

Proceedings of the retreat on

The Journal's Role in Scientific Misconduct

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Retreat cochairs

Jessica Ancker

*Traumatic Brain Injury Clinical Trials Network
Dept. of Biostatistics, Columbia University*

Faith McLellan

The Lancet

Proceedings recorder and editor

Jessica Ancker

Contents

Introduction	1
Dealing with Suspected Misconduct from the Journal Editor’s Perspective	1
Catherine D DeAngelis, Editor, <i>JAMA</i>	1
Richard Horton, Editor, <i>The Lancet</i>	2
Dealing with Suspected Misconduct from the Point of View of Academe, Oversight and Advisory Bodies, and Regulatory Agencies	3
C K (Tina) Gunsalus, Special Counsel, Office of the University Counsel, University of Illinois at Urbana-Champaign.....	3
Alan Price, Associate Director, Office of Research Integrity.....	4
James T (Jim) Kroll, Head of Administrative Investigations, National Science Foundation	7
Harvey Marcovitch, Syndications Editor, BMJ Journals.....	8
Case-Study Discussions	8
CASE 1: Investigators seek documents from journal	9
CASE 2: Images have been altered.....	10
CASE 3: A dispute among authors	10
CASE 4: The wording of a retraction	11
CASE 5: An author refuses to retract	11
CASE 6: A reviewer suggests that a journal reanalyze an author’s data.....	12
CASE 7: Investigators ask for peer reviewer’s name	12
CASE 8: Coauthors want their names cleared	13
Scientific Misconduct in the Physical Sciences	14
Martin Blume, Editor-in-Chief, American Physical Society	14
Cleaning Up the Aftermath of Misconduct	15
Martin Blume, Editor-in-Chief, American Physical Society	15
Sheldon Kotzin, Executive Editor, MEDLINE, and Chief of Bibliographic Services, National Library of Medicine.....	15
Can Misconduct Be Prevented?	17
Mary Scheetz, Director of Extramural Research, Office of Research Integrity.....	17
Alan Price, Associate Director, Office of Research Integrity.....	17
Harvey Marcovitch, Syndications Editor, BMJ Journals.....	18
Concluding Remarks	18
Richard Horton, Editor, <i>The Lancet</i>	18
Additional Resources on Scientific Misconduct and Journals	19
Policy Statements	19
Books and Chapters	19
Case Studies and Additional Resources.....	19

Introduction

Scientific journals play an important role in the exposure and correction of research misconduct. Peer reviewers may detect fraud before publication; readers, after publication. Journals also perform a vital service by publishing corrections or retractions after research misconduct has been confirmed.

Those responsibilities present ethical and practical challenges to journal editors, who may find themselves with little guidance about how to act. How should an editor decide whether to suspect misconduct? Should a journal's staff investigate allegations of misconduct, or should they refer cases to the author's academic institution, employer, or funding agency? Should editors talk to each other about such allegations, or should they treat cases as confidential? How should corrections, retractions, and expressions of concern be worded? What resources are available to help journal editors with these questions?

To help editors address such issues, the Council of Science Editors sponsored the Retreat on the Journal's Role in Scientific Misconduct on 7-9 November 2003. The Office of Research Integrity (ORI), in the US Department of Health and Human Services, supported the retreat with a \$20,000 grant, and its staff provided case studies and speakers for the event.

More than 70 people from around the world attended the intensive weekend event. Almost half the schedule was reserved for small- and large-group discussions so that editors could share their experiences with each other. In addition, speakers at prominent journals, funding agencies, academic institutions, and MEDLINE were invited to ensure that participants would have a chance to hear a wide array of viewpoints.

Most participants were affiliated with journals or academic institutions in the United States, the United Kingdom, Canada, or Western Europe. CSE also raised money to sponsor five editors from India, China, and Serbia who might not otherwise have been able to attend. The scholarships were made possible by contributions from Thomson ISI, Rockefeller University Press, Inera, Inc., Cadmus Professional Communications, and the ORI grant.

Joseph Martin, dean of the Harvard Faculty of Medicine, was scheduled to deliver the keynote address on Friday. However, he canceled his appearance because of the unexpected death of a friend. Instead, the retreat was opened with talks by Catherine D (Cathy) DeAngelis, editor of *JAMA*, and Richard Horton, editor of *The Lancet*.

This report summarizes the scheduled speeches and, to a lesser extent, the group discussions that took place over the weekend.

Dealing with Suspected Misconduct from the Journal Editor's Perspective

Catherine D DeAngelis, Editor, *JAMA*

DeAngelis said that journal editors are given some privilege in their roles as gatekeepers of the scientific literature, and in return there is an expectation that editors will be honest

The Journal's Role in Scientific Misconduct

and straightforward. In 1989, the US Public Health Service (PHS) published a definition of *scientific misconduct* as fabrication, falsification, plagiarism, or other serious deviations from the scientific norm. Detection lies in the hands of editors, peer reviewers, coauthors, and readers.

Examples of misconduct by scientists include describing data that don't exist, forgery, misrepresenting or deliberately distorting data, suppressing data, stealing other people's ideas, violating copyright, omitting coauthors' names, including noncontributors as authors, and misrepresenting publication status.

Editors and reviewers can also commit misconduct. Examples include delaying the peer-review process for personal gain, publicly using confidential information, and stealing ideas.

At *JAMA*, there has been only one incident of confirmed misconduct in a published article involving an author who lied. A student published an article about a personal experience for a column, but when the author's mentor read it, he noticed factual problems and reported them to *JAMA*. The journal asked the mentor to write a letter to the editor about the issue and then asked the student to write a response. *JAMA* published both letters and reported the incident to the dean of the student's institution.

In general, *JAMA* refers misconduct allegations to the relevant institution for investigation and publishes corrections or retractions if needed at the end of that process.

Richard Horton, Editor, *The Lancet*

Inspired by the popular movie series, Horton identified six elements that affect and are affected by research misconduct:

M(arket forces): How research fits into the marketplace.

A(ccess to information).

T(errorism): How published information could be used by bioterrorists.

R(eview): Peer review.

I(ntegrity): Scientific integrity.

X: The x factor, which is public trust in the research process.

He also shared a case study of research-misconduct allegations. An article reporting a strong beneficial effect of diet in heart disease was submitted to a journal, and after generally favorable reviews, the journal asked for some revisions. The authors said that some of the questions couldn't be answered, because the original data had been destroyed by termites, and they deleted portions of the article related to those questions. The revised article was published. The journal was then contacted by an editor at a second journal and by an epidemiologist reader. Both said that one of the coauthors (who was from India) had a history of questionable publications; when questions arose in connection with a previous publication, the author had also claimed that he could not supply his original data, because they had been destroyed by termites. The case had been reported to the Indian Council of Medical Research, which issued a report acknowledging that there were unanswered questions but did not give a verdict of fraud.

At that point, the journal editor asked the statistical coauthor (who was from

The Journal's Role in Scientific Misconduct

another country) for assurances about the data and suggested a visit to India to inspect the original data. Although the coauthor first denied that he had any responsibility for verifying the data, he later did visit India and said that he was satisfied with the integrity of the work. The article remains unpublished.

In response to a question, Horton said that British libel law would make it difficult to publish any direct allegation about the case, even a letter from a reader that questioned the integrity of the research. However, if the article were published, a journal could publish an expression of concern about the unavailability of the original data.

In discussion after Horton's talk, a representative from the Indian Council of Medical Research, Kanikaram Satyanarayana, said that the council had authority only over research that it had funded, and the researcher in question had no funding. He also said that it was important to work cooperatively, rather than punitively, with researchers.

Dealing with Suspected Misconduct from the Point of View of Academe, Oversight and Advisory Bodies, and Regulatory Agencies

C K (Tina) Gunsalus, Special Counsel, Office of the University Counsel, University of Illinois at Urbana-Champaign

Gunsalus discussed why institutions are often unable to resolve allegations of misconduct.

She began with an anecdote from her career in which a faculty member had been accused of misconduct, including embezzlement and falsification of data. In its investigation, the university committee had been influenced by the fact that the young accuser seemed emotionally unstable and not very credible, whereas the faculty member appeared confident and charismatic. Although the committee had concluded that the accusation was without merit, the faculty member was convicted years later of the same charges. Gunsalus pointed out that the university investigation committee, although well-intentioned, had never reviewed the raw data, in large part because it had been strongly influenced by the reputation and personalities of the two parties.

The anecdote illustrates that universities and research institutions do have a commitment to integrity, but there are reasons why this commitment does not always translate to good solutions.

Barriers

- *The burden of complying with the explosion of federal and other regulations.* Examples include compliance issues, human-subjects oversight, hazardous materials, animal-research oversight, contract certifications, additional state-level requirements, classified-research regulations, scientific misconduct, and conflict of interest. Gunsalus pointed out that federal regulation is always scandal-driven. She recommended reading the history of human-subjects protection because the

The Journal's Role in Scientific Misconduct

- history of ethical oversight in that field parallels the history of oversight of fraud in research.
- *Ambivalence throughout academe about assuming authority roles.* This includes an aversion to conflict.
 - *The perception that the concept of academic collegiality precludes any activity that could be classified as “judging” colleagues.*
 - *The unfortunate fact that the intuitive, compassionate response is often the wrong one.* For example, it is natural to agree to talk to a distraught junior researcher about ethical problems in confidence, but it is a dangerous agreement because if the confidential interview includes allegations of serious harm to patients, the administrator must not keep that in confidence.
 - *Lack of institutional memory.* Serious problems occur so rarely that few investigators accumulate experience in dealing with them. Gunsalus estimated the half-life of institutional memory at about 4 years.
 - *Bias and conflict of interest.*
 - *Obsessed whistleblowers.* Some whistleblowers may lack personal credibility because of their extremely strong opinions, but they may nevertheless be correct.
 - *Changes in the allegation over time.* In some cases, the allegation itself becomes a moving target as charges and countercharges multiply.
 - *Fear of litigation.*

Federal regulations and institutional obligations

When presented with an accusation of scientific misconduct, institutions must

- Inquire into allegations.
- Write a report.
- Provide a copy to the subject of the inquiry.
- Include the subject's comments in the record.
- Notify the funding agency (under some circumstances).
- Maintain records.

Aspects of the academic environment that make investigations difficult

- Decentralized authority, with the tenured professional the least accountable.
- Concepts of academic freedom and tenure.
- The “star” system, in which prominent researchers are treated as celebrities.
- A sense of collegiality that makes people unwilling to appear “noncollegial” by making a complaint.
- Gray areas in the norms.

Alan Price, Associate Director, Office of Research Integrity

ORI was created by the National Institutes of Health (NIH) in 1989 as the Office of Scientific Integrity. In 1992, it became an independent office in the Department of Health

The Journal's Role in Scientific Misconduct

and Human Services and was renamed the Office of Research Integrity.

The office receives about 200 allegations every year, although for many of these, the ORI determines that it has no jurisdiction. In the last 10 years, the office has made 142 findings of scientific misconduct, 90% for falsification and fabrication of data and 10% for plagiarism. The findings are published on the ORI Web site and in its newsletter and annual report, on the PHS online Administrative Actions Bulletin Board, in the NIH Guide for Grants and Contracts, in the General Accounting Office debarment list, and elsewhere as appropriate.

The PHS actions may require various administrative measures, including retractions or corrections of the literature if necessary. Thus, 49 of the ORI cases have involved retractions and corrections of the literature as part of negotiated voluntary agreements. In those cases, ORI also tells the editor to expect a full description of the agreement within 30 days and, if it is not received, to contact ORI for the full report of the case.

Sometimes, an editor is reluctant to publish, because the respondent argues. For example, the respondent may claim that the data are inaccurate but the conclusions stand or may ask to publish new data to replace the old, invalid data. Other respondents threaten lawsuits against journals, claiming that they have been unfairly treated, or delay agreeing to a retraction until all authors sign off on it or the editor decides to proceed directly with the retraction.

PHS can debar researchers from receiving any federal funds for a specified period (typically 3 years, sometimes 5 or 10 years). It can impose a supervision plan over an investigator's research or a certification plan over the reporting of the results for some period and prohibit the investigator from serving in study sections and other advisory capacities to the PHS.

Price summarized several completed misconduct cases involving editors and discussed how they had been resolved.

An investigation conducted by the University of California, San Francisco found that an author falsified data in a publication on AIDS research. According to the investigation, he selectively suppressed data that did not support his hypothesis and reported consistently positive data even though only one of four experiments had produced positive results. The falsified data were then used as the basis for a grant application to NIH. ORI concurred in the university's finding. The researcher executed a "voluntary exclusion and settlement agreement" with PHS in which he agreed not to apply for federal grant or contract funds and would not serve on PHS advisory committees, boards, or peer-review groups for 3 years. The publication was retracted. Price noted that when the author refused to agree to a retraction, *The New England Journal of Medicine* published the retraction without his signature but with the signatures of the rest of the coauthors and of the assistant vice chancellor of the university.

The editor of *Nucleic Acids Research* called the senior author of a manuscript because a reviewer had expressed concern that two experiments could not have been done as described and that autoradiographic images might have been falsified. The author first

The Journal's Role in Scientific Misconduct

claimed that the data were fine, then that errors stemmed from miscommunication with an undergraduate student, and then that he had other data to confirm the findings. On receiving those inadequate responses, the editor told the respondent that he would notify the author's institution, the Centers for Disease Control and Prevention (CDC); the respondent then did so himself. That led to a partial admission to CDC and a full investigation by ORI. The editor was contacted by ORI for information and said that he had consulted the reviewer and that the reviewer was willing to be identified to ORI if necessary. The author agreed to a "voluntary exclusion agreement" that prohibits him from public funding for 2 years and in which he agreed to supervision of his research. The author's defense was that he had been in a manic state and didn't know what he was doing when he submitted falsified data on an undergraduate student's work to the journal, but ORI found that he was being very critical of manuscripts of postdoctoral fellows and staff at the same time. The manuscript in question was never published.

ORI found that an author had selected data to create an apparent effect in two figures published in *FEBS Letters*, and it required the respondent to retract them. Instead, he requested that the editor allow him to publish new figures in their place. The editor consulted with ORI, and ORI counsel gave the editor a letter stating that the respondent's attempt to replace the figures violated the terms of his voluntary agreement. The respondent appealed again, and the editor agreed to a "corrigendum" in which the respondent retracted two figures as ORI required and cited his own Web site for his explanation. However, the editor added his own comment in the journal, citing an inconsistency in the author's new explanation and providing a link to ORI's Web site for full details (Corrigendum, Liburdy RP, edited by Editor, *FEBS Letters* 2000;23673; 1).

A principal investigator who found that his technician had falsified data reported the problem to the journal's editor. ORI had not yet issued a finding in the case. Rather than wait the 2 months for the ORI finding, the editor published what was called a "correction" (Xu *et al.*, *Journal of Biological Chemistry* 2003;278;38104), which read, "We regret to report that some results in this paper have been found to be non-reproducible, and therefore, the paper is retracted. Further information should appear on the website of the Office of Research Integrity." Price noted that this "correction" would raise some questions for readers. For example, it did not clarify whether misconduct was involved and, if so, which of the authors was at fault. It raises questions of whether it was fair for the innocent coauthors; perhaps the editor could have waited until the institutional investigation was closed or the ORI oversight was completed so that a full explanation could have been published to identify the person who falsified the data. Price also said that ORI cannot comment on pending investigations, so readers who had tried to contact ORI would not have received any answers.

Details about those and other cases are available at <http://ori.dhhs.gov/>.

In summary, Price said, ORI places the primary responsibility for investigations on the academic institution, but ORI's oversight mechanism may lead to PHS findings and administrative actions. Some of the administrative actions require publication of corrections or retractions, and ORI is happy to work with editors on such issues.

James T (Jim) Kroll, Head of Administrative Investigations, National Science Foundation

When an allegation comes before the National Science Foundation (NSF), the first phase is an inquiry to establish whether there is substance to it. The second phase, an investigation, seeks to determine whether scientific misconduct has occurred. The standard of proof required for research-misconduct investigations is preponderance of the evidence (usually more than 50% of the evidence). The investigators are also charged with considering intent; acts of carelessness are not considered misconduct.

Most investigations are referred to institutions, but the office will itself conduct investigations if the allegation involves a private business that does not have the facilities to conduct an investigation. The investigators must maintain subjects' confidentiality. When a case is referred to an institution, NSF becomes the complainant, and the original complainant is not named.

Federal policy has changed recently. The first definition of *scientific misconduct* (dating from 1989) included fabrication, falsification, plagiarism, and other serious deviations from the scientific norm. However, in December 2000, the phrase "other serious deviations" was deleted, and research-misconduct investigations now focus only on fabrication, falsification, and plagiarism. Such issues as retaliation against a whistleblower are no longer within the definition.

The most common allegation is intellectual theft. A researcher will claim that another researcher has taken his or her concept without giving due credit. Despite the frequency of this charge, the office has made only one finding of intellectual theft.

A common excuse of researchers is that funding proposals and grants shouldn't be held to the same standards as published journal articles, so plagiarism in a proposal isn't as bad as plagiarism in published work. NSF does not accept that excuse; it expects proposals to exhibit the same scholarly standards as any published article.

About 70% of the findings of research misconduct involve investigations of plagiarism, 11% involve fabrication, 11% involve falsification, and the remaining 8% are miscellaneous.

NSF can impose a requirement for assurances, in which a researcher is required to give personal assurance about the integrity of proposals or other documents submitted to the agency. NSF can also impose a requirement for certification, in which a dean or department chair must certify proposals or other documents submitted to the agency. In egregious cases, NSF can debar a person from receiving any federal grant money for a specified period (usually 1-3 years).

In response to audience questions after Kroll's talk, ORI's Price said that his office had encountered two recidivists and that ORI does not usually prosecute self-plagiarism. Gunsalus said that in her experience researchers who are guilty of one type of ethical problem are often found to be guilty of others.

Harvey Marcovitch, Syndications Editor, BMJ Journals

Marcovitch spoke about how enforcement in the United Kingdom differs from enforcement in the United States.

The General Medical Council (GMC) controls all UK physicians' right to practice and has draconian powers, including removal from the Medical Register. The GMC acts as whistleblower, judge, and jury. Two cases are described in detail at www.bmj.com (2002; 325: 1232-4 and 2003; 327: 940-1). The latter describes an unusual case in which children with a dangerous allergy were treated with desensitization therapy using small amounts of the allergen. Although such therapies are used in some other countries, they are not recommended in the UK, because the country's regulatory agencies have declared it unsafe. The physician who conducted the research wrote it up, and a peer reviewer claimed that informed consent could not have been obtained for the research inasmuch as the parents would have had to be informed of the small but real risk of death, and no parent would have agreed. By the time the investigation had started, the senior investigator had died, and his two residents were the only surviving authors. The investigation found that although the research had been referred to the hospital's ethics committee, no written record of its conclusion could be found. Instead, a surviving note suggested that the chair of the ethics committee and the investigator had talked about the situation, and the committee chair had decided that committee approval was not required, because the treatment did not constitute research. A consent form had been given to the parents, but it was very vague, merely warning that although the treatment might have serious consequences, senior doctors would be standing by to help.

In a second case, an obstetrician told his friend, the editor of a prominent journal, that he had developed a way to reimplant ectopic pregnancies and deliver them to term. The paper was written up, accepted without peer review, and published before it was discovered that the claim was completely false. The author's medical registration was withdrawn

The GMC has now said that all physicians have a duty to act quickly to protect patients from risk if they believe that a colleague is doing something that might threaten them. That duty covers includes publication of fraudulent research.

The only appeal from the GMC is to the Privy Council (which is broadly equivalent to the US Supreme Court). After that, the European Court would be the only recourse. The Professional Conduct Committee of the GMC meets as a court, with both complainant and doctor represented by an appointed legal team.

Case-Study Discussions

Retreat participants were divided into eight discussion groups, each containing 10 to 15 people. Two groups at a time were assigned to discuss each case study. After the small-group discussions, the groups convened in the assembly room to compare their conclusions.

CASE 1: Investigators seek documents from journal

A paper with seven authors was submitted to a journal and sent out for peer review. The authors were invited to revise the paper and resubmit it. When the revised paper was received, the section describing a series of assays had been removed, as had three authors' names. The corresponding author explained in the cover letter that the names had been deleted because the removal of assay information meant that those authors no longer met the International Committee of Medical Journal Editors (ICMJE) criteria for authorship. The revised paper was accepted. The editor then received a letter from one of the authors whose names had been removed. He said that he had not received the reviewers' comments from the corresponding author, that his name had been improperly deleted from the paper, and that he was filing a grievance with the corresponding author's institution. The journal "iced" the paper, pending resolution of the dispute. The institution's investigating official contacted the journal, asking for all correspondence and reviews related to the paper. What should the journal do?

Group 1: Decided that the editor was wrong in accepting the revision without a guarantee that the authors had agreed to be removed. The corresponding author is also in the wrong.

Group 8: Decided that the corresponding author is obliged to show reviews and correspondence to all coauthors. The group was unable to decide whether the journal was obliged to deliver materials to the institution. If the institution is considered a third party, the journal is obliged to maintain confidentiality. The journal should forward the request to the corresponding author and give him or her the opportunity to deliver the materials. All authors should have to sign off on any change of authorship.

Discussion: Should a journal insist that all authors sign off on authorship changes or revisions, or should it rely on the corresponding authors? How does signoff occur in electronic submissions?

DeAngelis reported that at *JAMA* acceptance is always provisional until the journal receives hard-copy letters containing signatures from all authors on statements detailing each author's responsibilities and specific contributions. Someone asked whether *JAMA* accepts the signed statements electronically. DeAngelis replied that *JAMA* accepts copies by mail, that the status of faxes hasn't been resolved, and that the editors have been advised not to accept electronic pdf copies.

Discussion points: If one journal rejects a suspect article, the authors could submit it to another journal that has no way of knowing about the problem. Do journal editors have obligations to other journal editors? How much should a journal continue to be involved in an investigation of scientific misconduct after it has rejected a paper? Does communicating with other journals breach confidentiality of submission and peer review?

In response to a question from the audience, Gunsalus said that if a journal is a private entity, it has the right to refuse to turn over correspondence to ORI or NSF without a subpoena. However, such a policy might not be in the journal's best interest. Also, the journal might not have that right if it is in an "open-records" state.

CASE 2: Images have been altered

A paper accepted by a journal contains several gel images. The production editor noted a duplicated band in one row of a gel image. The image was submitted as an eps file. When the production editor pressed "select all" in Adobe Illustrator, the last lane in the row was seen to be its own object, indicating that it had been placed in the row independently. Examination of the bands showed that the last two bands in the row were duplicates. The production editor asked the author about the duplicated band and alerted the senior editor who had handled the paper. The senior editor detected several other duplicated rows. The author apologized for "sloppy" preparation of the figures and offered to redo the experiments. What should the journal do?

Group 2: Decided that the author's response was essentially an admission of guilt. The journal should reject the paper and might also report it to the author's department chair or funding agency.

Group 7: Decided first to inform the author that the journal intended to alert the author's dean. The dean would determine whether to contact the research-integrity office of the funding agency. If the author withdrew the paper after that notification, the journal should still write to the dean and keep the materials.

Discussion: Can journals follow up every time a peer reviewer says that data or images are too good to be true? If a journal rejects a paper because of the peer reviewer's suspicions, does it have any additional responsibility in the case?

CASE 3: A dispute among authors

An author wrote to the editor of a journal, saying that his name had been omitted from a paper, about a case series, that the journal had published. He said that he had contributed more than half the cases reported. He charged that the first author had not only omitted his name but stolen his data and published the report without his consent. If the journal editor would not alert an oversight agency to "this clear case of scientific misconduct", he would do it himself. Now what?

Group 3: Wanted additional information about the relationship between the accuser and the other researcher, specifically, whether a nontenured faculty member or graduate student was making a complaint against a department chair or senior faculty member. It also wanted to talk to the complainant to see whether he qualified for authorship according to the Uniform Requirements or the journal's criteria. It decided that it would refer the case to the home institution by calling the dean, making it clear that the journal expected that there would be no retaliation against the complainant. The group also questioned the usefulness of the Committee on Publication Ethics (COPE) guidelines, which recommend contacting the author first with any allegations, because in this situation contacting the author was a recipe for potential retaliation and possibly the loss of the data.

The Journal's Role in Scientific Misconduct

Group 6: Would agree to publish an erratum adding the complainant's name if the first author agreed and if he met the criteria for authorship.

Discussion: Some participants thought that the journal might be in a good position to mediate between the authors, but others thought that the institution was the place to resolve such disputes. It might be advisable to copy the university president or dean in all correspondence to ensure that the department chair does not ignore the letters.

CASE 4: The wording of a retraction

A published paper has been found, by the authors' institution and the ORI, to contain data falsified by a doctoral student. The corresponding author, who was the student's supervising professor, sends the journal his own letter of retraction, in which he refers to his laboratory's "inability to reproduce the experiments described in the article" and apologizes for "any difficulties our erroneous report may have caused". Should the journal publish the corresponding author's letter?

Group 4: Decided that the letter was too vague and that the letter should state that this was a case of scientific misconduct adjudicated with ORI and should include specifics of the case. The article title should include the word "retraction".

Group 5: Would not publish the letter until the investigation at the institution was complete and the journal had received its findings. It would require signatures of all the authors on the letter.

Discussion: Retractions in MEDLINE are frequently worded vaguely. Price noted that in an informal study of several hundred MEDLINE retractions, he recognized two-thirds of them as ORI or NIH misconduct cases. It wasn't clear whether the others were misconduct cases. Even requiring signatures won't stop all cheating. Efforts to verify must be made, but in the end some amount of trust is required.

CASE 5: An author refuses to retract

A published paper has been found, by the lead author's institution, to contain fabricated data. Further investigation reveals fabrication or falsification in 17 other papers by the same primary author. Those papers involve dozens of coauthors. The lead author refuses to provide, to any of the journals involved, a retraction admitting misconduct. What should the journals do? Can the journals exonerate the coauthors?

Group 8: Decided to publish a clear and unequivocal retraction regardless of the fact that the author didn't agree. No formal measure should be taken to exonerate the coauthors, but perhaps a formal policy not to penalize them should be implemented.

Group 1: Agreed, with the caveat that because of the nature of clinical research, the coauthors could submit a letter to the editor describing their own roles in the research. The editor would then decide whether to publish the letters.

Discussion: Martin Blume, editor-in-chief of the American Physical Society, said that this situation was similar to the Lucent Technologies case. An experiment was

The Journal's Role in Scientific Misconduct

published, but no one could replicate the work. Lucent aggressively investigated, following the procedures as if it had had federal funding. It determined, by a preponderance of the evidence, that the paper contained fabricated data. It also interviewed all the coauthors. A Lucent vice president wrote a letter to the journals describing what had happened. The journals followed up and published the Lucent letter, linking it to the original article, which remained posted. Sheldon Kotzin, executive editor of MEDLINE, noted that in some cases a retraction has been issued by the institution's dean rather than by the author.

CASE 6: A reviewer suggests that a journal reanalyze an author's data

A paper describing a randomized controlled trial of a new drug for a common but largely untreatable problem was submitted to a journal. It has a number of authors, some at academic institutions in several countries and some at the company that manufactures the drug. One reviewer said that the results were not credible and that all signs suggested that the paper might be fraudulent. A statistical reviewer agreed that the results were unlikely but was not convinced of data manipulation; he suggested that the editors request the raw data. Now what?

Group 7: Recommended that the editor request the raw data. If the author refuses, the journal should ask the institution and the drug company.

Group 2: Agreed. The data would then be submitted to the statistical reviewer who called them into question.

Discussion: Several journal editors objected that their journals would not have the time or resources to analyze raw data. One said that a statistician had estimated that such a reanalysis would cost about \$25,000. In several cases, *JAMA* has required that a company have an academic statistician review the analysis at its expense, and the company has agreed. Wallace Sampson, editor-in-chief of the *Scientific Review of Alternative Medicine*, said that if claims seem implausible, it is up to the author, not the journal, to back them up. DeAngelis disagreed, saying that a medical journal that detects fraud bears a responsibility not to simply allow the claims to be published in other journals.

CASE 7: Investigators ask for peer reviewer's name

A journal editor called the senior author of a reviewed paper to discuss one reviewer's concerns that some experiments in the paper could not have been done as described and that images might have been falsified. The author's responses were vague and contradictory. The editor notified the author's institution, which began an investigation. The investigating official calls the editor, asking for the reviewer's name and contact details so that he can interview him. What should the editor do now? Suppose that an oversight agency, such as ORI, rather than the author's institution had asked for the reviewer's name; would the editor respond differently?

The Journal's Role in Scientific Misconduct

Group 6: Decided that revealing the reviewer's name would not be a problem if the journal has a signed reviewing system. In the case of an anonymous reviewing system, the journal would need the reviewer's consent before disclosing his or her name. If the reviewer did not consent, the journal would seek the advice of the publisher and lawyers before determining the next step.

Group 3: Decided that the journal should refuse to disclose the reviewer's name if the journal's review system is anonymous and the reviewer declines to be identified. The reviewer's name is irrelevant to the investigation anyway, because his or her opinion does not prove anything. The investigation still has to be conducted.

Discussion: The journal could act as an intermediary to allow the investigators to communicate with the reviewer without disclosing his or her identity; this might be helpful to ascertain what is being alleged, not to prove the case. Blume said that in an analogous case, his journal was sued to reveal the name of the referee in a patent dispute. The journal argued that it was protecting the identity of the reviewer. A judge determined that the plaintiffs were merely conducting a "fishing expedition" and upheld the journal. However, if the court had ruled the other way, Blume would have had to comply. Annette Flanagin, managing senior editor of *JAMA*, noted that *JAMA* had been involved in a 1994 case (*Cukier vs American Medical Association*) in an Illinois court that established case law protecting the privileged nature of peer review. Additional details are available in the *American Medical Association Manual of Style*, 9th Edition. Price said that to his knowledge, ORI has never asked a journal to disclose the identity of reviewers. In one case, however, he had wanted to make sure that a possible expert witness for ORI had not been the reviewer-complainant in a case, and the journal had agreed to answer that question.

CASE 8: Coauthors want their names cleared

A published paper is found to contain falsified data. One of the authors admits that he falsified the data but refuses to submit a retraction to the journal. The coauthors submit a retraction to the journal, but they want it made clear in the retraction that only one author was responsible for the scientific misconduct and that they had been unaware of the falsification and therefore could not be held responsible for it. What should the journal do?

Group 5: Wanted more information before coming to a conclusion. For example, Who found the falsified data? When were they falsified? Was it the corresponding author who refused to retract? Are the other authors at the same institution? What country is the institution in? If the falsified data were not crucial to the validity of the paper, the group said that it might accept a correction explaining what data were falsified rather than requiring a full retraction. Alternatively, the editor could change the authors' letter to include a more explicit description of the problem and tell the authors that the journal will publish a retraction if they do not accept the edited letter.

Group 4: Thought that the editor should notify the institution's dean. The group

The Journal's Role in Scientific Misconduct

said that the editor did not have the ability to exonerate any innocent coauthors. It also recommended that journals develop a coherent scientific-misconduct policy before any cases develop, stating that in cases of scientific misconduct a retraction can be published without the consent of all the authors. It questioned whether the ICMJE guidelines on the definition of authorship might be too idealistic; authors are unlikely to be able to take responsibility for everything in a paper.

Scientific Misconduct in the Physical Sciences

Martin Blume, Editor-in-Chief, American Physical Society

Blume discussed misconduct cases arising from the Schön case at Lucent Technologies' Bell Labs and the Ninov case at Lawrence Berkeley National Laboratory (LBNL). [In brief, Bell Labs fired Jan Hendrik Schön in 2002 after an investigation concluded that he had fabricated findings in molecular electronics. Among other problems cited in the investigation were findings that Schön had not retained his original data and that he had published identical graphs in several publications. In the Ninov case, Victor Ninov and colleagues reported in 1999 that element 118 had been discovered at LBNL. Ninov's coauthors later withdrew the claim and retracted the paper that had been published in *Physical Review Letters* after the experiments could not be replicated and an investigation found signs that data had been altered.]

Blume discussed similarities and differences between misconduct issues in the physical sciences and the biomedical sciences. He also discussed a similar misconduct retreat held recently by the International Union of Pure and Applied Physics (www.iupap.org/working/workshop.shtml).

He said that the APS journals are very international, with more than two-thirds of submissions coming from outside the United States. They deal with institutions around the world. International issues may affect misconduct. For example, foreign authors writing in English might lift passages wholesale from previously published work; the authors may view their action as a way of learning the language, or it may be in part attributable to cultural differences. It is difficult to punish international offenders. APS tries to refer cases to the offenders' institutions, but standards may be different in different countries. The organization has no other way to punish offenders--not even by withdrawing their membership (unless they fail to pay their dues).

Issues of conflict of interest are somewhat different in the physical sciences. Pharmaceutical funding is not an issue, but investigators might encounter other financial conflicts of interest and conflicts arising purely from professional competition.

The APS journals encounter plagiarism, duplicate submission, and referee misconduct. They refer authorship disputes and conflict of interest to institutions. In the Ninov case, the Department of Energy started investigating whether it was possible to recoup the funding for the fraudulent experiments, but it ended up dropping the case.

Blume discussed a recent case of plagiarism in which a paper described experiments that apparently replicated a theory published earlier, but the authors claimed

The Journal's Role in Scientific Misconduct

the discovery as their own. Furthermore, the text and references showed clear signs of plagiarism from the first paper. At first, the authors of the second paper proposed a so-called correction in which they repeated their claim of having made the discovery, but eventually they agreed to publish a retraction that was essentially drafted by Blume.

In one case, a group of researchers in India posted their own Web page to draw attention to allegations of plagiarism against another group.

In another case, a postdoctoral student wrote to a journal claiming that her thesis adviser had published her data without acknowledging her. APS reported the problem to the researchers' institution, which conducted an investigation and concluded that her name should be added. Blume's journal retracted the original article and replaced it with a new version that included her name.

Blume noted that in the investigation into Ninov's work on element 118, the investigators also looked at his earlier work identifying element 116 and found that the work that he published showed no evidence of having been done. Nevertheless, someone else verified the findings. Ninov would have retained the credit as the initial discoverer if the investigation had not taken place.

Cleaning Up the Aftermath of Misconduct

Martin Blume, Editor-in-Chief, American Physical Society

Blume spoke about the need for punishment. APS refers cases to the author's institution or funding agency, can refuse to accept later papers from that person, and can take actions based on the institution's findings. For example, if an institution makes a finding that an author should be added to a paper, the journal can publish a statement explaining the problem. If an author's name is dropped during revisions, APS policy is to confirm the change with that author.

Blume called conflict of interest the most difficult matter to deal with. Although he feels that it should be penalized, it is not clear how.

In cases of retraction, the original article is not removed from the Web site, but electronic links are placed on the retraction and on the original article so that readers can link in either direction. Notices are placed in the table of contents.

In one case of duplicate publication, the second article was withdrawn from the Web site, and a notation was placed on the first article that there had been duplicate publication. APS also refused to accept further papers from the author for 3 years.

Sheldon Kotzin, Executive Editor, MEDLINE, and Chief of Bibliographic Services, National Library of Medicine

Part of the NLM mission is to help users by updating MEDLINE by adding errata, notices of duplicate publication, comments, retractions, and other commentary on articles. Those notices can be added to MEDLINE only if they are published by the journal on a numbered page and thus can be given an independent MEDLINE citation. Every such notice is linked to the original citation.

The Journal's Role in Scientific Misconduct

NLM will classify articles as "comments" when they are substantive letters or articles that challenge, refute, or expand on the original article. Occasionally, NLM has used the comment label to describe an "expression of concern", in which an editor draws attention to possible problems but does not go so far as to retract or correct an article.

When errata are found in abstracts, NLM does not delete the inaccurate wording but instead adds the corrected wording in brackets. That permits the user to search for either the inaccurate wording or the corrected wording. The exception is a serious dosage error in an abstract, which will be corrected with the note "[corrected]".

Readers, authors, and editors sometimes contact NLM directly, but NLM will not generally take action unless a citable notice appears in an indexed journal or the editor indicates the issue and pagination of a forthcoming retraction or erratum notice. NLM does not differentiate between articles retracted because of error and those retracted because of plagiarism or other misconduct.

If NLM comes across a duplicate publication (one that entirely or substantively duplicates another by the same author), staff will label it as a duplicate without seeking author approval. However, it is unusual for NLM staff to discover one without being notified.

NLM never removes a citation in MEDLINE. On occasion, staff have blocked a citation because of a dosage error that would be lethal if followed; but once the error is corrected, access to the citation is reopened.

NLM has cited 540 retracted articles since the early 1980s; in the same period, it has added 6 million records to MEDLINE. The top-tier journals have issued the most retractions.

Examples of unusual requests by editors: Some have asked NLM to remove citations to politically sensitive articles, and the answer has been no. In one case, a twin of a study subject discovered that her own medical condition was revealed in an article; NLM removed a revealing subtitle but made no other change. In another case, an article in a Western journal was reprinted in its entirety in a Chinese journal; NLM decided to follow its ordinary policy, which was to take no action until the Chinese journal issued a retraction. NLM declines to get involved in controversy about validity of an article; in such cases, the citation remains in MEDLINE, and it is up to the reader to decide what has scientific merit.

Recent challenging situations: A faculty member's paper was plagiarized and published elsewhere, and the author of the second article refused to publish a retraction; the first author contacted NLM, which recommended publishing a letter reporting the problem and citing the first article. In another case, a Chinese-language journal reported a high risk of cancer death associated with a particular pollutant; 10 years later, an English-language journal reported the opposite findings in an article attributed to the same authors; NLM was contacted with a claim that the second article was fabricated by a utility company; NLM contacted the publisher of the second journal, which claimed to have no information about the allegation; no retraction has been published.

Can Misconduct Be Prevented?

Mary Scheetz, Director of Extramural Research, Office of Research Integrity

Scheetz is interested in how instructions for authors can be used as an educational tool. In a study, she reviewed the instructions for authors in 41 journals that ORI contacted in 1992-1999 for retractions or corrections in connection with PHS findings of misconduct (17 journals were in the basic sciences, 13 were clinical, and the rest were both).

Two-thirds or more of the instructions discussed copyright practices, authorship, and reference style. More than half also discussed publishing practices and financial disclosures. Fewer than half discussed policies about peer review and human or animal research protections. Many cited the Uniform Requirements but only for the definition of authorship. Only 15% said anything about retractions, corrections, and research misconduct (six mentioned scientific misconduct, but only two were specific about how it would be handled).

When she updated the study by inspecting 20 journals contacted since 1999, she found similar results. That is disappointing, particularly in light of the 1989 Institute of Medicine report that stated that “scientific journals should develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication.”

She recommended that all instructions contain that information. Retractions and corrections enhance the reputation of a journal by showing that it is serious about reporting good science. She also recommended that journals look for guidance in fields where precedent has been established. They should also feel free to seek help from ORI when appropriate and can make anonymous calls for advice.

Alan Price, Associate Director, Office of Research Integrity

Plagiarism (the theft or misappropriation of intellectual property and the substantial nonattributed textual copying of another's work) is investigated in ORI cases. However, disputes between collaborators are primarily the responsibility of the relevant institutions, not ORI. In one case, a former graduate student claimed that her mentor had "stolen" her thesis work and submitted it to the *Journal of Biological Chemistry*. She asked ORI to contact the journal and stop the publication, but ORI could not do so. Her notebooks showed that she had developed the ideas in collaboration with her mentor, using her mentor's biologic system, and the intellectual-property rights were released by the university to both her and her mentor. ORI asked the institution to address whether the matter involved scientific misconduct. From the institution's inquiry report, it appeared that the mentor had become frustrated after waiting for the former student to write up her work and had gotten another fellow to duplicate the work for publication, placing the original student's name in the acknowledgments as having provided the key reagent.

ORI's role is to refer such cases to institutional officials. It is the obligation of the institution to resolve credit and authorship disputes between students and mentors or collaborators.

Harvey Marcovitch, Syndications Editor, BMJ Journals

Marcovitch noted that most clinical research in the UK is conducted within National Health Service institutions, as is much basic-science research, so the General Medical Council has clout. The GMC has investigated 16 people over 3 years for serious professional misconduct. Four were found not guilty, and 12 were found guilty. Two received serious reprimands with public letters describing the issues. Five were suspended from medical practice for 1 year; this is equivalent to a fine of a year's salary and might cause problems in getting back on the career ladder afterwards. Five were allowed to maintain their practices but were banned from conducting or supervising research for 1 to 3 years. One was ordered to attend a course in medical ethics. One had to report to a mentor every month. And one was struck off the medical register (with little, if any, likelihood of ever returning).

Marcovitch also spoke about COPE (www.publicationethics.org.uk/), an organization of journal editors in the UK and Europe that meets regularly to discuss ethical issues informally and openly. The group provides a way for journal editors to get their peers' advice about resolving ethical problems, and it maintains a record of anonymous case studies for reference. The organization's guidelines for good publication practice are available on its Web site. Marcovitch recommended that editors in other countries consider establishing similar groups.

Concluding Remarks

Richard Horton, Editor, *The Lancet*

Horton said that it was unrealistic to believe that education will solve the problem of scientific misconduct, because education about scientific misconduct does not change the culture of science that drives the problem. There is a conceit that science is logical, but in reality, scientists have passions. As it is impossible to eliminate all human desire and passion, it is important to try to change the culture of science. Several actions are needed: fixing, investigating, reporting, advocating, correcting, researching, leading, convening, and irritating.

Fix the procedures, including raising awareness; don't shove the problem under the carpet or pass the buck to others. The challenge will be to do this without becoming more suspicious.

Investigate. Both the journal and the institution have to investigate; the institution should not bear the entire burden.

Report the problems as one way to raise awareness.

Advocate integrity by writing editorials, commissioning review articles, giving lectures, and raising awareness.

Correct your own mistakes as well as those of others.

Research the problem, as we do other problems. We still don't know how common it is, and we have no epidemiology of it. The peer-review congresses have

The Journal's Role in Scientific Misconduct

drawn attention to studies of research integrity.

Leadership in scientific societies and institutions is important.

Convene meetings, such as those of COPE or CSE, where normally competing journals can get together to share problems anonymously and work out solutions like case law. This will help to build up institutional memory of the problems so that new editors will not be completely at sea.

Irritate, by agitating and writing provocative articles. The mark of good editors is the number of quarrels they have in their tenure; if they're quiet, they've failed.

CSE's roles could be to gather resources for journal editors, hold meetings, develop an international union, promote informal liaisons between various groups, and develop policies, such as a template document that other editors could use for guidance.

Again, the challenge will be to investigate problems without corroding professional trust and public trust in science. Trust should not be thrown out; its opposite is not doubt but a pervasive public unease.

Ethics is essentially a promise to act with integrity. The promise creates an obligation or a duty to act that way, but there is no enforcement. So there is a burden on scientists to identify the conditions that encourage people to be deceptive and then to change them to create the inclination to discharge the promise of ethical conduct.

Additional Resources on Scientific Misconduct and Journals

Policy Statements

- Council of Science Editors Editorial Policy on Journal Referral of Possible Misconduct
(www.councilscienceeditors.org/services/draft_approved.cfm#ParagraphThree)
- International Council of Medical Journal Editors Statement on Corrections, Retractions, and "Expressions of Concern" about Research Findings
(www.icmje.org/index.html#correct)
- Committee on Publication Ethics Guidelines on Good Publication Practice. The COPE Report 2002.
(www.publicationethics.org.uk/cope2001/pages2001/COPEreports.htm)

Books and Chapters

- Iverson C and others. Scientific misconduct. In: American Medical Association manual of style. 9th edition. Baltimore; William & Wilkins; 1998:103-8.
- Gunsalus CT. Scientific misconduct: policy issues. In: Jones AH, McLellan F, eds. Ethical issues in biomedical publication. Baltimore: Johns Hopkins; 2000:223-49.

Case Studies and Additional Resources

- Office of Research Integrity (ORI) Web site (www.ori.dhhs.gov)

The Journal's Role in Scientific Misconduct

- Committee on Publication Ethics (COPE) Web site (www.publicationethics.org.uk)
- Web site of International Union of Pure and Applied Physics Workshop on Scientific Misconduct and the Role of Physics Journals in Its Investigation and Prevention (www.iupap.org/working/workshop.shtml)
- Links page on Web site of International Union of Pure and Applied Physics (www.iupap.org/working/ethics-resources.html)