Who Faces Criminal Sanctions For Scientific Misconduct?

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Richard Smith: Should scientific fraud be a co

December 9, 2013











At Britain's first and only summit meeting on research misconduct in 2000, Alexa of medical law and ethics, argued that research misconduct (the gentlemanly phi be a criminal offence. The idea seemed outrageous. Nobody took it seriously, but published an editorial not promoting but contemplating the idea. To me it begins research misconduct will eventually become a criminal offence.



Those are three highlights from a number of pieces that have appeared in Nature and Nature Medicine in the past few weeks. Not surprisingly, there are common threads, so



Help us: Here's some of what we're working on

A scientist was just sentenced to 57 months in jail for using \$11.6 million in federal dollars to fake data on AIDS vaccines. That's super rare — Han is one of the only scientists to go to prison for fraud, out of nearly 300 researchers found guilty of misconduct.

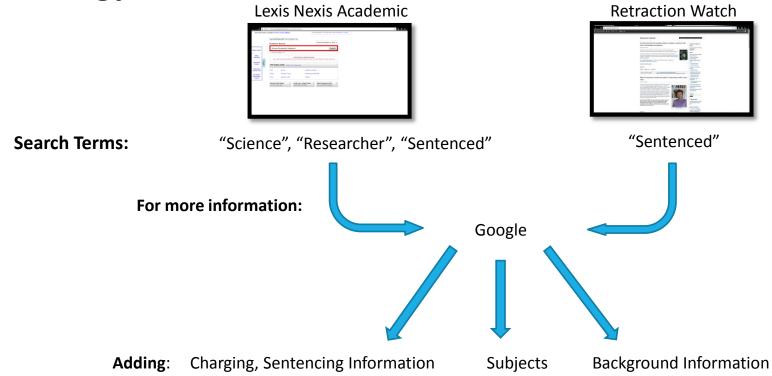








Methodology



Filtered out: Non-science researcher related, charges that were dismissed, charges of espionage

Three categories

Direct



Indirect



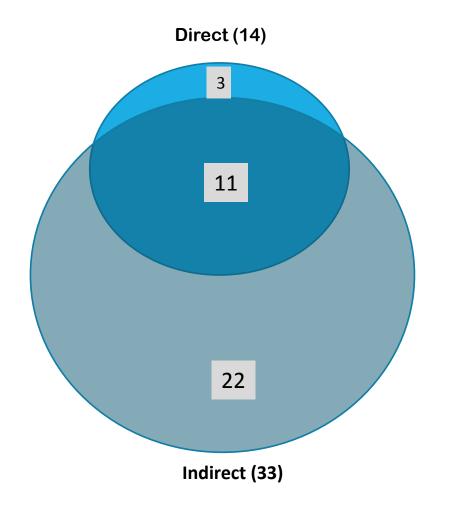
Perimeter

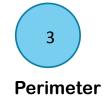


Between 1979-2015:

39 Researchers criminally charged4 awaiting final dispositions

Only 5 U.S. researchers had concurrent ORI misconduct findings (<2% of over 250 misconduct findings)





Geography:

US (27), China (7), Australia (2), one each Denmark, Russia, South Korea, UK

Range:

Fines and suspended sentences to 15 years in prison, with an outlier case involving a life sentence for 1st degree murder.

Indirect

2 investigations involved multiple persons being charged:



Seven researchers in China charged with embezzlement



Four United States researchers convicted of bribery

Direct and Indirect



Woo-Suk Hwang

- · Seoul, S Korea
- 1.5 years suspended sentence

SHARE









Korean Supreme Court Upholds Disgraced Cloner's Criminal Sentence

By Mi-Young Ahn, Dennis Normile | Feb. 27, 2014 , 12:45 PM

Discredited stem cell scientist Woo Suk Hwang suffered a setback in his bid to reclaim respectability today when South Korea's Supreme Court confirmed his conviction on embezzlement and bioethics violations. The court also sent Hwang's plea to overturn his dismissal from Seoul National University (SNU) back to a lower court for review and upheld previous rulings acquitting him of fraud charges.

Retraction Watch

Tracking retractions as a window into the scientific process

Fraud, retractions no barrier to US cloning patent for Woo-Suk Hwang

with 17 comments

Woo-Suk Hwang is having quite a comeback.

The cloning researcher's <u>fall from grace</u> in 2005 and 2006 was covered worldwide, featuring two high-profile retractions from <u>Science</u> and convictions (now under appeal) on charges he embezzled government funds and broke South Korea's bioethics law. But as <u>Nature reported last month</u> in a profile focusing on Hwang's Biotech Research Foundation:



Despite his legal troubles — and the widespread belief that his career was over — Hwang continued to work, thanks to the supporters who amassed US\$3.5 million to launch Sooam. About 15 scientists followed Hwang from SNU, and around half of those remain today among Sooam's 45 staff. His team now creates some 300 cow and pig embryos per day, and delivers about 15 cloned puppies per month.

And now, the U.S. Patent and Trademark Office has awarded Hwang a patent based on a cell line described in his retracted Science papers, as the Korea Times reports. The New York Times picked up the story Friday:



Despite all that, Dr. Hwang has just been awarded an American patent covering the disputed work, leaving some scientists dumbfounded and providing fodder to critics who say the Patent Office is too lay

"Shocked, that's all I can say," said Shoukhrat Mitalipov, a professor at Oregon Health and Science University who appears to have actually accomplished what Dr. Hwang claims to have done. "I thought somebody was kidding, but I guess they were not."

(An aside: Mitalipov's work, <u>published last year in</u> Cell, was subjected to <u>extensive corrections</u>.)

The <u>patent</u> cites both of Hwang's retracted *Science* papers, without noting they're retracted. Apparently that wasn't a problem, notes the Times:



But a spokesman for the United States Patent and Trademark Office, and some outside patent lawyers, said the system operates on an honor code and that patent examiners cannot independently

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Direct



pharmaceutical firm Aptuit in 2009 when he came up with the scam.

Retraction Watch

Tracking retractions as a

UK researcher who faked data gets three months in jail

without comments

Steven Eaton, a UK scientist who cooked experiments while at the U.S.-based contract research outfit Aptuit, has been given a three-month prison term, making him the first person to serve time under a 1999 British law called the Good Laboratory Practice Regulations, according to the <u>BBC</u>.



As the BBC reported:



Eaton, 47, was working at the Edinburgh branch of US pharmaceutical firm Aptuit in 2009 when he came up with the scam.

If it had been successful, cancer patients who took the drug could have been harmed, the court was told.

Edinburgh Sheriff Court heard how Eaton had manipulated the results of an experiment so it was deemed successful when it had actually failed.

He had been manipulating his results since 2003, it seems, including tests for compounds from Roche and AstraZeneca. These included a variety of drugs, from anti-cancer agents to anti-depressants, according to the Financial Times, via Fierce Biotech.

We haven't found any publications on which Eaton was an author, but that doesn't mean they don't exist.

Here's the notice from Aptuit about Eaton:



In light of the inquiries we have received following the MHRA's recent press release relating to its investigation of the bioanalytical group at our former Riccarton, Scotland site, Aptuit wants to clarify information related to the MHRA's prosecution of a former employee, Steven Eaton. Mr. Eaton was recently found guilty by Edinburgh Sherriff's Court for altering pre-clinical trial data at our Riccarton site. Here are the details:

In February of 2009, a supervisor at Aptuit Riccarton identified irregularities in some of Mr. Eaton's bioanalytical data as part of the company's Quality Control Procedures. Aptuit representatives promptly notified the MHRA and, based on that notification, an investigation was initiated. It was determined that the irregularities in the work of Mr. Eaton began as early as 2001

Eaton, Steven

- Edinburgh, UK
 - 3 months
- "first person to serve time under the UK's Good Laboratory Practice Regulations, 1999"

Direct and Indirect

Dong-Pyou Han

- Iowa, United States
- 57 months prison: 3 yrs probation: \$7,216.890.12 restitution, \$200 court fees

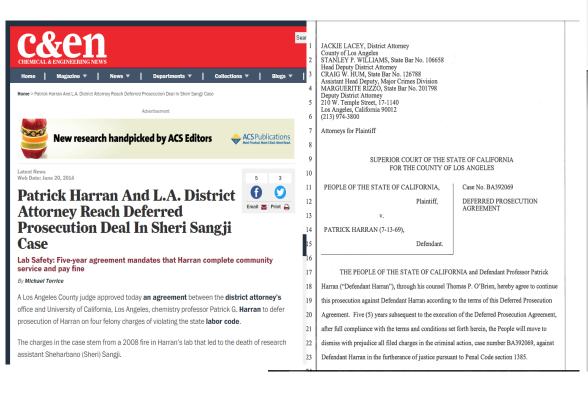




Indirect

Patrick Harran

- · California, United States
- 5 years, adjudication withheld





who was prosecuted for the 2009 accidental death of a 23-year-old researcher in his lab

Perimeter

Erin Potts-Kant

- North Carolina, United States
- Probation, Community Service

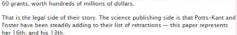
Retraction Watch

Tracking retractions as a window into the scientific process

Former Duke researcher at center of lawsuit lodges 16th retraction

Two former researchers at Duke University at the center of a lawsuit by a whistleblower to recoup millions in federal funding have lost yet another paper.

This is hardly the first retraction for Erin Potts-Kant, who used to work in the pulmonary lab of now-retired William Michael Foster. Earlier this year, a lawsuit filed by a former colleague of Potts-Kant and Foster was unsealed alleging that the pair along with the university — included fraudulent data in materials involving more than 60 grants, worth hundreds of millions of dollars.



Here's the notice for "Nitric oxide mediates relative airway hyporesponsiveness to lipopolysaccharide in surfactant protein A-deficient mice:



Following an inquiry at Duke University, the authors were informed that the flexiVent data reported in Table 1, Figure 1, and Figure 7 provided by the animal pulmonary physiology laboratory at Duke University may have been unreliable. An independent laboratory at Duke University led by Herman Staats was therefore asked to repeat the pulmonary physiology experiments. The laboratory was able to substantiate the results shown in Table 1 and Figure 1. However, the laboratory could not confirm the major finding of the publication that treatment with the inducible nitric oxide synthase-specific inhibitor 1400W abrogated relative airway hyporesponsiveness in LPS-treated SP-A -/- mice, nor could it confirm that treatment with 1400W further enhanced airway responsiveness in LPS-treated wild-type mice, as reported in Figure 7. Thus the data obtained from the repeated experiments do not support the main published conclusion that the relative airway hyporesponsiveness of the LPStreated SP-A -/- mice may be at least partly attributed to an inducible nitric oxide synthase-

In addition, the animal physiology laboratory at Duke University maintained a portion of the SP-A -/- mice and also provided an LPS stock solution that was used in Figure 6. However, the experiments in Figures 2 through 6 were generated an analyzed by laboratories other than the Duke animal pulmonary physiology laboratory; these data were not part of the unreliable flexiVent dataset.

We apologize to our colleagues and the scientific community for any inconvenience this might have

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What people are saying about

ketraction watch

Former Duke researcher charged with embezzlement has a paper retracted

Auten RL, Mason SN, Potts-Kant EN, Chitano P, Foster WM, Early life ozone



We offer our formal apologies for this error and for any inconvenience associated with the publication of the article. The paper is therefore being retracted by the American Physiological Society at the request of Dr. Auten and with the approval of the co-uthors.

Potts-Kant is Erin Nicole Potts-Kant, who is apparently no longer working at Duke. She may have bigg concerns than a retraction, however. In late March, about a week before the retraction notice appeared she was arrested on embezzlement charges. As <u>The Ideald Sun reported</u>.

She allegedly used the cards for \$14,616.34 in merchandise from Amazon.com, Target, Walmart, and TiperDirect between Dec. 12, 2008, and Nov. 6, 2012.

Potts-Kant was released on \$10,000 bail. She also holds a U.S. patent along with some of her former Duke colleagues, for a <u>yeav to treat lung disease</u>.

We've contacted the corresponding author of the paper for more details about how these errors came to the

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Whistleblower sues Duke, claims doctored data helped win \$200 million in grants

By Alison McCook, Retraction Watch | Sep. 1, 2016 , 2:00 PM

On a Friday in March 2013, a researcher working in the lab of a prominent pulmonary scientist at Duke University in Durham, North Carolina, was arrested on charges of embezzlement. The researcher, biologist Erin Potts-Kant, later pled guilty to siphoning more than \$25,000 from the Duke University Health System, buying merchandise from Amazon, Walmart, and Targeteven faking receipts to legitimize her purchases. A state judge ultimately levied a fine, and sentenced her to probation and community service.

Some people have concerns about criminal sanctions and science





Conclusions

- 1. Financial issues seemed to be the greatest driving force for criminal convictions
- 2. Need to assure consistency in processes. When applied, criminal sanctions should be used within clear guidelines and not just based on umbrage.
- 3. Need to thoroughly examine cost/benefit of pursuing more criminal prosecution of direct research misconduct
- 4. Need to provide education and guidance to those involved in a criminal justice procedure

"A research misconduct proceeding is more complicated than the regulations make it appear because there are a limited number of individuals who have the scientific background and experience to examine the allegations and the research. The individuals who have that background and experience may also have conflicts of interest that preclude them from participating in the proceeding. The federal regulations require the institution to ensure that the individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, researcher or witnesses involved in the proceeding. "http://www.thehealthlawfirm.com/resources/health-law-articles-and-documents/healthcare-fraud.html

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