

Two Sides of the Same Coin?: Research Misconduct and Conflict of Interest

- ❖ Scientific Misconducts and Frauds in Japan
- ❖ Scientific Misconduct in Historical Perspective
- ❖ From Public Science to Private Science
- ❖ Academia and university in the marketplace
- ❖ Emergence of Researchers as a profession
- ❖ Importance of “Management of Knowledge”

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Scientific Misconduct in Historical Perspective

- When and Why this phenomenon emerged in history?
 - The late 1970s and 80s in the US Academia
 - Change of Federal Government's funding commitment
 - From physic + engineering to life sciences
 - Fundamental breakthroughs in biomedical fields
- Pro-patent legislations in the 80s
 - 1980 Bay-Dole Act (1980)
 - Universities given right to retain the property rights to inventions made under federal funding
 - 1982 Small Business Innovation Development Act
 - Federal agencies with annual expenditure of more than \$100 million devote 1.25% to research performed by small business
 - 1984 National Cooperative Research Act
 - Special antitrust status to R&D joint ventures and consortia
- Commercialization of university research and its impact on academia

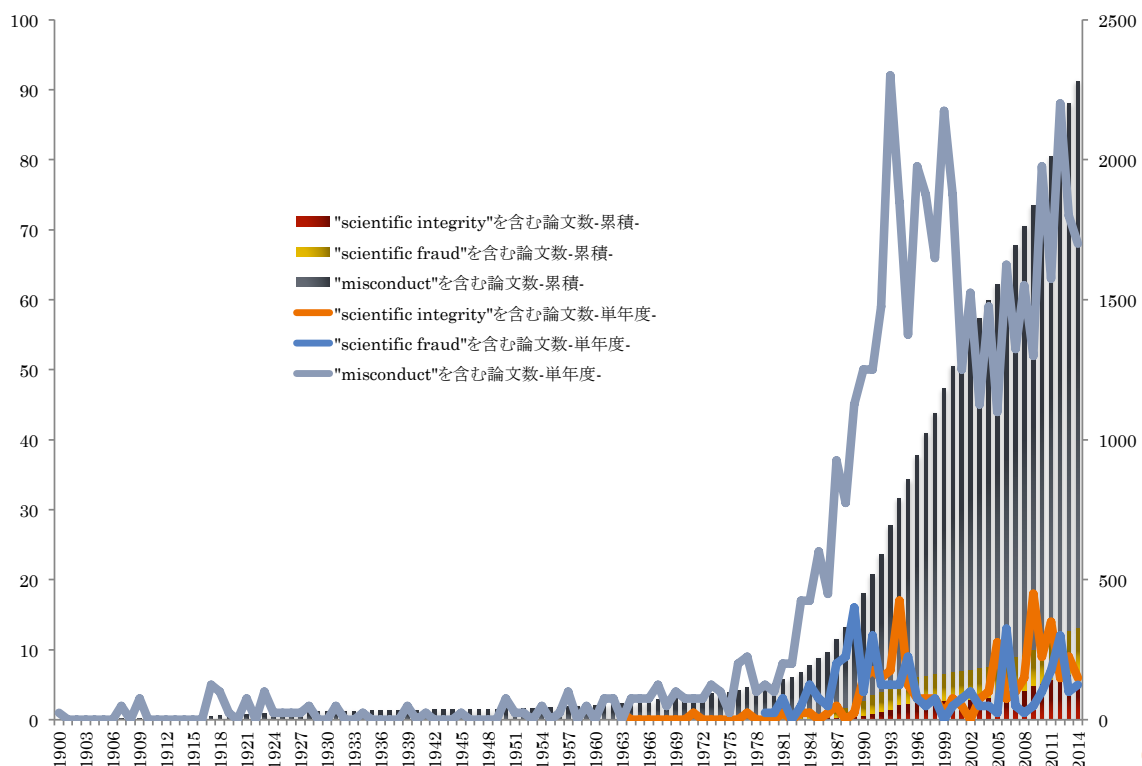
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COI and Misconduct appeared in professional Journals

- The keywords of COI, Scientific Misconduct, Scientific Fraud in the professional journals from 1970s.
- The 1980s was a watershed year in considering this phenomenon.
- After 1980s the interests and discussions on these keywords drastically stirred up.
- Political discussions to highlight this phenomenon.
 - House of Representatives, Hearings on Committee on Science and Technology, 1981, June. “Commercialization on University Biomedical Research: Ethical and Institutional Impacts”
 - U.S. 1988 Scientific Fraud and Misconduct and the Federal Response, House of Representatives, Committee on Governmental Operations.
 - U.S. 1988 Scientific Fraud and Misconduct in the national Institutes of Biomedical Grant Programs. House of Representatives

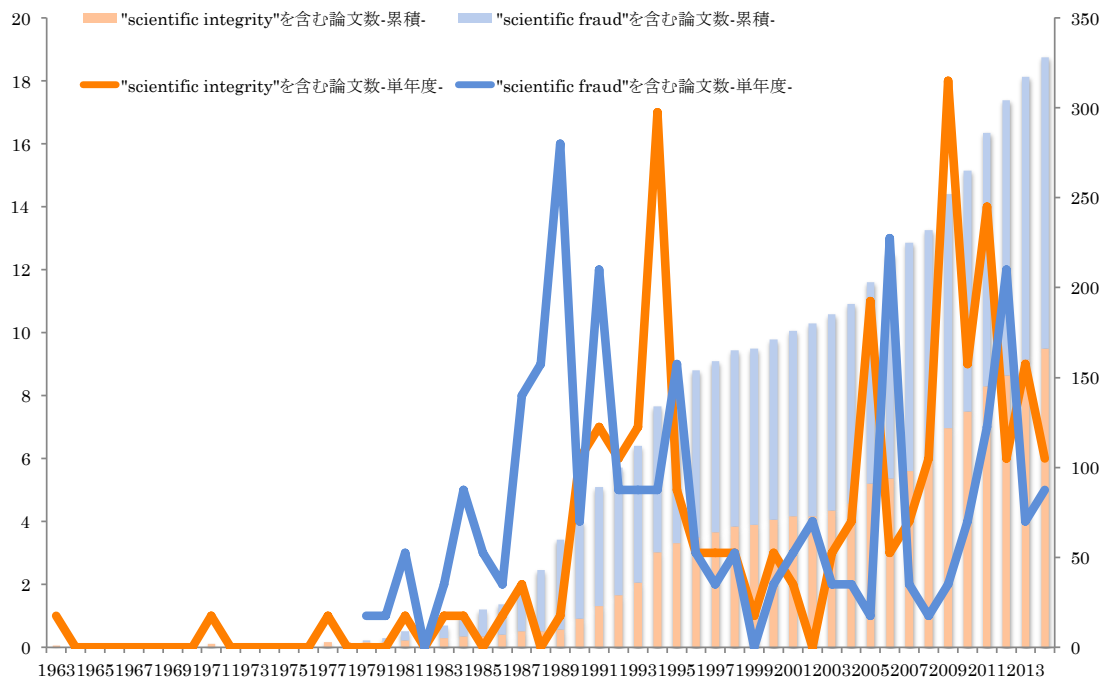
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Scientific Misconduct, Scientific Integrity and Scientific Fraud in Professional Journals

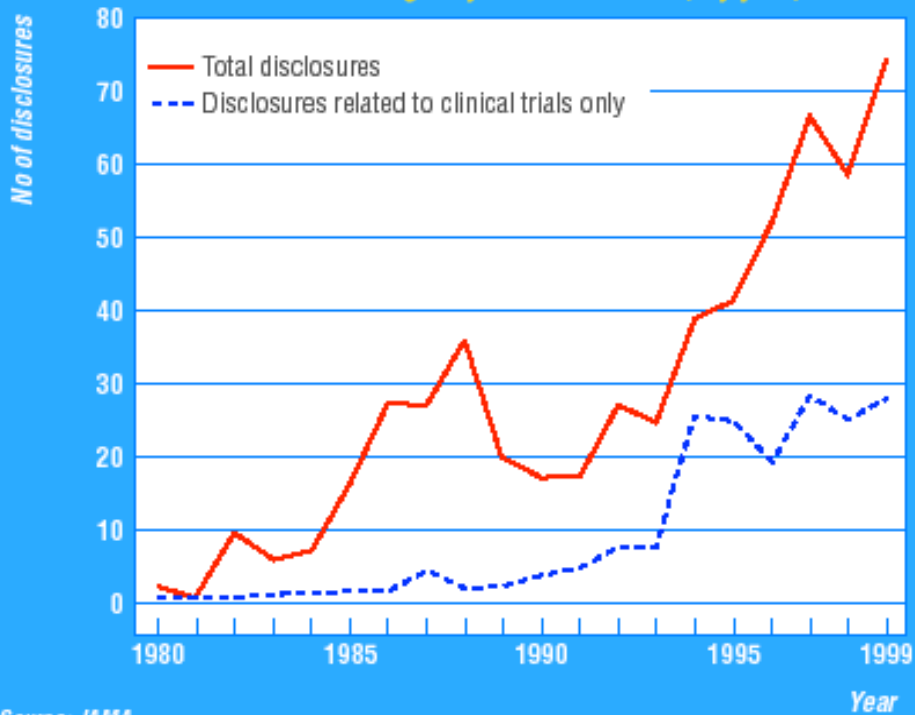


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"scientific fraud"/"scientific integrity"を含む論文数 Web of Science



Total number of disclosures of conflict of interest and number of disclosures relating only to clinical trials, by year, 1980-99



Source: JAMA

From Public Science to Private Science

- Concept of Technology Transfer
 - Rapid transfer of academic achievement to “private” company demanded.
 - Commercialization of academic works greatly expected.
 - Commercialization: Basic nature of university research requires further development by industry.
- Concept of Intellectual property
 - Intellectual property became very important in the fields of biotechnology and ICT software.
 - Mutual feedback between academia and industry greatly expected.
- Academia encountered the strong demand of moving from “public” to “private”.
 - Academic related works transformed its nature from pure “public” to “private”.

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UC OFFICE OF PRESIDENT MEMORANDUM

- UC wants to review ***all*** invention disclosures by faculty, staff, and graduate students (GSRs) to see if the university wants to assert ownership or co-ownership of the invention
- What must be disclosed?
all inventions made by a University employee must be disclosed to the University, **including inventions made during vacation, on weekends, while on leave, in the evening, or at home (“in the garage”) when engaged in paid or unpaid consulting work.** As noted above, disclosure is a legal obligation of employment at the University. It is not permissible to sign an agreement with an external party that precludes or limits disclosure of inventions to the University.*

* page 10 of March 3, 2003 memo

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STANFORD UNIVERSITY

- All potentially patentable inventions conceived or first reduced to practice in whole or in part by members of the faculty or staff (including student employees) of the University *in the course of their University responsibilities or with more than incidental use of University resources*, shall be disclosed on a timely basis to the University. Title to such inventions shall be assigned to the University, regardless of the source of funding, if any.
- The University shall share royalties from inventions assigned to the University with the inventor.
- **The inventors**, acting collectively where there is more than one, *are free to place their inventions in the public domain* if they believe that would be in the best **interest of technology transfer** and if doing so is not in violation of the terms of any agreements that supported or related to the work.

Emergence of Academic Researcher as a Profession

- Difference between Scientific Misconduct and Fraud
 - Fraud is an “intentional deception” to obtain personal gains or to destroy other person’s reputation.
 - Misconduct may not be a deliberate action caused by the failure to follow the right protocol or poor management of behavior.
- Misconduct is the most subtle and new issue
 - The simple autonomy of academia disappeared.
 - The Republic of Science is also gone.
 - Scientific and academic idea encountered “clients” for the first time in history.
 - Clients seek economic values in the marketplace.
 - The various types of “interests” provoke ethical problems.

DONALD KENNEDY
HOUSE OF REPRESENTATIVES, HEARINGS ON COMMITTEE ON
SCIENCE AND TECHNOLOGY, 1981, JUNE.

I believe, in summary, that basic research in universities need more, not less, relationship to industry. But I believe the conditions for that relationship need to be carefully structured, if a highly evolved and highly efficient mechanism for doing basic scientific work is not to be unwittingly damaged.

Here I would **warn not only against hasty regulatory reactions** by the universities, but by Government too. Imposed solutions are not likely to serve us well; the wisest course will **entail the structuring of incentives and the exercise of thoughtful oversight**. The enterprise we have built is a fragile one.

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SOME REMARKS ON COI AND MISCONDUCT

- Dual nature of guideline and regulation
 - The clearly articulated guideline is urgently needed in Japanese academia.
 - The monitoring protocol provides a rule of behavior that researchers should have in mind.
 - However, they are only for monitoring and controlling researchers?
 - We should not attribute researcher's misconduct to their "unethical" behavior.
- The guideline is also a mechanism to protect researchers from unintentional malpractices.
 - The clear guideline will enhance the degree of freedom in pursuing their researches.
 - It will protect researchers and university from "misconduct".
- The most important thing is "management of knowledge"
 - In such a highly complicated stage of knowledge-based society, we need to build a carefully configured management system of academia and university.

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