS in the case of patient Wendy Ann Noon Berner, who filed a lawsuit against the University of Kansas Hospital Authority, Kansas University Medical Center, KU Hospital and others, charging a misdiagnosis, needless surgery, and a cover up. The source for all statements in this timeline are the lawsuits filed in this case.

August 2015: Pathologist Meenakshi Singh, MD, who is Chair of Pathology at Kansas University Medical Center, diagnosed Berner with pancreatic neuroendocrine tumor.

Sept. 1, 2015: Patient undergoes a modified Whipple procedure and open cholecystectomy, during which her appendix, a portion of her small intestine, and her bile duct are removed.

Sept. 4, 2015: Pathologists conduct a post-surgery review of removed organs and find no evidence of cancer.

September 2015: Pathologist Lowell Tilzer, MD, informed KU Hospital's chief medical officer and risk management officer that a root-cause analysis was needed.

September 2015: CMO said Singh's diagnosis was correct because two other pathologists signed off on her report. In fact, Singh had added those pathologists' names in the record.

Sept. 17, 2015: Patient meets with surgeon Timothy Schmitt, MD, for post-surgery follow up and is told, "Good news. No Cancer." Berner interprets this statement to mean surgery successfully removed cancerous tumor.

Sept. 27-30, 2015: Patient returns to KUMC due to complications from surgery and is startled to learn from an ER physician that during surgery on Sept. 1, her surgeon had removed her appendix.

Oct. 8, 2015: In follow-up visit Berner asks Schmitt why her appendix was removed. Schmitt replies that it had to come out because it forms the same type of tumors the pancreas had.

Early 2016: During a QI review, staff of KUMC/KU Hospital reviewed the three FNA samples and classified them as "major misinterpretations" and determined that the misinterpretation led to unneeded surgery.

Early 2016: Singh lobbied supervisor of cytopathology to edit the QI document to minimize or eliminate references to "major misinterpretation" and to the fact that an unneeded surgery occurred.

April 1, 2016: Tilzer reported to the Joint Commission about the misdiagnosis and failure to correct the medical record.

April 5, 2016: Berner has another complication and needs hernia repair. Schmitt's surgical note states that the patient has "a history of neuroendocrine tumor of the pancreas."

April 6, 2016: Tilzer meets with director of risk management about the need for a root-cause analysis.

May 31, 2016: KU Hospital President Bob Page reprimands and attempts to intimidate Tilzer, and describes Tilzer's report to the Joint Commission as despicable behavior.

July 1, 2016: Tilzer files whistleblower lawsuit.

Aug. 1, 2017: Wendy Ann Noon Berner files lawsuit against University of Kansas Hospital Authority, Kansas University Medical Center, KU Hospital, The University of Kansas Physicians, Meenakshi Singh, MD, and Timothy M. Schmitt, MD.

At this point, Singh and Schmitt took additional steps to conceal the misdiagnosis, the documents show. "For example, according to Tilzer's whistleblower petition, Singh—who was the chair of the Pathology Department—did not report her misdiagnosis to KU Hospital's chief medical officer, Risk Management Committee, or risk manager. Upon information and belief, Schmitt also failed to report the critical misdiagnosis," the lawsuit says.

On Sept. 17, 2015, Berner met with Schmitt for a follow-up appointment. "Schmitt stated to plaintiff, 'Good news, no cancer.' Understandably, plaintiff interpreted Schmitt's statement to mean that Schmitt successfully removed the cancerous portion of her pancreas containing the neuroendocrine tumor previously identified by Singh," the lawsuit says.

Later that month, Berner was hospitalized due to complications from the surgery and heard startling news from an emergency room doctor. "Oh, I heard about you. You had an extended Whipple procedure and had your appendix out," the doctor told her, the lawsuit alleges.

Shocking News

This news shocked Berner because Schmitt had never mentioned removing her appendix, court papers show. On Oct. 8, 2015, Berner asked Schmitt about her appendix. "Schmitt said, 'Oh, I must have forgotten to tell you. I had to take that out because they form the same kind of tumors that your pancreas had," the lawsuit says.

In April 2016, Berner had another complication from surgery and needed an insicionnal hernia repair, the lawsuit states. In documenting the repair, Schmitt described Berner as "having a history of neuroendocrine tumor of the pancreas," the lawsuit states, adding, "This was not a clerical or charting error; it was a continuation of the efforts to cover-up the misdiagnosis and the unnecessary surgery."

Early in 2016, staff at KUMC/KU Hospital reviewed the three FNAs during a quality improvement session. "In doing so, KUMC/KU Hospital classified them as 'major misinterpretations,' and determined that the misinterpretations led to an unneeded, major surgery," the lawsuit says.

Lab's Review Of The Case

At this point, Singh lobbied the supervisor of cytopathology to edit the QI document to minimize or eliminate references to the 'major misinterpretations,' and to minimize or eliminate the fact that an unneeded, major surgery occurred, the court papers show. "Singh also instructed others to alter meeting minutes referencing her misdiagnosis, and the necessity of conducting a 'root cause analysis,'" the records show.

In September 2015, Tilzer told the KU Hospital's chief medical officer and risk management officer that a root cause analysis was needed. At the time, the CMO stated that Singh's original diagnosis was correct because two other pathologists had signed the report, the lawsuit says.

As was reported earlier, the pathologists did not agree with the original diagnosis, and their names were simply added to the electronic medical record. The CMO thus perpetuated the cover up, the lawsuit says, and a root cause analysis was never done.

After Singh requested that the medical records be altered and, after the hospital failed to conduct a root cause analysis, Tilzer reported the case to **The Joint Commission**. Court papers say he explained the misdiagnosis, the cover up, and that no effort was made to correct Berner's medical records or inform the patient of the misdiagnosis.

Attempt To Intimidate

Following Tilzer's report to The Joint Commission, Page reprimanded and attempted to intimidate him, the lawsuit explains. On the day Tilzer filed his whistleblower petition, Page sent an email to all KU medical staff, and perpetuated the

KU defendants' efforts to conceal the misdiagnosis and cover-up, the lawsuit says.

The lawsuit quotes from the email Page sent as follows:

"The hospital received word today (Friday, July 1st) that pathologist Dr. Lowell Tilzer had filed a 'whistleblower' lawsuit against us. The suit alleges a misdiagnosis was made on a cancer patient by a physician, leading to unnecessary surgery. The suit further alleges the hospital ignored Dr. Tilzer's calls for a review of the case and never informed the patient of the misdiagnosis. In short, this is simply not true."

Page's statements were patently false, the lawsuit says.

The CMS Investigation

In July 2016, the Kansas City Regional Office of CMS began investigating Tilzer's allegations. That month, Schmitt asked Berner to sign an affidavit to insulate the defendants from liability, the lawsuit says.

In the affidavit, Schmitt asked Berner to lie about the timing of when he deceptively told her, 'Good news, no cancer,' without informing her of the misdiagnosis, that she never had a cancerous pancreatic neuroendocrine tumor, and that she underwent an unnecessary surgery involving lifelong complications, the lawsuit says. The affidavit also failed to mention Schmitt's efforts to conceal the problems from Berner, records show.

At this point, Berner became suspicious and learned from a news article about Tilzer's whistleblower petition filed in July 2016, stating that she was misdiagnosed with cancer, that her medical records were incorrect, that she never had a cancerous pancreatic neuroendocrine tumor, and that she underwent an unnecessary surgery involving lifelong complications. After requesting a copy of her own medical records, Berner saw multiple references to the incorrect misdiagnosis, and saw that she had history for a pancreatic neuroendocrine tumor, the lawsuit says.

KUMC Issues Statement about the Berner Lawsuit

IN A STATEMENT TO DAN MARGOLIES of KCUR Radio, a spokesman for the University of Kansas Health System said the hospital was constrained in what it could say about Berner's case. "Ensuring the health and well-being of every patient at the University of Kansas Health System is our top priority," said spokesperson Dennis McCulloch. "We need to be respectful of patient privacy and confidentiality, and because of that we are limited in what we can say on this matter. That said, we do believe that our physicians and staff acted appropriately and with the best interests of our patient in mind."

Following its review, CMS found that "the hospital's medical staff failed to ensure the quality of care provided to [plaintiff] in that the surgeon and other hospital staff failed to inform the patient during her hospitalization that she did not have cancer and that her appendix had been removed during surgery; failed to update [plaintiff's] medical record to remove the diagnosis of cancer, and failed to completely and thoroughly investigate the incident," the lawsuit says.

CMS also found that the governing body of the hospital "failed to ensure the hospital promoted and protected the rights of [plaintiff] by failing to keep her fully informed of her diagnosis, a misread lab, and her surgical procedure."

In addition, CMS said the hospital's governing body, "failed to ensure that the Medical Staff Committee appointed a qualified pathologist to a position by not ensuring that she met the special qualifications listed on the application for privileges," and that the hospital's "deficient practices placed all patients receiving services at [the] hospital at risk for receiving care that does not meet acceptable quality and standards." TDR

—Joseph Burns

NYU Langone and Sonic Create Lab Outreach JV

➤Joint venture will serve 2,000 office-based doctors employed at NYU Langone Health system

➤➤CEO SUMMARY: NYU Langone Health recognized the clinical and financial advantages of providing competitive lab outreach testing services to its employed physicians. The laboratory joint venture with Sonic Healthcare USA will allow NYU Langone to increase use of its hospital labs and will facilitate standardizing its testing methods, results, and reference ranges. The first phase of the JV will begin Oct. 1, when NYU Langone will replace and enhance the services other third party labs currently perform.

BUILDING A PROFITABLE HOSPITAL LABORATORY OUTREACH BUSINESS continues to be attractive to some hospital administrators. On Aug. 15, **NYU Langone Health** and **Sonic Healthcare USA** announced an agreement to form a laboratory outreach joint venture.

The partners will operate the JV under the name **NYU Langone Diagnostics LLC**. In the first phase of business development, the JV will focus on serving more than 2,000 physicians that NYU Langone employs throughout the five boroughs of New York City and the two counties (Nassau and Suffolk) on Long Island.

Through the JV, NYU Langone expects to improve lab test turnaround times. "We hope to provide faster turnaround times by leveraging Sonic's laboratory testing capabilities in their facility on Long Island to supplement our own hospital labs," said Mark Pollard, Vice President of Hospital Operations for NYU Langone Health. "We already have fast turnaround times in our inpatient settings, and now we hope to offer similar capabilities for outreach testing.

"The ideal is to report outreach test results within 24 hours," he said. "That's not always the case, either because of the distance that specimens must travel to a commercial lab or what happens to those tests once they get there. But we're confident we will hit that 24-hour turnaround time in this relationship."

Improved TAT is possible because Sonic has the necessary infrastructure in the New York market to serve NYU Langone, Pollard added. "One of our main criteria when considering this potential partnership was the need for a strong infrastructure to manage this business," he commented.

NYU Langone will continue to manage its inpatient laboratories, but, as part of the JV agreement, it will make Sonic its primary lab for reference and esoteric testing. "The NYU Langone partnership initially is an 80-20 arrangement in which NYU Langone has an 80% stake and Sonic has a 20% stake," stated Noel Maring, Vice President of Hospital Affiliations for Sonic. "We have an option to grow our stake to 51%."

Administrators at NYU Langone recognized the clinical and financial opportunities that a dynamic outreach lab business could produce. At the same time,

Many Hospitals Assessing Lab Outreach Due to Cuts to Medicare Lab Test Fees on Jan. 1

AS JANUARY 1 APPROACHES, hospitals and health systems are becoming increasingly concerned about what effects the deep price cuts to Medicare Part B clinical laboratory fees will have on their lab operations.

"These Medicare fee cuts will make it necessary for hospitals to make important decisions about their lab outreach businesses," stated Noel Maring, Vice President of Hospital Affiliations for Sonic Healthcare USA. "Many hospitals are considering the cost-effectiveness of continuing in the lab outreach business after Jan. 1, when the Medicare price cuts will reduce what they are paid for lab tests. As a result, several health systems around the country have chosen to exit the outreach lab business. Our joint venture model provides hospitals with another more cost-effective option to stay in the lab outreach business.

"Almost every New York hospital has looked at this issue carefully," he added. "It was certainly a consideration for NYU Langone when it decided to form a joint venture with Sonic."

The outreach-only lab joint venture that Sonic Healthcare USA announced with the NYU Langone Medical Center in New York City in August is one example of a health system choosing a partner to assist in managing its lab operations, said Maring.

"Effective Oct. 1, we will begin 'insourcing' the lab business from NYU physicians to NYU hospitals and to Sunrise Medical Laboratories, our lab division on Long Island," explained Maring. "In an organized fashion over the next six to nine months, this lab testing volume will move from various commercial and hospital laboratories to NYU and Sunrise laboratories.

"NYU Langone is a not-for-profit health system that wants to work more closely with the 2,000 physicians it employs throughout the five boroughs of New York City and in the two counties on Long Island," he said. "At a later date, our lab joint venture may consider working with other NYU Langone physicians—meaning those not employed but affiliated.

"In this venture, Sonic shares in the cost, in the revenue stream, and in the associated profits," continued Maring. "The JV's primary goal is to use all the lab facilities of the two organizations in the most efficient manner possible, while providing improved service levels to NYU physicians.

"As its part of the lab outreach joint venture, Sonic's Sunrise lab will do pre- and post-analytical functions as well as provide testing services to the JV," he noted. "Pre-analytical processes will be standardized at all JV lab sites, and NYU hospitals will continue to perform some outreach testing.

"One interesting element in this lab partnership is that NYU wanted more standardization in how lab testing was handled throughout the health system," Maring observed. "For example, NYU has had six or more lab companies serving their different operations. That meant NYU's physicians—in the inpatient, outpatient, and outreach settings—were forced to deal with the different testing methods and different reference ranges of these six lab providers. The lab JV will solve that problem in ways that make physicians more productive in delivering improved patient care."

NYU saw the wisdom of finding a partner to take over its lab outreach program. This joint venture will replace and enhance the services other third-parties currently perform for NYU Langone physicians.

"We may be good at running clinical laboratories and providing high quality clinical laboratory test results, but we don't have the infrastructure to support a diverse and broad outreach laboratory

business, including such functions as courier services and laboratory customer service functions," Pollard said.

"Framing the discussion with the hospital from that perspective helped us to think differently about how we could provide a better model of outreach laboratory testing if we had somebody who could fill in the gaps outside of our hospitals' core services," he added.

Making Outreach a Strength

Now that NYU Langone is working with Sonic, Pollard said the medical center has confidence that its lab outreach business will be one of the strengths of its operations. Hospitals and health systems are questioning whether they should continue their outreach operations, sell them to a lab services company, or form a joint venture as NYU Langone has done.

"During the past 18 months, we have considered our options for the outreach business, but now, with Sonic, we have a unique venture in the NYC marketplace," he said. "Our health system feels strongly about maintaining an active role in the management and the production of outreach laboratory testing results. This partnership is a way for us to stay in that business.

"Not only will we stay in this business, but we will actually provide a better command and control over that whole book of business," Pollard added. "That's significant because outreach is an important component of our physicians' diagnostic process."

NYU Langone also recognized how a partner could help it standardize lab processes throughout the health system, including test results, testing methods, and reference ranges.

"With more than 2,000 physicians in the NYU Langone ambulatory healthcare network, the opportunity to standardize test results is significant," Pollard explained. "Not only is standardization important for physicians and patients, but it is also important so that we can mine our own clinical data.

"That data will give us a much better understanding of population health measures," he said. "Standardized, uniform test data will allow us to develop more predictive models for treatment and clinical interventions across our entire patient population.

"By partnering with a single laboratory provider we hope to enhance our ability to get at that outreach lab test data in a more timely manner," he added. "The lab test results will all reside in our **Epic** electronic health record system which will mean we'll have more and richer data as a result of this partnership.

"Because our outreach business is high volume and geographically dispersed, a robust courier system and accurate technology for tracking specimens are essential," he continued. "Equally important is high-quality customer service for patients who have questions about lab results or billing, and that supports the physician offices. Sonic brings all these resources to the table."

Another advantage is the ability to increase the utilization of the existing inpatient laboratories. "The partnership with Sonic gives us an opportunity to build up our volume by bringing more of the outreach testing back into the hospital labs," noted Pollard. "That additional blended test volume will help us lower the average cost of inpatient testing."

Regional Expansion

One interesting factor in the alignment of the partners in this venture is how the health system has expanded its regional footprint. "In recent years, NYU Langone Health System has acquired physician practices in Brooklyn and in Nassau and Suffolk counties," observed Pollard. "It turns out our expansion into these areas aligned nicely with where Sonic and its Sunrise Medical Laboratory division have existing operations. So, right off the bat, our lab joint venture begins with good synergy." **TDR**

—Joseph Burns

Contact Noel Maring at 512-439-1677 or NMaring@SonicHealthcareUSA.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, **23andMe** raised $250 million in a financing round led by **Sequoia Capital**. The company has an estimated value of $1.75 billion and has attracted $491 million in capital since its founding. In 2015, 23andMe formed a therapeutics division. This business unit is partnering with several major players in the pharmaceutical industry to use genetic data to develop new drugs. Much of the money from this latest infusion of capital will go the therapeutics division.

MORE ON: *23andMe*

Earlier this year, the company obtained FDA clearance to market the 23andMe Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. These include Parkinson's disease, Late-onset Alzheimer's disease, Celiac disease, hereditary hemochromatosis, and hereditary thrombophilia, among others. Sources report that 23andMe is working with the FDA to obtain clearance to offer genetic tests involving the breast cancer-related genes BRCA-1 and BRCA-2.

SUNQUEST TO BUILD PROTOTYPE LIS FOR QUEENSLAND

In Australia, the state of Queensland named **Sunquest Information Systems** as the preferred supplier for its new laboratory information system (LIS). The state wants to replace a 30-year-old LIS product called Auslab. The new LIS will handle not just clinical laboratory services in public hospitals, but also forensic pathology and public and environmental health. Sunquest must build a working prototype of the LIS for testing before a final contract will be issued by Queensland. The project has an estimated cost of $50 million to $100 million. This is another example of the globalization of medical laboratory testing.

PATHOLOGY'S NEWS OF THE WEIRD

On Sept. 13, it was reported that police in Brooklyn, Ind., had arrested a pathologist for suspicion of drunken driving. News reports said that, in his vehicle, police found a half-empty bottle of vodka and "human body parts." In later days, more details emerged. The pathologist was Elmo Griggs, MD, 75, who was a pathology vendor for the Marion County coroner's office. It was a half-empty bottle of Stolichnaya vodka. Griggs failed all field sobriety tests and, after his arrest, blood was drawn to determine his blood alcohol content. The body parts turned out to be containers of tissue from the private autopsy business where Griggs sometimes provided his services.

DARK Daily
Clinical Laboratory and Pathology News/Trends

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That's all the insider intelligence for this report. Look for the next briefing on Monday, October 9, 2017.

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Discuss What's Changing, New Compliance Regulations, Tougher Inspections, and Coming Priorities for 2018

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CMS

Denise Driscoll
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