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Partners, Brigham and Women's to pay \$10m in research fraud case

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Partners HealthCare's corporate offices in Somerville's Assembly Row.

By [Liz Kowalczyk](#) | GLOBE STAFF APRIL 27, 2017

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Partners HealthCare System and one of its hospitals, Brigham and Women's, agreed to pay \$10 million to resolve allegations that a stem cell research lab there fraudulently obtained federal grant money, the US attorney's office in Boston said Thursday.

The government said that the lab, run by well-known researcher Dr. Piero Anversa, included false scientific information in applications to the National Institutes of Health. His lab's controversial work raised the possibility that the human heart could repair itself, but many other scientists have been unable to replicate the research.

Anversa and two Brigham colleagues, Dr. Annarosa Leri and Dr. Jan Kajstura, "knew or should have known" that problems with the lab's work included "improper protocols, invalid and inaccurately characterized cardiac stem cells, reckless or deliberately misleading record-keeping, and discrepancies and/or fabrication of data and images," the government alleged.



The Brigham lab closed in 2015 and the three researchers no longer work at the hospital.

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Federal prosecutors commended the Brigham for disclosing allegations of fraudulent research at the lab and for taking steps to prevent future recurrences of such conduct.

Brigham and Women's stem cell study retracted over 'compromised' data

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Comments The retraction comes just a week after a Japanese scientist was accused of fabricating data in a major stem cell paper that was led by a different Brigham scientist.

“BWH is committed to ensuring that research conducted at the institution is done under the most rigorous scientific standards and has made significant enhancements to research integrity compliance protocols as a result of this event,” the hospital said in a written statement.

Those improvements include mandatory education for researchers focused on integrity and financial and data management, plus a research code of conduct that all investigators must attest to annually, the hospital said.

The settlement is the latest development in a troubling case that has riveted the cardiac research community, which has pushed hard to translate findings in the lab into experimental treatments for patients who have suffered heart damage.

The Anversa group’s research into how and whether stem cells can be used to treat heart disease has attracted millions of dollars in federal funding. NIH awards to the lab have totaled \$42 million, the Brigham said Thursday.



Tracy Miner, a Boston attorney representing Anversa and Leri, said they were not involved in the settlement negotiations. She said the Brigham “has sought to unfairly tarnish” them and said Kajstura is responsible for the problems with the research data and images, not her clients. Kajstura’s attorney could not be reached for comment. Miner said her clients now work at a research institute in Switzerland.

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The US attorney's office ^{Comments} declined to comment on whether they are under criminal or civil investigation.

The hospital and Harvard Medical School launched a review in 2014 into allegations that Anversa and Leri falsified or fabricated data. Around the same time, the medical school requested that the journal Circulation retract a major paper by Anversa and Leri published in 2012 because of “compromised” data. The authors claimed they had found evidence that heart muscle can regenerate at a higher rate than previously thought.

Harvard also notified editors of the British medical journal The Lancet that it was investigating the “integrity of certain data” used in two sets of images of cells in a 2011 paper overseen by Anversa.

Anversa and Leri sued the hospital and the medical school over their investigation, and that case is pending.

Jeffery Molkentin, a stem cell researcher at Cincinnati Children’s Hospital, said the settlement is a “sigh of relief for the field” that “this ongoing controversy is coming to an end.”

He said the concept that Anversa’s group promoted, that the heart has its own stem cells that can make new myocytes after injury, has not been replicated despite attempts by many other scientists. Some researchers already suspected Anversa group’s findings were invalid. But the government’s charges offer further evidence that will allow scientists to now focus efforts elsewhere as they try to help patients.

“We have a problem. When people have a heart attack they lose heart muscle and it doesn't come back,” he said.

John Thomas, a Virginia lawyer who represents whistle-blowers in health care misconduct cases, said the settlement is noteworthy because it is one of the few that have focused on the science itself, underscoring that the government “is serious about the accuracy of the information its grant recipients provide.”

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Other academic medical centers and universities have paid larger settlements but they usually involved administrative issues, he said.

In the late 1990s, New York University paid \$15.5 million to settle allegations it inflated its costs, while the University of Minnesota paid \$32 million to resolve a range of allegations, Thomas said. The Mayo Foundation, the parent organization of the Mayo Clinic, paid the United States \$6.5 million in 2005 to “resolve allegations that it charged the government under federal grants for research costs unrelated to the research projects sponsored by those grants,” according to a government press release.

Acting US Attorney William D. Weinreb said in a press statement Thursday that those who receive research funding from NIH “have an obligation to conduct their research honestly and not to alter results to conform with unproven hypotheses,” which “wastes scarce government resources” and “undermines the scientific process and the search for better treatments for serious diseases.”

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