

Synthetic Biology in the Social Context: The UK Debate to Date

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Abstract

The scientific community has shown unusual leadership in early and proactive identification of some of the social, environmental, ethical and security concerns raised by synthetic biology. The current influx of social scientists focusing their attention on the technology has, however, broadened the concerns and challenges of synthetic biology and, to some extent, altered the focus of the debate about social context. This article provides a snapshot of some of the main events and discussions that have taken place in the United Kingdom over the last few months on socio-political aspects of synthetic biology.

Keywords Collaboration, Governance, Public Critique, Public Engagement, Synthetic Biology, Translation

Synthetic organisms, parts and systems

Thirty years ago, the first gene was synthesized, measuring 207 base pairs in length (Khorana, 1979). A decade later, a plasmid measuring 2,100 base pairs was artificially made (Mandecki *et al.*, 1990), and, after another decade, a virus, measuring 7,500 base pairs (Cello *et al.*, 2002). Base pair sequences of 14,600 (Tian *et al.*, 2004) and 32,000 (Kodumai *et al.*, 2004) in length were synthesized two years after that, and last year saw the synthesis of *Mycoplasma genitalium*, a bacterium measuring an astounding 583,000 base pairs in length (Gibson *et al.*, 2008). Currently, scientists are working towards creating synthetic organisms and biological parts and systems that do not occur naturally, and they are also trying to re-engineer existing organisms to perform novel functions. The two lectures accompanying this piece—by Jay Keasling and Pam Silver—illustrate some of the advances leading scientists in the field have made on this so far.

Many commentators believe that synthetic biology has the potential for major wealth generation by means of the development of major new industries (Royal Academy of Engineering, 2009a). In health, for example, some predict that within the next five years the

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anti-malarial drug Artemisinin that Keasling's laboratory has developed will go into full production and will have an impact on malaria worldwide. It is also anticipated that synthetic versions of other natural substances with therapeutic properties will be produced using the same technique as with Artemisinin. For environmental applications of the technology, biosensors that detect arsenic in drinking water have already been developed and it is hoped that over the next ten years synthetic biology based biosensors will be developed to detect a range of toxins and heavy metals. The vision is that these could then be coupled to genetically modified bacteria that are capable of digesting and neutralizing the toxins and heavy metals. Silver, in her lecture, highlights the potential synthetic biology has for energy, where many believe that more advanced biofuels (typically biodiesel and bio-aviation fuels) will be developed that are more efficient—in that they convert a greater proportion of organic matter—than current processes. Many also predict that over the next ten years new types of synthetic biofuels are likely to be developed from renewable resources using branch-chain higher alcohols or new types of *E. coli* and other laboratory-based microorganisms. In agriculture, one of the most likely developments is anticipated to be the production of environmentally friendly pesticides, as well as the routine optimization of seed stocks to produce effective crops in difficult and complex environmental conditions. Synthetic biology also has potential applications in a range of other areas including materials and microprocessors.

The combination of engineering and the possibility of synthesizing whole genomes raises many troubling questions, however, and the synthetic biology community has shown unusual leadership in early and proactive identification of some of the social, environmental, ethical and security concerns raised by the technology. Already at the Second International Meeting on Synthetic Biology (Synthetic Biology 2.0), scientists in the burgeoning community made a declaration supporting the adoption of policies to ensure internal regulation and safe practice: 'A code of ethics and standards should emerge for biological engineering as it has done for other engineering disciplines' (Church, 2005: 423). Although such a code has yet to be developed, 'ELSI'¹ considerations have become an integral part of synthetic biology conferences, research networks, funding applications, special issues, policy groups and more.

Key social, environmental, ethical and security concerns

In highlighting social context concerns, the SYNBIOSAFE project—supported by the European Community's Sixth Framework Programme and the first project in Europe to research the safety and ethical aspects of synthetic biology—noted, for example, that:

... the ability to create novel organisms, or alter the DNA of existing ones, carries some risk that these organisms will behave in unexpected ways once they are released into the environment. Engineered bacteria, for example, can help to clean up

1 ELSI, or 'ethical, legal, and social issues', became a popular shorthand during the Human Genome Project to refer to the social context of the science.

contaminated soil but we should think of the consequences if the bacteria evolve the ability to spread through healthy ecosystems.²

Synthetic organisms might, for example, transfer their genes into existing organisms and alter the balance of the ecosystem. Synthetic organisms might also interact with naturally occurring substances and cause unexpected side effects, or they might evolve beyond their bespoke functionality and in that way produce unexpected side-effects on the environment and other organisms. Even if synthetic organisms are not purposely released into the environment, there is the risk of accidental release of such organisms that could have unintended and unanticipated detrimental effects on the environment or on human health. This, then, leaves us with questions such as: Who should be responsible for setting standards or determining the safety of synthetic organisms? Who should bear the burden or risk? How much should society spend on reducing risks from synthetic organisms to humans and the environment?

Synthetic biology also raises questions about fairness, equality and progress. One concern frequently raised in discussions about the social context of synthetic biology relates to patenting and commercialization of the technology (Rai and Boyle, 2007). At present, synthetic biology consists of both patented and open-source parts and processes, and these two strategies rest on fundamentally different approaches to questions about who should have control and who should have access to inventions and for whose gain. The J. Craig Venter Institute, for example, has applied to patent *Mycoplasma laboratorium*, the DNA sequence they claim represents the minimal requirements for life and could therefore act as a chassis for the development of bespoke microorganisms. Recently, the institute has also applied for broader patents that cover the creation of any synthetic genome, and their transplantation into cells. Intellectual property regimes are crucial for commercialization and for the economic opportunities of synthetic biology, but overly broad patenting could inhibit basic research and development and constrain the uses of the technology. Narrow patenting, on the other hand, could lead to a situation where the existence of patents on each of the hundreds of standardized parts that might be involved would simply not be feasible. Patents have also been opposed on the basis of morality and the inappropriateness of owning patents on living organisms (ETC Group, 2007). Open-source provides an alternative to patents, and a means to facilitate open scientific research by sharing parts and bringing about collaboration. The MIT Registry of Standard Biological Parts was established deliberately for this purpose, and researchers can freely use any of the 'BioBricks' and data within the registry provided any improvements or modifications are reported and that any new parts are registered on the same terms. Questions about fairness, equality and progress are also raised in discussions relating to the distribution of the risks and benefits of synthetic biology. A case in point relates to the anti-malarial drug developed by Keasling's laboratory, where some have expressed worries that the synthetic production of Artemisinin will make local production of natural *Artemisia* in developing countries unsustainable, and thereby exacerbate the already great discrepancy of wealth and health between rich and poor nations (Balmer and Martin, 2008).

2 Synbiosafe factsheet, published by the European Commission in 2007 and available at <http://www.synbiosafe.eu/uploads/pdf/Synbiosafe.pdf>

The creation of synthesized organisms that are not found in nature also leads to ethical questions about the role and responsibility of human beings in creating new kinds of life. Statements to the effect that the next 50 years of DNA evolution will take place ‘not in nature but in the laboratory and clinic’ clearly challenge our understanding of the natural world and our place within it. With innovations such as cell-free approaches, synthetic biology raises difficult questions about where the line should be drawn between what is ‘natural’ and what is not, and whether it is helpful to attempt to draw such a line at all (Royal Academy of Engineering, 2009a). It also raises questions about the role of humans in relation to ourselves, other creatures and the environment, and whether humans ought to intentionally create new life forms. As Parens *et al.* (2009) explain, some argue that the appropriate relationship of humans to nature is that of artists to their clay: we should see the natural world (including ourselves and our offspring) as ours to mould and modify as we want. If we did not take that view, we would lack antibiotics, plentiful food and clean drinking water, and we would remain victims of disease and slaves to our most basic needs. Others argue that if we begin to create lower forms of life and to think of them as ‘artefacts’ (as researchers in synthetic biology propose), it may in the long run lead to a weakening of society’s respect for higher forms of life and eventually to enhancement of human traits and capacities, and we risk undermining our respect for animals, and ultimately, humans as they naturally occur. They also argue that when we adopt the attitude of creators, we are making a category mistake—a mistake about the sorts of beings we really are. More specifically, we should not ‘play God’.

The concern that has received most attention in social context discussions about synthetic biology (albeit more so in the United States than in Britain and the rest of Europe) relates to biosecurity and the creation of synthetic organisms for malevolent or hostile purposes. The technology could be used, it is argued: to enhance the virulence of a pathogen, or a disease-causing biological agent, which would increase the severity of the resulting disease; to enhance the infectivity of a pathogen, or its ability to infect humans and cause disease; to increase the transmissibility of a pathogen within or between species; or to alter the host range of a pathogen, e.g. making an animal pathogen a human pathogen (National Research Council, 2006). The debate has so far been primarily focused on how synthetic biology may increase the risk of bioterrorism. Because there have been so few historical cases of terrorist use, fictitious scenarios have often been adopted as a means by which to assess the threat of bioterrorism, to explore the potential consequences of an attack, and to develop appropriate response mechanisms. Critics argue, however, that these scenarios paint an exaggerated picture of terrorist capabilities and the number of casualties resulting from an attack. While some terrorists might have the intent to carry out an attack with biological weapons that cause mass destruction and thousands of casualties, it is widely agreed by experts that they do not at present have the capability to do so. The critics argue that instead of focusing on terrorism, security concerns should focus on military uses of the technology. Not only is there a long history of military attempts to weaponize disease-causing biological agents, but significant amounts of money are currently being injected into synthetic biology by, for example, the US Department of Defense (DoD) and its Defense Advanced Research Projects Agency (DARPA). Indeed, a Defense Science Board Task Force on Military Applications of Synthetic Biology has been specifically set up in the

US to study possible ways to apply synthetic biology to military technology.³ Security concerns thus raise questions about how certain risks and threats are taken up (or not) in the policy discourse, who and what are the main drivers for the development of novel technologies, and how our governments and the international community should respond to these threats—should we, for example, be spending our limited resources on counter-terrorism and preparedness efforts against high-consequence but low-probability threats, or should we be spending our resources on other, more probable and more pressing, health and security concerns?

The evolving socio-political debate

The key social, environmental, ethical and security concerns raised by synthetic biology were identified at an early stage in the technology's development, often by scientists themselves, and are by now fairly familiar to those working in the field. The current influx of social scientists focusing their attention on the technology has, however, broadened the concerns and challenges of synthetic biology and, to some extent, altered the focus of the debate about social context. Some of this has occurred in the US—see for example the social and ethical research associated with SynBERC in California.⁴ However, there has also been a vigorous debate in Europe, and particularly in the UK, and the remaining few pages give a brief overview of how the debate about social context has evolved in Britain over the last few months.

Public engagement

Public engagement has been identified as a, if not *the*, critical factor affecting the development of synthetic biology, and—no doubt learning the lessons from other controversial technologies—there has been a widespread call for a new type of engagement: upstream engagement. This is meant to avoid the 'downstream' endeavours of previous phases, such as those associated with 'the public understanding of science' and with ELSI, as these, it has been argued, have involved consideration of socio-political issues at far too late a stage. Instead, the task now 'is to make visible the invisible, to expose to public scrutiny the values, visions and assumptions' that drive science (Wilsdon and Willis, 2004: 24).

The focus on public engagement has led to a surprising amount of effort to gauge public views and perceptions of synthetic biology at a stage when many of the claims about its powers and dangers remain somewhat hypothetical. The Royal Society, for example, issued a traditional call for views in June 2007 to find out what different stakeholders thought about synthetic biology, and to get their thoughts on what policy work the organization should undertake. Twenty-two responses were received from government departments, policy organizations, NGOs, academics and individuals, and these are available to view

3 Memorandum from John J. Young, Under Secretary of Defense for Acquisition, Technology and Logistics and Principal Deputy, Defense Research and Engineering, to the Chairman of the Defense Science Board entitled 'Terms of Reference—Defense Science Board (DSB) Task Force on Military Applications of Synthetic Biology' and dated 11 June 2008. Available online at: http://www.acq.osd.mil/dsb/tors/TOR-2008-06-11-Synthetic_Biology.pdf

4 See: <http://www.ars-synthetica.net>

on the Royal Society website.⁵ The European Community's SYNBIOSAFE project adopted a less traditional approach and held an open electronic conference in the spring of 2008, with the stated goal to 'stimulate a wider debate on the societal issues of synthetic biology in a proactive way' (Schmidt *et al.*, 2008). Brief descriptions of ethical, safety, security and other societal issues were posted on an online discussion board, allowing participants the opportunity to respond. The e-conference attracted 124 registered participants with different professional backgrounds from 23 countries, who wrote 182 contributions in six different categories: ethics, safety, security, intellectual property, governance and regulation, and public perception. These postings have been made available on the SYNBIOSAFE website.⁶ Yet another approach to public opinion polling was the survey commissioned by the Woodrow Wilson International Center for Scholars in summer 2008, in which Americans were questioned about their awareness of and attitudes towards nanotechnology and synthetic biology. Two focus groups were conducted in advance of the survey—one among women and one among men—to explore both unaided and informed impressions of synthetic biology, and to provide a context in which to better understand some of the survey findings. A report summarizing the findings from the 1,003 adults surveyed is available online.⁷

Drawing on the Woodrow Wilson survey, the British Royal Academy of Engineering conducted a similar poll on awareness of and attitudes towards synthetic biology in the UK. Two focus groups exploring people's perceptions, aspirations and concerns about synthetic biology preceded a 1,000-strong pool of telephone respondents answering questions such as 'How much would you say that you have heard about synthetic biology?', 'What words or phrases come to mind when I say 'synthetic biology'?', and 'What do you think synthetic biology might be?'. The findings—echoing those in the United States—were published in a Royal Academy of Engineering report and launched at a high-profile event at the Academy in June 2009.⁸ This event encouraged discussion of the survey and its findings, and of public engagement with synthetic biology more generally, and raised some helpful points to further the debate.

One of the key questions asked was: 'Where do we go from here?' Or, phrased differently: 'What is the goal of public engagement with synthetic biology?' Is it an exercise aimed at getting the public on board so that the research is not unnecessarily hindered and the potential benefits of the technology are not diminished? Or is it less about maintaining public legitimacy and support, and more about allowing citizens to offer an upstream critique of the values, visions and assumptions driving the research? Many of those present at the launch event felt that engagement was about this latter objective: to feed in a broad range of views and concerns at an early stage in the development of synthetic biology to avoid repeating the mistakes of the past, where technologies like asbestos, chlorofluorocarbons, DDT and thalidomide were developed before their risks had been adequately assessed, and where technologies like genetically modified foods were brought to market before both their impact on human and environmental health, and their impact on traditional

5 See: <http://royalsociety.org/document.asp?tip=0&id=7290>

6 See: <http://www.synbiosafe.eu/forum/>

7 See: <http://www.nanotechproject.org/process/assets/files/7040/final-synbioreport.pdf>

8 Available in hardcopy (Royal Academy of Engineering, 2009b) or online at http://www.raeng.org.uk/news/publications/list/reports/Syn_bio_dialogue_report.pdf

farming practices and other well-being concerns had been carefully—and democratically—addressed. Yet, as was also pointed out, this kind of public engagement will likely slow scientific and technological progress, and the question then remains: is this a price worth paying?

A second key question leading on from this is how to balance the concerns of the public with the concerns of professionals with expertise in fields such as sociology, ethics, law, security, philosophy, history, etc. Should more weight be given to concerns emphasized by the public, or to concerns emphasized by social scientists? Of course this is not an issue where the concerns align, but what do we do in cases when they do not? Should synthetic biologists or policy-makers pick and choose which particular concerns to give weight to and respond to? An element factoring into this is the malleability of public opinion—a point raised by Fiona Fox, one of the speakers at the launch and founder of the Science Media Centre. It was also a point demonstrated in the focus group research itself, where the participants were initially very positive and enthusiastic about synthetic biology following the first presentation on the science and potential applications of the technology, but following the second presentation, which outlined some of the concerns about the technology, they were less so. Another element factoring in that was also raised in the launch discussion is the finding from the research (not described in the report) that the focus group participants were apparently very happy to let others do the thinking for them. Does this mean there is no point in public critique and that it is better to leave the identification of concerns to professional social scientists, who think about risks and consequences as part of their job? Of course public critique has an important role to play, and this is discussed in more detail below, but if upstream engagement is to be taken seriously it is essential to establish how and to what extent public critique will feed into scientific and policy processes around synthetic biology, and to consider the weight this is given vis-à-vis the critique coming from social scientists.

The role of social scientists

The role of social scientists and of social science critique was taken up at the May 2009 workshop on ‘Synthetic biology and Science and Technology Studies’ organized by the Genomics Forum in Edinburgh. The workshop brought together the social scientists involved in the seven synthetic biology networks established by four of the UK’s research councils to build links across institutions and disciplinary boundaries.⁹ The networks, which were established last year and formally involve eight universities, are required by the funders to have an ELSI component: ‘It is very important that ethical and other social issues are identified at this early stage in the development of synthetic biology, before new products and processes are made, so that research funders and researchers can take these into consideration’ (BBSRC, 2008:5). Yet, what exactly ‘taking these [issues] into consideration’ actually involves has not been articulated by the network funders, and one of the aims of the Edinburgh workshop was to collectively discuss why social scientists are being invited to

⁹ The research councils involved are primarily the Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Research Council (EPSRC), but where relevant the Economic and Social Research Council (ESRC) and the Arts and Humanities Research Council (AHRC) are also involved.

join natural scientists in synthetic biology, and how our role is being constructed and imagined by the institutions and groups that have invited us to become engaged.

When the ‘why?’ question is asked of the network funders, the quick response is ‘We don’t want another GM’—a response familiar from and echoed in many other settings. The assumption underlying this response seems to be that the involvement of social scientists will in some way prevent such catastrophes happening again. Is the inclusion of social scientists an attempt, then, to shift the responsibility for all the non-scientific consequences of synthetic biology and the public reactions to these consequences away from natural scientists? Perhaps, but perhaps not. There may, of course, be other reasons for inviting social scientists in. The scientific and policy communities may genuinely think that synthetic biology raises important issues beyond the scope of their expertise. Or there may be a hope that the involvement of social scientists will give synthetic biology research legitimacy, or, indeed, that the involvement will somehow make the science more democratic.

To start exploring the role attributed to social scientists, Jane Calvert and Paul Martin, both social scientists who have been heavily involved in the UK synthetic biology community, sketched out a tentative analytical framework for discussion at the Edinburgh workshop.¹⁰ The framework suggests three different roles for social scientists: contributors, critics or collaborators. ‘Contributors’ are those who contribute to and facilitate the progress of the field, and include social scientists who act as intermediaries between scientists and the public, social scientists who represent ‘the public’, and social scientists who act as public communicators and advocates for the field. A more familiar role is perhaps social scientists as ELSI experts, who are also considered ‘contributors’ since this role rests on the assumption embedded in the way much ELSI research has been framed in the past—that scientists first do their research and the social scientists arrive afterwards to decide what the implications, effects or consequences of this work are for society. The ELSI label thus reinforces a strict division between the scientific and the social, where the idea that knowledge production itself could be changed, and perhaps even conducted in collaboration with non-scientists, is entirely absent. The category of ‘critic’ is a more traditional one for social scientists focused on science and technology. Here our role is one of deconstructing and challenging taken-for-granted assumptions by simultaneously embedding ourselves in the scientific field of study and standing back to reflect on current approaches. Yet, as Calvert and Martin point out, the role of a critic could be interpreted in the negative sense of finding fault with or denouncing the science rather than the more neutral judging of the qualities or merits of the science, and this causes difficulties when you want access to the field and have developed good working relationships, even friendships, with the scientists. An alternative to both contributor and critic is to see the role of social scientists as that of ‘collaborators’, where we are involved in the process of knowledge production itself, co-producing new forms of socially robust science. The invitation to join natural scientists can then be taken as a unique opportunity for genuine interdisciplinary work which does not just follow science but interacts with it, helping to shape future research directions and changing the relationship between life scientists and those who study them.

10 Calvert and Martin (forthcoming); see also Calvert and Martin (2009).

There was general agreement at the Edinburgh workshop that those of us involved in the UK synthetic biology community would prefer to be seen as collaborators—a role that is also ideologically in line with the notion of upstream engagement. It was recognized, however, that in practice it is sometimes difficult to avoid the tokenism and co-option of the contributor role, as well as the judging involved in the role as a critic. The discussion also raised the difficult question of how to go about forming genuine partnerships with the scientists. While there is no right answer and no one way to do this, what Nikolas Rose and I have tried to do in our collaboration with Imperial colleagues on synthetic biology is to ensure a real commitment to the partnership by, amongst other things, securing access and substantial funds for social science research, by genuine involvement on the strategy and management committees of our joint centre, by inserting requirements to consider social aspects in the job descriptions of lecturers, by sitting on the selection panels of new lecturers recruited, by hosting seminars and discussion meetings alternatively at Imperial and LSE between the natural and social science groups, by co-writing articles, and by teaching on their undergraduate and postgraduate courses and incorporating appropriate assessment of the social science components alongside those of the natural science. The launch of our Centre for Synthetic Biology and Innovation (CSynBI)—a centre funded by the Engineering and Physical Sciences Research Council (EPSRC) to spearhead UK research in synthetic biology—was another event that took place over the last few months, and which returns us to the role of public engagement and public debate and critique.

Public and commercial value

The CSynBI launch in May 2009 saw a series of juxtaposed presentations from natural and social scientists involved in synthetic biology, aimed at emphasizing the very close relationship between the scientific and the social. This was also a point made more explicitly by Nikolas Rose, Director of the BIOS Centre at the LSE and head of the social science effort at CSynBI, who noted in his presentation that the social almost seems to be built into the very conception of what synthetic biology is. Synthetic biology would not have generated the investment of time, energy and resources that it has if it was not seen to have a social utility, and if that social utility was not in some ways seen to have a public value and a commercial value.

But how, he went on to question, can you ensure the pathway from basic scientific research to commercialization and to products that will produce public value? In other areas of biomedical research this has proved to be a real problem. The Medical Research Council (MRC), for instance, has become concerned in the last few years that the very large investments it made into basic biomedical science on the dream of producing translational effects that would increase clinical efficacy and generate new therapeutics, have, for the most part at least, not yet been realized on the scale predicted. One of the reasons for this, Rose suggested, is that while a great deal of emphasis has been placed on the basic bioscience, not enough consideration has been given to the process of translation. While there are multiple elements that play significant parts in that process—such as achieving buy-in from scientists in a number of disciplines and developing proper career paths for the younger generation—Rose stressed the essential part a market pull plays from both public and private funders. This means that, right from the very beginning, synthetic biology raises questions of commercialization and intellectual property.

Concerns about private gain have in the past, if not destroyed, then at least undercut some other very promising technologies. One of the problems genetic modification (GM) faced, for example, was the belief among the public that this was simply a technology for commercial gain and that the use of the intellectual property regime to safeguard GM innovations was a device purely aimed at ensuring private, and not public, value. While some, like Craig Venter, downplay concerns about intellectual property, arguing that it is clearly a regime that enhances, rather than stifles, innovation, the disputes about the human genome and the patenting of basic gene sequences illustrate the problems of the intellectual property regime. To facilitate the commercialization of synthetic biology it is therefore critical that there is an assurance, right from the start, that the products of scientific research will enter the public domain and generate public value. The synthetic biology community has already gone some way towards this through its open-source system of making basic biological parts and processes freely available and only permitting the step of innovation, of actually doing something new with a function, to be amenable to patenting. Yet the system is still in its infancy and, without further development and demonstration that it is a sustainable intellectual property regime that allows the generation of public goods, then the public support and trust currently enjoyed by synthetic biology will wane.

Closely tied to the generation of public and commercial value are questions about the agenda synthetic biology should attempt to address. Unlike with GM, many of the products and applications that have come out of synthetic biology so far—such as the genetically engineered device to detect urinary tract infection and the biosensor to detect arsenic in drinking water—have had an immediate public relevance and it is clear that the technology can have a public advantage. Yet, without an early public debate and democratic dialogue on how the knowledge generated through synthetic biology can be used for human good—a debate and dialogue that opens up the question of what agenda synthetic biology should attempt to address and how to encourage a translation process focused on public value and not just commercial value—Rose concluded that the technology may go the way of GM.

In a somewhat ironic turn of events, having carefully tried to present the arguments for upstream engagement and early public debate on the agenda of synthetic biology, what actually got reported in *Nature* was that: ‘A synthetic-biology centre opening today at Imperial College London is hoping to pre-empt public concerns about the field by integrating social scientists into its research team.’¹¹ So although the message seems to have gotten lost this time round, we will continue our efforts and, with the help of many others, we will hopefully get to a stage where we can say we are genuinely making visible the invisible, exposing to public scrutiny the values, visions and assumptions underlying synthetic biology, and opening up a democratic dialogue on how we should develop and use this technology for human good.

Governance

The way in which we want to develop and use synthetic biology has implications for how we choose to regulate it, and the governance of synthetic biology was one of the key themes

11 See: <http://www.nature.com/news/2009/090512/full/news.2009.464.html>

discussed at the Nuffield Council of Bioethics ‘Forward Look’ workshop in April 2009. It was highlighted that the development of regulatory regimes for new technologies is the result of social negotiations between key participating groups. Social science scholarship has empirically detailed this balancing act across a number of life science technologies such as recombinant DNA, gene therapy, pharmacogenomics and stem cell therapies. For example, when recombinant DNA—a precursor technology to synthetic biology—was first introduced as a reality in the mid 1970s, the risks associated with the new technology were not self-evident. Wide differences in opinion about its possible impacts existed among scientists, as well as among other stakeholders, including academic communities, local authorities and environmental groups. Yet, within a relatively short period of time, consensus was achieved on the nature of the risks and on the nature of an appropriate response, as well as on who should make that response: the problem with recombinant DNA was reduced to technical research hazards and the appropriate response became finding technical fixes to contain those hazards, an issue best resolved by technical experts (Wright, 1994).

At the Forward Look workshop it was argued that we are currently at a critical stage in the development of a regulatory framework for synthetic biology, where the risks of the technology have not yet been agreed. Yet, while different concerns with the technology can still be found within the scientific and policy communities—such as the unintended and unanticipated detrimental effects of synthetic organisms on the environment or on human health, and the role and responsibility of human beings in creating new kinds of life, concerns that have already been described in this article—there is an increasingly narrow focus on biosecurity concerns and on preventing new opportunities for bioterrorists. While it is, of course, prudent to take this concern seriously and to put in place measures to address risks of this nature, it is equally important that other concerns, including the uncertainties and unintended consequences of synthetic biology, its long-term social and environmental impacts, the advisability of promoting its rapid expansion, and the use of the technology by private industry and the military, are not marginalized in the policy discourse.

The Nuffield Council of Bioethics ‘Forward Look’ workshops are an opportunity for the council to consider possible future work topics, and synthetic biology was one of four topics covered at its two-day workshop. Synthetic biology was also the topic of the council’s annual public lecture, this year given by Thomas Murray, President and CEO of the US-based Hastings Center, who spoke on ‘New genetic recipes: Are we cooking up trouble with synthetic biology?’ The council seems keen to further its involvement in synthetic biology, but rather than duplicate the many reports that have already been commissioned on the social and ethical issues raised by the technology, it seems likely to use synthetic biology as a case study alongside one or more other emerging technologies to consider some of the cross-cutting ethical questions they raise. This thinking to some extent reflects that of researchers at the Woodrow Wilson Center who say that:

Recognising synthetic biology as another emerging technology helps us avoid needlessly reinventing the ethical wheel each time we encounter a ‘new’ area of science. We acknowledge and understand that funders and grant writers might initially be tempted to describe the ethical issues surrounding synthetic biology as ‘new,’ but in the long run such a strategy can lead to disappointment. A more prudent, if less

dramatic, approach makes clear from the beginning that even if it makes sense to tackle the ethical issues as they arise with each field of science and technology, these issues are familiar and have been considered, although not necessarily resolved, in other contexts in the past. (Parens *et al.*, 2009: 11)

Indeed, the Woodrow Wilson researchers go so far as to say that it ‘would be a waste of resources to take up the ethical questions in parallel’ and that it ‘is time to go from speaking about hyphenated ethical enterprises (gen-ethics, nano-ethics, neuro-ethics, synbio-ethics) to speaking about the ethics of emerging technologies’ (Parens *et al.*, 2009: 4). Yet, while many of the ethical issues may be the same for emerging technologies, some of the socio-political issues differ. Synthetic biology, for example, raises different questions from genetics, nano-technology and neuroscience in terms of altering the balance of global food production, shifting energy production activities and synthetically producing new drugs. The drivers and consequences of the technologies in question may also differ—there are, for instance, different balances of personal and industrial interests between personal genomics and ‘garage biology’. Arguably, therefore, we need studies that address concerns specific to each new technology, as well as studies that address concerns cutting across the different technologies, to see similarities and recognize real differences, especially if we move beyond ethics to social questions.

Social and biological systems

This article has provided a snapshot of some of the key events and discussions that have taken place in the United Kingdom over the last few months relating to socio-political aspects of synthetic biology. This debate is no doubt going to continue evolving, because, if the promises of synthetic biology are going to be realized, they are going to be realized in the social context. Social systems are at least as complex, and perhaps even more unstable than biological systems, and if synthetic biology products are going to be designed and introduced into social systems and have the desired effects, we need to keep trying to understand that interaction between the social and the biological systems.

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