Community Engagement in *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*

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I. Introduction

In *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (*New Directions*), the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) examined ethical dimensions of the field of synthetic biology and other new technologies. It recommended actions to facilitate the progress of technological development in ethical ways that encourages public benefits and minimizes potential risks. The Bioethics Commission engaged with scientists, engineers, ethicists, religious leaders, and others to review and assess claims about science, ethics, and public policy related to synthetic biology. The Bioethics Commission initiated a public conversation through democratic deliberation to examine how affected communities can foster responsible development and appropriate oversight of synthetic biology and emerging technologies. In *New Directions*, the Bioethics Commission wrote that "active public engagement can enhance the decisions that are reached and the overall public understanding of them."[1] *Public engagement* enables citizens to address

[1] Presidential Commission for the Study of Bioethical Issues (PCSBI). (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 30.

issues of shared interest, and employs deliberation, dialogue, and action to better achieve complex community or societal goals. *Community engagement*, a subset of public engagement that focuses on affected communities, has been defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."[2] Finally, *community-engaged research* is an important research-focused component of community engagement that involves members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research.

II. Learning Objectives

Students should be able to:

1. Discuss the importance of democratic deliberation as it relates to the development of synthetic biology and other emerging technologies.

2. Understand the guiding ethical principles for assessing emerging technologies and how they relate to the incorporation of synthetic biology technologies into society.

3. Discuss how public and community engagement can impact technological development in synthetic biology and other emerging technologies, and ways to address the challenges of public and community engagement.

III. Background

Scientific and technological advances have the potential to benefit society in many ways, but also require careful consideration throughout development and adoption. Synthetic biology is a field of biotechnology that "aims to apply standardized engineering techniques to biology and thereby create organisms or biological systems with novel or specialized functions."[3] Proponents of synthetic biology cite its potential to reduce human reliance on fossil fuels and improve human health through medical advancements.[4] Critics raise concerns about disrupting existing

[2] Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement*, Second Edition (NIH Publication No. 11-7782). Bethesda, MD: National Institutes of Health (NIH), p. 7. Retrieved December 31, 2014 from http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf.
[3] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 2.
[4] Church, G.M., et al. (2014). Realizing the potential of synthetic biology. *Nature Reviews Molecular Cell Biology*, 15(4), 289-294; Savage, D.F., Way, J., and P.A. Silver. (2008). Defossiling fuel: How synthetic biology can transform biofuel production. *ACS Chemical Biology*, 3(1), 13-16; Weiss, R., Associate Professor, Department of Biological Engineering and Department of Electrical Engineering and Computer Science, Massachusetts Institute of Technology. (2010). Synthetic Biology: What New Methods and Products are Being Developed? Presentation to the

ecosystems thereby reducing biodiversity, devaluing the meaning of life, and threatening longstanding conceptions of nature.[5] In *New Directions*, the Bioethics Commission made recommendations with the goal of developing an ongoing process of prudent vigilance that encourages responsible development of synthetic biology while monitoring, identifying, and mitigating potential harms over time.

A. Guiding Ethical Principles

The Bioethics Commission framed its analysis in *New Directions* around five central ethical principles: public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation, and justice and fairness.

The principle of public beneficence requires that actions pursue and secure public benefits and minimize public harm. This principle encompasses the duties of societies and governments to promote individual activities and institutional practices, including scientific and biomedical research, that have the potential to improve the public's wellbeing.[6]

The principle of responsible stewardship calls for governments and societies to proceed prudently in promoting science and technology that can improve human welfare but also have the potential to cause harm, and to recognize the importance of citizens and their representatives acting collectively for the betterment of all.[7] This principle calls for governments and societies to proceed prudently in promoting scientific advancement by taking into account the interests and needs of those unable to represent themselves, including children and individuals with impaired capacity to consent.[8]

The principle of intellectual freedom and responsibility requires that scientists and other researchers, acting responsibly, use their creative abilities to advance science and the public good, while adhering to the ideals of research, avoiding harm to others, and taking professional responsibility for the benefits and burdens of their work.[9]

Democratic deliberation "reflects an approach to collaborative decision making that embraces respectful debate of opposing views and active participation by citizens."[10] Central to democratic

Presidential Commission for the Study of Bioethical Issues, September 13. Retrieved December 31, 2014 from http://bioethics.gov/node/172.

[5] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: the Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 21.

[6] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: the Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 24-25.

[7] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 25.

[8] Presidential Commission for the Study of Bioethical Issues. (2012, October). *Privacy and Progress in Whole Genome Sequencing*. Washington, DC: PCSBI, p. 29.

[9] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: the Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 27-28.

[10] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 28-29.

deliberation is an ongoing, public exchange of ideas and perspectives that promotes mutually respectful decision making and facilitates the correction of mistakes made while undertaking collective actions.[11]

Finally, the principle of justice and fairness calls upon the scientific community and the nation to ensure that benefits and burdens of synthetic biology and other emerging technologies are distributed fairly.[12] Public engagement can provide insight into the potential consequences of an emerging technology, including previously unforeseen benefits and harms. Members of the public are often in a unique position to identify how burdens of new technologies might disproportionately affect some communities.

These principles support the use of public and community engagement to influence the course of synthetic biology research and the development of novel technologies to promote public wellbeing.

In *New Directions*, the Bioethics Commissions focused on the importance of public engagement, which can improve the decisions that are reached with respect to emerging technologies, and improve public understanding of such technologies and related issues in science. In its examination of synthetic biology, the Bioethics Commission found encouraging examples of ways in which the public share various points of view as well as efforts to educate the public about this emerging field. By emphasizing how groups of citizens can come together to share their mutual interest and expertise in synthetic biology, the Bioethics Commission highlighted how citizens already are shaping the present and future of synthetic biology. Its recommendations in *New Directions* speak to several opportunities for strengthening these democratic efforts regarding ethics and synthetic biology specifically, and emerging technologies more broadly.[13] In addition to public engagement, the Bioethics Commission pointed to examples of community engagement in research.[14] Together, these activities provide opportunities for citizens, researchers, and policy makers to learn from each other, share concerns, and work together toward developing synthetic biology through safe and productive research.[15]

B. Bioethics Commission Recommendations

In its recommendations, the Bioethics Commission emphasized the importance of open, multidisciplinary dialogue to promote clear communication on the state of science and

[11] Gutmann, A., and D. Thompson. (1997). Deliberating about bioethics. *Hastings Center Report*, 27(3), 38-41.
[12] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: the Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 30-31.
[13] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 151-154.
[14] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 153.
[15] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 154.

technology and the need to engage the public in policy development, communication, and education regarding the science of synthetic biology.

The Bioethics Commission noted the importance of international dialogue and discourse regarding synthetic biology and emerging technologies. Comprehensive engagement should take into account that "the synthetic biology community is an interactive global network."[16] The Bioethics Commission recommended that the United States remain involved in both national and international discussions regarding synthetic biology and ensure coordination and consistency in regulatory oversight when possible.

> **Recommendation 8: International Coordination and Dialogue**
>
> **Recognizing that international coordination is essential for safety and security, the government should act to ensure ongoing dialogue about emerging technologies such as synthetic biology…[T]he Executive Office of the President, through the Department of State and other relevant agencies such as the Department of Health and Human Services and the Department of Homeland Security, should continue and expand efforts to collaborate with international governments, the World Health Organization, and other appropriate parties, including international bioethics organizations, to promote ongoing dialogue about emerging technologies such as synthetic biology as the field progresses.[17]**

One of the Bioethics Commission's recommendations in *New Directions* focuses on encouraging open discussion among the public and the synthetic biology community:

> **Recommendation 14: Scientific, Religious, and Civic Engagement**
>
> **Scientists, policy makers, and religious, secular, and civil society groups are encouraged to maintain an ongoing exchange regarding their views on synthetic biology and related emerging technologies, sharing their perspectives with the public and with policy makers. Scientists and policy makers in turn should respectfully take into account all perspectives relevant to synthetic biology.[18]**

Public deliberation about synthetic biology and emerging technologies also can be hindered by the use of imprecise or inaccurate language. Imprecise communication might lead to public misunderstanding about the implications of novel research and the limitations of technological capabilities. To address these concerns, the Bioethics Commission recommended the creation of a fact-checking mechanism overseen by impartial, qualified experts.

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[16] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 132.
[17] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 132.
[18] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 154.

Recommendation 15: Information Accuracy

When discussing synthetic biology, individuals and deliberative forums should strive to employ clear and accurate language. The use of sensationalist buzzwords and phrases such as "creating life" or "playing God" may initially increase attention to the underlying science and its implications for society, but ultimately such words impede ongoing understanding of both the scientific and ethical issues at the core of public debates on these topics. To further promote public education and discourse, a mechanism should be created, ideally overseen by a private organization, to fact-check the variety of claims relevant to advances in synthetic biology.[19]

Ethical integration of novel technologies into society requires meaningful citizen participation in related deliberations. To encourage public deliberation of scientific and ethical aspects of emerging technologies, citizens must be adequately educated, which requires creativity and innovation in our approaches to making science accessible to the general public. The Bioethics Commission recommended focusing on the importance of accessible science and public education:

Recommendation 16: Public Education

Educational activities related to synthetic biology should be expanded and directed to diverse populations of students at all levels, civil society organizations, communities, and other groups. These activities are most effective when encouraged and supported by various sources, not only government, but also private foundations and grassroots scientific and civic organizations…[T]he Executive Office of the President, with input from the scientific community, the public, and relevant private organizations, should identify and widely disseminate strategies to promote overall scientific and ethical literacy, particularly as related to synthetic biology, among all age groups.[20]

These recommendations provide a publicly accountable way to guide the field of synthetic biology as it works to improve human health and public welfare in an ethical manner. Ongoing dialogue and education about potential implications of synthetic biology for humans, other species, nature, and the environment should continue as synthetic biology develops into a mature field of scientific inquiry and innovation.

[19] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 156.
[20] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 158.

IV. Reading

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at www.bioethics.gov under "Projects"):

> Presidential Commission for the Study of Bioethical Issues (PCSBI). (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies.* Washington, DC: PCSBI, pp. 19-31 ("Introduction").
>
> *New Directions*, pp. 123-140 ("Responsible Stewardship").
>
> *New Directions*, pp. 151-160 ("Democratic Deliberation").

V. Discussion Questions

The following questions are based on the information provided above and through the indicated reading, and are intended to reinforce important aspects of public and community engagement that relate to the Bioethics Commission's *New Directions* report. Important points are noted with each question to help the instructor guide group discussion. The "Additional Reading" section will be helpful in answering these questions.

1. **How is public engagement distinct from community engagement and community-engaged research? What are some similarities of these forms of engagement?**

   Starting points for discussion:

   a. *Public engagement* enables citizens to address issues of shared interest, and employs deliberation, dialogue, and action to better achieve complex community or societal goals. *Community engagement* is the process of working collaboratively and engaging actively with groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people.[21] *Community-engaged research* is a type of community engagement that involves members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research.

   b. Both public and community engagement can contribute as components of a wider process of democratic deliberation; these practices encourage the inclusion of community members in active and ongoing participation in a public exchange of ideas.

[21] Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement*, Second Edition (NIH Publication No. 11-7782). Bethesda, MD: National Institutes of Health (NIH), p. 7. Retrieved December 31, 2014 from http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf.

2. **Promoting public engagement requires that information about synthetic biology and various viewpoints be shared in discussion. What common characteristics of public discourse might hinder effective communication and policy making? How might participating individuals overcome these challenges?**

   Starting points for discussion:

   a. *Example challenge:* Individuals, including scientific experts, disagreed about the degree of achievement announced by the J. Craig Venter Institute regarding the world's first self-replicating synthetic bacterial genome.

      Example resolution: Productive discussion of synthetic biology and other emerging technologies requires clear characterization and communication of the actual scientific achievement and minimization of scientific hype. In addition, the principle of democratic deliberation encourages public discourse to proceed respectfully and to involve consideration of a variety of perspectives.

   b. *Example challenge*: Scientific information can be difficult to communicate to the public because of the complex technical details and specialized scientific training needed to understand those details. For example, scientists might struggle to communicate—and journalists might find it challenging to report—highly technical scientific advances in a readily accessible way. Imprecise language can fail to accurately convey the state of the science to the public.

      Example resolution: Making science more publicly accessible might require innovation in public education. For example, some synthetic biology groups have begun outreach efforts, and these efforts can be expanded. Scientific literacy goes hand-in-hand with improved ethical literacy, indicating a need for educational efforts that also improve public understanding of moral traditions and the responsibilities of individuals and communities toward each other.

3. **In supporting the international focus of Recommendation 8, the Bioethics Commission noted, "[s]ynthetic biology is an international enterprise."[22] How might we best engage broader international communities in order to promote international dialogue about emerging biotechnologies?**

[22] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 10.

Starting points for discussion:

a. Universities, research institutions, professional organizations, and publications can encourage increased international collaboration among scientists, engineers, and policy makers.

b. Universities might incorporate consideration of international perspectives and discussion into education and training curricula for synthetic biologists and related professionals. While some ethics training is required for clinical researchers, the diverse range of actors engaged in synthetic biology research—including engineers, chemists, materials scientists, computer modelers, and others in practices outside conventional research settings—suggests that some groups might not yet be familiar with existing biosafety and biosecurity standards.[23]

4. **One challenge to public engagement is how the public learns about science and technology. For example, following publication of an article entitled "Creation of a bacterial cell controlled by a chemically-synthesized genome," press reports described scientists as having "created life."[24] Some members of the public perceived this to mean that the researchers were "playing God," which triggered fear and concern about the nature of synthetic biology research.[25] The Bioethics Commission noted that "the provocative nature of [such phrases] does more to obscure rather than illuminate those important moral concerns regarding synthetic biology that deserve serious consideration."[26] What mechanism(s) might be used to provide the public with accurate information about emerging technologies?**

[23] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, pp. 133-134.
[24] Alleyne, R. (2010, May 20). Scientist Craig Venter creates life for first time in laboratory sparking debate about 'playing god.' *The Telegraph.* Retrieved January 5, 2015 from http://www.telegraph.co.uk/science/7745868/Scientist-Craig-Venter-creates-life-for-first-time-in-laboratory-sparking-debate-about-playing-god.html; Sample, I. (2010, May 20). Craig Venter creates synthetic life form. *The Guardian.* Retrieved January 5, 2015 from http://www.theguardian.com/science/2010/may/20/craig-venter-synthetic-life-form. See Gibson, D.G., et al. (2010). Creation of a bacterial cell controlled by a chemically synthesized genome. *Science*, 329(5987), 52-56.
[25] The Telegraph. (2010). American scientist who created artificial life denies 'playing God.' *The Telegraph.* Retrieved January 8, 2015 from http://www.telegraph.co.uk/news/science/science-news/7747779/American-scientist-who-created-artificial-life-denies-playing-God.html.
[26] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 156.

Starting points for discussion:

a. An accessible and interactive fact-checking mechanism could encourage the public to suggest claims for review by project staff. Such a mechanism might be funded by private sources to avoid real or perceived conflicts of interest.[27]

b. Public and private organizations could identify and disseminate strategies to promote overall scientific and ethical literacy among all age groups, expanding educational activities related to synthetic biology to diverse populations, including students, civil society organizations, and communities.[28]

c. An online database run by an independent institution or organization could provide resources for the public to understand scientific studies. Online media might reach some communities more easily than others.

5. There is a broad range of opinions in support of and against the advancement of synthetic biology research. How can policy makers, ethicists, and researchers shape the investigation of synthetic biology technologies in ways that respect the diversity of views among the public?

Starting points for discussion:

a. Participating in public engagement acknowledges differing views and demonstrates respect for diverse perspectives.

b. Researchers can acknowledge the concerns of members of the public and incorporate their concerns in research design when possible.

c. Researchers and policy makers can educate members of the public about the risks and benefits of research on emerging technologies and the ways in which societal concerns are being addressed.

d. Researchers can continue to facilitate engagement throughout both research and development processes, for example, through the incorporation of a community advisory board or ongoing public meetings.

[27] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 157.
[28] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 158, Recommendation 16: Public Education.

VI. Problem-Based Learning

Scenario A. *Photosynthetic algae provide a potential tool for creating biofuels via synthetic biology. Under experimental conditions, algae produce substantially more energy per acre than land crops. Algae cells are grown, harvested, and treated chemically or thermally to recover the oil content inside algal cells. Development in synthetic biology might allow for the large-scale production of algal biofuels by engineering algae to secrete oil continuously through their cell walls, increasing the ease of oil collection and yield.*

For example, the company Aurora Algae is growing algae in open-pond systems consisting of readily available seawater. The demonstration production facility in Karratha, Western Australia, produces up to 15 tons of dried algal biomass per month in six one-acre ponds.[29]

Similarly, Synthetic Genomics engineered algal strains to create crude oil that can be used in refineries by using a continuous biomanufacturing process that sidesteps the intermittent cycle of growing and harvesting.[30]

A potential disadvantage to the production of biofuels via synthetic biology is possible harm to ecosystems from the required dedication of water, land, and other natural resources necessary for maintenance of algal cells and the production of biomass as feedstock.[31]

1. **With which groups might companies like Aurora Algae and Synthetic Genomics engage to gain relevant community perspectives?**

   Starting points for discussion:

   a. Members of the public in the immediate geographical area might have an interest in how changes to land, water, and other natural resources will affect their families and the community.

   b. If large areas of land were to be dedicated to biofuel development, this could put new pressures on land, potentially affecting food production, communities, and ecosystems.[32] Researchers can reach out to environmental and civil organizations that have a stake in protecting ecosystems and ensuring that natural resources are used fairly.

[29] Aurora Algae. (n.d.). Continuing Progress in South Texas [Webpage]. Retrieved January 7, 2015 from http://www.aurorainc.com/technology/south-texas/.
[30] Synthetic Genomics. (2012). What We Do: Next Generation Fuels and Chemicals [Webpage]. Retrieved January 5, 2015 from http://www.syntheticgenomics.com/what/renewablefuels.html.
[31] Thomas, J., Programme Manager, ETC Group. (2010). Benefits and Risks of Synthetic Biology. Presentation to the Presidential Commission for the Study of Bioethical Issues, July 8. Retrieved January 5, 2015 from http://bioethics.gov/node/166.
[32] Thomas, J., Programme Manager, ETC Group. (2010). Benefits and Risks of Synthetic Biology. Presentation to the Presidential Commission for the Study of Bioethical Issues, July 8. Retrieved January 7, 2015 from http://bioethics.gov/node/166.

c. Some supporters of new technologies highlight the potential economic benefits of developing synthetic biology, including more jobs and potential goods for export.[33] Researchers might want to engage with those who have an economic stake in emerging technologies.

2. How might different groups be engaged?

Starting points for discussion:

a. Public and community engagement mechanisms during research can take many different forms, for example:

   i. Stakeholder meetings
   ii. Local informational and educational events
   iii. Ongoing dialogue with community advisory committees or organizations
   iv. Focus group discussions
   v. Advisory groups
   vi. Participant group discussions and informational sessions
   vii. Meetings with pre-established community groups

b. The principle of deliberative democracy highlights the value of ongoing and public exchanges of ideas and perspectives. Public engagement can include various stakeholders, including members of the community, policy makers, researchers, and company representatives.

Scenario B. *The Bill and Melinda Gates Foundation awarded multiple grants to OneWorld Health, a drug development program for an international nonprofit organization aiming to transform global health through innovation. The grants supported a synthetic biology project at the University of California, Berkeley to produce artemisinin (a critical component in some malaria treatments) via genetically engineered yeast.[34] In August 2014, the first antimalarial treatments produced with semi-synthetic artemisinin entered the market, as large-scale batches were delivered to malaria-endemic countries in Africa.[35]*

1. Community engagement during synthetic biology research can help to anticipate the needs or interests of the communities where the semi-synthetic artemisinin could be used to treat malaria. In addition, members of the public might need to be engaged as a

[33] Aurora Algae. (2011, June 21). Aurora Algae Advances Commercial Facility Construction, Achieves Major Project Facilitation Status [Press release]. Retrieved January 7, 2015 from http://www.aurorainc.com/aurora-algae-advances-commercial-facility-construction-achieves-major-project-facilitation-status/.
[34] Sanders, R. (2013, April 11). Launch of antimalarial drug a triumph for UC Berkeley, synthetic biology. *UC Berkeley News Center.* Retrieved January 7, 2015 from http://newscenter.berkeley.edu/2013/04/11/launch-of-antimalarial-drug-a-triumph-for-uc-berkeley-synthetic-biology/.
[35] PATH. (2014, August 12). First antimalarial treatments produced with semisynthetic artemisinin enter market [Press release]. Retrieved January 7, 2015 from http://www.path.org/news/press-room/685/.

new product like semi-synthetic artemisinin enters the market. Who could be engaged to inform and evaluate, during both research and implementation of semi-synthetic artemisinin within a community?

Starting points for discussion:

a. Representatives of the countries and communities where synthetic biology technologies will be introduced can contribute important perspectives during both the research and implementation stages. Lessons also might be learned from previous efforts to employ new technologies in similar contexts.[36]

b. Engagement at each stage might differ. During research, interested community members might include patients, global health experts, and public health professionals. During implementation, public engagement might include patients, clinicians who would be recommending treatment, and global health experts who could anticipate economic aspects of introducing a new drug.

2. **Researchers studied semi-synthetic artemisinin in the United States for the purposes of implementation as a clinical treatment in Africa. If researchers were to conduct community-engaged research on the same topic, what considerations could they take into account during the planning process? Additionally, what potential benefits of community engagement might occur after the research is completed, during the application of a new technology?**

Starting points for discussion:

a. One of the most important and challenging aspects of community engagement is identifying which groups have a stake in research and its application. Researchers should consider thoughtfully which communities are affected by either research or implementation.

b. Researchers can consider different ways to engage affected communities. Mechanisms for community-engaged research fall along a continuum of increasing involvement and cooperation between community members and researchers (described in detail in the Community Engagement Background Module). Possible forms of community engagement in the research context include outreach to inform community members of ongoing research, consulting to identify community concerns and interests, or collaborating with community members to design the research.

[36] de Vries, J.D., et al. (2011). Ethical issues in human genomics research in developing countries. *BMC Medical Ethics*, 12, 5; Marsh, V.M. et al. (2011). Working with concepts: The role of community in international collaborative biomedical research. *Public Health Ethics*, 4(1), 26-39.

c. Researchers can consider how to incorporate or account for the perspectives offered by community members. Respectful and ongoing dialogue can help researchers manage community expectations of what the research process might yield. In addition, researchers should anticipate differing viewpoints on how to reconcile the potential benefits and risks of research, and the possibility that community members might have their own conflicts of interest.

d. Community engagement during the implementation stage might help to improve uptake of a helpful intervention later in the clinical context, by building relationships, fostering trust, establishing mechanisms to address unanticipated harms, and increasing the likelihood that technologies are relevant for the communities for which they were developed.[37] Individuals not affiliated with initial research, including health workers, public health professionals, and local leaders, can take an active role in engaging the community.

VII. Exercises

Exercise A. *Recently, synthetic biology applications have emerged across several consumer industries including cosmetics, household products, and flavorings. In May 2014, the* New York Times *reported that a liquid laundry detergent produced by Ecover, a company that makes "green" household products, contains an oil produced by synthetically-altered algae. Ecover deemed the algae-produced oil a "natural" replacement for palm kernel oil, whereas some environmental groups and consumer activists called for labeling to disclose whether synthetic biology was used to make product ingredients.[38] The article below highlights a number of issues raised by this technology:*

> Strom, S. (2014, May 30). Companies quietly apply biofuel tools to household products. *The New York Times*. Retrieved January 7, 2015 from http://www.nytimes.com/2014/05/31/business/biofuel-tools-applied-to-household-soaps.html?_r=2.

An open letter, published by 17 consumer, environmental, and farming groups, called for Ecover to cancel its plans to use oils derived from synthetic biology because the field represents "a new and poorly defined industry." Letter signatories also contended that synthetically derived

[37] Sieber, J. (2013). Consent and community engagement in diverse research contexts: Reviewing and developing research and practice. *Journal of Empirical Research on Human Research Ethics*, 8(4), 1-18; Joint United Nations Programme on HIV/AIDS (UNAIDS). (2011). *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials.* Geneva, Switzerland: UNAIDS; Woodsong, C., and Q.A. Karim. (2005). A model designed to enhance informed consent: Experiences from the HIV Prevention Trials Network. *American Journal of Public Health*, 95(3), 412-419.

[38] Strom, S. (2014, May 30). Companies quietly apply biofuel tools to household products. *The New York Times.* Retrieved January 7, 2015 from http://www.nytimes.com/2014/05/31/business/biofuel-tools-applied-to-household-soaps.html?_r=2.

products are neither "natural," "green," nor "ecological/sustainable."[39] *Jim Thomas of the ETC Group, a watchdog organization that tracks emerging technologies, also voiced his concerns about Ecover's move in an article published in* The Ecologist.[40] *Read the letter and the opinion piece:*

> Open letter to Ecover/Method. ETC Group. Retrieved January 7, 2015 from http://www.etcgroup.org/content/open-letter-ecover-method.
>
> Thomas, J. (2014, June 16). Ecover pioneers 'synthetic biology' in consumer products. *The Ecologist.* Retrieved January 7, 2015 from http://www.theecologist.org/News/news_analysis/2439594/ecover_pioneers_synthetic_biology_in_consumer_products.html.

Tom Domen and Dirk Develter of Ecover responded to Mr. Thomas' concerns in a follow-up piece published in The Ecologist, *refuting allegations that the company has been using synthetic biology to make soap ingredients, arguing that the process involves traditional fermentation, and that the company remains at the forefront of sustainability and responsible practice.*[41] *Read their response at:*

> Domen, T., and D. Develter. (2014, June 25). Ecover is as green as ever! *The Ecologist.* Retrieved January 7, 2015 from http://www.theecologist.org/blogs_and_comments/Blogs/2450666/ecover_is_as_green_as_ever.html.

In July 2014, Ecover announced that it would halt its use of algal oils and begin to engage in discussions with non-governmental organizations and scientists to address concerns raised by either party. The company will decide its future plans for algal oils after a six-month review period.[42]

The following article provides additional information on upstream public engagement in synthetic biology:

> Torgersen, H., and M. Schmidt. (2013). Frames and comparators: How might debate on synthetic biology evolve. *Futures*, 48(100), 44-54.

[39] ETC Group. (2014, June 2). 17 groups call on Ecover and Method to drop extreme genetic engineering plans [Press release]. Retrieved January 7, 2015 from http://www.etcgroup.org/content/groups-call-ecover-and-method-drop-extreme-genetic-engineering-plans.
[40] Thomas, J. (2014, June 16). Ecover pioneers 'synthetic biology' in consumer products. *The Ecologist.* Retrieved January 7, 2015 from http://www.theecologist.org/News/news_analysis/2439594/ecover_pioneers_synthetic_biology_in_consumer_products.html.
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[42] Chatsko, M. (2014, July 6). The world's largest green cleaning company just slammed the brakes on Solazyme. *The Motley Fool.* Retrieved January 7, 2015 from http://www.fool.com/investing/general/2014/07/06/the-worlds-largest-green-cleaning-company-just-sla.aspx.

1. **What are some of the different opinions presented by Ecover and the various consumer and environmental groups? What might each group hope to gain by engaging with others either during or after research? How does deliberative democracy provide an approach that establishes some goals and guidelines for engagement?**

    a. What are the different scientific and moral claims made to defend or object to Ecover's new practices?

    b. As Torgenson and Schmidt point out, individuals with a stake in the debate might have different goals when engaging with others. For example, some might be advancing commercial interests, and hope to gain a competitive advantage through engagement with others. How might different goals affect public engagement?

    c. Deliberative democracy promotes mutually respectful debate when making collective decisions. This approach encourages participants to adopt a societal perspective over individual interests.[43] Participants in democratic deliberation processes should be willing to compromise instead of advocating for a single position. What are the advantages of decisions or policies based on compromise or consensus, compared to those that might result from advocacy?

Exercise B. *During Session 6 of the Bioethics Commission's first public meeting in July 2010, speakers discussed engaging the public with synthetic biology. Transcripts and archived video of the session are available on the Bioethics Commission's website under Meeting 1, Session 6 beginning at 02:34 on the webcast video.*

1. **Speakers highlight important survey results that illustrate one form of public engagement about synthetic biology and emerging technologies. What are some of the considerations introduced by presenters and how might they inform future efforts at public engagement?**

    a. *Limited understanding or education:* Researchers should have a responsibility to communicate with community members at a level that they can understand. As high as 80 percent of the American public had heard little or nothing about synthetic biology in 2008 and 2009.[44] What does current public opinion reveal about potential goals for future public education efforts?

[43] Presidential Commission for the Study of Bioethical Issues. (2010, December). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. Washington, DC: PCSBI, p. 151-155.
[44] Rejeski, D., Director, Science and Technology Innovation Program, Woodrow Wilson International Center for Scholars. (2010). Ethics. Presentation to the Presidential Commission for the Study of Bioethical Issues, July 9. Retrieved January 7, 2015 from http://bioethics.gov/node/169.

b. *Distorted conceptions and media coverage:* If the public learns about synthetic biology and emerging technologies from the popular press and news media, community members might not have a fully informed view of synthetic biology, which is essential to informed communication and deliberation about the field. What efforts can researchers employ to acknowledge the influence of media coverage on public opinion and strive to communicate the science clearly?

VII. Glossary of Terms

Community advisory board: An advisory board consisting of community members that represents the interests of the community in advising and communicating with researchers or research sponsors.

Community-based participatory research: Research in which the community helps to identify the topic or issue to be studied based on local priorities, actively participates in developing the study design, and provides guidance to the researchers regarding participant recruitment and retention.

Community-engaged research: A mechanism to involve members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research.

Community engagement: The process of working collaboratively and engaging actively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people. [Adapted from *Principles of Community Engagement,* Second Edition (2011)].

Democratic deliberation: An approach to collective and collaborative decision making that seeks to clarify and articulate factual and ethical issues at the core of a debate, to create consensus whenever possible, and to map the terrain of disagreements in a respectful way—when agreement is not immediately attainable—by encouraging reciprocity, respect for persons, transparency, publicity, and accountability.

Distributive justice: An ethical principle that calls for equitable distribution of benefits and burdens across society—for example, the benefits and burdens of biomedical research, or of technological advances

Intellectual freedom and responsibility: The notion that scientists and other researchers, acting responsibly, should use their creative abilities to advance science and the public good, while adhering to the ideals of research, avoiding harm to others, and abiding by all associated rules.

Justice: An ethical principle that calls for equitable distribution of benefits and burdens across society—for example, the benefits and burdens of biomedical research, or of technological advances.

Public beneficence: An ethical principle that encourages us to pursue and secure public benefits while minimizing personal and public harm.

Public engagement: Processes that enable citizens to address issues of shared interest, often employing deliberation, dialogue, and action with the aim of better achieving complex community or societal goals.

Responsible stewardship: The act of ensuring and/or promoting consideration of the interests and needs of those not in a position to represent themselves in social discourse.

Synthetic biology: The field of biotechnology that aims to apply standardized engineering techniques to biology and thereby create organisms or biological systems with novel and/or specialized functions.

IX. Additional Resources

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