United States House of Representatives Committee on Science, Space, and Technology
Testimony for House of Representatives Subcommittee on Research and Technology;
"Engineering Our Way to a Sustainable Bioeconomy"
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The Ethical Issues in Engineering Biology

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Chairwoman Stevens, Ranking Member Baird and members of the subcommittee:

My name is Laurie Zoloth, and I am Professor of Religion and Ethics and Senior Advisor to the Provost on Programs in Social Ethics at the University of Chicago. I want to thank the committee for asking me to testify about the ethical issues that arise in the research and development of engineering biology, and for inviting a scholar of religion and moral philosophy to your deliberations about scientific research. While I will describe the ethical challenges that surely will be a part of this research, I want to say at the beginning of my testimony that I am supportive of this basic science research, intrigued by the stunning possibilities it might offer, and grateful that your committee is seriously considering what I believe is a strong and thoughtful bill to recommend funding and publicly supporting this research. I am particularly glad to see the inclusion of ethics education in this bill, and I will urge you today to extend that support still further.

Your talented staff has asked me consider four questions. I will address them one at a time.

1. **What are the range of ethical questions around engineering biology and what o funding is available to address these questions?**

When researchers talk about genetics, Americans worry about a range of possible problems. The first are the usual questions about any genetic alteration of nearly any sort in the natural world. We have begun to think of our DNA as fundamental to our identity. "It is in our DNA" is a common phrase to describe values we think are a part of our being as Americans. So, any changing of genetic codes raises issues of which can be changed, who should decide and who has control over the power to make such changes. Now, you can point out that humans have been breeding plants and animals for millennia, and that engineering biology is not, in principle, different. Still, we like to think of nature as fixed, as perfectly in balance, even normative, even moral, or morally good, and there are a series of questions are raised about the threat to the sanctity of the natural world. In the type of engineering projects that begin with existing organisms and then altering them, or using them to perform different tasks, ethical concerns are raised about the uncertainty of outcome, or about the complex errors that have occurred in the past, or about the essential dignity inherent to intact beings to whom we owe respect.

Safety concerns are also important: how will engineering biology affect humans or animals? Are the projects safe when used as intended? How dangerous are they when used in unintended ways, and how likely is that to occur? How likely are mistakes and unintentional

releases? If harm occurs, is it reversible? Are there ways to minimize risks while preserving benefits to individuals and society at large? In 1972, when e coli were first altered in the labs of Stanford, Columbia, and the University of California, early concerns were raised about safety, fears arose about out of control mutations, perhaps leading to cancers, for example. Members of the public questioned then whether sophisticated weapons could be fashioned from these technologies, and as early as 1973, ethical discussions began about how to regulate early genetic alterations. Now, in 2019, concerns about more sophisticated engineering technologies are raised about safety, accidents and the possible use of technology for nefarious ends. Projects that use naturally occurring evolutionary phenomena, such as self-sustaining gene drives are intended to be released and then continue in the natural environment, and while this has the potential for remarkable effectiveness in controlling deadly vector borne disease, it raises new questions about human power, and human error.

Genuine concern is raised around the ethical issues of informed consent or refusal, when biological engineering projects are intended to affect whole populations, or whole geographies. Will the benefits and burdens be distributed equally within the population? If not, will the benefits accrue disproportionately to those already advantaged, and burdens to those already disadvantaged? And to the extent that new technologies create burdens for some, will they be accompanied by offsetting policies – whether economic or social – that will ameliorate these effects? These questions can be asked about advances in computing, robotics, engineering, neuroscience etc. What distinguishes technologies that affect the genetic structure of beings is how it alters the very biological identity of organisms, leading to concerns about its effects on how we define nature and the human place in relationship to that concept, and the permanence of the effects. Americans are committed to the idea of equality, regardless of the situation of one's birth, and while we know that the genetic lottery can be unfair, we do not want it to be a fixed game. We worry about embedding choices we make today across generations. Linked to this concern are basic ethical questions of justice, justice in the choice of research goals, in the way the project tests its hypothesis, and, finally, in the distribution of the social goods that emerge from the research. Will access be open, or will it be constrained by the market? These justice issues are all familiar concerns, arising across all scientific and technical research intended to address human needs. As in all such biotechnology, there are concerns about patents, profits and publication credit.

But a new sort of problem arises when researchers talk about making entirely new, de novo creations, making synthetic chemical version of DNA sequences for example, or creating entirely new living entities, in essence, using a string of chemicals to make new life. This is in principle different from altering already living organisms. Here, we confront issues of mastery, control, and of course profound and unknowable uncertainty, and here we will disagree on issues that can fairly be called ontological and theological.

Ought we to tremble when we cross such a threshold of human knowledge? Ought we to worry that we may be going too far or too fast? Of course, for this sort of power raises difficult question about our human limits and obligations toward a world we might make, to know and to see things which were impossible to know or see a decade ago. Of course, we need to think soberly about the possibility that the research may fail utterly, or that it may

succeed but lead us into a place of great unpredictability—that is the very nature of research—that is what makes us both free and responsible.

Ethics asks the question: What is the right act and what makes it so? It is not a question that emerges from science itself, or within engineering, which ask questions, typically, about how things work. In the past, when NIH pursued the mapping of the human genome, it gave 5% of the budget to work on the Ethical, Legal and Social Implications (ELSI) of the project. "The National Human Genome Research Institute's (NHGRI) Ethical, Legal and Social Implications (ELSI) Research Program was established in 1990 as an integral part of the Human Genome Project (HGP) to foster basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities. The ELSI Research Program funds and manages studies, and supports workshops, research consortia and policy conferences related to these topics." [i] Similarly, the NIH and then the FDA housed the workings of the Recombinant DNA Advisory Committee (the RAC) which reviewed, initially, every funded clinical trial that used genetic interventions on humans. The National Academies have held a series of reviews about ethical issues on engineering biology, the human germ line research, and gene drives. Yet while the ELSI program allowed serious research on the ethical issues surrounding the mapping of the human genome, funding has been more limited for research on other biotechnologies.

2. **How can scientists and engineers collaborate with experts in the humanities, law, and social science to integrate social, legal, environmental and other ethical concerns into the design and conduct of engineering biology R and D?**

Engineering biology is a relatively new field, and it has, from its inception, been welcoming to other disciplines, seeking out scholars such as myself in ethics, in anthropology, in theology, law and policy and social science. The study of ethics and what the field calls "human practices," a name given by an anthropologist, has always been integrated into an important educational project called iGEM which brings international undergraduate students to the United States to a competition of between their synthetic biology projects. The first academic research collaboration, called SYNBerc and current ongoing academic research collaborations such as the Engineering Biology Research Consortium, or Target Malaria, an international academic consortium for gene drive research have always included social scientists, ethicists and policy scholars. This has been largely informal, and largely unfunded—these projects are interesting, creative, powerful, and potentially vastly socially important—this attracts scholars from my field. Critical to the growth of the field and to America's leadership will be the inclusion of scholars who will question the first assumptions of R and D, which is the selection of research targets, and the shaping of the research towards targets that aim to improve life for all of society.

The ELSI HGP showed that scholars of humanities and law are eager to think about science. What is needed now are incentives for scientists to understand humanities, law, and policy questions. Raising the ethical issues early in education will be critical. NIH grants typically mandate a course in human research protocols, but too often these are cursory. Much more needs to be done. Young scientists will choose the virtues that will guide them

early in their careers, and we need to be sure that they see being honest, humble, and just is part of what we mean by being a good scientist, and this means they must study historical debates about ethics and learn the complexities of competing moral appeals. We also need to educate bioethicists, scholars of philosophy, religion, law and political science for they need to understand science before they opine on the ethical questions it raises. Too often the debates about genetics and biology are reminiscent of science fiction movies, a danger if they are led by scholars without a serious background in science. Joint Ph.D. programs that admit young scholars in science and humanities at the same time would allow for a cohort of jointly trained scholars in the field and should be funded robustly.

3. **Do we need any kind of governance for non-human, non-animal cell engineering biology R and D e.g. plant and microbial research? If so, what might that governance look like and who should develop guidelines?**

Yes.

All such research will have enormous impacts on the human future (and that is why we need engineering biology—for our future has serious challenges—a changing climate, a rising need for energy, and a growing, hungry population-- that need new technologies and new social policies. We know that our world is very closely connected in complex webs with the smallest forms of life. Emerging microorganisms, viruses, new vectors for disease all moving at the microscopic level, and all can be critical to human survival. National Academies have been able to structure science guidelines with the help of directly involved scientists and scholars of ethics with open pubic involvement. At stake is who will enforce the guidelines, and for this, academic norms need to be supported—as they are in other countries—with state regulations. Protections for human subject research, IRBs, DSMBs and IACUCs are models of a norm-and-regulation-based system. One of important strengths of the bill under consideration today is the structure of academic and regulatory oversight. Your committee should give consideration for how ongoing ethics oversight is a part of the proposed new office.

The regulation and consideration of whether and how engineering biology can proceed ethically cannot only be a discussion between academics or among scientific experts. Because these big engineering projects are intended in many cases, for wide spread and self-sustained use, a community consent or refusal process needs to be constructed. Ideally, mandated citizen stakeholder engagement should be a part of every project that is publicly funded, and these engagement sessions should start at the beginning of the projects and should involve a wider reach then has previously been imagined, including members of trade unions, parent teacher associations, rural communities and religious and cultural groupings.

4. **What recommendations do you have, if any, for improving the *Engineering Biology Act*? What additional recommendations, if any, do you have for Congress or the federal science agencies that fund engineering biology research?**

I would propose more robust and integrated consideration of ethical issues—how do we decide what to research and how the research is framed is also an ethical issue. Other countries have more developed public discussions about this phase of their science and more

structured leadership about ethics as well. Being a leader in engineering biology is a tremendous responsibility. It will mean leadership in ethical, social, legal, and environmental research as well, and it will mean creating a deep and sustained relationship with the larger international research community.

In my testimony, I have recommended:

a. New Ph.D. programs in ethical decision making, sources of moral appeals, the history of ethics and science need to be funded along with programs for the science itself so the next generation of scholars can be trained.
b. Jointly administered Ph.D. and MA cohorts with train scientists in the humanities and social science and humanities scholars in science.
c. Funding for environmental impact studies with all projects that propose public use.
d. Public meetings to think carefully about projects are more successful if we can expand ideas about democracy and inclusion. Our American capacity for democratic decision making can be an important part of our scientific leadership plan, but funding for widespread education and inclusion must reach beyond the academy.
e. Norms and regulations created by the National Academies' processes and supported by administrative regulations, with consideration to the creation of a national oversight committee in the early stages of research and development.

The economy, the environment, and the human world in which we live is shaped by biology—our history, our needs, our limitations and our imagination. At stake is how we as a society will be able to respond, and when we respond, how we can do so with both courage and thoughtful humility. Other countries have already matured efforts both in engineering biology and in the public discussions about its use. Your efforts will be central to our American response. Thank you for this bill, and for having the wisdom to support and the courage to lead.

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[i] www.genome.gov/10001618/the-elsi-research-program/

Biographic Summary: Laurie Zoloth, Ph.D.

Professor Laurie Zoloth is the Margaret E. Burton Professor of Religion and Ethics and Senior Advisor to the Provost for Programs in Social Ethics at the University of Chicago. She has a long and distinguished career as a bioethicist, scholar of religion, and of Jewish ethics, writing or editing 7 books, and over 300 articles. She has also served as Dean of the Divinity School at the University of Chicago.

She was a Charles Deering McCormick Professor of Teaching Excellence, and the Founding Director of Brady Program in Ethics and Civic Life at Weinberg College of Arts and Sciences at Northwestern University, and was the director of The Center for Bioethics, Science and Society at Northwestern University`s Feinberg School of Medicine where she taught in the Medical Humanities and Bioethics Program, the Jewish Studies program and as of Professor of Religious Studies. From 1995-2003 she was a founder and Director of the Program in Jewish Studies at San Francisco State University.

She was elected both as President of the American Academy of Religion and as President of the American Society for Bioethics and Humanities. She was member of its founding board, receiving its Distinguished Service Award in 2007. She was a founder and vice president of the Society for Jewish Ethics. She was elected to the National Recombinant DNA Advisory Board in 2012. She served for two terms as member of the NASA National Advisory Council, the nation's highest civilian advisory board for NASA, for which she received the NASA National Public Service Award in 2005, the Executive Committee of the International Society for Stem Cell Research, and she was the founding Chair of the Howard Hughes Medical Institute's Bioethics Advisory Board. She has also been on the founding national boards of the Society for Bioethics and Humanites, the International Society for Stem Cell Research, The Society for Scriptural Reasoning, and NASA's International Planetary Protection Advisory Committee. In 2005 she was honored as the Graduate Theological Union's alumna of the year, and she has received distinguished teaching awards at Northwestern University and San Francisco State University.

Her book, Health Care and The Ethics of Encounter, on justice, health policy, and the ethics of community, was published in 1999. She is also co-editor of six books, Notes From a Narrow Ridge: Religion and Bioethics, with Dena Davis; Margin of Error: The Ethics of Mistakes in Medicine, with Susan Rubin; The Human Embryonic Stem Cell Debate: Ethics, Religion and Policy, with Karen LeBacqz and Suzanne Holland; and Oncofertility: Ethical, Legal, Social and Medical Perspectives. Published in 2010, with Teresa Woodruff, Lisa Campo-Edelstein, and Sarah Rodriquez, The John Evans Committee Report, with Carl Smith, Andrew Koppleman, Peter Hayes, and Jews and Genes, with Elliott Dorff published in 2015.