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CC: Tom Finnegan, Nuffield Council on Bioethics

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Re: Response to Consultation on Emerging Biotechnologies

The Ethical Implications of Synthetic Biology

You asked us to consider the way society and policy makers respond to new biotechnologies and to discuss how benefits from these technologies can be secured in an ethically appropriate manner. We have chosen in our response to focus on the ethical issues that are raised by recent developments in the field of synthetic biology. In what follows we provide an overview of the social and ethical implications of synthetic life technologies. We address topics that include risk management; dual use; hazards to human health and the environment; the 'playing God' objection; attitudes toward the living world; distinctions between organism and machine and between the natural and the artificial; justice; and institutional design.

Contents

1. Synthetic Biology: A Brief Introduction

Synthetic biology is a new discipline that lies at the interface of information technology and molecular developmental biology. It aims to apply rational engineering principles to the creation of biological organisms, sub-systems or their components. Synthetic biology is rapidly emerging as one of the most promising fields of science and technology, with the potential to deliver enormous benefits in areas such as medicine, energy, agriculture, pollution and climate change. Significant milestones achieved in the field to date include the de novo synthesis of functional viruses, the creation of a novel lineage of bacterium from a wholly synthetic bacterial genome, and the compiling of a registry of 'standard biological parts' which synthetic biologists aim to use as the building blocks for synthetic organisms and sub-systems designed for a wide range of human purposes. If this modular approach to rational design succeeds, a small increase in the number of building blocks available will lead to an exponential increase in the range of novel organisms and organismic properties that could be created. In the not too distant future, humans may be able to engage in the large-scale design and creation of forms of life that have never existed on this planet, would not have existed without human intervention, and are exquisitely tailored for human purposes. The proliferation of potentially inexpensive synthetic

life technology, including the capacity for digital design and manufacture of DNA sequences from scratch, raises a host of ethical issues that we consider below.

Although the scientific study of living organisms is replete with rational design metaphors, it is unclear whether the engineering approach to designing life from the ground up is likely to succeed, given the complexity of genotype-phenotype relations and the difficulties this creates for engineering and reverse engineering organismic functions. For the purposes of the present ethical analysis, however, we will assume that these substantial obstacles to the radical re-design of living things will eventually be overcome.

2. Benefits and Risks

As the first step of the ethical analysis of synthetic biology, the Nuffield Council on Bioethics ('Council') should assess the full range of potential benefits of synthetic biology. Potential applications include (inter alia) renewable biofuels, drugs or drug precursors, targeted medical treatments, biosensors, technical materials**,** nuclear waste disposal, chemical detoxification, superefficient agriculture, energy harvesting and conversion, and geoengineering. Creating a so-called 'minimal microbe' template could streamline the design of biological systems or their components, which could then be engineered for a host of specialized applications, such as those mentioned above. In addition, the capacity to engineer and reverse-engineer organisms may vastly increase our knowledge of the complex causal relations between genomes and the functional properties of living things, leading to unanticipated benefits.

Once the potential benefits have been identified, the Council should determine which of the identified benefits can only be obtained, or obtained at reasonable cost, through synthetic biology. It should evaluate what if any advantages synthetic biology has over alternative emerging technologies, such as genetic modification, the manipulation of gene expression and nanotechnology, as well as its advantages over more traditional forms of medicine and technology. Understanding the comparative advantages of synthetic biology will be crucial for making risk-benefit assessments, especially if it should turn out that synthetic biology poses distinctive risks.

The Council should recognize that the goal of regulatory action is not to eliminate risk, but to limit it to acceptable levels. Elimination of risk is rarely attainable, and beyond a certain point further risk-reduction is undesirable due to regulatory costs and the loss of possible benefits. The Council should help develop cautionary heuristics for decision-making in synthetic biology that take into account the best available evidence, are sensitive to current information deficits and known human biases, encourage the acquisition of knowledge relevant to future decisions, and take into account the potentially significant benefits of weaker restrictions. The Council should be wary of reliance on a single, simple, all-encompassing risk-reduction principle, such as the 'precautionary principle'; such a principle is unlikely to capture all of the ethical considerations that bear on these decisions. Reliance on a plurality of risk-reduction heuristics and a multi-faceted regulatory framework, to be modulated over time in the light of increasing knowledge, is much more reasonable—particularly in light of existing uncertainty

about how the field of synthetic biology will develop and the extent of the benefits that it might produce.

Furthermore, the Council should recognize that the realm of synthetic biology is broad. It includes not only the creation of new complete organisms but also living components that do not rise to the level of life forms, let alone complex life forms. It is unlikely that any single, all-encompassing approach to risk management will be flexible enough to accommodate the diversity of risk issues that are likely to arise in connection with synthetic biology. The Council should therefore consider whether different regulatory approaches are appropriate for different areas of this expansive domain. In addition, the Council might choose to develop a comprehensive classification of the risks associated with synthetic biology and attempt to determine which risks, if any, are peculiar to this domain or elements within it.

In our view, the most important classes of risks in the context of synthetic biology are (1) the risk of unintended consequences, such as harms to human health and the disruption of existing ecological systems, and (2) the risk associated with intentional misuse. We believe that both of these concerns are serious, but that the risk of intentional misuse may be the most difficult to address and should therefore be a primary focus of the Council's deliberations. Below we discuss two distinct 'Dual Use' problems that this risk creates. We then go on to examine what we take to be the major concerns regarding unintended consequences, in descending order of their perceived significance. These include harm to health and the environment, secular versions of the 'playing God' worry that are framed in terms of the limitations of human knowledge, the devaluing of life, and the potential moral implications of blurring the boundary between putatively discrete categories such as organism and machine.

3. Dual Use

The 'dual-use' problem refers to the possibility that knowledge produced by some technological enterprise, while beneficial to society, might also be intentionally misused to inflict unjustified harm. The dual use problem rises to the level of a 'dilemma' when the risk of unjustified use is sufficiently high that it is no longer obvious that the technology should be pursued or its fruits disseminated. We think it is important, here, that the Council notes that there are in fact two kinds of dual use problems. The first (Dual Use 1) is the worry that dangerous synthetic organisms or the recipes to produce them could fall into the hands of one's enemies, whether these are non-state actors (e.g. terrorists), opponent states, or politically unstable regimes with weakened levels of security. The second dual use problem (Dual Use 2) is the concern that the knowledge output of synthetic biological research and development could be incorporated into the offensive bioweapons programmes of one's own state or its allies, leading to the subsequent misuse of such weapons during military conflict. The Council should recognize that measures designed to reduce the risk of Dual Use 1 cases can, under certain circumstances, exacerbate the risks of Dual Use 2. For example, a government-funded anti-bioterrorist initiative may stimulate research on defensive strategies that the government then uses for unjustified offensive purposes. Notoriously, the line between defensive and offensive bioweapons development is hard to draw, and it is difficult to maintain levels of accountability that ensure the relevant actors keep within the authorized scope of defence. In addition, grants for anti-

bioterrorism research will result in more people being trained in skills that could be used for terrorist purposes.

As the 1996 report of the U.S. President's Advisory Committee on Human Radiation Experiments shows, there are serious risks associated with complicity between leading figures in science and unethical governmental programmes carried out with elements of secrecy and in times of perceived national emergency. The Advisory Committee reviewed radiation research that was sponsored by the federal government between 1944 and 1974. These experiments were conducted in furtherance of biomedical knowledge and national defence, and were routinely carried out without consent of or benefit to the human subjects involved. The Council should therefore pay careful attention to the ethical dimensions of the relationship between scientists and those in charge of national defence.

At present it is unclear whether it will become possible, in the foreseeable future, for state or non-state actors to design pathogens that could be significantly more harmful than wild types. The Council might consider requesting that more research be done to determine whether this is possible and, if so, what implication it might have for dual use dilemmas. Assessing the potential potency of synthetic biological agents, however, could itself carry dual-use related risks.

Some have suggested that, faced with the prospect of misuse, the scientific community or those responsible for regulating its activities may need to take steps to prevent the creation or dissemination of knowledge about particularly misusable forms of synthetic biology, such as by censoring scientific publications or diverting funding away from areas of science that are likely to produce 'dangerous' knowledge. To help assess the need for and appropriate nature of such measures, the Council should encourage the discipline of research ethics to broaden its scope. To date, research ethicists have focused mainly on the *means* by which scientists should produce scientific knowledge, and particularly on the protections required for human and animal research subjects. Given the concerns regarding misuse that are raised by synthetic biology and some other scientific areas, research ethicists should also consider questions about *what* knowledge scientists should pursue and how they ought to disseminate it.

4. Unintended Consequences: Harm to Health and the Environment

Although the release of synthetic or genetically engineered organisms into the wild remains a concern, there is to date little evidence that the deployment of genetically modified organisms (GMOs) has resulted in major ecosystem disruption, as many had initially feared. Nor have any serious negative health effects from the ingestion of genetically modified foods been demonstrated. The Council should ask the following questions: is there any reason to think that the products of synthetic biology pose inherently different levels or qualities of risk to health, ecosystems and the environment than (i) their genetically modified counterparts, or (ii) wild-type microbes? How would fabricated organisms of varying biochemical and genetic constitutions interact with living systems and ecosystems?

It might be helpful in this regard to consult the astrobiological literature concerning risks associated with extraterrestrial 'back-contamination' in the context of space programs involving

sample-return missions, which have considered the ecological implications of introducing life forms of radically different biochemical makeup from any that currently exist on earth. The Council should recognize, however, that there is controversy surrounding the ecological impact of introduced organisms. There seem to be two schools of thought on this matter. The first holds that the risk of negative interaction between introduced synthetic and endemic lineages would be minimal, given that strategic co-evolution requires prolonged evolutionary contact, and that in any case species will tend to diverge so as to avoid direct competition. This was the conclusion, for example, of the Task Group on Issues in Sample Return (1997), a body of the Space Studies Board of the National Research Council that was tasked by NASA to assess the risk of contamination of the Earth's ecosystems by extraterrestrial microbes. A second school of thought holds that endemic organisms and ecosystems are at high risk of being ravaged by invaders, since they are essentially akin to 'naïve' prey or competitors that are not adapted to defend or compete against these alien intruders. A more thorough understanding of the relevant causal, evolutionary and ecological variables is required in order to resolve these questions to any degree of certainty, and the answers may not generalize beyond individual cases. Nevertheless, we believe that in relation to radically novel forms of life that might be produced by synthetic biology, the latest evolutionary and ecological science points toward the 'minimal interaction' theory.

The Council should weigh potential harms to ecosystems as a result of the release or escape of synthetic organisms against the potentially significant ameliorative role that synthetic biological agents may play in repairing such damage (see section 1 above). Furthermore, the Council should look to ways of reducing health and environmental risk by drawing on strategies of containment and reversibility that were developed in the context of genetic modification technologies. One example of a containment strategy is the design of synthetic organisms with a crucial auxotrophy, that is, the inability to synthesize some organic compound necessary for its life cycle. Multiple redundancies in metabolic dependency might be expensive to institute, but they would help to prevent safety features from being breached through the ordinary course microbiological evolution.

In considering the problem of unintended ecological consequences, the Council should avoid invoking or tacitly appealing to simplistic notions such as the 'benevolent balance of nature' that have little theoretical or empirical grounding in contemporary evolutionary and ecological science, as such metaphors may distort a rational calculation of risks and benefits. The Council should ensure that its assessment of risk is not premised on fallacious views of nature and the natural, and that its judgments are informed by the best available evolutionary and ecological science. For example, the Council should avoid giving credence to objections to synthetic biology that are based on pre-Darwinian or teleological views of nature. It is not helpful, we believe, to view 'natural' organisms as akin to the products of a benevolent master engineer, as this can lead to the mistaken conclusion that human intervention in complex biological systems is inherently hubristic and only likely to produce undesirable harms to people and/or the environment. More generally, the Council should be careful in using terms such as 'normal', 'natural', 'nature', and 'human nature,' as these terms often conceal controversial moral assumptions as descriptive, factual claims.

Another common environmental concern in the context of GMOs is the so-called 'pollution' or 'contamination' of gene pools. This worry could be extended to synthetic life sciences if there is a possibility that synthetic organisms could exchange genes with wild types,

such as via lateral gene transfer if they are sufficiently similar genomically. This would be a legitimate worry if there were evidence that such events would have ecologically harmful consequences. In the absence of such evidence, 'genetic pollution' should not be a major concern for the Council, since in our judgment views about the supposed value of 'genetic purity' tend to rely on problematic conceptual and normative assumptions about 'the natural' that the Council would do well to avoid.

5. Playing God

A common criticism of emerging biotechnologies takes the form of an admonition that scientists should not 'play God'. The playing God objection is a familiar one in the context of genetic modification, and it is likely to be advanced even more vigorously against synthetic biology, which represents perhaps the paradigmatic case of playing God. Synthetic biology enables scientists to design and create new forms of life from basic organic components—an ability often imputed to God—as opposed to simply modifying existing living structures as entailed by genetic modification. Despite the novel possibilities associated with synthetic biology, it is plausible to think that the modification, design and de novo creation of life either all involve some problematic form of playing God, or none of them do. We therefore do not see synthetic biology as raising any qualitatively new ethical concerns in this area.

There are several ways to construe the playing God criticism. The first is deontological or theological: it asserts that humans should not intervene in certain realms of the natural world regardless of what the likely consequences of such interventions will be. Some people believe that the genetic modification or de novo creation of living organisms encroaches into such a forbidden realm, and hence they believe that there is something intrinsically wrong with these activities that warrants their prohibition. On some theological accounts, however, such technological interventions are viewed as consistent with God-given motivational, cognitive and cultural abilities for self and environmental improvement. There is thus no clear and consistent religious position on the matter. In any case, while we recognize that many people may share these religious intuitions, given that they can reasonably be contested, we do not think that they can justify placing an absolute moratorium on synthetic biology and foregoing the potentially enormous benefits that it might produce.

A second way to construe the playing God objection is in terms of moral virtues or character traits. It holds that the development and deployment of genetic engineering and synthetic life technologies reflects a hubristic desire for total mastery over nature. We believe that this criticism unfairly discredits the motivations of all of those who promote emerging biotechnology, many of whom are motivated not by a desire to master nature in any objectionable way but by the prospective social and medical benefits of these technologies. Like attempts to repair or improve human capacities through traditional biomedical means, the development of synthetic biology need not signal a desire for perfection or total mastery, but rather a reasonable commitment to improving the quality of human life.

Because intervention in nature in furtherance of human good is widely accepted in religious and secular circles alike (consider the eradication and treatment of disease, for example), one would need to come up with a principled basis by which to distinguish hubristic interventions that amount to playing God from those that are laudably foresighted, realistic, and

desirable. The focus, therefore, should be on the identification of risks, including the 'meta-risk' that we will overestimate our ability to act without undue risk. Note that the mere identification of this risk is not an objection to pursuing synthetic biology. The question is how serious this risk is compared to the benefits, and whether there are morally acceptable means of reducing the risk to acceptable proportions.

Perhaps the most plausible formulation of the playing God objection is the epistemic version, which expresses the worry that we might fail to give due consideration to the limits of our knowledge and thus overestimate our ability to improve on existing complex biological systems. This is essentially a variant on the concern about unintended consequences, discussed in section 3 above. However, we believe that even this version of the playing God objection should not be a focus of the Council. Though seemingly commonsensical, this formulation of the playing God concern is not helpful in the policy arena because it is not evidence-sensitive, it does not encourage the acquisition of relevant knowledge regarding the causal structure of the biological systems in question, it offers no substantive guidance with respect to the development of more appropriate safeguards based on this acquired knowledge, and it fails to take into account the potentially significant benefits of the technology.

6. Organism or Machine? Natural or Artificial?

As in the case of genetic modification, the Council should not assume that there is anything inherently ethically problematic about altering or synthesizing living systems, apart from the harmful consequences it may have—including, of course, its effects on human relationships, attitudes, and values.

Commentators often remark that the genetic engineering of organisms, and in particular the wholesale design and manufacture of living things from virtual genetic sequences, is blurring the line between organism and artefact, life and nonlife, natural and artificial—transforming the relationship between humankind and nature in ways that are exhilarating to some people but worrisome for others. Many fear that the blurring of these ontological categories will result in the creation of entities with reduced moral status, lead to the general devaluing of life, and/or encourage the belief that all life is of merely instrumental value.

There is disagreement about the extent to which current work in synthetic biology is already crossing ontological boundaries. For example, while some maintain that bacteria with synthetic genomes are a kind of 'artificial life', others hold that this is a mischaracterisation since in such cases only the bacterial genome has been synthesized de novo (the synthesized genome was transplanted into the cytoplasm of a natural cell). It seems likely, however, that future work in synthetic biology *will* challenge some of our everyday intuitions about ontological categories. What is less clear is whether this is in any way ethically problematic.

With regard to the anticipated public response to synthetic biology, the Council should avoid making any a priori predictions regarding social attitudes toward this technology, and it should realize that initial attitudes are likely to change as the technology becomes more commonplace. We would do well here to recall the welter of false a priori predictions about the

social stigma and its attendant psychological difficulties that persons created through IVF would be made to suffer. The Council should therefore refrain from issuing armchair predictions about sweeping patterns of attitude change—such as that people will lose their 'reverence' or respect for life if we were able to (and did) design and create it. These are all empirical questions, and even if these predictions are to some degree borne out, it remains an open policy question whether the negative effects of social attitudes and prejudices are better addressed through public education programs rather than through the prohibition of these technologies, particularly given the potentially significant benefits that are at stake.

The Council should not assume that the distinction between machines and living things, or between natural and artificial life, as might be applicable in the context of synthetic biology, is itself morally significant. Instead, it should stress that what matters for the purposes of ethical analysis is the *moral* status of an entity, and that this depends not on the aetiology or biochemical makeup of the being, but on its functional properties (such as homeostasis, sentience, consciousness, or rationality). How a being came to exist is not relevant to its moral status. For example, a person is a person, with all the rights and moral protections that this entails, regardless of whether she came to be through ordinary sexual reproduction, IVF, or, for that matter, cloning. Similarly, a bacterium would have no significant moral status regardless whether it was created through natural replication, *in vitro* culturing, or synthetic techniques. The Council should therefore not assume that the distinction between creating living or life-like entities via synthetic biology and creating them through other technologies, such as genetic engineering, embryo selection, sperm sorting, IVF or ordinary reproduction, is morally significant in itself, much less that it has implications for moral status. There is still much debate over the functional properties that are relevant to moral status. Candidates range from sentience and the ability to experience pleasure or pain to consciousness, self-consciousness, rationality and personhood. To the extent that synthetic organisms posses morally relevant properties, they will be morally considerable irrespective of their genealogy. Likewise, insofar as synthetic organisms possess instrumentally valuable intrinsic properties, they will be instrumentally valuable irrespective of their aetiology. The causal history of how an entity came to be is generally orthogonal to questions of intrinsic moral worth and instrumental value.

The council should not assume, however, that synthetic entities would have any significant moral status. Most of the entities likely to be created by synthetic biology would not fall into traditional categories of entities that are thought to be morally considerable. Nearly everyone believes that we are justified in killing or using bacteria or complex single-celled organisms whenever it suits us. We do not think that in doing so we violate any rights, obstruct any morally relevant interests, or undermine anything of intrinsic value. Few people argue that the bare fact of being alive (e.g. maintaining homeostasis) confers moral status on an entity.

In the longer term, more sophisticated entities may be created by synthetic biologists, and these might, due to their unusual functional capacities, possess an uncertain moral status. However, this is in a sense nothing new: the existence of non-human animals of varying degrees of cognitive capacity has long confounded attempts to classify entities according to their moral status, and these attempts are already being complicated by the possibility of creating chimeras, hybrids and transgenic animals that combine the characteristics of many different species from disparate branches of the tree of life. In any case, at least for the reasonably near future, synthetic

biology is unlikely to produce organisms with properties that we ordinarily associate with moral status, and hence this should not be a significant worry.

Some bioethicists have expressed the view that synthetic biology is the ultimate victory of reductionism, since it shows that life is 'just a conglomeration of molecules' and therefore not 'sacred.' We think that this interpretation of work in synthetic biology is both metaphysically and normatively misguided. First, synthetic biology does not demonstrate that higher-level properties 'reduce' to lower level properties any more than work in ordinary molecular-development or embryogenesis shows this to be the case. Second, even if it is true that higher-level properties (such as homeostasis or sentience or consciousness) reduce to lower-level properties, this has no implication whatsoever for moral status. The dominant philosophical view is that moral status depends on the existence (or potential existence) of certain higher-level properties regardless of whether these reduce or are irreducible to lower-level ones. So far, ethical discussions of the supposed reductionism of synthetic biology have been premised on a conflation of different senses of 'reductionism' and mistaken assumptions about the implications of reductionism for the moral status of living things and the relationship between human beings and nature. The Council could make an important contribution by providing a careful analysis of the relationship between reductionism and synthetic biology, and the ethical implications of this relationship.

Should the Council determine that the playing God admonition, concerns about the moral status of synthetic entities, or worries about the general devaluing life should be taken into account in policy decisions regarding synthetic biology and other emerging biotechnologies, it should nevertheless recognize that these are not conclusive objections to the development of such technologies, but rather concerns that must be balanced against potentially significant benefits (as described in section 1).

7. Justice

The Council should make considerations of justice a central focus of its inquiry concerning synthetic biology. It should consider the implications of synthetic biological innovations for human wellbeing and the environment in developed and developing nations, respectively, and it should assess the potential of emerging biotechnologies to ameliorate as well as to exacerbate global inequalities. For example, one concern that applies equally to conventional pharmaceuticals, relates to the lack of financial incentives for pharmaceutical companies to design and manufacture synthetic biological agents for predominantly poorer markets where they are most needed. Thus, if the Council were to examine the appropriate intellectual property arrangements for synthetic biology, it should consider not only the effects of these arrangements on the rate of innovation but also their distributive effects, paying careful attention to their impact on the global poor. In exploring intellectual property-related issues, the Council might also consider whether the current intellectual property rights regime is sufficiently equipped to accommodate the variegated entities that are likely to be produced through synthetic life technologies, including those that are the product of many synthesized genes that have been merged to form a single functional organism.

8. Public Policy and Institutional Design

The Council should recognize that ethics needs help from incentives. Therefore, in addressing dual use and other concerns raised above, the Council should be critical of proposals that rely primarily on voluntary constraints on the part of scientists. It should carefully consider the institutional effects of any policy recommendations and determine what institutional innovations may be needed, taking into account sound principles of institutional design. This means recognizing that different actors may have different incentives that encourage them to either overestimate or underestimate the costs of risk-reduction.

The Council should think in terms of designing institutions that are primarily tasked with fostering the development and dissemination of new technologies, but it should recognize that there are a number of goals and interests at stake. It should therefore aim for *optimization* rather than maximization of technological development and dissemination, subject to adequate risk prevention. For example, it is a mistake to think that in coping with the risk of Dual Use 1 (see section 2 above), there are only two values to be balanced: scientific freedom and security. A number of other factors must be taken into account as well, including the prospect that anti-bioterrorism initiatives will result in the unacceptable growth of government power over its citizenry, or in unjustifiably relaxed standards for the treatment of human or animal subjects in research.

The Council should consider problems of international governance that might arise in connection with synthetic bioweapons programs that are developed either by states or non-state actors, and which might pose a serious global risk. For instance, it should anticipate the practical and legal difficulties that are likely to be encountered in attempting to prevent the proliferation of dangerous synthetic biological agents and technologies, which may be even more difficult to contain and track than nuclear weapons materials. Moreover, it should consider whether existing regulatory resources are sufficient to guard against the risks associated with the proliferation of cheap genome synthesis technology and the availability of dangerous sequence information.

9. Concluding Thoughts

In all of these matters, the Council should avoid synthetic biology ‘exceptionalism’, or the idea that synthetic biology raises qualitatively different ethical issues than its biotechnological predecessors. Instead, it should regard synthetic biology as simply one area in the research and development of biomedical technologies, and even of scientific innovations more broadly, which involve similar categories and quantities of risk. The synthetic life sciences are advancing rapidly and globally. Any domestic attempt at wholesale prohibition is likely to drive these technologies underground or abroad where they are difficult to monitor, and to put biotech-abstaining nations at a substantial competitive disadvantage. Consequently, we believe that coordinated global regulation, grounded in evidence-based standards of risk assessment and management, is the most ethically appropriate avenue for reducing the risks associated with synthetic biology while simultaneously securing its benefits. We believe there are no decisive moral reasons for not pursuing this technology; to the contrary, given its potential range of benefits to human health and the environment, we believe there are decisive moral reasons for pursuing it.