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INSTITUT DE RECHERCHE SUR LA SCIENCE, LA SOCIÉTÉ ET LA POLITIQUE PUBLIQUE

INSTITUTE FOR SCIENCE, SOCIETY AND POLICY

CONFERENCE PROCEEDINGS

2012

Synthetic Biology at the Interface of Science and Policy

Summary of the proceedings of the conference "Synthetic Biology at the Interface of Science and Policy", held at the University of Ottawa September 30, 2011

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Executive Summary

The Issue

On May 20, 2010, the J. Craig Venter Institute announced the creation of the "first self-replicating synthetic cell". This announcement was accompanied by a publication in the journal *Science* and was followed by international media attention. The development of this technology prompts several key questions that deserve the attention of academics and policymakers internationally:

- How might this technology be taken as the beginning of a new industrial revolution?
- What might be the consequences of this technology, and who might be its beneficiaries and risk-bearers?
- To what extent is synthetic biology the first breakthrough technology that follows in-depth ethical analysis and debate, and have the analysis and debate been sufficient?
- Can policymakers and regulators keep up with future technological developments in the field, and what tools would be helpful to them to improve their abilities to keep up?

On September 30, 2011, the University of Ottawa's Institute for Science, Society and Policy (ISSP) hosted *Synthetic Biology at the Interface of Science and Policy* in order to promote a discussion of these questions. As part of the 24th annual conference of Les Entretiens du Centre Jacques Cartier, this one-day event brought together experts from academia, industry and government to discuss the science of synthetic biology as well as its legal, ethical, social, economic and political implications. The colloquium involved supporters and critics of this new technology. The event was held in English with simultaneous French interpretation.

The Science of Synthetic Biology

The morning of the conference was devoted to the science of synthetic biology. **Johannes Geiselmann** gave an overview of the science to frame the day's discussion. With a communal understanding of synthetic biology, **Alexandre Dawid** continued the scientific discussion explaining how synthetic biologists make use of computer simulations to design gene regulation mechanisms with RNA. Subsequently, **Francois Képès** discussed synthetic biology and global optimization of the transcriptional scheme in microorganisms.

After a short break, there were two talks on the creative applications of synthetic biology. First, **Mads Kaern** revealed how synthetic biology opens up new opportunities for genetic engineers. He described two initiatives launched to facilitate the engineering of biology: BioBricks, which is working toward ensuring that synthetic biology parts and tools are freely available for innovation, and the International Genetically Engineered

Machine competition (iGEM), which provides training to the next generation of genetic engineers and biotechnology entrepreneurs. Second, **Christina Agapkakis** illustrated how collaborations between engineers, biologists, designers and artists embracing evolution as a design tool and ecology as a model for robust systems, have the potential to lead to useful, environmentally responsible, and ethical synthetic biology projects and products.

Synthetic Biology and Policy

The afternoon session discussed the issues that arise at the interface of synthetic biology and policy. The topics were wide-ranging and each speaker presented a unique policy issue that must be addressed.

Keynote Address

In her keynote address, **Michele Garfinkel** discussed five key areas of societal concern regarding synthetic genomics: biosecurity, biosafety, environmental harms, distributive justice, and other ethical and religious concerns.

The first area she discussed was bioterrorism. The principal concerns regarding biosecurity are the increased availability of pathogens, and the possibility that a pathogen could be constructed so as to be especially virulent or resistant to treatment.

The second area Garfinkel addressed emerges when DNA has been assembled to construct a novel organism, at which point the particular microorganism, as opposed to the DNA out of which it is constructed, needs to be appraised from a safety standpoint. One option to consider is that the greatest regulatory benefits can come from policies which require the distributors of genetic material to know who they are providing the materials to and what the materials will be used for, and also to keep detailed records of any orders containing elements known to be potentially harmful, called *sequences of concern.*

The third area addressed the harm to the environment. While it may be adequate to assess other genetic engineering technologies on a case-by-case basis, the speed and scale of synthetic genomics technologies prompt particular concerns. For example, there may be existing legislation restricting work with a particular microbe, but now that researchers can construct a thousand variations of the particular microbe with potentially divergent properties, the existing legislation may be inadequate. Thus, legislators working on synthetic genomics face the formidable task of keeping up with the accelerating technology.

The fourth area of discussion was on distribution of benefits. Garfinkel explained that the complex scheme of laws by which intellectual property is determined can prompt questions about whether access to emerging technologies is just. Additionally, the technological prowess required to engage in synthetic genomics at a high level may be concentrated in a small number of firms, which raises questions about the gathering industrial and political influence of these firms. Garfinkel suggested that these themes may not distinguish synthetic genomics from other means of genetic engineering, but noted that the synthetic biology community is itself divided on the issue as to whether

synthetic biology is so special that the community needs to approach it in a way that scientists and engineers have not approached technology before.

The fifth area Garfinkel discussed was other ethical and religious concerns. She explained that particular hypothetical cases are being analyzed from a variety of different philosophical perspectives. Garfinkel stressed that so far, there is very little to be extrapolated across the various cases, but that it is too soon to dismiss the ethical and religious concerns surrounding synthetic genomics as just another example of opposition to science: the construction of a living organism may raise genuinely novel ethical considerations. Garfinkel closed by saying research on this is ongoing.

Afternoon Talks

After Garfinkel's keynote, the succeeding speakers expanded on some of the previously raised societal issues, as well as others.

Virginie Tournay continued the policy discussion by examining the existing regulatory policy in Australia and the EU toward genetically modified organisms and asked whether it can apply straightforwardly to synthetic biology. She explained that the variety of ways in which organisms can now be constructed poses challenges for policymakers, because a single definition of genetic modification will likely not catch all the practices already ongoing in the field.

According to Tournay, scientists and politicians need to work together to generate a whole new regulatory system for synthetic biology. Starting from scratch is the only way a sufficient level of scrutiny can be applied to both developing policies and developing research practices.

Another important policy issue is the role of intellectual property (IP). In light of recent empirical, policy and theoretical work on innovation in the life sciences, **Jeremy de Beer** suggested in his talk that existing proprietary models of innovation are not only inefficient but are unlikely to lead to industrial, environmental and health-related breakthroughs.

De Beer discussed three intellectual property options for policy makers. The first is to encourage as much acquisition and commercialization of intellectual property rights as possible. The second is to support the public domain through free revealing of knowledge and technology where there is no collection of IP rights. This strategy is driven by a belief that there is a public ethos that motivates researchers to reveal their knowledge in a public domain for the benefit of all human kind. The third is to leverage IP rights through open licensing models where a standard license not only discloses what the invention is but requires any users to share any incremental augmentation.

These models are not mutually exclusive. De Beer explained that the key role of policymakers is to articulate overarching principles that promote financial as well as non-financial return on investments while taking into account the broad range of stakeholder needs.

Jim Thomas' talk widened the context in which issues concerning synthetic biology are debated. Regardless of how scientists and legislators come to policy decisions and what those decisions turn out to be, there is already a tremendous amount of industrial activity being carried out in the name of synthetic biology. This activity is far from innocuous with

respect to global inequalities and environmental issues. Thomas detailed the rise of the synthetic biology industry, and in particular the use of biomass, and its social costs around the world. Communities around the globe have been destabilized by corporate land grabs with dire results. Additionally, given current industrial practices, there are reasons to be skeptical of any environmental benefits resulting from synthetic biology (broadly understood, including the biobased economy at large).

A Roundtable Discussion on Synthetic Biology and Governance

The day ended with a roundtable discussion moderated by **Peter Calamai**. The panel included **Christina Agapakis**, **Virginie Tournay** and **Jim Thomas**, as well as **Geoff Munro** and **Pierre Charest**. The panel had a debate on the following questions:

1. What are the respective responsibilities of researchers and scientists, society, and governments regarding emerging technology in general?
2. Do scientists, by virtue of being the creators of synthetic biology, have a responsibility to do the heavy lifting when it comes to dealing with the social implications of this new technology? With a transformative technology like synthetic biology, do scientists have a responsibility to weigh in on the social implications of their work before it finds applications outside of the laboratory?
3. Can the lack of public consultation in the Venter Institute's report, *Synthetic Genomics: Options for Governance*, be construed as a preemptive strike by the innovators themselves against potential dissent regarding their work in the wider public? Might the innovators have had a vested interest in being the ones to set the initial terms of the debate?
4. There is a growing political emphasis on entrepreneurialism as an economic engine. Would regulation of synthetic biology inhibit entrepreneurial activity, and thereby weaken economic growth?
5. How should we as a society and as researchers approach the issue of the dual use of synthetic biology – the possibility that this powerful new technology could fall into the wrong hands and be misused? How do we guard against this possibility or regulate against it, and is the existing regulation sufficient?
6. Is the genie already out of the bottle? Does the gathering intensity of corporate engagement with synthetic biology limit society's ability to catch up and evaluate this technological frontier?

Acknowledgments

The ISSP would like to acknowledge **Dara Jospe** and **Lucas Jurkovic** for their efforts in preparing this report.

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Synthetic Biology at the Interface of Science and Policy

I. Keynote Presentation
Synthetic Genomics: Science and Governance

Michele Garfinkel explained that at the J. Craig Venter Institute, policy research runs parallel to scientific research with each potentially influencing the other's development. Venter policy reports are intended to bring informed observers together and generate suggestions to improve the governance of synthetic biology.

Before discussing the reports she has contributed to, Garfinkel explained the nature of the scientific research carried out by Venter Institute. It is important to specify the technology at work so as to engage the right policy issues. Rather than work with the wider concept of synthetic biology, Garfinkel restricted her discussion to s*ynthetic genomics*. The term “synthetic biology” could refer to a whole host of projects that are distinct from the work at the Venter Institute. Synthetic biology could eventually include the creation of “large” organisms (relative to microbes), which would require yet another level of policy scrutiny in addition to what is being carried out now. At the moment, most work in synthetic biology deals with entities between the sizes of a virus and a bacterium that are assembled from synthesized DNA. The policy issues Garfinkel discussed engage with this kind of research practice, that is to say, synthetic genomics.

Garfinkel explained that the breakthrough the Venter Institute achieved in May of 2010, which for many observers established synthetic biology as a policy concern, was the chemical synthesis of the complete genome of *Mycoplasma mycoides*, which was then transplanted into a related bacterial species *Mycoplasma capricolum*. After several rounds of cell growth and division only the *M. mycoides* genome remains in the synthetic cells, essentially turning one bacteria (*M. capricolum*) into another (*M. mycoides*). The synthesized *M. mycoides* genome was essentially identical to the natural *M. mycoides* chromosome, with the addition of several sequences so that the synthetic genome could always be recognized. The value of achieving such a synthesis is largely heuristic. Successfully creating a cell which can sustain independent life allows researchers to look closely at the contributions of each of the 300 or so required genes. This improves the knowledge-base with which researchers engage in subsequent projects. Also, a minimal genome could be used like a chassis on which to build other more complex and useful organisms, and so brings researchers closer to understanding how to design synthetic cells that address societal problems, such as cells that could sequester carbon dioxide or produce energy.

The breakthroughs at the Venter Institute are indicative of the way in which synthetic genomics has supplanted recombinant DNA technologies as the quickest and easiest way to move forward on genetic engineering projects. To construct a minimal genome by recombining fragments of naturally occurring DNA would be intensely laborious and error prone. The technology that synthesizes DNA is a rapidly accelerating technology that

offers researchers direct access to the building blocks of organisms, eliminating the need for cumbersome DNA extractions. In 2002, seven researchers completed the synthesis of a polio virus that was in the making for about a year. In 2003 an organism of about the same size and complexity, called ΦX174, was synthesized by a team of four in about two weeks.

Garfinkel explicitly noted that synthetic genomics laboratories usually acquire their DNA from outside sources, sometimes called *gene farms*. Occasionally, a laboratory will purchase a commercial DNA synthesizer, but most often it is far more practical to make use of the growing industry of commercially available synthetic DNA. This widespread practice of acquiring DNA from specialized companies is important for understanding the policy issues confronting the research community.

The policy branch of the Venter Institute[1] conducted a study and issued a report on bio-terrorism and biosafety as it relates to synthetic genomics. A report on the opportunities and challenges for regulation in synthetic genomics has begun, and a report on further ethical concerns about synthetic genomics is forthcoming. These three reports cover five key areas of societal concern regarding synthetic genomics: bioterrorism, laboratory safety, harm to the environment, distribution of benefits, and other ethical and religious concerns. Before discussing each report, Garfinkel stressed that many other organizations are engaged in similar policy research, including governmental agencies such the U.S. Department of Energy and the U.S. National Academy of Science, and NGO's like the ETC Group (represented in this report by Jim Thomas). Academic interest in synthetic genomics is also profound and ongoing.

[1] The policy branch is made up of Robert Friedman and Michele Garfinkel, along with Drew Endy and Gerald Epstein.

Figure 1: Michele Garfinkel delivering keynote presentation

The first report, Synthetic Genomics: Options for Governance, was funded by the Alfred P. Sloan Foundation and included a working group of 14 individuals, comprising scientists (including J. Craig Venter himself), lawyers, policy experts, and social scientists. Garfinkel noted that there was no citizen engagement within the research process but that a meeting with stakeholders was organized after the report had been drafted, and the results of this meeting incorporated into the final document. The principal concerns regarding biosecurity and biosafety are the increased availability of pathogens, and the possibility that a pathogen could be constructed so as to be especially virulent or resistant to treatment.

Garfinkel noted that most pathogens are still far more easily obtained through other means than they are synthesized. There are some exceptions like smallpox and 1918 influenza, samples of which are hard to come by and which thus need to be synthesized to be studied at all. Regarding laboratory safety, Garfinkel argued that synthetic genomics is distinguished by the speed and scale of its results, but that the DNA in the laboratories is harmless to individuals and the environment. The concerns emerge when the DNA has been assembled into a novel organism at which point the particular microorganism, as opposed to the DNA out of which it is constructed, needs to appraised from a security or safety standpoint. Options in the report include policies that require the distributors of genetic material (gene farms) to know who they are providing the materials to and what the materials will be used for, and also keep assiduous records of any orders containing elements known to be potentially harmful, sometimes called sequences of concern.

The second study Garfinkel discussed relates to further societal impacts of synthetic genomics and possible regulation. One of these is potential harm to the environment. Garfinkel noted again that synthetic DNA on its own is harmless. The concerns emerge once the DNA has been assembled into something. While other genetic engineering technologies may be evaluated on a case-by-case basis, the speed and scale of synthetic genomics technologies prompt particular concerns. For example, there may be existing legislation restricting work with a particular microbe, but now that researchers can construct a thousand variations of the particular microbe with potentially divergent properties, the existing legislation may be inadequate. Thus, legislators working on synthetic genomics face the formidable task of keeping up with the accelerating technology.

There is also the issue of the distribution of benefits that come from synthetic genomics. The complex scheme of laws by which intellectual property is determined in the field can prompt questions about whether access to emerging technologies is just. Additionally, the technological prowess required to engage in synthetic genomics at a high level may be concentrated in a small number of firms, which raises questions about the gathering industrial and political influence of these firms. Garfinkel suggested that these themes may not distinguish synthetic genomics from other means of genetic engineering, but notes that the synthetic biology community is itself divided on the issue as to whether synthetic biology is so special that the community needs to approach it in a way that scientists and engineers have not approached technology before.

For the report covering ethical and religious concerns, Garfinkel explained that particular hypothetical cases are being analyzed from a variety of points of view. Different philosophical perspectives are being brought to bear on questions such as "*Would it be right to resurrect a wooly mammoth?",* and, "*Would it be right to create a bacteria which could make human feet smell like flowers?"* Garfinkel stressed that so far, there is very little to be extrapolated across the various cases, but that it is too soon to dismiss the ethical and religious concerns surrounding synthetic genomics as just another example of opposition to science. The construction of a living organism may contribute genuinely novel ethical considerations. The research on this is ongoing.

Garfinkel concluded with a brief discussion of existing regulations and guidlines that pertain to synthetic genomics, but do not yet necessarily sufficiently address it. As the technology of synthetic genomics continues to accelerate and the user base continues to expand, applications of the technology are quickly emerging. Garfinkel's talk showed that there is intense academic, industrial and governmental interest in generating robust options for oversight and review.

Figure 2: Michele Garfinkel delivering keynote presentation

II. Presentation Summaries

(See **Appendix I** for speaker biographies)

Synthetic Biology 101
Johannes Geiselmann

In this opening talk Johannes Geiselmann gave an overview of synthetic biology to frame the discussion. He defined 'synthetic biology' and illustrated its principles using selected examples, stating that synthetic biology aims to "create new functions in a biological organism that have not existed before."

Synthetic biology is an emerging discipline combining approaches from biotechnology, systems biology and engineering. Biotechnology does not attempt to invent something new, rather it takes existing functions of organisms and inserts them into other organisms or combines them in particular ways. Systems biology recognizes that the function of a gene depends on the underlying regulatory network. These regulatory networks are complex systems that cannot be comprehended intuitively, so modeling is necessary to understand behaviour. Modeling is fundamental for synthetic biology. Finally, the basic work flow of engineering is to specify, model, build, validate and then modify. Engineering biological systems follows the same trajectory.

Even though the techniques from each discipline are not altered in any way, the synergy between the disciplines represents a qualitative change in technology, producing results that go well beyond the classical sciences. Using knowledge of global functioning of an organism, we can imagine new biological functions, model the behaviour of the new system, and assemble the corresponding biological parts. These new biological functions can simply be additions to the behavioural repertoire of the host organism that remain almost independent of the host itself. Other modifications re-wire the regulatory networks of the target organism and profoundly alter its functioning, e.g., Craig Venter's 2010 chemical synthesis of an entire genome that transformed one species into another. There are applications in medicine (artemisinin), biosensors (measurements within the body), energy (biofuels) and fundamental research, for example, changing the way growth rate is regulated in bacteria can tell us much about the natural way the system works.

From Computer Simulations to Gene Design: the Case of RNA

Alexandre Dawid

Dr. Alexandre Dawid explained how synthetic biologists make use of computer simulations to model the behaviour of RNA and consequently design active RNA sequences.

RNA is a single-stranded biomolecule that largely serves as an intermediary between genes encoded in DNA and proteins expressed by cells. RNA is transcribed from DNA and is transported to ribosomes (protein factories) where it is translated into proteins. When a strand of RNA is transcribed, it forms complex structures through a process called folding. The structures formed are dictated by the sequence of the RNA and the presence of other signaling molecules in the cell. Folding can affect whether and how gene expression occurs. A certain protein or enzyme may or may not be produced depending on how the RNA becomes folded during its synthesis or its processing by the ribosomes. For example, certain sequences of RNA, called attenuators, regulate the transcription of the genes encoded downstream in the RNA strand.

In some cases, computer simulations allow researchers to see how this differential expression is possible by modeling the complex behaviour of RNA molecules. These simulations can in turn be used to reverse-engineer a regulatory RNA sequence – i.e. searching for a sequence that achieves a pre-defined desired behaviour. This approach illustrates the opportunities available to synthetic biologists who wish to create rationally designed biological functions. By reconstituting the link sequence-structure-function, researchers are potentially able to build new functions in a deterministic approach in living organisms.

Using computers to predict the behaviour of synthetic RNA also contributes to the health of the research community as a whole. The creation of synthetic RNA is a way to test the theories on which the models are based, providing opportunities for refining the theories and models. These refined simulations in turn provide richer resources for subsequent synthetic biology projects. In Dr. Dawid's phrase, synthetic biology involves “learning by design.”

Synthetic Biology and Global Optimization of the Transcriptional Scheme in Microorganisms

Francois Képès

Synthetic biology renews the agenda of biotechnology and sets new ambitions. Paradoxically, it attempts to perfect the industrial character of biotechnology (e.g., by emphasizing standard utilization and re-utilization) while, at the same time, freeing itself of the historical process of evolution to allow new degrees of creative freedom (e.g., by revealing that natural life as we know it is one form of life among many). Examples are used to show how in real life this apparent paradox does not exist; that in the end it is a single step from the analytic approach to the synthetic approach.

To begin, Dr. Képès used the possibility of the presence of a global transcriptional scheme in cells to demonstrate how analytic insights can be used in synthetic biology. In brief, Dr. Képès observed that genes that are co-regulated are also co-localized, i.e., they reside next to each other on a chromosome, or at regular intervals. Once DNA is coiled, those genes are hypothesized to be brought closer together, allowing them to be co-regulated by the same regulatory proteins. There are several observations that support this hypothesis: first, transcription occurs in focal points, not in diffuse areas of the nucleus. Second, transcription is sensitive to both one dimensional positioning and three-dimensional clustering when DNA loops. Finally, co-regulated genes tend to position periodically, so that upon DNA folding, co-regulated sites become co-localized in space.

What are the biotechnological implications of these analytic insights? Given a set of 15 genes involved in a synthetic pathway, how do we co-regulate them? We look to nature: three-dimensional co-localization is a principle in nature which can be applied in biotechnology. In other words, we can couple the analytic and the synthetic. We can mimic how things are implemented in nature, i.e., use life's design principles in a biotechnology context. In this way, systems biology explores the principles and synthetic biology exploits them. Similarly, we can couple experiments and theory – theory allowing experiments to be conducted more effectively and experiments inspiring new theory.

In this regard, the situation of biology is analogous to the situation of chemistry in the 19th century: analytic chemistry expanded and chemists wanted to have more products to analyze. Accordingly they started to synthesize natural products and subsequently non-natural products which lead to powerful industries. Analytic biology is now beyond this turning point; we are witnessing a more engineering-type approach with synthetic biology and we can expect the same look leading to a powerful industrialized synthetic biology in the 21st century.

Will synthetic biology be a revolution? It all depends on whether your perspective is 10 years or 40,000 years. In either case it is certainly one step in the stages of human mastery over the biotope.

Advancing Genetic Engineering through Synthetic Biology

Mads Kaern

Dr. Mads Kaern discussed how synthetic biology opens up new opportunities for genetic engineers. To a large extent, this is due to institutions that have sought to make the resources of synthetic biology available to interested parties and provide opportunities specifically for young scholars to engage with the emerging science. Dr. Kaern profiled two such institutions, BioBricks: a Registry of Standard Biological Parts, and the International Genetically Engineered Machine Competition (iGEM).

Dr. Kaern proposed that the breakthroughs of synthetic biology allow for a division of labour amongst researchers that makes it easier for genetic engineers to develop their projects. Now that synthetic biologists can create genomes with novel functionality, the components of these projects can be isolated and made available to other researchers as individual units, which can then be re-combined to produce other genomes with novel functionality. Because DNA is made up of numerous building blocks, synthetic biology can result in genetic engineering becoming more like software engineering, with the genetic engineers creating novel machines using a standardized system of components. These components can be made readily available to interested parties just like computers are readily available to budding software engineers.

BioBricks was founded at the Massachusetts Institute of Technology (MIT) in 2003 and manages the Registry of Standard Biological Parts, which is an always expanding collection of genetic components that can be combined to build synthetic biology devices and systems. The registry both values and benefits from a community of openness between synthetic biologists, operating on the principle of *get some, give some*. This means that:

> "Registry users benefit from using the parts and information available from the Registry in designing their engineered biological systems. In exchange, the expectation is that Registry users will, in turn, contribute back information and data on existing parts and new parts that they make to grow and improve this community resource." (http://partsregistry.org/Main_Page)

In addition to making its resources freely available to all registered laboratories and thus benefitting other research projects, BioBricks makes the International Genetically Engineered Machines Competition (iGEM) possible. For this competition, teams of undergraduate students are given a kit of biological parts from BioBricks' registry and under the supervision of professors and graduate students, compete to design bio-machines in a variety of categories. Over a hundred teams from all over the world participated in 2010. iGEM is also one of the reasons that BioBricks' registry continues to grow. Every project entered into competition is also placed in the registry allowing future participants to build on earlier successes. This also results in the constant improvement of training and education received by participants, and makes more and more resources available to laboratories.

Designing Biologically: Synthetic Biology Devices in an Environmental and Social Context

Christina Agapakis

In her talk, Dr. Agapakis discussed how synthetic biology fundamentally comes down to designing biology. Following the Global Agenda Council on Design, she understands design as "an agent of change that enables us to understand complex changes and problems, and to turn them into something useful." Researchers who study synthetic biology have an interest in turning this understanding of the complexity into something useful, e.g., therapeutic, environmental or agricultural solutions. Despite this interest, however, research in synthetic biology suffers from the principle of insufficient weirdness, a concept Agapakis derived from science fiction, where visions of the future represent civilizations that are technologically superior but socially identical to our own (e.g., in their gender roles).

Agapakis explained that in synthetic biology, the principle of insufficient weirdness applies in two ways. First, the 'weirdness' or complexity of biology is underestimated. Biology is weird – cells do weird things, they evolve, they adapt and they grow. They have functions more amazing than any human-made machine. Second, the principle applies to how we envision synthetic biology's impact on future technology and society. Synthetic biologists see the problems caused by industrial processes, and imagine how biology can help. However, the microbial factories they propose are very similar to the industrial factories they seek to replace. Likewise, synthetic biologists design biosensors to detect industrial pollutants and bioremediation strategies to clean up waste spills, but they do not address the underlying causes of environmental degradation. They work to make industry less bad rather than to make modes of production that are truly good.

According to Agapakis, we should follow Dunne and Raby's claim that "[w]e need to move beyond designing for the way things are now and begin to design for how things could be, imagining alternative possibilities and different ways of being, and giving tangible form to new values and priorities."

Learning from the rich complexity of living cells and the work of artists and designers studying the social implications of biotechnologies, Agapakis maintained that we can find the tools that make biology a good substrate for design and the principles for beneficial engineering at the human scale. One example of such collaboration is the International Genetically Engineered Machine Competition (iGEM), where imaginative students have already created some sufficiently weird things, e.g., bacteria that can play Sudoku, plants that can make sour things taste sweet and LCD screens made of yeast.

In closing, Agapakis emphasized that nothing in biology is wasted. We ought to re-imagine how we can use things that are waste and re-think the kind of designs we make. She concluded by saying that embracing evolution as a design tool and ecology as a model for robust systems has the potential to lead to useful environmental and ethical synthetic biology projects and products.

Synthetic Biology: Genetic Engineering Like Any Other?

Virginie Tournay

Dr. Virginie Tournay discussed existing regulatory policy toward genetically modified organisms, and whether it can apply straightforwardly to synthetic biology. She began with a provocative example from Australia, where scientists have injected mosquitoes with a bacterium that stops the mosquito from transmitting dengue fever. Even though Australia has regulatory legislation limiting genetic engineering (Australian Gene Technology Act), these modified mosquitoes do not count as genetically modified organism under that policy. This is because the bacteria modifying the mosquitoes are endemic to the same area as the mosquito. There is no new or foreign species being added to the region and so the Australian Gene Technology Act does not apply. Whether this should be taken as a welcome result is not entirely clear. But it is clear that the variety of ways in which organisms can now be constructed poses challenges for policy-makers. This is because a single definition of genetic modification will likely not catch all the practices already ongoing in the field.

It is thus necessary that certain details of the techniques whereby organisms are genetically modified be accounted for by those constructing the relevant legal frameworks. Tournay focused on EU Directive 2001/18, which provides a legal definition of “genetic modification.” Directive 2001/18 defines a GMO as “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.” There is both ambiguity and vagueness in this language. Organisms are constantly exchanging materials (including DNA) with their environments. Also, depending on what's in the environment an organism's genes may express themselves differently or not at all. Thus, prescribing that researchers do not alter an organism in unnatural ways could mean that researchers must not alter an organism such as could not happen in nature, or that researchers must not alter an organism such as does not happen in nature. And the nature of either of these is not easily made clear.

An organism's DNA is something like a template, akin to the chassis of a car, and becomes expressed through the development of the organism and its interactions with its world. The environment can have an enormous influence on how an organism's genes are expressed. In fact, the environment contributes just as much to the development of an organism as its DNA does. Gene expression is equal parts DNA and environmental context. Thus, relying on legal definitions of genes alone, without attending to the context in which they are expressed, tilts the discourse toward issues of unnatural tampering with genomes. Genetic engineering through synthetic biology can involve the synthesis of naturally occurring biological material whose insertion into an organism can result in beneficial traits that could also potentially occur naturally.

Tournay argued that legislation based solely on a definition of “genetic modification” involves a faulty assumption of genetic determinism. It is not the case that genetic material determines entirely the character of an organism, as different environments can result in different expressions of the same genes. In addition, such legislation is too

monolithic in that it applies the same risk management strategy to importantly diverse practices. Tournay maintained that a failure to incorporate factors additional to modification of an organism's genome results in legislative over-estimation of the risks related to GM technologies. Synthetic biology is comprised by many distinct activities with correspondingly distinct risks.

According to Tournay, to clarify the aims of researchers and policymakers, scientists and politicians need to work together to generate a whole new regulatory system for synthetic biology. Starting from scratch is the only way a sufficient level of scrutiny can be applied to both developing policies and developing research practices.

Synthetic Biology: The Case for Free Revealing

Jeremy de Beer

Intellectual property (IP) plays an important role in innovation generally and in synthetic biology specifically. In the context of a regulatory governance structure, IP provides ownership rights over technologies, controls access and structures the sharing of economic and social benefits. IP rights are used as an accelerator of innovation and designed to encourage more investment.

IP also represents the point where privatization of technology may occur; IP owners have significant legal power and control over the ways technology is employed (albeit owners are still subject to regulation). The private sector pressures policymakers to put strong IP protection in place to encourage investment. However, there are those that advocate accessibility to new technologies and accordingly encourage weaker IP rights. De Beer suggested shifting the focus of the debate from the relative strength or weakness of intellectual property rights, to the most efficient and effective models of managing intellectual property in practice.

Recent empirical, policy and theoretical work on innovation in the life sciences strongly suggests that existing proprietary modes of innovation are not only inefficient but are unlikely to lead to industrial, environmental and health-related breakthroughs. This is because of IP rights thickets, i.e., an innovation ecosystem with so many IP rights that taking strategic actions becomes effectively impossible.

In recognition of this real or perceived problem, there have been many advocates in the biotechnology and synthetic biology communities that suggest borrowing tactics from open source software. Open source software is essentially made available under a standard license which not only discloses what the invention is but requires any users of the software to share any incremental augmentation. Put simply, it is a license that requires you to share and share alike.

Historically, this type of IP right has created legal problems. Normally competitors cannot agree to not compete. However, where it is necessary to develop industry standards, competitors are allowed to act in their mutual strategic interest and pool together rather than compete. This strategy worked well with the communications industry for example, but was problematic for pharmaceutical companies and diagnostic testing. Synthetic biology seems to be analogous to the communications industry in the sense that it necessary to develop consistent standards to make innovation possible.

Another strategy is the free revealing model where there is no collection of IP rights. This strategy is driven by a belief that there is a public ethos that motivates researchers to reveal their knowledge into a public domain for the benefit of all human kind. This model is efficient because it is cheap; researchers simply reveal their research in the public domain and this does not cost them anything.

These models are not mutually exclusive. Policymakers' key role is not to choose among them but to articulate overarching principles that promote financial as well as non-

financial return on investments, while taking into account the broad range of stakeholder needs.

Whose Industrial Revolution is it Anyway?

Jim Thomas

Jim Thomas' talk widened the context in which synthetic biology issues are debated. Regardless of how scientists and legislators come to policy decisions and what those decisions turn out to be, there is already a tremendous amount of industrial activity being carried out in the name of synthetic biology. This activity is far from innocuous with respect to global inequalities and environmental issues. Thomas detailed the rise of the synthetic biology industry (broadly understood, including all novel uses of biomass) and its social costs around the world. Communities around the globe have been destabilized by corporate land grabs with dire results. Additionally, given current industrial practices, there are reasons to be skeptical of any environmental benefits resulting from synthetic biology.

Scientific leaders are explicit about the opportunity to execute a whole new commercial enterprise with synthetic biology. Thomas quoted Randy Rettberg, director of the iGEM competition discussed elsewhere in this report, who says that "[t]he goal is not just to do science and make something cool. It is to make an industry." This has already happened. The major industrial investors in synthetic biology are enormously powerful companies representing industries with huge political power. These include energy and fuel companies such as Shell and Chevron, pharmaceutical companies such as Pfizer, and giants of industrial agriculture like Monsanto and Dupont. Any attempt to generate legislation that regulates synthetic biology should take careful account of the massive commercial forces already at work establishing the industry.

The market size for synthetic biology is growing rapidly. In 2008 global investment in synthetic biology was $233.8 million and is expected to reach $4.5 billion in 2015. Much of this economic activity is predicated on the notion that synthetic biology is the future of fuel technology. This notion has already led to serious social costs. Corporations have aggressively purchased and appropriated land all over the world in order to develop stores of potentially fuel-producing crops. Most bio-fuel research involves the conversion of sugar, starch, and cellulose into biofuels such as ethanol and biodiesel. Thomas quoted Codexis CEO Alan Shaw exclaiming, "Sugar is the new oil." Unfortunately, huge amounts of human labour and technological activity are required to yield quantities of biomass sufficient to engage in high level fuel-production.

Most of the land suitable for producing biomass is in the developing world. As corporations have aggressively pursued this land, already impoverished communities have been sometimes uprooted, and sometimes exploited as harvesters. Given the instability in some of the regions afflicted by the land-grab, civilian resistance to corporate presence is sometimes met with violence. Thomas relayed the story of a group of nine who were murdered in Honduras trying to stop the appropriation of their land for biofuel crops. He also cited deaths in Guatemala and Brazil related to struggles over land.

In addition, as more land becomes used for producing biofuels, less is available for the production of food. This exacerbates existing problems for communities afflicted by food

shortages, many of which are found in the very regions being bought up by corporations. And globally, humans are already using 135% of the replenishable biomass on earth each year. Suddenly dedicating huge amounts of land to untested fuel technologies is not at all a step toward sustainability. Jim Thomas insisted that synthetic biology can already be appraised in light of its industrial manifestations and he explained that such an appraisal is not likely to be favourable. At the moment, industrial synthetic biology activity seems to contribute more social and environmental problems than it solves.

Figure 3: Roundtable Discussion
(from left) Virginie Tournay, Christina Agapakis, Peter Calamai, Geoff Munro, Pierre Charest, Jim Thomas

III. Rountable Discussion

The roundtable discussion at Synthetic Biology at the Interface of Science and Policy was moderated by **Peter Calamai**, a fellow of the ISSP, an adjunct research professor at Carleton University in the School of Journalism and Communication, a former Toronto Star science writer, and a founding director of the Science Media Centre of Canada. The panel included presenters from earlier in the day, **Christina Agapakis**, **Virginie Tournay** and **Jim Thomas**, as well as **Geoff Munro** (Chief Scientist and Assistant Deputy Minister at Natural Resources Canada) and **Pierre Charest** (Associate Vice-President, Corporate Planning and Policy Division, Natural Sciences and Engineering Research Council of Canada (NSERC)).

Calamai began by inviting Geoff Munro and Pierre Charest to introduce their perspectives on synthetic biology as they had not had opportunity to present earlier in the day. Mr. Munro began with his definition of synthetic biology. Given Munro's background in plant physiology, where research involves correlations between structures and functions, he explained synthetic biology as an enterprise which explores the effect of changes to existing biological structures on the functions they carry out. Munro then explained the institutional climate in which would-be regulators of synthetic biology operate. He explained that regulators at Natural Resources Canada must operate in conformity with the existing priorities set by the sitting government. Presently, these include sustaining and improving the economy, maintaining and improving citizen health, and maintaining and strengthening security. Regulators and funding administrators can only proceed with their agendas when doing so is demonstrably in service of one of these three goals.

Pierre Charest explained that synthetic biology has three important components, which could each give rise to particular policy challenges. First, synthetic biology involves the chemical synthesis of DNA, a technological feat already achieved. Second, there is the possibility of creating novel life forms from scratch, which raises additional issues. Finally, synthetic biology involves the creative design of new biological circuits and pathways, and this aspect of the community may also bring about new policy challenges.

Charest maintained that the priority at this point should be on discerning what is unique about synthetic biology in terms of its regulatory requirements. He offered one example. Canadian technological regulation is product based, which means that innovations are assessed as final products, and not according to the processes with which they are produced. This means that an organism modified by synthetic biology could be sanctioned by existing regulation based on an appraisal of its safety as a finished product. However, this may not be sufficient for the products of synthetic biology because organisms are intrinsically not finished products. They naturally continue to evolve. Descendants of modified organisms may display properties that we would have barred through regulation if they were present for the initial assessment.

Calamai then began the round table. He asked the group:

What are the respective responsibilities of researchers and scientists, society, and governments regarding emerging technology in general? (Calamai asked the group to speak to their experiences with synthetic biology as case studies in society's means of response to emerging technology.)

Agapakis responded that the responsibility taken by scientists and researchers can be minimal, consisting of occasional reflection on the ethical issues. She said that such considerations are becoming more central in laboratories, however. Tournay noted that it is difficult to have an organized response to an emerging technology which is not clearly defined. The existing criteria for a genetically modified organism are not sufficiently refined. Human attempts to influence the character of particular species vastly predate synthetic biology technology in the practices of domesticating animals and controlled agriculture. It is difficult to say what in particular is of concern regarding organisms modified through synthetic biology as opposed to other means of modification. Thus, it is difficult for stakeholders even to begin on a regulatory framework that is accountable to the particularities of synthetic biology.

Calamai then asked:

Do scientists, by virtue of being the creators of synthetic biology, have a responsibility to do the heavy lifting when it comes to dealing with the social implications of this new technology? With a transformative technology like synthetic biology, do scientists have a responsibility to weigh in on the social implications of their work before it finds applications outside of the laboratory?

Jim Thomas responded that it wouldn't be fair to place so much regulatory responsibility on the shoulders of scientists and researchers. To a large extent, the social implications of synthetic biology are being determined by the commercial actors fuelling the industry together with the investments of governments. These phenomena need to be addressed on the scale at which they are occurring. This technology has already led to upheavals of communities around the world, and weakened the food producing capacity of entire regions at the hands of industrial forces. Scientists are in no position to address this and so governments must pursue a suite of checks and balances which could prevent further harm arising from the real world practice of synthetic biology.

Geoff Munro added that neither the notion of scientists self-regulating nor that of governments pursuing unified responses to emerging technology is sufficiently nuanced to make progress on the regulatory challenges facing synthetic biology. Some scientists have training as regulators and some are not at all qualified to regulate, and for government regulators, the various roles and agendas strewn across the agencies can make it difficult to pursue a unified policy.

Pierre Charest explained that Genome Canada will only award funds to research projects with a strong element of ethical assessment. This is a minor example of the government

and scientists working together to assure social responsibility among researchers. The government indirectly contributes to the quality of technology assessment as a whole by restricting funding to those projects that perform strong technology assessments.

Jim Thomas responded to Charest. Thomas suggested that when an ethical assessment is part of the requirements of a developing project, it can become just another box to check in order to procure funding. To properly address a technology as potentially transformative as synthetic biology, communities need to be consulted and the viewpoints of citizens incorporated into restrictions on research trajectories. This is a much more reliable way to be sure that society approves of the research programs undertaken by scientists.

Charest responded to Thomas, clarifying that the ethical component of proposals submitted to Genome Canada is usually completed by social scientists working with the research group. He thus suggested that a modicum of non-scientific expertise is already being brought to bear on these projects, even if citizen outreach is not yet a requirement.

Calamai then asked:

Can the lack of public consultation in the Venter Institute's report, Synthetic Genomics: Options for Governance*, be construed as a preemptive strike by the innovators themselves against potential dissent regarding their work in the wider public? Might the innovators have had a vested interest in being the ones to set the initial terms of the debate?*

Jim Thomas responded by explaining that his ETC Group began working on synthetic biology when they discovered that researchers at the Synthetic Biology 2.0 Conference attempted to develop a code of voluntary self-regulation in an attempt to ward off interference from larger institutional bodies. Thomas explained that the same initiative gave rise to the Venter Institute report on Bioterrorism and Biosafety, and that it is no coincidence that self-regulation plays a large role in that report. Thomas explained that it is not appropriate for scientists to be setting the terms of governance regarding such a powerful technology. It is the societies which could be changed by this technology that should set the terms of its governance. [2]

[2] Though originally asked to respond to the question, Michele Garfinkel could not do so because of time constraints at the end of the day. She provided the following comment for inclusion in this report:

"First, I would like to clarify the nature of the project and the report, as by the framing in the question the process is implicitly misrepresented. This was not a report issued by the J. Craig Venter Institute. This was the report of a policy study conducted by policy researchers at the J. Craig Venter Institute (Robert Friedman and myself), a synthetic biologist from MIT/Stanford (Drew Endy) and a policy researcher/practitioner from the Center for Strategic & International Studies/AAAS (Gerald Epstein). These investigators led a working group. The study was funded

Calamai then asked about innovation agendas:

There is a growing political emphasis on entrepreneurialism as an economic engine. Would regulation of synthetic biology inhibit entrepreneurial activity, and thereby weaken economic growth?

Geoff Munro responded that on the contrary, entrepreneurial investment flows more freely when a regulatory environment is in place. Without an effective regulatory scheme, entrepreneurs are less likely to invest because an unregulated industry is full of uncertainties.

Calamai's next question concerned the dual use of technology, which refers to the way in which what is developed as a beneficial technology can also be used to do harm:

How should we as a society and as researchers approach the issue of the dual use of synthetic biology – the possibility that this powerful new technology could fall into the

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by the Alfred P. Sloan Foundation. The goal of the study was to expand, not pre-empt, discussion and debate.

In addition to the scientists on our working group of 14 people (a group that did include scientists from the Institute, specifically J. Craig Venter and Hamilton Smith) and additional subject matter experts invited to the three initial workshops, we included social scientists, ethicists, lawyers, technologists, bioterrorism and biosafety experts, etc. We also had observers from US government agencies, primarily individuals who were ex officio representatives at the time to the National Science Advisory Board for Biosecurity, but as well observers from other government agencies, including the US Executive and Congressional branches, as well as the European Union's delegation in Washington, DC. So while there may not have been a public consultation in a specific and narrow sense, the US government (and thus the public) was well aware of our work, and the public was represented in the meeting directly at least by the social scientists in the group and the governmental observers. Following these workshops, we did have a larger invitational meeting to include many more stakeholders than we could include in the small workshops.

Second, to clarify the content of the report: we did offer governance options for community regulation and for governmental regulation and oversight (e.g., the options for registration of small DNA synthesizers or the licensing of users of those machines and for requirements for gene firms to screen orders and/or keep records, are all inherently governmental activities). These options were derived from discussions with the working group and other stakeholders. Further, to clarify the foundations of the project: as noted, we were funded by the Alfred P. Sloan Foundation, which was also a funder of the Synthetic Biology 2.0 Conference, but these two projects were not related initiatives.

Finally, indeed, it is not appropriate for scientists to be setting terms of governance, but neither is it appropriate for them to be excluded. Through the working group, invitational meeting, and discussions with other stakeholders, we worked to assure as far as possible that as many views as possible were involved in constructing viable governance options. What the eventual balance of those and other options will be is the critical topic of discussion between stakeholders and policymakers right now."

wrong hands and be misused? How do we guard against this possibility or regulate against it, and is the existing regulation sufficient?

Virgine Tournay responded that an emerging technology always gives rise both to risk and uncertainty and that it is important to maintain the distinction between these. The objective of regulation is to quantify risk, but regulation cannot be expected to eradicate uncertainty. The eventual uses of a particular technology cannot all be ascertained even by the most informed speculators. Certain risks such as dual use are unavoidable with emerging technology.

Geoff Munro added that much of the work done on threatening uses of technologies is conducted behind the scenes in governmental institutions. These concerns engage delicate security matters and so the pertinent work is not usually publicized. Munro explained that a certain amount of trust must be accorded to society's ability to suppress threats.

Finally Calamai asked:

Is the genie already out of the bottle? Does the gathering intensity of corporate engagement with synthetic biology limit society's ability to catch up and evaluate this technological frontier?

Geoff Munro stated that this phenomenon is not unique to synthetic biology and suggests that a market-driven society accepts (often tacitly) the risk endemic to technology-fuelled economic growth. When Henry Ford created the internal combustion engine, it was hailed as an environmental benefit at the time, however much it is derided as an environmental problem now.

Pierre Charest suggested that it is important to separate the issue of what sort of society we'd like generally and what this implies regarding an optimum extent of corporate influence, from the particular policy challenges brought up by synthetic biology. Reining in the influence of multinational corporations is important but not the same issue as synthetic biology regulation.

Calamai commented that recent events in the U.S. in which corporate influence in the Senate resulted in questionable subsidies given to ethanol producers, suggest that we don't just have a market-driven economy, but a *market-run* economy.

Charest disputed this, claiming that when it comes to assuring the safety and health of citizens, governments are performing well. The character of the international commercial setting in which the industry of synthetic biology operates is a separate topic. To this, Jim Thomas responded that these debates are largely about power. In the case of synthetic biology, the issue is technological power, and the result of this power going unchecked could be more severe than other examples of unchecked power. Whereas a financial system may melt down as a result of being unregulated, in the case of synthetic biology, we face the possibility of serious harm to the basic physical world.

Appendix I

Speakers and Organizing Committee

Speakers

Christina Agapakis
Postdoctoral Research Fellow
University of California, Los Angeles

Christina Agapakis recently completed her PhD studies in Biological and Biomedical Sciences at Harvard Medical School and is currently a postdoctoral research fellow at UCLA. Her interests include synthetic biology, bioenergy, social studies of science, and art/science collaboration. She also blogs about biology, engineering, biological engineering, and biologically-inspired engineering on the Scientific American Network, and makes YouTube videos with Hydrocalypse Industries.

Peter Calamai (Moderator)
Fellow, Institute for Science, Society and Policy
University of Ottawa
Adjunct Research Professor
School of Journalism and Communication
Carleton University

A founding member of the Canadian Science Writers' Association in 1970, Peter Calamai served as the *Toronto Star*'s national science reporter from 1998 to 2008. He is an adjunct research professor in the School of Journalism and Communication at Carleton University in Ottawa and a contributing editor at *Cosmos*, a science magazine published six times a year in Australia. In 2010 Peter was one of the founding directors of the Science Media Centre of Canada and continues as chair of the Centre's editorial advisory committee.

Peter has a bachelor of science in physics from McMaster University and worked as correspondent and editor with the Southam company for 30 years. He is a three-time winner of Canada's highest print journalistic honour, the National Newspaper Award.

Pierre Charest
Associate Vice-President
Natural Sciences and Engineering Research Council of Canada
Corporate Planning and Policy Division

Pierre Charest joined NSERC as Associate Vice-President Corporate Planning and Policy in August 2011. Previously, he was Director General of the Science Policy Directorate at Health Canada starting in 2008. He had a brief stay at the Canadian Food Inspection Agency in 2007 and 2008 as Associate Vice-President Science. During the preceding 6 years, he held the positions of Director General of the Biologics and Genetic Therapies Directorate and Director General of the Office of Biotechnology and Science in the Health Products and Food Branch at Health Canada. Dr. Charest has over 20 years of experience in the areas of management, policy development and science in agriculture, forestry and health. Previous to joining Health Canada, Dr. Charest was Director of the Science Program for the Canadian Forest Service. He held a number of other positions with the Canadian Forest Service including Research Project Leader in Biotechnology.

Dr. Charest has authored or co-authored 77 scientific publications, presented 80 scientific communications and 28 invited lectures. He has been solicited frequently as a member of granting agencies review boards such as NSERC, the Canada Foundation for Innovation, the Canadian Institutes of Health Research, and Genome Canada. He has received numerous awards, including three Federal Public Service Awards.

Dr. Charest completed his PhD in Molecular Biology at Carleton University, and previously, his M.Sc. and B.Sc.A. from Laval University in agronomy.

Alexandre Dawid
Associate Professor
Laboratoire Interdisciplinaire de Physique– UMR5588
Centre National de la Recherche Scientifique
Université Jospeh Fourier – Grenoble 1

Alexandre Dawid is associate professor at Université Jospeh Fourier and works in the Laboratory of Interdisciplinary Physics. Dr. Dawid obtained a PhD from the ENS Paris /UPMC Paris 6 in 2005, working on single molecule studies of genetic recombination mechanisms. He completed postdoctoral studies at the Institut Curie (Paris) and was an EMBO fellow at the FOM Institute AMOLF (Amsterdam), working on rational design of RNA switches and the theory of evolution.

Jeremy de Beer
Associate Professor
Faculty of Law
University of Ottawa

Jeremy de Beer joined the Faculty of Law at the University of Ottawa in 2004. Before entering academia he practiced law with the Department of Justice as legal counsel to the Copyright Board of Canada. Professor de Beer was also the law clerk to Justice Allen Linden at the Federal Court of Appeal, and before that worked at the firm of Macleod Dixon LLP in Calgary, Alberta.

Professor de Beer's research and recent publications address topics ranging from digital copyrights to biotechnology patents, with particular emphasis on the intersection of technology, intellectual property and international development. Other interests include administrative law and litigation relating to intellectual property.

Michele Garfinkel
Manager, Science Policy Programme
European Molecular Biology Organization
Adjunct, J. Craig Venter Institute

Michele Garfinkel is the manager of the Science Policy Programme at the European Molecular Biology Organization. Previously she was a policy analyst at the J. Craig Venter Institute, where she worked on societal issues emerging from genomics-based technologies, particularly synthetic biology. She has also done policy research as staff at the American Association for the Advancement of Science, and as a research fellow at Columbia University's Center for Science, Policy & Outcomes.

Dr. Garfinkel holds a BA in Genetics from the University of California, a PhD in Microbiology from the University of Washington, and an MA in Science, Technology, and Public Policy from the George Washington University.

Johannes Geiselmann
Professor
Laboratoire Adaptation et Pathogénie des Microorganismes
Institut Jean Roget
Université Joseph Fourier

Johannes Geiselmann did his undergraduate work at the University of Tübingen (Germany) and he obtained a PhD in molecular biology from the University of Oregon in 1989. He then spent three years as a postdoctoral fellow at the Pasteur Institute in Paris working on the regulation of transcription initiation in *Escherichia coli*. He continued this research topic during his six year appointment as an assistant professor at the University

of Geneva. In 1998, he was appointed full professor at the Joseph Fourier University in Grenoble where he directs the “Control of Gene Expression” group.

His research interests, since his thesis work, concern different aspects of the regulation of gene expression in *E. coli*. His training in molecular biology and biophysics has led him to explore interdisciplinary approaches to study the molecular mechanisms underlying the control of gene expression. Since his appointment in Grenoble, his major focus has been on understanding the global behavior of transcriptional regulatory networks in bacteria using approaches of systems biology. Since 2004 his research group has also been part of the bioinformatics laboratory IBIS at the French National Informatics Institute (INRIA). In tight collaboration with his bioinformatics partner, Hidde de Jong, he combines mathematical modeling with experimentation. He uses systems biology to understand natural regulatory systems and synthetic biology to create new regulatory interactions in *E. coli*.

Mads Kaern
Canada Research Chair in Systems Biology
Ottawa Institute of Systems Biology
Assistant Professor
Department of Cellular & Molecular Medicine
University of Ottawa

Mads Kaern received his B.Sc. (1995) and M.Sc. (1997) from the University of Copenhagen. His M.Sc. thesis, “Biochemical Reaction Networks: From Elementary Reactions to Biological Self-organization”, resulted in three research publications in theoretical biology, and received the rarely awarded and highest possible grade of 13 for “outstanding and exceptional performance”. Dr. Kaern was a doctoral stipendiary with the Danish Research Academy from 1997 to 2000, and completed his PhD research on chemical and biological morphogenesis at the University of Toronto in 2001. As a postdoctoral fellow of the Danish Research agency, he then went to Boston University’s Department of Biomedical Engineering to work with McArthur “Genius” Award recipient Dr. James Collins and National Academy of Science members Dr. Nancy Kopell and Dr. Charles Cantor.

Dr. Kaern was appointed Canada Research Chair in Systems Biology in 2004. He is a core member of the Ottawa Institute of Systems Biology, and an Assistant Professor of Cellular & Molecular Medicine with cross-appointment in the Department of Physics at the University of Ottawa. He launched his Dynamical Systems Biology Laboratory and independent research program in 2005.

François Képès
Epigenomics Project
iSSB Genopole
Centre National de la Recherche Scientifique
Université d'Evry

François Képès is a cell and systems biologist. He is currently studying the dynamics and spatial development of regulatory networks in the cell.

Dr. Képès is a Research Director at CNRS (Centre National de la Recherche Scientifique). He is the Founding Director of the Epigenomics Project (Genopole®, CNRS), an Institute of Complex Studies that is dedicated to the emerging disciplines of systems and synthetic biology. He is an associate member of the Centre for Research in Applied Epistemology (CREA, École Polytechnique). He was until 2004 an Associate Professor of Biology at École Polytechnique.

He is the author of about 100 scientific publications and the editor or author of 15 books. He has organized or chaired numerous international and national scientific events, including some in synthetic biology since 2005, and supervises two current European projects. Dr. Képès serves as the editor of three international journals, referee for 19 others, and is an expert advisor for European, North- and South-American and Middle-East funding agencies. He is also acting as a referee for European Commission prospectives in systems and synthetic biology, as well as in complex systems and in bioinspiration. He acted as the team leader of the first French iGEM team, which was a finalist and won the first prize of foundational research at MIT in 2007.

Geoff Munro
Chief Scientist and Assistant Deputy Minister
Natural Resources Canada
Innovation and Energy Technology Sector

Geoff Munro was appointed the Assistant Deputy Minister of Natural Resources Canada's (NRCan) newest sector, the Innovation and Energy Technology Sector (IETS) on April 14, 2009. This appointment is in addition to his June 2007 appointment as NRCan's Chief Scientist.

In these capacities, Geoff works to position NRCan's science and technology (S&T) and its energy research and development within the Canadian innovation system and in broader international arenas. He is also leading the implementation of NRCan's S&T strategy by promoting greater synergy among federal, provincial, private and university sectors engaged in science and technology.

Geoff co-chairs two federal interdepartmental committees on S&T: the ADM S&T Committee (comprised of 20 federal departments, it delivers the federal S&T strategy as well as provides high-level strategic direction to common federal S&T issues); and the

S&T Integration Board (comprised of 13 federal departments, it addresses and provides direction on issues relevant to federal science departments who perform science). He is also the Canadian member of the United Nations Environment Programme (UNEP) Steering Committee of the International Panel for Sustainable Resource Management (Resource Panel).

Jim Thomas
Research Programme Manager and Writer
ETC Group

Jim Thomas's background is in communications, writing on emerging technologies and international campaigning. For the seven years previous to joining ETC Group, Jim was a researcher and campaigner on genetic engineering and food issues for Greenpeace International – working in Europe, North America, Australia/New Zealand and South East Asia. He has extensive experience on issues around transgenic crops and nanotechnologies and has written articles, chapters and technical reports in the media and online.

Trained as a historian to look back at the history of technology, Jim is now busy communicating the future of technology. He's a big fan of storytelling, slam poetry and sushi.

Virginie Tournay
Tenured Researcher in Political Studies
Institut d'Études Politiques
Grenoble

Virginie Tournay is a CNRS (Centre National de la Recherche Scientifique) permanent researcher in Political Studies, after initial training in medical biology. Her current research focuses on the dynamics of biotechnologies and the institutions that regulate them. She promotes the bridging of Science Studies and Political Studies by developing a pragmatic and evolutionary theory of institutions.

Her publications include the monographs *Vie et mort des agencements sociaux – De l'origine des institutions* (Presses Universitaires de France, 2009), *Sociologie des institutions* (Presses Universitaires de France, 2011) and the edited volumes *La Gouvernance des Innovations Médicales* (Presses Universitaires de France, 2007) and *Les technologies de l'espoir* (with Annette Leibing) (Presses universitaires de Laval, 2010), as well as numerous articles.

Organizing Committee

Marc Saner
Director
Institute for Science, Society and Policy
Associate Professor
Department of Geography
University of Ottawa

Marc Saner is the inaugural Director of the Institute for Science, Society and Policy (since July 1, 2010), and an Associate Professor in the University of Ottawa Department of Geography.

Prior to this appointment, he served as Executive Director, Regulatory Governance Initiative, School of Public Policy and Administration, at Carleton University, and Director of Assessments and Executive Vice-President of the Council of Canadian Academies. Previously, Dr. Saner was a Director at the Institute On Governance where he built the Ethics and Risk Management Sector and co-managed the Technology and Governance Program.

For the last decade, his primary interest has been multi-disciplinary work at the intersection of science, ethics and governance. He holds a PhD in applied ecology from the University of Basel, Switzerland (1991) as well as an MA in applied ethics from Carleton University (1999).

Dr. Saner publishes in peer-reviewed journals in the areas of technology ethics, bioethics, risk management, biotechnology and ecology and has been invited to speak at seminars, workshops and international conferences around the world. He was also appointed Adjunct Research Professor in Philosophy and in Biology at Carleton.

Daniel Figeys
Director
Institute of Systems Biology
Professor
Department of Biochemistry, Microbiology and Immunology
University of Ottawa

Daniel Figeys joined the University of Ottawa in July of 2004 as a Professor in the Department of Biochemistry, Microbiology and Immunology and the Director of the Institute of Systems Biology. Daniel obtained a B.Sc. and a M.Sc. in chemistry from the Université de Montréal. He obtained a Ph.D. in Chemistry from the University of Alberta and did his postdoctoral studies at the University of Washington.

Prior to his current position, Dr. Daniel Figeys was Senior VP of System Biology and Lead Profiling with MDS-Proteomics (2000-2004), where he was responsible for all the

analytical functions of the company. Before joining MDS-Proteomics, Dr. Figeys was Director of Mass Spectrometry and Applied Research at MDS Ocata, a privately held company, from January to December 2000. From 1998 to 2000, Dr. Figeys was a Research Officer at the NRC-Canada in the field of proteomics technology and application. He ran a very active research laboratory involved in industrial applications of proteomics.

Daniel Figeys' research involves developing proteomics technology and their applications in systems biology. This research is providing a comprehensive view of the interplay between the biomolecules involved in proteomics and system biology. Dr. Figeys and his group are developing micro fluidic technologies to measure the level of proteins in minute amounts of biological samples as well as developing a high-throughput mapping technology to detect various kinds of protein modifications. Dr. Figeys is also working on the application of proteomics with other "-omics" approaches to study human diseases in a systematic manner.

Johannes Geiselmann
(see page 35)

Dominique Vinck
Professor
Pacte Politique Organisations
Centre national de recherche scientifique
L'Université de Lausanne

In September 2011 Dominique Vinck joined the University of Lausanne (UNIL), where he has been developing his teachings in the field of Science and Technology in Society (STS). A full professor at UNIL, he teaches mostly engineers at the Swiss Federal Institute of Technology Lausanne (EPFL).

He conducts research at the Institute of Social Sciences, with an extensive but informal network of STS researchers, including staff at the Observatory for Science, Politics and Society (OSPS) (J.-Ph. Leresche, Director) and Interface Science-Society (A. Kaufmann, Director), as well as a group of sociology and history of medicine researchers (with F. Panese).

Appendix II

Conference Agenda

0900 Opening of Colloquium – Purpose, Agenda and Introductions

0915 Johannes Geiselmann (Grenoble) – *Synthetic Biology 101*

0930 Alexandre Dawid (Grenoble) – *From Computer Simulations to Gene Design: the Case of RNA*

1000 François Képès (CNRS) – *Synthetic Biology and Global Optimization of the Transcriptional Scheme in Microorganisms*

1100 Mads Kaern (University of Ottawa) – *Advancing Genetic Engineering through Synthetic Biology*

1130 Christina Agapakis (UCLA) – *Designing Biologically: Synthetic Biology Devices in an Environmental and Social Context*

1330 Keynote Address
Michele Garfinkel (EMBO and J. Craig Venter Institute) – *Synthetic Genomics: Science and Governance*

1430 Opening of Afternoon Session – Agenda and Introductions

1440 Virginie Tournay (Grenoble) – *Synthetic Biology: Genetic Engineering Like Any Other?*

1510 Jeremy de Beer (University of Ottawa) – *Synthetic Biology: The Case for Free Revealing*

1540 Jim Thomas (ETC Group, Ottawa) - *Whose Revolution is it Anyway?*

1630 Roundtable Discussion

- Moderator: Peter Calamai (Carleton University)
- Virginie Tournay (Grenoble)
- Christina Agapakis (UCLA)
- Jim Thomas (ETC Group, Ottawa)
- Geoff Munro (Natural Resources Canada)
- Pierre Charest (Natural Sciences and Engineering Research Council of Canada)

1715 Adjourn

The Institute for Science, Society and Policy

Centered at the University of Ottawa, the Institute for Science, Society and Policy carries out research, teaching and public outreach on the relationship between society and science, innovation and technology.

The ISSP offers a unique, holistic approach to understanding the social implications of science and technology. We're interested in how to use these different perspectives to inform science and technology policy.

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