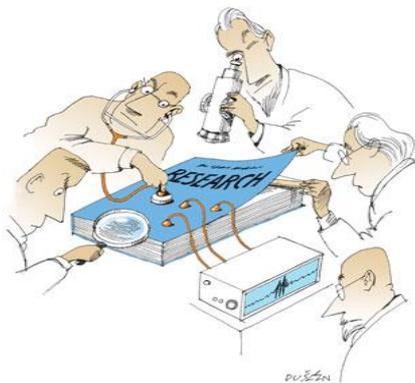
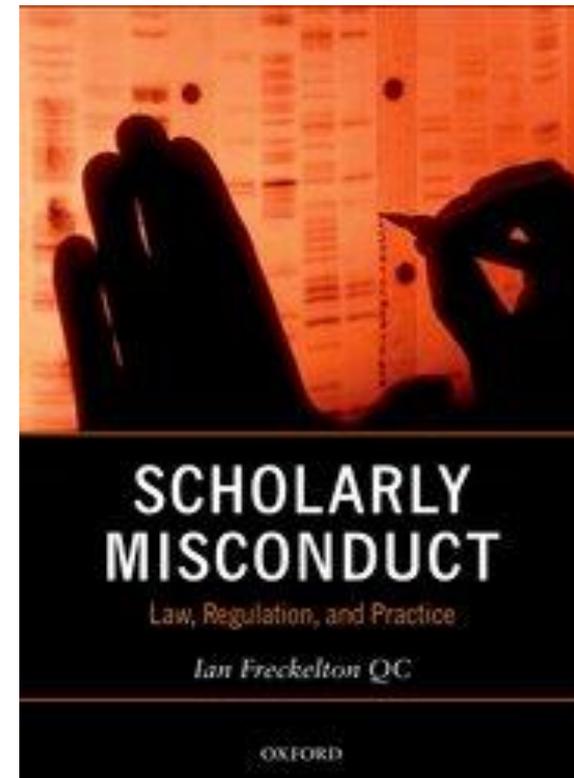


Research Misconduct and the Law: Intervening to Name, Shame and Deter

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See I Freckelton, *Scholarly Misconduct and the Law* (OUP, 2016)

Criminal Law



- Invoked by the state to punish, deter and protect

Compensation Actions

Providing encouragement to victims to come forward and to ventilate concerns about research integrity, and recognising that by doing so they are likely to suffer losses. Also deters.

Research Misconduct

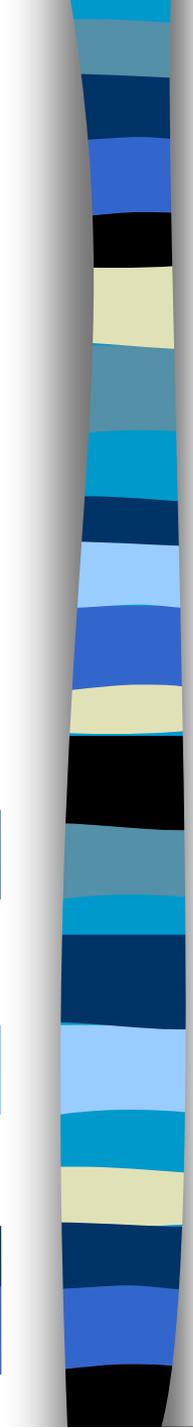
- Office of Research Integrity: “Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results”



The Lens of the Law on Research Misconduct



- Prosecutions for fraud: a form of white collar crime
- Appeals & judicial review
- Injunctions
- Workplace dismissal litigation
- Defamation actions
- Disciplinary/registration/licensure proceedings
- Harassment & discrimination actions
- Compensation actions (tort & qui tam)



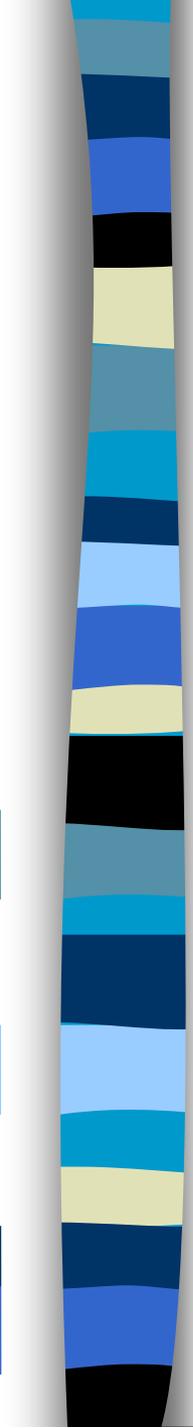
Contextualising Research Fraud by Reference to Criminal Law

- Undertaken by economically and otherwise privileged
- Premeditatedly done using knowledge and opportunity
- Has foreseeably adverse consequences for others – direct & indirect victims
- Undertaken for gain – career, economic, kudos etc
- Fundamentally dishonest:
manipulates/exploits funding –
directly/indirectly

Tom Nichols, *The Death of Expertise* (2017)

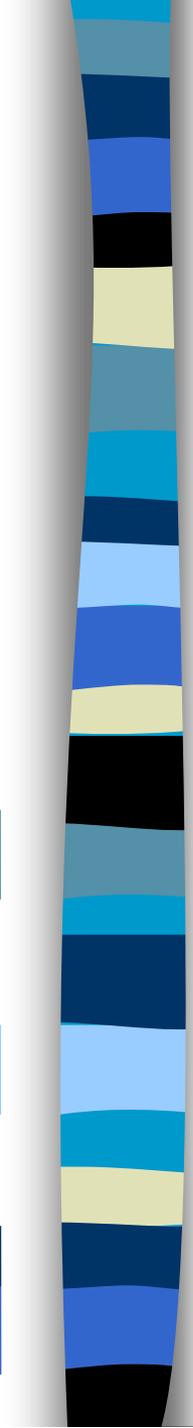


- When experts lie, they endanger not only their own profession, but also the wellbeing of their client: society. Their threat to expertise comes in both the immediate outcome of their chicanery and the erosion of social trust such misconduct creates when it is discovered.



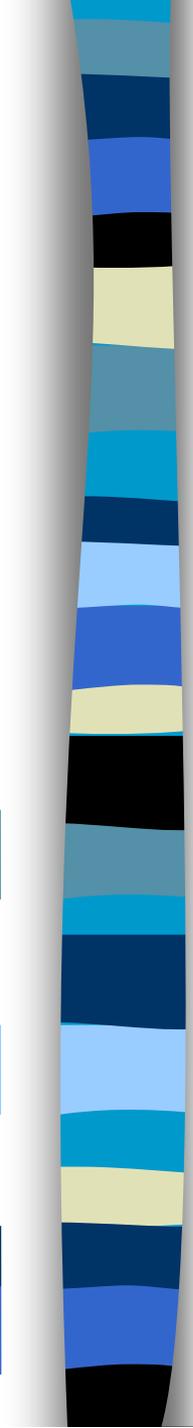
Julian McCrane, 2014

- Criminalizing research misconduct is a sad, bad, even mad idea that will only undermine the trust that is an essential component of research and requires good governance not criminal investigations



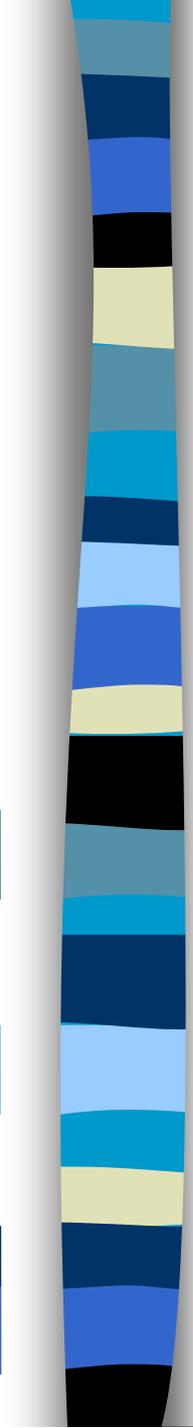
Learning from Those Who Have Been Prosecuted

- Stephen Breuning (US)
- Woo Suk-Hwang (Korea)
- Erik Poehlman (US)
- Luk Van Parijs (US)
- Scott Reuben (US)
- Steven Eaton (Scot)
- Dong Pyou Han (US)
- Milena Penkowa (Den)
- Christopher Gillberg (Sweden)
- Bruce Murdoch & Caroline Barwood (Aus)



Stephen Breuning (US, 1988)

- Prominent researcher on Ritalin & Dexadrine for ADHD
- Professor Sprague of Uni of Illinois noticed perfect agreement in independent ratings of tardive dyskinesia movements
- NIMH review found “only a few of the experimental subjects described in publications were ever studied”



Stephen Breuning (US, 1988)

- District Court of Maryland: charges
- Plea of guilty
- 60 days in halfway house, 5 yrs probation
- 250 hrs of probation
- Repayment of \$11,352
- Agreed not to undertake work as a psychologist for 10 years

Woo-Suk Hwang, Sth Korea, 2010-2014



- High profile veterinarian & Professor at Seoul National Uni: creator of Snuppy
- Claimed in 2004 to have created human stem cell lines using cloned embryos from patients with spinal cord injuries
- Admitted fraud in 2006
- Found guilty of embezzlement & purchasing eggs illegally

Woo-Suk Hwang, Sth Korea, 2010-2014

- Sentenced to 2 years' jail suspended for 3 years
- Appeals to High Court by Hwang and prosecution: sentenced reduced to 18 months' suspended for 2 years
- Unsuccessful appeal by Hwang to Supreme Court



Hwang Returns?



- I created an illusion and made it look as if it were real ... I was drunk in the bubble I created.'
- Lately Hwang has continued to feature in high profile international cloning experiments attempting to clone Ice Age lions, mammoths and Ethiopian wolves.

CLONING COMEBACK

Ten years ago, Woo Suk Hwang rose to the top of his field before fraud and dodgy bioethical practices derailed his career. Can a scientific pariah redeem himself?

BY DAVID STRANDBERG

The Korean Biotech Research Foundation settles on a weekend lab site in Cheon, a district on the southwestern outskirts of Seoul. Scientists, quiet and cold on this winter day, the grey-white exterior below the trees of activity within.

A door just off the open road is a corridor of sterile clean. In stalls on the left, Tibetan mastiff and Australian shepherd puppies are nursing. A Yorkshire terrier darts on back and forth on its hind legs. And an adult mongrel lurches with repetitive anxiety, each outburst down when the two-legged pups that she gave birth to are returned to her pen. She doesn't know that she is just another gate-keeper, nor that the pups are highly contaminated, engineered to show the symptoms of Alzheimer's disease.

The right side of the corridor houses a wall-sized window that looks into an operating theater. Inside, Woo Suk Hwang, in a blue surgical gown, cap and mask, is working on a bitch in labor. The green hair capers through a microscope lens and another explains that this is an emergency case of the puppies in shock in the cervix. He makes an incision and carefully probes the dog's womb until the whitish conceptus of a puppy emerges. After it is wiped down, Hwang holds it to his ear, listening for breath-of-life. He then gently nudges the grumpy pup into cross-sections and goes back for the last one. Minutes later he announces, "We have one of three cloned dogs." Hwang rises with pride.

Eight years ago, few could have imagined watching such a labrant scene. Hwang, a

world-famous cloning researcher, had just plummeted from the pinnacle of a scientific career, where 20 former stars that he had mentored had in two articles¹ describing their work still have checked boxes: cloned human embryos. Hwang had been given ethical license in the way Hwang had collected the human eggs for his experiments, and the papers were found to contain fabricated data. They were eventually retracted. It was one of the most widely reported and extremely disappointing cases of scientific fraud in history. In January 2006, U.S. Chief of Staff, then president of Seoul National University (SNU), where Hwang did the work, called the episode "an unacceptable blunder on the whole scientific community as well as our country."

If the state cannot be relied upon, perhaps it can be stepped out of memory by hundreds of pens and keyboards. With papers flooding from multiple pens, Hwang opened folders in July 2006. He has since cloned hundreds of animals—dogs, cows, pigs and horses. His path includes producing drugs, curing diabetes and Alzheimer's disease, providing transplantable organs, saving endangered species and cloning graft sites for pet owners. He has a raft of public relations companies, collaborations within and outside South Korea, and increasing institutional support from government agencies. He has a super team that manages the papers of Hwang, raised by the South Korean media in 2002. Distracted by the controversy, he was photographed in a hospital bed, unshaven and reportedly walking down a hallway.

Today Hwang plays down his involvement in 11 research labs, making the process a matter that has little application around the world.

He is a scientist, certainly, but he really did create the first live cloned human embryos even when he has never had success in getting other legal recognition of his data.

In December, he welcomed reporters into Seosan to tour the facilities and watch a different case of cloned puppies, but he declined to discuss the laboratory. He is "in a couple of months," he says to a reporter.

CLONING PROGRESS

A veterinarian by training, Hwang rose to fame in South Korea in the late 1990s by cloning animals—and by developing important software. "The rise and fall and rise of Woo Suk Hwang." He asked them President Kim Dae-jung to name the first cloned horse foal, and he presented a national agricultural boom from his cloned cells.

His popularity in South Korea grew, and in 2004 he shot to international fame when Science published a paper² in which he claimed to have created an embryonic stem cell line from a cloned human embryo—something that several groups had been trying to do. Hwang's success eventually offered an endless supply of wealth with practically no strings attached. Through this process, often called therapeutic cloning, it was hoped that doctors could replace worn-out tissues or organs, or that cells derived from people with virtually any disease could be used for research and drug screening. The following year his group published a second paper³, describing the development of 11 mouse stem cells, making the process a matter that has little application around the world.



Clumpy, the first cloned dog foal, was one of the first Hwang's successes. Today, after Hwang is publicly discredited, animals at an institute near Seoul.

the stem as his star was rising, cracks were beginning to show. In July 2004, one of Hwang's graduate students told Nature that she had donated eggs for experiments in the first paper (see Nature 430, 3, 2004). It was a controversial assertion many bioethicists worry that, in such situations, students might feel pressure to endorse a study and nonstandard procedures.

Hwang denied the charge and the student retracted her statement. But in November 2005, amid increasing criticism, Hwang admitted that he had. And (see Nature 438, 714, 1-17, 2005). The student had done nothing. Hwang even donated to the clinic, when she donated her eggs before returning to the lab to try to make cell-line clones of herself. Hwang had also paid donors for eggs used in the 2004 paper, contradicting what the paper said. And he continued to compensate donors even after a South Korean health law (later state after in January 2005) banning the practice.

Hwang's struggle soon snowballed further. In January 2006, an SNU investigation committee announced that both of his human-cloning papers were fraudulent. The committee found that the cell line reported in 2005, called NT-L, was not produced by cloning and was probably a product of parthenogenesis—the "virgin birth" process by which an egg needs no sperm. The 11 stem-cell lines claimed to be patient-specific clones in the 2005 paper turned out to be normal embryonic stem cells from a fertility hospital that had been established. Images and graphs in both papers were fabricated to give the appearance of clones. "The researchers of Professor Hwang

do not provide patient-specific stem cell lines or any scientific basis for cloning patients and so," the report concluded.

Hwang's empire crumbled. He was expelled from SNU in March 2006. The Seoul Prosecution Office started his laboratory and launched a massive investigation.

Hwang took responsibility for poor oversight of his lab, but maintained that he had been duped by a co-author. During the investi-

THE EPISODE DREW ATTENTION AND INTEREST FROM GOVERNMENT AND ORDINARY PEOPLE.

gation, one co-author admitted to creating some cells without Hwang's knowledge. But Hwang also admitted to creating and releasing fabricated data. A complicated web of these emerged in which Hwang admitted being involved in fraud but still maintained that the achievement was real.

One fabrication in particular in South Korea, but knowingly using bogus articles to get funding. The prosecutor's office charged Hwang with fraud, embezzlement and bioethical violations, and a three-year term was issued. In 2008, the court threw out the fraud charge, saying that the companies involved gave the money knowing that they would not benefit from the donation. Hwang was, however,

convicted of violating the country's bioethics law and of embezzling government funding. He was sentenced to 18 months in a cell under appeal. The term, later reduced to 10 months, is still under appeal in court. But even if Hwang loses his appeal, as long as he doesn't break the law during his probation, he will no spend any time in jail, says Steve Hwang, a partner at SDC Legal in Seoul.

WORLDWIDE

Despite his legal troubles—and the widespread belief that his career was over—Hwang continued to work. Thanks to the supporters who donated US\$1.5 million to launch Seosan, about 15 acetons followed Hwang from SNU and around half of those made it to the clinic. Hwang had also paid donors for eggs used in the 2004 paper, contradicting what the paper said. And he continued to compensate donors even after a South Korean health law (later state after in January 2005) banning the practice.

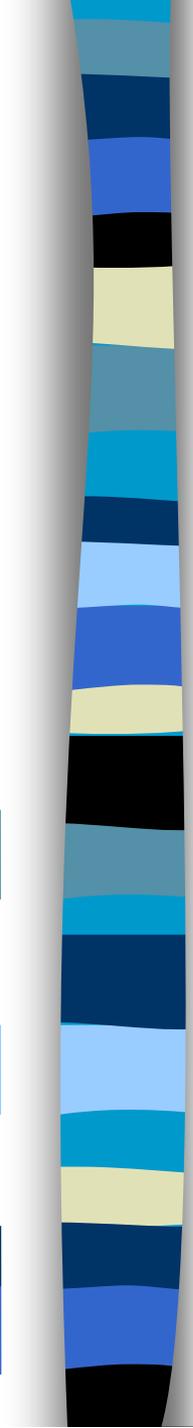
Hwang has long been interested in cloning dogs. He reported the world's first cloned puppy in 2001—a claim upheld by the SNU investigation. Since 2006, Seosan has cloned more than 400 dogs, mostly pets. Customers, the majority of whom are from the United States, pay about US\$100,000 for the service. Seosan has begun cloning dogs for the Korean National Police Agency in Seoul in the hope that clones of prison service animals will quickly learn their trade as sniffer dogs. And the next, it launched a contract for a UK owner to have a dog cloned for free—which would make the first cloned canine in the country.

Although Seosan could make more money from cloning pets if it expands and increases production, the new genetic organization wants to be more than a dog-cloning factory. "We are

Eric Poehlman (US, 2006)

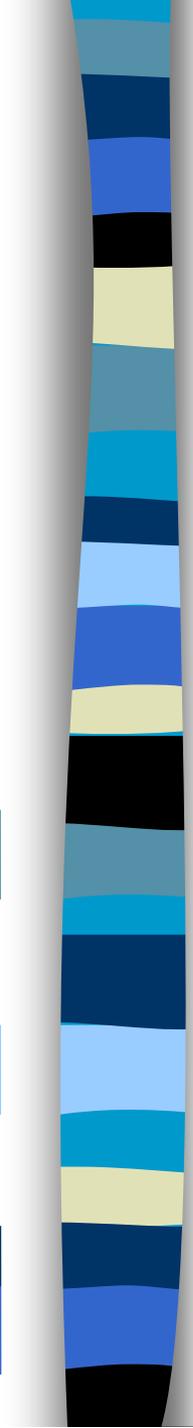
- Physiologist who published prolifically on human obesity & ageing
- Research technician identified anomalies in data
- Poehlman took data home and adjusted entries





Eric Poehlman (US, 2006)

- Uni of Vermont investigation found fabrication of data “to enhance his reputation and yield him further opportunities for publication and grant funding”
- Plea of guilty to falsification & fabrication in 10 articles between 1992 and 2001 in federal grant applications: \$3 million
- United States: one year jail + 2 yrs probation



Eric Poehlman (US, 2006)

- 'I was motivated by my own desire to advance as a respected scientist'
- 'I believed it was legitimate to 'misrepresent minor pieces of data to increase the odds' that grants would be awarded to me and his teams.
- Judge Sessions: When scientists use their skill and their intelligence and their sophistication and their position of trust to do something which puts people at risk, that is extraordinarily serious.

Luk Van Parijs (US, 2011)



- Assoc Prof at MIT
- Neuroimmunology: shutting down of genes
- Fabrication of results between 1997 and 2004
- District Ct of Boston
- Plea of guilty 6 months home detention with electronic monitoring + 400 hrs community service, repayment of \$60K

Scott Reuben US, 2010

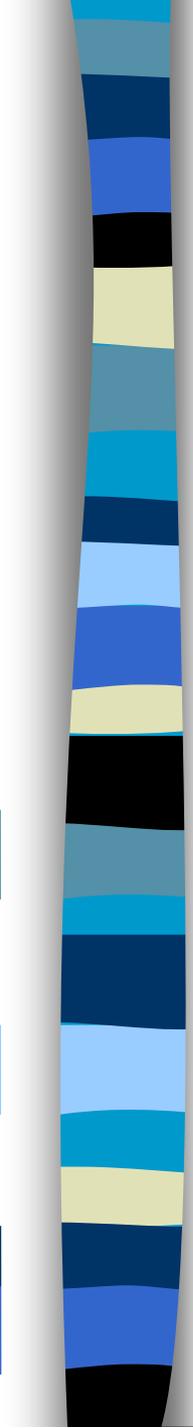


- High profile proponent of multi-
- modal analgesia therapy heavily funded by Pfizer, Merck & Wyeth
- Professor at Tufts University Medical School and Director of Pain Management at Baystate Medical Center in Springfield, Massachusetts
- 2008 investigation established 21 clinical trials over a 13 year period contained fabricated data

Scott Reuben US, 2010



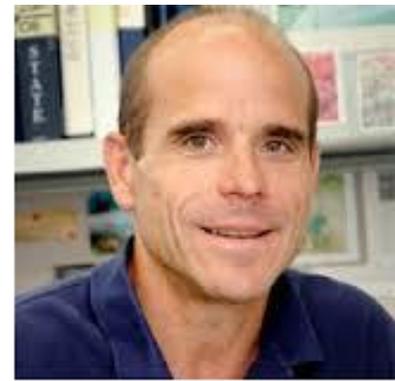
- Claimed not to have been motivated by greed, that funds received went to his employer, & that his conduct arose from bipolar.
- Sentenced to 6 months imprisonment & 3 years post-release supervision, 4391K in restitution & \$50K penalties



Steven Eaton, Scotland

- Manipulated drug trial results between 2003 and 2009, funded by Aptuit
- Faked results and selectively reported
- Claimed to have been under pressure and not to have profited personally.
Sheriff O'Grady: 3 months jail
 - You could have caused cancer patients unquestionable harm

Craig Grimes, United States, 2012



- Penn State Professor of Material Science & Engineering
- Converted carbon dioxide into energy
\$3m of frauds & false statements to NIH
- Claimed to have been zealous in wanting to help the world
- Sentenced to 41 months jail

Christopher Gillberg

Sweden, 2012



- Professor of Child & Adolescent Psychiatry
- Expert on autism & ADHD
- Destroyed clinical files after accusations in breach of court orders
- Fined 3,400 euros, appealed unsuccessfully through European Ct of Human Rights

Dr Dong Pyou Han, 2014



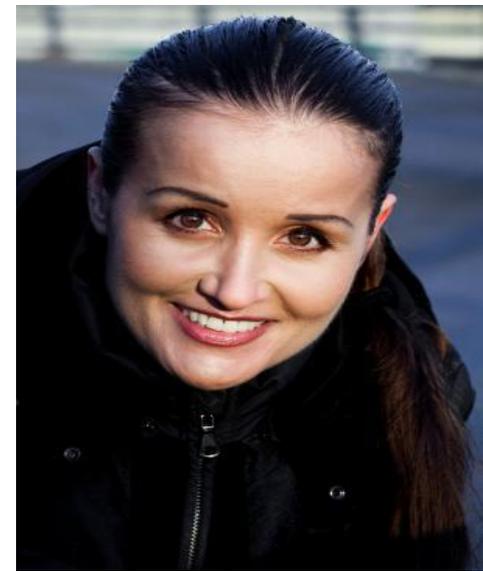
- Groundbreaking AIDS vaccine researcher
- Confessed to spiking rabbit blood with human antibiotics as part of a federally funded \$US19 million
- Assistant Professor, Iowa State University: resigned
- Arrested June 2014 & charged with 4 counts of making false statements

Dong Pyou-Han



- Suspicion had unfairly fallen on 3 others
- At first pleaded not guilty then entered into a plea bargain
- Asserted he **could not bring himself to dash the hopes of the research team**
- Received no extra funding but kudos
- 57 months' imprisonment, \$7.2 m in repayment to NIH, likely deportation to Korea

Milena Penkowa (Denmark, 2015, 2016)



- Neuroscientist
- Highly publicly and privately funded
- Suspended by University of Copenhagen for embezzlements from Danish Society of Neuroscience
- Then found guilty of scientific dishonesty in systematic supplying of false information involving rat experiments: multiple papers retracted

Milena Penkowa

(Denmark, 2015, 2016)

- 9 months suspended sentence + 2 years probation
- On appeal, sentence quashed on technical grounds although it was acknowledged she had committed fraud



Bruce Murdoch, Australia, 2016



- The Centre for Neurogenic Communication Disorders Research at the University of Queensland
- Fraud in relation to a Parkinson's disease study that was publicly and privately funded
- Murdoch claimed to have been suffering severe depression after a cancer diagnosis

Caroline Barwood, Australia, 2016



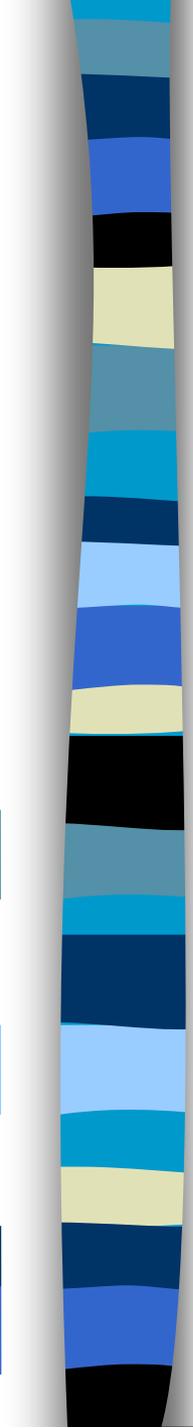
- Barwood claimed depression and stress after charges
- Both given 2 years' suspended sentence although Murdoch pleaded guilty and Barwood contested
- Sentencing judge classified B's fraud as 'brazen, unscrupulous and persistent'
- Rejected proposition she had not benefited from the fraud – it had a range of indirect advantages

Persons Not Charged: Many

- Haruko Obokata
- Joachim Boldt
- Yoshitaka Fujii
- Jon Sudbo
- Roger Poisson
- Diederik Stapel

- Reason not to charge?





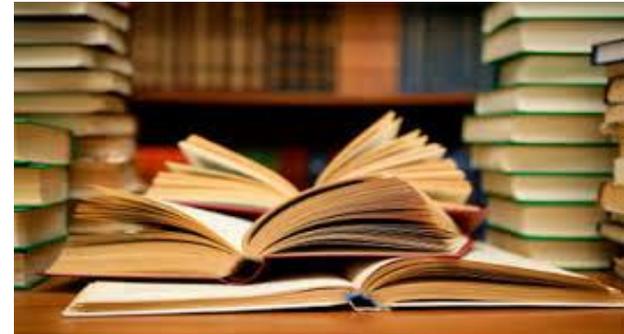
Lawson, 2012

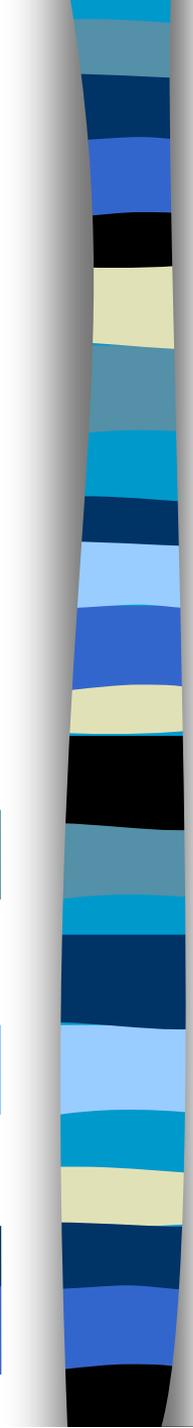
- The usual motivation appears to be a mixture of intense career and peer pressure to produce significant results and publications, financial incentives to obtain funding grants, and personality disorders or weaknesses, especially vanity and arrogance – the messiah complex. There appear to be two main groups of fraudsters. The first group is the overly ambitious young researcher, determined to climb rapidly up the career ladder. The second group is more perplexing – senior practitioners, often at the height of their careers, and often occupying prestigious positions.

Profiling Research

Fraudsters

- Grandiosity
- Narcissism
- Overly robust sense of entitlement
- Loosened grip on reality & propriety
- Indifference to effects on others
- Charismatic (often)
- Driven/ambitious
- Highly productive
- Obsessive in workplace
- Antagonistically defend allegations, at 1st





Characteristics of Defendants in Research Fraud Prosecutions

- Combination of senior and less senior practitioners
- Conduct premeditated and serial
- Rarely done in company: generally furtive and carefully disguised
- Achieved desired outcomes
- Clearly dishonest but often in combination with other unethical behaviours
- Multiple victims

Criminal Prosecution not *the Answer* but ...

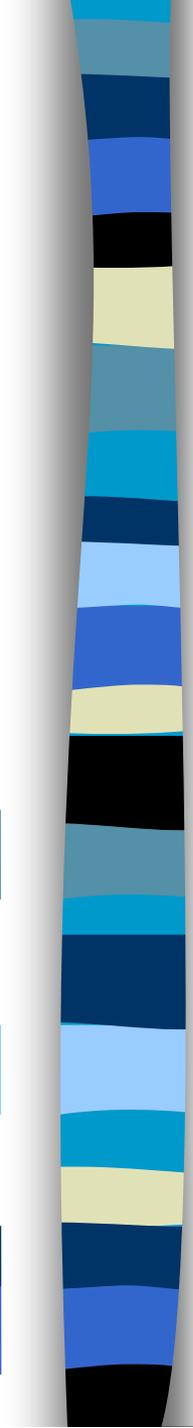
- ❑ Scientific research is largely self-correcting
- ❑ Research fraud betrays ethical values
- ❑ Government and private funding underpins it
- ❑ Research fraud is not victimless



Neil Gaiman, 2008



- The Law is a blunt instrument. It's not a scalpel. It's a club. If there is something you consider indefensible, and there is something you consider defensible, and the same laws can take them both out, you are going to find yourself defending the indefensible.



Disadvantages of Criminal Prosecutions

- Not adequately research-informed
- Slow
- Undermines trust
- Stressful
- Selective in defendants
- Focus on dishonesty rather than unethical conduct
- Insensitive
- Punitive
- Too harsh/too lenient

Advantages of Criminal Prosecutions



- Open proceedings: **declarative** - avoiding suspicions & insinuations of fraternalism:
- Offenders **named, shamed**, in context of moral culpability determination
- High **deterrence** factor
- Punishment tended to be modest but needed
- Recognises conduct seriously **harmful with multiple victims**, especially patients colleagues & profession
- **Vindication** for funders & whistleblowers
- Properly acknowledges **unacceptability** of conduct from perspective of profession