Regulation of the Life Sciences

Lecture No. 18

1. Outline

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Notes: The aim of this lecture is to introduce students to the discussions going on about what the life science community might do to reduce the risks of the hostile misuse of their work. The focus is on the control of the research and publication process.

2. Literature Reviews (i)

- Minimization of the risks posed by dual-use research: A structured literature review
  - "The MEDLINE data base was searched for studies concerning the ethics of biodefense, or the dual-use dilemma. Ten articles met all inclusion criteria and were thoroughly reviewed and analyzed."

Notes: This first literature review made a broad search using MEDLINE. Carried out by Mararita Dolgitser and published in 2007, it came to some clear conclusions that are of considerable interest. It should be noted that 'biodefense' here is being used in a broader sense than is usual in security circles.

3. Literature Reviews (ii)

- A structured literature review (continued)
  - "Within the peer-reviewed life science literature, the most commonly suggested strategy for minimizing the potential harm that could be caused by scientific research was self-regulation within the scientific community, followed by increased security within the scientific community, international cooperation, and finally, increased biodefense education for professionals….One article suggested that decreases in security would minimize the risk of dual-use bioterrorism through increased open scientific scrutiny and self-regulation within the community…"

Notes: What we see here is a very clear preference amongst life scientists for the community to be allowed to regulate its own activities rather than for example the introduction of new legislation and regulations by the government to control dual-use risks.

4. Literature Reviews (iii)

- “Among the articles that suggested self-regulation, a bottom-up approach, ideas for how this regulation needs to occur vary substantially….
- Many articles also recommended increased security, or a top-down approach….Suggested increases in security ranged from physical security measures…to rigorous background checks for staff, graduate students and faculty and limitations on access to information and knowledge…”

Notes: What we see here is a reflection perhaps of the lack of real debate that has so far taken place. Rather than an evolving consensus there is wide divergence of opinion not only about whether there should be a bottom-up or top-down approach but additionally there is no widespread agreement about what should be done within either type of approach.

5. Literature Reviews (iv)

- "…Following increased self-regulation and security, the next most common suggestion for increased biodefense was international cooperation….Proposals…focus first and foremost on establishing a clear international consensus on bioethical approaches….Other articles suggested the necessity of international treaties and frameworks limiting the development of dual-use research…"

Notes: Again here it does not seem unreasonable to suggest that the ongoing debate is not well advanced. For example, as we have seen in earlier lectures, the Biological and Toxin Weapons Convention would appear to need to be thoroughly understood in order to have an informed discussion of international cooperation to prevent the misuse of modern biology.

6. Literature Reviews (v)

- "…Many articles mentioned more than one of the preceding measures, often grouping them together. It is easy to see that one commonly follows from the next, such as increased education, leading to both increased international cooperation and increased security measures. Many of the measures were suggested to be used in tandem to offer increased protections…"

Notes: This is an important idea and has been much developed, for example by the ICRC, into the concept of a multifaceted 'web of prevention'. The development of that web of policies is the subject of the last lecture (21) in this series. It is now seen to extend far beyond just the points listed in this slide.

7. Literature Reviews (vi)

- “Synthetic life science is a typical ‘dual-use’ technology, it can be used for the greater good, but also for nefarious goals to cause considerable harm….When the polio study was published in 2002, most doubted that the same technique could be used to synthesize smallpox….But, technology has progressed so rapidly that the synthesis of smallpox is now possible…terrorists no longer need to gain access to the wild-type virus…”

Notes: This second, more extensive review by Gabrielle Samuel and her colleagues just deals with the difficulty of controlling what they call the synthetic life sciences (taken to include synthetic genomics and synthetic biology). They are in no doubt in this 2009 review that there are grave dangers of hostile misuse as is illustrated by their reference to smallpox - one of the ‘most feared bioweapons’ as they put it.

8. Literature Reviews (vii)

- “There is little disagreement that synthetic life science needs some form of regulatory control. However, the question of exactly what should be regulated, which regulatory structures should be implemented and the type of governance structures needed all remain a matter of debate. For the most part, scientists tend to support self-governance, or at least bottom-up governance and non-binding legislative frameworks…”

Notes: Again here we see a lack of consensus on the details of what might best be done, but a clear preference for bottom-up self-governance by the life science community.

9. Literature Reviews (viii)

- “Critics of self-governance dismiss such proposals as inadequate. They argue that the risks of synthetic life science are profound… and that research and researchers should be tightly regulated. They believe that it would be inappropriate for…[those] who might benefit…to regulate themselves. Instead they support government control - top-down governance of research and publication practices.”

Notes; Here then is an alternative possibility that would at present not be acceptable to most practicing life scientists, but which could easily come about if the matter has not been thought through and some new biological attack happens. There are,however, means by which the openness of science can be preserved by merging some of the advantages of both approaches. This idea is explored in a paper by Miller and Selgelid (2007).

Ref:

Miller,S., and Selgelid, M. J. (2007) Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences. *Science and Engineering Ethics*, **13**, 523 - 580. Available from http://www.springerlink.com/content/n514272v537582vv/

10. Literature Reviews (ix)

- “The synthetic life sciences seem to have emerged from nowhere, and their potential uses and misuses have taken the scientific and regulatory community by surprise. This illustrates not only how quickly science can develop…but also how the direction of science can be remarkably difficult to predict. More importantly, however, it is a reminder of how scientific development might leave moral, social and legal discourse in its wake, and lead to uncertainties as to how it should be regulated and controlled.”

Notes: This passage from the concluding section of Samuel et al’s paper suggests that we should not be very surprised that discussion of these matters is at an early stage amongst the life science community and that we should expect to have further such surprises as the revolution in the life sciences proceeds. The rest of this lecture looks at some of the ideas for control in more detail, starting with synthetic genomics.

11. Regulating Synthetic Genomics (i)

- "We define three major points for policy intervention:
  - Commercial firms that sell synthetic DNA (oligonucleotides, genes, or genomes) to users;
  - Owners of laboratory 'bench-top' DNA synthesizers with which users can produce their own DNA;
  - The users (consumers) of synthetic DNA themselves and the institutions that support and oversee their work."

Notes: In 2007 some of the people in the US involved in synthetic genomics and some of the policy people concerned about the potential misuse of their work produced a report on what might be done to mitigate the risks. The report defined three major points of policy intervention and then suggested a range of policies that might be applied at these different points. Whilst the report did receive criticism for being inadequate to deal with the extent of the problem it did show that life scientists can contribute their expertise to the development of new policies to protect their work from misuse.

12. Regulating Synthetic Genomics (ii)

- Options related to commercial firms
  - "Require commercial firms to use approved software for screening orders.
  - People who order synthetic DNA from commercial firms must be verified as legitimate users by an Institutional Biosafety Officer…."
  - Require both use of approved software by the commercial firm and that verification of the user is carried out.
  - "Require commercial firms to store information about customers and their orders."

Notes: At the first point of intervention - the commercial firm - a range of increasingly tough options are set out in the report and subject to analysis for their utility in reducing the risks and their costs of implementation. Clearly, use of approved software, for example, could help minimize the chance that someone could order parts of a dangerous genome. The same process is applied to the other two points of intervention as we shall see in the next two slides. Overall an insight is given into the possible policy landscape which is useful even though the report does not make any recommendations as to what might best be done.

13. Regulating Synthetic Genomics (iii)

- Options related to DNA synthesizers
  - "Owners of DNA synthesizers must register their machines.
  - Owners of DNA synthesizers must be licensed.
  - A license is required both to own DNA synthesizers **and** to buy reagents and services."

14. Regulating Synthetic Genomics (iv)

- Options related to users (consumers)
  - “Incorporate education about risks and best practices as part of university curricula.
  - Compile a manual for ‘biosafety in synthetic biology laboratories’.
  - Establish a clearinghouse for best practices.
  - Broaden Institutional Biosafety Committee(IBC) review responsibilities to cover risky experiments.”

15. Regulating Synthetic Genomics (v)

- Options related to users (customers) continued
  - "Broaden Institutional Biosafety Committee (IBC) review responsibilities, *plus* add oversight from a national advisory group to evaluate risky experiments.
  - Broaden IBC review responsibilities, *plus* enhance enforcement of compliance with biosafety guidelines."

Notes: This last set of options is interesting not just because it focuses on the users but also because it introduces the idea of a tiered system of review involving the local institution and a national advisory body (such as the US NSABB that we will return to in the next slide).

16. NSABB Proposals (i)

- “In this report, the NSABB identifies principles that should underpin the oversight of dual use life science research, lists key features of such oversight (e.g., federal guidelines, awareness and education, evaluation and review of research for dual use potential, assessment and management of risk, compliance, and periodic evaluation at the local (e.g., research institution) and federal levels of the impact of the oversight procedures) and proposes roles and responsibilities…”

Note: In 2007 the NSABB, set up by the government in the US following the report of the Fink committee, produced a report proposing a framework for the oversight of dual use life science research. This remains, probably, the most detailed official investigation of how the risks of dual use research might be mitigated.

17. NSABB Proposals (ii)

- “One of the fundamental tasks of the NSABB was to develop criteria for identifying dual use research of concern. The proposed criterion is ‘research that, based on current understanding can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material.”

Notes: There are some vague points in this definition such as ‘reasonably anticipated’ and ‘directly misapplied’ but clearly the potential range of the life sciences captured by this definition is very large.

18. NSABB Proposals (iii)

- “NSABB members agreed that the principle investigator, using the criterion set forth…should conduct the initial evaluation of his or her research for its potential as dual use research of concern. Those projects initially identified as dual use research of concern - and NSABB members anticipate that there will be very few projects that are truly dual use of concern - would undergo additional institutional review…”

Notes: Two points are of interest here: first that it is the investigator not the institutional review that makes the determination of what might be of dual use concern and second that very little is expected to be of concern.

19. Controlling Dangerous Pathogens (i)

- "For maximum effectiveness, an oversight system would have to be:
  - Globally implemented;
  - Applied without exception to all scientists engaged in relevant research;
  - Adequately financed;
  - Efficiently organized;
  - Backed by appropriate legal authority; and
  - Accompanied by credible provisions to prevent misuse of its authority."

Notes: Probably the most detailed analysis of the dual use problem and its regulation at the level of life science research has been undertaken by a group lead by John Steinbrunner at the University of Maryland in the US. They agree with the NSABB that most life science research will not need to be subject to oversight because of dual use concerns, but they propose a much tougher system of control over what is of possible concern. So while the NSABB proposals would not , for example, cover government biodefense, the Maryland system would cover all relevant work. It would also be legally enforced and be expected eventually to extend beyond work just with pathogens and to be global rather than national.

20. Controlling Dangerous Pathogens (ii)

- "The oversight process would include two key elements.
  - The first, *national licensing*, would be used to identify relevant individuals and research facilities and formalize their adherence to the basic norm….
  - The second element is independent *peer review* of relevant projects prior to their initiation. Any individual interested in conducting research covered by the oversight system would be required to provide information about their proposed project to the appropriate oversight body for review and approval…"

Notes: In the Maryland system then both institutions and individuals would have to be licensed nationally and the initial review of projects would be peer review at the institution. This shows a very different approach to that of the NSABB and indicated how much work needs to be done to find an efficient, effective and acceptable oversight system in many different countries.

Sample Questions

1. What appears to be the most favoured method of oversight amongst life scientists? What are the 'pros and cons' of this method?

2. What do you think of the proposals put forward by Garfinkel *et, al.,* (2007) for the regulation of synthetic genomics?

3. What is the US NSABB's definition of dual-use research of concern? Do you think this is an adequate definition on which to base an oversight system?

4. Compare and contrast the oversight systems proposed by the NSABB and the Maryland research group.

References

(Slide 2)

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