Harvard Medical School – Research Misconduct Leads to \$10 Million Settlement

Author

Enago Academy

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In 2014, the American Heart Association, the parent company of *Circulation*, retracted a cardiology <u>research paper</u> published in its journal in 2012 entitled "Cardiomyogenesis in the Aging and Failing Human Heart" after allegations of misconduct and medical research fraud related to data tampering by researchers at Harvard Medical School. The article, written by <u>Jan Kajstura et al</u>, reports that the human heart regenerates various cells throughout life; however, these results differ from those of a previous study.

The previous study by Frisén et al., which was published in 2009 in *Science*, assessed whether humans are born with a specific number of heart-muscle cells (cardiomyocytes) or whether the cells rejuvenate as we age. Using carbon-14 dating, they determined that these cells do regenerate, but the process decreases with age from 1% per year at the age 25, to less than half of that by age 75; however, the 2012 paper claimed that rejuvenation was much higher—19% at age 80—even though they allegedly used the same methods and protocols. Frisén, a stem cell researcher at the Karolinska Institute, contacted the authors of the new study and, after reviewing their data, suspected not only that the samples used were not pristine (i.e., contained other sources of carbon) but that the data had been not been correctly analyzed.



Investigation

In his <u>article published</u> in *The Harvard Crimson*, William L. Wang revealed that Harvard and Brigham and Women's Hospital (BWH), a Harvard Medical School teaching hospital, conducted an investigation into the allegations of misconduct by researchers Piero Anversa and Annarosa Leri, both professors at BWH who led and coauthored the study. *Circulation* then retracted the article based on BWH's findings that the data were "sufficiently compromised." This was not the first time a published piece by Anversa was retracted. A paper on the "regenerative potential of heart stem cells," published in *The Lancet* in 2011, was also criticized for <u>alleged scientific misconduct</u>. Even so, the coauthors claimed that Kajstura had altered the data without their knowledge, and hence they sued the school for damages to their reputations. They eventually lost the case.

According to a U.S. Department of Justice (DOJ) <u>press release</u> dated April 27, 2017, Anversa, Leri, and Kajstura ran a stem cell research lab, and by falsifying data and results, were able to obtain federal funding for their research. DOJ alleges that the researchers "failed to follow protocol, fabricated data and images, and submitted misleading data in National Institutes of Health (NIH) research grants and in publications." According to Wang, the *Boston Globe* reported that the lab had received about \$42 million in grants from NIH.

Lawsuit Settlement

After its investigation, BWH willingly disclosed the information to the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), and Office of Research Integrity, and was commended for cooperating with the government in the investigation. In its press release, DOJ announced that BWH, which includes Partners Healthcare, agreed to pay \$10 million to the U.S. government to resolve the allegations of fraudulent behavior. The Brigham lab closed down in 2015 and the three researchers no longer work at BWH.

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