GRAND CHALLENGES for Biological Engineering

The Institute of Biological Engineering

2009-2010

Bioethics Essay Contest Winners

TOPIC: "In the context of synthetic biology, how should the public's concerns regarding safety and ethics be heard and integrated?"

Participants were instructed to submit a 1000 to 1200 word, original essay (all entries were submitted to a plagiarism-checking service). Five semifinalists were selected and invited to read their winning essays at the 2010 Annual Meeting of the Institute of Biological Engineering (IBE) on March 5, 2010, in Cambridge, MA. The final ranking of the essays were determined after the reading of the essays at the Annual Meeting.

The top three winners received cash awards of \$150 for first place, \$100 for second place, and \$75 for third place. The first place essay will be reviewed for publication in the *Journal of Biological Engineering*, the official journal of IBE. **The following are the essays of the top three winners.**



First Place -

Four Suggestions for Addressing Public Concern Regarding Synthetic Biology

Alex David Hatch - Utah State University, Undergraduate

The very characteristics of synthetic biology that make it such a promising field are those that introduce concern. Concerns in the field come from a public sphere and from the scientific community itself (Vergano, 2008; Rodemeyer, 2009). As concerns arise, the scientific community has the responsibility to respond in a way that benefits the public first. Addressing all of the concerns facing synthetic biology is beyond the scope of this paper. This paper will focus, rather, on a discussion of the challenges associated with synthetic bioterrorism and a proposal of four steps that can be taken in the short term that would foster safety and trust between the community of synthetic biologists (community) and the public whom they serve.

Synthetic Biology, Bioweapons, and Bioterrorism

Synthetic biology is "an approach to engineering biology (Endy, 2008)." It builds on the foundational principles of recombinant DNA technologies and allows more efficient modification or enhancement of cellular function (Rejeski, 2009a). Specific applications that simplify and increase efficiency of the modification of cellular function include but are not limited to:

- Creation of databases of units of DNA that "encode basic biological functions" which are "freely available to the public" (BioBricks Foundation)
- Development of interchangeable biological parts that are easily combined (BioBricks, iGEM)
- Development and improvements in automated DNA synthesis and whole genome synthesis (Parens et al., 2009; Cello et al., 2002)
- Relative ease of ordering DNA parts or synthesized DNA (Parens et al., 2009)
- Potential to own oligonucleotide synthesizers that would enable independent automated DNA synthesis (Garfinkel et al., 2007)

As the technology develops participating in the science will become increasingly efficient and available to a wide range of people (Garfinkel et al., 2007). Reports have been released detailing how scientists synthesized pathogenic viruses including polio virus and the 1918 influenza virus (Cello et al., 2002; Wimmer, 2006; Kurzweil, 2005; Tumpey et al., 2005). Synthetic biology is obviously very powerful and could potentially be manipulated in a malevolent manner.

The Biological and Toxin Weapons Convention prohibits participant nations from using, developing, or stockpiling biological weapons (Atlas 2009). As Atlas indicates, there are weaknesses in this governing policy, but to this point in time it has prevented international biological warfare. One expert points out, however, that 9/11 demonstrates "that humans [are] capable of unimaginable evil (Marchant and Pope 2009)." It has also been suggested that, in contrast to research of the past, the foundational development of synthetic bioweapons could be performed with "little equipment and infrastructure (Atlas 2005)." The intention to use bioweapons and relative ease of implentation could be compatible with terrorist agendas.

Four Steps to Help Ensure Public Safety

Following are four steps that help address synthetic bioterrorism specifically, but also address concerns regarding synthetic biology. The four steps are:

- 1.) Community initiative to regulate the receipt of DNA constructs
- 2.) International regulation
- 3.) Increased investment in research of risk assessment and public perception
- 4.) Education
- 1.) In conjunction with the synthetic biology 2.0 and 3.0 conferences (2006, 2007), suggestions were made to establish best practices for gene synthesis companies (Maurer et al. 2006; Garfinkel et al., 2007). These reports indicated that not all gene synthesis companies performed routine screenings for potentially pathogenic DNA orders. It was proposed that the community refuse to do business with those companies that fail to implement routine safety and security practices. In the synthetic biology 3.0 conference it was suggested that a licensing/registration of individuals/equipment needed to perform automated DNA synthesis could take place. The community would then be allowed to determine who was licensed and ensure that known pathogenic constructs were controlled. Required screening and licensing of individuals and or automated DNA synthesis equipment would greatly reduce the ability of terrorist groups to obtain harmful constructs and to carry out potentially harmful research. This regulation quickly addresses one of the major



public concerns of synthetic biology with little change required in current practices (Pauwels, 2008).

- 2.) In dealing with bioterrorism and synthetic biology in general, regulations must exist at an international scale. A failure to have consensus on an international level will lead to difficulties in enforcement. The merging of cultures and backgrounds to create an international policy that meets the demands of contributing parties will be difficult. In the matter of regulating bioterrorism, however, unity must be reached. The attempt for individual nations to regulate will fail because the research can move to a location that has no formal policy against research in question (Marchant et al., 2009). In an effort to create international policy, the wishes of all participants will never be met, so there must be a willingness to recognize on all sides, fundamental practices that pose a risk to the safety and peace of society, and to act only on those most fundamental principles. International policy accepted in the community of synthetic biology must exist.
- 3.) While addressing the National Academy of Sciences (2009b), David Rejeski stated that approximately 30 million dollars in U.S. federal funding went toward synthetic biology each year. Of the 30 million dollars, he claimed that none was specifically devoted to public engagement or risk assessment. He stated that in studies he has overseen, the repeated wish of the public is risk assessment and regulation. Some indicate that at the present, the regulation of recombinant DNA technology also effectively regulates the current standing of synthetic biology (Rodemeyer, 2009). As the science progresses and becomes increasingly novel, increased risk assessment will be vital to safety, funding, and progress (International Risk Governance Council, 2008). Furthermore, public engagement will be necessary to determine which directions research should and should not take. Increased investment devoted to the study of risk assessment and public perception must take place, especially because the technology is dynamic and progressing, in order to reach the potential that synthetic biology possesses.
- 4.) While bioterrorism is a valid concern, a major attack using a synthetically derived bioweapon is not realistic at this point in time (Zilinskas, 2006). The public is introduced to synthetic biology in the media with bioterrorism often mentioned (Pauwels, 2008). As Hart Researchers learned in a survey (2009), about 20 % of the public in the U.S. has heard "a lot" or "some" about synthetic biology. Studies show that once an assessment has been made about a risk, the initial assessment rarely changes, but rather becomes stronger (Kahan et al., 2009). So, as the vast majority of the population is yet to learn about synthetic biology, it is vital that efforts be made to disseminate accurate knowledge to the public through appropriate avenues. Opportunities to discuss possible avenues for education could be

discussed at conferences dedicated to synthetic biology, especially the iGEM conferences. It is also important that at such meetings, responsibility is taught and accepted within the community of synthetic biology. As experts in the field, the teaching and application of safe practices will lead to public trust.

Conclusion

As synthetic biology evolves, public perception will greatly influence the destination of the science. A major concern of the United States public is bioterrorism introduced with increasingly efficient biological engineering technology. To address this concern four possible steps were suggested. These steps can be used as initial steps to hear and integrate public concerns.



References

Atlas, R. M. (2009). Responsible Conduct by Life Scientists in an Age of Terrorism. *Science and Engineering Ethics*, 15(3). 263-269.

Atlas, R. (2005). Ensuring biosecurity and biosafety through biopolicy mechanisms: Addressing threats of bioterrorism and biowarfare. *Asian Biotechnology and Development Rev*, 8, 121–137.

BioBricks Foundation. bbf.openwetware.org. Accessed 2009, September 10.

Cello, J., Paul, A. V., & Wimmer, E. (2002). Chemical synthesis of poliovirus cDNA: Generation of infectious virus in the absence of natural template. Science, 297, 1016–1018.

Endy, Drew: (2008) Defining Synthetic Biology. Video posted to http://2009.igem.org/Instructional_Videos, accessed 9/1/09.

Garfinkel, M., Endy, D., Epstein, G. L., & Friedman, R. M. (2007) *Synthetic Genomics – Options for Governance*. Retrieved from http://www.synbioproject.org/topics/synbio101/bibliography/governance/

Hart Research, (2009) *Nanotechnology, Synthetic Biology, & Public Opinion: What does the public think?*. Retrieved from http://www.synbioproject.org/events/archive/6380/

Kahan, Dan M., Braman, Donald and Mandel, Gregory N., Risk and Culture: Is Synthetic Biology Different? (February 20, 2009). Harvard Law School Program on Risk Regulation Research Paper No. 09-2; Yale Law School, Public Law Working Paper No. 190. Available at SSRN: http://ssrn.com/abstract=1347165

Kurzweil, R., & Joy, B. (2005, October 17). Recipe for destruction. New York Times, p. A23.

Marchant, G. E., Pope, L. L. (2009). The Problems with Forbidding Science. *Science and Engineering Ethics*, 15(3). 375-394.

Maurer et. al., (2006). From Understanding to Action: Community-BasedOptions for Improving Safety and Security in Synthetic Retrieved from http://gspp.berkeley.edu/iths/UC%20White%20Paper.pdf

Parens et al. (2009). *Ethical Issues in Synthetic Biology: An overview of the debates.* Retrieved from

http://www.synbioproject.org/library/publications/archive/synbio3/



Pauwels, E., Ifrim, I. (2008). *Trends in American and European Press Coverage of Synthetic Biology*. Retrieved from http://www.synbioproject.org/library/publications/archive/why_scientists_should care/

Rejeski, D. (2009a). Foreword-New Life Old Bottles: Regulating First-Generation Products of Synthetic Biology. Retrieved from http://www.synbioproject.org/library/publications/archive/synbio2/

Rejeski, D. (2009b). *Public Perceptions on the Technological Frontier.* Given at National Academy of Sciences July 10, 2009. Audio Retrieved from http://www.synbioproject.org/process/assets/files/6372/_draft/rejeski.ppt#268,1

International Risk Governance Council (2008). *Synthetic Biology: Risks and opportunities of an emerging field.* Retrieved from http://www.irgc.org/IMG/pdf/IRGC_ConceptNote_SyntheticBiology_Final_30April.pdf

Rodemeyer, M. (2009). *New Life Old Bottles: Regulating First-Generation Products of Synthetic Biology*. Retrieved from http://www.synbioproject.org/library/publications/archive/synbio2/

Tumpey, T. M., et al. (2005). Characterization of the reconstructed 1918 Spanish influenza pandemic virus. Science, 310, 77–80.

Vergano, D. (2009, August 30) 'Synthetic Biology' holds promise, but doubts simmer. *USA Today* Retrieved from http://usatoday.com/news/health/2009-08-30-synthetic-biology_N.htm

Wimmer, E., (2006). The test-tube synthesis of a chemical called poliovirus. EMBO Reports, 7, S3–S9.

Zilinskas, R., (2006). *Technical Barriers to Successful Biological Attacks with Synthetic Organisms, Security and Regulation of Experiments of Concern.* Retrieved from http://www.synbioproject.org/topics/synbio101/bibliography/governance/



Second Place -

Development of a Cohesive Strategy to Effectively Incorporate the Concerns of the Public into the Development of Synthetic Biology

Kirsten Sims - Utah State University, Graduate

In the year 1918, the world witnessed what some medical historians have called "the greatest medical holocaust in history," when nearly 100 million people were killed by an unusually virulent Influenza A virus- The Spanish Flu (Yen & Webster, 2009). In one year, the average life expectancy in the United States dropped by 12 years (Balmer & Martin, 2008). Less than a century later, a team of scientists published a paper in *Science* announcing that they had successfully rebuilt the virus that had once killed nearly 5% of the global population (Tumpey et al. 2005). Craig Venter, considered a genome pioneer, described this development as "the first true Jurassic Park scenario" (Balmer & Martin, 2008) when detailing the danger of such a development and the potential for great destruction at the hands of an emerging discipline- Synthetic Biology.

The purpose of this essay is to address the challenges associated with creating an interface between the field of Synthetic Biology and the general public. In order to develop an effective interface, the scope of Synthetic Biology must be addressed and its potential impact in the lives of individuals should be identified. We must then address some major concerns that have been raised by the public in order develop a comprehensive list of major ethical issues and potential dangerous scenarios that face the Synthetic Biology community. Finally, we must decide which organizations should share the responsibility of addressing these concerns and developing strategies to integrate the concerns of the public into Synthetic Biology.



1. Synthetic Biology- Goals and Potential Impacts

The goal of Synthetic Biology is to advance the fundamental knowledge of biological systems, and to develop efficient biology-based technologies that will lead to the development of products made from microorganisms (Benner & Sismour, 2005). The foundation of these processes is in recombinant DNA technologies and is based upon our ability to manipulate organisms by using interchangeable biological parts.

Technologies produced from Synthetic Biology include alternative fuels, biomedical products, diagnostic tools, and molecular-detection devices. Synthetic Biology is similar to other engineering disciplines in its efforts to understand its subject matter, make discoveries, and to overturn paradigms. As biological engineers, we have a responsibility to pursue the development of technologies that serve to enhance the quality of life of individuals. Therefore, it is absolutely necessary to incorporate the concerns of the public, whom we serve, into the development of the field of Synthetic Biology.

In order to begin developing a strategy to address the concerns of the public, we must gauge public familiarity with Synthetic Biology. A groundbreaking poll conducted by Peter D. Hart Research Associates found that although the public had very little awareness concerning the nature of Synthetic Biology, a strong majority think research in Synthetic Biology should be regulated by the federal government. The poll also found that public awareness of Synthetic Biology is increasing rapidly. The proportion of adults who say they have heard a lot or some about Synthetic Biology more than doubled in 2008 - from 9 to 22 percent. (Hart Research Associates, 2009)

2. <u>Classifying Major Ethical and Safety Concerns in the Field of Synthetic Biology</u>

It is important that the community of Synthetic Biology commit to teaching and practicing responsible methods and attitudes. We should not be afraid to imagine worst-case scenarios, and then work to prevent them. I will address here a few major concerns facing Synthetic Biology, however, the development of a complete list of concerns is beyond the scope of this essay.

- *Uncontrolled Release:* When seeking to create artificial chemical systems that behave according to Darwinian processes, we must consider the possibility that these artificial systems might cause damage if released from the laboratory. Biological organisms are essentially evolutionary machines, capable of gene flow. If accidentally released a prediction of exactly how mutations in a genome of a synthetically derived organism will interact with the environment is impossible.



- *Bioterrorism:* A Central Intelligence Agency report from 2003 presented a dark picture of the potential devastation should bioweapons be developed. The genomic revolution and pace with which Synthetic Biology is evolving makes traditional monitoring methods often inadequate (CIA, 2003).
- Creating Artificial Life: The term "Synthetic Biology" has been used with reference to efforts to recreate in unnatural chemical systems the emergent properties of living systems including inheritance, genetics and evolution. (Banner & Sismour, 2005). This naturally gives rise to a host of philosophical and religious discussions about "playing God" and the role of humans in manipulating biological systems.

3. Development of a cohesive strategy to address public concerns

The responsibility of addressing the concerns of the public should be shared primarily by the following three bodies: The scientific community, the government, and the media. As awareness of synthetic biology increases, the scientific community has seen a call for an "Asilomar for Synthetic Biology"- a reference to a conference in Monterey in 1975 that considered the public hazards of the recombinant DNA technology (Tucker & Zilinskas, 2006). The scientific community must establish a forum in which scientists can meet to discuss their concerns, such as the 1975 conference. In these forums, they should work to develop a distinct code of ethics to guide the development of the field of Synthetic Biology and encourage public input into the development of safety guidelines.

Synthetic Biologists must integrate "ethics" sessions into international conferences and encourage ethical debate in Synthetic Biology peer-reviewed journals. These debates should address both philosophical and practical applications of Synthetic Biology. Professional organizations (such as IBE) should publicly declare their commitment to education and to the development of safe practices in the scientific community.

Regarding the role of government, in response to the 1975 Asilomar conference, the National Institutes of Health established a Recombinant DNA Advisory Committee to develop biosafety guidelines and a process for institutional oversight that applies to NIH-funded research (Tucker & Zilinskas, 2006). The federal government should continue to develop a close working relationship with the scientific community and should establish an evolving system for risk-assessment that can be monitored by the public. The government must also encourage input from the public through the development of ethics panels that are composed of individuals with relevant backgrounds.

The government should also raise awareness within the scientific community of the potential military uses of certain biological technologies and encourage



members to be aware of misuse of those technologies. Government intelligence bodies should incorporate screening of genetic sequences that are being developed and sold by oligo companies in order to monitor ambiguous activities and to avoid the development of bio-weapons.

The media also plays a significant role in serving as an interface between the scientific community and the public. Journalists should become well versed in the technical field in which they are writing and should work to create forums in which the public can discuss their concerns about Synthetic Biology.

Conclusion:

Synthetic Biology is a discipline unique among other existing engineering fields and public awareness is rapidly increasing. Synthetic Biologists have set ambitious goals that will deepen our understanding of the intimate relationship between life at the molecular level and the emergent properties that drive the development of complex biological systems. In this pursuit of knowledge, however, we must recognize the potential dangers that these technologies hold and allow the Synthetic Biology community to be governed by a set of ethical, educational and communication guidelines that best incorporate the concerns of the public.

References:

Balmer, A., Martin, P. *Synthetic Biology Social and Ethical Challenges.* Biotechnology and Biological Sciences Research Council, May, 2008.

Benner, S.A., Sismour, A.M. Synthetic Biology. Nature Reviews Genetics 6, 533-543:

July, 2005

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Central Intelligence Agency. *The Darker Bioweapons Future* prepared by Office of Transnational Issues. November, 2003.

Hart Research Associates. *Nanotechnology, Synthetic Biology, & Public Opinion- A Report Of Findings*. Conucted on Behalf of Project on Emerging Nanotechnologies and The Woodrow Wilson International Center for Scholars. September 22, 2009.

Tucker, J.B., Zilinskas, R.A. *The Promise and Perils of Synthetic Biology.* The New Atlantas, 25-46: Spring 2006

Tumpey, T.M., Basler, C.F., Aguilar, P.V., Zeng, H., Solozano, A., Swayne, D.E., Cox, N.J., Katz, J.M., Taubenberger, J.K., Palese, P., Garcia-Sastre, A. Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus. Science 310, 77-80: 2005.

Yen, H.L., Webster, R.G. *Pandemic influenza as a current threat.* Curr Top Microbiol Immunol. **333,** 3-24: 2009

Third Place -

Bioethics Essay: Addressing Public Concerns about Synthetic Biology

Miranda Joelle Hagen - University of Maryland, Undergraduate

Synthetic biology can be defined as the design and construction of new biological parts, devices, and systems, and the re-design of existing, natural biological systems for useful purposes (syntheticbiology.org). This definition alone hints at the ethical implications of this up and coming field. How can one hope to design biological systems and essentially create life without a sparking a debate about social and moral concerns? Some ethicists would even go so far as to call synthetic biologists out for "playing God" and interfering with the natural system. Although it can be safely assumed that the majority of people would not be so brazen in their attack on the field of synthetic biology, most of the general public would have some serious concerns about the safety and ethics of constructing novel biological materials from scratch. Their concerns are not trivial and they need to be recognized by the scientific community and integrated into the future of this rapidly advancing field.

The first step on the path to accord between the biologists and the public is for the general concerns to be heard and acknowledged by the individuals with the highest ranks in the synthetic biology community. All over the world, laboratories are making great leaps in knowledge and experience, but none of it has significance unless there is public support for the findings. A parallel can be drawn between synthetic biology and stem cell research; they both have potentially monumental contributions to science and health in general, but will require public approval in order to move forward and benefit the greater good. Stem cell research has become stuck behind an ethical block that it has yet to surmount and the public unease has cast a negative light on the field as a whole. Researchers and scientists can see the gains that could be made if stem cell research was allowed to flourish, however moral and ethical concerns must be addressed before the field can advance. It would be a shame for synthetic biology to fall into the same trap that stem cell research has and therefore recognition of safety concerns is necessary for progression.

The public deserves to be kept aware of the discoveries made by the scientific community in order to learn about something that greatly affects them and to form an opinion about the research. Many times, negative reviews stem from the public being naive about the process and therefore suspicious of it, as anyone is suspicious of things that they don't understand. There should be no gray areas in synthetic biology which could lead to skepticism and criticism. The research needs



to be widely available and needs to contain thorough descriptions of how it could influence the world, both positively and negatively, as well as understandable methods and detailed descriptions of the results and unbiased analysis. A well-informed public will prevent some of the concerns about safety and ethics, since the people will know exactly what is going on, and they will not make judgments based on hearsay or rumors. This type of information sharing will at least eliminate the concerns which are based upon ignorance of the topic and old-fashioned beliefs. Only sound, well-researched concerns will be left for the ethicists to debate about and produce solutions to.

Bioethicists have been keeping a keen eye on synthetic biology ever since the field began to emerge and it became clear that we are not too far away from creating novels forms of life. In his essay, "The Wide Angle: Do Synthetic Biologists Play God?" Arthur Caplan states:

The possibility that humans can create life, either from pre-existing organic parts or from inorganic materials, has been the subject of considerable cultural worry and commentary from Mary Shelley's Frankenstein to Gene Roddenberry's creation of the android Data in Star Trek. While no one will be making living people from scratch anytime soon, the idea that humans can create even primitive life forms seems to some to cross a moral line.

One of the main arguments against synthetic biology is that creating life is the work of a higher power and that fundamental religious tenets will become obsolete if humans are given the power to create life from nonliving things. This concern must be addressed by the leading ethicists and care must be taken to confront the issue directly, not skirt around it and make false promises about future steps that will be taken. The public needs to be aware that the leaders in the field of synthetic biology are not taking the ethical implications of their work lightly. Scientists are not cavalier about their creations, nor are they simply screwing around and playing with the power that they have been granted. Research is taken very seriously and organisms are being created for research purposes: to advance medical discoveries, to develop solutions to crippling diseases, to progress toward knowledge about the world around us, both where we came from and where we're going. It would be unfair to accuse a serious synthetic biologist of playing God because first and foremost you are accusing him of "playing" which discredits the gravity of the potential advances that the biologist makes by performing their research every day.

One way to hear and integrate the public's concerns about synthetic biology is to educate the public so that their concerns become more relevant. As previously stated, people with a better base of knowledge about the topic are less likely to be opposed to the idea, simply because they are familiar with it and therefore more comfortable with the field. However, some concerns are not born of ignorance and instead are born of genuine apprehension about a particular aspect of synthetic biology. These concerns can be heard and recognized by giving the public many forums through which they can express their trepidation. Leading experts in the field can answer concerns or clarify any research that was sparking debate.

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Sometimes, the concern might be caused by a simple error in communication. Otherwise, if the concern is about a serious issue within the field, the synthetic biologists have an obligation to address the issue before furthering research in that particular area.

Solutions can be integrated by having debates about the ethics of the issue and coming to a reasonable conclusion which satisfies the needs of both sides. Science cannot progress without being in constant scrutiny from the public. A system of checks needs to be in place to limit the research to only relevant topics and ethical processes. But also, the public must realize that all science cannot and will not be without scruples. There must come a time when the ethicists and the scientists reach a consensus about what is acceptable, and progress can be made toward improving life as a whole by whatever means necessary, even if that includes creating novel life forms out of nonliving material. Synthetic biology is the next crucial step for biology and engineering and therefore the public's concerns play a key role in getting research off the ground and heading toward a future where natural systems can be harnessed and re-designed for useful, perhaps lifesaving purposes.

References:

Caplan, Arthur. "The Wide Angle: Do Synthetic Biologists Play God?" *Discovery Channel: Science, History, Space, Tech, Sharks, News.* Discovery Channel, 3 Aug. 2009. Web. 12 Oct. 2009. http://dsc.discovery.com/technology/my-take/synthetic-biology-caplan.html

"FAQ." *Synthetic Biology*. Web. 12 Oct. 2009. http://syntheticbiology.org/FAQ.html.

