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EDITORIAL

Synthetic Biology for Human Health: Issues for Ethical Discussion and Policy-making

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Synthetic biology, the application of engineering principles to (re)design and construct novel biological systems and devices, provides an emerging focus for ethical and policy debates on emerging biotechnologies. Happily, no scandal or accident has occurred to give rise to this ethical attention. Rather, it was the researchers themselves who invited the involvement of ethicists, explaining their work and asking for ethical commentary. This proactive stance was fuelled by the intention to avoid another backlash like the one that occurred against some gene technologies. Many consumers have been and are still highly sceptical about genetically modified food, with field trials (for example) regularly being met with public protest. By engaging with the ethical implications of their work early on, many researchers in synthetic biology hoped to prevent such reactions. So far, it looks as if they have been successful, as public attitudes towards synthetic biology are largely positive¹.

Despite significant early interest, the ethics of synthetic biology is still a young field. A recent search in PubMed, one of the major biomedical databanks containing much of the bioethical literature has yielded less than 100 entries for the search: “synthetic biology” AND (ethics or ethical). Some may claim that a reason for this relative lack of literature may be that synthetic biology does not give rise to any substantive ethical issues. However it is our hope that the papers in this special issue will convince you otherwise.

To date, reactions to synthetic biology in the literature as well as in the wider community have ranged from: What's the matter? We wash bacteria down the sink all the time! to: This is playing God on a grand scale! A number of reports – notably the 2009 Report Ethics of Synthetic Biology from the European Group on Ethics in Science and New Technologies² and the 2010 report from the US Presidential Commission for the Study of Bioethical Issues, New Directions: The Ethics of Synthetic Biology and Emerging Technologies³ – have recognized

both the ethical dimension and potential of synthetic biology, but have identified no grounds for a moratorium or other ban on this new research area. The relevance of safety and security issues has been recognized, however, as have potential implications for social justice and biodiversity.

This special issue of Bioethics focuses on the ethical issues arising from the potential application of synthetic biology to human health. Synthetic biology offers promise for developments to benefit health, such as innovative drugs, new vaccines, tissue regeneration, or even entirely synthetic cells.

Even if such applications are still rather hypothetical, they are important to anticipate and discuss as early as possible. Additionally, synthetic biology not only holds the prospect of bold new, and hopefully beneficial, applications. With its aim to design, engineer and build novel biological systems that do not occur in nature as well as to re-engineer systems that already exist, it raises fundamental ethical questions about the moral status of life, the conceptualization of risks and benefits as well as possible implications for future people. Finally, questions also arise about how we should approach these ethical issues and the moral grounding which ought to guide policy and regulatory issues in this area. This special issue covers aspects of all these topics through addressing questions such as: 'What are appropriate methodological paradigms for ethical debates over synthetic biology for human health?', 'What questions does synthetic biology for human health pose with regards to justice?', and 'When should we consider the risks that may arise in the development of synthetic biology applications for human health as morally justifiable to take?'

An important background to this issue is an international three-year project funded by the European Commission, 7th Framework. The Synthetic Biology for Human Health: Ethical and Legal Issues (SYBHEL) project ran from 2009 to 2012 (sybhel.org). It brought together five European institutions expert in varying components of the debate over Synthetic Biology. The project objectives included: to carry out quality ethical research and evaluation of Synthetic Biology as it will impact human health and wellbeing; to agree recommendations for regulation and commercialization of synthetic biology for human health; and to determine a strategy for policy deliberation in this area. Specific issues investigated, in addition to the project objectives, were: synthetic biology and the philosophical and ethical conceptions and definitions of life; critiquing various methodological approaches to applied ethics reasoning within synthetic biology as applied to human health; and analysis of substantive concepts in synthetic biology for health, such as 'suffering' and 'well-being'. Each objective and theme was also investigated with reference to several cross-cutting themes, including the definition of synthetic biology, the latest scientific advances in the field, safety issues and justice.

We are delighted that this special issue showcases articles that address the majority of the objectives, issues and themes of the SYBHEL project, with individual contributions addressing the ethical and policy issues of synthetic biology from different angles.

Joachim Boldt explores the ethical implications of the view that synthetic biology may prove advantageous for biodiversity, as synthesizing novel forms of life increases the numbers of

species. He concludes that a general moral obligation to create novel species to increase biodiversity is not warranted.

Sune Holm examines the concepts of health and disease in relation to the idea of engineered organisms. Holm argues that reflection on the possibility of artefactual organisms challenges naturalistic and functional theories of health and disease as proposed by Wakefield and Boorse. These theories rely on interpretations of disease as dysfunction in an evolutionary context and are not able to accommodate the possibility of disease in artefactual organisms. Holm raises the question of to what extent health and disease should be considered as states whose factual or value-neutral component is grounded in evolution.

David Hunter explores whether there are objections against synthetic biology from the perspective of social justice. New technologies, including synthetic biology, may be objectionable because their benefits may give an unfair advantage to some and impose unfair levels of risk on others. In his article, Hunter applies three types of justice-based objections: those based on procedural justice, on outcome justice and on patterned justice. He argues that from the perspective of justice, there may be some issues of regulation of synthetic biology, but that there is no case for banning this technology.

Bernard Baertschi deals with a central argument in the debate, the argument that redesigning and manipulating human life is a manifestation of hubris. Baertschi argues that, when adopting a scientific world view, the charge of hubris does not apply to synthetic biology: it is neither impossible nor immoral for human beings to create life.

Patrick Heavey examines how components of mainstream deontological perspectives may be used to assess the ethics of synthetic biology, drawing on much of the existing literature and debate in the process. Comparing deontological analysis with the consequentialist approach currently dominating the bioethics literature in synthetic biology, he posits that synthetic biology is ethical from a deontological point of view. He concludes by suggesting a way forward for bioethics debates in synthetic biology; one which combines analysis from differing methodological foundations.

Kevin Smith analyses the utilities and disutilities of synthetic biology. After considering (and rejecting) whether synthetic biology is wrong *per se*, Smith discusses several competing approaches to utilitarian analysis: a *laissez faire* approach, a dual use approach, a knowledge approach and a precautionary approach. He argues that ethics in synthetic biology should be assessed on a case by case basis using a *laissez faire* approach.

Synthetic Biology is a promising technology that raises challenging ethical and philosophical questions. This Special Issue brings together a range of theoretical perspectives to analyse the implications of synthetic biology as applied to human health: what are the implications for social justice, for our thinking about health and disease, our views on creation of life, the impact on biodiversity and risks for society? The issue brings together utilitarian and deontological approaches, perspectives of justice, philosophy of biology and philosophical anthropology. Such a multitude of perspectives may help to assess the acceptability, the risks and the merits of this new technology, which may help future policy-making. The

editors hope that this issue will help to inform and further develop the debate whether 'synbio' can be a blessing for human health or a source of serious concerns.

References

1. Royal Academy of Engineering, 2009. Synthetic biology, scope applications and implications. London: Royal Society of Engineering
2. European Group on Ethics in Science and New Technologies to the European Commission. 2009. Ethics of Synthetic Biology, Opinion No 25. Brussels: European Commission
3. President's Commission for the Study of Bioethical Issues. 2010. New Directions. The Ethics of Synthetic biology and Emerging Technologies. Washington: President's Commission for the Study of Bioethical Issues