Biological and Toxin Weapons Convention

- **Article I**
- Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
  - (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
  - (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

  - **Begins with development and not research**
  - **Allows for biodefense for prophylactic and protective purposes**

Research and the Dual Use Dilemma

- 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 or that science could be misused for biowarfare.

- There is "*forbidden knowledge*."
- Some information should be classified or shared on a limited basis

IAP STATEMENT ON BIOSECURITY

- In recent decades scientific research has created new and unexpected knowledge and technologies that offer unprecedented opportunities to improve human and animal health and environmental conditions. But some science and technology can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of "dual use" and the misuse of science and technology.

BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM: CONFRONTING THE DUAL USE DILEMMA

Report of the
Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology
"Fink Committee"
National Research Council
OF THE NATIONAL ACADEMIES

Aims of the Fink Committee

- Develop an architecture to help protect the life sciences scientific community against the potential misuse of biological materials and information
  - Bottom up approach aimed at helping reduce the threat of misuse of the life sciences
- Protect scientific enquiry and communication to the maximum extent possible
  - Build upon the previous (1982) NAS Corson report which dealt with the physical sciences.

Defining the Sphere of Concern

- For the near term the Committee considered microbial pathogens and toxins as the primary threat
- The Committee identified seven classes of "experiments of concern" that illustrate the types of endeavors or discoveries that will require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail.
- These classes are process rather than organism based.

Experiments of Concern

1. **Would demonstrate how to render a vaccine ineffective**.

   This would apply to both human and animal vaccines.

   IL-4 mousepox expermiments could fall into this category of experiments of concern.

Experiments of Concern

2. **Would confer resistance to therapeutically useful antibiotics or antiviral agents**

   This would apply to therapeutic agents that are used to control disease agents in humans, animals, or crops.

   Introduction of ciprofloxacin resistance in *Bacillus anthracis* would fall in this class.

Experiments of Concern

3. Would enhance the virulence of a pathogen or render a nonpathogen virulent

This would apply to plant, animal, and human pathogens.

Introduction of cereolysin toxin gene into *Bacillus anthracis* would fall into this class.

Experiments of Concern

4. Would increase transmissibility of a pathogen.

This would include enhancing transmission within or between species.

Altering vector competence to enhance disease transmission would fall into this class.

Experiments of Concern

5. Would alter the host range of a pathogen.

This would include making nonzoonotics into zoonotic agents.

Altering the tropism of viruses would fit into this class.

Experiments of Concern

6. **Would enable the evasion of diagnostic/detection modalities.**

   This could include microencapsulation to avoid antibody based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.

Experiments of Concern

7. Would enable the weaponization of a biological agent or toxin.

This would include environmental stabilization of pathogens.

Synthesis of viruses could also fall into this class of experiments.

Creation of a bomb to distribute biological agents would fall into this class.

A device for use on a gun to disseminate biological agents would fall into this class.

Response by the Scientific Community

- Oversight of Publications
- NSABB
- Review by Editors and Publishers
- Codes of Conduct

Code of Ethics

- 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.

Bluntly stated
overall goal of a code….

…to prevent the life sciences

from becoming the death sciences

through bioterrorism or biowarfare

ETHICAL PRINCIPLE

- **Safeguards** are needed to ensure fulfillment of the **public trust** and fiduciary obligations it engenders, and **protect against breach**, in particular, to ensure that **science** is **not used** for **bioterrorism or biowarfare**

- **What must we not do and do if we are to hold science on public trust…?**

IAP Principles for a Code

- 1. **Awareness**. Scientists have an obligation to do no harm. They should always take into consideration the reasonably foreseeable consequences of their own activities. They should therefore:
- • always bear in mind the potential consequences – possibly harmful – of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavour;
- • refuse to undertake research that has only harmful consequences for humankind.
- 2. **Safety and Security**. Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or common practice.

IAP Principles for a Code

- 3. **Education and Information**. Scientists should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research.
- 4. **Accountability**. Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies.
- 5. **Oversight**. Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation and act as role models in this regard.

A code of ethics for the life sciences…

"Ethics: A Weapon to Counter Bioterrorism"

Margaret Somerville[1] and Ronald Atlas[2]

[1] Margaret Somerville is Samuel Gale Professor of Law and Professor, Faculty of Medicine and Founding Director, McGill Centre for Medicine, Ethics and Law, McGill University, Montreal.

[2] Ronald M. Atlas served as President of the American Society for Microbiology and is Graduate Dean, Professor of Biology, Professor of Public Health, and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism at the University of Louisville.

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

CODE OF ETHICS FOR THE LIFE SCIENCES

(ii) by never knowingly or recklessly contributing to the 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.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 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.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 4. Seek to allow access to biological agents that could be used as biological weapons only to individuals about 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.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 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.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 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.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 8. Recognize, without penalty, all persons' rights of conscientious objection to participation in research that they consider ethically or morally objectionable.

CODE OF ETHICS FOR THE LIFE SCIENCES

- 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.