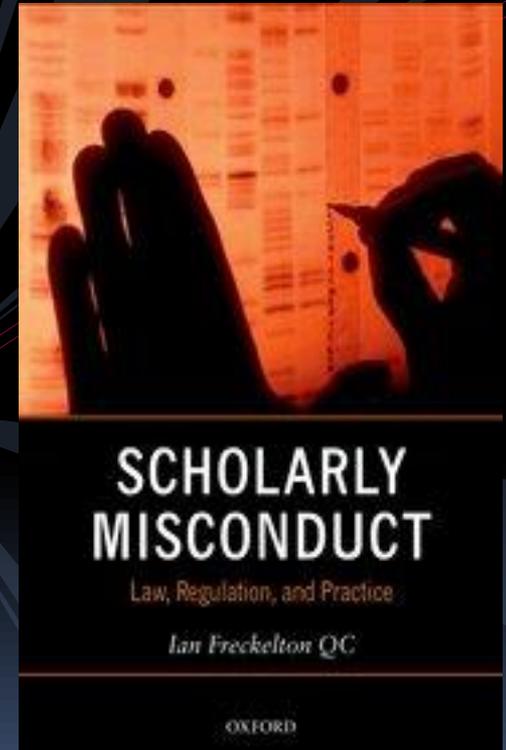


# “Harnessing the Law to Enhance Research Integrity”



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# 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)

# The Law is *not the Answer* but ...

- Legal oversight over findings and sequelae of research misconduct is inevitable
- Scientific research is largely self-correcting; trust is fundamental
- Research fraud betrays ethical values
- Government and private funding underpins it
- Research fraud is not victimless





# Protective Function of the Law

- False accusations are made
  - Highly toxic and reputation-damaging
  - Needs to be rigorous testing and evaluation of allegations
- Procedural justice / due process need to be extended in investigations leading to potential misconduct findings
- Protection needed for:
  - Funders
  - Whistleblowers
  - Victims/colleagues
  - Those accused (potentially unfairly / falsely)
  - The discipline of research



# Protective Function of the Law

- Redress required for those adversely affected
  - Funders: financial reparation
  - Institutions
  - Colleagues: reputational rehabilitation
  - Whistleblowers: non-discrimination

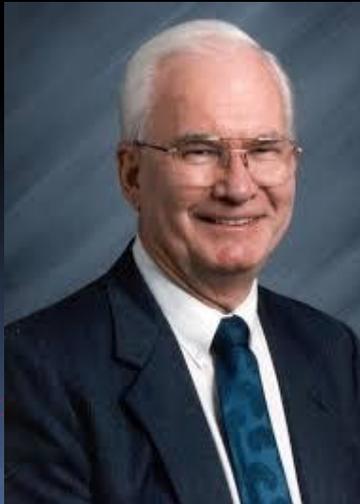
# Challenges for the Law: Protecting Whistleblowers



- Providing effective protection for whistleblowers
- A very difficult challenge
- Most studies show detrimental impact for young researchers who blow the whistle
- Part of the answer is extra-legal – creation of culture of robust, non-hierarchical, respectful questioning & openness of data
- Meaningful protection for discrimination and harassment against whistleblowers
- Recourse for retaliatory action against whistleblowers, for which the institution is liable

# Different Faces of Whistleblowing

- Nancy Olivieri, haematologist at the Toronto Hospital for Sick Children – dismissed, referred for disciplinary investigation
- Stephen Bolsin, anaesthetist at the British Royal Infirmary, no institutional support and left England for Geelong, Australia
- Robert Sprague, whistleblower re Stephen Breuning



# Challenges for the Law: Compensating victims

- Option for restitution orders, restoring situation for funders
- Often orders are not met: funds have been dissipated etc
- There are other victims: colleagues, institutions, patients
  - Most cannot be compensated (adequately)
- Option in the United States of qui tam proceedings under the False Claims Act (dating back to 1863 – “Lincoln’s Law”)



# False Claims Act Proceedings

- Order can be made for whistleblowers to receive 15-30% of funds recovered from fraud
  - Defendants are liable for acting with “deliberate ignorance” or “reckless disregard” of the truth
  - Preponderance of the evidence standard
  - Limitation period of 10 years
  - But ... nothing received if no recovery
  - Creates an incentive for making of allegations
  - Commercialises the disclosure of research impropriety: creates opportunity to attribute base motives to whistleblowers
  - Rarely used for research misconduct: Poehlman case an exception
- 



# Challenges for the Law: Compensating those Falsely Accused

- A legal entitlement to exonerating publicity to counter rumour and innuendo?
- But mud sticks
- Accusations are long-term damaging
- Can be subtle but important differences between “exonerated” and “not proved”



# 1995 Order against University of Alabama at Birmingham et al

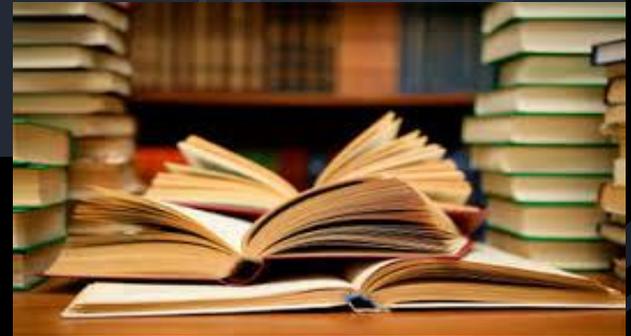
- Order to pay \$2 million to Federal Govt & Dr Berge who had conducted doctoral research of transmission of cytomegalovirus (CMV) which had not been properly credited, 30% to Dr Berge
  - Jury trial after allegations fully contested
  - However, reversed on appeal in 1997 on the basis that Dr Berge failed to show that the statements she alleged were false were material to the NIH's decision to fund a grant application or even that the statements were false
- 

# Research Misconduct False Claims Act Lawsuit Upheld: April 2017

A North Carolina federal judge Tuesday refused to dismiss a False Claims Act lawsuit claiming a University and some of its faculty knowingly falsified medical research data in order to get federal grants, saying that the whistleblower had adequately stated his case.

In a three-page order, U.S. District Judge Catherine C. Eagles denied dismissal motions by the University and individual defendants. The judge did not elaborate on her decision beyond saying that plaintiff had brought claims upon which relief could be granted.

# Criminal Proceedings



- Declarative
- Open & independent
- Focused on most serious misconduct, esp intentional dishonesty
- Deterrent and punitive at sentencing
- Recognise moral culpability
- Influenced in outcome by adverse impact upon multiple victims
- Can take into account personally mitigating considerations
- Appropriate for some cases

# It's time to criminalise serious scientific misconduct

Richard Smith, editor of the BMJ,  
1991-2004

New Scientist, September 2014



# Need for Involvement of Research Integrity Community

Providing guidance as to which cases should be prosecuted

Discussing informedly the appropriate tariff for offending

Nature survey as to Dong Pyou-Han's jail term:

42.94% (n = 2926) too harsh

36.16% (n = 2464) : appropriate

20.9% (n = 1424): too lenient





# The Challenges for the Law

**To do good:** to assist the process of enhancing scientific integrity

- Providing suitable (fair, informed & humane) redress and protection

**Not to do harm:**

- not to detract from ethical, cultural and practice inquiries
  - Not to be abused to thwart inquiries
  - Not to create a culture of mistrust or commodification of complaints processes
  - Not to supplant or deter other adequate forms of dispute or poor practice resolution
- 