Special Section: Synthetic Biology: Ethical and Philosophical Challenges

Synthetic Biology between Self-Regulation and Public Discourse

Ethical Issues and the Many Roles of the Ethicist

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Abstract: This article discusses the roles of ethicists in the governance of synthetic biology. I am particularly concerned with the idea of self-regulation of bioscience and its relationship to public discourse about ethical issues in bioscience. I will look at the role of philosophical ethicists at different levels and loci, from the "embedded ethicist" in the laboratory or research project, to ethicists' impact on policy and public discourse. In a democratic society, the development of governance frameworks for emerging technologies, such as synthetic biology, needs to be guided by a well-informed public discourse. In the case of synthetic biology, the public discourse has to go further than merely considering technical issues of biosafety and biosecurity, or risk management, to consider more philosophical issues concerning the meaning and value of "life" between the natural and the synthetic. I argue that ethicists have moral expertise to bring to the public arena, which consists not only in guiding the debate but also in evaluating arguments and moral positions and making normative judgments. When ethicists make normative claims or moral judgments, they must be transparent about their theoretical positions and basic moral standpoints.

Keywords: synthetic biology; self-regulation; public discourse; role of ethicists

Introduction

The publication of two articles in *Nature* in January 2000 can be seen as the birth of synthetic biology. One article demonstrated the construction of a genetic toggle switch,[1] the other the construction of a biological clock of sorts,[2] both based on the manipulation of the same three genes.[3] Since then, the field has been developing in leaps and bounds. An annual synthetic biology competition, the International Genetically Engineered Machine (iGEM) competition, was first held in 2004. In 2015, the iGEM competition drew 5018 undergraduate students from all over the world, who used kits containing biological parts from the Massachusetts Institute of Technology (MIT) Registry of Standardized Biological Parts, so-called biobricks, to design and construct novel biological systems.[4]

Synthetic biology first gathered public attention in 2010, when the J. Craig Venter Institute announced that it had for the first time created a functioning, self-reproducing bacterium, *Mycoplasma mycoides*, with a synthetic genome.[5] Although neither the genome, the bacterial cell containing it, nor the resulting organism, were strictly novel, this achievement powerfully demonstrated the technical possibilities of synthetic biology. An even greater milestone followed only 2 years later with the emergence of a new method for editing DNA, clustered regularly interspaced

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short palindromic repeats (CRISPR)-associated protein-9 nuclease–(Cas9), or just CRISPR, which is revolutionizing the field in a number of ways.[6] The effectiveness and affordability of the technology has brought genetic manipulation not only to the ordinary genetics laboratory, but also to do-it-yourself (DIY) biologists or biohackers, with basic bacterial DIY CRISPR kits being available, at the time of writing, for as little as US$ 140.[7]

More recently, two developments relevant to synthetic biology have grabbed the headlines. One is the possibility of creating so-called gene drives, a technique that ensures that a (possibly synthetic) gene is passed on to almost all offspring. A gene drive can be used to genetically manipulate, or eradicate, a whole population of organisms, such as disease-carrying mosquitos.[8] The other development concerns a plan to create a synthetic human genome, the so-called Human Genome Project-Write (HGP-write).[9] The main objective of HGP-write is to reduce drastically the cost of creating large genomes, just as the Human Genome Project (HGP-read) reduced the cost of sequencing large genomes.

The developments sketched here are seen to give rise to a number of ethical issues, in particular those concerning biosafety, biosecurity, and intellectual property. Justice is also an issue, as the benefits as well as the potential risks or burdens should be fairly distributed. There are also issues that are well known to those who are familiar with debates about genetic modification, in particular human germline modification, genetically modified organisms (GMOs), and worries about the almost unlimited power to manipulate nature, sometimes gathered under the title "playing God."[10] In so far as there are novel ethical issues arising from synthetic biology, they concern the relationship we humans have to nature or life when we can rationally design and engineer living systems free of the constraints of evolution. In any case, these and other ethical issues have raised the question of how to regulate or govern synthetic biology. It is not that the governance of synthetic biology has been given too little attention: between 2004 and 2011 at least 40 reports on synthetic biology were published in English.[11]

My concern in this article is the governance and regulation of synthetic biology and the role of the philosophical ethicist in that process. I am not so much concerned with any particular ethical issue, but rather with what sort of ethical issues matter, how they bear on regulation, governance and public policy, and what the ethicist can or should contribute to the debate.

In what follows I will assume that there is something to regulate, that is, that synthetic biology is not merely a compilation of techniques and tricks from different disciplines useful for engineering life or manipulating genes, but rather a field unified enough to merit or even require a regulatory oversight in its own right. Without going into the ethical issues in any depth, I will also assume that there are sufficient ethical issues to warrant a serious consideration of how and not just whether synthetic biology should be regulated.

Regulating Synthetic Biology

One way in which synthetic biology has been established as a field in its own right is through the International Meeting on Synthetic Biology, organized by the BioBricks Foundation for the first time in 2004 as Synthetic Biology 1.0, and planned for 2017 as SB7.0. At the second meeting, Synthetic Biology 2.0, held in 2006 in Berkeley, California, an attempt was made to introduce a code of conduct

to prevent the misuse of synthetic biotechnology. This was seen as an attempt at self-regulation similar to that of the famous Asilomar conference in 1975, where scientists gathered to discuss the risks of recombinant DNA technology and agreed on a moratorium on certain kinds of experiments until the risks were better understood.[12] Before the Synthetic Biology 2.0 conference, there was already a significant opposition to the proposed code of conduct. A group of 35 civil society organizations, including Greenpeace International and Genewatch, strongly opposed the plan and called for "inclusive public debate, regulation and oversight of the rapidly advancing field of synthetic biology."[13] There was also opposition from the scientists themselves, and eventually the code of conduct was not accepted.[14]

The Asilomar conference is sometimes hailed as a paradigm of scientists' social responsibility, as the scientists took it upon themselves to put limits on their work to ensure safety and ease public concern.[15] This way, they avoided, partly at least, a public controversy about the technology as well as any heavy-handed state regulation. In terms of ethical governance, there are clear problems with this sort of self-regulation. First, the scientists themselves decided what to regulate and how: "The meeting was an expression of scientific responsibility but also of control; the scientific community assumed the authority to define science's responsibilities in the present and to declare what promises can be made, what risks warrant worry, and what technological futures are possible, desirable, and good."[16] Second, it was stated at the outset that the only issue up for discussion was risk/biosafety, and any other ethical and social consequences were excluded. In short, the issues were limited to risk assessment, and the public was excluded from the debate. In the words of United States senator Ted Kennedy: "They were making public policy, and they were making it in private."[17]

Any sort of Asilomar-type of self-regulation for synthetic biology has been widely rejected for a number of reasons, including the commercial nature of modern biotechnology; the easy access to equipment, materials, technologies, and knowledge; and democratic requirements for a public debate about ethical issues.[18] There are, nonetheless, also strong forces against any statutory regulation of synthetic biology, or any other emerging technology, provided it does not pose a clear and direct threat to the public. These forces manifest themselves partly in an increasing push toward decentering regulation. Any code of conduct for a community, which is formed and accepted by that community, is often seen as better informed, more flexible, and more likely to prompt compliance, than anything the state could inflict on a community from above.[19]

The United States Presidential Commission for the Study of Bioethical Issues produced a report on synthetic biology, which endorses a principle of *regulatory parsimony* "recommending only as much oversight as is truly necessary to ensure justice, fairness, security, and safety while pursuing the public good [...] Self-regulation also promotes a moral sense of ownership within a professional culture of responsibility."[20] The report also endorses a principle of *democratic deliberation*, at the core of which is "an ongoing, public exchange of ideas, particularly regarding the many topics—in science and elsewhere—in which competing views are advocated, often passionately. Through formal and informal deliberative processes, decision makers and the people they represent should strive for mutually acceptable reasons to justify the policies that they adopt."[21] Emphasizing both self-regulation and the importance of democratic deliberation for public policy is not necessarily contradictory. Proper self-regulation excludes neither public debate nor regulatory oversight at the state level. Both the self-regulation of a

scientific community and state regulation need to encourage and be responsive to public debate and to democratic deliberation.

What is then the place of the ethicist in this? Ethicists may find themselves at any of these three levels: "embedded" in the scientific community, contributing in an official position to public policy, or independently contributing to the public debate. Before discussing these three, possibly overlapping, roles, two questions need to be answered: who is this "ethicist" and why is that person involved in the regulation of synthetic biology?

My concern here is with the philosophical ethicist, that is, someone who is trained in philosophy and can claim expertise in ethics through academic and professional activities, in particular research and teaching. In the context of the study of ethical issues in new technologies, the term "ethicist" is admittedly often used in a wider sense, including ethicists whose main academic background is not philosophy but social science, law, medicine, theology, or natural science, but whose academic work is focused on ethical issues, or at least is someone who can demonstrate an academic interest in ethical issues. Sometimes the term is even used "as a catch-all term for those who study new technologies but who are not scientists or engineers."[22] In some contexts the "ethicist" may even be a layperson whose role is to represent "public values." Although my discussion focuses on philosophical ethicists, I am not interested in enforcing disciplinary borders. My discussion applies to ethicists who may not have any formal training or qualifications in philosophy, but who have significant knowledge of moral theory, conceptual analysis, and philosophical argumentation. I deliberately avoid the term "bioethicist," although it overlaps to a great extent with my use of the term "ethicist." Bioethical practice and training has been institutionalized, especially in the United States, in ways that would require a somewhat different discussion to what I offer here, in particular with regard to interdisciplinarity, clinical practice, and empirical research.

Why would the philosophical ethicist become involved in the regulation of synthetic biology, whether at the level of scientific self-regulation, public debate, or public policy? Of course, the ethicists may simply have an academic interest in the ethical issues involved and contribute, especially to the public debate, more or less incidentally through their academic activities. What is more interesting is the need or demand for ethicists on behalf of scientists, science funding agencies, government organizations, and policymakers. The reasons for this demand may differ at the three levels, and I will discuss them in greater detail subsequently; but generally the main reasons include providing ethical expertise, asserting moral authority, ensuring public trust and acceptance, and, conversely, avoiding the sort of public controversy that engulfed genetically modified food in Europe.

The Embedded Ethicist

The field of synthetic biology has included discussions of ethical and social issues in different ways. The Biobricks Foundation's International Meetings on Synthetic Biology have variously included lectures, parallel sessions, and poster sessions on ethical and social issues. The iGEM competition encourages the competing teams to engage with ethical and social issues, awarding one team in 2009 a prize for the ethical and social analysis provided by an "embedded ethicist," a junior scholar who, according to one report, had "been in agony during the six previous months spent on the research team. She had been ignored, ostracized by the young science

students who worked enthusiastically to prepare their biological part for the international competition."[23] Anthropologists Paul Rabinow and Gaymon Bennett did not fare much better as embedded social scientists at the Synthetic Biology Engineering Research Center (SynBERC) in Berkeley, California. The plan was to collaborate with scientists and observe their daily work, bringing ethical and social issues into the very process of science, "upstream" as it is called, rather than dealing with the ethical and social consequences of the products of science downstream. The biologists were not pleased with the collaboration and observation of the social scientists and eventually Rabinow and Bennett left the ethics project, which was then reformulated to deal with risk assessment.[24]

Synthetic biology projects are often required to include "ethical, legal and social implications" (ELSI) activities. Such activities do not necessarily involve philosophical ethicists; they may involve social scientists, lawyers, or technical experts concerned with safety and security issues, risk management, or intellectual property. Such work may be categorized as ethics; however, it has little or no relation to ethics. It is merely a matter of prudence.[25] It has to do with developing synthetic biology in such a way that it optimizes benefits without causing significant or unnecessary harm. The only ethical issue is when people believe that there is nothing more to the ethics of synthetic biology than such prudence.

There are various reasons for having a philosophical ethicist on board in a synthetic biology project to address ethical issues. The ethicist may bring in ethical expertise, in particular with regard to identifying ethical problems, surveying possible approaches to them, and making explicit the assumptions behind different positions, thereby framing and structuring discussions on ethical issues in a fruitful manner. The proximity to scientists is then seen as mutually beneficial; the ethicist gains a scientifically better informed view of the ethical issues involved and the scientists gain an ethically better informed view of their scientific work. The ethicist may also provide ethics training, in order to increase awareness, understanding, and appreciation of ethical issues arising from synthetic biology. The ethicist can, through such training and other measures, contribute to a culture of ethical practices within the scientific community, which is a cornerstone of successful self-regulation. I shall term the provision of ethical analysis and training the "neutral academic role" of the ethicist.

A further reason to include, or "embed," an ethicist in a synthetic biology project is to assure concerned members of the public that ethical issues are taken seriously, in order to avoid public controversy and increase public trust and acceptance. The ethicist may even be expected to participate in "public engagement" or impact activities that aim at educating the public about the ethical issues arising from synthetic biology and how they are being dealt with, or that aim at encouraging and contributing to informed public discourse. This may give the ethicist a further "public engagement role."

There is a third role for the ethicist; namely, that of the ethical critic. This role is rarely, if ever, envisaged by the scientists or the science funding agencies, but is often an important, even essential, part of the ethicist's self-image. The ethicist as a critic does not merely describe ethical problems and analyze different positions and arguments, but also makes moral judgments. Whether a person thinks this role is appropriate depends on at least two things. First, it depends on that person's view of the nature of ethics. If someone thinks that there is nothing more to morality than some combination of moral psychology and social norms, the moral

judgments of the ethicist has no greater weight than the moral judgments of anyone else. One might say that the ethicist has no privileged access to moral truths, as those "truths" vary among individuals and cultures.

From this perspective, in order to settle moral disputes one should then either survey the moral views of the relevant population or conduct psychological experiments on a sufficiently large group of people to reveal their values and moral intuitions. A contrary view would not have to hold that moral values are real, universal, and knowable. It would suffice to hold that even a neutral analysis of an ethical issue (i.e., an analysis of relevant concepts, positions, and arguments) may show a certain position to be morally untenable or another position overwhelmingly (or just a little) more convincing than rival positions. It would then be wrong for the ethicist to present different positions as morally equal or not to make a moral judgment. When a moral judgment does boil down to basic moral values or an idea of the "good," one might also say that "what ethicists bring is an educated or refined moral perception, as well as skills of reasoning."[26]

Whether one thinks a critical role is appropriate depends also on the philosophical culture within which the ethicist is trained. Some philosophical cultures emphasize neutral approaches that make most arguments conditional; that is, a person sets out certain assumptions and proposes what follows from them. The arguments are then usually of the type "if you accept A, B, and C, then you will have to accept D." Other philosophical cultures are critical; that is, one is expected to take a clear position, defend it vigorously, and criticize its rivals aggressively. Philosophy is here seen as essentially a critical endeavor. These are not two separate cultures, but rather two extremes, with most philosophical cultures falling somewhere in between. Nonetheless, those who tend toward the neutral approach may be considered uninteresting or dull: they invite the question "but what do you *really* think?" Those who tend to the critical approach may be seen as overconfident or aggressive. Within the more critical types of philosophy, ethics (and political philosophy) are considered strongly normative and not merely descriptive. It would then be uncritical and hence unphilosophical to discuss ethical issues without making normative claims and moral judgments.

Embedding ethicists in synthetic biology projects invites a number of problems and dangers. There may be expectations by the scientists, the funding agency, or even university administrations, that the ethicist be supportive of synthetic biology. This may render independent, unbiased ethics research, whether neutral or critical/normative, impossible. Even if the ethicist is explicitly promised academic freedom, self-censorship is practically unavoidable. For senior academics, whose jobs are not on the line, biting the hand that feeds them may prevent future external funding for ethics projects. This means both loss of research income and loss of prestige. For junior academics, the situation is significantly worse. Not being sufficiently supportive of synthetic biology may cost them their job and in the worst case end their career, in particular when a future position depends on continuing external funding or simply on the support of a superior. Being supportive of synthetic biology, on the other hand, might cause an ethicist to doubt his or her own integrity, and may be seen by peers as biased and lacking credibility. This problem becomes even worse if the ethicist is taken to have a public engagement role in the project. This may lead to expectations that the ethicist practice public relations on behalf of the scientists, and that the ethicist's public engagements have

a clear pro-science message. Not delivering that message may lead to sanctions or punishments from the scientists, from university administration, or even from the ethicist's superiors. Critics of synthetic biology will see an ethicist's public engagements in support of synthetic biology as biased and paid for, which reduces the credibility of the ethicist in the public sphere.

Rather than embedding ethicists in scientific research projects, it would be preferable to support independent ethics projects through, for example, national research councils or the European Union funding bodies in Europe. There are ways to bring independent ethics projects together with science projects, but the ethics projects and the ethicist should not be academically and financially dependent on a science project or its project leaders.

The Ethicist Member of the Committee

Ethicists serve on national bioethics commissions and are frequently invited to advise various national and international organizations, as well as policymakers and government bodies, on emerging technologies such as synthetic biology. For ethicists, this is an opportunity to see their work make a difference at the policy level, and it often brings income and academic prestige. Academic ethicists are increasingly evaluated based on their impact, in particular with regard to influence on policy and legislation.

In their discussion of bioethicists' role in public policy, Udo Schüklenk and Jason P. Lott point to three sorts of problems, that they term "conflicts of interest," "impartiality," and "transparency."[27] Science funders or government bodies seeking advice may invite ethicists based on expected ideological agreement, whether it is liberal/conservative, religious/secular or a supporter/critic of the scientific program in question. The ethicists may in turn be drawn to adjust themselves to such ideological needs in order to secure research funding or the power and prestige of advisory positions. The ethicists may also adjust their research priorities to issues that are thought to require policy advice, rather than pursuing research topics based on their urgency or interest. Such conflicts of interest clearly undermine the integrity of ethicists.

Schüklenk and Lott note that even in the absence of conflicts of interest, ethicists are not, and should not, be impartial.[28] There are various sources of partiality, but an obvious one is that ethicists often favor particular ethical theories, which may predetermine the outcome of policy exercises if only ethicists who adhere to the same sort of ethical theories are included. It is an easy way to reach consensus in a policy committee, but it is not representative of the theoretical differences that exist within the field of ethics. The authors warn that such committees, at least when they produce advice for statutory purposes, are in any case not democratically representative, and they advise ethicists to stay clear of them.[29] The third source of problems is the common lack of transparency of advisory committees. They may produce a report or a set of guidelines or recommendations, but there is often no way of determining how the members were chosen, whether there were conflicts of interest, what materials were considered, what procedures were applied, and what disagreements were aired during the deliberations. To maintain the trust both of the public and of other ethicists, and for the sake of open, democratic procedures, transparency is essential.[30]

Schüklenk and Lott describe the role of bioethicists as follows:

> Bioethicists should be consulted to (a) give the committee some idea of the landscape of ethical positions relevant to the issue in question and (b) establish the parameters/boundaries within which committee deliberations should subsequently proceed. [...]Bioethicists thus assist committee deliberations by putting forth various ethical theories to consider and then helping the rest of the committee avoid contradictions and inconsistencies during the debate that follows.[31]

Although I agree largely with the analysis of the three types of problems, I think Schüklenk and Lott's view of the role of the (bio)ethicist is too narrow. In particular, the ethicist can contribute to committee deliberations by clarifying ethically relevant concepts, analyzing *and evaluating* arguments, and identifying where and how one encounters fundamental moral or ideological differences about moral values and attitudes. Ethicists should be clear and open about their theoretical convictions and standpoints and willing to acknowledge reasonable alternatives.

The Ethicist in Public Discourse

"Embedded" ethicists producing research on ethical issues in synthetic biology, as well as ethicists advising ethical commissions and other governmental bodies on such issues, often participate at the same time in the public discourse on synthetic biology. Embedded ethicists produce academic work, which ideally should be publicly accessible, and they may also directly contribute to public debate by engaging in impact activities or public engagement activities. Organizations that produce reports, guidelines, or recommendation about synthetic biology are more often contributing to the public discourse on the topic rather than directly to any regulations at the statutory level. Apart from the embedded ethicist and the ethicist advisor, there are also ethicists who are independent in the sense that they are neither tied to science projects nor official advisory positions. They are academics who contribute to the public discourse in the course of their academic work.

Ethicists are sometimes seen as moral authorities. As such they can exemplify any of at least three caricatures: the moralist, the moral police, and the rubber stamp. According to these descriptions, as moralists, ethicists know best what is good and right and they preach right conduct to others. As the moral police, ethicists enforce moral norms, sanctioning those who do not obey. As the rubber stamp, the ethicist's authority is used as a moral seal of approval. These are caricatures, which ethicists should and do avoid in the public arena. If ethicists do not have any moral authority, what can they bring to public debates about synthetic biology or other scientific and technical developments? I have already suggested that ethicists do have certain moral expertise, in that they are expert at analyzing and evaluating ethical concepts, positions, and arguments. Such work can contribute to and advance public debates about ethical issues in emerging technologies. Such work can also include normative claims and moral judgments. They must, however, be supported by analysis and argument, and not rely on assumed moral authority. The views of the ethicists have no more force than the arguments behind them.

If ethicists have something to contribute to public debates through their ethical expertise, they can still play different roles in the public arena. Tuija Takala has

identified four roles often assumed by (bio)ethicists, which she calls demagogues, firefighters, window dressers, and academics.[32] The demagogue has a specific normative framework that is applied dogmatically to all issues and debates. The firefighter is running after the latest scientific development and giving quick and simple normative answers before running off to comment on the next development. The window dresser is a sort of paid public relations person dealing with ethical issues. The demagogue and the firefighter are rejected as rigid and superficial, respectively. One can recognize these sorts of ethicists in the debate about synthetic biology, as in debates about other emerging technologies. The window dresser does receive hesitant acceptance, as providing honest service, but in this case there must be transparency about whom the window dresser works for. The most useful role for philosophical ethicists is the academic role. As Takala states: "Philosophical training in bioethics gives us many tools for dealing with bioethical dilemmas, and sharing and displaying these tools in the public forum can only enrich the discussion. To provide people with new arguments and viewpoints, considerations, and insights is compatible with the sort of expertise we have."[33] She warns, however, against giving simplified normative answers, which is particularly relevant when it comes to the complex ethical issues arising with the emergence of technologies such as synthetic biology.

Somewhat similar to Takala's position, Amy Tannery Campbell suggests a type of diplomatic role for ethicists in the public arena, using their expertise to guide public debate: "It is a diplomatic-like role, but one where bioethicists are not completely neutral arbiters but are guided by approaches and values they are expected to make transparent and justify. Bioethics, as a field, can bring this structured, mediating, analytical, educational and advisory role to the policy development process in a systematic way."[34]

The ethicist has a role to play in the public arena, guiding debate by providing ethical analysis and critical argumentation of ethical issues. In so far as ethicists go beyond analysis and description to make normative claims, they have to be supported by argument and analysis, and must be transparent and nondogmatic about theoretical commitments and normative frameworks, in order to maintain academic integrity and credibility.

Conclusion

Synthetic biology gives rise not only to familiar ethical issues concerning biosafety and biosecurity, intellectual property, and the fair distribution of benefits and burdens, but also to deeper ethical issues regarding our relationship to nature. As the governance of synthetic biology evolves, there is a certain tension between the ideal of self-regulation and a perceived need of stronger government regulation. The Asilomar Conference in 1975 served as a paradigm of self-regulation that worked well with regard to safety issues in recombinant DNA technology. However, research in synthetic biology and in the biosciences or biotechnology more generally is increasingly taking place in commercial organizations outside academia. The possibility of DIY-labs and biohackers creating novel organisms makes the ideal of self-regulation even more problematic.

In a democratic society, the development of governance frameworks for emerging technologies, such as synthetic biology, needs to be guided by a well-informed public discourse. In the case of synthetic biology, the public discourse has to go

further than merely considering technical issues of biosafety and biosecurity, or risk management, to consider the more philosophical issues concerning the meaning and value of "life" between the natural and the synthetic. I have considered in particular the role of philosophical ethics and ethicists at different levels and loci, from the "embedded" ethicist to the role of ethicists in public discourse and policymaking. I have suggested that ethicists have moral expertise to bring to the public arena, which consists not only in guiding the debate but evaluating arguments and moral positions and making normative judgments. When ethicists make normative claims or moral judgments, they must be transparent about their theoretical position and basic moral standpoint.

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