

# Chapter 2

## Scandals and Their Legacies

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### Learning Objectives

After reading this chapter, one should be able to:

- Understand the etiology and consequences of some iconic scandals
- Describe what the phrase “dark side of science” means
- Discuss the Nazi experiments, the Tuskegee syphilis study, the Guatemala syphilis studies, and the Willowbrook hepatitis study
- List the basic ethics principles that apply to scientific publishing

## 1 Introduction

Why is it important to study ethics-related scandals and their legacies? First, they provide insights on how the world of ethics has changed. Second, we don’t want to repeat them. It doesn’t hurt that they also make for interesting reading.

A *scandal* is an event that produces widespread outrage due to its perceived egregious nature. Scandals resemble avalanches; they arrive suddenly and they are impossible to control. Scandals also have lasting consequences. They devastate careers, change public perceptions, and sometimes lead to new laws and regulations.

The new rules are preventative, in that they selectively constrain professionals' freedom to act, and they establish punishments for similar future misdeeds. Scandals are also wake-up calls that can expose actual problems, and the responses to them can improve professional practices.

The scandals in scientific research and medical practice have involved the harming of research subjects and patients as well as several forms of cheating, such as stealing, lying, fabricating data, and plagiarizing others work. Because science is supposed to stand for truth, and medicine for benevolence, such transgressions are particularly shocking. Without sufficient integrity and benevolence, science and medicine have little value, and they would be unworthy of public support.

## 2 The Dark Side of Science

In his book, *Politics and Personalities, With Other Essays* (Russell 1917), George William Erskine Russell (1853–1918) penned a chapter, “The Dark Side of Science.” Russell was addressing the physical sciences, specifically physics and chemistry, and their roles in making war more efficient and destructive through the creation of massive guns, poison gasses, and submarines. He held that science was amoral and “merely a power” to be used for both prosperity and destruction.

With respect to the health professions, the “dark side of science” is a concept that includes a variety of offenses: falsification of data, omission of data, plagiarism, theft of material and ideas, cover-ups, and maltreatment of research subjects. The nature of such offenses, their discovery and associated punishments, and the impacts on science and the public good were explored in an American Association for the Advancement of Science (AAAS) symposium “Science, Deviance, and Society” that was held in 1982. Invited papers from the symposium were published in a proceeding, *The Dark Side of Science*, by the Pacific Division of the AAAS (Kilbourne and Kilbourne 1983). This publication stressed the seriousness of “deviant science” and the importance of fostering and protecting “good science.” There is widespread agreement that scientific research is indispensable, as it is the most reliable source of essential knowledge. Yet, the culture of science permits offenses and can even make them difficult to discover and eradicate.

The personal motivations for deviant behavior of scientists include the quest for fame, fortune, and power; biases against race, gender, ethnicity, and social status; and cynicism on the part of disillusioned scientists. Cheating is facilitated by the vastness of the literature (allowing for undetected plagiarism) and by the trust afforded to esteemed scientists and their prestigious institutions, such as major universities and medical research centers.

Getting caught for offenses can have serious consequences, including denial of research funding, expulsion from institutions, fines, incarceration, and in extreme cases execution (e.g., of Nazi physicians after World War II). Scientists, nurses, technicians, and administrators, along with the press, tend to be averse in uncovering misconduct and unforgiving when it is discovered. The lesson is clear that, despite the temptations and opportunities for misbehavior, health professionals must strive to stay on an ethical path.

**Table 2.1** Percentage of scientists that reported their own misbehavior in an anonymous survey

Behavior	Percent
Falsifying data	0.3
Plagiarizing ideas without citation	1.4
Omitting research data	15.3
Withholding methodology or results	10.8
Not reporting data that contradict prior research	6.0
Overlooking other’s flawed data or interpretations	12.5
Changing design, methodology, or results due to pressure from funding source	15.5
Publishing the same results more than once	4.7
Use of unauthorized confidential information	1.7
Inappropriate authorship credit	10.0
Violating human subject requirements	0.3
(a) Major requirements	7.6
(b) Minor requirements	27.5
(c) Record-keeping requirements	

Data from Martinson et al. (2005)

### 3 Scientific Fraud

*Overview*

In a *legal* sense, fraud involves (1) intentional deception and (2) deception that results in actual or possible injury to another person or their property. In the *scientific arena*, fraud (i.e., serious research misconduct) involves three core behaviors: fabrication, falsification, and plagiarism. Other offenses include ignoring some types of regulations, such as record-keeping and retention, not disclosing conflicts of interest, publishing the same data multiple times, assigning authorship improperly, inadequate record-keeping, over- or under-interpretation of results, not reporting negative studies, disclosure of confidential information, and other offenses.

How rare is scientific fraud? There have been dozens of high-profile cases, cases that were widely reported in the popular press. A survey of over 6000 researchers, with about a 50% response, revealed that in a 3-year period about 0.3% admitted to falsifying or “cooking” research data and that many were involved in other questionable research practices (Martinson et al. 2005). Sample data from the Martinson survey are shown in Table 2.1. The incidence figures from similar studies of fraud vary widely, most likely because of variations in defining “fraud” in science.

Even minor misconduct taints the scientific knowledge base, can result in flawed policy-making, damages medical practice, wastes public and private funds, and diminishes public confidence. In order to reduce the problem, there must be greater self-regulation within science and better governmental and institutional oversight and regulation.

*Some Notable Cases, According to William Broad*

William Broad, a prize-winning author and science journalist (for the *New York Times* and the journal *Science*), reviewed some scientific frauds in the period between 1960 and the early 1980s (Broad 1983). What follows in this section is

taken from Broad's chapter in *The Dark Side of Science* (Kilbourne and Kilbourne 1983). These cases and alleged facts are his, and they have not been verified by the author of this present book. The first example is the renowned psychology Professor, Sir Cyril Burt, who was called "Britain's most eminent educational psychologist" in an obituary (Broad 1983). Professor Burt apparently based his personal theory, that IQ was largely inherited, on fabricated data. As this theory was comforting to many scientists, it was not debunked during Burt's lifetime. In another case, a young Cornell University graduate student, Mr. W, had a major influence on cancer research. But his results were based on work that could not be replicated. Also, Dr. X, who moved from Jordan to the United States, was found to have plagiarized most of his 60 publications by stealing research articles from obscure journals. He was exposed only after several years of cheating. In a particularly sobering case, doctoral student Mr. Y eventually admitted faking most of his work at Birmingham University and retracted 11 papers, some of which were coauthored by one of his professors. The professor did not discover the fakery. Mr. Y blamed his problem on the system and people who "were just after results." Similarly, Dr. Z, while at the Sloan Kettering Institute for Cancer Research, painted portions of the fur on his mice to simulate successful skin grafts. He blamed his misconduct on "succumbing to extreme pressure" from the institute director. In these examples, and similar cases, ambition, cynicism, pressure, and lack of effective policing were significant factors in causing, allowing, and even encouraging the misconduct. According to William Broad, the culture and structure of science itself had some culpability.

### *The New Era in Publishing*

In response to perceived widespread publication fraud, publishers and the US government took action. Publishers of scientific papers established strict guidelines for authors and reviewers (Graf et al. 2007; Box. 2.1). The Office of Research Integrity of the US Department of Health and Human Services, along with the Departments of Defense, Labor, Transportation, and Veterans Affairs; the US Environmental Protection Agency; the National Aeronautics and Space Administration; the

#### **Box 2.1. Sample Guidelines for Academic Publishing**

- Transparency of funding, each author's affiliations, and originality of data
- Appropriate acknowledgment of authors
- Investigation of suspected misconduct and notification of appropriate officials
- Informing peer reviewers of any suspected misconduct
- Protecting research subjects including humans and laboratory animals
- Insuring integrity in peer review
- Publishing potential conflict of interest information
- Maintaining freedom from commercial pressures
- Insuring the accuracy of publications
- Preventing plagiarism and copyright infringements

Source of information, Graf et al. (2007)

National Endowment for the Humanities; the National Science Foundation; and the Smithsonian Institution, have developed policies and regulations for investigating, preventing, and punishing government-sponsored research misconduct (<http://ori.hhs.gov/federal-policies>, accessed 8/10/2016). The formerly lax arena of research publication has become much more rigorous and therefore more trustworthy.

## 4 Human Research Scandals

### *Comments*

Plagiarism, fabricating data, and other professional misdeeds are serious offenses, but they do not capture the public attention and censure to the extent that the maltreatment of human research subjects does. Most striking are the well-documented perceived abuses of subjects that are vulnerable, including prisoners, military personnel, ethnic and religious minorities, children, and mental patients. Such cases have stimulated sweeping governmental reforms.

### *World War II Nazi Experiments*

Perhaps the most notorious scandal was revealed during the prosecutions of World War II Nazi physicians. The Nuremberg tribunal was convened by the victorious allied governments to define and prosecute “crimes against humanity.” The “Doctors’ Trial” at the tribunal, conducted on behalf of the United Nations, judged the experimenters (predominantly physicians) and high-level administrators using the Nuremberg principles (Box 2.2) that were developed after the crimes were committed.

### **Box 2.2. Abbreviated Version of the Nuremberg Principles for Human Studies**

1. Voluntary consent is absolutely essential.
2. The experiment should yield results for the good of society, unprocurable by other means.
3. The experiment must be based on animal experimentation and other prior knowledge.
4. All unnecessary pain, suffering, and injury must be avoided.
5. No experiment should be conducted if death or disabling injury will occur.
6. The humanitarian importance must outweigh the risk.
7. The subject must be protected by proper preparations and facilities from injury, disability, and death.
8. The experimenters must be properly skilled and qualified.
9. The subject should be able to end the experiment.
10. The scientist in charge must be ready to end the experiment if they believe that continuation may cause injury, disability, or death.

Source of information: *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10*, Vol. 2, pp. 181–182, Washington, DC, US Government Printing Office, 1949



**Fig. 2.1** The Nazi World War II experiments used prisoners for studies on vaccines, oxygen deprivation, and cold water immersion. The physicians argued to no avail that they were following orders and that the studies were designed to save countless lives in the war (Reproduced with kind permission of the Air Pollution Laboratory, University of California, Irvine)

The problematic medical studies were conducted largely to facilitate the German war effort and to save soldiers' lives. Immersion in cold water, oxygen deprivation, and vaccine testing apparently led to severe unrelieved pain and even death in Jews and other disenfranchised prisoners (Fig. 2.1). The defendants pled that they were just "following orders" and even pointed out that similar wartime studies were carried out in the United States and other countries, but the tribunal held them responsible for their actions. In the Doctor's Trial, 22 high-ranking Nazi officials were sentenced thusly: 12, death by hanging; 7, imprisonment for 10 years to life; and 3, acquitted (Taylor 1955). Arthur Caplan (2005), Telford Taylor (1955), and Quincy Wright (1946) analyzed the judicial proceedings and the ethical aspects of the trial and the Nazi studies. This scandal revealed the need for the external oversight of research on human subjects. The tribunal established that *every person* involved in conducting a study is *ethically responsible* for their own actions.

### *Tuskegee Syphilis Study*

The revelation of the Nuremburg trials was a confirmation to the US public that the Nazis were bad and that Americans were above such evil. That comforting view vanished in 1973 when the press reported on the now infamous US Public Health Service Tuskegee Syphilis Study (Cobb 1973). The study, which began in 1932, involved about 400 black Alabama men. Physicians wanted to determine whether the common treatments for syphilis (e.g., arsenic, bismuth, and mercury) were worse than the untreated disease. Subjects were neither aware that they were in a study nor that they were untreated for their disease. Notably, when penicillin was discovered as

a cure for syphilis in 1941, the study was not discontinued (White 2000, 2005). At the time, penicillin was known to have acute toxicity (e.g., asthma attacks and fatal anaphylaxis), and unknown long-term effects (e.g., follow-on superinfections) were suspected. Throughout the study the physicians apparently believed that continuation without medical treatment was justified.

The experiments clearly violated several of the Nuremberg principles, specifically, those related to voluntary consent, adequate prior animal studies, possible death, and ability of the subject to withdraw. Also, there are risks of future syphilis infections in unprotected sexual partners and future children. The US Congress acted with speed and determination, creating regulations for government-sponsored research involving human subjects. The new regulations included formal local institutional review of proposed research protocols, approval or disapproval of studies, monitoring, and sanctions, all under the control of an institutional review board (IRB) (Thomson et al. 1981). The IRB must have members with specified expertise and diversity. They must have representation from more than one profession, including a nonscientist, and a member that is not otherwise affiliated with the responsible institution. IRBs will vary in composition according to the institution's needs. The IRB responsibilities are shown in Box 2.3. In addition, the influential National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979) was created.

### **Box 2.3. Institutional Review Board Responsibilities (Examples Only)**

- Have a diverse and qualified membership.
- Review submitted protocols, require needed changes, and approve or disapprove.
- Conduct continuing review and monitoring and if necessary terminate or suspend the study.
- Report serious noncompliance or serious injury to federal and institutional officials.
- Sample review criteria include (1) equitable subject selection; (2) minimization of risks; (3) reasonable risk to benefit ratio; (4) monitoring for safety; (5) privacy and confidentiality protection; (6) added protection for fetuses, pregnant women, children, mentally disabled, or other vulnerable subjects; (7) voluntary informed consent written in the research subject's language; (8) subject is free to withdraw without penalty; and (9) alternate treatments available, if the study involves medical treatments.

Several other lasting consequences resulted from the Tuskegee scandal. The social significance of the study was a loss of confidence by the public, especially minority communities, in both medical practitioners and medical researchers. This scandal has harmed the health of such potentially vulnerable communities (White 2005). The legal significance of the Tuskegee study was that it introduced the role of the federal government in regulating biomedical research. Most research institutions

now require IRB approval and monitoring for human studies that have any potential nontrivial risks, regardless of the source of funding. Similar oversight by local Institutional Animal Care and Use Committee (IACUC) is now widely required for laboratory animal studies (Pitts 2002).

### *Guatemala Syphilis Studies*

Experiments conducted from 1946 to 1948 by the US Public Health Service involved the deliberate infection with sexually transmitted diseases of Guatemalan prisoners, soldiers, sex workers, and mental patients. The studies were revealed over 60 years later in the journal *Science* (Kaiser 2011). Subsequently, the US government again acted quickly and thoroughly. The Presidential Commission for the Study of Bioethical Issues (The Commission) produced a substantial report, *Ethically Impossible: STD Research in Guatemala from 1946 to 1948* (The Commission 2011). The report acknowledged that the studies included some intentional infections of 1308 subjects with syphilis, gonorrhea, and chancroid (a painful ulcer on the genitalia caused by a bacterial infection). Commercial sex workers, some of whom were intentionally infected in the study, were used to attempt to infect some subjects. Only 678 subjects were documented as receiving some form of treatment for their disease. At the time, there was a clear need to find protective early treatments of exposed military personnel in order to maintain a fit defensive capability. Therefore, new exposures were required for testing the early treatments. The study was encouraged and even strongly supported by institutional officials of the US Public Health Service, the National Institutes of Health, and Guatemalan health officials, as well as some academic scientists.

Violations of ethical principles were found by The Commission in several categories including informed consent, minimization of risks, balance of risks and benefits, adequate scientific justification, privacy and confidentiality, and special protection of vulnerable subjects. Furthermore, the Nuremberg principles were apparently known to the investigators, and they attempted to prevent wide disclosure of their experiments. Formal apologies were issued by the US government, and a review of current US studies being conducted in other nations was instituted. This scandal led to requiring research conducted by US scientists in other countries to follow US federal rules, rather than those in force in the host country.

### *Willowbrook Hepatitis Study*

The Willowbrook hepatitis study, begun in 1955, involved the intentional infection of institutionalized mentally disabled youths in a New York State school for children. The students were given a mild form of the disease along with the vaccine (Krugman 1986). The intent was to protect the children and also to test a vaccine. The school was severely overcrowded, and children were at great risk (greater than 90%) for the developing of hepatitis. The study, which was approved by New York University and the New York State Health Department, enrolled new children only with permission from their parents, but consent could have led to priority in admission to the facility. The study eventually led to the development of a successful hepatitis vaccine. Although no serious adverse effects were believed to have occurred, the study was another embarrassment



to US biomedical science and evidence that even apparently properly conducted studies are not immune from scandal.

### *UCI Fertility Clinic Scandal*

Fertility medicine in the United States was involved in a scandal concerning a leading researcher and practitioner, Dr. Ricardo Asch, and two of his associates. Dr. Asch developed a successful technique that involved harvesting eggs, freezing them, and implanting them in women to induce pregnancy. His successful clinic at the University of California, Irvine (UCI), was accused of diverting harvested frozen eggs without consent to as many as 40 women that were unrelated to the uninformed donors (Roberts 1995). The doctors blamed the staff and vice versa. The story, revealed in a series of articles in 1995 in the *Orange County Register* ([www.ocregister.com](http://www.ocregister.com), accessed 8/5/2016), led to (1) lawsuits against Dr. Asch, two of his associates, and UCI; (2) a made-for-cable movie, *For the Future: The Irvine Fertility Scandal* by Lifetime Network in 1996; and (3) a 1996 Pulitzer Prize to the *Orange County Register* awarded for investigative reporting (<http://www.pulitzer.org/winners/staff-37>, accessed 5/25/2016).

The *Orange County Register* reported in 2011 (March 24) that “Patients filed more than 150 lawsuits related to the scandal, and the University has paid out more than \$27 million in settlements.” The act of diverting human tissue was not a crime at the time but the charges included not reporting almost \$1 million in clinic income and mail fraud. The ethical issues include potentially harming both the donors and the implanted women who had children that were not biologically theirs.

The university was accused of delaying its investigation for 2 years and not admitting a problem until the allegations were made public in the press. Dr. Asch left the United States for Mexico and Argentina and was considered to be a fugitive in the United States. He was charged with tax evasion. Extradition attempts have failed to bring him back to the United States. His attorney argued that the charges should be dropped because Dr. Asch was tried and acquitted by an Argentinean court, so bringing him to face a trial in the United States would constitute double jeopardy (*Orange County Register*, 3/24/2011). Dr. Asch maintains a website ([www.drascallegal.com](http://www.drascallegal.com), accessed 8/1/2016) that provides updates on his case, which is still unresolved as of 1/4/2017.

## 5 Ethics Guidelines

### *Human Subjects in Research and Clinical Practice*

The Nuremberg basic principles (Box 2.2) have been expanded numerous times. Because abuses in medical research continued after World War II, the World Medical Association met in 1964 in Helsinki to further develop guidelines (that had been worked on starting in 1953) for physicians conducting human studies. The *Helsinki Declaration* addressed protections for compromised research subjects (e.g., children, the mentally disabled, and the temporarily incapacitated). As there was a need to provide international guidance on implementing the Helsinki Declaration’s

principles, the Council for International Organizations and Medical Sciences (CIOMS) in conjunction with the World Health Organization (WHO) published *Proposed Ethical Guidelines* in 1982 (Macre 2007). Updates by the CIOMS in 1982, 1993, and later ([www.cioms.ch](http://www.cioms.ch), accessed 9/18/2016) were titled *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Box 2.4).

**Box 2.4. Sample Council for International Organizations and Medical Sciences (CIOMS) Guidelines and Considerations for Physicians Conducting Research on Human Subjects**

- Scientific and ethical justification for the research
- Ethical review
- Individual subject's informed consent
- Benefits and risks of the study
- Consideration of women children and other potentially vulnerable subjects
- Less risk for subjects who can't give consent
- Equitable distribution of risks and benefits
- Protection of confidentiality
- Treatment for injuries and compensation
- Sponsor's obligation to provide health-care services

See Macre (2007) for expanded list and [www.cioms.ch](http://www.cioms.ch) for updates (accessed 9/18/2016).

*The Belmont Report Principles*

As the CIOMS guidelines are relatively complex, the principles set forth in the *Belmont Report* (National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research 1979) are used to illustrate three fundamental requirements for performing ethical human subject research. The Belmont Report's "basic ethical principles" are:

- Respect for persons
- Beneficence
- Justice

It is instructive to elaborate on the Belmont Report's three principles because they are widely regarded as fundamental to health-related medical research ethics. *Respect for persons* has two aspects: (1) individuals must be treated as "autonomous"; and (2) persons with diminished autonomy must be afforded additional protections such as representation by parents, patient advocates, or others who legally represent the subject's personal interests. *Autonomous* individuals are capable of making decisions about their self-interest based on deliberation; i.e., they are fully capable of self-determination. Those who require additional protections include the immature, mentally disabled, imprisoned, not conscious, those in debilitating distress, or otherwise not autonomous. In clinical practice, respect for persons also includes

protecting privacy and confidentiality and respecting the ownership of tissue samples, such as harvested eggs and DNA samples.

*Beneficence* is a responsibility to “do no harm” without compelling justification and to maximize benefits and minimize harms. Some harms, such as adverse side effects, whether anticipated or not, cannot be eliminated in medical practice or medical research. For research purposes, prior analysis of the problem under study, a requirement for prior use of laboratory animal studies, and good judgment are required in the study design phase in order to insure that the anticipated benefits clearly outweigh any foreseeable risks. In research, the benefits can include those to science itself or the public good, not just the direct benefits to the research subjects. If in the conduct of a study (or treatment) unforeseen risks are discovered, the subjects (or patients) should be promptly notified and the procedures terminated or modified if the risk-to-benefit ratio is no longer favorable. Beneficence involves continually weighing risks and benefits.

*Justice* relates to providing an equitable distribution of risks and benefits, specifically considering who bears the risks vs. who receives the benefits. In clinical practice the patient bears the risks and also receives the benefits. Research is largely designed to benefit others and scientific knowledge; research also directly benefits the subjects in many studies. Investigators have an obligation to inform their subjects as to what the risks and benefits are and how they are distributed. The willingness of subjects to participate in research thus relies on their being fully informed and being free to consent to, decline, or withdraw from participation. *Equitable selection* of research subjects is a critical aspect of the justice criterion. For example, initial testing of new medications for side effects only in prisoners or others who are institutionalized is not considered equitable. Rather, it is seen as convenient, cost-effective, and efficient, unless the study is intended to benefit those groups that are studied. Similar considerations apply to children, mentally disabled, military personnel, and severely ill patients. Alternatively, the inclusion of groups, such as women, children, and the elderly, can give them access to the benefits of research. As it was true for the principle of beneficence, applying the principle of justice is not always simple; an IRB may struggle with protocols that select vulnerable populations and require additional protections including external monitoring of the study procedures.

### *Privacy and Confidentiality*

Protecting privacy and confidentiality involves preventing sensitive, private, or personal information from becoming known to outsiders. Files and data on patients and research subjects require stringent protections, such as being kept in locked areas or being coded or encrypted. Coding and encryption keys must be protected and not stored with patient or subject files. Individuals must be informed that even coded or otherwise protected information can be subpoenaed by a court order.

Electronic records and data are particularly susceptible to invasion and disclosure. The protection of electronic information usually requires the involvement of qualified information technologists. Training of everyone who has access to sensitive data on patients or research subjects is required under the US Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (Gostin 2001).

*Social disclosure* is also a form of loss of privacy or confidentiality. Being seen entering or leaving a room placarded “STD Study” or “Anger Management Clinic” can be a breach of confidentiality. Studies or treatments involving school children can expose them to social ridicule or embarrassment; classmates can be inquisitive and cruel. Simply calling a student out of their classroom to participate in a study can put them at social risk. Similar considerations apply to prisoners and other institutionalized groups.

#### *When Does Medical Practice Become Research?*

The boundary between research and medical practice is blurred when experimental or innovative treatments are used. *Medical practice* is primarily intended to serve the health-related needs of an individual patient or a group of people. *Medical research* has the objective of developing generalizable knowledge. For the purposes of requiring review, as by an institutional review board, treatment interventions that have any element of research (e.g., acquiring ancillary blood/tissue samples or data or testing new devices) must be reviewed and approved. Note that creative and innovative treatments in themselves are not classified as research from the standpoint of requiring review and approval. Exploratory surgery in the interest of the patient would not require review unless generalizable research components are involved.

#### *Publication Ethics*

The peer-reviewed scientific literature is the primary repository of verifiable knowledge. The integrity and originality of published data are essential ethical principles (Fig. 2.2). Beyond these fundamental principles, conformity with other ethical considerations is required. Have sources of ideas, illustrations, and data been identified and appropriately cited? Is the list of authors accurate, fair, and complete? If the research involves humans or other vertebrates, were required reviews and



**Fig. 2.2** Plagiarism, that involves use of other’s work without proper citation, is not justified by the assertion of the standing researcher, “It’s not plagiarism, I am just recycling good ideas” (Reproduced with kind permission of the Air Pollution Health Effects Laboratory, University of California, Irvine)

approvals achieved? Have each of the publication authors provided a conflict of interest statement? Have all sources of funding and/or other assistance been declared? Does the paper include sufficient detail for replicating the study? If patients were treated, was the standard of care appropriate? Are there other ethical concerns raised by reviewers, journal editors, or others?

Maintaining the integrity of the scientific literature is an important activity that requires the vigilance of a large number of people. In addition to the authors of a paper, others have various levels of responsibility for its integrity, originality, and other ethical criteria. Coauthors and technical assistants are responsible for their individual contributions. Institutional officials where the research was performed are responsible for ethical oversight and review if the study uses research subjects or falls under biohazard or other safety review requirements. Journal editors and peer reviewers are obligated to consider, identify, and report suspected ethical problems in the study or in the manuscript. Readers of published papers are encouraged to express their concerns to the journal editor. Finally, if misconduct is detected, or strongly suspected, investigation by the journal editors, institutional officials, funding agencies, and other stakeholders should be pursued (Graf et al. 2007). Tools now exist for discovering plagiarism in submitted papers. Software including those that compare strings of words to those already in the literature is available (Bazdaric et al. 2012). Such tools should be applied to all submitted papers. Publication ethics is also covered in Chap. 4 (Regulations, Guidelines, and Policies).

## 6 Lessons Learned

In short, openness, honesty, integrity, beneficence, justice, duty, and respect for persons are the basic principles that must guide health professionals. In opposition to these principles are secrecy, deception, self-interest, and paternalism. Following professional codes of conduct, as described in Chap. 7 (Professional Ethics), is expected for health professionals. Institutions, both private and public, must take responsibility for establishing ethical standards, reviewing professional activities, investigating suspected misconduct, and punishing proven offenders. All of this must be done without excessively burdening health professionals and their contributions to the public health and welfare. Training and certification of competency are also required for preventing professional misconduct. Chapter 6 has more information on compliance training.

## 7 Summary

Science and medicine are not immune to scandals. Abuse of patients and research subjects, falsification of research data, lying about one's conflicts of interest, plagiarism, and omission of contrary ideas do occur. In some cases violations of public

trust have been unintentional (e.g., due to honest mistakes or negligence). In other cases the motivations have been deliberate including personal fame, professional advancement, wealth, cynicism, or the drive to achieve a goal for which the ends justify the means.

Perpetrators have used several characteristics of the culture of science to hide their misdeeds. The vastness of the literature, with thousands of journals in dozens of languages, facilitates plagiarism. The prestige of physicians, researchers, and their institutions discourages inquiry from within and from the outside. Also, the availability of fame, prizes, tenure, promotions, and high salaries associated with success in science and medical practice are motivators for cheating. Personal integrity and following accepted professional ethical standards are the means of avoiding scandals. Institutions and other stakeholders have responsibilities for establishing and enforcing ethics requirements and for providing access to ethics training.

### Quiz

(Select the best answer)

1. Which statement is most true regarding human research scandals?
  - a. An essential element is a cover-up by institutional officials.
  - b. Perpetrators knew at the time that they were engaging in misconduct.
  - c. Scandals produce lasting repercussions and legacies.
  - d. The public tends to blame the media for manufacturing scandals.
2. The “dark side of science”:
  - a. Refers to science’s obscure technical complexity
  - b. Refers to misdeeds of opportunism and personal ambition
  - c. Is the title of a popular movie
  - d. Refers to the secrecy that is endemic to human subject research
3. Scientific fraud:
  - a. Does not include elements that differ from the legal definition of fraud
  - b. Includes elements that differ from the legal definition of fraud
  - c. Is defined by the Nuremberg principles
  - d. Was the charge against the Willowbrook study scientists
4. The Guatemala syphilis studies:
  - a. Were performed by Guatemalan physicians but not US physicians.
  - b. Were performed without the approval of Guatemalan officials.
  - c. Conformed to the principles of the Belmont Report.
  - d. None of the above is true.
5. The Willowbrook Hepatitis study:
  - a. Involved enrolling children with parental consent
  - b. Resulted in the deaths of mentally challenged children
  - c. Was conducted on military personnel

- d. Was continued after the death of a subject
- 6. The basic principles of the *Belmont Report* include:
  - a. That laboratory animal studies are inherently unethical.
  - b. That laboratory animal studies can be conducted with approval.
  - c. Respect for persons, beneficence, and justice.
  - d. Recommendations for protecting electronic health data from disclosure.
- 7. The HIPAA Privacy Rule:
  - a. Protects the confidentiality of medical records.
  - b. Protects the anonymity of peer-reviewers.
  - c. Was replaced by the *Belmont Report* principles.
  - d. None of the above is true.

### Discussion Topics

1. The concept, the dark side of science, was introduced in this chapter. Is science today adequately addressing and dealing with its dark side? What changes, if any, should be made to make the scientific research enterprise more ethical?
2. Does the author's treatment of scandals in this chapter let the perpetrators of misdeeds off too easily? Were some of the sanctions for their misdeeds too lenient or, conversely, too severe?
3. *Harms* and *wrongs* are similar, but wrongs are seen as more extreme. Harms can and should be minimized or at least weighed against the benefits to individuals, science, or society. Torture of evildoers to get information to save innocent lives or even the killing of a few innocents in the course of saving a larger number may be labeled by some as "wrongs" that should never be done. Are there harms or wrongs that must be forbidden in all circumstances? What are they?

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