Workshop Notes on Synthetic Biology and Engineering Ethics

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Description

This page includes notes from a workshop held at the National Academy of Engineering on September 30th 2010. The workshop posed the question “How can engineering ethics contribute to the positive potential of the new field of synthetic biology?” It brought together synthetic biology researchers and experts in engineering ethics and science and technology studies (STS), to examine how research and educational activities can help to achieve those positive goals.

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Introduction

On September 29-30, 2010, a small interdisciplinary group of eight scientists, engineers, social scientists, historians and philosophers[1] met at the Keck Building of the National Academy of Engineering to discuss whether and how engineering ethics might contribute to the development of synthetic biology. Notes from the meeting below identify issues and comments that, in my opinion, deserve further consideration. They are not inclusive and do not represent a summary of the discussion; they do not present any consensus opinions from the participants, nor have they received external review.

Using synthetic biology, scientists hope to circumvent the difficulties that very complex naturally occurring biological systems pose to controlling their activities. By building biological systems from the ground up, they hope to create entities that will function like computers or factories, producing the desired products at the times and in the amounts we want. While such industrial analogies do not appropriately capture the "living" element of synthetic biology, they do exemplify the field's central goal: to make biology easier to engineer, and to make products that will be safer than those possible through manipulation of naturally occurring systems.

Some argue that the involvement of several non-biological scientific and engineering disciplines is what clearly distinguishes synthetic biology from genetic engineering and 'classical biology'. Others describe genetic engineering as one of the tools of synthetic biology. However it is characterized, insofar as synthetic biology involves the manipulation and transfer of genes, it is intimately related to genetic engineering. Commercial gene synthesis companies are now able to manufacture virtually any DNA, built-to order. Synthetic biologists can type a particular sequence into an Internet order form and in a week or two the DNA arrives by mail. This advance effectively "black boxes" the DNA manufacturing process, by masking much of its complexity. The synthetic biologists use computer modeling, the building of de novo proteins, and bioinformatics to predict and analyze the products; their aims are to create systems that are not only less messy or complex than naturally occurring ones but also more efficient at producing the desired products.

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Day 1: Evening, September 29, 2010

The evening session identified several conundrums:

The engineers present did not recall any significant exposure to engineering ethics. Kristala Jones Prather noted that using one package of on-line engineering ethics assistance for students or faculty members attempting to be responsive to NSF requirements seemed to require 17 hours of work. From her perspective, that was not reasonable. Other participants noted a standard deficiency in such packages: the lack of opportunities for discussion and group engagement. They indicated that the questions go beyond honesty in engineering, to issues about the influence of engineering in society. Students are interested in these issues, but faculty members, busy with research, etc., are generally not. They added that, while several schools have programs that are responsive to these needs, such programs are by no means wide-spread. Some participants indicated that ABET "engineering and society" requirements have made a difference at the undergraduate level, and more might be made of its recognition.

Enthusiasm from faculty members is a requirement for engaging student interest, several noted, and enthusiasm may require the inclusion of ethics and policy questions in the synthetic biology/engineering curriculum, rather than as an add-on. Several indicated that historical and cross-cultural approaches can help students recognize how ethical concepts and perceptions change in time and place, and the role of politics or national priorities in relationship to new scientific and technological developments. Some identified a few academic institutions that do take an inclusive approach: Texas A&M and University of Virginia-Charlottesville are examples.

Questions arose about the meaning of ethics as well as the meaning of synthetic biology, which takes different forms in different departments in different schools. Several participants saw need for collaborations between scientists and ethicists, and asked how institutions could be encouraged to develop them – both academic and industrial. Industry views ethics as a component of hires that have passion about making the world a better place, but doesn't appear to single out ethics in hiring.

Overall, participants indicated the need to help people grapple with differences of language, culture, and history that exist between different fields and communities. Even in engineering courses, engineering can be hard to define, and biologists and engineers have very different views about the domain of synthetic biology. But it’s not too soon to evince concern as synthetic biology has reached the stage of product development for civilian and military purposes.

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Day 2: September 30, 2010

The introductory session identified further concerns as well as positions:

In general discussion, individual participants made the following points: One needs to distinguish getting the right things done and getting things done right. Issues of safety are especially sensitive where living organisms are under development. Ethics also raises questions, when it becomes a tool of experts to manage dissent and controversy in ways that may not satisfy public fears or reflect public ethics.

Biologists find the term synthetic biology controversial. Engineers have moved from chemical engineering to metabolic engineering to the nomenclature of synthetic biology. It could be called bioengineering, but that term is viewed as nearly synonymous with biomedical engineering; environmental engineering is also too general. Some synthetic biologists want to manage or reprogram microorganisms for service to society in environmentally and socially responsible ways. This needs education in ethics, as well as public discussion.

Ethics can be defined as reflection on what it means to be human, on what kind of life to lead? At its core, ethics means normativity, ought questions, recognition that moving from “is” to “ought” is problematic. Should ethics be viewed as science or as language, terms, concepts that create world views? Ethics presumes a shared rationale or rationality for thinking about behaviors, and looks for universality. Often morality may be used as a term describing implicit albeit general norms, where ethics may be explicit and involve particular standards, as in professional ethics.

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Presentation 1: Mariachiara Tallacchini

In the first workshop presentation, Mariachiara Tallacchini took the position that the introduction of new knowledge and technologies in synthetic biology, as in other sciences and engineering, also conveys a normative vision of what should get done and how. Synthetic biology supports a mechanistic interpretation of biological processes, which can influence views of risk control and containment and reinforce rather than critique problematic concepts such as substantial equivalence. Critical views questioning these normative assumptions are thus needed.

Similarly she noted the prevalent design of ethics and bioethics incorporates rather individualistic models of social relationships; in her view, this orientation now prevents rather than helps thinking about new technologies. Reflection about issues of responsibility surrounding synthetic biology requires new ways of connecting and harmonizing individuals and society in the presence of conflicts among individual and collective rights regarding public health and safety. In thinking about ethics, she said, we should discuss who is entitled or privileged to make the choices. There is danger in assigning the framing and understanding of ethics and values primarily to experts, outsourcing these matters from the political domain. The result may be, for instance, to limit the ethics discourse to a priority to improve competitiveness – marketing this position to the polity and fragmenting ethical discourse. Moreover, the executive usually appoints expert ethics bodies which then answer to that source rather than the legislative power supposedly representing citizens. Ethics is especially challenging in the European Union, where ethics is governed by the principle of subsidiarity and does not represent European citizens' values, but instead national governments' ethical views.

Tallacchini hopes that the US Bioethics Commission, whose composition seems to endorse a strong commitment to democracy, may help restore ethics to its broader domain. In defining the challenges, she believes we need interdisciplinary research and conversation; ethics becomes a critical practice rather than training. The goal is to expand imagination, extend peer-review, and consider how the ethics of engineering epistemologies have historically evolved. Can foresight exercises or anticipation by systematic thinking be integrated with and complemented by ethics and participatory exercises? This integration might enable broader consideration of the social dimensions of new technologies.

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Presentation 2: Kristala Jones Prather

The second presentation, by Kristala Jones Prather picked up from her comments of the preceding evening about educating synthetic biologists/engineers. In engineering, ethics is often thought of as synonymous with honesty, while biologists have looked at broader questions. There is a cadre of professionals in engineering outside of medical fields who don't think about these issues. If we think about educational change using the metaphor of fleet turnover, we may see that change incorporating ethics may take considerable time. Many faculty members are not enthusiastic. Engineering the biology and technology are considered to be benign; containment, possible. So let society decide whether to implement these "cool" new possibilities in DIY (do-it-yourself) biology. Any problems of whether results can be disconnected from the power source can be set aside in favor of the potential use for humanity. This view isolates "coolness" from professionalism – tinkerers become "competent" engineers without that link.

The question and answer period that followed the presentations raised many issues; its fragmentation seemed to mirror the fragmentation of the field.

What is synthetic biology and how does it map into educating engineers or biologists who do it? Engineers moving into biology bring their own language and approaches and metaphors. There is a need for multiple expertise; however, outsourcing ethics may not be good; there is need to reintegrate, but where and how? Synthetic biology is a research field. The relationship to undergraduate education is not clear. There is no core curriculum. Is it a new discipline? A new framework? From what domains of professional ethics can it draw? Biomedical ethics? Engineering ethics? Can decisions be left to the market versus informed consent – engineering as social experimentation?

Several participants indicated that examining the history of the professions of biology and engineering would be useful for understanding how each approaches ethical questions. The notion that moral responsibility is shared is useful for teaching and considering complicated questions about risk and responsibility/liability. The role of scale and context in changing the ethical questions needs attention. Institutional review boards (IRB) and informed consent are available for medical experiments. In other settings possibilities are public consultations, deliberative democracy, the upstream engagement of public in research, concern for non-human implications.

Who is responsible for safety of devices? More than honesty, competence is involved. What's DNA and how does it work? Synthetic biology creates a challenge to competency. The role of uncertainty is higher. Engineers don't quite get it – and the need for controls is different too. Working on one piece – who knows how pieces fit together? Communication and accountability have increased importance. There is some literature to draw from; it seems that a typology and overview might be useful as a starting point.

One important question is how will ethics translate into the industrial setting? Via the firm's chief integrity officer? There is the problem of many hands. Is it a question of responsibility or liability, regulation, and insurance managing risk – the social engineering of responsibility that can bring collective competence and spread ethics?

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Discussion Questions

In further discussion that followed, participants provided their perspectives on how engineering ethics might assist synthetic biologists. Four sets of questions framed the discussion. While they are identified below, the discussion during each session ranged broadly over many of the topics.

Session I: Can engineering ethics provide useful assistance to the field of synthetic biology? What ideas and activities can help synthetic biology to develop socially responsible research directions and applications? What individuals and organizations need to be involved, and what can or should they do?

Session II: How can biologists and engineers involved in synthetic biology be prepared better to identify and address ethical issues in a timely and effective fashion?

Session III: What individuals and organizations should be involved in developing, and in setting standards for, ethical training in synthetic biology and developing and integrating ethics into research and development?

Session IV: What research and teaching activities (for example, teaching modules and/or new curricula) as well as what materials focused on ethical issues in synthetic biology should be developed for the training of engineers involved in synthetic biology? Who should develop these teaching support and materials?

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General Discussion

Carl Mitcham emphasized the relationship between professional and human responsibility, noting that science, engineering and technology are transforming the human condition. Professional ethics must remember that hard power drives out soft power, and Mitcham suggested that religious traditions might provide a way to broaden the discourse and recognize the tension between goodness and truth, about which the Catholic Pope recently spoke. Broadening the spectrum of involved individuals and organizations is important. He and several others suggested embedding social scientists with engineers/synthetic biologists in lab-scale interventions that can promote discussion and re-evaluation, and opportunities for public involvement.

Mariachiara Tallacchini noted that the lack of a “home” for synthetic biology may provide engineering ethics the opportunity to reflect on its own premises (traditions, professional culture) and whether it is still useful? She noted that beginners are open to possibilities and exposure to other cultures.

Kris Prather reminded the participants that collaborative activities are needed to create a framework for change. Change will not happen by tossing it over the fence. For instance, some people might be helped by publishing outside their field or primary journal but others would be hurt. Leaders must be involved to protect junior faculty and individuals and organizations with stature need to give approval if juniors are to be protected. Nonetheless, she recommended that concerned faculty not postpone involvement because of tenure issues, since habits develop that are difficult to change. Initiative develops at the grass roots and deserves help.

Michael Loui stressed the foundations of professional ethics in engineering as also foundational in synthetic biology for engineers. Fundamental to the professions is service for the public good. Professionalism involves standards for competence and responsibilities, for scholarship and ways of inquiry. It emphasizes meeting obligations via codes and standards. Loui used an example involving product safety for travel cribs: The Playskool Travel-Lite Crib Case. In this case, the manufacturer declared that this new product met all existing standards for safety testing because there were no standards for testing. This case illustrates the general principle that to fulfill professional responsibility for the safety of the public, engineers should not merely comply with existing standards, but should sometimes go beyond legal requirements. When technical standards do not exist, engineers should use their judgment to devise appropriate procedures to promote safety. For example, for a new kind of product, they could adapt extant testing standards from similar previous products, as Prather mentioned that she had used existing standards for recombinant DNA research in setting up guidelines for research with the new synthetic biology technology.

Engineers should also be responsible for their creations through ongoing monitoring of any potential harm. One can examine the NRC report *On Being A Scientist* for examples. The Association for Practical and Professional Ethics is a good source for information and networking.

Brian Pfleger stressed the need for help for junior faculty. Engineering students are computational and focused; they lose sight of social impacts. They need help in conceiving ends and outcomes from engineering ethics. Faculty members need ideas for increasing student awareness of ethical problems. Embedding ethical questions in other activities such as undergraduate engineering competitions is great and might help get established leadership involved. A structure for testing is needed.

Deborah Johnson asked whether synthetic biology, which is still in the making, would benefit from developing a professional association. The synthetic biologists who were present at the meeting wondered whether it could get off the ground at this stage of the development of the field. Perhaps scientists and engineers might be attracted to a contest like that of the NAE Grand Challenges. An association would provide the possibility of long term memory.

James Kealey suggested the development of healthy dialogue between academia and industry to identify areas (buckets) of societal concern. How might ethical training be brought to industry? Via new hires, if educated. Sustainable development can be recognized as ethics – waste management of plastic disposables, hazards; educational component; consulting for ethics sensitivity among executives and board members. Ask them what wouldn’t you do for money? What are your social concerns? What are the important ends for the firm?

Bruce Rittmann talked of the need for quantitative and practical examples. Think about mass/energy balances. Example: can throw away test-tubes, but not a large-scale reactor. What are the long term big picture implications that we don't think about? An example: renewable carbon products – energy feed stocks. Individuals and organizations need to be involved in long term collaborative relationships where they learn each others' languages. We want organizations to do what's not in their short-term self-interest – a large challenge.

General discussion recognized that the concept of synthetic biology raises public fears, at least as indicated by focus group outcomes. Can fear be a motivating factor to develop scientific citizenship? The issue of "garage biology" or extra-institutional research practice in synthetic biology raises an interesting challenge for engineering ethics – synthetic biologists can be guns for hire or professionals; the latter are interested in ends, while the former have short term goals and emphasize doing something that's "cool."

Several participants examined the merits of early warning systems about issues of ethics and society that might be identified through embedding social scientists or ethicists in laboratories. This could start even in undergraduate education. It could develop in industry; it might bring people of different backgrounds together to develop new sustainable products in sustainable ways. It could emphasize a process to enhance ethical discourse about synthetic biology, involve scenario development, looking at various futures, and promote sensitivities.

Synthetic biology is looking for criteria to bring to bear on plans for new products, processes. It sees value in raising issues. In this way, it can contribute to the development of engineering ethics, which has been backward looking and micro in focusing on ethical problems for individual engineers, rather than macro-oriented or focused on technology and society. Who has examined the potential for positive futures involving various technologies? What scenarios would stimulate ethical discussion? Several museums of science and technology are having these conversations. How do we identify important problems accurately in advance? Scenarios can be misleading, and overlook significant possibilities for change – e.g., cell phone technologies. An interesting book is Allen Mazur's *True Warnings & False Alarms*. Are there criteria by which they can be separated? Participants recognized that defining a problem adequately, so as to recognize positive and negative potentials, is a major issue. For example, alternatives to fossil fuels will occupy much space – a large and general problem. Futures are likely to be very different from the past, so how to prepare is an important question. Individual participants suggested the need to ask what futures are desirable, stress two way or multi-directional communication, and take care not to over-promise. Acknowledge risk and uncertainty.

Another theme of discussion concerned issues of control. Outsiders may view synthetic biology as tampering with life, and this fear may get mixed with others. On the other hand, insiders may take the view that control is not a problem. These differences may reflect fundamental risk attitudes, and some insiders and outsiders will fall at different places in the continuum. Hubris would be thinking you are in control when you aren't. What do you say to someone who doesn't care? Who believes all risks can be annulled or mitigated? Evolution is not a common concept in engineering, and evolutionary risk may not rise to consciousness. At the time of the Asilomar conference, when biologists met to consider risks of recombinant DNA work, they shared a social context. This is no longer true. The influence of the virtual world and private interests pose additional risks and uncertainties.

Non-physical harms are not attended to in engineering ethics. Engineers and their societies have well established criteria to consider physical harms. But many people are concerned about non-physical harms. Perhaps computer science and engineering have attended to these factors more explicitly – issues of what it means to be human and of the distribution of benefits and harms. Ethics, noted several participants, gives priority to raising questions, not providing solutions. Solutions can come through the law and democratic practice; ethics and law and democracy need institutional organization and support.

Towards the final rounds of discussion, participants noted that guidelines or standards in ethics are unlike standards in the engineering sense. Ethics guidelines or standards provide general guidance, not specific or performance standards. Synthetic biologists and biology might benefit from a code of ethics, developed jointly with other relevant engineering or biology societies. The NRC might bring together scientists and engineers, perhaps representing appropriate professional societies, to identify applicable ethics guidelines. An international component might be useful in this exercise.

There are significant differences among the engineers and biologists about whether or not this is a new or coherent field. There is a need then to get both groups together to identify and address ethical issues and help to develop and set standards for ethical training/education. Concerns raised by “do-it-yourself” biology and the role of industry (in risk management and bio-safety matters) need addressing too.

A starting point is to look at existing guidelines and the issues that new kinds of research or technology raise, said Michael Loui. One can find similar cases – analogous issues posed by new products. A good example is the engineering ethics case that focuses on the development of traveling crib cases – what does due care require? Do engineering ethics codes address adequately the need for additional testing of innovative products?

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Developing Educational Materials

On the issue of developing materials for use in educational activities, Carl Mitcham raised the question of what can those in engineering ethics learn from synthetic biology? Might there be important reverberative effects on engineering? Such materials and findings would be useful on the NAE on-line ethics website. Brian Pfleger suggested that materials there might include relevant policy forum articles from Science, and perhaps even appropriate technical reports.

Michael Loui indicated that context matters. Teachers must do things differently in a large lecture class vs. a small discussion seminar. In any case, “drive by” ethics has little effect. The goal from a lecture course may be to improve students’ ability to identify ethical issues. To go beyond to improve reasoning and methods to resolve issues interaction is needed. Cases and role plays can work, and the literature about learning applies here.

Carl Mitcham suggested that team teaching can work well, particularly when faculty members develop relationships over time. In his classes, students have to write a personal ethics code, with justifications; and examine both code and justifications. People in industry might do the same, and examine them in light of the core values of the corporation.

Cases are a tried and true method that seems to work. An issue of containment failure is one suggestion. A class might start with an historical recombinant DNA case and outcome, and ask about its implications for synthetic biology. Historical cases include GMO corn, which has contemporary follow-on examples; or the FDA and Atlantic salmon. Other examples brought up: asbestos and prions as cases where warnings were disregarded or came too late. Individuals suggested the following sorts of cases: dealing with uncertainty; social learning and unlearning (forgetting); security and dual use problems, e.g., weaponizing a bacterium; distinguishing chance from intentionality; identifying analogous examples. FAS material includes the case of the synthetic polio virus. Positive cases are important; several participants noted the case of the development and dissemination of artemisinin (an anti-malarial therapeutic developed using synthetic biology techniques; see www.amyrisbiotech.com/markets/artemisinin). It raises issues of adequate testing, substantial equivalence, the role of philanthropy and that of cost-benefit analysis, and monitoring after deployment. Another case for discussion would be the development of bio-brick standards. Many of these examples have international and cross-cultural dimensions.

The participants indicated that the bibliography for the workshop – particularly the priority readings - provided good materials for faculty to use in teaching ethics and synthetic biology. The report to come from the US Bioethics Commission might provide another useful source. Collection and analysis of media articles and interviews also provide material that interests students.

Teachers need to be thinking about the outcomes or lessons they want students to absorb. Underlying them are needed a basic vocabulary and typology and recognition of different views. Background papers could be usefully posted in OEC Resources.

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Dissemination

In the final session, individual participants identified some dissemination mechanisms and channels. Several gave priority to getting materials into industrial settings. The Industry Fellows Forum is one channel, which may also reach some DIY communities. In commerce the difficulties of communication between researchers and sales is recognized; more attention to these differences (such as managing chronic illness vs. cure; the need for new antibiotics that don’t get funded because they won’t be blockbusters) and how to overcome them might pay off.

Several endorsed the idea of embedding post-docs in various labs; they could meet once a month to help sort out issues in the field. Such a project needn't be expensive and it could help shape synthetic biology ethics in academia and industry. For the development of course materials, it would be crucial to involve a collaborative team with social science and humanities as well as synthetic biology expertise. Other ideas included panels and sessions at professional meetings such as APPE, AAAS, ASEE, ACS, AIChE. The AAAS R&D forum could hold a session and have industry and university commentators. National centers undertaking relevant research with federal agency support should be involved.

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Rights

Discipline(s)

Synthetic Biology
Engineering