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Regulating What Has Yet To Be Created: An Introduction

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Abstract

The emerging field of synthetic biology—with the potential for engineering life from scratch—has inherited the laws and regulations of its biotechnology precursor. Yet, synthetic biology allows scientists to do entirely new things. This Article considers the resulting legal and ethical issues after surveying the technological capabilities developed within the field of synthetic biology.

I. Introduction

When Zika swept the world a few years ago, one of the proposed solutions was to adapt male *Aedes aegypti* mosquitoes so that when they mated with female mosquitoes in the wild, they would produce offspring that could not survive to adulthood, thereby reducing the mosquito population.[1] Although not ultimately adopted, this is only one of several high-profile uses of synthetic biology; others include possible cures to many of the worst ailments plaguing humanity. Such technology is coming onto the marketplace, fueled by billions of dollars of funding for synthetic biology

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1. Julie Steenhuysen, *U.S. One Step Closer to Releasing Engineered Mosquito to Fight Zika*, REUTERS (Aug. 8, 2016), https://www.scientificamerican.com/article/u-s-one-step-closer-to-releasing-engineered-mosquito-to-fight-zika/ [https://perma.cc/EQ2L-XJVE].

companies,[2] and already has "been used to manipulate information, construct materials, process chemicals, produce energy, provide food, and help maintain or enhance human health and our environment."[3]

This relatively new field has been described as a cross between biology and engineering, which aims to design and construct "new biological parts, devices, and systems, and the re-design of existing, natural biological systems for useful purposes."[4] If biology raises legal and ethical concerns, then so does synthetic biology. This Article considers these concerns after surveying the technological capabilities developed within the field of synthetic biology.

II. The Science

The blueprint for life in every self-sustaining organism is contained within its deoxyribonucleic acid, or DNA. Embedded in the DNA are genes, which are essentially the instructions for making specific proteins. These proteins, in turn, make up all essential structures, including tissues and organs found within an organism. DNA also encodes regulatory elements, which ensure that proteins are made in the right place and at the right time. Small differences in the genetic material encoding genes are essentially what differentiate species, with more closely related organisms sharing a larger percentage of their DNA.[5]

An essential feature of the genetic material DNA is that it exists in the form of a double helix comprising two complementary strands of opposite polarity, as first deduced by Watson and Crick based on Franklin's fiber diffraction image of hydrated DNA.[6] Natural DNA comprises four nitrogen-containing bases: A (adenine), T (thymine), G (guanine), and C (cytosine). Within the double helix, A pairs exclusively with T and G with C. As noted by Watson and Crick, "It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for

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2. Calvin Schmidt, *These 98 Synthetic Biology Companies Raised $3.8 Billion in 2018*, SYNBIOBETA (Dec. 19, 2018), https://synbiobeta.com/these-98-synthetic-biology-companies-raised-3-8-billion-in-2018/ [https://perma.cc/3CF7-7GKV].

3. Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005).

4. *Synthetic Biology*, NATURE.COM, https://www.nature.com/subjects/synthetic-biology [https://perma.cc/64PF-5A5Y].

5. For example, chimps share 99% of human DNA, but that 1% difference results in a very different species. Kate Wong, *Tiny Genetic Differences between Humans and Other Primates Pervade the Genome*, SCI. AM. (Sept. 1, 2014), https://www.scientificamerican.com/article/tiny-genetic-differences-between-humans-and-other-primates-pervade-the-genome/ [https://perma.cc/6M25-48DU].

6. Rosalind E. Franklin & R.G. Gosling, *Molecular Configuration in Sodium Thymonucleate*, 171 NATURE 740, 740–741 (1953); J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953).

the genetic material."[7] During replication, the strands are separated by a DNA helicase and copied by a DNA polymerase. Each strand directs synthesis of a complementary strand through base pairing; the result is an exact copy of the original duplex.

One of the first advances fueling the field of recombinant DNA technology was the development of methods for synthesizing DNA. Previously, these bases had to be synthesized from sugar cane or taken from living organisms, such as salmon.[8]

These bases can then be arranged in any sequence to build variants of genes or entirely new genes. In theory, "DNA sequences can be assembled together like building blocks, producing a living entity with any desired combination of traits."[9] Synthetic biologists can now make DNA sequences according to published gene sequence information or obtain them from DNA foundries such as the BioBricks Foundation, which offers a catalog of standardized genetic sequences that encode proteins that perform specified biological functions when inserted into an organism.[10]

The ability to synthesize any natural sequence of interest is just the beginning. Synthetic biologists have now gone beyond what nature provides in the form of nitrogen-containing bases and created entirely new bases with the ability to pair, effectively expanding the genetic code from the 4 letters found in natural DNA to 6,[11] and most recently, 8 letters (A, T, C, G, Z, P, S, and B) in hachimoji DNA.[12] The latter expanded genetic system—hachimoji DNA—retains the exclusive pairing mechanism found in natural DNA. This is synthetic biology, which creates new genomes and thus new proteins and, ultimately, new life.

The ability to insert synthetic DNA into cells was the foundation for the field of recombinant DNA technology, which is routinely used to express proteins of interest in bacteria or other cells and then purified for further

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7. Watson & Crick, *supra* note 6, at 397.

8. *See, e.g.*, *DNA-Na (Salmon Milt Extract)*, FABRICHEM, https://fabricheminc.com/cosmetic-oral-care-ingredients/dna-na-salmon-milt-extract/ [https://perma.cc/M5TS-WWQE].

9. Gregory N. Mandel & Gary E. Marchant, *The Living Regulatory Challenges of Synthetic Biology*, 100 IOWA L. REV. 155, 159 (2014).

10. BIOBRICKS FOUNDATION, https://biobricks.org/ [https://perma.cc/6XWJ-4LDK].

11. *See generally* Millie M. Georgiadis et al., *Structural Basis for a Six Nucleotide Genetic Alphabet*, 137 J. AM. CHEMICAL SOC'Y 6947 (2015); Kiyofumi Hamashima et al., *Creation of Unnatural Base Pairs for Genetic Alphabet Expansion Toward Synthetic Xenobiology*, 46 CURRENT OPINION CHEMICAL BIOLOGY 108 (2014); Yorke Zhang et al., *A Semisynthetic Organism Engineered for the Stable Expansion of the Genetic Alphabet*, 114 PROC. NAT'L ACAD. SCI. 1317 (2017).

12. *See generally* Shuichi Hoshika et al., *Hachimoji DNA and RNA: A Genetic System with Eight Building Blocks*, 363 SCI. 884 (2019).

functional characterizations.[13] This artificial DNA can be introduced within a cell in the form of a plasmid (small circular DNA) that will be replicated transiently by the cellular machinery or within the context of an element that will integrate into the host's genome and become a permanent part of that organism's genetic material.[14] Extending that technology to the field of synthetic biology, the genomics research institute J. Craig Venter Institute announced in 2010 in *Science* that it had created the first synthetic cell,[15] whose synthetic DNA had a watermark to distinguish it from natural DNA to prove its synthetic origins. In this case, the cell's original DNA was gutted and replaced by the synthetic DNA.

Thus far, synthetic biologists have been using simple organisms to generate proteins of interest but may in the future create entirely new organisms. Even a simple cell is sufficient for certain goals—a cell can "produce valuable chemical compounds, assemble beautiful structures, move with purpose, and process information."[16] Examples include a protein that can strengthen immunity or produce insulin for a diabetic, bacteria and viruses that create diesel gas or synthetic fibers, or organisms that perform as poison sensors or pollution eaters.[17] A recent commercial application modified yeast to produce rose oil for perfume instead of extracting it from Turkish roses through burdensome procedures.[18]

Synthetic biology modifies the behaviors of an organism for essentially one of two purposes. The first is to redesign existing biological systems and the second is to create entirely new ones that do not already exist in the natural world.[19]

The origins of the possibilities for synthetic biology started a long time ago. With technological breakthroughs in DNA sequencing, it has been

13. Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 151, 153–54 (1995); *see also* Stephen H. Schilling, Note, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 735 n.32 (2011).

14. Cubert, *supra* note 13, at 153–54.

15. Jordan Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 PENN ST. L. REV. 53, 53 (2012).

16. Bryan A. Bartley et al., *Synthetic Biology: Engineering Living Systems from Biophysical Principles*, 112 BIOPHYSICAL J. 1050, 1050 (2017).

17. Brendan Parent, *Reproduction-Powered Industry: Coordinating Agency Regulations for Synthetic Biology*, 15 N.C. J.L. & TECH. 307, 309, 311 (2014).

18. Justin Chen, *A Rose by Any Other Name Would Smell as Yeast*, MIT NEWS (July 14, 2017), http://news.mit.edu/2017/rose-by-any-other-name-would-smell-as-yeast-emily-havens-greenhagen-0714 [https://perma.cc/UQ4R-6NCT]; *see also* Sarah Zhang, *A Perfume That Smells Like Roses—But Is Actually Made from Yeast*, GIZMODO (Mar. 5, 2015), https://gizmodo.com/a-perfume-that-smells-like-roses-but-is-actually-made-f-1689526675 [https://perma.cc/P6ZW-5FS4].

19. Jonathan Kahn, *Synthetic Hype: A Skeptical View of the Promise of Synthetic Biology*, 45 VAL. U. L. REV. 1343 (2011).

possible to sequence entire genomes of organisms from bacteria to humans. Through sequencing, researchers found that genome sizes are quite disparate. For example, the human genome contains 3.2 billion base pairs while that of *E. coli* has 4.6 million base pairs.[20] They also found that the predicted number of genes for specific organisms does not correlate well with the size of the genome or perceived complexity of that organism. Humans, for example, have about the same number of genes, approximately 20,000, as mice and nematodes.[21]

Researchers then developed tools that could isolate, cut, transfer, and insert genes from one organism to another.[22] They thus started editing DNA sequences.

Synthetic biologists are now creating novel DNA from scratch. They are not just reading and rearranging genetic code, or even substituting DNA in one organism for that in another, but writing it.[23]

III. The Law

Currently, pre-existing regulations governing biotechnology are applied to synthetic biology despite the differences between the two fields.[24] One distinction is that biotechnology uses living organisms or their parts to develop or create different products, while synthetic biology can use laboratory-created materials to create living organisms.[25] Another unique characteristic of synthetic biology is that it uses engineering principles to intentionally build organisms.[26] In other words, "[w]hile traditional biotechnology involves the transfer of a small amount of genetic material

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20. Carl Zimmer, *And the Genomes Keep Shrinking . . .* , NATIONAL GEOGRAPHIC: THE LOOM (Aug. 23, 2013), https://www.nationalgeographic.com/science/phenomena/2013/08/23/and-the-genomes-keep-shrinking.html [https://perma.cc/2NLN-QNMN].

21. Leslie A. Pray, *Eukaryotic Genome Complexity*, NATURE EDUCATION (2008), https://www.nature.com/scitable/topicpage/eukaryotic-genome-complexity-437/ [https://perma.cc/Q2SV-YZLH].

22. Parent, *supra* note 17, at 311.

23. FRIENDS OF THE EARTH U.S., INT'L CTR. FOR TECH. ASSESSMENT, & ETC GRP., *The Principles for the Oversight of Synthetic Biology* (Dec. 12, 2012), https://www.etcgroup.org/sites/www.etcgroup.org/files/The%20Principles%20for%20the%20Oversight%20of%20Synthetic%20Biology%20FINAL.pdf [https://perma.cc/B975-WHXL].

24. Mandel & Marchant, *supra* note 9, at 173. *Cf.* Parent, *supra* note 17, at 310; John D. Loike & Robert Pollack, *Ethical Boundaries Needed on the Use of Synthetic DNA*, THE SCIENTIST (Mar. 1, 2019), https://www.the-scientist.com/news-opinion/opinion--ethical-boundaries-needed-on-the-uses-of-synthetic-dna-65549 [https://perma.cc/W326-M4ZD].

25. Luis Serrano, *Synthetic Biology: Promises and Challenges*, 3 MOLECULAR SYS. BIOLOGY 158, 159 (2007).

26. Luis Campos, *That Was the Synthetic Biology That Was*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 5, 17 (Markus Schmidt et al. eds., 2009).

from one species to another, synthetic biology will permit the purposeful assembly of an entire organism."[27]

Nonetheless, biotechnology laws and regulations also apply to synthetic biology, thus far having been determined sufficient to govern this area.[28] The legal framework governing biotechnology—and now synthetic biology—was established by the *Coordinated Framework for Regulation of Biotechnology* (Coordinated Framework).[29] The White House Office of Science and Technology Policy proposed this framework in 1984 and finalized it in 1986.[30] It outlined the U.S. policy for regulating the development of products derived from biotechnology.[31] The *Coordinated Framework* determined that genetically engineered organisms did not pose any unique risks in comparison to those conventionally created.[32] Thus, genetically engineered products are regulated instead of their processes, and contemporary laws were determined sufficient to address the risks.

In response to the J. Craig Venter Institute's announcement of its creation of the first synthetic cell in 2010, President Obama asked his Commission for the Study of Bioethical Issues to examine the risks of synthetic biology. The Presidential Commission released its report *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* in 2010.[33] Although it recommended "prudent vigilance" to oversee synthetic biology, it provided no specific recommendations for oversight.[34]

The *Coordinated Framework* therefore continues to provide the current regulatory oversight. Today, federal agencies continue to regulate the product, not the process, of synthetic biology. However, the process itself

27. Mandel & Marchant, *supra* note 9, at 157.

28. "Our research concludes that the U.S. regulatory agencies have adequate legal authority to address most, but not all, potential environmental, health and safety concerns posed by anticipated near-term microbes, plants, and animals engineered using synthetic biology. Such near-term products are likely to represent incremental changes rather than a marked departure from previous genetically engineered organisms. However, we have identified two key challenges to the current U.S. regulatory system posed by the introduction of organisms engineered using synthetic biology into the environment." SARAH R. CARTER ET. AL, J. CRAIG VENTER INSTITUTE, SYNTHETIC BIOLOGY AND THE U.S. BIOTECHNOLOGY REGULATORY SYSTEM: CHALLENGES AND OPTIONS 4 (May 2014), https://www.jcvi.org/sites/default/files/assets/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf [https://perma.cc/H823-ZC3Z].

29. Executive Office of the President, Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology* (June 26, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf [https://perma.cc/TZB2-DNDR].

30. *Id.* at 13.

31. *See generally id*.

32. Parent, *supra* note 17, at 346–47.

33. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES (2010).

34. *Id.* at 27.

might have dangers in it, such as fuel-producing algae gone awry.[35] Furthermore, "the conventional regulatory focus on end-products may be a poor match for novel organisms that produce products."[36] However, there is no doubt that it is also important to regulate the products of synthetic biology, which may go on to interact with the natural environment and humans.

U.S. agencies involved in the regulation of synthetic biology include the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Department of Agriculture (USDA).[37] Much of the oversight of synthetic biology comes from the EPA's Chemicals Program under the authority of the Toxic Substances Control Act (TSCA), which regulates the manufacture, use, distribution in commerce, and disposal of "chemical substances and mixtures."[38] Through the *Coordinated Framework* policy statement and a 1997 EPA Rule, new microorganisms formed through deliberate combinations of genetic material—such as those produced in synthetic biology—are included as substances within this authority.[39] Anyone intending to manufacture, import, or process microorganisms for commercial purposes is required to file either a Microbial Commercial Activity Notice (MCAN) or a TSCA Experimental Release Application (TERA).[40]

There are legal questions about both the unintentional and intentional harms of synthetic biology. Unintentional harms include the possibility that artificial organisms could escape into the wild and cause environmental havoc.[41] "Microorganisms adapt on their own terms, and the best scientists have little clue how to control this."[42] It is also well-documented that alteration of a single base pair within the billions found in the human genome is sufficient to cause disease when that change results in an amino acid

35. Parent, *supra* note 17, at 320.

36. Mandel & Marchant, *supra* note 9, at 155.

37. Lynn L. Bergeson et al., *Creative Adaptation: Enhancing Oversight of Synthetic Biology Under the Toxic Substances Control Act*, 10 INDUS. BIOTECH. 313, 314 (2014).

38. 15 U.S.C. § 2601 (2012); *see also* Benjamin D. Trump, *Synthetic Biology Regulation and Governance: Lessons from TAPIC for the United States, European Union, and Singapore*, 121 HEALTH POL'Y 1139, 1141 (Table 1) (2017) (providing a summary of the regulatory coverage of synthetic biology).

39. Bergeson et al., *supra* note 37, at 315.

40. *Microbial Products of Biotechnology*, KELLER AND HECKMAN LLP (Jan 1, 2014), https://www.khlaw.com/1194 [https://perma.cc/YH5R-3WTX]. For considerations regarding the TSCA's applicability to living organisms, see Mandel & Marchant, *supra* note 9, at 175.

41. "Regarding biosafety measures, a key ethical rationale is protection from harm. It is important to ensure the products of synthetic biology do not leave populations or environments worse off." Ainsley J Newson, *Synthetic Biology: Ethics, Exceptionalism and Expectations*, 15 MACQUARIE L.J. 45, 49 (2015).

42. Parent, *supra* note 17, at 633; *see also* Newson, *supra* note 41, at 48.

substitution or a truncation error in an essential protein rendering it dysfunctional.[43]

Intentional harms include the production of biological weapons, such as the malicious design of pathogens. "Th[is] worry has been sufficiently great that the synthetic biology community recently released a declaration publicly committing itself to improving the software that checks DNA synthesis orders for sequences encoding hazardous biological systems."[44] Furthermore, where there are engineers, there are hackers.[45] At the Synthetic Biology 2.0 meeting in 2006, a self-regulation attempt was therefore made to introduce a code of conduct to prevent the misuse of synthetic biotechnology.[46]

NIH guidelines address research involving recombinant DNA.[47] Researchers at academic institutions may also receive some oversight through the NIH grant process and, before publication is allowed on human subjects, Institutional Review Board (IRB) review.[48] However, industry and non-profit institutions are often self-funded and do not publish their research; therefore, they are not subject to the same restrictions. For example, the Gates

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43. Carles Ferrer-Costa et al., *Characterization of disease-associated single amino acid polymorphisms in terms of sequence and structure properties*, 315 J. MOLECULAR BIOLOGY 771, 772 (2002).

44. Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEXAS L. REV. 1745, 1747 (2007).

45. *See* Parent, *supra* note 17, at 317; *see also* Newson, *supra* note 41, at 48 ("Although researchers have established key components of biological knowledge, such as the sequence of the human genome, research to determine the *function* of genes and *regulation* of gene expression in complex organisms is less developed.").

46. Gardar Arnason, *Synthetic Biology between Self-Regulation and Public Discourse: Ethical Issues and the Many Roles of the Ethicist*, 26 CAMBRIDGE Q. OF HEALTHCARE ETHICS 246, 247–48 (2017).

47. *NIH Guidelines*, NAT'L INST. OF HEALTH: OFFICE OF SCI. POLICY (APRIL 2019), https://osp.od.nih.gov/biotechnology/nih-guidelines/ [https://perma.cc/66N5-NF2M].

48. While both public and private—as well as non-profit and for-profit—organizations are all eligible to receive NIH grants, much funding goes to academic or NIH researchers. *See Budget*, NAT'L INST. OF HEALTH (last updated Jan. 24, 2019), https://www.nih.gov/about-nih/what-we-do/budget [https://perma.cc/2VWM-D8MM]; *see also* BOS. PLANNING & DEV. AGENCY, BOSTON: MOST NIH FUNDS FOR 23 CONSECUTIVE YEARS 8 (2018), http://www.bostonplans.org/getattachment/5cac1d8e-6fd7-4931-a029-6e5f39a28947 [https://perma.cc/5322-2XBD]; *Grants & Funding*, OFFICE OF EXTRAMURAL RESEARCH, NAT'L INST. OF HEALTH, https://grants.nih.gov/grants/who-is-eligible.htm [https://perma.cc/7LJX-4QJN]; *but see* Gil Ben-Menachem et al., *Doing business with the NIH*, 24 NATURE BIOTECHNOLOGY 17, 17 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782946/ [https://perma.cc/9WLT-V85Q]. Yet, synthetic biological research occurs in university labs as much as for-profit commercial labs. Some science can even be done by individuals in their garages. Newson, *supra* note 41, at 49. For background on IRB review, see Lauren B. Solberg, *Data Mining on Facebook: A Free Space for Researchers or an IRB Nightmare?*, 2010 U. ILL. J.L. TECH. & POL'Y 311, 329–34 (2010).

Foundation funds various synthetic biology projects for commercial use,[49] and it was Oxitec's technology in the Florida Keys that would have produced non-viable mosquito offspring in response to Zika.[50]

There are additional complications to comprehensive regulation.[51] Synthetic biology research is conducted all across the globe. While there have been international efforts to address synthetic biology,[52] governance systems are struggling to keep pace with the technological change. Once consensus occurs, the technology changes.[53]

Some kind of comprehensive regulatory framework may eventually emerge, but not without difficulty.[54] In the meantime, the result is a patchwork of laws. Yet, the implications of the technology are sweeping, raising ethical questions as well.

IV. The Ethics

A legal framework in itself is insufficient to oversee synthetic biology. Laws are confined to jurisdictions, but synthetic biology developments occur all around the world. In addition, the law may have trouble keeping up with innovation.[55] In such cases, ethical considerations may assist in guiding synthetic biology research.

While similar to previous concerns with biotechnology,[56] new ethical concerns have been raised. Loike and Pollack have recently called for an Asilomar-style conference to evaluate future risks of synthetic biology.[57] "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

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49. Jenny Rooke, *Synthetic biology as a source of global health innovation*, 7 SYS. & SYNTHETIC BIOLOGY 67, 68 (2013).

50. *See supra* note 1 and accompanying text.

51. There are other legal implications, including intellectual property. *See, e.g.*, Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629, 633 (2010).

52. *See, e.g.*, Karolyn White & Subramanyam Vemulpad, *Synthetic Biology and the Responsible Conduct of Research*, 15 MACQUARIE L.J. 59, 59–60 (2015) (noting international responses).

53. *See, e.g.*, Ayelet Blecher-Prigat, *Rethinking Visitation: From a Parental to a Relational Right*, 16 DUKE J. GENDER L. & POL'Y 1, 11 (2009) ("Thus far, current law has failed to keep up with changing social norms and bio-technological changes[.]").

54. Parent, *supra* note 17, at 338. In the U.S. context, what legislation will be required, and how will it get through Congress? The research itself might be a target for regulation, as well as the resulting products. *See* Newson, *supra* note 41, at 53 ("Three approaches to governance are anticipatory governance, adaptive governance and responsible research and innovation (RRI).").

55. *See id.*

56. *See e.g.*, Newson, *supra* note 41, at 55 ("It seems clear that synthetic biology does not present any completely new ethical issues, and that ethical analysis within synthetic biology should not be described as a discrete field of inquiry within bioethics.").

57. *See* Loike & Pollack, *supra* note 24.

rationally design and engineer living systems free of the constraints of evolution."[58]

Many of the ethical questions raised by synthetic biology relate to questions about life. Should scientists create new life forms that do not already exist by synthetically creating DNA sequences, thereby circumventing the natural process of evolution? Furthermore, what about mistakes in creating life that affect the organism negatively? Should life be specifically created for unpleasant roles, such as yeast for gulping up oil? Thomas Hobbes predicted that life outside society would be "solitary, poor, nasty, brutish, and short,"[59] and perhaps that is where some synthetically created life would fall. This raises concerns regarding the treatment of life created by synthetic biology, which requires determining "at what point a new life form created by synthetic biology attains moral status."[60]

Yet, synthetic biology challenges the very definition of life. Previously, genes needed to be inherited. Now, they can be created in a laboratory and linked to make an entirely new life form. Defining "life" is already difficult without synthetic biology to push the boundaries, and even in simpler contexts, no consensus has developed.[61] Requirements for a genetic information system that could sustain life include nucleobase building blocks that are chemically stable, thermodynamically stable, replicable by enzymes such as polymerases, and kinetically selectable.[62] Life is not just an organism containing DNA, however. Origin-of-life scientists would insist that life, by definition, requires the ability to evolve.[63]

Furthermore, does it matter if the life began in a laboratory? Is it life if it could have never existed naturally or if it was built from a synthetic genome? At least to these questions, a consensus is emerging that "we should

58. Arnason, *supra* note 46, at 247.

59. THOMAS HOBBES, LEVIATHAN: OR THE MATTER, FORME, AND POWER OF A COMMON-WEALTH, ECCLESIASTICALL AND CIVILL 77–78 (1651).

60. Newson, *supra* note 41, at 48.

61. Much literature concludes that "a single definition [of life] is not possible nor would such a definition be stable." *Id.* at 47. "The pre-theoretic notions of the concept of 'life' do not match up with the diversity of beings we see in nature. A common response has been to continue this debate in hope of coming to a consensus with respect to these counterexamples. Others . . . are pessimistic about current approaches and seek new evidence. Their 'wait-and-see' approach is gaining in popularity." Carlos Mariscal & W. Doolittle, *Life and Life Only: A Radical Alternative to Life Definitionism*, SYNTHESE 1, 4 (2018) (citations omitted), https://doi.org/10.1007/s11229-018-1852-2 [https://perma.cc/WZA4-YXUQ].

62. Eörs Szathmàry, *Why Are There Four Letters in the Genetic Alphabet?*, 4 NATURE REVIEWS GENETICS 995, 995 (2003).

63. *See, e.g.*, William A. Dembski & Jonathan Wells, *Must Life Evolve?* EVOLUTION NEWS (July 27, 2017), https://evolutionnews.org/2017/07/must-life-evolve/ [https://perma.cc/SF56-AQN2].

look at the properties of an entity to determine its moral status, not how that entity was made."[64]

Regardless of the definition of life, synthetic biology is the tool to build life as we want it to be, but how far should it go? Creating yeast that emits perfume is one thing, but what about building other creatures? Synthetic biology can bring back extinct creatures and prevent future extinction by constructing entire creatures with artificial genomes. It can also create a synthetic human by building all of its genome in the lab—early plans, now scaled back, included synthesizing the entire human genome.[65] There is, however, an incentive of synthetic biology to be limited to simple biological structures because those can be better programmed.[66]

Some implications of the technology are more palatable than others—palatable enough to make the whole field of synthetic biology so. For example, a synthetic biology product that people swallow can replace the current unpleasant colonoscopy test.[67] Whereas the legal regulation of synthetic biology has taken a piecemeal approach, much of the ethics work has evaluated synthetic biology as a whole, but are the field and its consequences clear yet?

As the technology evolves, what about the ethical aspects related to benefit sharing, such as whether patenting an artificially synthesized genome is appropriate?[68] Ethical considerations could affect pricing and accessibility to the resulting products. Institutions have approached this differently. The J. Craig Venter Institute patented the sequence of the minimal genome in 2007, in contrast to the BioBricks Foundation, which has adopted an open-source model.[69]

64. Newson, *supra* note 41, at 48; *see also* Gerard Jagers op Akkerhuis, *Explaining the Origin of Life is not Enough for a Definition of Life*, 16 FOUNDATIONS OF SCIENCE 327, 328–29 (2011).

65. Elie Dolgin, *Genome-synthesis effort shifts focus*, 557 NATURE 16, 16 (2018), https://www.nature.com/magazine-assets/d41586-018-05043-x/d41586-018-05043-x.pdf [https://perma.cc/9STR-6LLN].

66. Torrance, *supra* note 51, at 636 ("To be programmable like a computer, an organism or cell would probably have to possess at least some computer-like characteristics, such as relative structural simplicity and functional predictability. By contrast, if an organism or cell were to exhibit structural complexity or functional unpredictability, programming it would be difficult and would not tend to yield consistent results. One approach synthetic biology takes to ensure programmability is the deliberate reengineering of biological parts and systems to make them structurally simplified and functionally predictable.").

67. Jade Boyd-Rice, *Will Swallowing Microbes Replace the Colonoscopy?*, FUTURITY (April 11, 2017), https://www.futurity.org/colitis-engineered-bacteria-1399182-2/ [https:// perma. cc/ 5YMH-8E5A].

68. Newson, *supra* note 41, at 50.

69. *See* Ethan R. Fitzpatrick, Comment, *Open Source Synthetic Biology: Problems and Solutions*, 43 SETON HALL L. REV. 1363, 1363, 1373 (2013).

Finally, what are the ethics of *not* using synthetic biology? Whether it is food, fibers, perfumes, or plastics, many products made today require immense resources to extract their basic materials. This may become problematic as the population continues to grow around the world, increasing the demand for these products to unsustainable levels.[70] Synthetic biology offers a new way to fabricate the same goods with far fewer resources. Cell-produced products could replace many industrial and chemical processes in food, fuel, medicine, proteins, and materials, except with far fewer inputs and negative side effects. Hundreds of versions of microbes can be tested to find the ones that maximize production.[71] Synthetic biology may become less elective as the world's resources become more strained.

V. Conclusion

Although the current legal framework treats synthetic biology as the continuation of the status quo, synthetic biology allows scientists to do more than ever before. Considering the short history of synthetic biology, however, the future is unknown. Now is the time to explore the relevant legal and ethical questions, with some of them having spilled over from biotechnology and similar fields.

Innovation is essential.[72] While Frankenstein is a mythical result of synthetic biology technology, an example of what has yet to be created, and the symbol of doom and gloom resulting from human tinkering with biology, a host of solutions to humanity's greatest problems—human health, welfare, and environment—is also possible.

70. *See, e.g.*, Sabrina Haake, *The M Word*, 4 HUM. RTS. & GLOBALIZATION L. REV. 3, 31 (2011).

71. *See* Megan Molteni, *A New Lab Is Brewing Microbes to Create Makeup and Medicines*, WIRED (February 12, 2019), https://www.wired.com/story/culture-biosciences-is-fermenting-microbes-for-meat-makeup-and-fuel/ [https://perma.cc/ZP3G-N6SM].

72. Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 8 (2008).