Written testimony of Gregory E. Kaebnick to the House Committee on Energy and Commerce
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Mr. Chairman, Ranking Member Barton, and Distinguished Members of the Committee, thank you for inviting me to these hearings and for bringing attention to the ethical and social issues raised by this significant new field.

I am a research scholar at The Hastings Center, an independent, nonpartisan, and nonprofit research institute that has been studying ethical issues in medicine, health policy, medical research, and biotechnology since 1969. I am also editor of one of our journals, the *Hastings Center Report*. We are now in the second year of a two-year project, funded by the Alfred P. Sloan Foundation, to investigate the ethical issues of synthetic biology.

My goal this morning is chiefly to set synthetic biology within a widely accepted framework for thinking about the ethics of new technologies. I will also comment briefly on the appropriate governmental response to the field.

The ethical issues raised by synthetic biology are familiar themes in an ongoing conversation this nation has been having about biotechnologies for several decades. Moreover, I am pleased that the conversation is continuing, not only in this panel, but also with President Obama's Presidential Commission for the Study of Bioethical Issues, which will be holding hearings on synthetic biology this summer and delivering a report to the president later this year.

The concerns fall into two general categories. One has to do with whether the creation of synthetic organisms is a good or a bad thing in and of itself, aside from the consequences. These are thought of as intrinsic concerns. Many people had similar intrinsic concerns about reproductive cloning, for example; they just felt it was wrong to do, regardless of benefits. Another has to do with potential consequences—that is, with risks and benefits. The distinction between these categories can be difficult to maintain in practice, but it provides a useful organizational structure.

1. Intrinsic Concerns

I will start with the more philosophical, maybe more baffling, kind of concern—the intrinsic concerns. They are an appropriate place to start because the work just published by researchers at Synthetic Genomics, Inc., has been billed as advancing our understanding of these issues in addition to making a scientific advance.

This announcement is not the first time we have had a debate about whether biotechnology challenges deeply held views about the status of life and the power that biotechnology and medicine give us over it. There was a similar debate about gene transfer research in the 1970s and 1980s, about cloning and stem cell research in the 1990s, and—particularly in the last decade but also earlier—about various tools for enhancing human beings. They have been addressed by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and

Behavioral Research in 1983, by President Clinton's National Bioethics Advisory Council, and by President Bush's President's Council on Bioethics. These concerns are related to even older concerns in medicine about decisions to withhold or withdraw medical treatment at the end of life.

The fact that we have had this debate before speaks to its importance. I believe the intrinsic concerns deserve respect, and with some kinds of biotechnology I think they are very important, but for synthetic biology, I do not think they provide a basis for decisions about governance.

A. Religious or Metaphysical Concerns

The classic concern about synthetic biology is that it puts human beings in a role properly held by God—that scientists who do it are "playing God," as people say. Some may also believe that life is sacred, and that scientists are violating its sacredness. Prince Charles had this in mind in a famous polemic some years ago when he lamented that biotechnology was leading to "the industrialisation of Life."

To object to synthetic biology along these lines is to see a serious moral mistake in it. This kind of objection may be grounded in deeply held beliefs about God's goals in creating the world and the proper role of human beings within God's plan. But these views would belong to particular faiths—not everybody would share them. Moreover, there is a range of opinions even within religious traditions about what human beings may and may not do. Some people celebrate human creativity and science. They may see science as a gift from God that God intends human beings to develop and use.

The announcement that Synthetic Genomics, Inc., has created a synthetic cell appears to some to disprove the view that life is sacred, but I do not agree. Arguably, what has been created is a synthetic genome, not a completely synthetic cell. Even if scientists manage to create a fully synthetic cell, however, people who believe that life is sacred, that it is something more than interacting chemicals, could continue to defend that belief. A similar question arises about the existence of souls in cloned people: If people have souls, then surely they would have souls even if they were created in the laboratory by means of cloning techniques. By the same reasoning, if microbial life is more than a combination of chemicals, then even microbial life created in the laboratory would be more than just chemicals. In general, beliefs about the sacredness of life are not undermined by science. Moreover, even the creation of a truly synthetic cell would still start with existing materials. It would not be the kind of creating with which God is credited, which is creating something from nothing—creation ex nihilo.

B. Concerns that Synthetic Biology Will Undermine Morally Significant Concepts

A related but different kind of concern is that synthetic biology will simply undermine our shared understanding of important moral concepts. For example, perhaps it will lead us to think that life does not have the specialness we have often found in it, or that we humans are more powerful than we have thought in the past. This kind of concern can be expressed without talking about God's plan.

Synthetic biology need not change our understanding of the value of life, however. The fact that living things are created naturally, rather than by people, would be only one reason for seeing them as valuable, and we could continue to see them as valuable when they are created by people. Further, in its current form, synthetic biology is almost exclusively about engineering single-celled organisms, which may be less troubling to people than engineering more complex organisms. If the work is contained within the laboratory and the factory, then it might not end up broadly changing humans' views of the value of life.

Also, of course, the fact that the work challenges our ideas may not really be a moral problem. It would not be the first time that science has challenged our views of life or our place in the cosmos, and we have weathered these challenges in the past.

C. Concerns about the Human Relationship to Nature

Another way of saying that there's something intrinsically troubling about synthetic biology, again without necessarily talking about the possibility that people are treading on God's turf, is to see it as a kind of environmentalist concern. Many environmentalists want to do more than make the environment good for humans; they also want to save nature from humans—they want to save endangered species, wildernesses, "wild rivers," old-growth forests, and mountains, canyons, and caves, for example. We should approach the natural world, many feel, with a kind of reverence or gratitude, and some worry that synthetic biology—perhaps along with many other kinds of biotechnology—does not square with this value.

Of course, human beings have been altering nature throughout human history. They have been altering ecosystems, affecting the survival of species, affecting the evolution of species, and even creating new species. Most agricultural crop species, for example, are dramatically different from their ancestral forebears. The issue, then, is where to draw the line. Even people who want to preserve nature accept that there is a balance to be struck between saving trees and harvesting them for wood. There might also be a balance when it comes to biotechnology. The misgiving is that synthetic biology goes too far—it takes human control over nature to the ultimate level, where we are not merely altering existing life forms but creating new forms.

Another environmentalist perspective, however, is that synthetic biology could be developed so that it is beneficial to the environment. Synthetic Genomics, Inc. recently contracted with Exxon Mobil to engineer algae that produce gasoline in ways that not only eliminate some of the usual environmental costs of producing and transporting fuel but simultaneously absorb large amounts of carbon dioxide, thereby offsetting some of the environmental costs of burning fuel (no matter how it is produced). If that could be achieved, many who feel deeply that we should tread more lightly on the natural world might well find synthetic biology attractive. In order to achieve this benefit, however, we must be confident that synthetic organisms will not escape into the environment and cause harms there.

Concerns involving Consequences

The second category of moral concerns is about consequences—that is, risks and benefits. The promise of synthetic biology includes, for example, better ways of producing medicine,

environmentally friendlier ways of producing fuel and other substances, and remediation of past environmental damage. These are not morally trivial considerations. There are also, however, morally serious risks. These, too, fall into three categories.

Concerns about Social Justice

Synthetic biology is sometimes heralded as the start of a new industrial age. Not only will it lead to new products, but it will lead to new modes of production and distribution; instead of pumping oil out of the ground and shipping it around the world, we might be able to produce it from algae in places closer to where it will be used. Inevitably, then, it would have all sorts of large-scale economic and social consequences, some of which could be harmful and unjust. Some commentators hold, for example, that if synthetic biology generates effective ways of producing biofuels from feedstocks such as sugar cane, then farmland in poor countries would be converted from food production to sugar cane production. Another set of concerns arises over the intellectual property rights in synthetic biology. If synthetic biology is the beginning of a new industrial age, and a handful of companies received patents giving them broad control over it, the results could be unjust.

Surely we ought to avoid these consequences. It is my belief that we can do so without avoiding the technology. Also, traditional industrial methods themselves seem to be leading to disastrous long-term social consequences; if so, synthetic biology might provide a way toward better social outcomes.

Concerns about Biosafety

Another concern is about biosafety—about mechanisms for containing and controlling synthetic organisms, both during research and development and in industrial applications. The concern is that organisms will escape, turn out to have properties, at least in their new environment, different from what was intended and predicted, or maybe mutate to acquire them, and then pose a threat to public health, agriculture, or the environment. Alternatively, some of their genes might be transferred to other, wild microbes, producing wild microbes with new properties.

Controlling this risk means controlling the organisms—trying to prevent industrial or laboratory accidents, and then trying to make sure that, when organisms do escape, they are not dangerous. Many synthetic biologists argue that an organism that devotes most of its energy to producing jet fuel or medicine, that is greatly simplified (so that it lacks the genetic complexity and therefore the adaptability of a wild form), and that is designed to work in a controlled, contained environment, will simply be too weak to survive in the wild. For added assurance, perhaps engineering them with failsafe mechanisms will *ensure* that they are incapable of surviving in the wild.

Concerns about Deliberate Misuse

I once heard a well-respected microbiologist say that he was very enthusiastic about synthetic biology, and that the only thing that worries him is the possibility of catastrophe. The kind of thing that worries him is certainly possible. The 1918 flu virus has been recreated in the laboratory. In 2002, a scientist in New York stitched together stretches of nucleotides to produce a string of DNA

that was equivalent to RNA polio virus and eventually produced the RNA virus using the DNA string. More recently, the SARS virus was also created in the laboratory. Eventually, it will almost certainly be possible to recreate bacterial pathogens like smallpox. We might also be able to enhance these pathogens. Some work in Australia on mousepox suggests ways of making smallpox more potent, for example. In theory, entirely new pathogens could be created. Pathogens that target crops or livestock are also possible.

Controlling this risk means controlling the people and companies who have access to DNA synthesis or the tools they could use to synthesize DNA themselves. There are some reasons to think that the worst will never actually happen. To be wielded effectively, destructive synthetic organisms would also have to be weaponized; for example, methods must be found to disperse pathogens in forms that will lead to epidemic infection in the target population while sparing one's own population. Arguably, terrorists have better forms of attacking their enemies than with bioweapons, which are still comparatively hard to make and are very hard to control. However, our policy should amount to more than hoping for the best.

Governance

In assessing these risks and establishing oversight over synthetic biology, we do not start from square one. There is an existing framework of laws and regulations, put into action by various agencies and oversight bodies, that will apply to R&D and to different applications. The NIH is extending its guidelines for research on genetic engineering to ensure that they are applicable to research on synthetic biology. These Guidelines are enforced by the NIH's Recombinant DNA Advisory Committee and a network of Institutional Biosafety Committees at research institutions receiving federal funding. Many applications would fall under the purview of various federal laws and the agencies that enforce them. For example, a plan to release synthetic organisms into the sea to produce nutrients that would help rebuild ocean food chains would have to pass muster with the EPA. The USDA and FDA also have regulatory authority over applications. The FBI and the NIH's National Science Advisory Board for Biosecurity are formulating policy to regulate the sale of synthetic DNA sequences that might pose a threat to biosecurity.

At the same time, the current regulatory framework may need to be augmented. First, there are questions about whether the existing laws leave gaps. Research conducted by entirely privately funded laboratory might not covered by the NIH's Guidelines, for example. Field testing of a synthetic organism—that is, release into the environment as part of basic research—might not be covered by the existing regulations of the EPA or the USDA. Questions about the adequacy of existing regulations are even more pointed when it comes to concerns about biosecurity, particularly if or when powerful benchtop synthesizers are available in every lab.

The other big question is whether the regulatory bodies' ability to do risk assessment of synthetic biology is adequate. Synthetic biology differs from older forms of genetic engineering in that a synthetic organism could combine DNA sequences found originally in many different organisms, or might even contain entirely novel genetic code. The eventual behavior of these organisms in new environments, should they accidentally end up in one, may therefore be hard to predict.

The synthetic biologists' goal of simplicity is crucial. One of the themes of traditional biology is that living things are usually more complex than they first appear. We should not assume at the outset that synthetic organisms will shed the unpredictability inherent to life. Life tends to find a way. As a starting assumption, we should expect that artificial life will try to find a way as well.

Another difficulty in assessing concerns about both biosafety and deliberate misuse is that, if the field evolves so that important and even innovative work could be done in small, private labs, even in homes, then it could be very difficult to monitor and regulate. The threats of biosafety and deliberate misuse would have to be taken yet more seriously.

Concluding Comments

I take seriously concerns that synthetic biology is bad in and of itself, and I believe that they warrant a thorough public airing, but I do not believe that they provide a good basis for restraining the technology, at least if we can be confident that the organisms will not lead to environmental damage. Better yet would be to get out in front of the technology and ensure that it benefits the environment. Possibly, some potential applications of synthetic biology are more troubling than others and should be treated differently.

Ultimately, I think the field should be assessed on its possible outcomes. At the moment, we do not understand the possible outcomes well enough. We need, I believe:

- more study of the emergence, plausibility, and impact of potential risks;
- a strategy for studying the risks that is multidisciplinary, rather than one conducted entirely within the field;
- a strategy that is grounded in good science rather than sheer speculation, yet flexible enough to look for the unexpected; and
- an analysis of whether our current regulatory framework is adequate to deal with these risks and how the framework should be augmented.

Different kinds of applications pose different risks and may call for different responses. Microbes intended for release into the environment, for example, would pose a different set of concerns than microbes designed to be kept in specialized, contained settings. Overall, however, while the risks of synthetic biology are too significant to leave the field alone, its potential benefits are too great to call for a general moratorium.

Thank you for this opportunity to share my thoughts.