Science and responsibility:
One of the most powerful arguments for investing in scientific research and development is that the results can end up having broad impact on people's lives: leading to the development of new technologies, new treatments for diseases, and a better understanding of the world. Scientific research may also come into conflict with societal values, post risks to health and safety, or impose uneven economic benefits (or costs). How should society consider these issues when deciding what research to pursue? Who should have input on those decisions? And how would any consensus about what research to pursue be enforced?

Section 1: What are the mechanisms through which the pace/direction/etc of scientific research controlled by scientists, individuals, or society?

Funding - Funding priorities (e.g. Precision Medicine initiative) and federal funding restrictions (e.g. research on gun control) exert significant, but not complete, influence over the course of scientific research in the U.S.
*How does increased (and highly targeted) private funding of research affect the effectiveness of this mechanism?

Regulations - Regulations (either legal or guidance) can place limits on allowable research (e.g. the "14 day rule" for cultured human embryos). Further development can be regulated by agencies that control commercial distribution or health and safety (e.g. FDA oversight of medical research through marketing rules and through human subject protection).

Voluntary or Imposed Risk Management - Government agencies or scientific consortia can agree to limits on research (e.g. Asilomar) or can cooperate with with industry and government to establish voluntary limits and systems to control research and/or who is doing research (e.g. Ethical, Legal, and Social Implications (ELSI) Research Program of the Human Genome Project).

Advocacy – Individuals or nongovernmental organizations can force change in the direction or regulation of science. Examples include changes made to the FDA rules regarding clinical trials and drug approval as a result of breast cancer advocacy and the lessening of interest in genetic engineering in food crops as a result of concerns raised by advocacy groups.

Section 2: How can we evaluate if these mechanisms are sufficient/appropriate?
Who?
"When the US National Science Foundation funded a 'National Citizens Technology Forum' in 2008, which brought average, previously uninformed Americans together to deliberate about regulatory policy towards agricultural biotech, the result was a miserable failure. Even after being 'educated', the group made recommendations that were unwarranted and contrary to the judgements of… experts with decades of experience." (Giddings and Miller, 2016)

- What kind of expertise is required to decide on the risks/rewards of scientific research?
- What happens when scientific consensus about risks/rewards conflicts with public understanding/consensus?
    - Is the involvement of non-scientists a concession to "alternative facts"?
    - Is it ethical to make binding recommendations/regulations *without* public comment?

What?
"In reality, it is impossible to be completely 'science based' in a regulatory system…. Empirical evidence matters, but human interpretation brings meaning to that evidence, and multiple perspectives can strengthen understanding. Thus, an oversight system should focus on what concerns a diversity of stakeholders and citizens have, what evidence or risk-mitigation strategies can help address those concerns, and what classes of … products or processes should receive regulatory scrutiny." (Kuzma, 2016)

- How do these considerations change depending on the complexity or scale of the technology under consideration (e.g. democratized fields like robotics *vs.* large scale like large hadron collider)?
- Does the intended/anticipated use of the research affect how it should be monitored/regulated?

Where?

"Different publics may identify and gauge relative benefits and harms somewhat differently…. [T]here might be differences of opinion about how that benefit compares against potential harms ...., either to humans or to the environment. Moreover, a society that is affected by a disease may place a much greater value on eliminating that disease than would a society where the disease does not occur." (NASEM, 2016)

- If development of technology and its application may be in different regions, who evaluates risks and rewards (e.g. release of modified mosquitoes for disease control, modified golden rice)?
- If regulations/norms decided on a national level, will scientists in other regions/nations follow?

When?

"[*Science*] reports that 'The feat [first cloned human embryos] also raises concerns about cloned babies, But that seems unlikely for now.' In the world of innovation imagined by the *Science* report, one wonders when, if ever, it would be appropriate for the public to voice concerns about cloned babies. Only after researchers … announced they had succeeded in inducing a pregnancy with their cloned embryos? Surely, though, by that stage a new 'is' would overwhelm the possibility of a more nuanced and precautionary 'ought'" (Jasanoff, 2016)

- What kind of scientific research should be subject to regulation and/or control?
- Should research contained in labs be regarded differently from "applied" research or technology out in the world?

How?

"It has become clear, however, that not all challenges associated with synthetic biology can be dealt with through technical safeguards…. In addition, we must confront the challenge of uncertainty characteristic of all scientific research. Although some risks are presently understood, we lack frameworks for confronting a range of new risks that fall outside of the previous categories." (Rabinow and Bennett, 2012)

- What factors should be considered? (both risks and rewards)
- Is it even possible to meaningfully evaluate the risks or benefits of a nascent/new application?
- Is there a principled way to incorporate fundamentally different types of factors?
- How are any agreed upon norms enforced?

References:

Jasanoff, S. *The Ethics of Invention*. W. W. Norton & Company: New York; 2016.

Rabinow, P. and Bennett, G. *Designing Human Practices: An experiment with synthetic biology.* University of Chicago Press: Chicago, 2012.

National Academies of Sciences, Engineering, and Medicine. *Gene drives on the horizon*. The National Academies Press: Washington, D.C.; 2016. doi: 10.17226/23405

Kuzma, J. 2016. Policy: Reboot the debate on genetic engineering. *Nature*, 531, pp. 165-167. doi: 10.1038.531165a

Giddings, L. V. and Miller, H. 2016. US National Academies report misses the mark. *Nature Biotechnology*, 34(12), pp. 1226-1228. doi: 10.1038/nbt.3746

Case study #1: AI research (Crawford, *et al*, 2016 and Crawford and Calo, 2016)

What is at issue:

Recent advances in artificial intelligence technologies have brought it increased attention, and implementation. AI advances are already being implemented and their impacts are being felt across society, without a full explanation or understanding of their effects.

What mechanisms are being used for regulation?

Regulation mostly derives from the industry in which technologies are applied - e.g. personalized medicine applications governed by HIPAA, possibly FDA

What are the major concerns?

***Concern 1*:** AI/automation effects on work/management structures - putting low-skill jobs at risk for replacement

Recommendation 1: Update fair labor standards, social safety nets to keep pace with dynamics

***Concern 2*:** AI systems may not be sophisticated/well-understood enough to avoid unintended consequences (e.g. amplification/reinforcement of biases, individual de-anonymization). Those impacted by these shortcomings may not realize the source of the decision, and even if they do they may have no reliable recourse.

***Recommendation 2*:** Support research towards development of reliable systems of measurement, accuracy, fairness, and transparency. Investigate the impact/feasibility of the ability to "opt out"

Concern 3: AI systems deployed/developed without the involvement of those directly impacted and/or experts in the field in which they are deployed. (e.g. AI systems implementation in law, medicine, or finance may run afoul of norms/ethics established in those fields)

Recommendation 3: Work to "codesign" with accountability to communities and experts. Work with domain experts to create or update professional codes of ethics for both practitioners and AI professionals

Questions:

Do these recommendations sufficiently address the concerns?

What role of scientists/experts is put forth in these recommendations? What role is put forth about non-experts?

What do these concerns say about the oversight process so far?

References

Crawford, K and Calo, R. 2016. There is a blind spot in AI research. *Nature*, 538, pp. 311-313.

Crawford, *et al*. The AI Now Report: The social and economic implications of artificial intelligence technologies in the near-term. Available at artificialintelligencenow.com

Shapiro, Aaron. 2017. Reform predictive policing. *Nature*, 541, pp. 458-460.

Case study #2: Gene Drives (Oye, 2012, NASEM, 2016)

What is at issue:

Gene drives are being touted as a method to rapidly spread/alter populations to address public health concerns (e.g. the release of modified mosquitoes to prevent disease transmission). Have the potential to rapidly change ecosystems, introduce new functions.

What mechanisms are being used for regulation?

NIH funded research is subject to NIH guidelines on biosafety and oversight
Hybrid governance system implemented by HHS, researchers, and private companies limits dissemination of components associated with gene drives, dual-use sequences (e.g. viral sequences)
Existing federal agencies/regulations may eventually cover released/marketed genetically modified organisms, but jurisdiction will depend on use and is not yet clear

What are the major concerns?

Concern 1: The release of gene drive systems may irreversibly change natural ecosystems
Recommendation 1: Design "reversible" drive systems

- modulate drive characteristics for minimal penetration while still achieving goal
- only release drives after consultation, communication with public

Concern 2: Increasing ease of engineering may put drives within the reach of terrorist groups
Recommendation 2: Hybrid governance system restricts manufacture, distribution of genetic components associated with gene drives/malicious drive components (e.g. viral genes)

Concern 3: Initial uses of gene drives target diseases endemic in low- to moderate- resource countries, raising questions of exploitation, sufficient controls, and meaningful communication with affected populations
Recommendation 3: ensure that planning and decision making involve affected communities, proceed with commitment to long term involvement and support, especially in the event of unanticipated harms

Questions:

Do these recommendations sufficiently address the concerns?
What role of scientists/experts is put forth in these recommendations? What role is put forth about non-experts?
What do these concerns say about the oversight process so far?

References:

Oye, K.A. 2012. Proactive and adaptive governance of emerging risks. A paper prepared for the *International Risk Governance Council - Public Sector Governance of Emerging Risks.*

National Academies of Sciences, Engineering, and Medicine. *Gene drives on the horizon: advancing science, navigating uncertainty, and aligning research with public values*. The National Academies Press: Washington, D.C.; 2016. doi: 10.17226/23405