



Deception at Duke: Fraud in cancer care?

Were some cancer patients at Duke University given experimental treatments based on fabricated data? Scott Pelley reports.

Chemotherapy can be a tough road for people with cancer, often debilitating and even dangerous. Which is why five years ago, when Duke University announced that it had an advanced, experimental treatment that would match chemotherapy to a patient's own genetic makeup, it was hailed as the holy grail of cancer care. The scientist behind the discovery was Dr. Anil Potti, and soon Dr. Potti became the face of the future of cancer treatment at Duke, offering patients a better chance even with advanced disease. However, when other scientists set out to verify the results, they found many problems and errors. What our 60 Minutes investigation reveals is that Duke's so-called breakthrough treatment wasn't just a failure -- it may end up being one of the biggest medical research frauds ever.

The following is a script of "Deception at Duke" which aired on Feb. 12, 2012. Scott Pelley is the correspondent. Kyra Darnton, producer.

Five years ago, Duke University announced it had found the holy grail of cancer research. They'd discovered how to match a patient's tumor to the best chemotherapy drug. It was a breakthrough because every person's DNA is unique, so every tumor is different. A drug that kills a tumor in one person, for example, might not work in another. The research was published in the most prestigious medical journals. And more than a hundred desperately ill people invested their last hopes in Duke's innovation.

In 2010, we learned that the new method was a failure. But what isn't widely known, until tonight, is that the discovery wasn't just a failure, it may end up being one of the biggest medical research frauds ever - one that deceived dying patients, the best medical journals and a great university.

[Dr. Anil Potti: Duke has made a commitment to fight this war against cancer at a much higher level.]

Dr. Anil Potti, featured in this commercial for Duke University, had made a discovery that promised to change the face of medicine.

[Potti: Genomics will revolutionize cancer therapy. It actually identifies a fingerprint that's unique to every individual patient.]

Dr. Rob Califf: This is sort of like the holy grail of cancer.

Dr. Rob Califf is Duke's vice chancellor of clinical research.

Scott Pelley: Was the idea here that this would change the way we thought about treating cancer?

Califf: Well, you've never seen such excitement at an institution, and it's understandable.

It wasn't just Duke that was excited. A hundred and twelve patients signed up for the revolutionary therapy. Hope was fading for Juliet Jacobs when she learned about it. She had Stage IV lung cancer. And this would be her last chance.

Walter Jacobs: She was my best friend, but that's kind of cliché. She's, she's somebody who after 49 and a half years, I was still madly in love with.

She and her husband Walter were looking into experimental treatments. They had to choose carefully because there was only time for one.

Scott Pelley: When you met Dr. Potti, what did you think?

Jacobs: We felt that he was going to give us a chance. He was... He was very encouraging.

For a patient with no time, Dr. Potti's research promised the right drug, right now.

Pelley: Fair to say Potti was a rising star at Duke?

Califf: Potti was one of our most important rising stars.

A lot of people were pleased that it was Dr. Potti who made the discovery of a lifetime. Born in India, he was known as an earnest, modest, hardworking Rhodes scholar, who did research at the University of North Dakota before reaching Duke in 2003. He was a young man with a big idea, which he explained in an interview for Duke.

[Potti: And that's the goal, is to...is to be able to tell a patient with cancer that I'm not just a cancer doctor, I'm here to treat your particular cancer.]

Dr. Potti made the breakthrough in the renowned lab of Dr. Joseph Nevins. The Nevins Lab had built a reputation for important work. Dr. Nevins saw something in Dr. Potti and he chose the young researcher to mentor and support.

Nevins: Very bright, very smart individual, very capable. He was a very close colleague to many, many people.

Pelley: And to you.

Nevins: And to me.

When Dr. Potti decoded the genetic makeup of hundreds of tumors, the research created huge computer files of data. That data was the underlying proof in research papers under the names of Potti and Nevins that were a sensation in the top medical journals.

Kevin Coombes: It was going to change medicine. It was gonna change how we treat patients.

Doctors everywhere were eager to save lives with the new discovery. At MD Anderson Cancer Center in Houston, Kevin Coombes and Keith Baggerly began analyzing Dr. Potti's data to verify his results.

Pelley: And as you dug into the data, what did you find?

Keith Baggerly: We started some basic processing, and we noticed some things that were really odd that we just couldn't explain.

Coombes and Baggerly are experts in the kind of data created in Dr. Potti's research. They emailed their questions to Duke and Dr. Potti admitted a few clerical errors, but he said that new work confirmed his results. Duke moved ahead. Drs. Nevins and Potti applied for patents and started a company to market the process. They and Duke stood to make a fortune. Patients enrolled in the clinical trial so that their tumors could be surgically biopsied to be matched with the best drug. But at MD Anderson, during months of analysis, Baggerly and Coombes kept finding errors that they thought were alarming.

Baggerly: One of the things that was especially disturbing was that these types of errors happened again and again and again. That was far beyond anything that we'd seen.

They suspected Dr. Potti had somehow reversed some of the data and that some of the patients could be getting, not the best drug for their tumor, but the worst.

Coombes: Then you would be giving patients drugs that would definitely not benefit them. So there's clear, potential for harm there.

Pelley: Exactly the opposite of what this was supposed to be.

Baggerly: So-- yes. So we wrote them and we said, "This-- this-- this is a big problem."

Baggerly and Coombes eventually concluded that Duke's holy grail was worthless. But Drs. Nevins and Potti disagreed.

Pelley: I wonder why, at that point, you didn't say, as the director of the lab, "Look, stop. Too many questions. We have to get to the bottom of this." And put a team together to figure that out.

Nevins: I didn't feel it ever got to that point. I felt that we had addressed the issues that had been raised.

But that changed when researchers here at the National Cancer Institute said they too were having trouble with the data. Duke suspended the enrollment of patients and asked an outside review committee to analyze Dr. Potti's discovery. After three months, the review committee concluded that Dr. Potti was right.

Baggerly: My immediate reaction was an expletive, which I will not repeat here.

Coombes: We'd gone through the usual channels. We'd written letters to journals. We'd written the article. We'd succeeded in getting the trial suspended, and somebody investigated it. We'd done everything we could.

Duke restarted the clinical trials. And that's when Juliet and Walter Jacobs sat down for their first meeting with Dr. Potti.

[Walter Jacobs, audio recording: I'm recording this with your permission.]

Potti: Absolutely. That's a good thing 'cause you're gonna miss a lot.]

The Jacobs were told, based on the research, that the chances of finding the right drug were approximately 80 percent. Walter Jacobs says no one mentioned that the clinical trial had been suspended because of so many questions.

[Potti: I will help you. Trust me.]

Many trusted because Dr. Potti's work had been vindicated. But there was just one more thing - discovered, not by a scientist, but by Paul Goldberg, the editor of a small independent newsletter called "The Cancer Letter." Goldberg got a tip from a confidential source: check Dr. Potti's Rhodes scholarship. It was right there on his applications for federal grants. Trouble was it wasn't true.

Pelley: You asked him about it?

Nevins: Certainly I asked him about it.

Pelley: What did he say?

Nevins: He said that while it wasn't the Rhodes scholar as we know the Rhodes scholar, it was a fellowship from Australia from a group of Rhodes scholars in Australia. So, a stretch of the truth.

Pelley: Was that the moment when you realized?

Nevins: Amazingly, I was still hanging on to the notion of "there must be a good explanation here." This was--

Pelley: Why were you deluding yourself at that point in time? What is it that you want to believe?

Nevins: I want to believe that somebody that I had trusted, that was a colleague for the last four, five years, someone that I viewed as a friend, was who I thought they were. And then you're faced with the reality of you've been deceived.

Fearing that reality, Joseph Nevins, whose own reputation was at stake, reviewed the original data which had justified the clinical trials for 112 patients. Dr. Nevins discovered that when the underlying data disproved Dr. Potti's theory, the data were changed.

Nevins: It became clear that there was no explanation other than there was a manipulation. A manipulation of the data, a manipulation of somebody's credentials and a manipulation of a lot of people's trust.

Pelley: Manipulated data? These were not errors?

Nevins: That's correct, it simply couldn't be random. It simply couldn't be inadvertent. It had to have been based on a desire to make something work.

Pelley: Is it a close call? Or is it abundantly clear that the data were fabricated?

Nevins: Abundantly clear.

Pelley: When you switch the data, the theory is proved. If you put the data back the way it's supposed to be, the theory fails.

Dr. Rob Califf: The theory's a dud if you put the data back to where-- the way it was supposed to be.

Pelley: How could that switch happen?

Dr. Rob Califf: If it happened by chance, it would be roughly equivalent to an asteroid hitting the earth.

Duke University agreed to tell us this story as a cautionary tale for other institutions. Vice Chancellor Rob Califf is implementing new procedures for Duke and also overseeing the retraction of Dr. Potti's papers from the medical journals, one of the most significant retractions in medical history. He's examining how both a prestigious university and outside investigators missed all the warning signs.

Pelley: How could they have found nothing wrong, nothing suspicious about the work at that point?

Califf: They were analyzing a data set that had been prepared by Dr. Potti. So, the data set they got was one that produced the same results that had been seen in our own analyses.

Pelley: You know there are people watching this interview who are thinking to themselves, "Look, they stood to be wealthy. The university stood to make a lot of money. No one wanted to believe that this research was corrupt." To what extent was that the reason that the warning signs were overlooked?

Califf: In my view, it was not the money that was the primary driver, it was this great opportunity to help people that was driving people to say, you know, we've got to make this work because it looks so good.

Pelley: The patients were told that there was an 80 percent chance that precisely the right drug for their tumor would be found. That wasn't true. Do you bear any responsibility for that?

Nevins: I regret that some of the issues that were raised along the way I didn't recognize earlier, and that this could have been brought to a halt at an earlier time.

Juliet Jacobs died three months after she entered the clinical trial. Walter Jacobs and eight others have filed suit. In his answer to the Jacobs lawsuit, Dr. Potti says he was "not aware that false or 'improper' information had been included in the research." Duke has apologized for the trials. And even though the patients hoped that they were getting an innovation that could save their lives, Duke says no one was really harmed because all of them received the standard of care in chemotherapy.

Jacobs: They did not advertise this as a standard of care program, they advertised this as an advanced clinical trial with great results. For what happened to my wife, I have to blame Potti and anyone else associated with him who knowingly promoted a false counterfeit clinical trial exploiting human beings.

Dr. Potti resigned from Duke. He faces an investigation into research misconduct. He told us, in an email, that it would be inappropriate for him to comment. He wrote, "My primary concern at all times is and will be the care of patients and seeking new ways to treat cancer." These days, he's working as a cancer doctor in South Carolina. And if you look online, you will see that he is celebrated for "his significant contribution to the arena of lung cancer research." The websites were created with the help of an online reputation consultant, perhaps to put the best face on the available data.