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BUSINESS DAY

Pursuit of Cash Taints Promise of Gene Tests

By REED ABELSON and JULIE CRESWELL JUNE 24, 2015

Dr. Scott Wilson often participated in medical studies, so the one being proposed by the New Orleans laboratory Renaissance RX seemed reasonable.

An assistant would swab inside the cheeks of qualified patients and send the samples off to the company, which was doing research in the fast-growing arena of personalized genetic medicine.

Dr. Wilson signed on to what was supposed to be one of the largest and most definitive studies of its kind. In exchange, he and other doctors would be paid $75 for every patient they enrolled and tracked.

But Dr. Wilson left the study last year, saying the company pressured doctors to enroll patients regardless of whether they were eligible. In a lawsuit, he also accused the company of improper billing. Renaissance denies the accusations.

The story of Renaissance offers a view inside the intoxicating brew of hype and hope in the field of genetic testing. All over the country, labs and research firms are popping up, eager to study strands of DNA to better identify who is at risk for developing a disease, to guide existing treatments and to develop new ones. But the troubles at Renaissance speak volumes about how difficult it is for Medicare and private insurers to keep up with the proliferation of tests being offered.

After receiving $130 million in Medicare funds and $55 million from a unit of the private investment giant TPG, Renaissance halted its study late last year after Medicare suspended payments and began reviewing the company's billing practices.

The Justice Department is also looking at whether the company's billing and payment practices violated federal laws. Renaissance officials say the federal government is unfairly targeting the company.

"It is unfortunate that the Medicare review process has effectively crippled a burgeoning start-up," the company said in a statement. "While the principals of Renaissance RX have confidence about the eventual outcome of the review, this extended delay continues to create great challenges."

Nearly all of the company's 800 employees have been laid off and questions are swirling around its principals and top executives, three of whom came from a similar company in Washington State that wound up under criminal investigation by the Justice Department over similar problems.

The entire lab industry is undergoing heightened federal scrutiny over its relationship with doctors.

Across the industry, investors are pumping tens of millions of dollars into clinical laboratories that are developing and selling the genetic tests. President Obama recently called on Congress to spend $215 million next year on personalized medicine, calling it "one of the greatest opportunities for new medical breakthroughs that we have ever seen." A major use of the federal funds would be to create a research group of a million volunteers that would provide scientists with an enormous collection of data.

Doctors and their patients, finding it hard to resist the promise, are being swept up in the excitement. The number of tests has almost doubled in the last few years, creating a $6 billion industry.

"It sounds so legitimate — who doesn't want safe medicine?" asked Dr. Howard L. McLeod, who is medical director of the personalized medicine institute for Moffitt Cancer Center in Tampa, Fla.

Few doubt that some genetic testing companies are doing valuable, cutting-edge research — in cancer treatment, for example — that has the potential to change the course of medicine. But many of the genetic tests, which can cost $1,000 each, have not proved valuable in improving patient care.

Until the tests are proved useful, Medicare generally should not pay for them, said Dr. Elaine Jeter, a medical director at a Medicare contractor responsible for paying for care in Virginia and elsewhere. She is trying to develop national guidelines on individual tests. The evidence, she said, "has to be compelling."

But aside from the question of the value of any particular tests, federal regulators have become increasingly worried that the area is a hotbed of fraud. In the summer of 2014, the Office of Inspector General for the Department of Health and Human Services, which oversees Medicare, said labs could be using improper tactics to get doctors to order tests. In April, federal officials reached a $47 million settlement with Health Diagnostic Laboratory in Richmond, Va., over improper payments as part of an industrywide crackdown.

Companies have run afoul of the law when they seem to offer the payments, not as compensation, but as a way to entice doctors to participate or to enroll more patients than they might otherwise.

Renaissance, for example, said that the $75 per patient payment it made to doctors reflected the amount of work the physician needed to do to select the patients and track their progress under the study. The company said two outside firms had vetted the appropriateness of the payments.

But an internal chart reviewed by The New York Times suggests the company was not shy about pointing out that doctors could amass a substantial income by participating. If a doctor enrolled five patients per day and took 110 swabs per month, that physician could earn as much as $125,400 in compensation from the study over a year, according to the document.

The company's general counsel, Brandy Sheely, who said she was unaware of any inappropriate attempts to persuade doctors to sign up patients, said the

company forbade its sales force from engaging in such behavior. Through Ms. Sheely, the three principals of Renaissance RX declined to comment.

A Company With Troubled Roots

Renaissance had relatively humble beginnings, opening in 2012 as UTC Laboratories. Originally a toxicology lab that did urine and saliva analysis, UTC soon added genetic testing and began operating as Renaissance RX, a nod to the rebirth of New Orleans after Hurricane Katrina. The company had applied for — although apparently never received — state grants to encourage business development.

At its helm was Dr. Tarun Jolly, a well-connected pain specialist in New Orleans. Dr. Jolly invested in real estate and took stakes in a variety of business ventures, including pharmacies and surgical centers. He has family ties to the wife of Gov. Bobby Jindal of Louisiana.

Two of Renaissance's three principals, Barry Griffith and Patrick Ridgeway, and the company's chief medical officer, Dr. Karthikeshwar Kasirajan, were all fresh from a Washington State company called Natural Molecular Testing Corporation.

Natural Molecular was also a laboratory that had offered pharmacogenomic testing, the kind of genetic testing used to determine response to medication.

Under the guidance of Dr. Kasirajan, a well-regarded vascular surgeon who trained at the Cleveland Clinic, Natural Molecular had established a national registry in 2012 that focused on whether doctors should change a patient's prescription for heart medicine based on that patient's genetically determined metabolism.

But by August of that year, after Medicare had paid Natural Molecular tens of millions of dollars for various genetic tests, the agency's fraud contractor began reviewing the company's billing. A separate private lawsuit filed in 2013 raised questions about the payments that Natural Molecular was making to physicians to be part of its registry.

In April 2013, Medicare suspended all reimbursements, citing "credible allegations of fraud," according to records in the company's bankruptcy filings in Seattle.

Medicare, according to bankruptcy records, had unearthed signs of potential fraud, including billing patients for tests to determine a genetic sensitivity to warfarin, a blood thinner, when the patients were not on the drug. The Justice Department began a criminal investigation. Natural Molecular filed for bankruptcy in October 2013.

By then, however, Mr. Ridgeway, Mr. Griffith and Dr. Kasirajan of Natural Molecular were already in place at Renaissance, where they had even bigger ambitions.

While other studies typically enroll a few hundred to a few thousand patients, Renaissance's study was unusually sweeping, aiming to enroll 250,000 patients. Rather than focusing on a particular drug or set of drugs, it included a wide variety, as diverse as painkillers and the anti-clotting drug Plavix.

Renaissance's executives needed Medicare's approval so the agency would pay for the tests. Company officials said they worked closely with Dr. Mitchell Burken, a medical director at Novitas Solutions, the local Medicare contractor for clinical laboratories in Louisiana, who eventually agreed, despite the study's scope and the investigation of Natural Molecular. He had also authorized payment for tests from two other labs that had similar registries.

Fast-Paced Growth

To enroll a quarter-million people in its study, Renaissance needed to grow quickly. It went from a company with a handful of employees in 2012 to one with hundreds by 2014.

With Medicare seeming to have blessed the study, Renaissance had little difficulty signing up doctors. Dr. John Fullerton, a San Francisco geriatrician, said company representatives "certainly indicated that they were endorsed by Medicare." The research was in the early stages, but the idea of helping his patients take less medication and experience fewer adverse reactions appealed to him. He ended his involvement in the study as he grew concerned about the company's tactics. "They seemed to push volume," he said.

The company appeared to prosper. It made a series of hires, including a new head of its lab operations and a chief financial officer. In September, Dr. Jolly announced plans to create 425 high-paying jobs by moving to a larger headquarters. To secure the project, the State of Louisiana offered a grant of nearly $1 million. Governor Jindal was expected to appear at a news conference announcing the state support for Renaissance RX but the event was abruptly canceled as the governor's staff raised questions over his relationship to Dr. Jolly and Dr. Jolly's financial interest in the company, according to internal emails obtained from state economic officials.

But signs that Renaissance RX was having difficulty began to emerge. A Duke University researcher, Dr. Deepak Voora, who was supposed to take the lead on the analysis necessary to publish the results in an academic journal, parted ways with the company in early 2014 because of differences over the research.

In October, Medicare stopped payments, according to Ms. Sheely.

Renaissance's chief medical officer, Dr. Kasirajan, said he immediately sent an email to Dr. Burken at Novitas, trying to determine what had happened.

"I said to him, 'Our data was looking so good,' " recalled Dr. Kasirajan. " 'Can we talk? What have we done? What was the mistake?' "

Dr. Kasirajan said he was told by Renaissance officials that all communications with Novitas needed to go through the legal department. Dr. Kasirajan said he knew the study was over and he left the company in late 2014.

The contractor and the agency declined to comment.

Dr. Burken, who is no longer reachable at Novitas, did not respond to multiple telephone calls seeking comment.

Despite the payment suspension, in mid-November 2014, TPG Growth, the venture capital arm of the private equity giant that invests in riskier start-up companies, invested $55 million for a 20 percent stake in the company.

Renaissance officials did not notify Louisiana officials of the Medicare review until after doctors and others raised concerns, emails from state officials show. The state says no payments from its development fund were ever made to Renaissance. A spokesman for TPG declined to comment on the record.

Enthusiasm Outpaces Evidence

Critics of the rapid rise in testing say Renaissance represents some of the perils of the industry.

“It’s fairly easy to put a product out in the market,” said Dr. Robert McDonough, senior director of clinical policy research and development at Aetna, the large insurer. Where the labs often fail, he said, is being able to show that the results can lead to better care. “We want to make sure the enthusiasm doesn’t outpace the evidence,” he said.

In some ways, that appears to have been the case at Renaissance. Its rapid rise and fall point to concerns about whether private investors and Medicare, which is heavily reliant on local contractors to make payment decisions, did enough due diligence. Did the study at Renaissance really qualify for Medicare funding — which generally pays for proved treatments, not experimentation?

Some experts said the study was disorganized and too big and unfocused to be of real value. And others in the industry say the payments, which are supposed to reimburse doctors for their time, may have been used to entice them to get their patients to participate.

Competition is fierce among labs, and success often depends on a lab’s ability to persuade doctors to order a test from it rather than a competitor. The industry, which has a long history of companies paying doctors illegally to refer patients, is seeing a resurgence of these activities. “They seem to be coming back with a vengeance,” said Marc Raspanti, a lawyer representing whistle-blowers in the Health Diagnostic Laboratory settlement.

The decision also points to a weakness in Medicare oversight in which contractors have different rules about what they will pay for and may not

communicate effectively about areas of potential fraud or abuse. Kristine Ashcraft, an executive with Genelex, a personalized medicine competitor, says the government should be better at weeding out fraud because this kind of behavior makes the overall industry “tainted.”

The proliferation of these tests is also making it challenging for local contractors to keep up with the science. Local contractors are known for making inconsistent decisions in this area, said Lakshman Ramamurthy, a consultant for Avalere Health, who describes it as “a symptom of a technology and science growing so fast.” The agency is deciding whether to address the problem by selecting a handful of contractors, like the one run by Dr. Jeter, to make those determinations.

Whatever becomes of the review of Renaissance, its former leaders, including Dr. Jolly, are moving on. And the email domain of the company’s chief counsel has been changed from Renaissance to UTC Labs.

At the same time, others are resurfacing in other laboratories.

Dr. Kasirajan, who left Renaissance, is now at Ally Clinical Diagnostics, a Texas lab whose chief executive came from a battery company. At Ally, Dr. Kasirajan published a paper last month on how the genomic tests can reduce bad drug reactions.

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