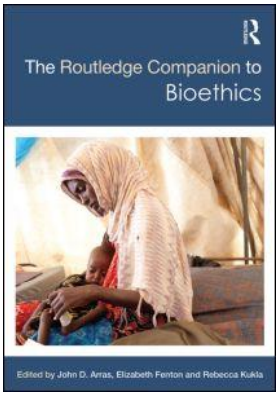

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Bias, Misconduct, And Integrity In Scientific Research

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BIAS, MISCONDUCT, AND INTEGRITY IN SCIENTIFIC RESEARCH

David B. Resnik

Introduction

Integrity in science involves adherence to ethical norms for the conduct of research. Integrity is essential to good scientific research, as it plays a key role in collaboration, peer review, publication, confirmation, mentoring and education, and data acquisition, analysis, and management. Integrity helps scientists to secure the public's trust and support, and is important in interactions with the public, such as communicating with the media and providing expert testimony in legal proceedings on government advisory committees. Integrity is also indispensable in research involving human subjects or animals. Some of science's ethical norms include honesty, openness, carefulness, objectivity, fair sharing of credit, social responsibility, and respect for students, peers, and research subjects (Shamoo and Resnik 2009).

One reason why integrity is essential in research is that scientists build on each other's work and share information, materials, methods, and ideas. As Isaac Newton once said, "If I have seen further, it is by standing on the shoulders of giants" (Newton 1676). Scientists must be able to trust that the data and results reported in publications are truthful, accurate, and reliable, and that collaborators, editors, and reviewers will honor their obligations and commitments.

Two different types of ethical problems in science can undermine trust: bias and misconduct. The difference between bias and misconduct is that bias may be unintended, whereas misconduct is intentional. Although both bias and misconduct can compromise the integrity of research, misconduct is regarded as a worse ethical transgression because it involves deliberate deception. The person who publishes biased research may be regarded as negligent or incompetent, whereas the person who publishes fraudulent research may be viewed as morally corrupt (Shamoo and Resnik 2009).

Bias

One of the overarching goals of scientific research is to develop knowledge that is free from personal, financial, political, religious, or other biases. Scientific hypotheses and theories should be based on empirical evidence and sound argumentation, not on

subjective opinions or beliefs, erroneous assumptions, careless mistakes, political ideologies, or religious dogma. Because scientific knowledge is based on human observations, concepts, and theories, it is impossible to eliminate all types of bias, but scientific methods can help reduce or control for bias. Objectivity is worth pursuing as a goal even it is not completely attainable (Haack 2003; Resnik 2007).

Clinical trials, for example, include several different methods to control for bias. Randomization helps to reduce biases that might arise if investigators or subjects decide which treatment to take. In a clinical trial that compares an experimental drug and one that is already approved (the control), subjects are randomly assigned to receive either the experimental drug or the control. If investigators determine the assignment, they might decide that the healthiest patients should receive the new drug, which could bias the results. Double-blinding helps to control biases related to the placebo effect, a phenomenon in which a person's belief that they are receiving an effective therapy influences their response to treatment. Preventing investigators and subjects from knowing who is receiving the experimental drug or the control helps to counteract biases due to the placebo effect (Gallin 2007).

Science's peer review system also helps to reduce and control bias. When scientists submit a paper to journal, the editors ask independent experts to review the work to determine whether it meets appropriate standards of research and scholarship. In their critical assessment of the paper, reviewers will typically address the following questions: Is the research original and important? Does the evidence support the conclusions? Are the methods well described and appropriate for the research? Have the authors reviewed and cited the appropriate literature? Is the paper well written and organized? Have the authors made any unjustified assumptions? Though the peer review system is not perfect—editors and reviewers sometimes fail to catch obvious errors and other flaws and have their own biases—it is by far the best way of ensuring that published research is accurate, reliable, and significant (Shamoo and Resnik 2009).

Different types of bias can still impact the publication process, despite peer review. One of these is the tendency to publish positive results rather than negative ones. A positive result is evidence showing support for a particular hypothesis, while a negative (or null) result is evidence showing no support for the hypothesis. In clinical research, a positive result could be evidence that an experimental drug is more effective than placebo or that an approved drug is more effective than competing drugs (Easterbrook et al. 1991). Negative results are still published in science, especially when they challenge well known and accepted hypotheses or theories, but they are published less often than positive ones.

The underreporting of negative results can skew the publication record. For example, in meta-analysis scientists use statistical techniques to synthesize data from many different studies. If an investigator performs a meta-analysis of different studies of a particular drug, the analysis may be biased in favor of the drug if it does not include unpublished, negative data, or results. A similar type of bias may arise when a scientist writes a review article that does not include unpublished data or results (Resnik 2007).

There are several reasons for a bias in favor of publishing positive results. First, editors and reviewers may be more interested in positive results rather than negative ones. A study that reports new and exciting positive results is more likely to pique the interest of editors and reviewers than a study that reports negative ones (Olson et al. 2002). Second, investigators may decide not to submit negative results to journals, because they believe there is little chance of publication or they don't regard the results as interesting

(Easterbrook et al. 1991). Third, negative results sometimes have less statistical significance than positive results, and statistical significance is an important factor in editorial decision-making (Dickersin et al. 2002). Fourth, private companies may decide not to publish results that are unfavorable to their products. For example, a pharmaceutical company that sponsors several different studies of its drug might publish only the studies that show its drug is effective (Resnik 2007).

Problems with pharmaceutical company Merck's drug Vioxx illustrate the hazards of repressing negative results. The U.S. Food and Drug Administration (FDA) approved Vioxx in 1999 as a treatment for arthritis and chronic pain. In 2001, Merck scientists possessed data showing that Vioxx increases cardiovascular risks, but the company did not publish these data. Merck sponsored a study, known as the VIGOR trial, which compared Vioxx with other pain medicines. The study showed that patients receiving Vioxx had five times the risk of heart attack or stroke compared with those taking naproxen. The VIGOR study did not include all the cardiovascular risk data. Merck did not publish these data, although it submitted them to the FDA, which treated the data as confidential business information. In 2001, the FDA warned Merck that it had misrepresented Vioxx's safety profile, and in 2002 it issued a black box warning. A subsequent trial, known as the APPROVE study, showed that Vioxx had twice the cardiovascular risks compared with placebo. The study was stopped prematurely in 2002 to protect patients taking Vioxx from risks. On September 30, 2004, Merck withdrew Vioxx due to patient safety and legal liability concerns. Since then, thousands of lawsuits have been filed against the company (Resnik 2007).

Repression of negative results conflicts with the normative ideal of openness. Openness—the sharing of data, methods, materials, and tools—helps advance scientific knowledge by enabling scientists to build on each other's work, thereby saving time, effort, and resources. Openness is also crucial for the exchange of information and ideas that stimulates creativity, innovation, dialogue, criticism, and debate in science. Although some secrecy is justifiable in science for legitimate reasons, such as to protect preliminary work and the confidentiality of research participants or the peer review process, openness that leads to biased results or harms the public is not justifiable (Resnik 2007).

In response to suppression of data by Merck and other pharmaceutical companies, biomedical journals now require clinical trial registration as a condition for publication of research reporting the results of clinical trials. Clinical trial registration involves submitting key information about a study to a public database, such as ClinicalTrials.gov, which is run by the National Library of Medicine. Submitted information includes the treatments under investigation, study design and objectives, methods and procedures, research sites, related publications, and contact information. The FDA also requires registration of most clinical trials, except phase I studies in which drugs or biologics are tested for the first time in human beings to assess their safety (Laine et al. 2007).

Although clinical trial registration can make it more difficult for companies to suppress data, it does not guarantee that all clinical trial data will be published or made otherwise available to investigators or clinicians, because registrants are not required to submit original data. However, there are good reasons for not making all data immediately available to the public, because data must be validated, analyzed, and interpreted prior to publication to deal with errors, inconsistencies, and other problems. Publishing raw clinical trial data on a public website could be misleading. Even though clinical trial

registration does not eliminate the problem of data suppression, it makes investigators and clinicians aware of the studies that are being conducted and whom to contact if they want more information (Resnik 2007).

Another way of dealing with the problem of unpublished data is to provide a forum for the publication of negative and non-significant results. Some journals have been established that focus specifically on negative results, such as the *Journal of Negative Results* and the *Journal of Negative Results in Biomedicine* (O'Hara 2011). Others have suggested that computer databases be established to provide open access to unpublished data (Schooler 2011). However, the idea of publishing negative and non-significant results, which has been discussed for two decades, has failed to catch on. One reason why scientists have not made much progress in this direction is that they are not adequately rewarded for publishing negative and non-significant results, since tenure and promotion committees are interested in publications that report positive, significant results. An ethical concern with publishing insignificant results is that they might be misleading due to small sample sizes. Scientists who use these results should be aware of their limitations.

Conflicts of interest (COIs) can also bias research and skew the publication record. Many scientists today have relationships with research sponsors, such as stock or equity, consulting arrangements, and intellectual property, which can bias their judgment and undermine the integrity of research. For example, 11 out of the 12 investigators conducting the VIGOR study had financial ties to Merck (Resnik 2007). There is considerable evidence that financial interests can influence the outcome of a study. A review of the literature on financial interests found that industry-funded clinical trials are more likely to report results that favor a company's product than publicly funded studies (Ridker and Torres 2006). Most journals today have policies that require authors to disclose their financial interests related to the research. Disclosure may not prevent bias, but it at least helps readers to understand the financial relationships that may impact a study, which may be useful in evaluating the research (Resnik and Elliott 2013). A critical examination of the ethics of COIs in science would take us well beyond the main focus of this article, so this topic will not be explored in depth here. For further discussion, see Krimsky (2004), Resnik (2007), and Elliott (2011).

Misconduct

As mentioned earlier, misconduct involves the deliberate violation of science's ethical norms. The U.S. government defines misconduct as fabrication, falsification, or plagiarism (FFP). Fabrication is making up data or results; falsification is changing, omitting, or manipulating data or materials in a way that misrepresents the research; and plagiarism is claiming someone else's words, ideas, methods, data, or images as one's own (Office of Science and Technology Policy 2000). Most organizations include FFP in the definition of misconduct, and some include other misbehaviors, such as interference with a misconduct investigation or egregious violations of rules for conducting research with human or animal subjects (Resnik 2003).

Misconduct is not just unethical; it is also usually illegal. In the U.S., federal regulations prohibit misconduct in research supported by government funds. An individual who is found to have committed misconduct may be barred from receiving federal funds for research. He or she may also receive sanctions from his or her institution, such as loss of employment. In some cases, researchers who have committed misconduct may be

prosecuted for criminal fraud. For example, University of Vermont clinical researcher Eric Poehlman was sentenced to serve one year and one day in a federal prison in 2006 for defrauding the government. An investigation by the university found that Poehlman fabricated or falsified data on 17 grant applications (worth $2.9 million) and 10 papers from 1992 to 2001. Seoul National University stem cell scientist Woo Suk Wang, who was found by a university investigation to have fabricated data in two papers on human therapeutic cloning published in the journal *Science* in 2004 and 2005, was sentenced to serve two years in prison in 2009 for embezzlement and bioethics law violations, though his sentence was suspended (Shamoo and Resnik 2009).

It is difficult to get an accurate estimate of the incidence of misconduct, due to limitations of surveys methods. In one survey of 2,000 university faculty and students, 6–9 percent said they had direct knowledge of faculty falsifying data or plagiarizing research (Swazey et al. 1993). Other surveys with similar designs found similar results (Titus et al. 2008). In a more recent survey of over 3,000 federally funded researchers, 0.3 percent admitted that they falsified or cooked data in the last three years (Martinson et al. 2005). Fanelli (2009) examined 21 surveys and 18 meta-analyses of misconduct and found that, on average, about 2 percent of scientists admitted to fabricating or falsifying at least once in their careers and 14 percent said they had observed colleagues falsifying data.

Surveys have potential shortcomings. Surveys in which participants are asked whether they have observed misconduct tend to overestimate the incidence of misconduct because some of the behaviors the participants have observed may appear to be misconduct, but are, in fact, not. The participants may not have sufficient knowledge to determine whether misconduct has occurred. Surveys in which participants report their own misconduct tend to underestimate the incidence of misconduct, because people may not be willing to admit to unethical or illegal behavior, even on an anonymous survey (Shamoo and Resnik 2009).

Steneck (2000) estimated the incidence of misconduct to be 1 event per 100,000 researchers, based on 200 confirmed cases of misconduct in 20 years of National Institutes of Health funded research. This methodology probably grossly underestimates the rate of misconduct, because it only includes data from confirmed cases. Probably many more people commit misconduct than are caught doing it (Titus et al. 2008).

Misconduct has adverse impacts on those directly affected by it (such as individuals who collaborate or study with someone who commits misconduct), the institution, and the research community. A misconduct investigation is burdensome for all involved parties, from the defendant to the witnesses to investigators. It can take several years to completely resolve a misconduct allegation. An investigation can be stressful not only for the defendant but for others as well. Misconduct investigations usually involve major disruptions of scientific work, because records may be seized and research may be suspended, pending the outcome of the investigation. A student who is working with a researcher who is found to have committed misconduct may lose funding and may need to transfer to another university. An innocent researcher who is wrongly accused of misconduct may still have to endure a lengthy investigation, and the researcher's reputation may be damaged. The research community can also be negatively impacted because misconduct can tarnish the integrity of science and erode the public's trust in research (Shamoo and Resnik 2009). And last, but certainly not least, misconduct leads to the publication of fraudulent and erroneous results that undermine the search for knowledge. Scientists who rely, unknowingly, on fabricated or falsified data may be led astray.

There are two different explanations of why misconduct occurs. According to the "bad apples" theory, misconduct is committed by people who are morally corrupt or psychologically unstable. Some cases seem to fit this pattern. For example, in 1974, Sloan Kettering immunology researcher William Summerlin admitted to fabricating data in skin transplant experiments. He was attempting to develop a technique to make white-haired mice accept skin transplants from black-haired mice. His deception was discovered when a laboratory assistant who was cleaning the mice noticed that the black patches on the white mice could be washed off with alcohol. Summerlin admitted that he used a black felt-tip pen to draw the black patches on the white-haired mice. A committee that investigated the incident determined that Summerlin was suffering from mental health problems (Shamoo and Resnik 2009).

In 2002, Bell Laboratories physicist Jan Hendrik Schön was found to have fabricated data in at least 17 publications. Schön was a rising star who had been publishing at an unbelievable rate of a paper every eight days. His papers had appeared in *Science*, *Nature*, *Physical Review Letters*, and other prestigious journals. An investigation by the University of Konstanz, which had awarded Schön his PhD, found that he had also fabricated data in his dissertation. The university revoked his degree (Shamoo and Resnik 2009).

The Summerlin and Schön cases seem to fit the bad apples theory. Summerlin had mental health problems. Indeed, a person who was mentally well would probably not attempt to get away with such an obvious scam. Even if no one detected the initial data fabrication, problems would arise when other investigators attempted to replicate his results. In Schön's case, it seems likely that he was incredibly arrogant to think that he could get away with such a tremendous amount of deception throughout his career. At some point someone would question his unprecedented rise to stardom, and his fraud would be detected.

The other explanation of misconduct is that it is produced by a research environment that encourages unethical behavior. Scientists face tremendous pressures to produce results, publish, and obtain funding. Competition for government grant dollars has grown even more intense as the budgets of funding organizations have shrunk in the recent economic downturn. In defending his actions, Poehlman said that he falsified data because he felt immense pressure to keep grant dollars flowing into his laboratory to support students and staff. The pressure to produce can be overwhelming for postdoctoral fellows, graduate students, and other researchers who depend on grants for their employment (Shamoo and Resnik 2009). In some countries, such as China, the government provides economic incentives for publishing research in top-tier journals and requires graduate students to have a specific number of first-author publications before they can receive their doctorate (Zeng and Resnik 2010). In the United States, hiring, tenure, and promotion decisions are usually based, in large part, on the number of publications one has (Shamoo and Resnik 2009).

Inadequate supervision of students and subordinates can also encourage or at least fail to prevent misbehavior. Many scientists are in charge of large laboratories staffed by students, post-doctoral fellows, and research staff. They sometimes do not take time to explain to their students and subordinates how to design experiments, keep adequate records, analyze data, produce figures and tables, cite articles, and so on. Lab directors (and other supervisory scientists) may fail to communicate properly and inform students and subordinates about research expectations. Additionally, cross-cultural variations in practices related to authorship, plagiarism, data management, and other aspects of scientific behavior may lead to misunderstandings and differences of opinion concerning the ethical conduct of research (Resnik and Shamoo 2009).

Industry ties may also encourage misbehavior. As noted earlier, many scientists today own stock in companies that sponsor their research or have paid positions with industry. Scientists also pursue patents and other forms of intellectual property. These conflicts of interest may encourage not only bias but also misconduct. A scientist who has an economic stake in the outcome of a study may be tempted to cut corners or manipulate data in order to produce results. Since COIs are a risk factor for misconduct, it is important to manage them properly (Shamoo and Resnik 2009).

Additional evidence for the research environment theory is that ethically questionable behaviors, such as inappropriate authorship assignment, republishing data or results without proper citation, violating animal or human research rules, unauthorized use of confidential information, failing to disclose conflicts of interest, and poor record-keeping, are much more common than misconduct (Swazey et al. 1993; Martinson et al. 2005). Researchers who commit minor infractions may be more willing to engage in major transgressions, such as misconduct.

Both of these explanations of misconduct probably contain part of the truth. Psychological factors, such as mental illness and moral depravity, probably play an important role, but so do social and economic factors, such as the pressure to produce results, poor supervision, and financial interests. Efforts to prevent misconduct via education, mentoring, policy development, and enforcement should therefore take all of these different factors into account. Though education and mentoring may have little impact on researchers who are "bad apples," they may help guide ordinary researchers who are tempted to bend or break the rules or who do not understand what is expected of them.

Preventing misconduct needs to be a top priority for research institutions. Some strategies for prevention include education and mentoring on the responsible conduct of research, policy development, institutional leadership involving a commitment to ethics, mechanisms for reporting misconduct and other ethical concerns, and enforcement of ethics policies. Additionally, institutions should consider reforming their hiring and promotion practices so that there is less emphasis on the quantity of publications (Titus et al. 2008; Shamoo and Resnik 2009; Koocher and Keith-Spiegel 2010).

Deciding whether to report misconduct can be a difficult dilemma for would-be whistle-blowers because fulfilling the ethical duty to report suspected misconduct can come at considerable personal expense. Witnesses must be available to testify, which can take time and effort and cause stress. If the defendant is the accuser's supervisor, the accuser may lose his job or need to transfer to another institution if the defendant is fired. In some cases, the accuser may fear retribution from the defendant or others. Although federal and state laws protect whistle-blowers from direct retaliation, such as loss of employment or demotion, other repercussions may still happen. A whistle-blower may be shunned or branded as a trouble-maker, for example. Of course, in some situations the whistle-blower may be implicated in misconduct if he does not report it. For example, if the whistle-blower is a co-author on a paper in which he believes one of his collaborators has faked data, then he may face a misconduct allegation if he does nothing and someone else discovers the impropriety. Whistle-blowers must therefore consider their options carefully when deciding whether to report misconduct. They should make sure that they have not misinterpreted the defendant's behavior and that they have sufficient evidence to make an accusation (Shamoo and Resnik 2009; Malek 2010).

A recent example of whistle-blowing occurred when research assistants and a graduate student working in Harvard psychology professor Marc Hauser's laboratory in 2007

suspected that he had fabricated data concerning pattern recognition experiments in monkeys. In these experiments, an animal listens to a sound pattern played repeatedly through a speaker, and then the pattern is changed. If the animal looks at the speaker when the pattern changes researchers infer that the animal can recognize sound patterns. In the experiment, two independent observers, Hauser and an assistant, coded videotaped monkey responses. To reduce bias, both observers were not allowed to hear the sound. A second assistant analyzed the results and found that while Hauser's coding indicated that the monkeys recognized sound patterns, the assistant's did not. The second assistant and a graduate student asked Hauser if they could recode his data to make sure they were correct, but Hauser refused. The assistant and the student then recoded Hauser's data without his permission, and they found that the videotaped behavior bore little relation to what Hauser claimed that he observed. The assistants and the student consulted other people in Hauser's laboratory and found that they had similar concerns about his work for several years. The whistle-blowers made an official allegation to the university ombudsman, which led to an informal inquiry and then a misconduct investigation. In August 2010, a Harvard committee determined that Hauser committed eight counts of research misconduct. In August 2011, Hauser resigned his position at Harvard. He has not admitted to misconduct, though he does claim to regret some mistakes he made (Gross 2011). In 2012, the Office of Research Integrity (ORI) reviewed Hauser's case and determined that he had fabricated and falsified data in several publications. Under the terms of the agreement reached with ORI, Hauser's research must be supervised for three years. Hauser did not admit that he committed misconduct as part of the agreement, though he did admit that ORI had evidence that he did (Office of Research Integrity 2012).

The Hauser case illustrates several important points about bias and misconduct. First, the methods used in cognitive ethology are designed to reduce bias, so that researchers will not inappropriately infer that animals display human-like behaviors. Assigning two people to independently code data concerning the animal's behavior without knowledge of whether the sound pattern has been changed provides a way of producing results that are reliable and replicable. It also minimizes the chance that the coders will draw conclusions based on what they expect or hope to observe. One of the main problems with Hauser's research, according to the investigatory committee, is that he did not follow these methods properly (Gross 2011). Second, Hauser's research has misled the scientific community, because he published results that cannot be verified or replicated. He made bold claims about pattern recognition in monkeys, some of which do not stand up to further scrutiny. Third, the entire incident has caused considerable harm to Hauser, Harvard University, and the field of animal cognition. Hauser's reputation and career prospects have been damaged permanently. These and other adverse consequences underscore the importance of preventing bias and misconduct in research.

Conclusion

Bias and misconduct are unethical because they undermine the integrity of research and erode the public's support for science. It is crucial for scientists to avoid them, and to teach their students and staff how to avoid them. Institutions, government agencies, and journals can help promote the responsible conduct of research by developing policies that prohibit misconduct and promote the objective reporting of data and results. Institutions and government agencies can also support education and

mentoring in the responsible conduct of research by providing scientists with teaching resources and requiring that students, trainees, and others receive instruction in research ethics.

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Related Topics

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