



# Research Misconduct

## Recent Developments



Will discuss

New Federal Regulation

Recent cases involving research  
misconduct

# New Federal Regulation – Key Provisions

Final rule published at 70 Fed. Reg. 28370.

Purpose = protect the public health and safety, the integrity of scientific research, and the conservation of public funds.

# Federal Government Definition

Research misconduct = "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

The destruction or absence of research records is also evidence of research misconduct.

Does not include honest error or differences of opinion.

# Findings of research misconduct

Require a “significant departure from accepted practices to the relevant research community”;

That the misconduct be committed intentionally, knowingly, or recklessly; and

That it be proven by the preponderance of the evidence.

# Federal Regulation – cont'd

Regulation provides that:

- Institutions are responsible for conducting an inquiry and investigation.
- If institution makes findings of research misconduct, it must notify ORI.
- ORI will conduct oversight review of the investigation and its findings.
- ORI can make findings of research misconduct and propose administrative

# Federal Regulation – cont'd

Regulation provides Respondent with an opportunity to request a hearing to adjudicate the Federal Government's findings of misconduct.

Hearing is before an Administrative Law Judge (ALJ) with the Departmental Appeals Board for HHS.

# Federal Regulation – cont'd

## During hearing:

- Witnesses will be called, or
- Written testimony can be provided
- certain documents relating to the misconduct are subject to discovery.

## Federal Regulation – cont'd

At the conclusion of the hearing process, ALJ issues a decision.

Assistant Secretary for Health can review the ALJ decision and either adopt or reject the decision.

Respondents can appeal an adverse decision to the Federal Courts.

# Recent Cases

There are usually at least four parties to research misconduct cases.

- Complainant
- Respondent
- Institution
- Government

Will discuss:

- U.S. v. Poehlman
- Susan Aronica
- Au et al v. Ma
- Chandok v. Klessig

# U.S. v. Poehlman

Poehlman was a nationally-recognized academic researcher at UVM. (Respondent/Defendant)

In 2000, a graduate student reported to UVM that he suspected that Respondent engaged in scientific misconduct. (Complainant)

After UVM initiated a federally mandated investigation into the allegation of scientific misconduct, Respondent brought suit in federal court seeking an injunction. This was later dismissed at the request of Respondent.

## U.S. v. Poehlman, cont'd

UVM found that Respondent falsified and fabricated data related to his federally-funded research.

In addition to ORI's oversight review, matter was referred to the Department of Justice (DOJ) for civil and criminal prosecution.

- ORI's scientific investigators and its scientific conclusions were crucial to the DOJ's case.

## U.S. v. Poehlman, cont'd

In March, 2005, Defendant Poehlman entered into a global settlement whereas he agreed to plead guilty to one count of making a material false statement, and to a lifetime debarment from receiving Federal funds.

On June 29, 2006, Defendant was sentenced to imprisonment for a period of 12 months and 1 day, followed by 2 years of supervised release, and ordered to pay \$180,000 in restitution.

# Susan Aronica

Dr. Aronica was a Postdoctoral student at Indiana University – Perdue University (IUPUI). ORI found that Dr. Aronica committed 21 acts of scientific misconduct by falsifying and fabricating data in her research notebooks, in 17 figures and figure panels, in two tables published in the *Journal of Biological Chemistry* and *Blood*, and in two figures in a manuscript submitted for publication in *Blood*.

## Susan Aronica, cont'd

ORI issued a charge letter enumerating these findings to which Dr. Aronica requested a hearing.

ALJ dismissed the case based on his finding that the hearing request was insufficient under the Federal Regulation.

Federal Regulation specifically states that in order for a hearing request to be valid, the Respondent must admit or deny each finding of research misconduct, and each denial must be detailed and substantive. 42 C.F.R. 93.501(c).

## Susan Aronica, cont'd

As a result of the ALJ's ruling to dismiss, ORI's administrative actions became final:

- Dr. Aronica was debarred from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the Government for a period of 5 years; and
- She was prohibited, for the same period of time, from serving in an advisory capacity for the Public Health Services.

Several retractions of papers in major publications were also requested.

# Au v. Ma

## Parties:

- Plaintiffs – Drs. Au and Wientjes
- Defendant – Dr. Ma

## Defamation Lawsuit

- Based on an email sent to Ohio State University from Defendant alleging research misconduct, statements made to colleagues and others in scientific community.
- Plaintiffs also alleged that Dr. Ma was the author of an anonymous letter to the Office of Research Integrity, HHS, asserting research misconduct by Drs. Au and Wientjes.

## Au v. Ma, cont'd

Jury found in favor of the plaintiffs and awarded damages in the amount of \$750,000, plus \$250,000 in punitive damages.

At the summary judgment stage, prior to the actual trial, the judge indicated that Dr. Ma likely made his allegation of misconduct in bad faith.

- Intent to damage reputation, and likely knew that his allegation was false.

# Chandok v. Klessig

Plaintiff filed suit claiming that defendant defamed her when he:

- Made an allegation to research misconduct to the Boyce Thompson Institute of Plant Technology (BTI);
- Made statements to BTI during investigation
- Made statements in an article published in *Science* magazine

Case is set for trial for spring of 2007.

## Defamation Lawsuits, why is this important?

Two cases in the span of one year.

Without complainants (whistleblowers),  
research misconduct would likely go  
unknown.

Complainants can face personal loss if  
their allegation is found to be in bad faith.

## Defamation Lawsuits, why is this important?

Institutions should be aware that this is an emerging problem in the research misconduct arena

- There is confidentiality provision in the regulation as well as a definition of “good faith”
- Institutions also required to protect reputations of the parties during the investigation process.

# Lessons Learned

Research misconduct cases can have substantial affect on many parties:

- Institutions – responsible for setting standards for prevention and investigating (all cases).
- Complainants – must act in good faith or face consequences. (Au v. Ma)
- Respondents – should cooperate during investigation. Engaging in research misconduct could result in administrative, civil and criminal sanctions. (Poehlman)
- Government – misuse of public funds, which were meant to advance our knowledge base in science. (all cases)
- Public – affects the public health and safety. (all cases)