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Source: *Science*, New Series, Vol. 307, No. 5717, The Gut: Inner Tube of Life (Mar. 25, 2005), pp. 1881-1882

Published by: American Association for the Advancement of Science

Stable URL: <http://www.jstor.org/stable/3841864>

Accessed: 13-10-2017 20:13 UTC

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Ethics: A Weapon to Counter Bioterrorism

Margaret A. Somerville and Ronald M. Atlas*

Advances in the life sciences, especially in molecular biology and informatics, and the potential for misuse of scientific research (the “dual-use” dilemma) raise the possibility that an act of terrorism could involve biological agents. International consensus is crucial on the steps needed to reduce this grave threat to humanity. One such step is to ensure that all people and institutions involved in science are aware of their ethical obligations.

An important way to promote the necessary international consensus and to raise the necessary awareness is through adoption of a code of ethics to govern research in the life sciences. It is with this thought that we set out to capture the critical elements that a code of ethics for the life sciences should include—one that we believe can help prevent the life sciences from becoming the death sciences (see the table on page 1882).

The code we propose is built on ethically relevant facts and the substantive and procedural principles of ethics that must govern its interpretation and application (1). They include nonmaleficence; beneficence; respect for life, especially human life; maintaining trust; embedding ethics in science; establishing a high ethical tone in institutions; acknowledging individual and collective responsibilities; and recognizing and fulfilling needs for ethics review and monitoring, notification of breaches of ethics, ethics education, and the transmission of ethical values to colleagues and those we mentor.

Yet, although many agree with such an approach, many strongly oppose it for reasons ranging from cognitive (it won't work) to emotional (fear that it will shut down science); philosophical (science is value free, it's only its applications that need ethical guidance); misguided (scientists are ethical people, and all that ethics requires is that

they act in good conscience); monetary (it will bankrupt our company); and personal (it will ruin my career). But even those who question the value of a code agree that research in the life sciences, including biodefense research, must be conducted in a safe and ethical manner. Bodies speaking out publicly about this need for ethics include the General Assembly of the World Medical Association (2), the British Medical Association, (3) the U.S. National Research Council, (4) the British Parliament (5), and the Asia-Pacific Economic Cooperation (APEC) Leaders (6), among others (7).

There have been recurring debates since the tragic events of September 11, 2001, concerning what research should and should not be conducted and what information should and should not be disseminated in the open literature (4, 5, 8). That dialogue has generated calls for a code or codes of conduct to provide guidance for scientists, publishers, and others facing extremely difficult decisions in the context of the dual-use dilemma. The National Science Advisory Board for Biosecurity (NSABB) of the National Institutes of Health has been charged with developing such a code for professional organizations and institutions (9). In 2005, the Expert and State Parties Meeting of the Biological Weapons Convention (BWC) will consider how to promote a common understanding of needed actions toward this end as well.

We know that a code will not be sufficient to ensure that science is not misused—we have already heard the laments “pious words will not solve the problem.”... “they are not worth the paper they are written on,” ... “they have no teeth” (10, 11). Codes of ethics did not prevent scientists and physicians from leading the efforts of Aum Shinrikyo to develop biological weapons (12). Even the Hippocratic Oath has been violated by physicians' participating in biological weapons programs (13–17). Ken Alibek, for example, led the bioweapons program of the former Soviet Union even after the signing of the Biological Weapons Convention banned such programs (18); and Shiro Ishii

directed the secret Japanese unit that engaged in human experimentation for biological weapons development during World War II (19, 20).

Recognizing that past breaches of ethics have occurred, despite the existence of a code, presents a challenge, namely, guarding against the cynicism or despair that may evoke. Research in the philosophy of science shows that as long as a small clustered nucleus of ethical voices remains, ethics has a high probability of reasserting itself (21, 22). We must continue to try to be ethical and to encourage and to help others to do likewise. A code of ethics will help in both respects.

Ethics brings deep values and beliefs into play, which means we may not always agree with each other. But we need to establish a code and then use it as a basis for engaging in an ongoing debate, because ethics is an ongoing process not an isolated event (23). A code not only raises awareness of the need for ethics and provides guidelines against which to judge the ethical acceptability of any given conduct, but also functions as a teaching tool and provides less senior people, including students, with a means of raising ethical concerns, especially with respect to the conduct of those in authority. We should continue to foster “ethics talk”—because that is an important way in which ethics can move forward in conjunction with science as it advances (23).

To reiterate the ancient Hippocratic Oath, physicians and scientists must today, even more crucially than in the past, first do no harm. To paraphrase a provision in the modern Hippocratic Oath: Physicians and scientists shall remember that they have a pact with society to advance knowledge and to apply that knowledge for the good of humanity. Scientists and scientific institutions must act responsibly to limit potential misuse of scientific materials and information by bioweaponers.

A code is a living instrument that will need to be supplemented, on a continuing basis, by interpretations, applications, and analysis of new case examples. Below, we consider how it would apply in one recent situation. In this analysis, the applicable articles of the proposed code are referenced.

Thomas Butler, a researcher at Texas Tech and former director of their medical center's Division of Infectious Diseases, had reported to the responsible university official in 2003 that he could not account for 30 vials of cultures of *Yersinia pestis*; later, he claimed that he had inadvertently

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CODE OF ETHICS FOR THE LIFE SCIENCES

All persons and institutions engaged in any aspect of the life sciences must

1. Work to ensure that their discoveries and knowledge do no harm
 - (i) by refusing to engage in any research that is intended to facilitate or that has a high probability of being used to facilitate bioterrorism or biowarfare; and
 - (ii) by never knowingly or recklessly contributing to development, production, or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types or in quantities that cannot be justified on the basis that they are necessary for prophylactic, protective, therapeutic, or other peaceful purposes.
2. Work for ethical and beneficent advancement, development, and use of scientific knowledge.
3. Call to the attention of the public, or appropriate authorities, activities (including unethical research) that there are reasonable grounds to believe are likely to contribute to bioterrorism or biowarfare.
4. Seek to allow access to biological agents that could be used as biological weapons only to individuals for whom there are reasonable grounds to believe that they will not misuse them.
5. Seek to restrict dissemination of dual-use information and knowledge to those who need to know in cases where there are reasonable grounds to believe that the information or knowledge could be readily misused through bioterrorism or biowarfare.
6. Subject research activities to ethics and safety reviews and monitoring to ensure that
 - (i) legitimate benefits are being sought and that they outweigh the risks and harms; and
 - (ii) involvement of human or animal subjects is ethical and essential for carrying out highly important research.
7. Abide by laws and regulations that apply to the conduct of science unless to do so would be unethical and recognize a responsibility to work through societal institutions to change laws and regulations that conflict with ethics.
8. Recognize, without penalty, all persons' rights of conscientious objection to participation in research that they consider ethically or morally objectionable.
9. Faithfully transmit this code and the ethical principles upon which it is based to all who are or may become engaged in the conduct of science.

destroyed the cultures. The initial report submitted by the university official (article 3) sent Federal Bureau of Investigation agents racing to the campus and set off panic that terrorists might have acquired the cultures. Butler was a leading researcher who had pioneered therapy for treating plague victims that has saved innumerable lives. Butler, apparently, had carried the plague-containing material on a commercial airliner from Tanzania to the United States, had sent cultures back to Africa by air transport, and had transported cultures to laboratories within the United States—including government laboratories of the U.S. military and the Centers for Disease Control and Prevention—all without obtaining the necessary authorizations [articles 1(i) and 6]. He was criminally charged with illegally transporting Tanzanian plague samples and with defrauding the university in research contracts (article 7). Several Nobel laureates and others came to the defense of Thomas Butler, protesting his prosecution (24, 25). Although their loyalty and concern for him are to be admired, the same is not true of their implied acceptance of his breach of laws and regulations. Our code calls for compliance with the law unless it would be unethical to do so, and working to change

laws and regulations with which one does not agree (article 7).

The Butler case sent a clear signal to the research community, especially scientists and university researchers, that all ethical and legal requirements must be respected when undertaking research [articles 1(i), 4, 6, and 7]. Biosafety regulations are not merely legal technicalities. They constitute some of the terms of the pact between science and the public that establishes public trust. That trust is the basis upon which research is conducted.

Certainly, the code we put forward is not the total solution, but it can contribute, in conjunction with other measures, to the deterrence of bioterrorism and biowarfare. Past experience tells us that violations of a code can result in loss of respect by peers; loss of public trust and thereby public support; loss of research funding; and censures for breaches of ethics and legal penalties, including loss of professional licenses to practice (26). But more important than the consequences for breaches, a code of ethics can serve as a guide for all persons engaged in science, articulating the values to which we all must aspire and the standards to which we all must adhere to ensure our conduct is ethical and fulfills our fiduciary responsibilities to society.

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