

Deceit at Duke: How fraud at a university research lab prompted a \$112M fine

By Edward Martin Posted August 1, 2019 In August 2019

In the mouse room, the tiny research subjects took in less than a milliliter of air with each breath, a fraction of that of humans. But their bean-sized lungs eerily resemble those in people, and the technician who forced the mice to inhale substances, such as a drug that simulates asthma attacks, was accustomed to their Lilliputian dimensions. Someday, her data might help save human lives.

Erin Potts-Kant, then 24, joined Duke University in January 2006 and became an expert in measuring miniscule lung reactions to pollutants. A favorite of researchers in pulmonologist William Michael Foster's lab, she had been named clinical research coordinator.

"She ran a machine, an instrument, but basically she was a lab technician, not a researcher," says a close friend. "She was not the scientist. That was Foster." Nevertheless, Potts-Kant, with an undergraduate degree from UNC Chapel Hill, co-authored 38 research papers with the lab's prestigious lead investigator.

In September 2008, a young biologist who'd become enthralled with science joined Duke's cell biology lab. Four years later, he transferred to Foster's airway physiology lab as a research associate. Working shoulder to shoulder, Joe Thomas performed similar tasks and quickly became suspicious of her work. It was "too good," he fretted, with unusually low error rates.

Potts-Kant had a knack for routinely delivering data sought by researchers. Foster, a veteran professor in his 60s who joined Duke in 2002, exploded one day when another technician's ozone research didn't jibe with Potts-Kant's. "Erin always got these experiments to work!" he yelled.

Thomas was just out of graduate school and had degrees from two small Pennsylvania colleges, but he nevertheless began challenging his superiors at Duke, one of the world's premier research institutions.



Ralph Volt

Taking his first post-college job at Duke University in 2008, researcher Joe Thomas had increasing doubt about the accuracy of his colleague Erin Potts-Kant's work. His suspicions led to a \$33.7 million whistleblower award.

"He thought he had to, not that he wanted to," says John Thomas, his brother. He bristled when they turned a deaf ear, and he had a chilling notion why they did.

Each year, the National Institutes of Health awards some \$40 billion in 50,000 competitive grants, triggering a feeding frenzy among scientists. Though Duke has an operating budget of about \$2.7 billion this year, its research largely funds itself through grants, as at many universities. At nearby UNC Chapel Hill, for example, about 70% comes from such sources. In 2018, Duke was the nation's eighth-largest NIH recipient, with more than 800 grants totaling \$475 million.

Behind the placid deportment, though, grant pressure is palpable on research campuses. Academic reputations and the jobs of Thomas, Potts-Kant and others in the lab may depend on landing government money. Grants are awarded based on their potential for medical good, but another factor is even more important.

In academia, it's called research integrity, and Thomas was increasingly certain Potts-Kant was doctoring the data from her tiny subjects.

Capping a years-long legal fight that spanned the globe, a federal court agreed with Thomas. In March, Duke agreed to pay \$112.5 million for "use of falsified data to claim millions of grant dollars from the National Institutes of Health," according to Maureen Dixon, special agent in charge of the Inspector General's Office of the U.S. Department of Health and Human Services.

Matthew G.T. Martin, U.S. attorney for the Middle District of North Carolina, casts doubt on Duke's defense that it didn't know about the falsification. In any case, that's no excuse, the Greensboro-based prosecutor says.

"Individuals and institutions that receive research funding from the federal government must be scrupulous in conducting research for the common good and rigorous in rooting out fraud," he says.

The most stunning turn might involve Thomas, now 35, living in Cary and plotting his future. He filed a lawsuit against Duke under the federal False Claims Act in 2013, alleging that Potts-Kant, Foster, other researchers, the university and its health system knowingly used flawed data to obtain grants from the NIH and U.S. Environmental Protection Agency, worth more than \$200 million. His legal team included his brother, John, a white-collar crime attorney in Roanoke, Va., who is an expert in science law and a Marine Corps Reserve lawyer.

A settlement, shielded from public view until recently, shows that Thomas was awarded \$33.7 million as a whistleblower. He left Duke in 2014 — he "had no choice" because of a poisoned work environment, according to his brother. He took a position performing similar research at UNC Chapel Hill the following year but recently left that position. He is considering starting a consulting practice in research integrity, his brother says.

"It's the largest-ever False Claims Act settlement against a university," adds Ivan Oransky, a co-founder of Retraction Watch, a New York-based nonprofit that tracks flawed and fraudulent medical research worldwide. "If I were in any research university anywhere around the country, I'd be taking a long and careful look at that."

As part of the settlement, the government agreed not to seek criminal charges for fraudulent activity, opting instead for financial reimbursement and penalties. Despite the huge verdict, Duke does not formally admit guilt in the legal agreement.

Still, Duke President Vincent Price makes no bones that the school dropped the ball. "Our processes for identifying and preventing misconduct did not work," he said in a statement. "This settlement results primarily from willful misconduct that took place in one laboratory, but which affected the work of many more researchers."

The scandal is Duke's second major research debacle in a decade, with far-reaching implications for the university and the state. The federal authorities have placed Duke on what it calls "special surveillance status," putting its research under a microscope.

"The feds were not impressed with how Duke has handled cases of misconduct, and that's an extraordinary step," says Oransky, a Harvard-trained physician. "The NIH clearly thought Duke was wanting." He and other experts say the Duke case also focuses new attention on an old problem.

A 2009 study by the nonprofit Public Library of Science found one in 50 researchers admitted to fabricating data. A review of Oransky's database of about 19,000 research retractions worldwide spanning the last several decades shows 93 in North Carolina. Retractions, as opposed to corrections, take place when research is fraudulent or inherently wrong. Those projects include embarrassing cases at UNC Chapel Hill and Wake Forest University. While many retractions are for honest mistakes, some aren't.

FALSE NARRATIVE

the timeline of Duke's Foster/Potts-Kant imbroglio

2006

Research assistant Erin Potts-Kant joins Duke's airway physiology lab under noted researcher William Foster.

2008

Biologist Joe Thomas joins a Duke cell-biology lab.

2010

Duke researcher Anil Potti falsifies cancer data, forcing Duke to beef up its research ethics rules, later settling a lawsuit by injured human victims.

2012

Thomas transfers to the pulmonary lab and begins working with Potts-Kant.

2012-13

Thomas notes pattern of suspicious Potts-Kant data on airway studies in mice, not humans.

2013

Potts-Kant is arrested, pleads guilty to embezzling \$25,000 from Duke Health System and is fired.

2014

Thomas leaves Duke and files a federal False Claims lawsuit, alleging nearly \$200 million in falsified data was used to obtain government grants.

Duke begins four-year court fight attacking Thomas' allegations.

2015

Foster voluntarily retires.

2018

A three-year Duke internal investigation finds 50 falsified projects, and the school retracts the data.

2019

Previously sealed court records reveal whistleblower Thomas would receive \$33.7 million of \$112.5 million that Duke was forced to repay in reimbursement penalties.

UNC researcher Steven Leadon, who'd received more than \$2.5 million in federal grants, resigned after the federal Office of Research Integrity ruled in 2003 and again in 2006 that he'd falsified data in studies on breast cancer. About the same time in 2005, Wake Forest University's Gary Kammer resigned after admitting that he made up two families he'd claimed to have studied in lupus research. In 2015, Wake researcher Brandi Blaylock was cited for faking data from a dozen monkeys she supposedly studied in drugaddiction research.

Such cases cast a shadow over

North Carolina's blossoming reputation as a nationwide leader in biotechnology and life sciences. "We contribute about \$83 billion a year in direct and induced economic impact and direct employment of 63,000 workers," says Sam Taylor, executive director of the Research Triangle Park-based N.C. Biosciences Organization. "Research is the wellspring of all innovation, and life sciences are no exception."

Potts-Kant, a UNC Chapel Hill graduate who had previously worked in research at her alma mater, declined to discuss her work at Duke. "She just wants to put this behind her," says her Chapel Hill attorney, Amos Tyndall.

Foster, now retired and living in Durham, refused requests for interviews. Duke agreed to provide written responses to inquiries, declining to make Price or other principals available. The university would not say if Foster or anyone else was disciplined. Full professors at Duke average \$214,000 in annual compensation, according to industry publication Inside Higher Ed, though medical school faculty typically earn much more.

Joe Thomas is "getting ready for the next phase of his life," brother John says.

Through interviews and thousands of pages of recently unclassified court documents emerges a rare glimpse inside the pressure-cooker of academic research. It's evident that rivalries are rampant, careers ride on the ability to obtain funding, and an ever-present temptation to cheat forces schools to implement elaborate compliance mechanisms.

Former Duke researcher Anil Potti exaggerated his academic credentials and falsified data that purported to show he'd developed a way to guarantee 80% of cancer patients were getting the most appropriate, effective drugs. Funded by the American Cancer Society, and unlike the case involving Potts-Kant, his research involved human subjects — and pain.

Two patients and several families sued the university, its Duke University Health System, Potti and several other doctors, alleging they were subjected to false hope, unnecessary chemotherapy and other treatments in clinical trials based on Potti's fake data, and that Duke tried to cover it up. The suit was settled out of court in 2015, and details remain confidential.

Duke responded with mandatory ethics training for School of Medicine researchers and by appointing a dean for academic integrity, among other things. The school is taking similar steps after the latest scandal, including the appointment of an Advisory Panel on Research Integrity made up of researchers at other U.S. universities.

"There's tremendous pressure on researchers," John Thomas says. "It's like 'publish or perish.' They want interesting results, so it's not helpful to just rule something out. You want an interesting new discovery, and sometimes, all those conditions in the wrong environment can lead to pushing the envelope too far."

The Potts-Kant scandal took hold gradually over nearly a decade. Julie Ledford, a doctor and assistant professor in the lab from 2007-11, helped Potts-Kant carry her office belongings to her car on the day she was fired. She believes the pattern of falsifying data began as early as 2007. The environment was ripe.

The airways lab, with its sterile, painted concrete-block walls as a backdrop, was the lair for fraud. There, Potts-Kant would subject mice to lethal amounts of lung-damaging substances, such as the chemical elements in diesel fuel, then measure the results. It was dizzyingly technical work with papers bearing titles such as "The Pathogenesis and Genetics of Environmental Asthma." Few outside Foster's lab's intimate circle could fathom the work. But Joe Thomas could.

He'd grown up on a sheep farm in northwest Pennsylvania, a hundred miles inland from Lake Erie, where his siblings noticed his interest in science. After high school, he enrolled in 1,300-student Westminster College in New Wilmington, Pa., where he earned a biology degree in 2006. Two years later, he received an MBA at Clarion University, in Clarion, Pa., with an enrollment of about 4,800.

His first postgraduate job was in the cell biology lab at Duke, a 15,000-student campus with an undergraduate admission rate of about 7% and annual tuition topping \$58,000. There, he found Potts-Kant using large machines to analyze the response of mice forced to breathe toxic substances that killed them.

Thomas saw that Potts-Kant could come up with results much faster than he or other technicians, who, when they tried, often couldn't duplicate her results. At first, that caused little alarm.

"A lot of scientific research can't be reproduced or replicated," John Thomas says. "That's not necessarily fraud or misconduct, it's just that sometimes, experiments produce a fluke. The problem is, a lot of other researchers want to hang their hats on those results."

Thomas and Potts-Kant were paired, though court documents show her faked data had begun to find its way into scores of research papers at Duke and elsewhere several years earlier. Government lawyers contend she had begun falsifying data soon after she was hired in January 2006 and as late as April 2018, remnants were still making their way into grant applications.

After leaving Foster's lab, Joe Thomas still couldn't shake the notion that Potts-Kant's tainted work was going unchecked. By the next spring, March 2013, Duke's close-knit research community was in turmoil with "a flurry of activity of frantic researchers checking data," he says. "Tensions were extremely high."

The cause: Potts-Kant had been arrested and charged with using her lab credit card to buy \$25,000 worth of goods from Walmart, Target and other sources from 2008 through 2012. Ledford, the researcher, says she'd watched as Potts-Kant used the cards to pay for dinner and drinks. Duke fired her, and she pleaded guilty to two charges of embezzlement, paid restitution and was ordered to perform community service.

HEALTH CARE HOTSHOT

The basketball team isn't the only powerhouse at Duke University. The institution's health services make up a key economic engine of North Carolina with a massive medical-research enterprise.



FULL-TIME EMPLOYEES

Duke University Health System

Duke University Medical School

19.000

1.000

THE DUKE SCHOOL OF MEDICINE

consists of more than

academic and clinical faculty in 37 departments, centers and institutes.

More than

students, residents and fellows were enrolled in

Duke is among largest U.S. biomedical-research enterprises in the country with almost

in annual sponsored research expenditures. The university website lists 34 research labs including key areas of focus such as cell receptors and signaling, vascular biology, immunology and cancer pharmacology.



Basic research is conducted in each of the 12 divisions of the

Department of Medicine.

The Department of Medicine averages about

DUKE UNIVERSITY SCHOOL OF NURSING

has enrollment of

and six research centers and





DUKE UNIVERSITY HEALTH SYSTEM

consists of three hospitals and more than 200 clinical offices.

people were admitted to the three hospitals in the 2018 fiscal year.

.4 million

outpatient visits

were recorded in 2018.

The university is also a joint investor in publicly traded **DUKE LIFEPOINT**. a network of community hospitals.



Duke and the National University of Singapore

Duke Clinical Research Institute

Duke suddenly was confronted with the unthinkable — that the data she'd been compiling for eight years might be dishonest too. Joe Thomas says the university began an internal investigation, but he and others questioned its sincerity. He says he repeatedly voiced his concerns, even though it jeopardized his career at Duke, and court documents and other sources indicate that his complaints weren't ignored. Duke allegedly took steps to contain the bad news, as it had in the previous case.

In a lawsuit filed against the school as a result of the 2010 Potti case, lawyers charged that Duke "threatened the staff with retribution, including legal action," if they spoke out. Now, Joe Thomas "wanted some outside accountability," his brother says. "He was concerned that left alone, it wasn't necessarily going to be addressed properly."

Thomas' fears were on target, Oransky says. In its internal investigation of Thomas' accusations, at least one Duke member of the inquiry cautioned others to communicate only by phone, in order not to leave a paper trail.

"We learned it from our good old friend Tricky Dick [Nixon]," Oransky adds. "It's not the crime that gets you, it's the cover-up."

After Potts-Kant's arrest and firing by Duke in 2013 for embezzlement, Joe Thomas increasingly shared his suspicions with his brother, John, that the school was sweeping her falsifications under the rug. John's law firm, Gentry Locke Attorneys, filed a lawsuit under the False Claims Act, a Civil War-era law intended to keep unscrupulous war provisioners from defrauding the Union. It allows an individual to sue on behalf of the government to recoup ill-gotten funds and keep up to about one-third of the settlement.

In the lawsuit, Thomas charged that Duke "attempted to conceal and minimize the extent of wrongdoing." Duke responded by hiring two global law firms, Houston-based Norton Rose Fulbright LLP and Pittsburgh-based Reed Smith LLP, pitting them against the much smaller Roanoke practice.

Over the next five years, court records and documents swelled to thousands of pages, and lawyers for both sides crisscrossed the nation, seeking to discredit their opponents. John Thomas and his colleagues compiled more than 50 sworn depositions from scientists who unknowingly used faked data.

Meanwhile, Joe Thomas left Duke in September 2014. "He worried his continued presence was going to jeopardize the investigation," his brother says. He was unemployed for a year before landing a lab job at UNC.

Complicating the case was the question of why Potts-Kant would make up false data. Despite her guilty plea to embezzling money to buy clothes and other pedestrian items, there's no evidence she rigged research for personal gain.

"Like everybody in the lab, her job was funded by grants, but she didn't have any direct financial motive," says a person familiar with the case, who asked to remain anonymous. John Thomas adds, "There may have been indirect personal benefit, but primarily, she seemed to be helping the lab get grants and helping her colleagues get papers published."

Meanwhile, Duke has depicted Potts-Kant as a rogue scientist, though Price, the president who came to Duke in 2017, agrees that Foster and other researchers share the blame. "When those who are aware of possible wrongdoing fail to report it, as happened in this case, we must accept responsibility, acknowledge that our processes for identifying and preventing misconduct did not work, and take steps to improve," he says.

On an early spring morning in Greensboro, Catherine Eagles, a federal judge in the U.S. Middle District Court of North Carolina, was quietly fuming. Since November, lawyers for the government and Duke had promised to settle the fake-data case, but negotiations dragged on.

It was March 25, almost six years to the day since the arrest of a low-level laboratory technician who abused her lab credit card had blown into one of the nation's largest academic scandals, ended or besmirched the careers of several researchers, tarnished the reputation of a prominent university, and resulted in a record financial reckoning for a whistleblower.

Instead of scolding lawyers, Eagles found herself scanning a 12-page document signed by the Duke president, head of its health care system and others, and nodded her approval.

Near the end was the scrawled name of Joseph M. Thomas.

"He did it for the right reasons," says his brother, who'd first listened half a decade earlier as Joe fretted over what he'd seen in the Duke lab. "And in the end, it was for a good result."