“The Life Sciences, Biosecurity, and Dual Use Research”

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Project on Dual Use Research in Life Sciences

- Increased concern about bioterrorism and biowarfare amongst policy makers following 9/11 and anthrax letter attacks

- Discussions about the potential for misuse of biological research and how to prevent it

- Seminar Objective: to encourage an interactive discussion amongst practising scientists and students about the possible malign misuse of the life sciences

Playing Your Role

- Powerpoint slides will address relevant issues in dual-use research and ask questions.
- First respond from the perspective of your character.
- Try to understand the reasons a person might hold these views and the implications of such an opinion.
- If you wish you may state your own views if they differ from that of your character.

Communication

The first set of slides concern the communication of research results. The publication of certain dual use research results have provoked recent discussions about potential misuse.

Australian Mousepox Experiment
An Example of Dual-Use Research

- Plagues of hundreds of millions of mice cause millions of dollars of damage in Australia's grain belt.
- To prevent or mitigate such plagues Australian researchers try to induce sterility in mice by altering an infectious virus that affects mice: mousepox.
- They insert egg protein gene into mousepox genome to create antibody response against eggs and thus rejection.
- They also insert the IL-4 gene to enhance the antibody response.

Communication Questions

- The researchers produced a recombinant virus with greatly increased lethality.
- The virus with IL-4 killed mice genetically resistant to mousepox and those immunized against it.
- Concerns arise because of the potential for increased lethality of other pox viruses, including smallpox.
- Published in *Journal of Virology* Feb. 2001.

Do you agree with the decision to publish?

If so, why? If not, why not?

What follows on from your views?

Another Kind of Communication

- January 2001Australian researchers worked with a popular magazine to publish a preview of their paper.
- *New Scientist* published an article with the following title:

"Disaster in the Making: An engineered mouse virus leaves us one step away from the ultimate bioweapon"

Rationale: "We wanted to warn the general population that this potentially dangerous technology is available…We wanted to make it clear to the scientific community that they should be careful, that it is not too difficult to create severe organisms." -- R. Jackson

How do you view the decision to popularly publish (why, what follows on from this, etc.)?

Another Model for Communication

- Suggestion that British researchers had previously obtained similar results to the Australian mousepox research.

- The researchers were said to have informed Health and Safety Executive, but deliberately avoided discussing or alluding to bioweapons implications in their publication.

- A literature search revealed a **1998** *Journal of Virology* article that might be research in question:
  - IL-4 insertion in modified vaccinia virus (VRBm)
  - "A mortality of 100% was observed for mice immunized with VRBmIL-4 [modified vaccinia with IL-4 gene]… This contrasted with that for mice immunized with rVV expressing low levels of IL-4…which showed no ill effects…"

What are the merits of this "softly-softly" approach?

Funding

Ideas of restricting research and publications are generally treated as matters of concern by practicing life scientists. However, the funding of various lines of research has also provoked discussions of interest in relation to dual use research.

What is Being Funded: Keeping Ahead Through Research

US Program: "Biodefense for the 21st Century"

- NIH biodefense research ~$50million (2001)
  ~$1.6 billion (2005)
- National Institute of Allergy and Infectious Diseases in 2005 roughly 190 research awards about therapeutics, diagnostics, host response, vaccines, basic biological mechanisms
- 13 BSL-3 and 7 BSL-4 research facilities under construction
- Other civilian programs under Department Health and Human Services, Departments of Agriculture, Homeland Security, etc. totalling ~$3.4 billion (2006) for research programs and facilities

Is this to be welcomed and why?

Oversight

As concerns about the possible misuse of research have grown, attention has increasingly focused on whether new forms of oversight of research are required. The final set of slides address this issue.

Development of Biosafety Oversight

- In 1970's life scientists began to manipulate genomes.
- Many countries have instituted review procedures to ensure biosafety of such experiments.
- In US, Asilomar Conference in 1975 led to NIH funded research subject to rDNA review procedures.

James Watson and
Sydney Brenner at Asilomar

US National Academies Fink Report *"Biotechnology Research in an Age of Terrorism"*

- Expand **existing** local and national *biosafety* review for **NIH funded** rDNA research to include *biosecurity.*
- Apply new procedures to 'experiments of concern' in **US** e.g.:
  - Making vaccines ineffective
  - Altering host range or enhancing virulence of pathogens
  - Conferring resistance to useful antibiotics or antivirals
- Establish National Science Advisory Board for Biosecurity to:

  review, survey and educate bioscientists including to 'develop guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis...'

Are biosecurity oversight mechanisms to be welcomed?

Why or why not?

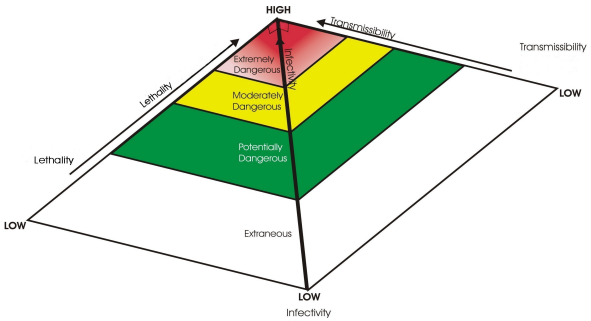
What Else Might be Done

If Fink recommendations *not welcomed*, what about…

"We're looking for the scientific community to come forward itself because the government will not do this very efficiently and not do it very well at all. We are looking for scientific community to come forward to help establish these kinds of criteria [for the oversight of research], to debate them openly."

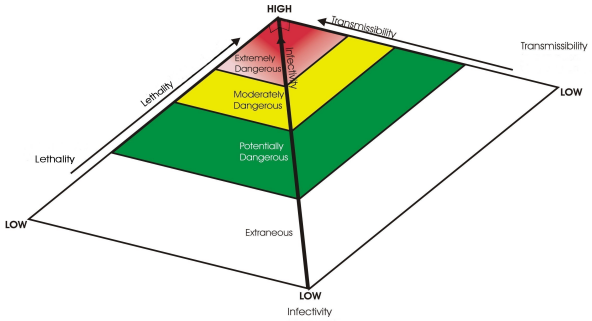
-- Penrose Albright (2003)
Office of Homeland Security
White House Office of Science & Technology Policy

What Else Might be Done?
"Protective Oversight System"



- Former government officials now at University of Maryland and an international team developed a legally based system.
- Three-tiered categorization based on potential consequences:
  - **International** oversight of **extremely** dangerous research = greater than currently active agents.
  - **National** oversight of **moderately** dangerous research = the worst of the current select agents.
  - **Local** oversight of **potentially** dangerous research = agents that might be elevated to moderate or extreme categories by use of advanced manipulation techniques

"Protective Oversight System" cont.



- **Mandatory** for all relevant facilities including:
  - Military
  - Commercial
  - Government
  - Academic
- Require **licensing** of facilities and researchers on biosecurity grounds including background checks and training

Is this type of oversight system to be welcomed? Why or why not? Implications?

Weighing the Risks and Benefits

- In 2003 thirty-two scientific journals (ASM journals, *Science*, *Nature*) agreed on a process for reviewing, modifying, and perhaps even rejecting research articles where ‘the potential harm of publication outweighs the potential societal benefits.’

- UK Wellcome Trust has taken dual-use potential of research into account in reviewing proposals

wellcome trust

Results of Applying Risk/Benefit Analysis

- No publication yet stopped in any journals; though two were modified.
- Wellcome Trust never refused an application or imposed publication restrictions because of dual use concerns
- 'Extreme' case: 2005 Sequencing and reconstruction of 1918 Spanish Flu virus: NSABB, *Science*, *Nature* agree benefits outweighed the risk

Will the risks ever outweigh the benefits?

Thank You & Debrief

Debriefing the Role Play

- What role did you find yourself identifying with most strongly? Why?
- What aspects of the role assigned to you did you find easiest to present?
- What aspects of the role assigned to you did you find most difficult to present?
- Do you have additional arguments, insights or opinions that were not represented by people playing the other roles?