ETHICAL ISSUES IN SYNTHETIC BIOLOGY

A thesis submitted to the University of Manchester for the degree of Ph.D. in Bioethics and Medical Jurisprudence in the Faculty of Humanities.

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ABSTRACT

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Ethical Issues in Synthetic Biology

Synthetic biology has been defined as: “the design and construction of new biological parts, devices, and systems, and the re-design of existing, natural biological systems for useful purposes” (syntheticbiology.org). The convergence of scientific fields such as molecular biology, computer science and others have rendered it a natural progression, based on existing knowledge.

The fact that humanity has reached a stage of development where it seems feasible to “create” life, or design it to a high degree of specificity, is a significant milestone in its history. It generates important ethical questions: Is synthetic biology something good, a natural use of humanity’s talents, or is it a step towards megalomania, playing God, a usurpation of his role? Is it really a natural progression, nature advancing to a state where its products can, in turn, improve nature itself; or does it challenge the dignity of nature by virtue of its “unnaturalness”? Is it an expression of the creative talent of humanity, thus enhancing human dignity, and perhaps that of all life, or does it challenge the dignity of life itself? Regarding its potential consequences, it may, if it succeeds, lead humanity to a new level of development, a paradigm shift comparable with the scientific or industrial revolutions, through a vast increase in scientific knowledge, and subsequent technological developments in all relevant areas, including medicine, food production and fuel development. However, there is potential for serious accidents if synthetic organisms interact with naturally occurring ones, possibly affecting the future course of evolution. Synthetic biology also offers the possibility of creating ever more powerful weapons, more easily than ever before; the technology is reaching a stage where any interested members of the public may be able to create weapons of mass destruction. Synbio is a dual use technology, offering potential for both good and evil. Its potential for either appears to be greater than any other technology that has existed.

In this thesis I evaluate the ethics of synthetic biology from the following ethical perspectives – deontology, consequentialism and theology. I am approaching it from several viewpoints so as to give as wide an analysis of the issues as possible. I also evaluate the effectiveness of these standard ethical tools for evaluating synbio ethics. In addition, I examine whether ethics should be more deeply integrated into the day-to-day scientific research in synbio. As a secondary study, I discuss regulation, the main legal issue that synthetic biology generates.

DECLARATION

No portion of the work in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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THE AUTHOR

Patrick Heavey obtained a B.Sc. in Physics and Applied Mathematical Science from the National University of Ireland, Galway. He backpacked through Europe, Australia, Asia, and a little of Africa for a couple of years after graduation, working his way around the world. He studied again at the Cavendish Laboratory, Cambridge University, for a taught M.Phil. in Microelectronic Engineering and Semiconductor Physics. He worked in the US for some years, including spells in IT and research. He returned to Ireland to run the family business, and studied for a part-time, modular M.Sc. in Bioinformatics at Oxford University; it was there that he became interested in Bioethics, particularly the ethics of emerging biotechnologies.

Publications:

Patrick Heavey (2013). "Synthetic Biology: A Deontological Assessment." To be published in *Bioethics*, Special Issue on Synthetic Biology, November 2013.

Patrick Heavey (2012). "Global Health Governance for Synthetic Biology." *American Journal of Bioethics*, 12(12): 64-65. doi:10.1080/15265161.2012.739840

Patrick Heavey (2011). "The Place of God in Synthetic Biology: How Will the Catholic Church Respond?" *Bioethics* 2013, 27(1): 36-47. doi:10.1111.j.1467-8519.2011.01887.x

Conference Presentations:

Patrick Heavey (2012). "A Worst Case Balancing Act – Peak Oil, Biofuels and Synthetic Biology." *Presentation, 26th European Conference on Philosophy of Medicine and Healthcare, Nazareth*, 23rd August.

Patrick Heavey (2012). "Consequentialism and the Synthetic Biology Problem." *Poster, International Association of Bioethics: 11th World Congress of Bioethics, Rotterdam*, 29th June.

Patrick Heavey (2010). "Ethical Issues in Synthetic Biology." *Presentation, University of Manchester School of Law Postgraduate Research Conference*, 17th September.

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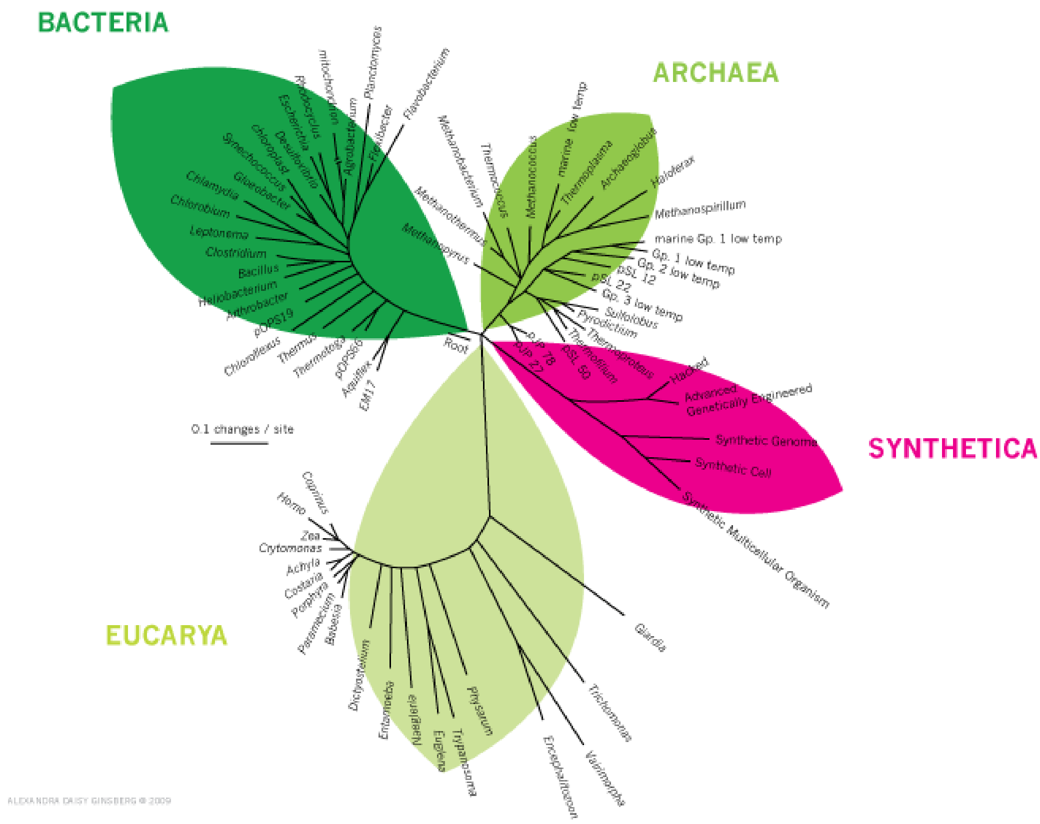
A NOTE ON THE FORM OF THIS THESIS

The *PhD in Bioethics and Medical Jurisprudence* at the University of Manchester is assessed by a "structured doctoral thesis," which differs somewhat from normal doctoral theses in the UK. At its heart is a number of published or publishable articles, typically three or four. These are preceded by an introductory section, originally written as a first year report, and updated in the final year. This introduces the topic of research, and sets out its scope. According to the rules of the programme it requires both ethical and legal analysis, to justify the award of a doctorate in bioethics and medical jurisprudence; also a section on methodology, and definition of the research questions.

The published/publishable articles can focus on ethics or law, or a combination of the two.[1] Mine focussed on ethical issues, with one short legal paper. A conclusion ties the various sections together. This structure can engender some repetition and a little discontinuity in argumentation. The articles are independent units; some points have to be made in multiple articles to make each article complete, particularly in describing this topic of synthetic biology, which is still relatively unknown. Regarding references, I kept them in the journal format for published articles, albeit footnoting them where appropriate.

[1] University of Manchester, School of Law (2012). *The Doctoral Programme (PhD) in Bioethics and Medical Jurisprudence Programme Handbook.*

The Synthetic Kingdom: A Natural History of the Synthetic Future[2]



The **Tree of Life**, which categorises life, has changed with evolving scientific knowledge. In the 1700s, Carl Linnaeus classified life into two main branches, animal and plant, with sub-classifications in each. Charles Darwin saw the Tree as something dynamic, some branches (of species) withering and falling away, while new ones bud. Currently, the Tree of Life is considered to have three main branches: *Prokaryotes [or Eubacteria]* (single-celled life, without a cell nucleus), *Eukaryotes* (single or multicelled lifeforms, with a cell nucleus) and *Archea* (similar to prokaryotes, but with a different evolutionary history.[3] Artist Alexandra Daisy Ginsberg, in collaboration with some synthetic biologists, has proposed a new branch for the Tree of Life, *Synthetica*. In her own words:

Synthetic organisms are no different from other life forms, except that we invented them. We'll simply have to insert an extra branch into the Tree of Life to classify them. Perhaps the synthetic kingdom is part of our new nature?

The Synthetic Kingdom mirrors synthetic biology's ideology; it's a future fashioned by engineering logic, a rationalisation of the complexity of living systems, an engineering solution to an engineering problem. But it also puts our designs back into the complexity of nature rather than separating us from them.[4]

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[2] Alexandra Daisy Ginsberg (2009). *The Synthetic Kingdom: A Natural History of the Synthetic Future.* http://www.daisyginsberg.com/projects/synthetickingdom.html Accessed December 9th 2012
[3] Tree of Life Web (ToL) Web Project Homepage (2005). http://tolweb.org/tree/ Accessed December 20th 2012.
[4] Alexandra Daisy Ginsberg (2012). In Geoff Baldwin, Travis Bayer, Robert Dickinson, Tom Ellis, Paul S. Freemont, Richard I. Kitney, Karen Polizzi and Guy-Bart Stan (2012). *Synthetic Biology: A Primer.* (London: Imperial College Press), p. v.

If the dominant science in the new 'Age of Wonder' is biology, then the dominant art form should be the design of genomes to create new varieties of animals and plants. This art form, using the new biotechnology creatively to enhance the ancient skills of plant and animal breeders, is still struggling to be born. It must struggle against cultural barriers as well as technical difficulties, against the myth of Frankenstein as well as the reality of genetic defects and deformities. If this dream comes true, and the new art form emerges triumphant, then a new generation of artists, writing genomes as fluently as Blake and Byron wrote verses, might create an abundance of new flowers and fruit and trees and birds to enrich the ecology of our planet.

Freeman Dyson[5]

The scientists at the J Craig Venter Institute expected to be told that they were "playing God", and they were not disappointed. Yes, if one believes that life was created by God, then this comes as close to "playing God" as humans have come so far.

Peter Singer[6]

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[5] Freeman Dyson (2009). "When Science & Poetry Were Friends." *The New York Review of Books*, 13th August. http://www.nybooks.com/articles/archives/2009/aug/13/when-science-poetry-were-friends/?pagination=false Accessed December 20th 2012.
[6] Peter Singer (2010). "Scientists Playing God Will Save Lives." *The Guardian*, 13th June. http://www.guardian.co.uk/commentisfree/2010/jun/13/science-playing-god-climate-change Accessed December 20th 2012.

PART I INTRODUCTION

CHAPTER 1 INTRODUCTION TO SYNTHETIC BIOLOGY

The world was to me a secret which I desired to divine. Curiosity, earnest research to learn the hidden laws of nature, gladness akin to rapture, as they were unfolded to me, are among the earliest sensations I can remember . . . It was the secrets of heaven and earth that I desired to learn; and whether it was the outward substance of things or the inner spirit of nature and the mysterious soul of man that occupied me, still my inquiries were directed to the metaphysical, or in its highest sense, the physical secrets of the world.

Mary Shelley, *Frankenstein*[1]

INTRODUCTION

Synthetic biology is a new scientific discipline, which has emerged within the last decade. It can be defined as:

- the design and construction, from scratch, of new:
  - – life-forms,
  - – biological parts, and
  - – devices made from biological parts; and also
- the redesign of existing biological organisms or parts for useful purposes.[2] [3]

Research is currently taking place at the microbial level, but may be applicable to higher life-forms as the science progresses. Synbio's first international conference,

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[1] Mary Shelley (1818). *Frankenstein: Or The Modern Prometheus*. (London: Lackington, Hughes, Harding, Mavor and Jones), pp. 44-45.

[2] Syntheticbiology.org (undated). http://syntheticbiology.org/ Accessed December 1st 2012.

[3] ETC Group (2007). *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. (Ottawa, ON: ETC Group), p. 1. http://www.etcgroup.org/content/extreme-genetic-engineering-introduction-synthetic-biology Accessed December 20th 2012.

Synthetic Biology 1.0, was held in 2004.[4] A dedicated journal exists,[5] though mainstream journals also publish advances. One textbook has been published at the time of writing, in late 2012.[6] A handful of universities, including many of the world's most prestigious, offer courses – individual courses within undergraduate degrees such as biology and engineering, and some specialised masters and doctoral programmes.[7]

Synbio has, as its foundation, fields as diverse as molecular biology (its primary basis), genetic engineering, bioinformatics, systems biology, mathematics, engineering, computer science, physics, chemistry and nanotechnology. The convergence of such fields has reached a level where synthetic biology research has become feasible.[8] Indeed it is a natural progression based on current scientific knowledge. Synbio has been described as a move from "artisan" biotechnology to a biotech based on professional engineering standards, which includes concepts such as standardization, modularization, and development of abstraction hierarchies.[9]

Standardisation of biological parts is a foundational element in synbio. For example, screws and threads are made to standard measurements, so that parts bought

[4] Synthetic Biology 1.0 Homepage (2004). www.syntheticbiology.org/Synthetic_Biology_1.0.html Accessed December 29th 2012.

[5] *Systems and Synthetic Biology* Homepage (2012). http://www.springer.com/biomed/journal/11693 Accessed December 1st 2012.

[6] Geoff Baldwin, Travis Bayer, Robert Dickinson, Tom Ellis, Paul S. Freemont, Richard I. Kitney, Karen Polizzi and Guy-Bart Stan (2012). *Synthetic Biology: A Primer.* (London: Imperial College Press).

[7] For example, Cambridge University offers a Synthetic Biology course as part of its Plant Sciences undergraduate degree - see http://www.sysbiol.cam.ac.uk/index.php?page=part-iii-course-in-systems-biology; Imperial College London offers a taught masters degree in systems and synthetic biology http://www3.imperial.ac.uk/pgprospectus/facultiesanddepartments/instituteofsystemsandsyntheticbiology/postgraduatecourses For a list of universities offering doctoral studies in synthetic biology, see: http://syntheticbiology.org/Graduate.html All accessed December 1st 2012.

[8] Ryan McDaniel and Ron Weiss (2005). " Advances in Synthetic Biology: On the Path from Prototypes to Applications." *Current Opinion in Biotechnology,* 16: 476-483.

[9] Markus Schmidt, ed. (2012). *Synthetic Biology: Industrial and Environmental Applications.* (Weinheim: Wiley-Blackwell), p. xvii.

from any source are interchangeable. An ongoing, and important area in synbio research is to develop similar standards for biological parts. *Modularisation* means that parts and devices can be added and removed without affecting the organism as a whole, or other parts and devices. This does *not* mirror the reality of nature; it simplifies it, so as to reduce nature's complexity to a level that can be understood and managed by humans. *Abstraction hierarchies*, which exist throughout engineering, mean that tasks in synbio are rigorously and formally divided into a hierarchy; expertise at one level of the hierarchy does not require expertise at any other level. This allows for a high degree of specialization by researchers.[10]

Synthetic biology is seen by its practitioners as an engineering discipline, primarily, rather than a biological one.[11] More of its practitioners are engineers and computer scientists than biologists. There is an aphorism: "a scientist discovers those things that are in nature, but an engineer makes things which have never existed before," and synbio's primary focus is on creating new entities rather than discovering nature's inner workings. Baldwin et al have observed that:

> The main aim of synthetic biology is to reduce to a minimum both the experimental laboratory work and the scientific enquiry of the discipline, and instead turn it into a predictable technology suitable for systematic biological design and industrialization.[12]

However, it is likely to lead to new discoveries in fundamental science, as a byproduct; learning how to create biological systems from scratch should greatly enhance knowledge of the underlying processes. A motto of the Nobel Prize winning physicist, Richard Feynman, appears frequently in the synbio literature: "what I

[10] Geoff Baldwin et al (2012), *op. cit.*, note 6.
[11] Drew Endy (2005). "Foundations for an Engineering Biology." *Nature,* 438: 449-453.
[12] Geoff Baldwin et al (2012), *op. cit.*, note 6, p. 56.

cannot create, I do not understand." A version of the motto has also been encoded into the first synthetic genome, Craig Venter's *Synthia*.[13]

In addition, any new items created may have very useful applications, in areas as diverse as therapies, drugs, food, fuels and new chemicals.[14] Already, useful drugs have been made using synthetic biology techniques, and research is ongoing into applying it to replace fossil fuels.[15] Creation of new artefacts will lead to tools that further enhance pure scientific knowledge as well as leading to valuable applications. Synthetic biology could, if it succeeds, lead to a revolution in knowledge, and in how biology is done, and in its applications; a revolution in science possibly as great as the Copernican revolution, the theory of evolution, or the paradigm shift from classical physics to relativity and quantum theory. In terms of society, its impact could be as transformative as the industrial revolution.

Like any tool, synthetic biology could be used for good or evil. In the words of a report published jointly by the J. Craig Venter Institute, the Center for Strategic and International Studies, and MIT:

> Synthetic genomics… is a quintessential "dual-use" technology—a technology with broad and varied beneficial applications, but one that could also be turned to nefarious, destructive use. Such technologies have been around ever since the first humans picked up rocks or sharpened sticks. But biology brings some unique dimensions: given the self-propagating nature of biological organisms and the relative accessibility of powerful biotechnologies, the means to produce a "worst case" are more readily attainable than for many other technologies.[16]

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[13] "What I cannot build I do not understand." See George Church and Ed Regis (2012). *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves.* (New York: Basic Books), p. 177.
[14] Parliamentary Office of Science and Technology (2008). "Synthetic Biology." *Postnote* January, No. 298.
[15] ETC Group (2007). *op. cit*., note 3.
[16] Michele S. Garfinkel, Drew Endy, Gerald L. Epstein and Robert M. Friedman (2007). *Synthetic Biology: Options for Governance*. (Rockville, MD: J.Craig Venter Institute ; Washington, DC: Center for Strategic and International Studies ; and Cambridge, MA: MIT), p. 1.

Human history suggests that it will be used for both good and evil (I discuss this in some depth in Chapters 2, 3 and 5). Hence important ethical issues arise. Before discussing ethics, it is useful to describe, briefly and in overview, some of the types of research that are taking place in the field, as the details of synbio are still relatively little known. This will set the context for the ethical discussions.

SOME IMPORTANT AREAS OF RESEARCH

DNA Design – Writing Novel Genomes:

DNA design differs from genetic engineering in that while genetic engineering manipulates existing life forms – for example, placing a gene from one organism into another – this branch of synbio aims to design novel DNA. It represents a move, in essence, from "reading the genetic code to writing it."[17] Genetic engineering grew in an experimental "wet lab" environment – *in vivo*. Synthetic DNA design adds various tools to genetic engineering techniques, such as engineering design principles, algorithm development, and computer programming – an addition of biological research *in silico*. *In vivo* biological research alone is not enough for this field to progress.[18]

It has been possible to synthesise DNA for 40 years; but it was, until recently, expensive and very slow. Now it can be done at speed. Synthetic biology advances upon this, aiming to design genes that have not previously existed. Thus the

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http://www.synbiosafe.eu/uploads/pdf/Synthetic%20Genomics%20Options%20for%20Governance.pdf Accessed December 1st 2012.

[17] Craig Venter. In Antoni Regaldo (2005). "Next Move for Venter: Create Entire Sets of Genes from Scratch." *The Wall Street Journal*, 29th June, p. A1.

[18] ETC Group (2007). *op. cit.*, note 3.

modification of organisms, or creation of new ones, can be taken to a new level.[19] When added to microbes, "designer" DNA changes their function, to achieve specific purposes.

The most successful accomplishment in synthetic biology so far has been the development of an artificial bacterium, *Synthia*; news of its creation made headlines around the world.[20] Craig Venter's team decoded the genome sequence of a bacterium, *Mycoplasma mycoides*, built a synthetic copy, and placed that copy into a different bacterium, *Mycoplasma capricolum*. *M. capricolum* then changed into *M. mycoides*.[21]

An important subfield of DNA design is the creation of *BioBricks*. The concept here is to design DNA parts that perform specific functions. These can be combined with other parts to perform composite functions; they are biological equivalents of devices in an electronic circuit. They can then be added to a bacterium to change its function.[22] A pioneer of the field is Drew Endy, of Stanford; one ambition of his is to reprogram the genome of a tree so it grows into a house.[23] Another idea is to program cells to devour cholesterol.[24] BioBricks are open source/

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[19] Ibid.

[20] Even in the *Daily Mail*. For a surprisingly good article, see: Fiona Macrae (2010). "Scientist Accused of Playing God after Creating Artificial Life by Making Designer Microbe from Scratch - But Could it Wipe out Humanity?" *Daily Mail*, 3rd June. http://www.dailymail.co.uk/sciencetech/article-1279988/Artificial-life-created-Craig-Venter--wipe-humanity.html Accessed December 1st 2012.

[21] Daniel G. Gibson, John I. Glass, Carole Lartigue, Vladimir N. Noskov, Ray-Yuan Chuang, Mikkel A. Algire, Gwynedd A. Benders, Michael G. Montague, Li Ma, Monzia M. Moodie, Chuck Merryman, Sanjay Vashee, Radha Krishnakumar, Nacyra Assad-Garcia, Cynthia Andrews-Pfannkoch, Evgeniya A. Denisova, Lei Young, Zhi-Qing Qi, Thomas H. Segall-Shapiro, Christopher H. Calvey, Prashanth P. Parmar, Clyde A. Hutchison III, Hamilton O. Smith, and J. Craig Venter (2010). "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome." *Science*, 2 July, 329(5987): 52-56. doi: 10.1126/science.1190719

[22] Biobricks Foundation Homepage (2012). http://bbf.openwetware.org/ Accessed December 1st 2012.

[23] ETC Group (2007). *op. cit.*, note 3, p. 16.

[24] Ibid.

non-commercial, freely available on the Biobricks website.[25] There is an online encyclopaedia of such biological parts, the *Registry of Standard Biological Parts*.[26]

The BioBricks Foundation runs an annual competition – *iGEM (International Genetically Engineered Machine Competition)*; admission was restricted to teams of undergraduates initially, but secondary school students have recently been allowed to compete.[27] The scientific level of the best teams is very sophisticated. Past entries include bacteria that smell of bananas, or blink different colours;[28] computing with living hardware; biological implementations of algorithms and unconventional computing; teaching bacteria how to dance; the "Cell-See-Us" cellular thermometer; development of a novel biosensor for the detection of arsenic in drinking water;[29] and, ambitiously, using synthetic biology to "green" the desert, by engineering bacteria to promote plant root growth in hostile climates.[30]

The Minimal Microbe Genome

This research is attempting to find the minimum number of genes (and which genes) are necessary for microbial life, with the intention of using this knowledge as a chassis on which to build new microbial life-forms. The research is done either by knocking out genes, one by one, and finding out which are necessary for an organism

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[25] The Biobricks Foundation (2013). http://biobricks.org/ Accessed April 7th 2013.
[26] Registry of Standard Biological Parts (undated). http://partsregistry.org/Main_Page Accessed December 1st 2012.
[27] George Church (2012). *op. cit.*, note 13.
[28] ETC Group (2007). *op. cit.*, note 3, p. 16.
[29] *IET Synthetic Biology* (2007). http://scitation.aip.org/dbt/dbt.jsp?KEY=ISBEBU&Volume=1&Issue=1-2 Accessed December 1st 2012.
[30] iGem (2011). *Team Imperial College London Presentation.* http://2011.igem.org/Team:Imperial_College_London Accessed December 1st 2012.

to survive, or by comparing many genomes to determine which genes occur across a multitude of life-forms. The first approach is performed *in vivo,* the second *in silico*.[31]

The Minimal Genome Project, run by the J. Craig Venter Institute, studied the bacterium *M. genitalium,* a urinary tract parasite, *in vivo*; chosen because it has one of the smallest genomes. It was found that 386 of its 517 genes were necessary for basic life function; the others could be done without. [32] Similar work on *Bacillus subtilis* found that only 271 of its 4,800 genes were necessary to sustain life.[33]

The *in silico* approach has shown that about 60-70 genes are found in all organisms; a small number, much less than the minimum number required for life, as the same functions are frequently carried out by different genes in different organisms. However, by comparing only closely related organisms (eg *Mycoplasma* varieties), the *in silico* approach gives comparable figures to the *in vivo*.[34]

The idea in synbio is to synthesize such a minimal genome, then place it into a bacterium, creating a new form of life, *M. laboratorium*. Specially designed "genetic cassettes" could then be added to this chassis, designing life at will. Hoped for applications include the design of biofuels, as a replacement for fossil fuels; and an enhancement of photosynthesis, to increase carbon dioxide absorption and reduce climate change.[35] At the *Synthetic Biology 2.0* conference, Craig Venter predicted that synthetic biology could soon replace the oil industry.[36]

[31] Geoff Baldwin et al (2012), *op. cit.*, note 6
[32] ETC Group (2007), *op. cit*., note 3.
[33] Geoff Baldwin et al (2012), *op. cit.*, note 6
[34] Ibid.
[35] ETC Group (2007), *op.cit.*, note 3
[36] Ibid., p. 27.

Enhancing the Genetic Code: Could Life-forms Exist that are not DNA Based?

Research is ongoing into enhancing the genetic code, i.e., attempting to create life-forms that have a different genetic code to current living creatures. DNA is the basis of all life on earth, storing genetic information. It has the following chemical structure: four chemical bases (or nucleotides) – adenine (A), cytosine (C), guanine (G) and thymine (T) – are attached to, strung along, a chemical backbone made of sugar and phosphate; this combination makes a strand of DNA. Two such strands are wound around each other in a double-helix shape, to form a DNA molecule. The question could be asked: could a life-form be created which has a different chemical basis to life? For example, a DNA-type molecule with extra bases added, or entirely different bases, or a backbone made of a different chemical? Or something entirely unlike DNA altogether? This research attempts to answer that question. Steven Benner, a leading researcher in the field, stated that "We can't think of any transparent reason that these four bases are used on earth…and it wouldn't surprise me in the slightest if life on Mars used different letters."[37]

In 2004, Benner and his team at the University of Florida synthesised a molecule similar to DNA that contained six nucleotides instead of four.[38] This molecule could be copied successfully and repeatedly (in a standard process known as the polymerase chain reaction (PCR)), leading to an exponential growth in the number

[37] Andrew Pollack (2001). "Scientists are Starting to Add Letters to Life's Alphabet." *New York Times,* 24th July. http://query.nytimes.com/gst/fullpage.html?res=9E04EEDE113AF937A15754C0A9679C8B63&scp=1&sq=Scientists+are+starting+to+add+letters+to+life%92s+alphabet&st=nyt Accessed December 1st 2012.

[38] A. Michael Sismour, Stefan Lutz, Jeong-Ho Park, Michael J. Lutz, Paul L. Boyer, Stephen H. Hughes and Steven A. Benner (2004). "PCR Amplification of DNA Containing Non-standard Base Pairs by Variants of Reverse Transcriptase from Human Immunodeficiency Virus-1" *Nucleic Acids Research,* 32(2): 728-735, 2nd February. http://nar.oxfordjournals.org/cgi/content/full/32/2/728?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=benner&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT Accessed December 1st 2012.

of copies of itself. It could mimic the evolutionary process of naturally occurring DNA – the team caused it to evolve over five generations.[39] The team has created modified DNA with up to 12 nucleotides.

Building Artificial Cells:

Craig Venter's work on minimal microbe genomes requires that artificially created genomes be placed in living cells in order to create synthetic life. But other researchers are attempting to go a step further – to create completely artificial cells, or *protocells*.

It is uncertain whether artificial cells that are indistinguishable from real cells can be created – but the attempt is likely to yield great insights into the underlying biology. A bottom-up approach, which attempts to construct a living cell from inert chemicals, using an external source of energy as metabolism, is being used.[40] This contrasts with the top-down approach of Craig Venter's team. Although the top-down approach is very complex, the bottom-up approach is far more complex still, a more ambitious project which will take much longer.[41] [42] Ultimately, if successful, the two approaches may meet at some stage.

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[39] University of Florida News (2004). *UF Scientists Create the First Artificial System Capable of Evolution*. 24th February. http://news.ufl.edu/2004/02/20/artificialdna/ Accessed December 1st 2012.
[40] Bob Holmes (2005). "Alive! The Race to Create Life from Scratch." *New Scientist* , 2486, 12th February.
[41] ETC Group (2007). *op. cit*., note 3.
[42] *Workshop: Bridging Non-living and Living Matter* (2003). Los Alamos and Santa Fe, New Mexico, 9-11th Sept. http://www.ees.lanl.gov/protocells/bridging/protocells-text7.pdf Accessed December 1st 2012. See also the first conference proceedings in the field, which set out the main approaches to the research: http://www.ees.lanl.gov/protocells/bridging/agenda12.pdf Accessed December 1st 2012.

A significant centre for the research is the Los Alamos National Laboratory, New Mexico.[43] (Ironically, this centre for research into creating life was where the atomic bomb was developed.[44]) The team, led by Danish physicist Steen Rasmussen, is attempting to build a cell consisting of three distinct parts: a molecule that stores and transmits information, including heredity (like DNA); a metabolism that provides energy; and a membrane which encloses and protects everything.[45] [46] The information storage molecule is based on DNA, but is not DNA. Rather, *PNA* is used, which has the same structure and nucleotides as DNA but has a backbone made of peptides instead of DNA's sugar-phosphate. One of the reasons for this difference is safety – the hope that if any such artificial life-forms escapes into the environment, it is unlikely to survive. As well as using PNA instead of DNA, protocells will not be exact physical reconstructions of nature's cells. Nevertheless, they will, if successful, mimic cell function.[47]

Although scientists will not be able to create protocells in the time-frame it took to make the atomic bomb – 3 years – they do expect to make significant progress. Much of the theoretical background to the work comes from computer science (the science of self-organising systems, pioneered by Nobel laureates Ilya Prigogine and Manfred Eigen.[48]) The research has been described as an attempt to "literally [breathe] life into a beaker full of inanimate molecules… a Frankenstein

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[43] Protocell Assembly Project Homepage (2012). http://protocells.lanl.gov/ See also: http://www.ees.lanl.gov/protocells/index.shtml Accessed December 1st 2012.
[44] ETC Group (2007). *op. cit.*, note 3.
[45] Steen Rasmussen, Liaohai Chen, David Deamer, David C. Krakauer, Norman H. Packard, Peter F. Stadler, Mark A. Bedau (2004). "Transitions from Non-living to Living Matter" *Science*, 303(13): 963-965 http://www.ees.lanl.gov/staff/steen/papers/963.pdf Accessed December 1st 2012.
[46] ETC Group (2007), *op.cit*., note 3, p. 17.
[47] Bob Holmes (2005). *op. cit.*, note 40.
[48] Michael Stroh (2005). "Life Built to Order" *Popular Science*, February. http://www.popsci.com/scitech/article/2005-02/life-built-order Accessed December 1st 2012.

vision… that will unfold on the nano scale."[49] Hoped-for applications include cells that can clean arteries and deliver drugs to exact targets in the body.[50]

There are other groups. Between 2004 and 2008 the European Commission funded the *PACE Consortium – Programmable Artificial Cell Evolution*[51] – a group which involved a number of European and American universities and companies. At the University of Rome, Pier Luigi Luisi has developed a membrane which is similar to a cell membrane. He is adding, step by step, various cellular components and enzymes, hoping to create a simple working cell.[52] [53] [54] [55]At Harvard, Nobel Laureate Jack Szostak[56] is attempting to create a DNA molecule which has been enhanced to catalyse its own replication. This chemical system is bound in a membrane. Szostak's view is that the time-frame for this research is 10-20 years: "I've been saying that for the last 10 or 20 years… and it's still true."[57]

Metabolic (or Pathway) Engineering

In this research, new metabolic pathways in microbes are being designed, making them into chemical factories that produce desired chemicals. This should allow mass production of rare naturally occurring materials, and creation of new ones. For example, the anti-malaria drug *Artemisinin* has been manufactured this way.

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[49] Ibid.
[50] ProtoLife Press Release (2005). *It's Life, Jim, But Not As We Know It*. PRWeb Press Release Newswire, 24th January.
[51] PACE website (undated). http://complex.upf.es/~ricard/PACEsite See also: http://www.istpace.org//index.html Accessed December 1st 2012.
[52] Bob Holmes (2005), *op. cit*., note 40.
[53] Pier Luigi Luisi and Pasquale Stano, eds. (2011). *The Minimal Cell: The Biophysics of Cell Compartment and the Origin of Cell Functionality*. (Dordrecht: Springer).
[54] Pier Luigi Luisi (2011). *The Emergence of Life: From Chemical Origins to Synthetic Biology*. (Cambridge: Cambridge University Press).
[55] Pier Luigi Luisi Synthetic Biology Lab (2008). http://www.plluisi.org/ Accessed December 7th 2012.
[56] Szostak Lab (2007). http://molbio.mgh.harvard.edu/szostakweb/ Accessed December 7th 2012.
[57] Bob Holmes (2005), *op. cit*., note 40.

Naturally-occurring Artemisinin has been used in Chinese medicine for over 2,000 years, extracted from the Artemisinin herb – but it is rare and expensive, and supplies are sporadic. Now it can be produced much more cheaply, and synthetic biology research is ongoing to make it cheaper and more plentiful still.[58] [59] [60]

Living Machines:

The convergence of nanotechnology and biology is being used to develop machines with living components. The research is currently at the most elementary level, and is outside the mainstream of synbio research. An EU funded project called *Mol Switch* has developed switches using biological components. A subsequent project, *BioNano-Switch*, headquartered at the University of Portsmouth with teams in six EU countries, has developed a biological motor, which produces electrical signals; its output can therefore be read by computers. The device consists of DNA on a microchip; a tiny magnet is attached to the DNA. Adenosine triphosphate (ATP), the source of biochemical energy in cells, moves the DNA and hence the magnet; in turn, the moving magnet produces electricity. Hoped for applications include using such signals to replace those of damaged muscle, allowing for the development of advanced artificial limbs. The interaction of drugs with the body's DNA may also be observable.[61]

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[58] ETC Group (2007) *op. cit.*, note 3.
[59] Keasling Laboratory (2012). http://keaslinglab.lbl.gov/ Accessed December 7th 2012.
[60] Jeffrey A. Dietrich, Yasuo Yoshikuni, Karl J. Fisher, Frank X. Woolard, Denise Ockey, Derek J. McPhee, Neil S. Renninger, Michelle C. Y. Chang, David Baker, and Jay D. Keasling (2009). "A Novel Semi-biosynthetic Route for Artemisinin Production Using Engineered Substrate-Promiscuous $P450_{BM3}$." *ACS Chemical Biology*, 4(4): 261-267.
[61] European Commission (2007). *Synthetic Biology* (Luxemburg: Office for Official Publications of the European Communities), p. 8-9. ftp://ftp.cordis.europa.eu/pub/nest/docs/5-nest-synthetic-080507.pdf Accessed December 1st 2012

Another project, CELLCOMPUT, attempts to mimic biological communication mechanisms in hardware. The "wiring" in biology is very complex, and not generally reproducible in current technology; this project attempts to find ways to mimic it. Possible applications include the design of biodevices that could restore damaged tissue, or detect and destroy pathogens, disease, external pollutants or any undesired chemicals.[62]

A significant advantage to using biological components in such devices is that they can self-assemble – researchers have developed simple self-assembling machines. Significant disadvantages are that biological components may be relatively short-lived and unstable, and may evolve.[63]

DIY Biology

In parallel with the mainstream research, performed by universities, government research institutes (including the military) and corporations of various sizes, described above, an underground "do it yourself biology" movement has emerged. Sometimes referred to as *garage biohacking*, it is similar to early Silicon Valley computer culture where "garage hackers," often teenagers, created innovative hardware and software in their garages and bedrooms.[64] Much of the foundation of the current computer era was laid outside academia and business, in the homes of these hackers. Some of them, including Bill Gates and Steve Jobs, went on to found the

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[62] Ibid. p. 10-11
[63] Ibid.
[64] See, for example, Biopunk Homepage (2012). http://www.biopunk.org/; the Open Biohacking Project Homepage (2008). http://biohack.sourceforge.net/; and *Biopunk* article in *Wikipedia*: http://en.wikipedia.org/wiki/Biopunk Accessed December 1st 2012.

computer corporations which are such an important part of the world's fabric today.[65] Bill Gates has said that if he was starting out today, DNA hacking would be his focus.[66]

Biohacking is known by various names: *Biopunk, DIY Biology, Grinding,…* [67] DNA design is the main technology among those described that is currently accessible by biohackers.[68] Some metabolic engineering may also be achievable. Unlike the early Silicon Valley computer hackers, biohackers are interconnected through a variety of websites and forums. These feature news from both the biohacking and mainstream scientific world (there is an element of connection between the two, of course, and biohacking is very dependent on scientific advance). Exploring them can give a good insight to the culture. For example, categories on the *Grinding* website include: artificial intelligence, augmented reality, bacteria, bio-hacking, biomimicry, cyborging, DNA computing, ethics, immortality, intelligence augmentation, microrobotics, next nature, pirate utopia, posthumanism, security, self-surgery, surveillance and weapons.[69]

Biohacking is broader than synbio, but synbio is a part of it and will become more so as it develops. Biohacking may be commercialiseable:

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[65] For a description of the garage hacking world, see: Robert X. Cringely (1996). *Accidental Heroes: How the Boys of Silicon Valley Made their Millions, Battle Foreign wired. Competition, and Still Can't Get a Date.* (New York: HarperCollins).

[66] Steven Levy (2010). "Geek Power: Steven Levy Revisits Tech Titans, Hackers, Idealists." *Wired*, 19th April. http://www.wired.com/magazine/2010/04/ff_hackers/all/1 Accessed December 1st 2012.

[67] Peter Rothman (2011). "Biopunk and Biohacking Status Update and Interview with Lukas Dimoveo." *H+ Magazine*, 5th October. http://hplusmagazine.com/2012/10/05/biopunk-and-biohacking-status-update/ Accessed December 23rd 2012.

[68] See, for example: Pam Baker (2011). "Biohacking 101: Tools of the Biopunk Trade." *Genome Alberta*, 5th May. http://genomealberta.ca/blogs/biohacking-101-tools-of-the-biopunk-trade.aspx; Also: Ben Beaumont Thomas (2012). "How to Make a Biohack Lab." *Wired (UK)*, 21st February. http://www.wired.co.uk/magazine/archive/2012/03/how-to/make-a-biohack-lab Accessed December 23rd 2012.

[69] Grinding Homepage (2012). http://grinding.be/category/bio-hacking/ Accessed December 29th 2012.

> Rayfish, a custom footwear company, is marketing leather sneakers that come in every color from shimmering gold to neon green, in patterns that mimick giraffes, zebras, leopard, and lady bugs. And they claim that these designs are grown directly on the hides of custom-engineered stingrays.[70]

Some of the culture of biohacking is underground, some quite mainstream. Underground websites frequently have a "rock 'n roll look;" others look corporate. Director X of the *Transhuman Underground* blog expresses the "alternative" side of the culture well:

> Things are being worked on right now. Wonderful things. Things that would get me arrested if I blogged about them. You aren't ready…
> All of your patents belong to us. Sorry corporations, inventors, and engineers. Your patents are like blueprints to the Grinder community. Biohackers and rogue chemists will dissect your formulas and introduce the useful ones on the black market years before you get FDA approval. Your contributions are appreciated, but we feel that tech wants to (and ought to) be free…
> LOLethics. Sorry ethics committees. When did every invention suddenly become a topic of ethical debate? Who keeps forming these ethics committees and why? I'm joking! I really don't care who or why. My right to transcendence is an individual pursuit of happiness that trumps your fear of hypothetical negative social impacts… Imagine how ridiculous these questions will seem to us in 100 years from now. Imagine how we will wonder at the weird dystopia we lived in where ethics were discussed ad nauseum and to the point of inaction. The future is not entirely foreseeable. Get over it.…
> Sorry scientists… The DIY crowd is not to be reasoned with and this stuff will happen with or without your guidance.[71]

There are also physical spaces where biohacking is taught. For example, Genspace, which describes itself as "New York City's community biolab," offers an intensive biohacker boot camp, and introductory courses in synthetic biology and biotechnology.[72] The most expensive of these courses is currently $300; all (at the time of writing) are taught by PhD holders.[73]

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[70] Ibid.
[71] Director X (2012). "DIY Culture and Future Implications." *Transhuman Underground*, 19th June. http://transhumanunderground.blogspot.ie/2012/06/diy-culture-and-future-implications.html Accessed December 1st 2012.
[72] Genspace Homepage (2012). *Events at Genspace*. http://genspace.org/events/courses Accessed December 4th 2012.
[73] Ibid.

SYNTHETIC BIOLOGY AND TRANSHUMANISM

Within thirty years, we will have the technological means to create superhuman intelligence. Shortly after, the human era will be ended.[74]

Vernor Vinge, 1993.

George Church, Professor of Genetics at Harvard Medical School and one of synthetic biology's pioneers, has written a semi-popular account of the field and its potential applications. He mentions transhumanism, referring to "H. sapiens 2.0;" transhumanism is suggested in the book's title: *Regenesis: How Synthetic Biology Will Reinvent Nature* and *Ourselves.*[75] The idea that synbio could be applied to create enhanced humans is common in the literature, both among professionals like Church and biohackers.

Drew Endy, another professional, has suggested replacing current methods of human reproduction with synbio techniques that enable designer offspring to be created: "If you could complement evolution with a secondary path, decode a genome, take it off-line to the level of information...we can then design whatever we want, and recompile it... At that point, you can make disposable biological systems that don't have to produce offspring."[76]

Many amateurs have taken transhumanism to heart; some have designed simple self-enhancing experiments. Synthetic biology is not advanced enough to be a

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[74] Vernor Vinge (1993). "The Coming Technological Singularity: How to Survive in the Post-Human Era." In G.A. Landis (ed.) *Vision-21: Interdisciplinary Science and Engineering in the Era of Cyberspace*. NASA Publication CP-10129, pp. 115–126

[75] George Church and Ed Regis (2012). *op. cit.*, note 13.

[76] Michael Specter (2009). "A Life of its Own. Where will Synthetic Biology Lead Us?" *The New Yorker*. 28th September, p. 61. http://www.newyorker.com/reporting/2009/09/28/090928fa_fact_specter Accessed December 2nd 2012.

significant part of this yet, but will be incorporated into it if it becomes so – it is widely discussed online. Some biohackers are currently trying to enhance themselves by using present-day technology; simple things can be used very inventively, leading to a nickname, *scrapheap transhumanism*, for this subculture.[77]

Scrapheap transhumanism's creative attitude indicates how synbio is likely to be embraced when it advances enough. Examples of topics from an amateur forum, *biohack.me*, include: "Just installed a magnet in my finger, but I'm not sure if it's deep enough,"[78] and "communication using the central nervous system;"[79] self surgery, to "upgrade" oneself. Embedding magnets in the fingertips, deep in the tissue, is popular, as it can allow the nervous system to detect electromagnetic fields, including their strength and shape; thus giving the bearer of the magnet a sixth sense.[80] The *Grinding* website describes the experience:

> Our artist, Mike Seeler, has larger than average magnet implants in both hands. Traveling through New York City is a very different experience for the both of us. He is constantly discovering magnetic fields pouring out of the street, the subway, the bus, and buildings. He has even had a few dreams including his magnetic sense.[81]

One DIY transhumanist, Lepht Anonym, performs home surgery using scalpels, with alcohol for sterilisation; she has implanted numerous devices into her

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[77] Lepht Anonym (2010). "Scrapheap Transhumanism." *H+ Magazine*, 11th February. http://hplusmagazine.com/2010/02/11/scrapheap-transhumanism/ Accessed December 29th 2012.
[78] Suamanahaii (2012). "Just Installed a Magnet in my Finger, but I'm not Sure if it's Deep Enough." http://discuss.biohack.me/discussion/298/just-installed-a-magnet-but-im-not-sure-it-is-deep-enough.#Item_12 Accessed December 1st 2012.
[79] Lukas (2012). "Grindhouse Wetwares Update: HELEDD and Nervous System - Nervous System Communication." http://discuss.biohack.me/discussion/309/grindhouse-wetwares-update-heledd-and-nervous-system-nervous-system-communication#Item_18 Accessed December 1st 2012.
[80] Liat Clark (2012). "Magnet Implanting DIY Biohackers Pave the Way for Mainstream Adoption." *Wired Magazine (UK)*, 4th Sept. http://www.wired.co.uk/news/archive/2012-09/04/diy-biohacking?page=all Accessed December 1st 2012.
[81] m1k3y (2012). "Magnetic Dreams." *Grinding*, 13th October. http://grinding.be/category/bio-hacking/ Accessed December 1st 2012.

body, including magnets, to increase her perception.[82] [83] [84] Regarding the dangers (she has been hospitalized several times), she said: "Bodily health takes a big fuck-off second seat to curiosity."[85] [86]

Such body enhancement has also been done by professional scientists, most notably Kevin Warwick, Professor of Cybernetics at the University of Reading and a member of the Nuffield Council on Bioethics Working Party on Novel Neurotechnologies.[87] Among other projects, he has installed electronic transmitters into his body, and detectors around his lab building. The detectors recognised his presence, greeted him by name and opened doors for him. With this setup, he can control some electrical equipment with his thoughts, and has established electronic communication between the central nervous systems of himself and his wife, a scientific first.[88] [89] At another level, DARPA (Defense Advanced Research Projects Agency), the research wing of the US military,[90] is attempting to use synthetic biology to build "cybernetic organisms," living robots.[91] Harvard scientists have also

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[82] John Borland (2010). "Transcending the Human, DIY Style." *Wired*, 30th December. http://www.wired.com/threatlevel/2010/12/transcending-the-human-diy-style Accessed December 1st 2012.

[83] trefuzzy-punk (undated). "Lepht Anonym." http://www.tumblr.com/tagged/lepht-anonym Accessed December 1st 2012.

[84] Adam Sinicki (2012). "The Biohacking and Grinding Movement – How to Become a Transhuman." *TheBioMatrix.net* http://www.the-biomatrix.net/grinders-biohackers.htm Accessed December 1st 2012.

[85] John Borland (2010), *op. cit.*, note 82.

[86] Lepht Anonym (2010). *Cybernetics for the Masses: Implants, Sensory Extension and Silicon – All For You!* Presentation, 27th Chaos Communication Congress, Berlin, 30th December. http://events.ccc.de/congress/2010/Fahrplan/day_2010-12-30.en.html Accessed December 2nd 2012. Videos of the presentation are available on youtube: *Cybernetics for the Masses 1*, http://www.youtube.com/watch?v=a-Dv6dDtdcs; *Cybernetics for the Masses 2*, http://www.youtube.com/watch?v=7RV_6Axb80g; and *Cybernetics for the Masses 3*, http://www.youtube.com/watch?v=L5n2aJeAGyM. Accessed December 2nd 2012.

[87] Kevin Warwick Homepage (2012). http://www.kevinwarwick.com/ Accessed December 2nd 2012.

[88] Ibid.

[89] Kevin Warwick (2004). *I, Cyborg*. (Champaign, IL: University of Illinois Press).

[90] DAPRA Homepage (undated). http://www.darpa.mil/ Accessed December 2nd 2012.

[91] Geoffrey Ingersoll (2012). "The Military is Building Integrated Hybrid Living-Nonliving Robotic Organisms." *Business Insider: Military & Defense*, 16th October. http://www.businessinsider.com/the-military-just-put-out-a-research-request-for-what-amounts-to-cybernetic-organisms-2012-10 Accessed December 2nd 2012.

created “cyborg cells”, with electrical components deeply integrated into cardiac cells.[92] [93] If it can be done for single cells, it may be possible to scale it up for multiple ones.

A company founded by biohackers, *Grindhouse Wetware,* describe themselves as “a dedicated team working towards a common goal - augmenting humanity using safe, affordable, open source technology.”[94] They offer free materials to amateur biohackers aiming for a transhuman future, and sell technical hardware for that purpose. Their website asks: “"What would you like to be today?" Grindhouse hardware and software are designed with the hacker in mind.”[95] One team member, a science undergraduate, describes his motivation as follows:

> I firmly believe that each individual has the right to modify themselves as they wish. Each person has their own "inner image" of themselves, and there is nothing wrong with self-modification to project that image into the external world, as has been done for millenia. In addition to this, technology from both now and the near future will allow people to modify themselves in ways previously unattainable, opening the possibility of overcoming humanity itself.[96]

Synthetic biology has the potential to take current hobbyist experimentation to an unrecognisably higher level.

Vernor Vinge, a professor of mathematics, has predicted that technological advances will eventually lead to superintelligent machines, and/or superintelligent

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[92] Bozhi Tian, Jia Liu, Tal Dvir, Lihua Jin, Jonathan H. Tsui, Quan Qing, Zhigang Suo, Robert Langer, Daniel S. Kohane and Charles M. Lieber (2012). "Macroporous Nanowire Nanoelectronic Scaffolds for Synthetic Tissues." *Nature Materials*, 11(11): 986-994. doi:10.1038/nmat3404

[93] Will Ferguson (2012). “Cyborg Cell is Half Living Tissue, Half Electronics.” *New Scientist*, 2880, 28th August. http://www.newscientist.com/article/dn22217-cyborg-tissue-is-half-living-cells-half-electronics.html Accessed December 2nd 2012.

[94] Grindhouse Wetware Homepage (2012). http://www.grindhousewetware.com/about-us Accessed Dec 2nd 2012.

[95] Ibid.

[96] Ian Linnel (2012). “Grindhouse Team: Ian Linnel.” http://www.grindhousewetware.com/grindhouse-team Accessed December 2nd 2012.

humans created from biological research, which will far surpass human capabilities, and so end the era of human dominance – a development which he refers to as *the Singularity*.[97] [98] The concept dates back to the mid 19th century,[99] and has been popularised by engineer and futurologist Ray Kurzweil, who estimates that organic human brains, with all their skills, will merge with the far superior information processing capability of computers, resulting in a being that is vastly evolved from "Humanity 1.0." He also predicts that we will be able to exchange bodies at will, and freely adopt new personae. The effect that this could have on illness, injury and infirmity is obvious. For what it's worth, he predicts that this will occur by 2045.[100]

Regarding recreational and commercial applications of such technological advances, some transhumanists are already ahead of the game. While academic Markus Schmidt has written of the possibility of synbio being used to synthesise illegal drugs,[101] Director X takes it much further:

> How would one go about programming an acid trip for AI [artificial intelligence]? How does an AI reconcile this data when the experience subsides. Can it be programmed to handle it like a human would? Digital drug addiction is another thing that someone has to capitalize on so it might as well be me.[102]

The underground aspect of biohacking suggests that a transition to Humanity 2.0, if it occurs, may not be an orderly, streamlined process, presided over by benign scientists. Such a scenario may be part of any such transition, but the transition may also contain elements of competitive "über-geekery;" also of the "madness of

[97] Vernor Vinge (1993). *op. cit*., note 74.
[98] James Patrick Kelly and John Kessel (2012). *Digital Rapture: The Singularity Anthology*. (San Francisco, CA: Tachyon Books).
[99] George Church and Ed Regis (2012). *op. cit.*, note 13, p. 250.
[100] Ray Kurzweil (2005). *The Singularity is Near*. (New York: Penguin).
[101] Markus Schmidt (2008). "Diffusion of Synthetic Biology: A Challenge to Biosafety." *Systems and Synthetic Biology*, 2(1-2): 1–6. doi: 10.1007/s11693-008-9018-z
[102] Director X (2012). "Influence Mapping and Digital LSD." *Transhuman Underground*, 23rd October. http://transhumanunderground.blogspot.ie/ Accessed December 1st 2012.

crowds," such as the irrational behaviour in stock market or housing booms; along with the growth of scrapheap transhumanist cottage industries, perhaps comparable, in worst cases, with back street abortion clinics. Also, corporate abuses seem plausible, along with the involvement of both petty and organised crime. The cost of being left behind, if a transhumanist scenario becomes scientifically possible, may be so great that the scramble for advantage may lead to significant societal upheaval in the transition period.

Back in the scientific mainstream, the Singularity University,[103] founded by Kurzweil and others, aims to bring the Singularity to fruition. Located in the NASA Research Park in Silicon Valley, some of its faculty and advisors come from a who's who of the US's top universities and technology corporations.[104] It offers scientific, healthcare and executive programs. It is involved in synthetic biology.

Kurzweil has been criticised by many scientists, who argue that he doesn't appreciate biological complexity, and the probable insurmountable barriers that it mounts against such a scenario. Kurzweil counters that he does appreciate it, and that the current exponential growth of biological knowledge will reduce biological complexity to a degree that is manageable.[105] Time will tell who is right. Other problems have been posited. For example, a science fiction plot discussed a scenario where the biological part of the brain may not be able to cope with the speed of the

[103] The Singularity University Homepage (2012). http://singularityu.org/ Accessed December 2nd 2012.
[104] Singularity University FAQs (2012). http://singularityu.org/faq/#VM3 Accessed December 2nd 2012.
[105] Lev Grossman (2011). "2045: The Year Man Becomes Immortal." *Time Magazine*, 10th February. http://www.time.com/time/magazine/article/0,9171,2048299-1,00.html Accessed December 2nd 2012.

electronics, while the electronics' logic could not cope with the illogical part of humanity; perhaps a fundamental and unsolvable incompatability.[106]

Regardless, this illustrates that some see synbio as a foundational technology for the development of Humanity 2.0 and beyond. Whether the technology ever reaches a point where this is feasible cannot be plausibly predicted at present; but it is clear that some are aiming to take it there, and will do so if it turns out to be technically possible. The connection between transhumanism and synbio as a foundational technology, is beginning to be noted within the bioethics community.[107] [108] [109]

Other than this brief introduction, I do not intend to discuss the ethics of synthetic biology's interaction with the transhumanist agenda (although it's essential to mention it, as every bioethicist studying the field should be aware of its potential use here). The reasons are that there is already a significant literature on the ethics of transhumanism, and its ethics do not necessarily depend on the technology used to develop it. Also, synbio, which currently operates only at the microbial level, generates many ethical issues at its current state of development; it seems more appropriate, therefore (in a thesis with a limited word count) to discuss its ethical problems in the here and now, rather than speculate about what ethical issues may arise if it can be developed to a high level – something which is not certain.

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[106] Maria Pellegrini (2012). *Planets Under Glass*. (Amazon Digital Services, Kindle Edition).
[107] John Harris (2008). "Who's Afraid of a Synthetic Human?" *The Times*, 17th May. http://www.almendron.com/tribuna/who%E2%80%99s-afraid-of-a-synthetic-human/ Accessed December 15th 2012.
[108] John Harris (2010). *Enhancing Evolution: The Ethical Case for Making Better People.* (Princeton, NJ: Princeton University Press).
[109] Stuart Newman (2012). "Meiogenics: Synthetic Biology Meets Transhumanism." *GeneWatch, Council for Responsible Genetics.* http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=411 Accessed December 20th 2012.

A BRIEF HISTORY OF SYNTHETIC BIOLOGY (AND THE LESSONS THAT CAN BE LEARNED FROM HISTORY)

We must either succeed in producing living matter artificially, or we must find the reasons why this is impossible… Nothing indicates, however, at present that the artificial production of living matter is beyond the possibilities of science.

Jacques Loeb, 1912.[110]

Synthetic biology has not appeared out of the blue, in isolation; its germination period has extended over centuries. This hasn't always been appreciated. When Luis Campos, a historian of synthetic biology, entered an abstract on the history of synbio to the *Synthetic Biology 1.0* conference, the organizers reacted with surprise, saying they didn't know the subject had a history.[111]

Although synthetic biology's current incarnation appeared shortly after the completion of the human genome project, the phrase was previously used in 1974 by Polish geneticist Wacław Szybalski, who wrote:

> Let me now comment on the question "what next". Up to now we are working on the descriptive phase of molecular biology. ... But the real challenge will start when we enter the synthetic biology phase of research in our field. We will then devise new control elements and add these new modules to the existing genomes or build up wholly new genomes. This would be a field with the unlimited expansion potential and hardly any limitations to building "new better control circuits" and..... finally other "synthetic" organisms, like a "new better mouse". ... I am not concerned that we will run out of exciting and novel ideas,... in synthetic biology, in general.[112]

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[110] Jacques Loeb (1912). *The Mechanistic Concept of Life*. (Chicago, IL; University of Chicago Press), pp. 7-8.

[111] Luis Campos (2011). "A History of Synthetic Biology." *Imperial College London Institute of Systems and Synthetic Biology Autumn Symposium*, 17th November. https://workspace.imperial.ac.uk/systemsbiology/Public/Autumn%20Symposium%20Programme%202011%20-%20revised%20Aug%2017%202011.pdf Accessed December 1st 2012.

[112] Wacław Szybalski (1974). "In Vivo and in Vitro Initiation of Transcription," Page 405. In: A. Kohn and A. Shatkay (Eds.), Control of Gene Expression, pp. 23–4, and Discussion pp. 404–5 (Szybalski's concept of Synthetic Biology), 411–2, 415–7. (New York: Plenum Press.)

Four years later, he wrote of a forthcoming "new era of synthetic biology where not only existing genes are described and analyzed but also new gene arrangements can be constructed and evaluated."[113]

The first use of the term, however, was by the French scientist Stephan Leduc in 1910,[114] in the book *Théorie physico-chimique de la vie et générations spontanées*, which contained a chapter entitled *La Biologie Synthetique*. [115] [116] He followed this by a complete book on the subject, *La Biologie Synthetique* in 1912.[117]

Leduc argued, 64 years before Szybalski, that every science goes through three phases of development: a period of observation of phenomena; then an analytical phase, where those phenomena are explained; then, when the underlying science is understood, a synthetical phase, where those mechanisms are reproduced by humans, harnessing the natural laws to their will. Biology has chemistry as its foundation, i.e., biological organisms are made up chemicals, so once the biochemical laws are understood, it should be possible to apply those laws in designing new organisms.[118]

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[113] Wacław Szybalski and A. Skalka (1978). "Nobel Prizes and Restriction Enzymes". *Gene,* 4(3): 181–2. doi:10.1016/0378-1119(78)90016-1

[114] Luis Campos (2010). "That Was the Synthetic Biology That Was." In Markus Schmidt, Alexander Kelle, Agomoni Ganguli-Mitra and Huib Vriend, eds, *Synthetic Biology: The Technoscience and Its Societal Consequences*. (Dordrecht: Springer Academic Publishing.)

[115] Stephan Leduc (1910). *Théorie Physico-chimique de la Vie et Générations Spontanées*. (Paris: A. Poinat). Available at: http://archive.org/stream/thoriephysicoc00leduuoft#page/n9/mode/2up Accessed December 31st 2012.

[116] English translation of Leduc (1910): Stephan Leduc (1914). *The Mechanism of Life*. Translated by W. Deane Butcher. (London: William Heinemann). Available at: http://archive.org/stream/mechanismoflife029804mbp#page/n0/mode/2up Accessed December 1st 2012.

[117] Stephan Leduc (1912). *La Biologie Synthetique*. (Paris: A. Poinat). Available at: http://www.peiresc.org/bstitre.htm Accessed December 1st 2012.

[118] Stephan Leduc (1914). *op. cit.*, note 116, p. 113.

The desire to create life goes back further than Leduc. Peter Singer noted that a 16th century alchemist, Paracelsus, tried it by placing sperm into the decaying uterus of a horse.[119] There is an ancient Jewish tradition of the *golem*, an artificial creature. Various legends exist, one being the creation of a golem by the 16th century Rabbi Loew of Prague to protect the Jewish people. Golems could, allegedly, be moulded from soil, then brought to life by reciting God's name, or by writing the name of God on the mould.[120] Mary Shelley's *Frankenstein*, first published in 1811, also shows that people were interested in the topic in that era.[121]

Leduc was a prominent researcher among several of his era who were attempting to create artificial life, and their attempt was the most serious in history up to that point.[122] They failed, because although their foundational thesis was logically correct, they lacked the scientific knowledge to implement it; they had no knowledge of DNA, genes and modern molecular biology, among other things. Biological knowledge was far greater when Szybalski wrote his prediction, yet was nowhere near advanced enough – for example, not a single genome sequence was known for any creature, nor was it known how many human genes there were, never mind what their purposes might be or how they interacted with each other.

Scientific knowledge has advanced to a stage which is unrecognisable compared with the knowledge of Leduc and the other early synthetic biology

[119] Peter Singer (2010). "Scientists Playing God Will Save Lives." *The Guardian*, 13th June. http://www.guardian.co.uk/commentisfree/2010/jun/13/science-playing-god-climate-change Accessed December 1st 2012.
[120] Alden Oreck (2012). *The Golem*. Jewish Virtual Library. http://www.jewishvirtuallibrary.org/jsource/Judaism/Golem.html Accessed December 1st 2012.
[121] Mary Shelley (1818). *op. cit.*, note 1.
[122] Evelyn Fox Keller (2003). *Making Sense of Life: Explaining Biological Development with Models, Metaphors and Machines.* (Cambridge, MA: Harvard University Press).

pioneers. Yet it remains to be seen whether it has advanced sufficiently for humanity to create life. There are still large gaps. For example, recent research has suggested that the concept of individual genes as units of heredity, strung along the genome, may be obsolete, as genes are so highly interconnected, influencing each other's expression, that it may be meaningless to speak of genes in isolation. A new definition has been proposed for the gene: "a union of genomic sequences encoding a coherent set of potentially overlapping functional products."[123] Also, approximately 97% of DNA is of unknown function. Until a few years ago, it was referred to as junk DNA,[124] the belief being that it was evolutionary debris of no function. Later the suspicion arose that it may be functional, possibly for regulatory mechanisms, though it was not really known what the functions may be.[125] In recent months, preliminary results have been released from the ENCODE (Encyclopedia of DNA Elements) Project, which aims to determine all functional parts of the human genome. These preliminary results suggest that up to 20% of the genome is functional, and may regulate genes.[126]

The background scientific knowledge is ever evolving. There isn't even full consensus on what constitutes current scientific knowledge. A *Nature* editorial has observed:

> Two philosophers of science recently surveyed 500 geneticists to ask their opinion on whether 14 different sets of genetic information constituted a gene, or more than one gene. Fortunately, the bulk of the respondents felt able

[123] Mark B. Gerstein, Can Bruce, Joel S. Rozowsky, Deyou Zheng, Jiang Du, Jan O. Korbel, Olof Emanuelsson, Zhengdong D. Zhang, Sherman Weissman, and Michael Snyder (2007). "What is a Gene, Post-ENCODE? History and Updated Definition". *Genome Research*, 17(6): 669–681. doi:10.1101/gr.6339607
[124] Andrew Brown (2000). "Fox Among the Lab Rats." *The Guardian*, 4th November. http://www.guardian.co.uk/books/2000/nov/04/books.guardianreview6 Accessed December 1st 2012.
[125] Elizabeth Pennisi (2007). "DNA Study Forces Rethink of What It Means to Be a Gene". *Science*, 316(5831): 1556–1557. doi:10.1126/science.316.5831.1556
[126] ENCODE Project Homepage (2012). http://www.genome.gov/10005107 Accessed December 1st 2012.

> to answer the questions definitively. Less fortunately, their answers were inconsistent, with the sample quite often evenly split on the question of how many genes were present… [Geneticists] don't always know where one gene ends and the next begins.[127]

Gerstein et al state the difficulties (as perceived by present-day science) well:

> We probably will not be able to ever know the function of all molecules in the genome. It is conceivable that some genomic products are just "noise," i.e., results of evolutionarily neutral events that are tolerated by the organism... Or, there may be a function that is shared by so many other genomic products that identifying function by mutational approaches may be very difficult. While determining biological function may be difficult, proving lack of function is even harder (almost impossible). Some sequence blocks in the genome are likely to keep their labels of "TAR of unknown function" indefinitely. If such regions happen to share sequences with functional genes, their boundaries (or rather, the membership of their sequence set) will remain uncertain.[128]

The difficulty of building synbio on such a foundation should not be underestimated.

There are other unknowns, particularly the issue of *emergence* – the fact that in a complex biological system, an organism is greater than the sum of its parts. Aristotle wrote, in *Metaphysics*, that: "the totality is not, as it were, a mere heap, but the whole is something besides the parts."[129] He distinguished the material of an organism from its essence, and this view persisted until the 19th century. Until then, scientists believed that life was conferred by a vital force, a *vis vitalis*, or immaterial soul, which combined with the material in some way, yet was quite separate from anything in the physical world – the *vitalism* hypothesis. Various experiments in the 19th century showed that the properties of living things could be explained, in ever

[127] Nature (2006). "Editorial: Coping With Complexity: A More Detailed Understanding of Scientific Concepts Does Not Lead to Simplicity." *Nature*, 441(7092): 383-384.
[128] Mark B. Gerstein et al (2007). *op cit*., note 123, p. 679.
[129] Aritotle *Metaphysics.* Book H 1045a 8-10.

greater depth, by their physical and chemical properties.[130] The vitalism hypothesis largely died when Friedrich Wöhler synthesized urea, an organic compound normally found only in living things, from two inert compounds, cyanic acid and ammonia.[131] Vitalism is no longer a significant part of scientific discourse, where a reductionist philosophy tends to prevail.[132]

Yet reductionism shows that "emergent" properties arise in biology. Life itself is an emergent process, arising from a combination of inert chemicals. The science of emergence is little understood; for the most part, emergent properties can be neither predicted nor explained. It does not necessarily equate to vitalism – emergent properties exist across nature, not just in living things – but to all intents and purposes, it is as mysterious. It should be noted that a body is chemically identical a few seconds before death and a few seconds after, suggesting that chemistry and physics alone may be inherently sufficient to explain life.

Added to the above selection of "known unknowns" can be added Rumsfeld's "unknown unknowns." No doubt nature's secrets will be unveiled to an ever greater degree as science progresses. Scientific knowledge of the present era will appear relatively primitive to scientists of centuries in the future. Such difficulties do not mean that synbio cannot succeed. But whether scientific knowledge is now advanced enough to enable the creation of synthetic life at any level of sophistication remains to be seen.

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[130] E. Kinne-Saffran and R.K.H Kinne (1999). "Vitalism and the Synthesis of Urea: From Friedrich Wöhler to Hans A. Krebs." *American Journal of Nephrology,* 19:290-294.
[131] Friedrich Wöhler (1828). Über künstliche Bildung des Harnstoffs. *Ann Phys Chem* 12:253–256.
[132] Nature (2007). "Editorial: Meanings of 'Life:' Synthetic Biology Provides a Welcome Antidote to Chronic Vitalism." *Nature,* 447: 1031-1032. doi:10.1038/4471031b

THE RESEARCH QUESTIONS

In the light of the above, it seems plausible that synbio will generate significant ethical and legal issues. I will examine such issues in Chapters 2 and 3 (which introduce synbio's legal and ethical issues, respectively); I will develop these themes in more depth in the submitted papers section of the thesis.

At this point I outline my research questions, which are at the heart of this thesis, so as to put the chapters that follow into context. (I describe the questions, and my methodology, in more detail in Chapter 4):

- *Is synthetic biology ethical?* This is the core question of the thesis, to be examined using philosophical analysis.
- Is synbio "playing God," a sinful manifestation of hubris? Or is it a praiseworthy use of humanity's creative powers? I examine this using theological analysis.
- Should synthetic biology be regulated? If so, how? There will be difficulties in regulating it well (see Chapters 2 and 9).

The question arises here as to whether synthetic biology poses unique ethical issues, different, at least in part, from those posed by other controversial scientific advances such as genetic engineering, nanotechnology, or 3D printing; or are its ethical issues largely a rehash of the ethical issues posed by them? As my discussion in the following chapters shows, there is significant overlap between synbio ethics and the ethical issues posed by other emerging technologies. However, synbio also has its own unique issues. Central is whether designing new life is a step too far for humanity to take. Has the human race the intellectual and moral capacity to take such a path? Is it the right thing to do? Is it an attempt to usurp God's role? Another issue, related to the first, is the DIY biology issue, the fact that such a powerful technology will be useable by any interested members of the public, possibly with far-reaching effects, some of which may be vastly destructive. Another issue is regulation; synbio needs good regulation to keep it safe, but it may be very difficult to regulate effectively, due to the great diversity of actors involved, across the world, ranging from large government and private labs to individuals with labs in their homes. Synbio may present the greatest challenge that regulators have ever faced.

CHAPTER 2 LAW – REGULATION

Everything which is not forbidden is allowed.

Legal Maxim.[1]

"He's suffering from politician's logic. Something must be done, this is something, therefore we must do it."

From *Yes, Minister.*[2]

INTRODUCTION

Oliver Cromwell once stated: "It will be found an unjust and unwise jealousy to deny a man the liberty he hath by nature upon a supposition that he may abuse it. When he doth abuse it, then judge."[3] Leaving aside *ad hominem* attacks on Cromwell, his words offer a useful guide to regulators of all hues; regulation diminishes human freedom, and can be stultifying, crushing innovation. Yet experience shows that some laws and regulations, "those wise restraints that makes us free,"[4] are essential in human affairs; the correct balance being key.

Regulating matters of intellectual enquiry and scientific investigation is a particularly difficult issue. What criteria should be used to define what should be

[1] In Maria de Jesus Medina Arellano (2012). *The Quest for Stem Cell Science Regulation in Mexico: Ethical, Legal and Religious Controversies*. PhD Thesis, School of Law, University of Manchester, p. 216.
[2] Antony Jay and Jonathan Lynn. "Power to the People," episode of "Yes, Minister." In Kevin Houston (2009). *How to Think Like a Mathematician.* (Cambridge: Cambridge University Press), p. 69.
[3] William Evans and Thomas Evans (eds) (1837). *The Friends Library*, Vol I. (Philadelphia, PA: Joseph Bakestraw), p. 31.
[4] Marvin Hightower (2011). *The Spirit and Spectacle of Harvard Commencement*. (Cambridge, MA: President and Fellows of Harvard College). http://commencement.harvard.edu/background/spirit.html

investigated by scientists, and how the results of such investigations should be applied? Also, who should define these criteria? In science, where so many discoveries are serendipitous, over-regulation could greatly inhibit progress, and the societal benefits that flow from it. Yet under-regulation can lead to disaster. Whether or how synthetic biology is regulated is a significant ethical question. The approaches developed now may greatly impact the future of the science's development, and whether its effects on society tend to being positive or negative.

The synthetic biology community has engaged with the need for regulation from an early stage. Good self regulation is their preferred approach (see "The Synthetic Biology Community calls for Regulation," below). Critics have questioned their motivation, however, regarding it as self serving.[5] The ETC Group have called it "a concerted attempt to stave off government scrutiny."[6] They may have a point, though imputing bad faith is not always accurate. There can be disadvantages in allowing a technical discipline to be regulated by non-specialists, who may not fully understand it.

In this chapter, I discuss the most plausible dangers of synbio, and how regulation may help in minimising these dangers. I describe how scientific research is normally regulated; also how synbio's possible dangers suggest that a stricter regulatory regime than is normal for pure scientific research may be appropriate. I then discuss the current regulation of synbio. At present, regulation of the field is largely reliant on rules which were drawn up before it emerged, before its challenges

[5] See, for example: ETC Group (2007). *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. (Ottawa, ON: ETC Group). http://www.etcgroup.org/content/extreme-genetic-engineering-introduction-synthetic-biology Accessed December 22nd 2012.
[6] Ibid., p. 4.

became apparent. This would suggest that regulations should be updated to take account of it. I discuss the synthetic biology's community's proposals for regulation. After this, I discuss the inherent difficulties of regulating the field, the merits of various regulatory approaches, and the approaches considered in a selection of government-level reports on the issue. I also discuss the merits of rule-based vs. principles based approaches.

The potential benefits and dangers of synbio are great (see Chapter 5). Regulations are needed which will enhance its use for good, while diminishing its potential for misuse. The greatest challenges for regulators will be the growth of DIY biology, also the cross-border nature of synbio, and the unknowability of where the research will go.[7] It is likely that a mix of different types of regulation, ranging from self regulation to imposition of external controls, operating on a broad level that ranges from national to global, will be required to deal with synbio's challenges.

REGULATION OF SCIENTIFIC RESEARCH

Normally, there is relatively little regulation of pure scientific research. Academic freedom is allowed, and it has served science and society well. Applications of science, and certain procedures, are regulated in national laws and international regulations – for example, those governing medicines[8], dangerous

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[7] Joy Y. Zhang, Claire Marris and Nikolas Rose (2011). *The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the 'Art' of Governance*. (London: BIOS [Centre for the Study of Bioscience, Biomedicine, Biotechnology and Society]). http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/publications/2011/4294977685.pdf Accessed December 28th 2012.

[8] For examples, see the website of the Medicines and Healthcare Products Regulatory Agency: http://www.mhra.gov.uk/index.htm Accessed December 9th 2012.

chemicals,[9] nuclear technologies[10] and cloning.[11] While pure synthetic biology research is largely unregulated at present, its applications (whatever they turn out to be) will, at least for the most part, be covered by such regulations.

The boundaries between pure and applied research can, at times, be fuzzy. Additionally, there is some regulation of pure research; for example, animal research is regulated at national and EU level;[12] the UK's *Human Fertilisation and Embryology Act 2008*[13] also regulated some pure research. Some pure research has been classified – for example, wartime research into radar. America's *Atomic Energy Act, 1946* went further, introducing the concept of certain types of atomic research being "born secret" – i.e., kept secret in perpetuity (unless declassified), due to the

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[9] For example, the UN's GHS (Globally Harmonised System of Classification and Labelling of Chemicals): http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html; and the EU's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals): http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm; and the UK's COSHH (Control of Substances Hazardous to Health): http://www.hse.gov.uk/coshh/. All accessed Dec 9th 2012. There are many others.

[10] Numerous regulations exist, in areas such as waste disposal, radiation protection and the transport of nuclear materials. The EURATOM Treaty, 1957, a founding treaty of the EEC, gave supra-national regulatory powers to the European Commission in the areas of general safeguards, radiation protection, and fissile materials. Subsequent regulations have been developed at EU and national level, covering further issues such as power station safety and waste disposal. For a list of current EC legislation, see http://ec.europa.eu/energy/nuclear/legislation/community_en.htm. Some UK regulation include the *Nuclear Installations Act* 1965, the *Ionising Radiations Regulations* 1985, the *Nuclear Generating Stations (Security) Regulations* 1996, the *Radioactive Material (Road Transport) Act* 1991, and *Radioactive Substances Act* 1993. See http://www.world-nuclear.org/info/inf84.html. All accessed December 9th 2012.

[11] For example, the UK's *Human Fertilisation and Embryology Act* 1990. http://www.legislation.gov.uk/ukpga/1990/37/contents Accessed December 23rd 2012.

[12] *Animals (Scientific Procedures) Act* 1986 in the UK. http://www.archive.official-documents.co.uk/document/hoc/321/321.htm Accessed Dec 4th 2012. *Directive 86/609/EEC on the protection of Animals used for Experimental and other scientific purposes, 1986* (which covers vertebrates) at the EU level. http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l28104_en.htm Accessed December 5th 2012.

[13] *Human Fertilisation and Embryology Act* 2008. http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211 Accessed December 5th 2012.

very nature of the research.[14] The Act did not ban the research – it permitted it, while prohibiting public disclosure of its results.

DANGERS OF SYNTHETIC BIOLOGY

Not all products of synbio may be positive. While synthetic biology has the potential to greatly advance human progress, for example in scientific knowledge, and its applications to fields ranging from medicine to food production to fuels, it also poses a significant threat; the *dual use* dilemma.[15] [16] The problem is that positive advances in synbio could also be used for negative goals, such as the development of bioweapons – the issue of *biosecurity or bioterror*.[17] As a comparison, research into the structure of the atom advanced knowledge of the universe, and resulted in great medical advances, but also gave humanity the atomic bomb and has, additionally, led to loss of life and environmental damage due to nuclear accidents. Accidents could also occur in synbio research – the issue of *biosafety*.[18] For example, workers could suffer health effects; or synthetic products could be released accidentally into the environment. Possible problems in the latter case could include environmental damage; or the combination of synthetic life-forms with natural ones in unpredictable ways, that could possibly affect the future course of evolution. Issues of emergence may also occur; new genetic combinations may have unpredictable effects.

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[14] Howard Morland (2005). "Born Secret." *Cardozo Law Review*, 26(4): 1401-8. http://fas.org/sgp//eprint/cardozo.pdf Accessed December 5th 2012.
[15] Ronald M. Atlas and Malcolm Dando (2006). "The Dual Use Dilemma for the Life Sciences: Perspectives, Conundrums and Global Solutions." *Biosecurity and Bioterrorism: Biodefense, Strategy, Practice and Science*, 4(3): 276-286.
[16] Margarita Dolgitser (2007). "Minimization of the Risks Posed by Dual Use Research: A Structured Literature Review." *Applied Biosafety*, 12(3): 175-178. http://www.absa.org/abj/abj/071203dolgitser.pdf Accessed December 5th 2012.
[17] Jonathan B. Tucker and Raymond A. Zilinskas (2006). "The Promise and Perils of Synthetic Biology." *The New Atlantis*, 12: 25-45. http://www.thenewatlantis.com/publications/the-promise-and-perils-of-synthetic-biology Accessed December 23rd 2012.
[18] Ibid.

While this is a concern for industrial/academic level research, it is a greater one for biohacking. Even in pre-synbio biohacking, accidents occur. Lepht Anonym's relatively simple experiments with inserting magnets under her skin have resulted in hospitalisation on several occasions (see Chapter 1). Although bloody, this is quite a simple procedure. Scale up to DNA hacking, and the potential for accidents is far greater. As with academic level research, general errors, mistakes in design, unknown DNA functions, unexpected emergent properties, unpredictable patterns of mutation, evolution of synthetic organisms, interaction of synthetic organisms with natural ones, and more could result in very negative consequences in the worst cases.

Most people currently involved in the biohacker culture are technically oriented, as were the early computing pioneers.[19] [20] Even in this group, accidents will occur. But as the technology becomes more widespread and more easily usable, it may become as ubiquitous as the internet, used by people with little or no technical ability. Synbio is getting easier: for example, in 2009, a BioBrick assembly kit was created for purchase, to enable hobbyists to build synthetic organisms, opening synbio to a wider audience.[21] Physicist Freeman Dyson has written of a possible near future:

> Domesticated biotechnology, once it gets into the hands of housewives and children, will give us an explosion of diversity of new living creatures… Designing genomes will be a personal thing, a new art form as creative as painting or sculpture.[22]

[19] Markus Wohlsen (2011). *Biopunk: Solving Biotech's Biggest Problems in Kitchens and Garages*. (New York: Penguin).
[20] Steven Levy (2010). *Hackers: Heroes of the Computer Revolution*. (North Sebastopol, CA: O'Reilly.
[21] New England BioLabs (2009). *BioBrick Assembly Kit.* http://www.neb.com/nebecomm/products/productE0546.asp Accessed December 5th 2012.
[22] Freeman Dyson (2007). "Our Biotech Future." *The New York Review of Books*, 19th July. http://www.nybooks.com/articles/archives/2007/jul/19/our-biotech-future/?pagination=false Accessed December 5th 2012.

As more powerful technology gets into ordinary people's hands, the accidents could become more deadly. Also, malevolent and criminal hacking was not part of the early computer hacking culture, but as computers spread to the general population, such activity became more common.[23] A similar evolution is likely to occur with biohacking.

Currently, the genomes of lethal pathogens tend to be held in secure locations, or are otherwise hard to acquire.[24] Synthetic biology may allow them to be manufactured with relative ease by any interested persons.[25] Atomic weapons research, in contrast, requires the resources of a state behind it, and only a handful of states are capable of doing it. Which raises the question: should the pure science aspect of synthetic biology research be regulated? – because once the science reaches a certain level of advancement, it may become easy to apply it in negative ways.

To help answer the question, consider the following DNA sequence:

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cggacacaca aaaagaaaga aaagtttttt
atactttttg tgtgcgaata actatgagga
agattaatca ttttcctcaa actcaaacta
atattaacat tgagattgat ctcatcattt…
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It is the first 120 bases of the Sudan Ebola virus genome. I obtained it easily by Googling "ebola genome." It, and the entire Sudan Ebola virus sequence, is listed on

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[23] Mark Bowden (2011). *Worm: The First Digital World War*. (New York: Atlantic Monthly Press).
[24] Hans Bügl, John P. Danner, Robert J. Molinari, John T. Mulligan, Han-Oh Park, Bas Reichert, David A. Roth, Ralf Wagner, Bruce Budowle, Robert M. Scripp, Jenifer A.L. Smith, Scott J. Steele, George Church and Drew Endy (2007). "DNA Synthesis and Biological Security." *Nature Biotechnology,* 25(6): 627-629. http://arep.med.harvard.edu/pdf/Bugl07.pdf Accessed December 5th 2012.
[25] Thomas Douglas and Julian Savulescu (2010). "Synthetic Biology and the Ethics of Knowledge." *Journal of Medical Ethics,* 36: 687-693. doi:10.1136/jme.2010.038232

the National Center for Biotechnology Information's (NCBI) Nucleotide database,[26] [27] [28] which is open to all and free; it is hosted by the US government's National Institutes of Health (NIH). The sequence of any virus can be obtained; all are freely available online.

Now consider: it is easy to buy a DNA synthesiser on or offline,[29] and to buy the relevant chemicals. (I have seen second hand synthesisers on E-Bay for as little as US$200.) With the above information and materials, a person with a basic technical competence could synthesise some of the world's most deadly pathogens, and use them as weapons of mass destruction. This is already a potential concern with current technology, but unrestricted advances in synthetic biology are likely to make it much easier.

Scientists have already created a polio virus from scratch, using mail order chemicals; on injecting it into laboratory mice, they found that it worked.[30] Another group created a tweaked version of mousepox, which is more toxic than the naturally occurring version.[31] Others have reconstituted the 1918 flu virus, which killed more

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[26] NCBI Nucleotide (2009). *Sudan Ebolavirus, Complete Genome*. NCBI Reference Sequence: NC_006432.1. http://www.ncbi.nlm.nih.gov/nuccore/NC_006432.1 Accessed December 2nd 2012.

[27] For a technical description of the sequencing, see: Anthony Sanchez and Pierre E. Rollin (2005). "Complete Genome Sequence of an Ebola Virus (Sudan Species) Responsible for a 2000 Outbreak of Human Disease in Uganda." *Virus Research*, 113(1): 16-25. http://dx.doi.org/10.1016/j.virusres.2005.03.028

[28] See also the complete genome of the *Zaire Ebola virus, Mayinga strain*: http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=10141003 Accessed December 2nd 2012.

[29] For example, here: http://www.bioautomation.com/ Accessed Dec 2nd 2012.

[30] ETC Group (2007). *op. cit.*, note 5.

[31] Salvia Pagan Westphal (2002) "Ebola Virus Could be Synthesised." *New Scientist*, 17th July. http://www.newscientist.com/article/dn2555-ebola-virus-could-be-synthesised.html Accessed December 5th 2012.

people than World War I.[32] As the technology advances, it will become ever easier to create synthetic pathogens.

It is not even necessary to synthesise such a genome oneself in the lab; they can be ordered from commercial DNA synthesis companies. In 2006, a journalist from the *Guardian* ordered a fragment of the smallpox virus to be synthesised, from a commercial DNA synthesis company (VH Bio, Gateshead). They delivered it to his house and did not screen it to see what it was. *The Guardian* found that none of the four major DNA companies in the UK performed such routine screening.[33] (However, to translate a genome into a working virus does require extra steps. Even for a trained scientist, there is risk of contamination.)

It is plausible, therefore, that synthetic biology research could enable members of the public, including criminals, the mentally ill and terrorists, to produce deadly bioweapons.[34] A report from the Carnegie Corporation of New York states: "Compared with nuclear and chemical weapons of mass destruction, biological weapons are in some ways the most dangerous; they are easy to produce and their ingredients are readily available and equally useable for harmful or benign purposes. That's why they have been referred to as "the poor man's atomic bomb."[35]

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[32] ETC Group (2007). *op. cit.*, note 5.

[33] James Randerson (2006). "Revealed: The Lax laws that could Allow Assembly of Deadly Virus DNA." *The Guardian*, 14th June. http://www.guardian.co.uk/world/2006/jun/14/terrorism.topstories3 Accessed December 5th 2012.

[34] Thomas Douglas and Julian Savulescu (2010). *op. cit.*, note 25.

[35] Carnegie Corporation of New York (2009). *Crafting Strategies to Control Biological Weapons*. (New York: Carnegie Corporation), p. 2. http://carnegie.org/fileadmin/Media/Publications/PDF/carnegiereview_bioweapons2009.pdf Accessed December 8th 2012.

The authors of a 2008 US bi-partisan Congressional report, entitled *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism World at Risk*,[36] wrote: “"The more that sophisticated capabilities… spread around the globe, the greater the potential that terrorists will use them to develop biological weapons. The challenge for U.S. policymakers is to prevent that potential from becoming a reality by keeping dangerous pathogens — and the equipment, technology and know-how needed to weaponize them — out of the hands of criminals, terrorists and proliferant states."[37] They quote Richard Danzig, former Secretary of the US Navy: “Only a thin wall of terrorist ignorance and inexperience now protects us.”[38]

THE CURRENT STATE OF REGULATION

For a technology that poses such a potential threat, it is surprising to note that the field is very loosely regulated at present. A Canadian environmental research organisation, the ETC Group, has observed of this new science: “the 'artificial life industry' is growing up in a 'Wild West' free-for-all environment with virtually no regulatory oversight.”[39]

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[36] Bob Graham, Jim Talent, Graham Allison, Robin Cleveland, Steve Rademaker, Tim Roemer, Wendy Sherman, Henry Sokolski and Rich Verma (2008). *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism.* (New York: Vintage Books). http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA510559 Accessed December 22nd 2012.
[37] Ibid. p. 23.
[38] Ibid.
[39] ETC Group (2007). *op. cit.*, note 5, p. 4.

This is an exaggeration; synbio falls under the remit of many biotechnology, criminal and civil laws.[40] (Bar Yam et al have compiled a comprehensive list of regulations that apply to it, across the world, both at national and global level.)[41] [42] Yet there is an element of truth in the ETC Group's claim, in that synbio *per se* is little regulated, and what regulation exists is quite piecemeal, relying on regulations that were largely developed before it emerged.[43] It should be questioned as to whether this is wise. Synthetic biologists have generally taken appropriate steps to ensure their research is safe. Yet accidents have happened in the nuclear and oil industries, whose workforces contain many elite-level scientists and engineers, and misbehaviour also occurs among such professionals. The question must be asked – can loosely regulated synbio research be ethical? The potential dangers suggest that regulations governing synthetic biology should be drawn up. Which raises the questions: What degree of regulation is appropriate? Should this research even be allowed?

THE SYNTHETIC BIOLOGY COMMUNITY DISCUSSES REGULATION

MIT computer scientist Marvin Minsky wrote, on scientific regulation, that:

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[40] Presidential Commission for the Study of Bioethical Issues (2012). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. (Washington, DC: Presidential Commission for the Study of Bioethical Issues), p. 80.

[41] Shlomiya Bar Yam, Jennifer Byers-Corbin, Rocco Casagrande, Florentine Eichler, Allen Lin, Martin Oesterreicher, Pernilla Regardh, R. Donald Turlington and Kenneth A. Oye (2012). *The Regulation of Synthetic Biology: A Guide to United States and European Union Regulations, Rules and Guidelines.* (Arlington, VA: National Science Foundation (Synthetic Biology Engineering Research Center (SynBERC)). http://synberc.org/sites/default/files/Concise%20Guide%20to%20Synbio%20Regulation%20OYE%20Jan%202012_0.pdf Accessed December 6th 2012.

[42] For example, the UK has implemented the EU's *Directive 90/219/EEC on Contained Use of Genetically Modified MicroOrganisms*[42] in *The Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831)).* See: Europa: Summaries of EU Legislation Homepage (2008). *Directive 90/219/EEC on Contained Use of Genetically Modified MicroOrganisms.* http://europa.eu/legislation_summaries/other/l21157_en.htm Also: Legislation.gov.uk (undated). *The Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831).* http://www.legislation.gov.uk/uksi/2000/2831/contents/made Both accessed December 23rd 2012.

[43] Bar Yam et al (2012). *op. cit*., note 41.

> … few scientists are especially good at predicting or evaluating the long-term effect of what they discover. So ideally, that would be the job of people who excel at those skills… our societies need scientists to be free to discover new possibilities – but the public should learn to understand that scientists are not especially good at making judgements about what other people should do![44]

In this vein, the need for regulation has been discussed within the synthetic biology community, who have invited bioethicists and others to most of their early conferences, integrating discussions on ethics and regulation with the science. This is unusual at scientific conferences, but then synthetic biology's potential threats are far beyond the norm. As mentioned, self regulation represents the general consensus.

At the second international conference on synthetic biology, *Synthetic Biology 2.0* in 2006, a debate was held on what type of regulatory regime should be in place. The assembled scientists and others produced a statement, *the Declaration of the Second International Meeting on Synthetic Biology* (2006) which proposed four resolutions:

- Software tools should be developed to allow DNA synthesis companies to screen for hazardous DNA sequences, and a working group should be established to support this;
- DNA synthesis companies should use sequence-checking technology to check orders, and screen customers. The synthetic biology community should boycott companies that do not do this;
- The synthetic biology community should discuss ethical issues, especially safety and security challenges, on an ongoing basis;

[44] Marvin Minsky (2007). Reply to: *Marvin Minsky's Dreams of Immortality* http://www.thinkbuddha.org/article/290/marvin-minskys-dreams-of-immortality Accessed December 5th 2012.

- Ongoing discussions should take place about governance and policy issues, among all interested parties, to ensure constructive applications of the technology.[45]

These were not formally voted on, or adopted as community policy, however; agreement could not be reached within the synbio community[46] (some oppose any regulation),[47] and the idea of the community regulating itself generated opposition from environmental, policy and other groups.[48]

The J. Craig Venter Institute, one of the major research institutes in synthetic biology, produced a report on regulation in 2007, in co-operation with M.I.T. and the Center for Strategic and International Studies: *Synthetic Genomics: Options for Governance*. The report aimed to: "Design ways to impede malicious use of the technology, while at the same time not impeding, or even promoting beneficial ones,"[49] and suggested three areas for policy intervention:

- Requirements should be imposed on firms that commercially synthesise DNA – these should include the screening of orders, using special software, for DNA that may be harmful.

[45] Declaration of the Second International Meeting on Synthetic Biology, Berkeley, California. (2006). http://openwetware.org/wiki/Synthetic_Biology/SB2Declaration Accessed December 5th 2012.
[46] Peter Aldhouse (2006). "Synthetic Biologists Reject Controversial Guidelines." *New Scientist*, 23rd May. http://www.newscientist.com/article/dn9211-synthetic-biologists-reject-controversial-guidelines.html Accessed December 27th 2012.
[47] ETC Group (2007). *op. cit.*, note 5.
[48] Peter Aldhouse (2006). *op. cit.*, note 46.
[49] Michele S. Garfinkel, Drew Endy, Gerald L. Epstein, and Robert M. Friedman (2007). *Synthetic Genomics: Options for Governance*. (Rockville, MD: J. Craig Venter Institute ; Washington, DC : Center for Strategic and International Studies ; and Cambridge, MA ; MIT), p. 6. http://www.jcvi.org/cms/research/projects/syngen-options/ Accessed December 5th 2012.

- Regulation of DNA synthesising machines and reagents. For example, machines should be registered and licenses should be needed to buy certain reagents.
- Education of users. For example university courses should explicitly mention best practices, and risks of technology; and ethics committees should oversee experiments.[50]

Their ideas are similar to those produced at *Synthetic Biology 2.0*. Self-regulation appears to be the primary mode envisaged, and only in a few specific areas.

At the *Advances in Synthetic Biology* conference in Cambridge, 2008, a scientist (in an informal exchange) called for self-regulation in the field using the *Jedi Knight Principle*. Referring to the code of Jedi Knights in the science fiction films *Star Wars*, he envisaged that a small core of elite scientists would behave according to a code of honour. Unethical behaviour would be punished by expulsion from the elite group[51]. He did not specify who would define the code, how the "in-group" would be defined, who would expel errant members, or on what criteria. It is difficult to imagine who would enforce this – science does not have strong professional structures, unlike other professions like medicine and law.[52] I discuss, below, how this model failed in, for example, the cases of Craig Venter and Hwang Woo-suk. The cases are very different; Hwang was guilty of deliberate scientific fraud, while Venter was a maverick, taking a divergent path from his colleagues regarding both research

[50] Ibid.
[51] Select Biosciences, Advances in Synthetic Biology Conference (2008), Hinxton, UK, March 7-8th
[52] Matti Hayry (2003). "Do Bioscientists Need Professional Ethics?" In Matti Hayry and Tuija Takala (editors) *Scratching the Surface of Bioethics*. (Amsterdam: Rodopi), pp. 91-96.

directions and business practices. Neither felt constrained by any desire to stay within a scientific in-group, however.

The International Association Synthetic Biology (IASB),[53] an industry association based in Heidelberg, issued a *Code of Conduct for Best Practices in Gene Synthesis,* in 2008.[54] It set out a self-regulation regime, involving screening of DNA orders and of individual customers. There was some acrimony over details – some companies split from the IASB over the Code of Conduct, and became involved in setting up a rival industry association, the International Gene Synthesis Consortium (IGSC).[55] [56] A standards war came into being for a time.[57] Initially, the IGSG wanted automated screening only, whereas the original IASG Code required a degree of human monitoring. After some revisions, the IGSC issued their own protocol a couple of weeks after the IASB's – the *Harmonised Screening Protocol*[58] – which converged with the IASB's Code. At present, the majority of synbio companies – 80% by capacity, in Europe the US and China – follow such a regime.[59] [60] The guidelines only cover DNA synthesis, not other research areas.

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[53] International Association Synthetic Biology Homepage (undated). http://www.ia-sb.eu/go/synthetic-biology/ Accessed December 5th 2012.
[54] International Association Synthetic Biology (2009). *Code of Conduct for Best Practice in DNA Synthesis*. (Cambridge, MA: IASB). http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf Accessed December 5th 2012.
[55] International Gene Synthesis Consortium Homepage (2012). http://www.genesynthesisconsortium.org/ Accessed December 5th 2012.
[56] Meredith Wadman (2009). "US Drafts Guidelines to Screen Genes. *Nature News*, 4th December. doi:10.1038/news.2009.1117
[57] Mark Bunger (2010). "Competing Biosafety Protocols Open a Rift in the Synthetic Biology Industry." *Lux Populi*, 1st January. http://www.luxresearchinc.com/blog/2010/01/competing-biosafety-protocols-open-a-rift-in-the-synthetic-biology-industry/ Accessed December 5th 2012.
[58] International Gene Synthesis Consortium (2009). *Harmonized Screening Protocol: Gene Sequence & Customer Screening to Promote Biosecurity*. http://www.genesynthesisconsortium.org/wp-content/uploads/2012/02/IGSC-Harmonized-Screening-Protocol1.pdf Accessed December 28th 2012.
[59] Stephen M. Maurer (2011). "End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It." *Valparaiso University Law Review*, 45(4): 75-132. http://scholar.valpo.edu/cgi/viewcontent.cgi?article=2217&context=vulr&sei-redir=1&referer=http%3A%2F%2Fwww.google.ie%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3Dsynthetic%2520biology%2520worse%2520than%2520atomic%2520bomb%26source%3Dweb%26cd%3D6%26ved%3D0CE4QFjAF%26url%3Dhttp%253A%252F%252Fscholar.valpo.edu%252Fcgi%252Fviewc

Also, informal self-regulation exists – for example, several synthetic biology companies screen orders for pathogenicity using special software known as *BlackWatch*, which is open source.[61] [62] Other proposed software includes *VIREP (Virulence Factor Information Repository)*, to contain virulence factor information, [63] and *DOTS (DNA Order Tracking System)*, an order tracking database for automatic monitoring DNA orders, analysing sequences for pathogenicity and co-operating with U.S. security services.[64]

At the *Applied Industrial Synthetic Biology in Europe: Status Quo and Perspective*s conference in April 2009,[65] a session was devoted to the discussion of regulation. The VH Bio/*Guardian* case was talked about. Some observed that their companies had received requests for the synthesis of potentially suspicious DNA sequences, and they had refused such requests. It is heartening that they are doing so; it is disheartening that they are receiving such requests, particularly when one considers that such requests could be the tip of an iceberg. It was noted by participants that though resources such as *BlackWatch* may be developed to a high degree of

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ontent.cgi%253Farticle%253D2217%2526context%253Dvulr%26ei%3Dsl_XUJn5IsiRhQedk4DoBA%26usg%3DAFQjCNFpPqP9T5dzTNscedXXa2sDe3UFEQ#search=%22synthetic%20biology%20worse%20than%20atomic%20bomb%22 Accessed December 26th 2012.

60 For further discussion, and the US regulatory authorities response to these guidelines, see Chapter 9 (Conclusion); also Stephen M. Maurer (2011). *op. cit*., note 59.

61 Craic Computing (undated). *Craic BlackWatch: Hazardous Biological Agent Sequence Detection.* http://biotech.craic.com/blackwatch/ Accessed December 5th 2012.

62 Hubert Bernauer, Jason Christopher, Werner Deininger, Markus Fischer, Philip Habermeier, Klaus Heumann, Stephen Maurer, Heinz Schwer, Peer Stahler and Tobias Wagner (2008). *Report on the Workshop : Technical Solutions for Biosecurity in Synthetic Biology*. (Heidelberg: International Association Synthetic Biology [IASB]). http://www.synbiosafe.eu/uploads///pdf/iasb_report_biosecurity_syntheticbiology.pdf Accessed December 5th 2012.

63 Ibid.

64 Tom Greene (2009). "Hunting Dangerous Genes, Inbox by Inbox." *The Mitre Digest*, February. http://www.mitre.org/news/digest/advanced_research/02_09/genes.html Accessed December 5th 2012.

65 Biofine: Applied Industrial Synthetic Biology in Europe: Status Quo and Perspectives Conference (2009). Freiburg, 16-17th April.

sophistication, they can always be got around by a person who purchases a DNA synthesizer from the internet. Which leaves a huge security gap.

DIFFICULTIES IN REGULATING SYNTHETIC BIOLOGY

At the same *Applied Industrial Synthetic Biology in Europe* session, some speakers said that they were involved in negotiations with government bodies, including the FBI, regarding regulation. They observed that neither they nor the FBI knew what to do. It is not immediately apparent what regulatory approach – or, rather, mix of regulatory approaches – should be used for synthetic biology research.[66]

Especially problematic is the fact that advances in the science will advance biohacking in ways that are completely unpredictable. Also, while some regulatory overview of the entire field may be possible, each and every research area within the field will have to be examined. For example, the regulatory issues governing metabolic engineering are likely to be quite different from those covering BioBricks. Each sub-field will need to be examined; the fields are so diverse that an overarching regulatory paradigm for synbio is unlikely to be sufficient. Also, the possible evolution of synthetic organisms over time, and the issue of unpredictable emergent properties, pose significant regulatory challenges.[67]

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[66] Ibid.

[67] Michael Rodemeyer (2009). *New Life, Old Bottles: Regulating First Generation Products of Synthetic Biology.* (Washington DC: Woodrow Wilson International Center for Scholars). http://www.synbioproject.org/library/publications/archive/synbio2/ Accessed December 5th 2012.

REGULATION SHOULD BE INTERNATIONAL IN SCOPE

Another difficulty: a synthetic biologist said to me, on hearing that I was researching ethical issues in the field: “If I decide to clone something this morning, & have to wait two months for approval, it would be a nightmare. If you people start regulating me, I’ll move to China.”[68] And therein may lie a significant problem: Is it possible that mobility of individual scientists, and of international corporations and international capital, means that tight regulation of the field in some Western countries may, paradoxically, lead to looser, more permissive regulations for the field overall, as practitioners move to places where regulation is least? A member of the US’s National Science Advisory Board for Biosecurity (NSABB), Stuart Levy, said about regulation: "We do not want to deter the science. If we deter too much, the gene-synthesis industry will go outside the US and outside our purview, and it will come back to haunt us." [69]

This concern may overlook the possible sanctions that such scientists may face. They may be regarded as unprofessional by many of their colleagues, work produced by such means may lack credibility as a result, funding possibilities may be reduced, and their colleagues may be less likely to collaborate with them.”[70] While this is largely true, maverick scientists may not be bound by such concerns. Craig Venter, currently the leading synthetic biologist, is a case in point. When he set up a rival consortium to the Human Genome Project, with the intention of patenting the human genome, he was reviled by most of the scientific community. Leading molecular biologists referred to him by names such as “asshole,” “Frankenstein,”

[68] Informal conversation at *Select Biosciences, Advances in Synthetic Biology Conference* (2008), Hinxton, UK, 7-8th March.
[69] Meredith Wadman (2009). *op. cit*., note 56.
[70] Sarah Devaney, University of Manchester (2012). Private communication.

"Darth Vadar," and "blood sucker."[71] Nobel laureate James Watson said Venter wanted to "own the human genome the way Hitler wanted to own the world."[72] Venter persisted, however. He was supported by a small minority of leading scientists, including Nobel prize winner Hamilton O. Smith,[73] and obtained private funding.[74] After his success with synthesising *Synthia*, he is now firmly, if uneasily, back in the scientific establishment.[75] [76]

There is also the case of Hwang Woo-suk, a once world-leading stem cell research scientist, whose reputation was destroyed when it was discovered that much of his most significant research, including attempts at human cloning, was fraudulent. An article in the *Korea Times* noted:

> while scientists abroad raised eyebrows — after all, human cloning was a hyper-sensitive area of science with no room for moral lapses — most of Hwang's local support remained firm. Ethical guidelines, their point seemed to be, were less important than the potential end results of Hwang's research. After all, the national economic miracle had been birthed by a

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[71] Rafaela von Bredow and Johann Grolle (2010). "Speigel Interview with Craig Venter: We Have Learned Nothing from the Genome." *Speigel Online International*, 29th July. http://www.spiegel.de/international/world/spiegel-interview-with-craig-venter-we-have-learned-nothing-from-the-genome-a-709174.html Accessed December 22nd 2012.

[72] Wil S. Hylton (2012). "Craig Venter's Bugs Might Save the World." *New York Times Magazine*, 30th May. http://www.nytimes.com/2012/06/03/magazine/craig-venters-bugs-might-save-the-world.html?pagewanted=all&_r=0 Accessed December 22nd 2012.

[73] Ibid.

[74] Oral History Collection (2005). "John Sulston on Craig Venter." http://library.cshl.edu/oralhistory/interview/misc/biotechnology/sulston-craig-venter-and-celera-genomics/ Accessed December 22nd 2012.

[75] For example, his work on *Synthia* was published in one of the leading scientific journals, *Science*. See: Daniel G. Gibson, John I. Glass, Carole Lartigue, Vladimir N. Noskov, Ray-Yuan Chuang, Mikkel A. Algire, Gwynedd A. Benders, Michael G. Montague, Li Ma, Monzia M. Moodie, Chuck Merryman, Sanjay Vashee, Radha Krishnakumar, Nacyra Assad-Garcia, Cynthia Andrews-Pfannkoch, Evgeniya A. Denisova, Lei Young, Zhi-Qing Qi, Thomas H. Segall-Shapiro, Christopher H. Calvey, Prashanth P. Parmar, Clyde A. Hutchison III, Hamilton O. Smith, J. Craig Venter (2010). "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome." *Science*, 329(5987): 52-56. doi:10.1126/science.1190719. Also, he was invited to give a 50th anniversary update to Erwin Schrödinger's seminal lecture, *What is Life* – see: Trinity College Dublin (2012). Craig Venter's Lecture "What is Life: A 21st Century Perspective" Video Now Online." https://www.tcd.ie/Communications/news/news.php?headerID=2606&vs_date=2012-07-24 Accessed December 23rd 2012.

[76] See also: Rafaela von Bredow and Johann Grolle (2010). *op. cit.*, note 71.

government and businessmen who took, when necessary, very considerable liberties with regulations and laws in order to reach their goals.[77]

Hwang now leads a privately funded research institute in Korea, attempted to set up a research institute in Gaddafi's Libya, and is currently attempting to clone a woolly mammoth, in collaboration with a Russian university.[78]

Cases such as these illustrate that some scientists may not feel constrained by the normal ethical standards of the profession, and, ultimately, may not face sanctions for such breaches if their work results in success. They suggest that some research could move to where the oversight is least; so an international approach to regulation seems advisable.

It is all very well to talk about international regulation in the abstract, but it may be very difficult to obtain agreement on such regulations between different cultures.[79] Advances in biotechnology can cause passionate disagreements. For example, England and Wales' *Human Fertilisation and Embryology Act 2008* allowed creation of human-animal hybrid embryos for research purposes in the UK.[80] Gordon Brown wrote an impassioned defence of this research, claiming it was "an inherently moral endeavour that can save and improve the lives of thousands and, over time, millions of people."[81] Such research has been banned in France and Germany,

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[77] Andrew Salmon (2012). "Hwang Woo-suk: Rise and Fall of Korea's Most Famed Scientist." *Korea Times*, 11th April. http://www.koreatimes.co.kr/www/news/issues/2012/12/363_108769.html Accessed December 22nd 2012.

[78] Asian Scientist (2012). "S. Korean Hwang Wu-suk to Clone Extinct Woolly Mammoth." http://www.asianscientist.com/topnews/south-korean-hwang-woo-suk-sooam-biotech-to-clone-extinct-woolly-mammoth-2012/ Accessed December 22nd 2012.

[79] Catherine Rhodes (2010). *International Governance of Biotechnology: Needs, Problems and Potential.* (London: Bloomsbury).

[80] Human Fertilisation and Embryology Act (2008), *op. cit.*, note 13.

[81] Gordon Brown (2008). "Why I Believe Stem Cell Researchers Deserve Our Backing." *The Observer*, 18th May.

however, and the then US government also responded to it negatively, and with equal passion. In his State of the Union Address in 2006, George W. Bush said:

> Tonight I ask you to pass legislation to prohibit the most egregious abuses of medical research: human cloning in all its forms, creating or implanting embryos for experiments, creating human-animal hybrids, and buying, selling or patenting human embryos. Human life is a gift from our Creator – and that gift should never be discarded, devalued or put up for sale.[82]

How can agreement be reached between such opposing viewpoints? Similar problems may exist for future areas of synthetic biology research. It will be very difficult to get international agreement on these issues, and to produce good regulation. As a minimum, international regulation on safety should be aimed for.

No regulatory regime in synthetic biology can eliminate all human error and misbehaviour. Even outright banning of the research may not achieve this. For example, Ken Alibek, a former scientist in the Soviet Union's bioweapons research programme, wrote that he was told that carrying out such research was a patriotic endeavour. He was not told that it was illegal under the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* (BTWC) of 1972,[83] that the USSR had signed up to.[84] Shutting down synthetic biology research entirely, so as to avoid its negative applications, may not work. It could make things worse, in driving the research underground, only for some negative results to be unleashed, at some stage,

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http://www.guardian.co.uk/commentisfree/2008/may/18/stemcells.medicalresearch Accessed December 5th 2012.

[82] George W. Bush (2006). *State of the Union Address 2006* http://www.cnn.com/2006/POLITICS/01/31/sotu.domestic/ Accessed December 5th 2012.

[83] The Biological and Toxic Weapons Website (undated). http://www.opbw.org/ Accessed December 23rd 2012.

[84] Ken Alibek (2000). *Biohazard: The True Story of the Largest Covert Biological Weapons Program in the World.* (New York: Arrow).

on an unsuspecting world which has no antidote. If the research continues, on the other hand, scientists may be better able to cope with such attacks.

George Church has observed that twenty years after the BTWC was signed, the number of countries developing or otherwise in possession of biological weapons had doubled (according to US intelligence), and most of those countries had signed the convention. Church also refers to prohibition of alcohol in the US in the 1930s, and its current war on drugs. The failures of such bans suggest that banning synbio may not minimise its threats, particularly as so much information is already in the public domain.[85]

WHAT REGULATORY APPROACH SHOULD BE USED?

As mentioned, self regulation is favoured by the many in the field, and good self regulation, both formal and informal, is essential. It can be difficult for experts in a scientific field to accept regulation from non-experts. Yet, the current financial chaos should provide a guide to self regulation's limitations. A document published some years ago by the New York Stock Exchange stated that "the U.S. securities industry regulates itself in a careful and thorough manner."[86] Such self-regulation has led to near catastrophe. John Mack, former CEO of Morgan Stanley, appealed for more regulation, saying: "Regulators have to be much more involved… We cannot

[85] George Church and Ed Regis (2012). *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves*. (New York: Basic Books).
[86] New York Stock Exchange (undated). *The Regulatory Pyramid.* http://www.nyse.com/pdfs/TheRegulatoryPyramid.pdf Accessed December 19th 2012.

control ourselves."[87] [88] Effectively, financial markets were not regulated under this system, which allowed for reckless, and at times criminal, behaviour to take place. (Of course, criminal behaviour is defined by local laws; much of the behaviour in the financial world did not break national laws, in many countries, largely as a result of deregulation,[89] which allowed unethical and destructive acts to go unpunished.)

Such behaviour is likely to be less common in the ivory tower of science, but it does happen, as mentioned. If it does, the worst case scenario in a synthetic biology disaster could be far more severe than financial collapse. The US Congressional report, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism,*[90] has stated that an attack with a weapon of mass destruction on the US is likely within a few years – their predicted date, for what it's worth, was 2013 – and that such a weapon is most likely to be a bioweapon.[91]

The potential risks suggest that self-regulation alone may be too risky for a regime for synthetic biology. If the worst happens, there may be no second chance to get it right. Tony Foley, notes that "self-regulation has a tarnished image and is often reviled... as being a charade;" and that it is "best driven by the 'spectre of a coercive state.'"[92] Gunningham and Grabosky have noted that self-regulation tends to work

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[87] Dealbo%k (2009). "Morgan Stanley's Mack: "We Cannot Control Ourselves."" 19th November. http://dealbook.nytimes.com/2009/11/19/morgan-stanleys-mack-we-cannot-control-ourselves/ Accessed December 5th 2012.
[88] Bloomberg (2012). "Morgan's Mack Welcomes Tighter Regulation From Fed." http://www.youtube.com/watch?v=Vo9uyNR2zxE Accessed December 5th 2012.
[89] My thanks to Sarah Devaney, University of Manchester, for this point.
[90] Bob Graham, et al (2008). *op. cit*., note 36.
[91] Ibid.
[92] Tony Foley (2004). "Using a Responsive Regulatory Pyramid in Environmental Regulation". *2004 QELA Conference: Carrots, Sticks and Toolkits*. http://www.qela.com.au/_dbase_upl/1.foley.pdf Accessed December 21st 2012.

best when some type of external pressure is applied – co-regulation.[93] The absence of good regulation could also, paradoxically, inhibit beneficial research by generating opposition to it: Joyce Tait has observed that a perceived lack of adequate regulation can give public credibility to those who oppose research on ideological grounds.[94]

Self regulation relies on scientists' collective goodwill; not all will display it. Also, there may be sincere differences in the correct moral path to take. There are more spectacular cases than Venter's attempted patent grab and Hwan's fraud. For example, William Shockley, inventor of the transistor, Nobel laureate, and one of the pioneers of the electronic/computer age, was a strong advocate of eugenics, and compulsory sterilisation of those with an unsatisfactory IQ.[95] The German Nobel Prize winners Johannes Stark and Phillip Lenard were committed Nazis.[96] A scientist told me, at a synthetic biology conference, that he worked for a private company who were developing biological weapons for his country's military. When I asked him if he had ever thought about the ethics of his research, he reflected for a moment, then said, with a smile, "no." After a little more reflection he added "the only ethics my bosses care about is making money."[97] An attitude of "trust the scientists," regarding such a potentially dangerous technology, seems unwise.

On the other hand, regulating the field too rigidly has disadvantages. Too much regulation could stifle scientific creativity, preventing significant advances that

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[93] Neil Cunningham and Peter Grabosky, with Darren Sinclair (1988). *Smart Regulation: Designing Environmental Policy*. (Oxford: Clarendon Press), p. 55.
[94] Joyce Tait (2009). "Governing Synthetic Biology: Processes and Outcomes." In Markus Schmidt, Alexander Kelle, Agomoni Ganguli-Mitra, and Huib de Vriend, eds. *Synthetic Biology: The Technoscience and Its Societal Consequences.* (Dordrecht: Springer), pp. 141-154.
[95] Joel N. Shurkin (2007). *Broken Genius: The Rise and Fall of William Shockley, Creator of the Electronic Age.* (London: Macmillan).
[96] Gerard J. DeGroot (2004). *The Bomb: A Life*. (London: Jonathan Cape), pp. 294-5
[97] Informal conversation, *IET BioSysBio Conference* (2009), Cambridge University, March 23rd-25th.

could advance science and civilisation, and reduce suffering through advanced technologies and therapies. Also, external regulation is not a panacea. Criminal laws which include severe penalties do not prevent all crime, though they may prevent some. It is also worth noting that although criminal penalties are usually more severe in the USA than in Europe, crime rates there are generally much higher.[98]

Yet it seems reasonable that precautions should be taken against possible negative scenarios. The ETC Group has noted:

> Options for governing synthetic biology must not be set by the synthetic biologists themselves - broad societal debate on synbio's wider implications must come first. Synthetic microbes should be treated as dangerous until proven harmless and strong democratic oversight should be mandatory - not optional…[99]
> In keeping with the precautionary principle, ETC Group believes that – at a minimum – there must be an immediate ban on environmental release of *de novo* synthetic organisms until wide societal debate and strong governance are in place.[100]

This has been backed up to an extent in a report issued by the Presidential Commission for the Study of Bioethical Issues in the US, though their suggestion is weaker than the ETC Group's: "Field release should only be permitted after reasonable risk assessment."[101]

It is questionable as to whether either go far enough. Bügl et al, in a paper written by a group synthetic biology industry executives, law enforcement

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[98] Civitas.org.uk (2012). *Civitas Crime Briefing: Comparison of Crime in OECD Countries*. http://www.civitas.org.uk/crime/crime_stats_oecdjan2012.pdf Accessed December 23rd 2012.
[99] ETC Group News Release (2007) – *Syns of Omission: Civil Society Organizations Respond to Report on Synthetic Biology Governace from the J. Craig Venter Institute and Alfred P. Sloan Foundation*, 17th October. http://www.etcgroup.org/content/syns-omission Accessed December 5th 2012.
[100] ETC Group (2007), *op. cit*., note 5, p. 1.
[101] Presidential Commission for the Study of Bioethical Issues (2010). *Press Release: Presidential Commission Calls for Enhanced Federal Oversight in Emerging Field of Synthetic Biology*. http://bioethics.gov/cms/sites/default/files/news/PCSBI-Synthetic-Biology-Report-Press-Release-12.16.10.pdf Accessed December 3rd 2012.

professionals, and academic scientists, have called for an overarching regulatory framework for DNA synthesis which achieves the following objectives. It should prevent potentially malevolent behaviour of synbio users; be simple and enforceable; promote beneficial advances; be international in scope; and build upon current biotech regulations. Under this regime, customers of biosynthesis companies should be identifiable, orders would be screened using special software, companies would work with security agencies and each other to achieve best practice, and malevolent users would be reported to law enforcement.[102]

Special regulatory committees are needed, containing people with appropriate scientific expertise in synthetic biology, other aspects of biology, ecology, engineering and its foundational disciplines, public health, medicine, law and diplomacy. Also, a one-off set of regulations would be of little use, as the science may develop rapidly. As a possible solution to this problem, Alexander Kelle has suggested a "5-P governance strategy," focussing on the **p**rincipal investigator, **p**roject, **p**remises, **p**rovider and **p**urchaser (of synbio material). The first three categories also focus on the research itself. [103] This cannot be considered to be a comprehensive regulatory paradigm, obviously; it's far too weak by itself, and only focuses on what the regulation should look at, as opposed to the principles of the regulatory model. It could, however play a role as part of a comprehensive model. It illustrates the concept that whatever type of regulation is chosen, it needs to be ongoing, adapting to scientific advances.[104] [105]

[102] Hans Bügl et al (2007), *op. cit.*, note 24.
[103] Alexander Kelle (2009). "Ensuring the Security of Synthetic Biology – Towards a 5-P Governance Strategy." *Systems and Synthetic Biology*, 3(1-4): 85-90. doi: 10.1007/s11693-009-9041-8
[104] Thanks to Sarah Devaney for making this point.
[105] For a description of regulatory approaches in biotech, regulation see; Catherine Rhodes (2010). *op. cit.*, note 79.

The above analysis suggests that a mix of regulatory modes, for each sub-field, may be the most effective approach: national laws, strong international laws and strong self-regulation with outside monitoring (regulatory agencies cannot monitor every lab at every moment; the scientists need to be involved). For international laws, while UN declarations and the like may serve the purpose of setting out a moral framework, they would not be sufficient for the purposes of synbio regulation. For example, UNESCO's *Universal Declaration on the Human Genome and Human Rights*[106] declares that states should ensure that genomic research is only applied for peaceful purposes (Article 15) and that ethics committees should evaluate ethical, social and legal issues relevant to genomic research (Article 16).[107] These are not always implemented.[108] Strong regulation, with sanctions, is necessary.[109]

Generally, the EU's minimum harmonisation technique could provide a useful model; it is a bottom platform below which no-one can go, from which states can regulate.[110] Former U.N. Under-Secretary General, Margaret Anstee, has observed: "It is difficult to get 192 countries to agree, but it can be done… Admittedly, agreement means compromise, and sometimes you're left with what looks like the lowest common denominator. But even that is better than nothing, because you can build on it for the future…"[111]

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[106] UNESCO (1997). *Universal Declaration on the Human Genome and Human Rights.* (Paris: UNESCO). http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html Accessed December 5th 2012.
[107] Ibid.
[108] Similarly, *The Universal Declaration of Human Rights* is frequently honoured more in the breach than the observance
[109] See: Catherine Rhodes (2010). o*p. cit.*, note 79.
[110] Peter G.G. Davies (2004). *European Union Environmental Law: An Introduction to Key Selected Issues.* (Aldershot, Hants: Ashgate), pp. 58-59.
[111] Margaret Anstee (2010). "Is International Agreement Possible in the 21st Century?" *Cambridge Alumni Magazine*, 59:16.

Lloyd's Insurance Emerging Risks Team, in their report *Synthetic Biology: Influencing Development,*[112] have described relevant worldwide regulations. They recommend, *inter alia*, more effective regulation and greater societal debates, stating:

> There is no consistent global view on the appropriate approach to regulating Synthetic Biology; public opinion on the use of this technology appears to differ regionally. Within regions it is typical that there are several agencies with potential jurisdiction over processes using the new methods. It would be useful (as in the case of nanotechnology in the US) if a single body was set up in each region to oversee and coordinate the approach and to aim for global consistency. The data for a traditional risk analysis will often be lacking in which case a precautionary approach is appropriate when the risks are potential very high. Regulations should require developers to consider low probability, high impact events as part of the risk management process. The use of Synthetic biology should be tracked carefully and labelling be introduced if it is used directly in food.[113]

GOVERNMENT STUDIES OF SYNBIO REGULATION

Various international government bodies have studied this issue. In this section I will describe the major discussions and reports (it is not an exhaustive record).[114] Debate is ongoing as to what specific, more in depth, regulatory approaches to take.

The European Group on Ethics in Science and New Technologies (EGE) has issued a report to the European Commission, *Ethics of Synthetic Biology*.[115] It makes several policy recommendations, the first being that any promotion of synthetic biology should depend on safety being adequate. It suggests that risk assessment be

[112] Lloyd's Emerging Risks Team (2009). *Synthetic Biology: Influencing Development*. (London: Lloyd's), p.3. http://www.lloyds.com/~/media/25352cf96fee4a8fb28f4ab1746f58ac.ashx Accessed December 6th 2012.

[113] Ibid., p.3.

[114] For a detailed account, see: Stephen M. Maurer (2011). *op. cit.*, note 59.

[115] The European Group on Ethics in Science and New Technologies to the European Commission (2009). *Ethics of Synthetic Biology*. (Brussels: European Commission). http://ec.europa.eu/bepa/european-group-ethics/docs/opinion25_en.pdf Accessed December 5th 2012.

undertaken, and regulatory gaps be filled at EU and national level. When appropriate regulations are created, the EU should then negotiate with international counterparts on creating appropriate rules on a worldwide basis. The release of synthetic organisms to the environment should not be permitted until proper risk assessment has been carried out, using the precautionary principle. Some research should be limited or prohibited under the BTWC.[116] The European Commission, with the EGE, should define a framework for ethical and security issues in the field. The EU should also encourage the synthetic biology community to develop ethical guidelines. The EU should use global fora to discuss regulation of synbio. It should also promote public knowledge of the field. Comprehensive regulation of biotechnology research already exists at the EU level.[117] But it is necessary to evaluate how appropriate those rules are for synthetic biology, and what changes are appropriate.

In the US, President Obama's Commission for the Study of Bioethical Issues issued a report in December 2010, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*.[118] They have recommended ongoing responsive regulatory and security evaluation of synbio. Among their proposed precautions are: public funding for research on risk evaluation and minimisation; public funding for the most beneficial research; study of containment methods, including suicide genes/kill switches in synthetic organisms, and the building of organisms which depend on novel forms of nutrition found only in specific labs; field release to be permitted only after risk analysis; international co-operation and dialogue, with other

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[116] Biological and Toxic Weapons Convention (BTWC) Homepage (2011). *op. cit*., note 83.
[117] Catherine Rhodes and LGC Ltd. (2006). *Users Guide to European Regulation in Biotechnology*. (Brussels: European Commission).
[118] Commission for the Study of Bioethical Issues (2010). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*. (Washington, DC: Presidential Commission for the Study of Bioethical Issues.) http://bioethics.gov/cms/sites/default/files/news/PCSBI-Synthetic-Biology-Report-12.16.10.pdf Accessed December 3rd 2012.

governments, the WHO and international bioethics institutes; ethics education, similar or superior to that provided to healthcare students, should be provided to students of all sciences that could be connected to synbio, including engineering and materials science; ongoing evaluation of ethical objections to synbio; government should support, oversee and evaluate self regulation on an ongoing basis; and scientists, policymakers and concerned groups in society should remain in open dialogue. The Committee has recommended further study of regulatory issues, to determine whether the US's "patchwork quilt" of biotech regulation is adequate to cover synbio.[119] In short, they have been reluctant to subject the field to external regulation.

The US's *NIH Guidelines for Research Involving Recombinant DNA Molecules*[120] have been updated to mention synthetic sequences. They are to be treated in the same way as naturally occurring sequences, and are only covered by the regulations when used to create a living organism.[121] These guidelines apply to research funded by the US government.[122] The National Science Advisory Board for Biosecurity (NSABB) has issued a report identifying salient issues regarding synthetic biology and biosecurity.[123] The US government published draft guidelines for synthetic DNA production – *Screening Framework Guidance for Synthetic Double-Stranded DNA Service Providers.*[124] These recommended that both DNA sequences

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[119] Ibid.

[120] National Institutes of Health, Office of Biotechnology Activities (2009). *NIH Guidelines for Research Involving Recombinant DNA Molecules.* (Bethesda, MD: Office of Biotechnology Activities). http://oba.od.nih.gov/rdna/nih_guidelines_oba.html Accessed December 5th 2012.

[121] Ibid.

[122] Michael Rodemeyer (2009). *op. cit.*, note 67.

[123] National Science Advisory Board for Biosecurity (2010). Addressing Biosecurity Concerns Relating to Synthetic Biology. (Bethesda, MD: National Science Advisory Board for Biosecurity). http://oba.od.nih.gov/biosecurity/pdf/NSABB%20SynBio%20DRAFT%20Report-FINAL%20%282%29_6-7-10.pdf Accessed December 5th 2012.

[124] Department of Health and Human Services (2010). *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA.* (Washington, DC: Department of Health and Human Services).

and customers be screened.[125] Michael Rodemeyer has written that the creation of a specific regulatory regime in the U.S. for synthetic biology is improbable; but that current biotech laws may need to be updated to take account of the issues that are unique to it.[126]

PRINCIPLES-BASED REGULATION vs. PRESCRIPTIVE RULES

Developing and applying prescriptive rules for the purpose of synbio regulation is likely to fail, if used as the only approach, because of the potential for the science to change rapidly, leaving the rules outdated. Sarah Devaney gives an example of its limitations:[127] The UK's Human Fertilisation and Embryology Act 1990 attempted to ban cloning by prohibiting the substitution of an embryonic cell nucleus with that of "a nucleus taken from a cell of any person, embryo or subsequent development of an embryo."[128] However, the cloning technique for Dolly involved replacement of an egg, not an embryo, which seemed to mean it wasn't covered by the Act.[129] This reasoning was followed in the court of first instance in *R (Quintavalle) v Secretary of State for Health*.[130] Appeals to the Court of Appeal and the House of Lords led to the rejection of such reasoning by both. They interpreted the

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http://www.phe.gov/preparedness/legal/guidance/syndna/Pages/default.aspx Accessed December 5th 2012.

[125] Meredith Wadman (2009). *op. cit.*, note 56.

[126] Michael Rodemeyer (2009). *op. cit.*, note 67.

[127] Sarah Devaney (2011). "Regulate to Innovate: Principles-Based Regulation of Stem Cell Research." *Medical Law International*, 11: 53-68.

[128] *Human Fertilisation and Embryology Act (1990),* S. 3.3(d). http://www.legislation.gov.uk/ukpga/1990/37/section/3. Accessed December 23rd 2012. See Sarah Devaney (2012). *op. cit.*, note 127.

[129] Sarah Devaney (2012), *op. cit.*, note 127, p. 56.

[130] *R (on the application of Quintavalle) v Secretary of State for Health* (2001) 4 All ER 1013; (2002) 2 All ER 625 (CA); (2003) 2 WLR 692 (HL).

wording of the Act in a purposive manner rather than a literal one,[131] so that the intentions of the legislators could be upheld. They noted that the technology in question wasn't known to legislators at the time the Act was drawn up.[132]

So it could be argued that prescriptive rules can be adapted to evolving science, if the courts are flexible enough in their interpretation of statutes. However, it would seem unwise to rely on this as a regulatory strategy. Neither are prescriptive rules likely to be entirely effective in combination with self regulation; scenarios which have never been seen before may arise, perhaps leaving researchers without regulatory guidance. Judicial interpretation may lack consistency.

Principles-based regulation (PBR) offers a different approach: "The defining characteristic of PBR is a move from the use of 'detailed, prescriptive rules', such as legislation, to 'high-level, broadly stated rules or Principles' which set standards by which regulated individuals or companies must abide."[133] Such an approach could be combined with some prescriptive rules, to set limits to research, to ensure it doesn't cross safety and ethical boundaries, and such rules should evolve with the science.[134]

However, principles-based regulation was applied to financial services in recent years, and it failed spectacularly. Among the problems were that the principles were ignored by financiers, and regulators did not attempt to enforce them. Financiers were encouraged to ignore regulations by the financial incentive structures of the

[131] Ibid. See also: Oonagh Corrigan, Kathleen Liddell, John McMillan, Alison Stewart and Susan Wallace (2006). *Ethical, Legal and Social Issues in Stem Cell Research and Therapy*. (Cambridge: Cambridge Genetics Knowledge Park).
[132] *R (Quintavalle) v Secretary of State for Health* (2003*), op. cit.*, note 130.
[133] Julia Black, Martin Hopper and Christa Band (2007). "Making a Success of Principles-Based Regulation." *Law and Financial Markets Review*, 1(3): 191.
[134] Sarah Devaney (2011). *op. cit*., note 127, p. 60.

industry.[135] Synthetic biologists could be subject to similar temptations, both in terms of profits and scientific acclaim.

Devaney suggests that rejection of a rigid regulatory approach could help to attain international agreement.[136] This may be true, but the failures of such a regulatory system for finance provide a warning; such a failure cannot be allowed to happen for synbio, where the consequences may be far more severe than financial loss.

Yet a PBR approach may permit regulators and the scientific community to set goals and to adapt, with advancing science, to achieve them. Consensus may be difficult to reach on what those goals are, however.[137] Though PBR could play a useful role in regulating synbio, is unlikely to be sufficient in itself. There can be no guarantee that its failures in finance wouldn't be repeated in synbio; it has been proven to fail. However, a combination of PBR with rule-based and self regulation, may be a viable approach.

CONCLUSION

Synthetic biology poses unique regulatory challenges, very different from the normal regulation of scientific research. The different sub-fields within synthetic biology (see Chapter 1) may pose very different regulatory problems. Each will need to be dealt with appropriately, each governed by an appropriate regulatory regime that

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[135] Ibid., pp. 62-63.
[136] Ibid., p. 63.
[137] Ibid., pp. 63-64.

can evolve with the science. The research undertaken by institutions can be regulated up to a point, but there is always the possibility for rule breaking – as in Ken Alibek's experience with the Soviet biological weapons programme.

Various regulatory solutions have been proposed for synthetic biology, ranging from no regulation to varying forms of self-regulation, to the proposals of the European Group on Ethics in Science and New Technologies (EGE) Group to the European Commission, that call for regulation at the national, EU and, ultimately, global level – a level of oversight that may include limiting or banning certain aspects of the research to maintain safety. Also, Lloyd's have argued for dedicated regulatory bodies.

Human history shows that a technology that could lead to the creation of some of the deadliest weapons in history poses a serious threat to the world's security. Based on my observations about the potential dangers of synbio, it would seem sensible that if the EGE Group's proposals can be introduced into policy, such threats may be greatly reduced, while beneficial applications of synbio may be allowed to flourish. Lloyd's recommendations also seems wise; synbio is a significant enough to require this, to put it mildly. Overall, an overarching principles based regulation, backed up by rules that evolve with the science and strong self regulation, may be a useful approach.

The biggest difficulty will come in attempting to regulate biohacking. The *Open Biohacking Project/Kit*, which provides a DIY manual for biohackers, observes:

> Admit it: you cannot deny the potential for misuse. Though the information to construct novel, deadly bacteria does not exist in this package

> (nor will it ever), the pieces are already out there on the internet and they will only become increasingly more consolidated. It is a real threat *now* and ignoring these threats is not the solution... [138]

Biohacking may become as regular an occurrence as today's computer hacking, in the near future. This means that pure research may have to be regulated, to prevent it being applied in negative ways, even where it is not negative in itself and, indeed, may have many positive applications. As it is impossible to regulate every amateur lab, every home, so it may become necessary to prevent (or keep from the public domain) certain advances in the science.

The potential dangers are great. It is not obvious that synthetic biology research in its present form is ethical. Indeed, it appears to invite probable disaster. But good regulation *may* make it acceptably safe; the issue of regulation is likely to be the lynchpin on whether synthetic biology research can be ethical or not. Safety can never be guaranteed, but risks may be minimised to an acceptable degree by proper regulation. The science is in its infancy, so is regulation of it; regulators and scientists are finding their way.

In Chapter 9, in the publications section, I propose a structured method for developing global, national and regional regulatory oversight. Based on a framework of global health justice and governance for healthcare, developed by Jennifer Prah Ruger,[139] it includes the setting up of local, national and international institutions, specific to and with expertise in synthetic biology, to oversee appropriate development of the science.

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[138] Open Biohacking Project/Kit (undated). http://biohack.sourceforge.net/ Accessed December 9th 2012.

[139] Jennifer Prah Ruger (2012). "Global Health Justice and Governance." *American Journal of Bioethics*, 12(12): 35-54.

Finally, the authors of the *World at Risk* report observe:

> It is our hope to break the all-too-familiar cycle in which disaster strikes and a commission is formed to report to us about what our government should have known and done to keep us safe. This time we do know. We know the threat we face. We know that our margin of safety is shrinking, not growing. And we know what we must do to counter the risk. There is no excuse now for allowing domestic partisanship or international rivalries to prevent or delay the actions that must be taken. We need unity at all levels—nationally, locally, and among people all across the globe. There is still time to defend ourselves, if we act with the urgency called for by the nature of the threat that confronts us.[140]

In the words of Oliver Wendall Holmes: "the law [needs] to be tailored with a mind not toward 'good men' (who would look to law as a guide to proper action) but with a mind toward 'bad men' (who would try to evade the legal strictures of society)."[141] "Good men" should be allowed the freedom to benefit humanity with beneficial applications of synthetic biology research. The bad, misguided and incompetent should be prevented from damaging humanity and the environment; while possible errors should be minimised. Because of the dangers and potential benefits of synthetic biology, and its broad array of sub-fields, getting the regulatory mix right will be among the most challenging and important tasks ever faced by regulators.

[140] Bob Graham et al (2009). *op. cit.*, note 36, p. xiii.
[141] Ian Ayres and John Braithwaite (1992). *Responsive Regulation: Transcending the Deregulation Debate*. (New York: Oxford University Press), p. 16.

CHAPTER 3 ETHICAL ISSUES

The same science that may cure some of our worst diseases could be used to create the world's most frightening weapons.

CIA[1]

INTRODUCTION

It will be difficult to create an overarching ethical paradigm for all of synthetic biology, as it is broad in scope. For example, people who support the development of synthetic drugs and biofuels may reject applying synbio to re-engineer human embryos. In order to properly evaluate the ethics of the field, it is therefore necessary to examine the various aspects of research individually. Yet synthetic biology does exist as a whole in the sense that all of its subfields involve engineering or re-creating life; also advances in one area of research may drive advances in other areas. For example, advances in genome synthesis which are developed with the intention of creating medicines may be usable in creating bioweapons.[2] Craig Venter's top down approach to creating an artificial cell may eventually merge with the bottom up approach of protocells. In general, different research areas may converge as they become more advanced. So an overarching ethical view of the field needs to be developed too, in as far as it is possible; it is necessary to examine the general and the particular in synthetic biology research. (A similar approach is needed in regulation.) At present, ethical evaluations tend to study the field in overview. In this chapter I

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[1] Central Intelligence Agency Directorate of Intelligence (2003). *The Darker Bioweapons Future*. (Washington, DC: CIA). http://www.fas.org/irp/cia/product/bw1103.pdf Accessed December 24th 2012.

[2] ETC Group (2007). *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. (Ottawa, ON: ETC Group). http://www.etcgroup.org/content/extreme-genetic-engineering-introduction-synthetic-biology Accessed December 24th 2012.

will briefly review the current literature, outlining the main ethical issues related to synthetic biology; these will be developed in further depth in the papers for publication.

"IN THE MIDST OF REVOLUTION;"[3] or "FAKING ORGANISMS:"[4] AN OVERVIEW OF THE ETHICAL DISCUSSION

As mentioned, the bioethics literature has not exactly been set on fire with debate on the ethics of synthetic biology; quite the contrary. Nor have I been able to locate any other doctoral theses on synbio ethics; this may be the first. A number of reports have been issued, and some papers published. I will give an overview of the main points.

Reports

The most significant reports are: The European Group on Ethics in Science and New Technologies to the European Commission (EGE Group)'s report, *Ethics of Synthetic Biology;*[5] and, in the US, the Presidential Commission for the Study of Bioethical Issues report, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*.[6] I have discussed their recommendations regarding

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[3] Mildred K. Cho and David Relman (2010). "Synthetic 'Life,' Ethics, National Security and Public Discourse." *Science,* 329: 38-39. http://cirge.stanford.edu/documents/ChoRelman2010.pdf Accessed December 14th 2012.

[4] William Saletan (2011). "Faking Organisms: How Can We Govern the Garage Biologists Who are Tinkering With Life?" *Slate,* 1st February. http://www.slate.com/articles/technology/future_tense/2011/02/faking_organisms.html Accessed December 16th 2012.

[5] The European Group on Ethics in Science and New Technologies to the European Commission (EGE Group) (2009). *Ethics of Synthetic Biology.* (Brussels, European Commission). http://ec.europa.eu/bepa/european-group-ethics/docs/opinion25_en.pdf Accessed December 13th 2012.

[6] Presidential Commission for the Study of Bioethical Issues (2010). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies.* (Washington DC: Presidential Commission for the

regulation in the previous chapter. I will also discuss reports commissioned by the UK's Biotechnology and Biological Sciences Research Council (BBSRC), *Synthetic Biology, Social and Ethical Challenges*;[7] the Woodrow Wilson International Center for Scholars' *Ethical Issues in Synthetic Biology: An Overview of the Debates*;[8] and the ETC Group's *Extreme Genetic Engineering: An Introduction to Synthetic Biology*.[9]

The EGE Group states that the progress of synthetic biology should be founded on ethical principles. For them, these ethical principles are enshrined in UN, UNESCO and Council of Europe declarations and conventions, and the Charter of Fundamental Rights of the European Union.[10] First and foremost among these principles is the concept of human dignity. While acknowledging that the concept can be vague, they attempt to make it concrete by incorporating a working definition:

> The exalted moral status which every being of human origin uniquely possesses. Human dignity is a given reality, intrinsic to human substance, and not contingent upon any functional capacities which vary in degree… The possession of human dignity carries certain immutable moral obligations. These include, concerning the treatment of all other human beings, the duty to preserve life, liberty, and the security of persons, and concerning animals and nature, responsibilities of stewardship.[11]

Study of Bioethical Issues). http://bioethics.gov/cms/synthetic-biology-report Accessed December 13th 2012.

[7] Andrew Balmer and Paul Martin (2008). *Synthetic Biology: Social and Ethical Challenges*. (Swindon: BBSRC). http://www.bbsrc.ac.uk/web/FILES/Reviews/0806_synthetic_biology.pdf Accessed December 15th 2012.

[8] Woodrow Wilson International Center for Scholars (2009). *Ethical Issues in Synthetic Biology: An Overview of the Debates*. (Washington DC; Woodrow Wilson International Center for Scholars). http://www.synbioproject.org/process/assets/files/6334/synbio3.pdf Accessed December 16th 2012.

[9] ETC Group (2007). *op. cit.*, note 2.

[10] Charter of Fundamental Rights of the European Union (2000). http://www.europarl.europa.eu/charter/pdf/text_en.pdf Accessed December 13th 2012.

[11] William Cheshire (2002). *Ethics and Medicine*. 18:2. In EGE Group (2009). *op. cit.*, note 5.

Humans have rights and duties; duties include considerations of the responsibilities on one's actions, including their effects on others people, animals and the environment.[12]

They note that developing an ethical evaluation for synbio is complicated by differing ethical methodologies in relevant, related fields, such as biomedicine, biotechnology, agriculture and environmental ethics. They suggest that the following should be incorporated for evaluating and guiding synthetic biology: concepts of nature, and of life; procedural principles that ensure democratic influence of scientific policy, responsibility and accountability; and transparency.

First, the advent of synbio forces us to confront the question: what is life? Depending on how the question is answered, our concept of ourselves and other creatures may be challenged, perhaps to a very deep degree. Synthetic biology could cause a paradigm shift regarding the conception of life. Terminology is important in such discussion – the use of phrases such as "living machines" or "synthetic cells" can be value laden, and influence our conclusions. The EGE Group has called for the European Commission to set up a forum to debate such issues, which should include philosophical and religious input. The EGE Group attempted to define life:

> 'Life' is the condition that distinguishes active organisms from inorganic matter, including the capacity for growth, functional activity and continuous change preceding death. A living organisms can be seen as having a number of capacities that differentiate it from inorganic matter, such as metabolism, homeostasis, capacity to grow, reproduce and, through natural selection, adapt to its environment over successive generations.[13]

The Group also distinguish between, for humans, the biological body and the sense of "self," observing that, for some, the human being is more than their biological body,

[12] EGE Group (2009). *op. cit*., note 5, p. 39.
[13] Ibid. p. 40.

which is explainable (up to a point) in scientific terms. This raises a question: how far should we see humanity, life and the biosphere as commodities or instruments?[14]

There is a significant literature on environmental ethics, and the EGE Group refer to it. One branch of environmental ethics, eco-centric ethics, sees intrinsic ethical value in the biosphere, in nature. Some eco-centric ethicists may see synbio as a challenge to nature's integrity. On the other hand, anthropocentric environmental ethicists focus on humans as occupying the centre of the environmental "stage;" therefore humans can validly, ethically, use nature as a tool. This does not extend to severely damaging the environment, as we have duties towards future generations of humans.[15]

From these foundational ideas, the EGE Group describe what they see as the main ethical issues generated by synthetic biology. They see four such issues: biosafety, biosecurity, justice and intellectual property.

Regarding biosafety, the Group note that interaction of synthetic biology products, even harmless ones, with natural ones may have unpredictable effects. Human health is key as to whether such products can be ethical. Risk assessment is ongoing, and synthetic biologists should incorporate features to make their products safe. Effects of synthetic/natural interactions that can be predicted include horizontal gene transfer from synthetic to natural organisms, change of ecological balance in habitats, and evolution of synthetic organisms in unknowable ways. In addition, accidental release of harmful synbio products may occur. Human dignity and

[14] Ibid. p. 41.
[15] Ibid.

autonomy require that people be protected from the worst effects of such scenarios, and any other unknowable scenarios.

The Group invoke the precautionary principle as being central to ethical debate on synbio, and to regulation of it. They state that the burden of proof as to the safety of the technology lies on those who promote it.[16] There should be a requirement that synthetic organisms should be designed so that they cannot survive outside the lab environment. Where dangers are great, freedom of research cannot be used as an argument against regulation, whether that research is at the professional or hobbyist level.[17]

Regarding biosecurity, the Group discuss the potential use of synbio in garage terrorism, biowar, biohacking, etc., where synbio may make it ever easier to synthesise deadly pathogens and design new ones, by techniques such as DNA design or metabolic engineering: "The ability to carry out DNA synthesis is no longer confined to an elite group of scientists… Now anyone with a laptop computer can access public sequence databases via the internet, access free DNA design software, and place an order for synthesised DNA design for delivery."[18] They have produced an impressive list of diseases that have been, or could be, weaponised: anthrax, Ebola, Marburg virus, plague, cholera, tularemia, brucellosis, Q fever, machupo, Coccidioides mycosis, Glanders, Melioidosis, Shigella, Rocky Mountain spotted fever, typhus, Psittacosis, yellow fever, Japanese B encephalitis, Rift Valley fever,

[16] Ibid., p. 42.
[17] Ibid., p. 43.
[18] Ibid., pp. 43-44.

and smallpox. Other useable toxins include ricin, SEB, botulism toxin, saxitoxin and various mycotoxins.[19]

The Group estimated that 15 million orders per month for synthetic DNA would be placed with commercial synthesis companies by 2012 (the report was published in 2009), and that companies should use software such as BlackWatch to screen for virulence. (The existence of adequate databases of toxic DNA sequences is implied here.) They suggest the following additional precautions: support for open source software production; help for companies, especially small to medium enterprises, to ensure that they apply proper safety standards; help in cost reductions for synthesis companies; reporting structures to connect synthesis companies with appropriate authorities when suspect DNA is submitted; both privacy for those who submit information to databases, and also accountability.[20] These requirements are useful, but they offer only a partial shield against danger; a teenager with a laptop and a DNA synthesizer would avoid them.

The Group note that justice is key to synthetic biology ethics. They call for debate, particularly for the following topics: citizens' rights with respect to nature; a social contract relating desires of leaders with those of citizens; inter-generational justice; technology divides; and preservation of the biosphere against accidents, etc.[21]

The Group also discuss intellectual property. A correct balance should be maintained between the common good and the rights of inventors. The EGE Group observe, correctly, that there has been a shift to private rights in recent years, and this

[19] Ibid., p. 43.
[20] Ibid.
[21] Ibid., p. 45.

is more pronounced for poorer countries. They suggest a categorisation for inventions in synthetic biology, and biological inventions in general:

- Inventions or discoveries that are the common heritage of humanity, which cannot be patented or utilised commercially (e.g., the human genome);
- Commercially viable inventions which should be placed in the public domain, on an open access basis. There could be various reasons for this, including the fact that the discovery or invention is too great to be exploited properly by any one organisation;
- Biological inventions that are suitable for patenting.[22]

The Group notes that there is no international consensus on patentable biological material, and that the debate is ongoing. (My own reading of the literature suggests that while this is true, on balance there is an overwhelmingly negative response to patentability of naturally occurring, uninvented, biological materials, especially genetic materials.)[23] [24] The Group note significant differences between the patent regimes of the EU and the US with respect to issues such as usefulness, replicability and public morality.[25]

The Group highlighted what they perceived to be the most pertinent ethical issues for synbio. They did not provide an in depth philosophical discussion, rather they establish a foundation for such a discussion, at least in part. Based on their analysis, they also make 25 recommendations; these chart a path for an ethical

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[22] Ibid., p. 46.
[23] Patrick Heavey (2007). *The Ethics of DNA Patenting*. M.Sc. (Bioinformatics) thesis, Oxford University.
[24] For a good introduction to the literature on the topic, see: David Resnik (2004) *Owning the Genome: A Moral Analysis of DNA Patenting*. (Albany, NY: State University of New York Press).
[25] EGE Group (2009). *op. cit*., note 5.

synthetic biology. The main recommendations are: Synbio should only go ahead if it is safe to do so. Therefore risk assessment should be carried out at EU and national level; also gaps in biotech regulation should be filled. The European Commission should engage in international debate on synbio safety. A code of conduct should be produced. Risk assessment, including long-term impact assessment, should be carried out before any synthetic organisms are released to the environment; the precautionary principle should be used when evaluating such data. If synbio products are used in food, at some stage, then labelling should be considered. An ethics and security structure should be established by the European Commission. The BTWC should be changed so as to deal with synbio's challenges. Such changes could include limiting or banning certain types of research. Strong governance of synbio should be established in the EU, and the responsibilities of various actors (political, administrative, industrial, military, scientific) defined. The scientific community should engage with ethics, both as a community and as individuals.[26]

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When Craig Venter's group announced the successful development of *Synthia*, President Obama requested that the Presidential Commission for the Study of Bioethical Issues study synbio's ethical implications.[27] The study resulted in a report, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*.[28] The Commission based its deliberation on five ethical principles: "(1) public beneficence, (2) responsible stewardship, (3) intellectual freedom and responsibility, (4) democratic deliberation, and (5) justice and fairness."[29] These were a foundation to

[26] Ibid., pp. 49-56.
[27] Presidential Commission for the Study of Bioethical Issues (2010). *op. cit.*, note 6, p. 2.
[28] Ibid.
[29] Ibid., p. 4.

"illuminate and guide"[30] a public policy which would, hopefully, ensure an ethical synthetic biology.[31] [32]

The Commission defined these principles. *Public beneficence* means the minimisation of potential harms and maximisation of potential benefits. *Responsible stewardship* means protection of the common good, for current and future generations; which includes protecting the environment. It requires that challenging technologies, such as synbio, should be subject to ongoing assessment as they develop. *Intellectual freedom* is self explanatory; with it comes moral responsibility. The Commission sees intellectual freedom as a foundation of democracy. Intellectual freedom is best served by regulatory parsimony – no more oversight than is necessary to maintain security, safety, justice and the common good. Emerging technologies are changing and have uncertain boundaries; this makes it difficult to define regulatory limits. Inappropriate limits could hold back technological progress, including advances in safety and security. *Democratic deliberation* implies that there should be open discussion on synbio and its implications, in an atmosphere of mutual respect, with decisions reached in a transparent manner. *Justice and fairness* mean that synbio's positives and negatives should be fairly allocated throughout society.[33]

Under these headings, the Commission made a number of recommendations. Generally speaking, these emphasise modes of regulation, also types of government and other support, rather than ethics. I mention the recommendations in Chapter 2.

[30] Ibid.
[31] Ibid.
[32] William Saletan (2011). *op. cit*., note 4.
[33] Ibid., pp. 4-5.

Risk-benefit analysis is the dominant mode of thinking. But the Commission also briefly discussed ethical arguments, both for and against synbio.

They discuss several deontological criticisms. Synbio has been called wrong in itself, a manifestation of hubris, which disregards the special nature of life. Advances in it may enhance such tendencies, and may lead to a diminution of respect for all life, including naturally occurring creatures. [34] Synbio may also challenge the dignity of nature, due to its inherent unnaturalness; it steps away from Darwinian evolution, to a human-guided design of species. They rejected such concerns, noting that humans have always interacted with nature; it could be considered natural for such interaction to occur. Also, synbio is not different in kind to previous such scientific interactions.[35] Consequentialist critiques are also considered, particularly possible damage to human health, and to biodiversity if synthetic organisms interact with natural ones, causing complex ecosystems to change. Biosecurity is also an issue here. These critiques are dealt with in their recommendations on regulation (see Chapter 2) – which could be described a slight touch. The Committee also discussed religious views, noting that organised religions had not objected to synbio, and some religious thinkers argued against those who said it diminished the value of life.

There is a degree of convergence between the EU and US reports, as well as significant differences.[36] The EGE Group engages more deeply with the issues, generally; the Commission on Bioethical Issues' report is scholarly, but frequently

[34] Ibid., p. 135.
[35] Ibid., p. 139.
[36] For a point-by-point comparison of major issues, see: synbioproject.org (undated). *High Convergence: US-EU Synthetic Biology Commissions.* http://www.synbioproject.org/process/assets/files/6500/_draft/us_eu_recommendations_final.pdf Accessed December 24th 2012.

avoids dealing with the controversial issues, in enough depth, particularly regulation and IP. Its *raison d'etre* in these cases could be described as plausible blandness. Regarding regulation, dialogue and observation seem to be their primary tools, at present, to keep synbio safe. The Committee rejected a proposal from George Church, one of synbio's founding fathers, for licensing and surveillance of DIY biologists.[37] Friends of the Earth have noted that licenses are required for hairdressers and tattoo artists in many places, so it seems incongruous that they are not for synthetic biologists.[38] Although the Commission allows for change in this regard as the science evolves, it is arguable that their approach should be more proactive now, given the potential grand-scale lethality of synbio. As for IP, after they discuss the issues, they conclude: "The Commission offers no specific opinion on the effectiveness of current intellectual property practices and policies in synthetic biology"[39] – which is extraordinary, given its importance. On the release of the report, 58 groups, including religious groups and environmentalists, sent a letter of protest to the Commission, criticising its light-touch approach.[40]

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In the UK, the BBSRC's report, *Synthetic Biology: Social and Ethical Challenges*[41] identifies the following ethical issues: bioterror, accidental release; intellectual property; trade/global justice; and the value of life. For each of these it discusses ethics, and appropriate policy and scientific responses.

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[37] Jocelyn Kaiser (2012). "Updated: Synthetic Biology Doesn't Require New Rules, Panel Says." *Science Insider*, 16th December. http://news.sciencemag.org/scienceinsider/2010/12/synthetic-biology-doesnt-require.html?ref=hp Accessed December 21st 2012.
[38] Friends of the Earth (2010). *Synthetic Solutions to the Climate Crisis: The Dangers of Synthetic Biology for Biofuels Production*. (Washington DC: Friends of the Earth), p. 36. https://www.cbd.int/doc/emerging-issues/foe-synthetic-biology-for-biofuels-2011-013-en.pdf Accessed December 21st 2012.
[39] Presidential Commission for the Study of Bioethical Issues (2010). *op. cit.*, note 4, p. 121.
[40] Jocelyn Kaiser (2012). *op. cit.*, note 37.
[41] Andrew Balmer and Paul Martin (2008). o*p. cit., note 7.*

Regarding bioterror, they note that there are potential threats from both state controlled military research and biohacking; also, that synthetic biologists have a low awareness of the major debates and policy documents on the issue.[42] [43] So there is a possibility of sleepwalking into danger. They quote from a CIA report: "engineered biological agents could be worse than any disease known to man,"[44] noting that methods of monitoring weapons of mass destruction may no longer be sufficient due to advances in technology. Proper regulation may minimise such threats, but the form that regulation should take is still being debated. In particular, there is a divide between proponents of self regulation and external regulation, though both could be used in a complimentary fashion.[45] [46] Also, researchers and policymakers need to be on their guard against threats, and the current lack of awareness should not continue. [47]

Accidental release or, more generally, biosafety, needs to be engaged with to minimise dangers. Reasonable approaches include design of organisms which cannot survive outside the lab, or which contain kill switches. The precautionary approach could guide research, and release of organisms; also proper regulation should be developed.[48]

Regarding intellectual property, Balmer and Martin note that large investments are being made in synbio, with the hope of significant profits. Monopolies could be a

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[42] Ibid.
[43] Alexander Kelle (2007). *Synthetic Biology and Biosafety Awareness in Europe*. *Synbiosafe/Bradford Science and Technology Report No. 9. University of Bradford.* http://www.brad.ac.uk/acad/sbtwc/ST_Reports/ST_Report_No_9.pdf Accessed December 15th 2012.
[44] Central Intelligence Agency (2003). *op. cit.*, note 1.
[45] Andrew Balmer and Paul Martin (2008). *op. cit.*, note 7, p. 22.
[46] Nature (2006). "Editorial: Policing Ourselves." *Nature*, 441: 383. doi:10.1038/441383a;
[47] Balmer and Martin (2008). *op. cit.*, note 7.
[48] Ibid., p. 18.

consequence; a small number of people may benefit from synbio's advances, with little benefit for the common good.

Related to this are issues of trade and justice. For example, the creation of synthetic medicines, such as Artemisinin (wormwood), may damage or destroy the livelihoods of those who produce it naturally, most of whom are small farmers in Africa and East Asia. Synthetic production of this antimalarial in Western countries could kill local production of it, requiring Artemisinin to be imported. If such scenarios arise on a broad basis, synbio could be a cause of poor countries falling further behind.[49]

For some, synbio per se may challenge the value of life, and issues of "playing God" may arise for some. An *Economist* article on Venter's Synthia was titled: "And man made life," and was illustrated with an adaptation of Michelangelo's *Creation of Adam* from the Sistine Chapel.[50] Regardless of issues of playing God, the research may raise questions ranging from the dignity of life to, in more depth, what is life, and how can boundaries be defined between the natural and the artificial? Can scientists define life? Balmer and Martin note that no such broadly accepted definition exists at present, which raises questions about scientists' ability to modify or create it to a high level.[51]

They have made the following policy recommendations: That synbio should not challenge public morality in its research, positive applications should be

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[49] Ibid., p. 25-26.
[50] The Economist (2010). "Editorial: And Man Made Life." *The Economist*, 20th May. http://www.economist.com/node/16163154 Accessed December 15th 2012.
[51] Andrew Balmer and Paul Martin (2008). *op. cit*, note 7, pp. 26-29.

developed, and hype minimised; scientists should lead societal and ethical debate; scientists should engage with ethicists and social scientists to establish a "socially acceptable science;" and good regulation should be developed before synbio produces applications. Which seems reasonable.

The Woodrow Wilson International Center for Scholars,[52] in the US, is operating a Synthetic Biology Project,[53] which "aims to foster informed public and policy discourse concerning the advancement of synthetic biology."[54] They have issued reports on various aspects of the field,[55] including one on ethics: *Ethical Issues in Synthetic Biology: An Overview of the Debates*.[56] They identify dual areas of ethical debate: issues of physical harm (biosafety and bioterror) and non-physical harm (to wellbeing), noting that while reasonable consensus can be achieved on the former, it is more difficult for the latter. At the Synthetic Biology 3.0 Conference, Laurie Zoloth argued that consensus can't be achieved on the latter, even by logical argument, as presuppositions differ so widely.[57] The Wilson Center scholars note that consensus can be difficult to achieve over concepts of wellbeing – for example in debates on transhumanism, germ-line engineering and human-animal hybrids – yet it is a conceptual and practical error to therefore dismiss such discussion and ignore what consensus can be and has been achieved. They call for serious reflection on the issue of wellbeing in general, requesting that people should enter such debates with awareness of their own ethical presuppositions. As for regulation, they note that: "The

[52] Wilson Center Homepage (2012). http://www.wilsoncenter.org/ Accessed December 16th 2012.
[53] Synthetic Biology Project Homepage (2012). http://www.synbioproject.org/about/ Accessed December 16th 2012.
[54] Ibid.
[55] Synthetic Biology Project Library (2012). http://www.synbioproject.org/library/ Accessed December 16th 2012.
[56] Woodrow Wilson International Center for Scholars (2009). *op. cit.*, note 8.
[57] Laurie Zoloth (2007). "Hide and Seek: The Ethics of Curiosity and Security in Synthetic Biology." *Presentation: Synthetic Biology 3.0, Zurich*, June 24-26th. In Woodrow Wilson International Center for Scholars (2009). *op. cit.*, note 8.

goal is to avoid repeating the mistakes of the past, where technologies like asbestos, chlorofluorocarbons, DDT and thalidomide were developed before their risks had been adequately assessed."[58]

A Canadian-based environmentalist group, the ETC Group (Action Group on Erosion, Technology and Concentration) have issued a report on synbio: *Extreme Genetic Engineering: An Introduction to Synthetic Biology*.[59] Witty, scholarly and critical in tone, it analyses the science of synbio and evaluates its ethics. The main ethical issues it discusses are bioweapons/bioterror, biosafety, IP and the creation of monopolies, fair trade, biodiversity and the environment, and regulation. They reject the idea of synbio being a mere advance on genetic engineering, arguing that it is a revolutionary step. They are critical of the side of synbio that is "a corporate-dominated science and technology that thrives on aggressive patenting activity,"[60] and warn of "synthesising new monopolies from scratch."[61] Also, they argue that synbio introduces new threats to human society, and regulation should take account of its threats. They argue that self regulation alone is inadequate because of the magnitude of the threats, quoting Plato: "The discoverer of an art is not the best judge of the good or harm which will accrue to those who practice it."[62] In that spirit, they recommend good regulation, with the involvement of international bodies such as specialist groups in the UN; they also recommend the establishment of a specialist international body for synbio. They call for broad debate on synbio throughout society, and on its potential convergence with other emerging technologies such as nanotech. They have issued several more specialised reports relating to aspects of

[58] Woodrow Wilson International Center for Scholars (2009). *op. cit*., note 8, p. 22.
[59] ETC Group (2007). *op. cit*., note 2.
[60] Ibid., p. 36.
[61] Ibid., p. 32.
[62] Plato. *Phaedrus*. In ETC Group (2007). *op. cit*, note 2, p. 49.

synbio,[63] and have acted as activists; for example, when Craig Venter applied for patent protection on the minimal microbe genome, they challenged it in the courts.[64] [65] They tend to focus on potential negatives on synbio, to the detriment of positives; yet if their approach was more widespread, potential negatives may be minimised to a greater degree.

Bioethics Literature and Conference Debates

An early and significant paper on the ethics of synthetic biology appeared in 1999, by Mildred Cho et al: *Ethical Considerations in Synthesizing a Minimal Genome*.[66] They noted that Dolly's sudden arrival illustrated the dangers of allowing ethical debate to fall behind scientific progress. Ethicists' and regulators' lack of engagement with advances in genetics meant that Dolly's advent was a surprise; and the response on her arrival was an over-reaction. If ethicists and regulators had engaged with the genetics as it progressed, there wouldn't have been such a surprise; also, they could have evaluated whether the science should have been allowed to take that direction. It would be better if such mistakes were not repeated in the case of synbio, and early attempts to synthesise a minimal genome were discussed by Cho et al with this in mind.

[63] ETC Group (undated). *Synthetic Biology*. http://www.etcgroup.org/issues/synthetic-biology Accessed December 16th 2012.
[64] Nature Biotechnology (2007). "Editorial: Patenting the Parts." *Nature Biotechnology,* 25: 822. doi:10.1038/nbt0807-822
[65] Peter Aldhous (2007). "Tycoon Seeks Patent for 'Minimal Genome.'" *New Scientist* , 8th June. http://www.newscientist.com/article/dn12021-tycoon-seeks-patent-for-minimal-genome.html Accessed December 17th 2012.
[66] Mildred K. Cho, David Magnus, Arthur L. Caplan, Daniel McGee and the Ethics of Genomics Group (1999). "Ethical Considerations in Synthesizing a Minimal Genome." *Science,* 286(5447): 2087-2090. doi: 10.1126/science.286.5447.2087

Potential ethical issues they discuss include the fact that research may not end up in the place where it was initially intended to go; intellectual property; bioterror; inadequate regulation (which they describe as "disturbing"); and whether the science should be regulated (an if so, at what levels) – or should regulation be limited to its applications? They also critique reductionist attitudes to life, observing that though reductionism has led to great advances in biological science, it also has inherent limitations, which can, on occasion, lead to scientific error. It can also limit ways of thinking, seeing life as being merely a collection of interacting chemicals, omitting much of the totality of human experience. This can have societal effects, leading to a devaluing of the concept of life.

They discuss religion, and dismiss the "religion vs science" world view, observing that perceived hostility between the two results from ignorance, lack of contact, and extremist positions being voiced loudly. They did not detect hostility from the mainstream religious thinkers that they engaged with, nor did their study of mainstream Western religions lead them to see any inherent opposition between the religious and scientific world views. On the contrary, they saw that many Western religions would view scientific enquiry and its applications as inherently noble, "exemplary of human nature and the highest human values."[67] They noted differences among religious thinkers, however, which varied from always equating scientific research with human advancement, to those who saw it as a form of pride, to those in the middle, who saw humans as stewards of creation, but possessing both great abilities and great limitations – which implied "proceed, with caution." Though

[67] Ibid.

religious thinkers differed as to appropriate degrees of caution, the mainstream among them did not see an ethical problem with researching the minimal genome.

They concluded that ethicists should engage with the science now (1999), not fall behind it, keeping up with advances, and identifying the key ethical, metaphysical and religious issues as the science progresses. Unfortunately this hasn't happened to a significant degree, as I have mentioned; therefore synbio has the potential to present humanity with surprises.

11 years later, on the announcement of *Synthia*, Mildred Cho and David Relman wrote what could be considered as a follow up to this paper;[68] it was published in the same issue of *Science* as the announcement of Synthia.[69] Describing synbio's current scenario as being "in the midst of revolution," they noted considerable advances in certain aspects of the science and technology, such as DNA synthesis and directed molecular evolution. However, there are still important gaps in knowledge, such as lack of predictability of function, and of emergent properties, which means that the knowledge to meaningfully design life is still lacking. They observed that greatest difficulty for addressing concerns in ethics and biosecurity will be to devise appropriate regulation and oversight, due to the dual use nature of synbio. Different conceptual frameworks for regulation may need to be developed, because of the unpredictable nature of synthetic biology advances. They noted the limitations of drawing up lists of dangerous pathogens, as genetic diversity is great enough, and taxonomic boundaries fuzzy enough, so as to render such lists somewhat redundant.

[68] Mildred K. Cho and David Relman (2010). "Synthetic 'Life,' Ethics, National Security and Public Discourse." *Science*, 329: 38-39. http://cirge.stanford.edu/documents/ChoRelman2010.pdf Accessed December 14th 2012.
[69] Though the formal announcement of *Synthia* actually occurred a few weeks before, in the online *Science Express*.

They noted that IP laws have not adapted to meet synbio's challenges. Also, ethics should be integrated into scientific thinking as far upstream as possible from research design, to make is as effective as possible. Benefits and risks should be evaluated in the broadest terms possible; not just in terms of biosecurity and biosafety, but also in terms of social, environmental and economic terms. They observed, too, that terminology such as "artificial life" is misleading, both scientifically and ethically, as it exaggerates scientists' ability to create and control life. As with Cho et al's first paper, there are wise recommendations here; one can hope that they will be taken more seriously this time.

Peter Singer, in a *Guardian* article written after the announcement of *Synthia*, quoted bioethicist Art Caplan on how this would affect our views on life: it "would seem to extinguish the argument that life requires a special force or power to exist."[70] This is simplistic, perhaps to a ridiculous degree; the synthetic DNA was a copy of natural DNA, and it was placed in a living cell. However, perception can be stronger than reality, and such thinking could take hold, even if it's erroneous. Singer himself states: "Synthia's very existence challenges the distinction between living and artificial…"[71] But *Synthia's* artificiality should not be overstated. Perhaps an organism will be developed, in the future, that does challenge that distinction; then again, perhaps not. These quotes illustrate how misunderstandings can occur over such issues; such misunderstandings in society at large could have negative effects regarding life's dignity. Singer noted that synbio's threats are real, and the release of synbio creations should be subject to regulation; but other looming threats, such as

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[70] Peter Singer (2012). "Scientists Playing God Will Save Lives." *The Guardian*, 13th June. http://www.guardian.co.uk/commentisfree/2010/jun/13/science-playing-god-climate-change Accessed December 15th 2012.
[71] Ibid.

climate change, may require that synbio research go ahead, as it may offer the potential to solve such problems. Benefits seem to "decisively" outweigh risks.[72] Singer also mentioned IP; while he noted that many arguments could be made against patenting sentient beings, it is harder to argue against the patenting of humanly designed, highly functional microbes, which are not sentient.

John Harris also responded to the announcement of *Synthia*, with an article in the *Financial Times*.[73] He pointed out some "moral reasons" for synbio research – such as advances in biofuels, drugs, vaccines, improvements in clean water, and food, and bacteria that can devour oil spills. He observed that the dangers, bioterror and biosafety, pose a threat, and that good regulation is necessary. He dismissed concerns about unnaturalness, noting that we are in frequent battle with nature's destructive power, ranging from diseases and parasites to earthquakes and tsunamis; it is right, not wrong, to work to mitigate such negatives. Like Singer, he mentioned IP, but with a different focus, writing that current patenting activity (he mentioned Craig Venter's "form"), may inhibit synbio's progress; there are moral arguments for requiring synbio's potential to benefit the common good.[74] Singer's analysis on IP does not go deep enough. Harris gets it right; a patent rush by researchers could prevent the science from ever reaching its potential.

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[72] Ibid.

[73] John Harris (2010). "Promise and Risks from 'Life Not as We Know It.'" *Financial Times*, 26th May. http://www.ft.com/cms/s/0/edf64e8e-68f4-11df-910b-00144feab49a.html#axzz2FA30xLoj Accessed December 15th 2012.

[74] Ibid.

Julian Savulescu spoke to synthetic and systems biologists at a panel discussion at the *BioSysBio Conference* in Cambridge in 2009.[75] He said there were two main ethical concerns: possible malevolent use, and undermining the moral status of living things. He said that while the latter may not be a major issue now, it could become one in the future. Would synthesized life be something between machine and life? In a transhuman scenario, would it be between human and machine? Persons have rights and intrinsic value; machines have none. Animals have some. It is unclear what value synthetic life would have. Could synthetic life be considered superior to natural life, including humans? If it was, rightly, then humans and animals could be harmed. If it wasn't, wrongly, then synthetic creatures could be harmed. Also synbio could lead to a widespread reductionist view of life, as being a mere set of components.[76]

Regarding synbio's dangers, he said that he spent much of his career writing against the precautionary principle, but he would invoke it here: "You have 80 units of wellbeing. An intervention means 99% chance of losing all 80, 1% chance of going to 90. Should you do it? NO!"[77] He noted that synbio "may present the greatest ethical challenges humanity has dealt with."[78] But he didn't call for a ban – though he said he may change that opinion in the future, when synbio starts to deal with higher life-forms. On that point, however, even synthetic microbes could be used in ways that benefit or harm higher life forms. He noted the following main challenges: For regulators, it is to minimize risk; for scientists, it is to predict how research will be

[75] Julian Savulescu (2009). "Panel Discussion: Perspectives on Synthetic Biology: Ethics, Public Engagement, Biosecurity and more." With Matthew Harvey (Senior Policy Advisor, Royal Society); Piers Millet (Biological Weapons Convention Implementation Support Unit, UN Office, Geneva); Drew Endy (Stanford University), *IET BioSysBio Conference*, Cambridge, 24th March.
[76] Ibid.
[77] Ibid.
[78] Ibid.

used; and for philosophers, it is to determine criteria for moral status and ascertain how to weigh risk vs. benefit. Also, he asked whether the value of knowledge, for its own sake, trumped other moral values, over-riding every other? He said that this was wildly implausible.

Drew Endy responded to his presentation by saying we could spend the rest of our lives talking about risks vs. benefits. Savulescu said that the concerns were real. He compared synbio with nuclear weapons technology; nuclear weapons are inaccessible for most, while synbio is accessible, cheap and easy. Endy responded that people should be taught to love synthetic biology; if they love it, they won't misuse it. This seems dangerously naive, and represents a shift in viewpoint; a few years earlier, Endy said: "I expect that this technology will be misapplied, actively misapplied and it would be irresponsible to have a conversation about the technology without acknowledging that fact."[79] It's an interesting change; could it represent a leading scientist being jaded, to a degree, with discussing ethics? It may be a broad phenomenon: the earliest synbio conferences usually had a large ethics component, but this has largely vanished in recent years.[80]

In an article for *The Times Higher Education Supplement*, [81] Savulescu pointed out synbio's potential positives, but observed that its negatives may outweigh them. His main arguments here are: "In the 1950s and 1960s, only a handful of people had the capacity to destroy the world. Soon, the biological revolution will place that

[79] ETC Group (2007). *op. cit*.., note 2, p. 23.
[80] For a list of conferences (comprehensive, but not complete), with programs, see: http://syntheticbiology.org/Conferences.html Accessed December 15th 2012.
[81] Julian Savulescu (2012). Master the New Loom Before Life's Tapestry Unravels at Our Hands." *The Times Higher Education Supplement*, 12th April. http://www.timeshighereducation.co.uk/story.asp?storycode=419685 Accessed December 15th 2012.

power in the hands of many."[82] Also, there's the biosafety issue, the fact that "radically different lifeforms,"[83] in their interaction with the ecosystem, could cause havoc. He called for discussion, ideally to be led by synthetic biologists, on issues such as publication rules, access to technology and chemicals, and regulation.[84] He concluded:

> The biological revolution is at once exciting, even mesmerising, but terrifying. The genie is out of the bottle. Our challenge is to ethically master the machines we are creating. At present, they are relatively simple and benign. But synthetic biology offers the prospect of annihilating life as we know it.[85]

He made similar points in a JME article, co-written with Thomas Douglas.[86] They wrote that synbio's advent suggests that bioethicists should engage with what types of knowledge should be investigated – something akin to a paradigm shift from current bioethical evaluations. This could guide regulation and other risk management methods. Evaluating the appropriate values in dual use situations could be a useful beginning.[87] Savulescu's writings display a greater urgency on synbio's dangers than others. He isn't quite a voice in the wilderness here; virtually all writers mention the dark side of synthetic biology. But Savulescu emphasises it to a greater degree. The concerns he expresses are all too real.

Some papers have dealt with synbio from a deontological focus. Christopher Preston wrote that because synthetic biology may offer a disconnect from Darwinian evolution, therefore a break from nature's processes, it is deontologically wrong,

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[82] Ibid.
[83] Ibid.
[84] Ibid.
[85] Ibid.
[86] Julian Savulescu and Thomas Douglas (2010). "Synthetic Biology and the Ethics of Knowledge." *Journal of Medical Ethics*, 36: 687-683. doi: 10.1136/jme.2010.038232 http://www.bep.ox.ac.uk/__data/assets/pdf_file/0020/17516/Douglas.Savulescu_Synthetic.Biology_JME.2010.pdf Accessed December 16th 2012.
[87] Ibid.

crossing a “moral line in the sand.”[88] (I evaluate his arguments in Chapter 6.) Joachim Boldt and Oliver Mueller raise the issue that synbio’s radicalness – its shift from genetic engineering’s *manipulatio* to its own *creatio* has ethical significance.[89] As with Preston, they suggest that an ethical line is being crossed regarding humanity’s relationship with nature, and that synbio’s *creatio ex existendo* has more in common with an eventual *creatio ex nihilo*, should science make it possible, than with *manipulatio*. Against this, I would argue that humanity has always had a inventive relationship with nature; for example, irrigation, advanced farming techniques, cross breeding of plants and animals, building, transport, medicine, etc., are highly creative interventions aimed at adapting nature to our needs; it could similarly be argued that synbio is equally is an advance in a continuum of changing technologies rather that a radical discontinuity. Yet their points are important, worth exploring in some depth.

CONCLUSION

I have reviewed the major parts of the bioethics literature, along with some private and government-level reports, on synthetic biology. The literature is relatively small for a topic of such importance, which has been in development for over a decade, particularly when one considers the magnitude of the ethical issues that synbio gives rise to. Yet the small literature that exists offers, generally, a thoughtful analysis of the major ethical issues raised by synbio.

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[88] Christopher Preston (2008). “Synthetic Biology: Drawing a Line in Darwin’s Sand.” *Environmental Values*, 17:23-39.
[89] Joachim Boldt and Oliver Mueller (2008). “Newtons of the Leaves of Grass.” *Nature Biotechnology*, 26(4): 387-389. doi:10.1038/nbt0408-387

In this thesis, I add to the debate by evaluating, in some depth, whether synbio is ethical. Much of the current ethical analysis has been based on principlist or risk-benefit analysis. I use the techniques of moral philosophy to analyse and critique the topics already discussed in the literature. I also discuss other topics, such as synbio's possible effects on the scientific enterprise *per se*, on medicine, agriculture, the world food supply and fuel. In the next chapter I describe and justify my methodology, and briefly summarise the contents of my papers. In the chapters that follow, I evaluate the ethics of synthetic biology from consequentialist, deontological and theological perspectives (Chapters 5, 6 and 7, respectively); and Chapter 8 will examine the adequacy of ethicists' current levels of engagement with the science, and of scientists with ethics, and of their approaches.

CHAPTER 4 RESEARCH QUESTIONS AND METHODOLOGY

A large tranche of contemporary bioethical inquiry is self-consciously focused on purpose and methodology. Bioethics is a field of disparate disciplines, and it is not always clear what role the philosopher plays in the wider scheme. Even when philosophical reflections can, in principle, find application in the real world (and often, in bioethics, there is too heady a degree of abstraction for this), there can be difficulty in finding sound resolution between the competing perspectives. Where fundamentals differ, we face apparent deadlock, with theorists seemingly able only to talk across each other.

John Coggon[1]

…man cannot discover the work which has been done under the sun. Even though man should seek laboriously, he will not discover; and though the wise man should say, "I know," he cannot discover.

Ecclesiastes 8:17

INTRODUCTION: REFLECTIONS ON METHODOLOGY IN BIOETHICS

Some time ago, I spent a month in hospital for a back injury, which generated other symptoms. The doctors put me through a variety of tests to determine what was wrong – tests on blood, examination of the heart with a camera, and many more. All this was done to no avail – they couldn't determine what was wrong. Eventually –

[1] John Coggon (2011). "Guest Editorial: On Method and Resolution in Philosophical Bioethics." *Cambridge Quarterly of Healthcare Ethics*, 20(2): 159-162. doi:10.1017/S0963180110000800

after nearly a month of persuasion by me, which involved me going over their heads – they performed an MRI on my back, and correctly diagnosed the problem. They had resisted doing this, as MRIs are more expensive than other tests (€250, according to my insurance bill), the hospital only had one MRI machine, and waiting lists to use it were long – up to several months. Doctors were very reluctant to use it.

While in hospital, one of my visitors was a reflexologist. She glanced at my foot, and instantly diagnosed that I had back injuries. She was able to tell where they were on the spine (according to reflexology, back injuries cause swelling along the arch of the foot, each area of the arch corresponding to an area of the back) and (approximately) how severe they were. Her diagnosis, which was instantaneous on seeing the foot, was later confirmed by the MRI. After leaving hospital, I visited a chiropractor. On hearing my explanation of the symptoms, he diagnosed the problem – the same diagnosis as the reflexologist and the doctors. It took him about 3 minutes.

Initially the doctors made several diagnoses, among them diabetes. If I had accepted this, I would now be receiving lifelong treatment for it, even though I don't have it, while the actual problem would have remained undiagnosed. Although they eventually found the problem, it took a month, cost the taxpayer a lot of money; and the delay could, in some conditions, have had serious repercussions.

The main reason for the different efficiency levels between the various healthcare practitioners was the methodological approach; issues of competence and knowledge could also have been factors. From what I could see, every hospital patient, whether suffering from a sports injury, alcoholism, or a motorcycle crash, was put through a similar battery of tests, for blood pressure, diabetes, and so on. This methodology made it difficult to diagnose injuries or illnesses outside a narrowly defined area.

Methodology matters. Faulty methodologies can lead to catastrophically bad consequences in every field of endeavour, be it medicine, engineering, science, skilled trades work – and, of course, philosophy and bioethics. In bioethics, opposing conclusions can be reached on serious issues, and these conclusions may depend on the methodology used. It is not the only factor – others can include starting assumptions and, as mentioned, levels of knowledge, and competence – but it is very significant.

So, is there a best methodological approach to solving bioethics problems? Bioethics is a new discipline, coming into its own from the late 1960s[2] (though some argue that it began with the Nuremberg Codes of 1949[3]). Initially it was based on principles which were thought to be universal. "Principlist" thinking meant that the correct ethical solutions to bioethical problems could be deduced from these principles. The textbook *Principles of Biomedical Ethics* by Tom Beauchamp and James Childress[4] "popularised," within the bioethics field, four key principles – autonomy, beneficence, justice and nonmaleficence[5] – which were used as starting

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[2] Susan M. Wolf (1994). "Shifting Paradigms in Bioethics and Health Law: The Rise of a New Pragmatism." *American Journal of Law and Medicine,* 20 (4): 395-415.

[3] Ibid.

[4] Tom Beauchamp and James Childress (2008). *Principles of Biomedical Ethics*, 6th edition. (New York: Oxford University Press).

[5] The four principles were originated by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was created by the US Congress, in 1974, to be the first government body to debate bioethics policy in the US; In *The Belmont Report: Ethical Guidelines for the Protection of Human Subjects* (1978). http://videocast.nih.gov/pdf/ohrp_belmont_report.pdf Accessed 12/12/12.

points to solve bioethics problems.[6] This paradigm dominated bioethics thinking in the 1970s and 80s (in the U.S. at least – little attention was paid to it in Europe). It permitted agreement on morality between consequentialists and deontologists.[7]

Later, that paradigm began to evolve; also new methodological approaches were proposed, such as (a revival of) casuistry; virtue ethics; narrative ethics (drawing on the stories of individual people to derive ethical principles); and care ethics (which emphasises the interdependence of people).[8] It has also been argued that feelings, such as moral repugnance, can be a useful guide in determining good ethical solutions.[9]

Different methodological approaches are not necessarily mutually exclusive, though there can be rivalry between them.[10] [11] Beauchamp and Childress have noted this point,[12] and have gone further, observing that for principles to be applied correctly to given situations, good character is needed – thus combining principlism with virtue ethics.[13] Carse and Nelson, proponents of the ethic of care, acknowledge that it is not an all-encompassing moral theory.[14] Charon suggests that principlist and narrative approaches are complementary; principles are necessary, but individual

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[6] Susan M. Wolf (2004). *op. cit*., note 2.
[7] Tuija Takala (2001). "What is Wrong with Global Bioethics?" *Cambridge Quarterly of Healthcare Ethics*, 10: 73-78.
[8] Patricia A. Martin (1999). "Bioethics and the Whole: Pluralism, Consensus and the Transmutation of Bioethical Methods Into Gold." *Journal of Law, Medicine and Ethics*, 27(4): 316-329.
[9] See, for example, Leon R. Kass (1997). "The Wisdom of Repugnance." *The New Republic* 216(22). http://www.catholiceducation.org/articles/medical_ethics/me0006.html Accessed 12/12/12; Tuija Takala (2001), *op. cit*, note 7; and Anne McClean (1993). *The Elimination of Morality: Reflections on Utilitarianism and Bioethics.* (London: Routledge).
[10] Tuija Takala (2001). *op. cit*., note 7.
[11] Søren Holme (2011)."Classification and Normativity: Some Thoughts on Different Ways of Carving Up the Field of Bioethics." *Cambridge Quarterly of Healthcare Ethics*, 20(2): 165-173. doi:10.1017/S0963180110000812
[12] Ibid.
[13] Ibid.
[14] Alisa Carse and Hilde Lindemann Nelson (1996). "Rehabilitating Care," *Kennedy Institute of Ethics Journal*, 6: 19-35. Quoted in Patricia A. Martin (1999). *op. cit*, note 8.

narratives can help in applying them to given situations.[15] Jonsen and Toulmin, who argue for a casuist approach, acknowledge that such an approach is based on principles.[16]

Gert, Culver and Clauser are somewhat critical of the "ad hoc nature of biomedical ethics,"[17] which has existed from the earliest days of the discipline:

> Typically, several ethical theories are presented with no attempt to reconcile them. Kant would say this, Mill would say that, and Rawls would say something else. The student naturally concludes that moral theory is either confused, irrelevant or completely relativistic. Often the anthologies suggest using one theory to solve a particular kind of problem and another theory for a different kind of problem. Yet there is neither unification among the different theories nor a clue as to how problems are to be assigned to which theory.[18]

Their book *Bioethics: A Return to Fundamentals* attempts to counteract that, attempting to develop the basis of a all-inclusive moral theory applicable to all ethical situations.[19] It is based on the assumption that we have a common morality. That foundational assumption has been queried, however – Mark Sheehan suggests that we do not necessarily share a common morality; even if we do, it must be argued for, not just assumed.[20]

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[15] Rita Charon (1994). "Narrative Contributions to Medical Ethics; Recognition, Formulation, Interpretation, and Validation in the Practice of the Ethicist," in E.R. DuBose et al., eds., *A Matter of Principles? Ferment in U.S. Bioethics.* (Valley Forge: Trinity Press). pp. 260-83. Quoted in Patricia A. Martin (1999). *op. cit*., note 8.
[16] Albert R. Jonsen and Stephen E. Toulmin (1988). *The Abuse of Casuistry: A History of Moral Reasoning.* (Berkeley: University of California Press). See also Albert R. Jonsen (1995). "Casuistry: An Alternative or Complement to Principles?," *Kennedy Institute of Ethics Journal,* 5: 237-51. Quoted in Patricia A. Martin (1999). *op. cit.*, note 8.
[17] Bernard Gert, Charles M. Culver and K. Danner Clouser (1997). *Bioethics: A Return to Fundamentals*. (New York: Oxford University Press), p. 3.
[18] Ibid., p. 4
[19] Ibid.
[20] Mark Sheehan (1997). "Book Review: *Bioethics: A Return to Fundamentals* by Bernard Gert, Charles M. Culver and K. Danner Clouser (New York: Oxford University Press)." *APA Newsletters: Newsletter on Philosophy and Medicine (1999),* 98: 2.

Similarly, Takala and others have criticised the principlist model;[21] while most may agree that the four principles are good, they may disagree as to what constitutes justice, for example, in given situations.[22]

Bennet and Cribb have proposed two models of bioethics methodology.[23] *Model One* applies the methods of moral philosophy to investigate bioethical issues. In this model, bioethics is a branch of philosophical ethics, and the tools of moral philosophy are required to solve bioethics problems, regardless of the issue in question or the academic background of the enquirer. *Model Two* sees bioethics as being inherently multidisciplinary in nature. In this model, enquirers use the methods of their own disciplines to investigate problems in bioethics.[24]

Clearly, there does not exist a methodology, or a set of methodologies, in bioethics, as there is/are in the sciences, that can be generally agreed upon. Perhaps many different approaches may be required in the search for the best ethical solution.

METHODOLOGICAL APPROACHES TO THIS RESEARCH

Given the multiplicity of methodologies that exist (and may intertwine) the task of choosing one or more can, initially, appear problematic. The analysis of ethical issues in synthetic biology is likely to benefit from a multidisciplinary approach. Philosophical reasoning is a powerful and necessary foundation of the field. Its

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[21] See, for example: Tuija Takala (2001). *op. cit.,* note 7.
[22] Ibid.
[23] Rebecca Bennett and Alan Cribb (2003). "The Relevance of Empirical Research to Bioethics: Reviewing the Debate." In Matti Hayry and Tuija Takala, eds. (2003). *Scratching the Surface of Bioethics*. (Amsterdam: Rodopi), pp. 9-18.
[24] Ibid.

methodology, of reasoned argument, is a very functional tool in a world where differing moralities exist side-by-side. It permits arguments to be thoroughly tested and evaluated. It can be used by people of very different backgrounds, academic and moral. Philosophical reasoning can also be enhanced by techniques from other fields, such as findings from empirical research,[25] and together they can be used to reach the "truth" of the matter – or at least get closer. Of course, the question posed by Gert et al – which type of philosophical reasoning – must be addressed. As divisions exist, particularly between deontologists and consequentialists, I intend to examine ethical issues in synthetic biology from both points of view; both to obtain a broader perspective of the issues, and to respect (and persuade) both sides.

It is also necessary to examine the most important legal issues relating to synthetic biology. Law at its best could be considered as the enforcement of ethics, in those situations where enforcement is necessary. In an area like synthetic biology, which has such obvious dangers, mere philosophical discussion of the issues is not enough. Ultimately it may be necessary to enforce ethical solutions (anything from self regulation to legislation or outright bans on certain types of research), to attempt to prevent dangerous scenarios from coming to pass. Otherwise, the discussion can be merely like "an abstract exercise carried on over sherry in the tutorial rooms of academic ivory towers"[26] – this being the Wellcome Trust's view on the limitations of the purely philosophical approach. It is not sufficient to talk and write philosophically about the ethics of synthetic biology. Such reflection is essential, but legal issues should also be addressed when there is potential danger, and legal debate should be informed by the discussions of ethicists. I have discussed, in Chapter 2, the main legal

[25] Bennett and Cribb (2003). *op. cit.*, note 23.
[26] Bennett and Cribb (2003). *op. cit*, note 23.

issue that affects synthetic biology: regulation. The other most significant legal issue, which space does not permit a proper evaluation of here, is intellectual property.

I have also evaluated synthetic biology from a theological viewpoint. Religious beliefs could have a significant influence on the intellectual and societal environment in which the research is done.[27] It would be useful, therefore, to examine possible theological attitudes towards synthetic biology. Another reason to include a theological discussion is that it could broaden the argument; theological and (secular) philosophical arguments could inform each other, and deepen the discussion.

Part of my methodology has involved the use of anecdotes and historical analogies. This ranges from discussing the rise and fall of synbio in the early 20th century to the effects of genetic engineering and other applications of science in the current era. In the short-term, many of synbio's results seem likely to parallel those of comparable research, as synbio is an advance on current biotech and other scientific research. It does not exist in a vacuum, it builds upon previous scientific knowledge, the successes and failures of which may be replicated, to an extent, in synbio. This can help to place synbio in a conceptual ethical and regulatory framework.

THE RESEARCH QUESTIONS

I have already mentioned my research questions, in Chapter 1. To re-iterate, and expand on those ideas, the questions are:

[27] Michael B. Berkman, Juliana Sandell Pacheo and Eric Plutzer (2008). "Evolution and Creationism in America's Classroms: A National Portrait." *PLos Biology*, 6(5): e124. doi:10.1371/journal.pbio.0060124. http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pbio.0060124&ct=1 Accessed 12/12/12.

- *Is synthetic biology ethical?* This is the core question of the thesis, to be examined using deontological and consequentialist analysis.
- Does synthetic biology impinge on God's role? Is it a sinful manifestation of human pride, or a praiseworthy use of humanity's creative powers? I have examined these questions and more by applying the teachings of the Catholic Church to the issue (I explain why I focused on Catholic teaching in Chapter 7).
- Published ethical evaluations examine the field in overview. Is this sufficient? Should the field be evaluated in more depth, at the level of day to day research, to attempt to spot dangers and benefits that may arise from research that is ethically neutral in itself but may be applicable in negative ways?
- Are the main ethical theories of bioethics adequate to decide on whether synbio is ethical? There is no single agreed methodology in bioethics, and disagreements on the most profound issues are the norm. In the case of synthetic biology, with its potential for such great destruction, as well as great benefit, such disagreements do not serve humanity well.
- Should synthetic biology be regulated? If so, how? There will be difficulties in regulating it well (see Chapters 2 and 9). I have proposed a regulatory framework that operates, according to ethical principles, on a global, national, and regional level (see Chapter 9). Adoption of such a framework may enable the development of a good regulatory regime.

PUBLISHED/PUBLISHABLE PAPERS

In light of the above discussion, I have written the following papers:

Paper 1: Consequentialism and the Synthetic Biology Problem

This paper evaluated the field using a consequentialist approach. The contents of the paper are:

(1) A description of synthetic biology and its main areas of research.

(2) Philosophical analysis: the analysis examined the morality of synthetic biology in terms of benefits and risks, by studying its probable effects on the advancement of science, agriculture and food, medicine, and fuel production. It also discussed synbio's dangers, particularly its potential use in bioweapons production, as well as the possibility of accidental release of synthetic organisms into the environment.

(3) Conclusion: as to the morality of synthetic biology in consequentialist terms.

(4) Although I had not intended to critique methodology as part of this paper, the results of my analysis were so striking regarding its limitations that I included such a critique.

The paper is under review, at the time of writing, by the *Kennedy Institute of Ethics Journal.*

Paper 2: A Deontological Analysis of Synthetic Biology:

This paper evaluates the morality of synthetic biology in deontological terms. It is structured as follows:

(1) I refer to the dual use dilemma, which inevitably occurs in consequentialist analysis, and suggest that a deontological analysis may eliminate this problem by evaluating whether synthetic biology is ethical in itself.

(2) I evaluate whether synbio challenges the integrity of nature, the dignity of life, and the relationship between God and his creation. For this latter point, I examine, briefly, the attitudes of the major world religions to the research as well as secular attitudes to "playing God."

(3) Conclusion: as to the morality of synthetic biology in deontological terms.

(4) I then evaluate the usefulness of deontology as an appropriate methodological paradigm for evaluating synbio ethics. As with consequentialism, deontology's limitations here are striking. However, combining the two ethical theories leads to greater ethical truth.

The paper has been accepted for publication in *Bioethics*.[28]

<u>Paper 3: The Place of God in Synthetic Biology: How will the Catholic Church Respond?</u>

There have been very few religious evaluations of synthetic biology so far. I have provided such an evaluation, developing a (likely) Catholic theology of synthetic biology.

The structure of the paper is as follows:

[28] Patrick Heavey (2013). "Synthetic Biology: A Deontological Assessment." *Bioethics* Special Issue on Synthetic Biology, November.

(1) A description of the essence of the Catholic Church, and of its teaching authority (*Magisterium*), according to its own self understanding – because this is unlikely to be known by most readers. This includes the levels of authority within the Magisterium, which relate to the different levels of truth that exist. I have explained how the Catholic faithful are required to respond to Magisterial teachings, and how these teachings relate to and should be responded to by the world at large.

(2) A description of the Church's attitude to science in general, and biotechnology in particular.

(3) Inference of a probable Catholic teaching on synthetic biology, based on Magisterial pronouncements on other areas of biotechnology and science. Such documents included papal encyclicals and other papal teachings, documents of the Congregation of the Doctrine of the Faith[29] (which is in charge of doctrinal matters), the *Catechism of the Catholic Church*[30], the *Compendium of the Social Doctrine of the Church*[31], and documents and conference proceedings of the Pontifical Council for Life. I also referred to relevant academic literature.

This paper has been published in *Bioethics*.[32]

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[29] Congregation for the Doctrine of the Faith (2012). *Complete List of Documents*. http://www.vatican.va/roman_curia/congregations/cfaith/doc_doc_index.htm Accessed December 10th 2012.

[30] *Catechism of the Catholic Church* (1993). http://www.vatican.va/archive/ENG0015/_INDEX.HTM Accessed December 10th 2012.

[31] Pontifical Council for Justice and Peace (2004). *Compendium of the Social Doctrine of the Church.* http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html Accessed December 10th 2012.

[32] Patrick Heavey (2011). "The Place of God in Synthetic Biology: How Will the Catholic Church Respond?" *Bioethics* (2013) 27(1): 36-47. doi:10.1111/j.1467-8519.2011.01877.x

Paper 4: Integrating Ethics "into the DNA" of Synthetic Biology

The paper is structured as follows:

(1) A brief discussion of how everyday synbio research tends to have few, if any, ethical implications.

(2) A brief historically based discussion of how results from ethically unproblematic research may be combined, downstream, with those from equally ethically unproblematic research, to create an output which raises significant ethical concerns.

(3) An approach is suggested to deal with this; namely ethically evaluate all synbio research at all levels, and how research outputs interact with each other. Synthetic biology's knowledge structure offers a "map" with which to approach this.

(4) Also, I suggest that synthetic biologists be required to evaluate the ethics of their research as a requirement for publication.

This paper has been submitted to *Medicine, Healthcare and Philosophy.*

Paper 5: Global Health Justice and Governance for Synthetic Biology

The paper is structured as follows:

(1) A description of a theory of global health governance for healthcare, developed by Jennifer Prah Ruger,[33] which operates on global, national and regional levels, and is based on ethics.

[33] Jennifer Prah Ruger (2012). "Global Health Justice and Governance." *American Journal of Bioethics.* 12(12): 35-54. doi: 10.1080/15265161.2012.733060

(2) The need for regulation of synbio, of a type that permits beneficial applications of the research to flourish, while minimising the risks.

(3) A linking of the global health governance theory to synbio regulation's requirements.

The paper has been published, as an open peer commentary, in the *American Journal of Bioethics.*[34]

CONCLUSION

Because synthetic biology is potentially so important, I have evaluated it using deontological, consequentialist and theological analysis to get as broad a perspective as possible. I examined the efficacy of the methodologies, both solely and in combination with each other. I also examined whether the current approach of examining its ethics, by evaluating the field at an overview level, was adequate. I applied insights obtained from the ethical evaluation to propose a regulatory framework from which a good regulatory regime could be developed. It is important at this early stage of synthetic biology, when the field is in its infancy, to evaluate it ethically from as broad a perspective as possible, and decide on appropriate regulation. More specialised evaluations, which are also essential, can come later.

[34] Patrick Heavey (2012). "Global Health Justice and Governance for Synthetic Biology." *American Journal of Bioethics*,12(12): 64-65. doi: 10.1080/15265161.2012.739840.

PART II ARTICLES SUBMITTED FOR PUBLICATION

CHAPTER 5 CONSEQUENTIALISM AND THE SYNTHETIC BIOLOGY PROBLEM

Currently under review at the *Kennedy Institute of Ethics Journal*

ABSTRACT

In this paper I analyse the ethics of synthetic biology from a consequentialist perspective, examining potential effects on food and agriculture, on medicine, and fuel; I also examine the issues of biosafety and biosecurity. A consequentialist analysis offers an essential road map to policymakers and regulators as to how to deal with synbio. I also discuss the limitations of consequentialism as a tool for analysing synbioethics. Is it possible to predict, with any degree of plausibility, what the consequences of synthetic biology will be in 50 years time, or 100, or 500? Synbio may take humanity to a place of radical departure from what is known or knowable.

If the painter wishes to see features that would enrapture him, and if he wishes to see monstrous things… he is their lord and god… In fact, therefore, whatever there is in the universe through essence, presence or imagination… he has to find it in his mind and thus in his hands.

Leonardo da Vinci[1]

INTRODUCTION

Synthetic Biology, the attempt to create new life, or engineer existing life to desired specifications,[2] [3]may be the most daring step taken in scientific, indeed human, history. Its ethical implications are profound; it has been suggested that it may pose the greatest ethical challenge ever faced by humanity.[4]

Synthetic biology, in its current incarnation, could be said to have formally begun in 2004, with the first synthetic biology conference, *Synthetic Biology 1.0* at MIT. (Obviously research was taking place before that.) However, the phrase was first coined in the early 20th century by Stephane Leduc, a French professor of medicine.[5] He spent some years trying to create synthetic life,[6] and wrote, in 1911:

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[1] Leonardo da Vinci (undated). *A Treatise on Painting*.
[2] ETC Group (2007). *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. (Ottawa, ON: ETC Group), p. 1. www.etcgroup.org/upload/publication/pdf_file/602 Accessed May 30th 2012.
[3] Parliamentary Office of Science and Technology (2008). Synthetic Biology. *Postnote*. January 2008, Number 298.
[4] Julian Savulescu (2009). *Panel discussion: Perspectives on synthetic biology: Ethics, public engagement, biosecurity and more*. With Matthew Harvey (Senior Policy Advisor, Royal Society); Piers Millet (Biological Weapons Convention Implementation Support Unit, UN Office, Geneva); Drew Endy (Stanford University), *IET BioSysBio Conference*, Cambridge, 23rd-25th March.

[5] Luis Campos (2009). "That was the Synthetic Biology that was. In Markus Schmidt, Alexander Kelle, Agamoni Ganguli-Mitra, Huib de Vriend (editors). *Synthetic Biology: The Technoscience and its Societal Consequences*. (Dordrecht: Springer), pp. 5-21.
[6] Ibid. p. 7.

> The course of development of every natural science has been the same. It begins by the observation and classification of the objects and phenomena of nature. The next step is to decompose the more complex phenomena in order to determine the physical mechanism underlying them – the science has become analytical. Finally, when the mechanism of a phenomenon is understood, it becomes possible to reproduce it, to repeat it by directing the physical forces which are its cause – the science has now become synthetical.
>
> Modern biology admits that the phenomena of life are physic-chemical in their nature… every further discovery confirms our belief that the physical laws of life are identical with those of the mineral world and modern research tends more and more to prove that life is produced by the same forces and subject to the same laws that regulate inanimate matter.[7]

Leduc's observation appears correct, and the progression he describes has been displayed in physics and chemistry, and their applications to engineering. It has not been displayed in biology, however, until the recent advent of synthetic biology, the reason being that the necessary background knowledge was not there: Leduc, and later generations of scientists, had no knowledge of modern biochemistry and molecular biology, including the science of DNA. The current state of biological science, and the application of engineering methodology to it, which includes the integration of knowledge from disciplines such as physics, chemistry, nanotechnology, mathematics and computer science, has led to current attempts at synthetic biology. The science is in its infancy and it remains to be seen whether it will succeed and become a mature science. It appears that there is potential for it to do so. But it could also be that the scientific knowledge of this era is still not advanced enough for humanity to create life.

If synbio succeeds, the consequences are likely to be profound. The popular online literature abounds with references to the creation of superhumans, for example, and the radical harnessing of nature to be more in tune with humanity's needs. It is

[7] Stephan Leduc (1911). *The Mechanism of Life*. (London: William Heinemann), p. 114.

possible that a successful synbio will be used for such purposes. At present, though, synthetic biology pioneers (who are working at the cutting edge of science, and indeed human intellectual endeavour) are researching at the microbial level, and there is no guarantee of ultimate success.

Synthetic biology is an umbrella term that covers a variety of research fields, each quite different in aims and methodologies, and also in ethical implications. They share the common factor of attempting to engineer and create aspects of artificial life. Its practitioners are drawn from a variety of scientific and engineering disciplines. The main research areas are:

- Design of DNA, to achieve desired properties/functionality in organisms;
- Metabolic (or pathway) engineering – engineering the metabolisms of cells to produce chemicals, such as drugs or fuel;
- The minimal microbe genome – finding the minimum number of genes that are essential for microbial life. These could then be used as a chassis on which to build new, designed, life forms;
- Expanding the genetic code, i.e., discovering chemical combinations that can act as alternatives to DNA;
- Protocells – artificial cells, whose design is based on, but far simpler than, naturally occurring cells.[8]

These are the main sub-fields, but some research doesn't quite fit within these parameters. For example, research funded by the EU in recent years includes: fusion

[8] ETC Group (2007). *op. cit.,* note 2.

of nanoscale machines with living organisms (the machine-life interface), tuning natural protein-based motors, and building biological computers from cells.[9]

Just as synthetic biology has its foundation in a convergence of different sciences, it is possible, if the field succeeds, that these different branches of research will converge and be applied in more complex ways, possibly to create higher lifeforms.

In this paper, I will evaluate the ethics of synthetic biology from a consequentialist perspective. Rather than examine the ethics of the sub-fields individually, I will evaluate sybio ethics under some likely applications of these research areas, as that is a more intuitive approach. Therefore I will examine synthetic biology's potential effects on the advancement of science per se; also on agriculture, medicine and fuel. I will also discuss biosecurity (the danger of deliberate malevolent use) and biosafety (the danger of accidental damage to the environment by, for example, accidental release of a synthetic organism)[10] [11] – these latter two are the most commonly discussed in the relatively (and surprisingly) sparse literature that exists on the subject.

Such a study yields essential insights into the ethics of synthetic biology. It also raises a question: is a consequentialist approach adequate for examining the

[9] European Community (2007). *EUR 22426 – Synthetic Biology – A NEST Pathfinder Initiative.* (Luxembourg: Office for Official Publications of the European Communities). ftp://ftp.cordis.europa.eu/pub/nest/docs/5-nest-synthetic-080507.pdf Accessed March 23rd 2012.

[10] IDEA League Summerschool *Synthetics: The Ethics of Synthetic Biology*. The Netherlands, 2007. http://www.ethicsandtechnology.eu/images/uploads/Ethics_of_synthetic_biology.pdf Accessed May 30th 2012.

[11] See, for example, Andrew Martin and Paul Balmer (2008). *Synthetic Biology: Social and Ethical Challenges*. (Swindon, Wilts: Biotechnology and Biological Sciences Research Council). http://www.bbsrc.ac.uk/organisation/policies/reviews/scientific_areas/0806_synthetic_biology.pdf Accessed May 30th 2012.

ethics of humanity creating life? Synbio may present challenges to consequentialism like nothing that has gone before. Although consequences can rarely be predicted to a high degree of certainty, the uncertainties introduced by synbio may be so great as to ask whether consequentialist analysis is meaningful beyond a very limited time horizon.

EFFECTS ON THE ADVANCEMENT OF SCIENCE

> *Knowledge for its own sake… knowledge of truth; knowledge sought out as the pure desire to know, to find out the truth… simply out of an interest in or a concern for truth and a desire to avoid error or ignorance… The good is not the knowledge of truth obtained, it is the pursuit of knowledge of truth that is the good… it is the quest that matters, and behind the quest, the motivation – curiosity… Knowledge is an aspect of authentic human flourishing.*
>
> J.W. Harris[12]

At first glance, it appears that synthetic biology's potential effects on science, in itself, are likely to be positive – indeed overwhelmingly so, and for all of its research areas. The Nobel prize-winning physicist Richard Feynman summarised much of his scientific thinking with: "what I cannot create, I do not understand."[13] [14] Biology is extremely complex, and biological knowledge is still quite primitive compared to that in other scientific disciplines. A leading researcher has stated that its

[12] J.W. Harris (1997). *Legal Philosophies,* 2nd edition. (Oxford: Oxford University Press), pp. 60 and 64.

[13] George Church and Ed Regis (2012). *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves.* (New York: Basic Books), p. 177.

[14] This quotation is encoded, as a "watermark," into the DNA of *Synthia*, the world's first synthetic cell, where it has been slightly changed to: "What I cannot build, I cannot understand." There are two other quotes encoded in *Synthia's* genome: "To live, to err, to fall, to triumph, and to recreate life out of life" (James Joyce, *Portrait of the Artist*); and "See things not as they are but as they might be" (J. Robert Oppenheimer). In David Biello and Katherine Harmon (2010). "Tools for Life: What's Next for Cells Powered by Synthetic Genomes?" *Scientific American,* August. http://www.scientificamerican.com/article.cfm?id=tools-for-life; and Aaron Saenz (2010). "Secret Messages Encoded into DNA of Venter Synthetic Bacteria." *Singularity Hub*, May 24th. Available at: http://singularityhub.com/2010/05/24/venters-newest-synthetic-bacteria-has-secret-messages-coded-in-its-dna/ Accessed May 30th 2012.

current state compares with the state of physics knowledge in the 17th century.[15] Undoubtedly, advances in synthetic biology, "building" life, will help to advance the overall field of biology, adding significantly to human knowledge. Consequent advances in derivative fields such as medicine, agriculture and fuel production are likely to result. If the field succeeds, it is likely to lead to a change in human civilisation as significant as the industrial or, indeed, the Copernican revolution.

The opening quote, from J.G. Riddal, is a useful description of the scientific quest when it's at its best, its most pure. But it can be asked whether the scientific quest is always pure? Is weapons research a good thing? Even research in pure science, and the unveiling of the natural world, can have negative consequences. Albert Einstein's discovery of the relationship between mass and energy, $e=mc^2$, was applied to develop the atomic bomb. He later commented on his discovery: "If I had only known, I would have been a locksmith."[16] Leaving aside societal and moral issues, are such developments beneficial to science in itself?

This raises the question: should all experiments be allowed – should anything that can be done, be done? It is clear that the answer must be no. Few would attempt to justify Dr. Josef Mengele's experiments on concentration camp inmates. Nobel Prize winning biologist Peter Medawar described the attitude "if we can do it, let's do it" as "a source of temptation."[17] Erwin Chargaff, one of the founders of molecular biology, described "the devil's doctrine" as being: "what can be done must be

[15] Minoru Kanehisa (2000). *Post-Genome Informatics*. (Oxford: Oxford University Press), p. 24.
[16] Glen Elert (2012). *The Physics Hypertextbook: Nuclear Weapons.* http://hypertextbook.com/physics/modern/weapons/ Accessed May 30th 2012.
[17] Peter Medawar (1990). *The Threat and the Glory: Reflections on Science and Scientists*. (Oxford: Oxford University Press), p. 17.

done."[18] And Francis Bacon's description of sin was "the effecting of all things possible."[19] Science, like all areas of human endeavour, can be ethical or unethical.

It also raises the question: how is scientific progress defined? Was the atomic bomb progress? Are biological weapons? There was a time when science was seen as a solution to the world's problems; that optimism no longer exists, generally. Scientific knowledge can be applied in good or bad ways. When it's applied in bad ways, it tends to have negative consequences; additionally, public confidence in it diminishes, and it may fail to attract funding and new generations of talent.

Synthetic biology is a dual use field of research, i.e., it could be used for good or evil. While almost everything in life could be considered dual use – a stone, fire, the spoken or written word,… the potential for both good and evil in synbio is extreme – possibly far greater than for anything that has occurred previously in human history.

Negative perceptions of synbio, and negative outcomes, pose dangers. The present era is marked by a rising scepticism against scientific thinking, ranging from indifference to hostility.[20] Such scepticism is not a majority view – yet – but it could become so. If it does, there could be very negative consequences for science, possibly putting its dominance in Western culture under threat. A disaster, or worse, multiple disasters, in synthetic biology research are likely to increase anti-science feelings; in the worst case, to a degree which may greatly undermine science.

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[18] Ibid.
[19] Ibid.
[20] PA (2011). "Attenborough Sees Conditions of Life on Earth Eeteriorating." *Irish Times*, 18th October.

It is worth describing, briefly, the main sources of anti-science rhetoric, to put this in context. Anti-science feeling tends to be strongest in the US, the world centre of scientific research. It occurs most significantly in certain subgroups on both the academic left and the political right.

On the left, in a movement that reached its heyday in the 1990s and provided, to an extent, an intellectual foundation for current conservative attacks on science, some philosophers and social scientists rejected the very idea that there is such a thing as a scientifically observable reality that can be objectively studied; instead positing a subjectivist approach to truth. [21] Such challenges occurred in the postmodern context, in which the grand narratives of western society had largely collapsed, to be replaced by greater individualism, greater freedom from restraints such as social class, and a diminishment of universally held perspectives. [22] Narratives, including scientific and religious world views, may remain, but allegiance to them is not universal.[23] There are many who argue that science is a mere social construct, without inherent truth.

An idea of the mentality here was revealed by a 1994 publication, by physicist Alan Sokal; he challenged such critics by submitting a hoax anti-science paper to a leading social studies journal, *Social Text*.[24] The paper was, in Sokal's own words "a mélange of truths, half-truths, quarter-truths, falsehoods, non sequiturs, and

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[21] Paul R. Gross and Norman Levitt (1998). *Higher Superstition: The Academic Left and Its Quarrels With Science*. (Baltimore, MD: Johns Hopkins Press).
[22] Jean Francoise Lyotard (1984). *The Postmodern Condition: A Report on Knowledge*. Geoff Bennington and Brian Massumi (trans.). (Minneapolis, MN: University of Minnesota Press).
[23] Lieven Boeve (2003). *Interrupting Tradition*. (Leuven: Peeters Press).
[24] Alan D. Sokal (1996). "Transgressing the Boundaries - Toward a Transformative Hermeneutics of Quantum Gravity," *Social Text*, 46/47, 217-252. An annotated version of the paper, describing its deliberate errors, is available in Alan Sokal (2008). *Beyond the Hoax: Science, Philosophy and Culture*. (Oxford: Oxford University Press).

syntactically correct sentences that have no meaning whatsoever;"[25] written that way so as to be "like the genre it is meant to satirize."[26] It argued, with bad logic, for absurd conclusions, such as that the values for pi and the universal gravitational constant no longer held true. He quoted various anti-science commentators from various fields, for example Jacques Derrida: "The Einsteinian constant is not a constant, is not a center. It is the very concept of variability -- it is, finally, the concept of the game. In other words, it is not the concept of something – of a center starting from which an observer could master the field – but the very concept of the game." Nobel prize winning physicist Steven Weinberg commented on this: "I have no idea what this is intended to mean."[27] *Social Text* published Sokal's paper in a special issue devoted to anti-science. When he revealed his hoax,[28] the editors did not accept that intellectual standards in their journal or their field were a problem; rather, they reacted with anger.[29]

In Sokal's words, to say that "physical reality is a social and linguistic construct" is just plain silly;[30] he referred to an assault on science by "the barbarian hordes of lit. crit."[31] He made an open invitation to those who deny the objective truths of science: "Anyone who believes that the laws of physics are mere social conventions is invited to try transgressing those conventions from the windows of my apartment. I live on the twenty-first floor."[32]

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[25] Alan Sokal (1996) "Transgressing the Boundaries: An Afterword." *Dissent*, 43(4): 93-99. http://physics.nyu.edu/sokal/afterword_v1a/afterword_v1a_singlefile.html Accessed May 30th 2012.
[26] Ibid.
[27] Steven Weinberg (1996). "Sokal's Hoax." *The New York Review of Books*, XLIII(13): 11-15. http://www.physics.nyu.edu/faculty/sokal/weinberg.html Accessed May 30th 2012.
[28] Alan D. Sokal (1996). "A Physicist Experiments with Cultural Studies," *Lingua Franca*, May/June, 62-64.
[29] Steven Weinberg (1996). *op. cit.*, note 27.
[30] Alan Sokal (1996). *op. cit*., note 25.
[31] Ibid.
[32] Ibid.

Such statements, though, are rejected by many influential "postmodernist/poststructuralist/social-constructivist"[33] academics. I once attended a history of science seminar at Harvard University. I was amazed at the confidence with which faculty and graduate students asserted that scientific discoveries do not represent any kind of truth. One of the most famous attacks on the integrity of science was quoted with approval – feminist philosopher Sandra Harding's claim that Newton's mechanics could be referred to as "Newton's rape manual," as scientific study violated nature just as rape violates a woman.[34] (Her book in which this was argued won an award from the American Sociological Association.)[35] At this meeting, a defence of science would have been equivalent to heresy or blasphemy among a Medieval Christian group. In conversations with Ivy League students, undergraduate and graduate (in various disciplines including science), I have been told that science's discoveries are not and cannot be objectively true, and that science is, inherently misogynistic; this latter view being "proved" by the existence of "offensive" terminology such as "big bang."

The damage that such attitudes, held at the highest levels of academia, could do to science should not be underestimated. Such attitudes could become seriously problematic if those who hold them come to influence government policy on science, including its funding.

On the US's political right, opposition to evolution is becoming increasingly common, usually on religious grounds. There is also strong opposition to scientific

[33] Ibid.
[34] Sandra Harding (1986). *The Science Question in Feminism*. (Ithica, NY: Cornell University Press).
[35] American Sociological Association (2011). *Jessie Bernard Major ASA Award*. http://www.asanet.org/about/awards/bernard.cfm Accessed May 30th 2012.

consensus on man-made global warming.[36] Here scientific analysis is frequently rejected, without any scientific counter-arguments being offered, or any intellectual engagement at all. Chris Mooney, author of the *Republican War on Science*,[37] notes that under the Bush administration, attempts were made to suppress scientific research, and to ignore published findings in areas such as environmental regulation, where those findings challenged prevailing ideologies or business interests.[38] He proposes several reasons for conservative hostility to science. First, conservatism tends to value the preservation of society's status quo, and is threatened by the inherent subversiveness of science, which constantly generates new ideas and technologies, and is based on the search for truth, without deference to authority. This conflict has occurred repeatedly in history, the Galileo and Darwin controversies being good examples.[39] In the US, a certain political mix can be added to this: the influence of corporate interests and the religious right, combined with a distrust of big government, for which much of science is dependent for funding.[40] In addition, anti-intellectualism is common among many present-day US conservatives; and science could be seen as the pinnacle of intellectualism.

As one moves rightward in the political spectrum, anti-science viewpoints become less amenable to change by reasoned argument. A Yale study on political attitudes to global warming showed that those Tea Party members who reject science's findings are most likely to say that they "'do not need any more

[36] Joseph Romm (2008). "Anti-science Conservatives Must Be Stopped." *Salon.com*, June 30th. http://www.salon.com/2008/06/30/climate_act/ Accessed May 30th 2012.
[37] Chris Mooney (2006). *The Republican War on Science*. (New York: Basic Books).
[38] Ibid.
[39] Ibid.
[40] Ibid.

information'…to make up their mind."[41] The following quote, from a conservative Christian website, illustrates the attitudes of some: "There is no truth in science: laws of science are a human invention; empiricism is not a source of truth; science is never true but can be useful;"[42] and "science has nothing of any value to offer faith."[43] The following quote from a Republican official is also telling: he "dismissed "the reality-based community,"[44] stating that "we're an empire now, and when we act, we create our own reality."[45]

With such a mentality, people can blithely reject scientific findings, or righteously believe in their opposite. This is significant because such views have entered into the mainstream in the US's Republican Party, and have influenced science policy.[46] [47] They are held by large sections of society. 2012 US presidential candidate Mitt Romney stated that he believed that climate change was taking place, as a result of human activity. To which radio host Rush Limbaugh said: "there goes the nomination." Subsequently, Romney drew back from that position.[48]

In March 2011, US presidential scientific advisor John Holdren arranged for climate change scientists to address the American Congress. Their presentation of the

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[41] Anthony Leiserowitz, Edward Maibach, Connie Roser-Renouf, and Jay D. Hmielowski (2011) *Politics & Global Warming: Democrats, Republicans, Independents, and the Tea Party*. (New Haven, CT: Yale Project on Climate Change Communication; and Fairfax, VA: George Mason University Center for Climate Change Communication), p. 4. http://environment.yale.edu/climate/files/PoliticsGlobalWarming2011.pdf Accessed May 30th 2012.
[42] www.truthdefined.com (2011). "There is No Truth in Science." http://www.truthdefined.com/4-NoTruthInScience.htm Accessed May 30th 2012.
[43] Ibid. "Science and Faith." http://www.truthdefined.com/75-Science&Faith.htm Accessed May 30th 2012.
[44] Chris Mooney (2006). op. cit., note 37, p. 266
[45] Ibid.
[46] Ibid.
[47] Karen Tumulty and Mark Thompson (2006). "The Political Science Test." *Time Magazine*, 5th February. Available at: http://www.time.com/time/magazine/article/0,9171,1156577-1,00.html Accessed May 30th 2012.
[48] Shawn Lawrence Otto (2011). "Decline and Fall." *New Scientist*, 212(2836): 38-42.

scientific facts did not convince climate change sceptics, however; rather, it caused opposition to increase. *New Scientist* bureau chief Peter Aldhouse observed:

> Holdren's prescription was a classic example of the "deficit model" of science communication, which assumes that mistrust of unwelcome scientific findings stems from a lack of knowledge. Ergo, if you provide more facts, scepticism should melt away. This approach appeals to people trained to treat evidence as the ultimate arbiter of truth. The problem is that in many cases, it just doesn't work.
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> Perversely, just giving people more information can sometimes polarise views and cause sceptics to harden their line. "We can preach the scientific facts as long as we want," says Dietram Scheufele, a specialist in science communication at the University of Wisconsin-Madison. "This is replicating the same failed experiment over and over again.[49]

A number of causes have been identified for the retreat from the scientific worldview. As well as the postmodern context, inherent conservative suspicion, and the rise of fundamentalist religion, factors such as the use of science to develop weapons of mass destruction, pollution arising from industrialisation, and environmental disaster are significant.[50] The incomprehensibility of many scientific publications (even to researchers in closely related fields), combined with a general reluctance of scientists to explain research to the public, are also factors.[51] [52]

Anti-science sentiment is strongest in the US. It is not unique to America, however; such sentiments are arising in Europe and elsewhere.[53] In this intellectual

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[49] Peter Aldhouse (2011). "Don't Tell It So Straight." *New Scientist*, 212(2836): 42-45.
[50] Shawn Lawrence Otto (2011). "Special Report – Science in America: Decline and Fall." *New Scientist*, 212(2836): 38-42.
[51] Peter Aldhouse (2011). *op. cit.*, note 49.
[52] Zachary F. Meisel and Jason Karlawish (2011). "Narrative vs Evidence-Based medicine – And, Not Or." *Journal of the American Medical Association*, 306(18): 2022-2023. doi: 1 0.1001/jama.2011.1648; and Katherine Harmon (2011). "Does Science Need More Compelling Stories to Foster Public Trust?" *Scientific American Blogs*, 8th November. http://blogs.scientificamerican.com/observations/2011/11/08/does-science-need-more-compelling-stories-to-foster-public-trust/ Accessed May 30th 2012.
[53] Almut Graebsch and Quirin Schiermeier (2006) "Anti-evolutionists Raise their Profile in Europe." *Nature*, 444: 406-407. doi:10.1038/444406a;
Vienna Leigh (2008). "Interview with Steve Jones: The Threat of Creationism." *Science in School*, 9: 9-17. http://www.scienceinschool.org/2008/issue9/stevejones Accessed May 30th 2012. In Australia,

environment, the rise of synbio could pose problems for the entire enterprise of science. A number of disasters caused by synbio could lead to an increased turning away from science in Western culture. Even without disasters, an improper public presentation of it – media stories about "Frankenstein science," for example – could be very damaging.[54] Even the mere existence of synbio could cause problems when it becomes more widely known. When Craig Venter published the details of his *Synthia* creation, a large number of hostile comments arose on internet forums.[55] Synthetic biology, probably science's greatest advance, its creative peak, has the potential to lead to a further diminution in respect for science.

The scientific era is a relatively small portion of human history. In the worst case, synbio gone wrong could be a step towards its end. Is that going too far? One would hope so. But the threat appears real. Richard Dawkins has noted that on a visit to a London bookshop, he saw three times as many books on crystals, fortune-telling and fairies as he did on science. He observed that: "The enlightenment is under threat. So is reason. So is truth. So is science."[56] Paul Nurse, winner of the Nobel Prize in Physiology or Medicine, and current president of the Royal Society, wrote, in a 2011 *New Scientist* editorial on the rise of antiscience, that: "It is time to reject political

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Sydney's Cardinal Pell is an outspoken opponent of the scientific consensus on climate change – see Cardinal George Pell (2011). "The Tablet Speeches – Pell Attacks Climate Change Propagandists." *The Tablet*, 4th November. Available at: http://mobile.thetablet.co.uk/blogsub.php?id=196&ti=18 Accessed May 30th 2012.

[54] See for example: John Schwartz (2007). "Of Gay Sheep, Modern Science and the Perils of Bad Publicity." *New York Times*, 25th January. http://www.nytimes.com/2007/01/25/science/25sheep.html?_r=1&scp=1&sq=gay%20sheep&st=cse Accessed May 30th 2012.

[55] Manuel Porcar et al (2011). "The Ten Great Challenges of Synthetic Life." *Systems and Synthetic Biology*, 5(1-2): 1-9.

[56] Sarah Cassidy (2006). "Dawkins takes Fight Against Religion Into the Classroom." *The Independent*, 27th November http://www.independent.co.uk/news/education/education-news/dawkins-takes-fight-against-religion-into-the-classroom-426057.html Accessed May 30th 2012.

movements that reject science and take us back into the dark rather than forward into a more enlightened future."[57]

It isn't just scientists who are raising this concern. Pope Benedict XVI has also written on the issue. In an Encyclical on the current economic and social crisis, *Caritas in Veritate*, he observed: "today… we are witnessing an upsurge of ideologies that deny *in toto* the very value of development, viewing it as radically anti-human and merely a source of degradation. This leads to a rejection, not only of the distorted and unjust way in which progress is sometimes directed, but also of scientific discoveries themselves, which, if well used, could serve as an opportunity of growth for all. The idea of a world without development indicates a lack of trust in man and in God."[58]

The hostility to science is part of a broader disengagement with rationality and reason."[59] In certain academic circles, concepts such as evidence and objectivity are sneered at.[60] Al Gore has written of a lessening of reason in public life, resulting in a "vacuum… filled by fear, superstition, ideology, deception, intolerance…"[61]

Anti-scientific prejudice is not unique to our era. In 1923, the Nobel Prize winning physicist, Robert Millikan, wrote, in the era of the Scopes monkey trial, that creationists were: "men whose decisions have been formed, as are all decisions in the

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[57] Paul Nurse (2011).. "Editorial: Stamp Out Anti-Science in US Politics." *New Scientist*, 211(2830): 5.

[58] Benedict XVI (2009). *Caritas in Veritate*. (Vatican City: Libreria Editrice Vaticana), para 14. http://www.vatican.va/holy_father/benedict_xvi/encyclicals/documents/hf_ben-xvi_enc_20090629_caritas-in-veritate_en.html Accessed May 30th 2012.

[59] Al Gore (2007). *The Assault on Reason*. (New York: Penguin), p. 3

[60] Ophelia Benson (2002). "Higher Superstition Revisited: An Interview with Norman Levitt." *Butterflies and Wheels*. http://www.butterfliesandwheels.org/2002/higher-superstition-revisited-an-interview-with-norman-levitt/ Accessed May 30th 2012.

[61] Al Gore (2007). *op. cit*., note 59, p.21

jungle, by instinct, by impulse, by inherited loves and hates, instead of by reason. Such people may be amiable and lovable, just as is any house dog, but they are a menace to democracy and to civilization."[62] Millikan also observed, in the same book: "the history of central Asia, once at the center of the earth's civilization, and again, the very recent history of Russia, both show that it is possible to destroy civilization completely in a very few years of time."[63]

The Islamic world was once pre-eminent in world science (from the 8th to the 15th centuries), and some ideas that were developed there still influence modern science.[64] Various causes have been posited for it scientific decline, including financial and political deterioration of the Islamic world, the rise of a new religious paradigm which saw scientific enquiry as inimical to faith, and the ever-increasing relative power of the West.[65] The decline of science in the Islamic world had far-reaching effects on its society, which last to the present era. What happened there is proof that a scientific era can end.

Another relevant issue is the economic environment in which synthetic biology exists. Traditionally, scientific advances have been shared openly via peer-reviewed journals. Status is obtained in the profession by the quality and number of discoveries and publications. A different scenario has come into being in some of areas of biotechnology, however, where many discoveries are now being patented, and scientific knowledge is being privatised. It is within this environment that synthetic biology is coming into being, and patents are being applied for many

[62] Robert Andrews Millikan (1925). *Science and Life*. (Freeport, NY: Books for Libraries Press), p. 76
[63] Ibid., p. 75.
[64] Jim Al-Khalili (2012). *Pathfinders: The Golden Age of Islamic Science*. (London: Penguin).
[65] Sayyed Misbah Deen (2011) *Science Under Islam: Rise, Decline and Revival*. (Raleigh, NC: LULU).

foundational discoveries, such as the minimal microbe genome.[66] If a new field of science comes of age in such an environment, and becomes successful, it may have a knock-on effect throughout science.

It is worth quoting Millikan again: in his view science is not about the making of money. Rather, "in the final analysis, the thing in this world that is of the most supreme importance, indeed the thing which is of most *practical* value to the race, is not, after all, useful discovery or invention, but that which lies far back of them, namely, "the way men think" – the kind of conceptions that they have about the world in which they live and their own relations to it. It is this expanding of the mind of man, this clarifying of his conceptions through the discovery of truth which is the immediate object of all studies in the field of pure science."[67]

The corporate, profit-driven economic and political environment in which synthetic biology is coming into being challenges such a conception of science. Synthetic biology in itself is neutral on such issues, and there is also a large open source movement within it, acting in opposition to the profit-driven approach; it maintains traditional scientific values. Yet if the profit-driven approach comes to predominate – and it appears to be becoming ever more powerful – then the success of synthetic biology in such an environment could lead to an erosion of scientific values, spreading throughout the sciences. It could corrupt science to its core.

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[66] Peter Aldhous (2007). "Tycoon Seeks Patent for 'Minimal Genome.'" *New Scientist,* 8th June 2007. http://www.newscientist.com/article/dn12021-tycoon-seeks-patent-for-minimal-genome.html Accessed May 30th 2012.

[67] Robert Andrews Millikan (1925). *op. cit*., note 62, p. 2-3.

On balance, synthetic biology appears to offer both potentially positive and negative effects for science *per se*. Positives could be revolutionary in scope. So could negatives. The ethical dilemma of synthetic biology can, perhaps, be summed up by a *Wired* magazine headline: “Reverse evolution: scientists know how to turn a chicken into a dinosaur. What could possibly go wrong?”[68] Unfortunately, plenty could go wrong; possibly beyond our ability to imagine. Synthetic biology could herald new scientific and industrial revolutions, yielding new depths of knowledge about the essence of life. But there is potential for disaster in this research too, and also irrational panic; if these come to pass, it could have long-term negative consequences for the enterprise of science.

EFFECTS ON AGRICULTURE

Some recent research hints at synbio’s potential for revolutionising the food supply. A Dutch scientist, Mark Post, has manufactured synthetic beef by removing stem cells from cow muscle and using them to create synthetic beef protein. This technology, though in its infancy, indicates where a mature synbio may lead. As synthetic biology becomes more successful, it may be feasible to synthesise food, ending the problems caused by failed harvests. It has the potential, if successful, to end world hunger, alleviate much animal suffering, and minimise the land use needed for farming (hugely important in an era where population increase requires ever more land for food cultivation, and habitation).[69] Throughout history, food shortages and

[68] *Wired* (US edition) (2011). *Headline, front page*. October.
[69] Becky Ham (2012) “Meat from the Lab, Soon Ready for Market.” *American Association for the Advancement of Science Annual Meeting News*. http://news.aaas.org/2012_annual_meeting/0219the-new-meat.shtml Accessed February 28th 2012.

famines have been frequent. Could synthetic biology help? Or make things worse? There is great promise, but there are also potential negatives.

One such negative is that nature may not respond to synthetic organisms being placed in its midst in a manner that is convenient to humans. An example, from a relatively simple genetic engineering scenario, illustrates the problem. Recent studies have shown that several weed species in the US have become immune to a major weedkiller, *Roundup*. This is significant, because many crops have been genetically engineered to depend for their survival on the use of this weedkiller. An entire crop can be sprayed with Roundup, which is non-toxic for humans and animals; only the weeds die. Currently, 93% of US soya beans are Roundup resistant, as are the majority of cotton and corn. But between 2007 and 2011, there has been a fivefold increase in weeds that are Roundup resistant.[70]

Genetic variation in the weed population meant that while most were killed by Roundup, a few outliers were not; these survived repeated application of the weedkiller, and passed their advantageous genes onto their offspring, resulting in the evolution of weeds that were Roundup resistant. Numerous species of weed have now evolved such resistance. Some of these species make agriculture more difficult; for example, pigweed can grow to the thickness of a baseball bat, and put a combine harvester out of action; giant ragweed can grow to over 10 feet high. This problem hasn't arisen in Europe, though, as GM crops are not generally in use there.[71]

[70] Gerry Adler (2011). "The Growing Menace from Superweeds." *Scientific American*, 304(5): 74-79.
[71] Ibid.

GM plants which are genetically resistant to more than one weedkiller are now being developed; only those weeds that evolve immunity to both being able to survive, something that is far more difficult to do.[72] Thus there is a battle here between human ingenuity and evolution. Which will win in the long term? Biochemistry professor William Reville observes that that: “It is only to be expected that natural selection would give a good account of itself in any contest. After all this is the mechanism that powered biological evolution from the first simple life form that arose on Earth almost four billion years ago to the myriad species of life that today colonise every environmental niche on Earth.”[73] [74] The long term consequences of this particular battle could, instead of advancing agriculture, be very damaging for it.

There are other potential problems. For example, synthetic food may not be as efficient as natural. The underlying science is very complex, and more is unknown than is known. For example, recent research showed that a GM crop yield was smaller than that of natural plants – GM soya was found to produce 10% less yield than natural soya. Investigation showed that this may have been caused by the engineered soya being less efficient at taking up manganese from the ground.[75] Also, GM corn has been found to kill monarch butterflies; it isn’t known why.[76]

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[72] Ibid.
[73] William Reville (2011). “Seeds of Disharmony.” *The Irish Catholic*, 15th December, p. 22. http://www.irishcatholic.ie/site/content/seeds-disharmony-prof-william-reville Accessed January 16th 2012.
[74] Gerry Adler (2011). *op. cit.*, note 70.
[75] Geoffrey Lean (2008). “Exposed: The Great GM Crops Myth.” *The Independent on Sunday*, 20th April. http://www.independent.co.uk/environment/green-living/exposed-the-great-gm-crops-myth-812179.html Accessed March 7th 2012.
[76] David B. Resnik (2004) *Owning the Genome: A Moral Analysis of DNA Patenting.* (Albany, NY: State University of New York Press), p. 181.

Even without complex engineering at the genetic level, problems can occur. For example, in 1910, Wilhelm Normann, a German chemist, invented a process that allowed solid edible fats to be developed from vegetable oils; these were cheap and long-lasting, and widely used as food additives. Fifty years on it became clear that they were harmful to health, causing heart disease and millions of deaths across the world.[77] Also, it has been suggested that many common chemicals (found, for example, in plastics, paint and mattresses) contribute to obesity and diabetes; some scientists dispute this.[78]

Scientific unknowns may multiply when creating synthetic food products as opposed to slightly modifying existing ones. This is a serious limitation, and it raises questions as to the inherent risks of such research. Negative effects may be observable only after significant damage is done, decades or more later. This does not necessarily mean that the research should not go ahead. But it does mean that it should proceed with caution, oversight and regulation. Oversight and regulation do not offer a panacea, though – they could not have prevented most of the problems mentioned in the previous paragraphs.[79] But they may, at least, prevent some careless or malevolent applications of the research.

An example of potentially dangerous use of GM technology is the attempt to create seeds that produce infertile plants; farmers using them would need to buy new seeds every year. The technique is known as *genetic use restriction*

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[77] Simon LeVay (2008). *When Science Goes Wrong*. (London: Plume), p. 269.
[78] Rebecca Smith (2012). "Everyday Chemicals Linked to Obesity Crisis: Report." *The Telegraph*, 20th March. http://www.telegraph.co.uk/health/healthnews/9153443/Everyday-chemicals-linked-to-obesity-crisis-report.html Accessed March 22nd 2012.
[79] Ibid.

technology (GURT), or more popularly, *terminator technology*.[80] [81] [82] Plants that yield infertile seeds could be dangerous; natural plants have been affected through the normal reproductive process, by genetically modified seeds being carried in the wind,[83] so this technology poses a possible threat to the world food supply. It could permit monopolies over much of the food supply to come into being, and these could be abused.[84] For example, Canadian biotech company Monsanto has been aggressive in enforcing its ownership rights over genetically modified seeds. It has sued some inadvertent recipients of its wind-born seeds, for using them without a license.[85] It has also sued a labourer whose job was to sort seeds, for "aiding and abetting" the farmers who owned the seeds; unknown to him, some wind-born patented seeds were among them.[86] The UN Convention on Biological Diversity has recommended a partial moratorium on terminator technology.[87] [88] This scenario illustrates the type of dangers that could result from synthetic biology: it could lead to monopolies and food shortages rather than abundance.

The convergence of current intellectual property laws with synbio has the potential to pose problems. The prospect of achieving fortunes from patented food

[80] David B. Resnik (2004). *op. cit*., note 76, p. 181.
[81] Derek Eaton, Frank Van Tongeren, Niels Louwaars, Bert Visser, and Ingrid Van der Meer (2002), "Economic and Policy Aspects of 'Terminator' Technology." *Biotechnology and Development Monitor*, 49: 19-22.
[82] ETC Group (2008). *Terminator: The Sequel*. (Ottawa, ON: ETC Group). http://www.etcgroup.org/content/terminator-sequel Accessed May 30th 2012.
[83] CBS Evening News *Agricultural Giant Battles Small Farmers* http://www.cbsnews.com/stories/2008/04/26/eveningnews/main4048288.shtml Accessed May 30th 2012.
[84] Hope Shand (1999). "Terminator technology: Genetically Altered Seeds Will Destroy Both Diversity and Good-producing Capacity." *Christian Social Action*, 12(9): 7-10.
[85] Ibid.
[86] Ibid.
[87] ETC Group (2007). *op. cit.*, note 82.
[88] EcoNexus and the Federation of German Scientists (2006). *Submission to the Convention on Biological Diversity on Advice on the Report of the Ad Hoc Technical Expert Group on Genetic Use Restriction Technologies*. http://www.cbd.int/doc/meetings/tk/wg8j-04/information/wg8j-04-inf-17-en.pdf Accessed July 3rd 2012.

encourages corporations to invest heavily in such research, thus speeding up the science.[89] [90] However, some companies, to boost profits, have started to show troubling attitudes in their current use of genetic engineering technology. Robert Farley, a former Chief Technology Officer of Monsanto has been quoted as saying: “What you are seeing is not just a consolidation of seed companies, it is really a consolidation of the entire food chain.”[91] Was the company seriously considering cornering the world market on seeds, the basis of plant life? In the same statement, Farley also said: “Since water is as central to food production as seed is, and without water life is not possible, Monsanto is now trying to establish its control over water.”[92]

There are obvious dangers here. In Bolivia, the World Bank forced the privatisation of water in 1999, with part ownership of the water in Cochabamba, Bolivia’s third largest city, going to a Monsanto partner, Bechtel, along with two other companies. As soon as it obtained the rights, the partnership doubled the price of water, making it beyond the means of many poor people. Public disturbances, which resulted in the declaration of martial law and the death of protesters, ultimately caused the government to abandon the privatisation scheme in 2000.[93] [94] [95]

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[89] Robbin Shoemaker , ed. (2002). “Economic Issues in Agricultural Biotechnology.” *U.S. Department of Agriculture Information Bulletin*, 762. http://www.ers.usda.gov/Publications/AIB762 Accessed May 30th 2012.

[90] Rick Weiss (2008). “Firms Seek Patents on ‘Climate Ready’ Altered Crops.” *Washington Post*, May 13th, p. A04. http://www.washingtonpost.com/wp-dyn/content/article/2008/05/12/AR2008051202919.html?hpid=moreheadlines Accessed May 30th 2012.

[91] Vandana Shiva (1999) “Now Monsanto is After Our Water.” *The Ecologist*, 29(5).

[92] Ibid.

[93] Franz Chavez (2006). “Cochabamba’s ‘Water War’, Six Years On.” *Inter Press Service*, 8th November. http://ipsnews.net/news.asp?idnews=35418 Accessed May 30th 2012.

[94] Vandana Shiva (2002) *Water Wars*. (Cambridge, MA: South End Press), p. 102.

[95] The 2010 film *Tambien la Lluvia* (*Even the Rain*), a Spanish academy nomination for the Oscars, dramatises the Cochabamba water wars. The title refers to the fact that it was illegal even to collect rainwater, as that was deemed to be Bechtel’s property. The official film website is at: http://www.tambienlalluvia.com/en/ Accessed May 27th 2012.

It is estimated, too, that 53% of the world's supply of commercial seeds for food are controlled by three companies; 73% are controlled by ten companies.[96] There is potential for cartels and monopolistic abuses to arise.

Famine occurs with natural farming, due to factors such as weather, disease, and political issues. But there may be more danger if the process goes synthetic. It was said at the height of 19th century capitalism that some businesspeople would obtain ownership over the world's air supply if they could, and sell it at vast profits, letting those who could not afford it die (I do not have the reference). There is potential for a version of this scenario to become real if synthetic production of food becomes the dominant mode.

It has also been argued, by the ETC Group, a Canadian-based environmental advocacy society, that current plans for industrial-level synthetic biology research will require such a large amount of plants that ecological damage could result, reducing supplies of soil and water, damaging biodiversity and destroying small farming communities. They argue too that it will lead to large-scale commodification of natural biological products. [97]

On balance, successful synthetic biology research on food and agriculture may offer both the promise to solve many of the world's food supply problems, and the danger of creating monopolies that threaten it. There is also the possibility for

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[96] ETC Group (2012). *The Greed Revolution: Megafoundations, Agribusiness Muscle in on Public Goods.* (Ottowa, ON: ETC Group), p. 4. http://www.etcgroup.org/upload/publication/pdf_file/ETComm108_GreedRevolution_120117.pdf Accessed March 21st 2012.

[97] ETC Group (2008). *Commodifying Nature's Last Straw? Extreme Genetic Engineering and the Post-Petroleum Sugar Economy.* http://www.etcgroup.org/en/materials/publications.html?pub_id=703 Accessed May 30th 2012.

catastrophe due to error and unknown consequences. There are currently enough resources to feed the world; however, there isn't always the will to distribute those resources justly. The creation of synthetic food may not, therefore solve the problems of food supply, and could make it worse. Advances in synthetic biology are unlikely to be a panacea here, and wise regulation is needed to oversee this research and its applications.

EFFECTS ON MEDICINE

At this early stage of the research, it is difficult to say with certainty how synthetic biology will affect medicine. It seems likely, though, that synbio will revolutionise it, if the science advances to an appropriate level.

Some potential benefits in the near to medium term can be reasonably predicted, based on current research. Gene therapy, which replaces disease-causing genes with their normal counterparts, is currently showing limited promise; [98] synbio has the potential to allow it to flourish. It may permit the establishment of personalised medicine.[99] New drugs may be developed; *Artemisinin*, an anti-malarial drug, is the most successful product of synthetic biology so far.[100] Artemisinin can be obtained from the artemisinin herb, and has been used in Chinese medicine for over 2,000 years. Yet supplies are sporadic. The synthetic production of artemisinin results

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[98] Donald B. Kohn and Fabio Candotti (2009). "Gene Therapy Fulfilling its Promise." *The New England Journal of Medicine*, 360(5): 518–521. doi:10.1056/NEJMe0809614

[99] J. Craig Venter (2012). *Understanding Our Genes: A Step to Personalised Medicine*. Presentation to California Institute for Regenerative Medicine, January 17th. http://www.youtube.com/watch?v=HAU6ObEJHaE Accessed March 23rd 2012.

[100] Andrew Balmer and Paul Martin (2008). *Synthetic Biology: Social and Ethical Challenges*. (Swindon: Biotechnology and Biological Sciences Research Council), p.4. http://www.bbsrc.ac.uk/organisation/policies/reviews/scientific_areas/0806_synthetic_biology.pdf Accessed May 30th 2012.

in a more reliable supply of the drug at a far cheaper price. It seems likely that many more drugs and therapies will result from synthetic biology.

Research into the machine-life interface may produce radical medical advances.[101] For example, one project in this area has developed a biological motor, which produces electrical signals. The device consists of a microchip containing DNA; a tiny magnet is attached to the DNA. Adenosine triphosphate (ATP), the source of biochemical energy in cells, moves the DNA and hence the magnet; in turn, the moving magnet produces electricity. Hoped for applications include using such signals to replace those of damaged muscle, allowing for the development of advanced artificial limbs. The interaction of drugs with the body's DNA may also be observable.[102]

Current research in medical robotics may indicate how such research, combing synbio and robotics, could result in far more advanced applications. Neuronal interfaces (also known as brain-computer interfaces) permit electrical signals from the brain to be harnessed to control electronic devices.[103] Artificial limbs are now being developed that can be controlled by a patient's brain, their thoughts, giving basic limb use to amputees. These artificial limbs have problems: they are so heavy and uncomfortable to wear that some patients have refused to use them. Also, changes in the electrical resistance of their contacts due to moisture, including rain, damp or

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[101] Anna Deplazes and Markus Huppenbaur (2009). "Synthetic Organisms and Living Machines." *Systems and Synthetic Biology*, 3:55-63. doi:10.1007/s11693-009-9029-4

[102] European Commission, Directorate General for Research (2007). *Synthetic Biology*. (Luxemburg: Office for Official Publications of the European Communities). ftp://ftp.cordis.europa.eu/pub/nest/docs/5-nest-synthetic-080507.pdf Accessed May 30th 2012.

[103] Daily Telegraph Health News (2012). "Woman Wants Her Hand Cut Off and Replaced with Bionic Limb." *Daily Telegraph*, 19th March. http://www.telegraph.co.uk/health/healthnews/9152883/Woman-wants-her-hand-cut-off-and-replaced-with-bionic-limb.html Accessed May 30th 2012.

sweat, can cause them to malfunction.[104] Making such limbs out of biological materials may eliminate such problems, possibly allowing them to be fully integrated into the body.

Experiments that attempt to restore movement to paralysed people using this technology are also being carried out.[105] [106] [107] Prototypes have been developed which encase a body in a metallic cover; monkeys have been trained to move it using their thoughts, thus restoring basic movement to the paralysed.

A recent experiment allowed a two paralysed people, one man and one woman, to move robotic arms with their thoughts. A pill-sized electrode (called *BrainGate*) was implanted into their brains; it could electrically detect the neural activity from their thoughts, and "translate" those thoughts into motor activity. The woman used the movement to sip coffee; it was the first time she could "move" in 15 years. One of the researchers, Brown University neuroengineer Leigh Hochberg, noted: "the smile on her face when she did this is something that I and our whole research team will never forget."[108] [109] [110] The technology is quite rudimentary at

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[104] Andrei Ninu (2009). "Neurally Controlled (Thought-Powered) Arm Prosthesis – Case Study." *Conference Presentation: Android and Eve*, Vienna Biocenter. November 12-13th.

[105] Manfred Bijak (2009). "Stimulating Eve: The Usage of Electrical Current to Reactivate Lost Body Functions." *Conference Presentation: Android and Eve*, Vienna Biocenter. November 12-13th.

[106] JD Simeral, S-P Kim, MJ Black, JP Donoghue and LR Hochberg (2011). "Neural Control of Cursor Trajectory and Click by a Human with Tetraplegia 1000 days after Implant of an Intracortical Microelectrode Array." *Journal of Neural Engineering*, 8(2): 1-24. doi:10.1088/1741-2560/8/2/025027

[107] Susan Gaidos (2011) " Mind Controlled." *Science News*, 180(1): 126. http://www.sciencenews.org/view/feature/id/331395/title/Mind-Controlled Accessed May 30th 2012.

[108] Ian Sample (2012). "New Implant Helps Stroke Victim To Move Robotic Arm by Thought." *Irish Times*, 17th May. http://www.irishtimes.com/newspaper/world/2012/0517/1224316239473.html Accessed May 30th 2012.

[109] Leigh R. Hochberg, Daniel Bacher, Beata Jarosiewicz, Nicolas Y. Masse, John D. Simeral, Joern Vogel, Sami Haddadin, Jie Liu, Sydney S. Cash, Patrick van der Smagt and John P. Donoghue (2012). "Reach and Grasp by People with Tetraplegia using a Neurally Controlled Robotic Arm." *Nature*, 485: 372–375. doi:10.1038/nature11076

[110] BrainGate Homepage (2012). http://braingate2.org/ Accessed May 30th 2012.

present. To how high a level could such systems be developed from biological materials?

Simple artificial eyes have also been made.[111] They allow blind patients to see large objects in a very rudimentary way. [112] Mimicking a human eye to any degree of sophistication is currently impossible technologically as, among other issues, its complexity and its number of interconnections cannot be replicated electronically. Such problems may be solvable to a far higher degree if future artificial eyes are made from biological materials.

Research is ongoing into biological microdevices which, when placed in the body, could act as sensors for detecting and taking action against abnormal conditions.[113] It is hoped that such devices could also repair cells and tissues. Also, synthetic devices could be created that detect and destroy cancer cells (or other diseased cells), leaving normal cells untouched;[114] a marked advance on current chemotherapy, which destroys both cancerous and healthy cells and is destructive to health.

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[111] J.D. Loudin, D.M. Simanovskii, K. Vijayraghavan, C.K. Sramek, A.F. Butterwick, P. Huie, G.Y. McLean, and D.V. Palanker (2007). "Optoelectronic retinal prosthesis: system design and performance" *Journal of Neural Engineering*, 4 (1): S72–S84. doi:10.1088/1741-2560/4/1/S09

[112] Eberhart Zrenner (2009). "Subretinal Microelectrode Arrays Allow Blind Retinitis Pigmentosa Patients to Recognize Letters and Combine them with Words." *Conference Presentation: Android and Eve*, Vienna Biocenter, November 12-13th.

[113] For example: Cardoso VF, Catarino SO, Martins P Rebouta L, Lanceros-Mendez S and Minas G. (2008). "Biological Microdevice with Fluidic Acoustic Streaming for Measuring Uric Acid in Human Saliva." *Annual International Conference of the IEEE, Engineering in Medicine and Biology Society.* doi: 10.1109/IEMBS.2009.5334449.

[114] European Commission Directorate General for Research (2005). *Synthetic Biology: Applying Engineering to Biology*. (Luxembourg: European Communities). ftp://ftp.cordis.europa.eu/pub/nest/docs/syntheticbiology_b5_eur21796_en.pdf Accessed March 9th 2012.

Synthetic biology has the potential to be almost Biblical in its ability to heal the sick, if it succeeds, eliminating much of human physical suffering, saving and enhancing countless lives. Like all human endeavours, however, the research could have negative consequences. Accidents may occur, or there could be unknown consequences to the research. Thalidomide is a classic example of an unforeseeable consequence; synbio has the potential to create something worse, as it is more complex and unknowns are therefore more inherent.

There is also potential for misuse. Robotics researcher Kevin Warwick has implanted his own body with a silicon chip transponder. In a “smart” building, with appropriate detectors, doors were opened for him and devices greeted him by name as he walked around. He could also operate devices, at a distance, by thought. [115] Such an implant could be programmed to contain personal information, including medical records, financial records, and more, and could be updatable.[116] Research is also ongoing into the barcoding of life, converting information from DNA into machine readable barcodes that allow lifeforms to be uniquely identified. Two major databases already exist to contain and classify this information.[117] Such technology could be used to improve health and make life more convenient, but authoritarian governments could use it to enforce hitherto unknown levels of monitoring and control. Of course, the above technology has developed without any input from a nascent synthetic biology, but a mature synbio would certainly advance it to a far higher level.

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[115] Kevin Warwick (2004). *I, Cyborg*. (Champaign, IL: University of Illinois Press).
[116] Kevin Warwick Homepage (2012). http://www.kevinwarwick.com/index.asp Accessed May 29th 2012.
[117] Consortium for the Barcoding of Life (2012) *What is DNA Barcoding?* http://www.barcodeoflife.org/content/about/what-dna-barcoding Accessed March 10th 2012.

On balance, synthetic biology appears to offer tremendous potential benefits to medicine; it has the potential to revolutionise it, greatly alleviating human suffering. Adequate ethical review and regulatory oversight is essential, though, to attempt to minimise negatives. Though disasters do occur in medicine, the overall benefits of medical research and clinical practice have greatly improved human wellbeing, and a well directed synthetic biology has the potential to take medicine to a new level of development, probably to heights which cannot currently be imagined.

EFFECTS ON FUEL PRODUCTION

> *The fuel of the future is going to come from fruit like that sumach out by the road, or from apples weeds, sawdust – almost anything… There's enough alcohol in one year's yield of an acre of potatoes to drive the machinery necessary to cultivate the fields for 100 years.*
>
> Henry Ford, 1925[118]

Several research institutes are attempting to create biofuels using synthetic biology.[119] [120] [121] Fossil fuel reserves are diminishing, and when they run out, civilisation could revert to that of an earlier era unless a replacement is found. The transition could be traumatic. Rising fuel costs, as fuel supplies contract, would have a knock on effect throughout the economy, affecting the price of consumer goods generally, including food. Also, thousands of consumer products, including plastics,

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[118] Christian Aid (2009). *Growing Pains: the Possibilities and Growing Pains of Biofuels*. (London: Christian Aid), p. 7 http://www.christianaid.org.uk/images/biofuels-report-09.pdf Accessed March 21st 2012.
[119] Neil Savage (2007). "Making Gasoline from Bacteria: A Biotech Startup Wants to Coax Fuels from Engineered Microbes." *Technology Review*, 1st August. http://www.technologyreview.com/Biztech/19128/ Accessed May 30th 2012.
[120] Paras Chopra and Akhil Kamma (2006). "Engineering Life Through Synthetic Biology." *In Silico Biology*, 6(5):401-410.
[121] ETC Group (2008). *op. cit*., note 97.

cosmetics and paints depend on fossil fuels for their manufacture.[122] In addition, fossil fuels are a source of climate change, another potential threat to humanity; replacing them with greener fuels could play a significant part in reducing it. This research may have the potential, without exaggeration, to save our current civilisation.

Biofuels have been used, to an extent, since the early 20th century. A greater focus on them occurred from the 1970s, largely as a result of the oil crisis. Obviously, classical (non-synthetic) biotechnology methods were used.[123] Biofuels are derived from biomass (i.e., plants, algae, fungi, municipal waste, etc.)[124]; unlike fossil fuels, they are a renewable energy resource. Production of biofuels is not just a technical issue. It is already having political, economic and social and ecological impact. As well as the provision of fuel security and mitigation of climate change, another potential benefit is the enhancement of economic development, providing famers (particularly in the developing world) with new sources of income, and generating jobs.

Yet significant ethical problems have been identified with current methods of biofuel production. A 2011 report by the Nuffield Council on Bioethics concluded that that current biofuel production policies in the UK and Europe are unethical.[125] [126]

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[122] Ibid.

[123] Justine Bontemps, Mathilde Burel, Alina Dragomir and Eugen Dumitrescu (2009). *Biofuels and Food Production: Ethical Issues.* (Lublin: EU Socrates Erasmus IP Bioethics in Life Sciences and Environmental Sciences). http://bioethics.agrocampus-ouest.eu/pdf2009/Biofuels_and_food_production.pdf Accessed March 14th 2012.

[124] Sustainable Energy Ireland (undated). *What is Biomass?* http://www.seai.ie/Archive1/Files_Misc/REIOBiomassFactsheet.pdf Accessed March 14th 2012.

[125] Nuffield Council on Bioethics (2011). *Press Release: Current Biofuels Policies are Unethical, Says Report*. http://www.nuffieldbioethics.org/news/current-biofuels-policies-are-unethical-says-report Accessed March 14th 2012.

[126] Alena Buyx and Joyce Tait (2011). "Ethical Framework for Biofuels." *Science*, 332: 540-541. http://www.sciencemag.org/content/332/6029/540.full.pdf?keytype=ref&siteid=sci&ijkey=SIZbuHkWKZWNk Accessed March 14th 2012.

A 2010 study from the ETC Group reached a similar conclusion.[127] Growing crops for biofuels on land formerly used to grow food has led to a rise in food prices. It is very questionable ethically whether land normally used to produce food should be given over to produce fuel, in a world where food shortages occur – the food vs. fuel debate. Should food be taken from the poor to provide transport for the relatively well off?[128] Biofuel production was a factor in the food shortages, and food riots, in many third world countries in 2008.[129] It has been calculated that using biofuels to replace 20% of the UK's fuel demand would use almost 100% of the UK's food cropland. A large-scale move to biofuel production could result in starvation.[130]

Its production may also cause environmental damage. MIT research scientist Ahmed Ghoniem has stated: "If fossil fuels were to be replaced by biofuels in the transportation sector, the need for land, water, fertilizers, etc., would rise significantly, and the associated ecological impact could be devastating, let alone its impact on food prices."[131] It is also the case that the amount of energy required to produce biofuels using current technology can equal or exceed the energy extractable from the biofuel.

In addition, there is a danger of a reduction of biodiversity by these activities, including the possibility of some species being driven to extinction. Deforestation has also resulted, as have human rights abuses – land grabs by companies, driving

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[127] ETC Group (2010) *The New Biomassters: Synthetic Biology and the Next Assault on Biodiversity and Livelihoods.* (Ottowa, ETC Group). http://www.etcgroup.org/upload/publication/pdf_file/biomassters.pdf Accessed March 21st 2012.
[128] George Monbiot (2004). "Feeding Cars, Not People." *The Guardian*, 23rd November. http://www.monbiot.com/2004/11/23/feeding-cars-not-people/ Accessed March 21st 2012.
[129] John Beddington (2009). *Food, Energy, Water and the Climate: A Perfect Storm of Global Events?* (London: Government Office for Science). http://www.bis.gov.uk/assets/goscience/docs/p/perfect-storm-paper.pdf Accessed March 21st 2012.
[130] Christian Aid (2009). *op. cit.*, note 118.
[131] Ahmed F. Ghoniem (2011). "Needs, Resources and Climate Change: Clean and Efficient Conversion Technologies." *Progress in Energy and Combustion Science*, 37(1): 15-51.

indigenous people from their land, also exploitative conditions for workers, including child labour.[132] While the latter human rights problems are not inherent to biofuel research, they have become a part of current practice.

Biofuels have the potential to have a positive impact on climate change, but they could also make it worse, depending on what crops and processes are used. Reduction in greenhouse gas emissions of between 70 and 100%, in comparison with fossil fuels, have been identified. However, under different conditions, biofuels were found to increase emissions by up to 2,000%.[133]

In order to ethically evaluate biofuels, and synthetic biology's role in their production, it is necessary to examine the different types of biofuels and how they are classified. Two main classifications exist, primary and secondary. Primary biofuels are unprocessed solid fuels, yielding energy in their natural form, through burning: examples include wood, plant residues and manure. Secondary biofuels require processing of biomass to yield their energy. Secondary biofuels are classified as first, second or third generation, according to their source and the technology used in their production.[134]

The two most important secondary biofuels are bioethanol and biodiesel, which can be blended with petrol and diesel, respectively. Others exist, solid, liquid,

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[132] Nuffield Council on Bioethics (2011). *Biofuels: Ethical Issues.* (London: Nuffield Council on Bioethics). http://www.nuffieldbioethics.org/biofuels-0 Accessed May 30th 2012.

[133] United Nations Environment Programme (UNEP) (2009). *Biofuels: New Report Brings Clarity to a Burning Issue*. (Nairobi: UNEP). http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=599&ArticleID=6347&l=en&t=long Accessed March 20th 2012.

[134] Tara Buckley (2008). "Sustainability of Biofuels: Future Generations." *Biomass Magazine*, October. http://biomassmagazine.com/articles/2070/sustainability-of-biofuels-future-generations Accessed March 23rd 2012.

and gaseous.[135] First generation biofuels – bioethanol, biodeisel, plant oils, biogases, and some processed/compacted solid fuels – have been developed using classical biotechnology. Bioethanol can be produced from the sugar and starch in corn, wheat, sugar cane and similar crops. Biodiesel can be produced from oil obtained from sunflower, soybean, rapeseed, palm and similar. These crops are also used for food, leading to the fuel vs food conflict.[136]

In second generation biofuels, lignocellulosic biomass (non-food sources, such as wood and all parts of plants, not just the edible parts that yield oil, sugar and starch) and biomass waste – are converted to bioethanol and biodiesel by fermentation and thermochemical conversion, respectively. Other biofuels, such as biomethanol, biohydrogen and others, can also be produced from thermochemical conversion. Third generation biodiesel and bioethanol can be produced from algae. The processing technology is similar to that of the second generation. This technology is currently at an early, investigative stage[137]

Successful development of second and third generation biofuels offers the potential to reduce, by technical means, many of the ethically problematic issues of first generation biofuels. Certain algae types can produce oils that may be utilisable as biofuels; ultimately, such oils may be indistinguishable from fossil fuels.[138] They can be cultivated in a wide variety of conditions, including some of the planet's most extreme. Metabolic engineering could be used to refine their output to a high degree

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[135] Nuffield Council on Bioethics (2011). *op. cit.*, note 132, p. xvii
[136] United Nations Environmental Programme (UNEP) (2009). *Towards Sustainable Production and Use of Resources: Assessing Biofuels.* (Nairobi: UNEP), p. 25. http://www.unep.fr/scp/rpanel/pdf/Assessing_Biofuels_Full_Report.pdf Accessed May 30th 2012.
[137] Ibid.
[138] Nuffield Council for Bioethics (2009). *op. cit.*, note 132, p. 55.

of specificity. Their output can be significantly higher than oilseed crops, and they also require far less water.[139] Depending on the species, they could be cultivated at sea, or in seawater tanks on infertile land, thus avoiding competition with food producing crops and negating the need for fresh water.[140] High yields of biofuels have already been obtained, but their use is not currently cost effective when harvesting and processing costs are taken into account.[141] [142] Technological development may change this.

New types of crops, specially designed to maximise efficient biofuel production, could be designed at the DNA level. Also, metabolic engineering could be used to engineer organisms other than algae to produce desired outputs of various biofuels. Large scale biorefineries could result.[143] For example, current research aims at producing microbial solar cells; the response of cyanobacteria to light at the genetic level is being studied, with the hope that this information can be used to generate hydrogen from the bacteria when exposed to sunlight.[144]

Building a genetic network, designed to produce specific molecular outputs from micro-organisms, onto a minimal microbe genome, is another possible approach.[145] Synthetic biology could also be used to design better fermentation

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[139] John Sheenan,Terri Dunahay, John Benemann and Paul Roessler (1998). *A Look Back at the US Department of Energy's Aquatic Species Program – Biodiesel from Algae*. (Golden, CO: National Renewable Energy Laboratory), p. iii. www1.eere.energy.gov/biomass/pdfs/biodiesel_from_algae.pdf Accessed May 30th 2012.
[140] Royal Society (2009). *Sustainable Biofuels: Prospects and Challenges*. (London: Royal Society), p. 9. http://royalsociety.org/WorkArea/DownloadAsset.aspx?id=5501 Accessed March 21st 2012.
[141] Ibid.
[142] John Sheenan,Terri Dunahay, John Benemann and Paul Roessler (1998). *op. cit.*, note 139.
[143] Royal Society (2009). *op. cit.*, note 140.
[144] Royal Society (2008). *Synthetic Biology: Scientific Discussion Meeting Summary*. (London: Royal Society). http://royalsociety.org/WorkArea/DownloadAsset.aspx?id=5486. Accessed March 21st 2012.
[145] Nuffield Council for Bioethics (2009). *op. cit.*, note 132.

processes.[146] Also, some biofuel crops may enable degraded land to recover.[147] At present, about 86% of the world's biomass, on land and sea, is not being used for commercial products. Synbio offers the potential for a far greater proportion of it to be utilised.[148] Synbio may also promise a higher level of economic development via the creation of more skilled, better paid jobs. On the other hand, some of the world's least productive land is utilised by poor farmers; using it for synthetic biofuels could destroy their livelihoods.[149] Also, unintended consequences, such as "collateral damage" to the environment, could occur. One example: if bacteria are engineered to convert biomass plant waste (e.g. stalks) into fuel, there may be ecological problems if these are not returned to the soil.[150]

It is clear that applying synthetic biology to biofuels research could advance the field significantly, reducing or eliminating many of the ethical obstacles (it could also add new ones). Of course, there is no guarantee that this research will succeed, but successful outcomes do seem plausible, based on the current state of the science.

Synthetic biology poses its own problems, however. Biosafety is one issue (see *Biosafety* section, below). The issue of bioterror is another – advances in synbio, achieved in biofuels research, could be applied negatively in other areas (see *Bioterror*, below). Also, patenting of the various underlying biological processes may prevent fuels from being developed by other, more efficient competitors, holding back

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[146] Royal Society (2009). *op. cit.*, note 140.
[147] United Nations Environmental Programme (2009). *op. cit*., note 136, p. 19
[148] ETC Group (2010). *op. cit*., note 127, p. 1.
[149] David Wei (2012). *Next Generation Biofuels and Synthetic Biology. Briefing Paper, Foundation for International Environmental Law and Developm*ent. (London: FIELD). http://www.field.org.uk/files/synthetic_biology_biofuels_briefing_paper.pdf Accessed March 23rd 2012.
[150] Ibid., p. 27-31.

the science. A small number of corporations could effectively corner the world's fuel supply, potentially leading to very high prices; for example, instead of owning a group of oilfields, as they do now, they could come to own oil itself. Such patenting may also inhibit or shut down research in neighbouring areas.

Sir John Beddington, chief scientific advisor to the British government, has observed that a perfect storm may be facing humanity by the mid-21st century – namely, a population increase of approximately 50%; a consequent increase in demand for food, water, energy and land; and climate change, which may be destructive to agriculture and the food supply. He concludes that science may help to solve the problems, and that this has to be a directed effort.[151] [152] It seems reasonable that research into synthetic biofuels may be a significant part of any scientific solutions, and it seems to be an ethical imperative that such research is carried out. But it is not without its dangers; caution by researchers and appropriate regulation are needed. A report from the United Nations Environmental Programme (UNEP) has recommended that governments integrate biofuel policy into a combined policy that govern agriculture, land and water use, energy use and climate change, to benefit the economy, environment and society overall.[153] In the words of the Achim Steiner (Executive Director of UNEP and Under-Secretary General of the UN): "Biofuels are

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[151] John Beddington (2009). *op. cit.*, note 129.

[152] In 1972, a group of MIT researchers produced a report, *Limits to Growth*, which used computer modeling to simulate how population growth, industrial output, pollution, food production, and the consumption of fossil fuels would effect civilization in the long term. Their model suggested a near apocalyptic scenario if significant changes were not introduced. See: Donella H. Meadows, Dennis L. Meadows, Jorgen Randers and William W. Behrens III (1972). *The Limits to Growth: A Report for the Club of Rome's Project on the Predicament of Mankind*. (New York: Universe Books); Donella H. Meadows, Jorgen Randers and Dennis L. Meadows (2004). *Limits to Growth: The 30-Year Update*. (White River Junction, Vermont: Chelsea Green Publishing Co.); Graham Turner (2007) *A Comparison of the Limits to Growth with Thirty Years of Reality*. (Canberra: Commonwealth Scientific and Industrial Research Organisation). http://www.csiro.au/files/files/plje.pdf Accessed March 21st 2012.

[153] United Nations Environment Programme (2009). *Op. cit.*, note 133.

neither a panacea nor a pariah but like all technologies they represent both opportunities and challenges."[154]

BIOSAFETY

Synthetic biology is seen by many of its practitioners as an engineering discipline rather than a biological one.[155] Failure – structural, electronic, etc. – is an integral part of engineering. All materials and devices have a limited lifespan; in the words of a textbook on engineering failure: "it is not a question of whether the device will fail, but when."[156] Courses on failure analysis and risk in engineering are taught in undergraduate engineering degrees,[157] and there are graduate degrees in the subject;[158] there is, of course, a broad professional literature.

A famous engineering failure was that of the Tacoma Narrows Bridge, Washington state, in 1940. At the time, it was the third largest suspension bridge in the world. A few months after opening, a high wind caused it to resonate wildly until it collapsed – dramatic videos can be seen online. It is a textbook case, mentioned in standard undergraduate engineering and physics books; subsequent bridge design has

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[154] Ibid.

[155] E. Andrianantoandro; S. Basu; D.K. Karig; and R. Weiss (2006). "Synthetic Biology: New Engineering Rules for an Emerging Discipline." *Molecular Systems Biology*, 2:28. doi:10.1038/msb4100073.

[156] J.W. McPherson (2010). *Reliability Physics and Engineering: Time to Failure Analysis*. (New York: Springer), p. vii.

[157] See, for example, University of Maryland syllabus for course ENRE 600: Introduction to Failure Mechanisms in Reliability Engineering. http://www.christou.umd.edu/ENRE600_syllabus.pdf Accessed March 24th 2012.

[158] For example, Herriot-Watt University (undated). *M.Sc./Diploma in Safety, Risk and Reliability Engineering*. http://www.postgraduate.hw.ac.uk/course/22/ Accessed March 24th 2012.

been greatly influenced by what happened to it.[159] Its designer, Leon Moisseiff, an engineer at the top of his profession, who also worked on the design of the Golden Gate and Manhattan Bridges,[160] said that he did not understand why it collapsed, because it was built in accordance with engineering rules. He was attempting to build the world's slenderest suspension bridge, however, and changing the design parameters slightly meant that the standard rules were no longer adequate.[161]

Biological organisms also fail: they experience sickness, injury and, ultimately, death. Scientific knowledge of many of the process that cause failure is incomplete. Such failures are likely to be more common in synthetically designed organisms; the current state of knowledge in biological science means that it is very difficult to design and accurately predict the properties of novel organisms.[162] Biology is orders of magnitude more complex than civil engineering. Small changes in a biological system can have cascading effects throughout densely interconnected biological networks. Much of the science is still unknown, and such effects are unpredictable. Microbiological processes are usually stochastic (random, probabilistic) in nature. Their stochastic nature results from internal processes – thermal, spatial and temporal fluctuations at the molecular level, and external ones – changes in nutrients, temperature, pressure, etc.[163] For example, genetic mutations and gene expression are stochastic; the same genetic code in the same chemical

[159] K. Yusef Billah and Robert H. Scanlan (1991). "Resonance, Tacoma Narrows Bridge Failure, and Undergraduate Physics Textbooks." *American Journal of Physics,* 59 (2): 118–124. doi:10.1119/1.16590.
[160] pbs.org - American Experience (undated). *Biography: Leon Moisseiff.* http://www.pbs.org/wgbh/americanexperience/features/biography/goldengate-moisseiff/ Accessed March 25th 2012.
[161] Jonathon Keats (2012). Picture Imperfect: Technology is as Flawed as the People who Design It." *New Scientist,* 213(2856): 51.
[162] Mildred K. Cho and David A. Relman (2010). "Synthetic 'Life,' Ethics, National Security and Public Discourse. *Science,* 329 : 38-9. doi:10.1126/science.1193749
[163] Dan S. Tawfik (2010). "Messy Biology and the Origins of Evolutionary Innovations." *Nature Chemical Biology,* 6: 692–696 doi:10.1038/nchembio.441

environment can result in very different expression, due to random variations.[164] Such differing expressions could be beneficial, neutral or toxic. The mechanisms underlying mutation in genomes are not understood.[165]

Biological systems' stochastic nature is not an inherent obstacle to biological design. Nevertheless, when added to biology's inherent complexity, and the large amount of scientific unknowns, it makes biological design far more challenging than that of standard engineering. Standard engineering curricula offer failure prevention and analysis as a standard part of the syllabus, as mentioned, yet failures still occur. Synthetic biologists are aware of this, of course, and will endeavour to eliminate or minimise failure, just as engineers do in their designs. For example, Craig Venter's "synthetic cell," *Synthia* was designed with the intention that it couldn't survive outside the lab.[166] PNA, a replacement for DNA, is used in attempts to design new genetic codes, one reason being that it may minimise the chances of organisms based on it interacting with natural organisms.[167] Nevertheless, it seems plausible that failures will occur, and reasonably frequently.

It may be useful to give some examples of unintended and unforeseen consequences of scientific research. For example, the East Coast of the U.S. has lost 70% of its bee population in recent years, and the West Coast 60%. A London beekeeper stated that 23 out of 40 of his hives have recently been abandoned. The

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[164] Michael B. Elowitz, Arnold J. Levine, Eric D. Siggia and Peter S. Swain. (2002). "Stochastic Gene Expression in a Single Cell." *Science*, 297(5584): 1183-1186 doi: 10.1126/science.1070919

[165] Iñigo Martincorena, Aswin S. N. Seshasayee and Nicholas M. Luscombe (2012). "Evidence of non-random mutation rates suggests an evolutionary risk management strategy." *Nature*, 485: 95–98. doi:10.1038/nature10995

[166] Ewen Callaway (2010). "Immaculate Creation: Birth of the First Synthetic Cell." *New Scientist*, 20th May. http://www.newscientist.com/article/dn18942-immaculate-creation-birth-of-the-first-synthetic-cell.html Accessed March 28th 2012.

[167] ETC Group (2007). *op cit.*, note 2, p. 32.

cause of this is not certain, but it appears that mobile phone signals may be affecting the behaviour of bees. Power lines may also be a factor. As most crops need bees to pollinate them, the widespread use of mobile phones could damage the world food supply, if they are indeed the cause of this.[168] Such effects could not be predicted when mobile phone technology was being developed.

Chlorofluorocarbons (CFCs) are another example. Invented in 1928 by Thomas Midgely, they replaced dangerous chemicals such as ammonia, which had been used for refrigeration and aerosol sprays, and appeared to offer a much safer alternative. Yet in recent decades, it became clear that they were damaging the ozone layer.[169]

There is plenty of scope for unforeseen consequences in synthetic biology research. Approximately 97% of DNA is of unknown function. Initially referred to as "junk DNA"[170] by scientists, it is now becoming apparent that much of it may have some function, though it isn't yet known what that function may be.[171] Introducing changes at the DNA level when there is such a large degree of unknowability may result in unpredictable outcomes. In addition, genes interact with each other in complex ways and a small change may have multiple knock-on effects. For example, human height results from the interaction of almost two hundred genes;[172] a change

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[168] Geoffrey Lean and Harriet Shawcross (2007). "Are Mobile Phones Wiping Out Our Bees?" *The Independent on Sunday*, 15th April. http://www.independent.co.uk/environment/nature/are-mobile-phones-wiping-out-our-bees-444768.html Accessed June 29th 2012.
[169] Simon LeVay (2008). *op. cit.*, note 77, p. 269.
[170] Susumo Ohno (1972). "So Much 'Junk' DNA in Our Genome." *Evolution of Genetic Systems. Brookhaven Symposia in Biology*, 23: 366-70.
[171] Christian Biémont and Christine Vieira (2006). "Genetics: Junk DNA as an evolutionary force". *Nature*, 443(7111): 521–4. doi:10.1038/443521a
[172] Hana Lango Allen, Karol Estrada, Guillaume Lettre et al (2010). "Hundreds of Variants Clustered in Genomic Loci and Biological Pathways Affect Human Height." *Nature*, 467: 832–838. doi:10.1038/nature09410

imposed on one or several genes in the network may affect the entire network in unpredictable ways. Patholgies could result. Jay Keasling, who heads the Artemisinin project, has said that 95% of research time is spent on finding and correcting for unforeseen interactions between biological parts.[173] Given that there are so many potential unknowns in this research, the question arises: is synthetic biology too big a risk? Monsters could be created inadvertently, at the microbial level or higher.

It is possible that some newly created organism could be accidentally released into the environment. It may have the ability to replicate, evolve, and affect the course of evolution of other organisms it interacts with. There may be no consequences to such a release; but on the other hand, significant ecological damage could be caused. A worst case scenario has been proposed, adapted from Eric Drexler's description of *grey goo* in nanotechnology; here self replicating robots continuously build copies of themselves, filling the earth and killing all life in the process.[174] A "green goo" version of this has been postulated for new biotech creations gone out of control.[175] [176] Drexler, regarded as the 'father of nanotechnology,' describes *grey goo* as follows:

> If the first replicator could assemble a copy of itself in one thousand seconds, the two replicators could then build two more in the next thousand seconds, the four build another four, and the eight build another eight. At the end of ten hours, there are not thirty-six new replicators, but over 68 billion. In less than a day, they would weigh a ton; in less than two days, they would outweigh the Earth; in another four hours, they would exceed the mass of the Sun and all the planets combined.[177]

[173] Joachim Henkel and Stephen M. Maurer (2007). "The Economics of Synthetic Biology." *Molecular Systems Biology*, 3 : 117-120. doi: 10.1038/msb4100161
[174] K. Eric Drexler (1990). *Engines of Creation: The Coming Era of Nanotechnology*. (Oxford: Oxford University Press).
[175] ETC Group (2003). *Green Goo: Nanobiotechnology Comes Alive*. (Winnipeg: ETC Group) http://www.etcgroup.org/upload/publication/174/01/comm_greengoo77.pdf Accessed May 30th 2012.
[176] Daith Hanluain (2004). "Green Goo: The New Nano-Threat." *Wired*, 19th July. http://www.wired.com/medtech/health/news/2004/07/64235 Accessed May 30th 2012.
[177] Eric Drexler. Quoted in ETC Group (2003). *op. cit.*, note 175, p. 2.

It's an apocalyptic scenario, and Drexler has distanced himself from it in recent years (largely on the basis that he believes such machines won't come into common use, and that monitoring will prevent it; he doesn't reject the science behind it).[178] [179] [180]

Some nano-engineered particles have been found to have unpredicted toxic properties (as they get smaller, they become toxic).[181] [182] Although the issues in synthetic biology are different, there could be equally deadly unknown negative effects; the complexity and lack of scientific knowledge about engineered organisms is greater. Even though a green/grey goo scenario is a worst case scenario, there is potential for significant damage to the environment being caused by an accidental release of a synthetic organism.

In short, potential dangers appear to be so great regarding biosafety that questions arise as to whether synbio can be considered ethical *per se*. This is the case even without human error and accidents (which, of course, can never be disregarded). At present the research is going ahead without much in the way of specific regulation.[183] George Church, a synthetic biologist at Harvard Medical School, and one of the field's pioneers, has called for regulation, saying that synthetic biologists

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[178] Chris Phoenix and Eric Drexler (2004). "Safe Exponential Manufacturing." *Nanotechnology*, 15(8): 869-872. doi:10.1088/0957-4484/15/8/001 http://www.iop.org/EJ/abstract/0957-4484/15/8/001/ Accessed May 30th 2012.

[179] Liz Kalaugher (2004). "Drexler Dubs Grey Goo Fears Obsolete." *Nanotechweb.org* http://nanotechweb.org/cws/article/indepth/19648 Accessed May 30th 2012.

[180] Paul Rincon (2004). "Nanotech Guru Turns Back on 'Goo'." *BBC News Online*, 9th June. http://news.bbc.co.uk/1/hi/sci/tech/3788673.stm Accessed May 30th 2012

[181] Ibid.

[182] Royal Society (2004). *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*. (London: Royal Society, 2004), pp. 35-50. http://www.nanotec.org.uk/finalReport.htm Accessed May 30th 2012.

[183] ETC Group (2007). *op. cit*., note 2.

should be licensed, just as aviation personnel are.[184] The potential dangers are great, and the precautionary principle is largely being ignored at a policy level at present, throughout the world.[185] Potential benefits are great too, though, so much so that it could be considered unethical to ban synbio outright. Perhaps the weak form of the precautionary principle should be invoked, permitting the research to take place while taking precautions, enforced via strong regulation, at each stage.[186] Regulation should allow for innovation, while attempting to predict and prevent worst-case scenarios.

BIOSECURITY

One of the first publications in synthetic biology was written for DARPA (Defense Advanced Research Projects Agency),[187] the scientific research wing of the US military.[188] DARPA is regarded as one of the world's most innovative scientific research institutes.[189] A current DARPA synbio project aims to eliminate randomness in evolution and to create immortal organisms; for military use, of course.[190] It is no surprise that military researchers are among the first to recognise the potential of synthetic biology. Warfare appears to be intrinsic to human nature, and with that instinct to fight comes the drive to develop more powerful weapons than potential enemies.

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[184] Ewen Callaway (2010). "Immaculate Creation: Birth of the First Synthetic Cell." *New Scientist*, 20th May. http://www.newscientist.com/article/dn18942-immaculate-creation-birth-of-the-first-synthetic-cell.html Accessed March 28th 2012.
[185] ETC Group (2007). *op. cit.*, note 2.
[186] Daith Hanluain (2004). *op. cit.*, note 176.
[187] DARPA Homepage (undated). www.darpa.mil. Accessed March 30th 2012.
[188] Adam Arkin and Drew Endy (1999). "A Standard Parts List for Biological Circuitry." *DARPA White Paper*. http://dspace.mit.edu/handle/1721.1/29794 Accessed March 25th 2012.
[189] Michael Belfiore (2009). *The Department of Mad Scientists: How DARPA is Remaking Our World, from the Internet to Artificial Limbs*. (New York: Harper).
[190] Katie Drummond (2010). "Pentagon Looks to Breed Immortal 'Synthetic Organisms,' Molecular Kill Switch Included." *Wired*, 5th February. http://www.wired.com/dangerroom/2010/02/pentagon-looks-to-breed-immortal-synthetic-organisms-molecular-kill-switch-included/ Accessed March 25th 2012.

Biological weapons have a long pedigree. Their design frequently reveals great ingenuity, and dates back to humanity's earliest history. It is known that in the 6th century B.C. the Assyrians, one of the Old Testament's Israelites' conquerors, poisoned enemy wells with rye argot,[191] a disease of rye that generates the following symptoms when consumed by humans:

> Convulsive ergotism is characterized by nervous dysfunction, where the victim is twisting and contorting their body in pain, trembling and shaking, and wryneck, a more or less fixed twisting of the neck, which seems to simulate convulsions or fits. In some cases, this is accompanied by muscle spasms, confusions, delusions and hallucinations, as well as a number of other symptoms.
>
> In gangrenous ergotism, the victim may lose parts of their extremities, such as toes, fingers, ear lobes or in more serious cases, arms and legs may be lost. This type of ergotism causes gangrene to occur by constricting the blood vessels leading to the extremities. Because of the decrease in blood flow, infections occur in the extremities, accompanied by burning pain. Once gangrene has occurred, the fingers, toes, etc. become mummified, and will eventually fall off as a result of infection. If the infected extremities are not removed, infection can spread further up the extremity that has been infected.[192]

In the 4th century B.C., arrows dipped in manure and decomposing bodies were used by the Scythians. Tartars catapulted bodies which had died from plague into a besieged city in the 14th century A.D., causing an epidemic in the city. Spanish troops put blood from leprosy sufferers into French wine in the 15th century. The blankets of smallpox sufferers were given as gifts to American Indians by both the British and Spanish. This technique was also used by the Confederate side in the American civil war, who arranged for smallpox infected clothing to be sold to Union troops.

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[191] Arizona Dept. of Health Services, Bureau of Emergency Preparedness and Response *History of Biowarfare and Bioterrorism*. http://www.azdhs.gov/phs/edc/edrp/es/bthistor2.htm Accessed May 30th 2012.

[192] George J. Wong (undated). *Ergot of Rye - I: Introduction and History* http://www.botany.hawaii.edu/faculty/wong/BOT135/LECT12.HTM Accessed May 30th 2012.

The production of biological weapons increased greatly in the 20th century, following advances in technology. Various bioweapons were developed at the time of World War I. Use of bioweapons increased during World War II. In 1931 the Japanese tried to kill members of the League of Nations by infecting their fruit with cholera. In 1941 they released 150 million fleas that were infected with plague over parts of China. They released intestinal typhoid into Soviet water supplies in 1939. The British attempted to develop bombs which could deliver anthrax to populations during World War II. The U.S. researched the effectiveness of botulism, plague, anthrax, brucellosis and tularaemia in warfare during this period and for some decades after. The research included the release of harmless organisms into the New York subway, to observe how effectively they would disperse.

In 1972, the Bioweapons Convention[193] was signed by many countries. It forbade bioweapons research and stockpiling of previously developed bioweapons. Many signatories continued such research, however. In 1979, anthrax was accidentally released from a Soviet bioweapons facility, killing hundreds of civilians.

Some bioweapons have been used by terrorist groups and individuals. A raid on a Red Army faction house in Paris revealed the presence of a laboratory which contained botulinium. In the U.S., two members of a right wing groups, the Minnesota Patriots Council, attempted to produce ricin, with the intention of killing government agents by putting it on doorknobs. In Japan, AumShinrikyo attacked the Tokyo

[193] Officially known as *The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* (BTWC). See United Nations Office for Disarmament Affairs (UNODO) Biological Weapons Convention page (undated). http://www.un.org/disarmament/WMD/Bio/ Accessed May 30th 2012.

subway with sarin gas in 1995. Biological toxins were found in their possession, including ebola and anthrax.[194]

Synthetic biology offers the probability of taking biological weapons to a new level. Some dangerous pathogens have already been "written" synthetically, including the 1918 Spanish flu virus.[195] This virus, which killed tens of millions of people (more than World War I) and died out with its last victims, has been reconstituted, partially from victims buried in Alaskan permafrost. The feat was published in *Nature* and *Science* in 2005. In 2002, a research team at the State University of New York, Stony Brook, synthetically created a polio virus, building the genome using mail order chemicals. They examined its efficiency by injecting it into mice – it was the genuine article. Dr. Eckard Wimmer led the team. He did it to show that it could be done, and commented: "If some jerk… takes the sequence of [a dangerous pathogen] and synthesises it, we could be in deep, deep trouble."[196]

It is feasible that Ebola, or similarly deadly viruses, could be synthesised and released (it has already been constructed using genetic engineering techniques).[197] Currently there are no laws against doing this. Nor is it illegal to produce, advertise and sell kits containing all the relevant materials, and detailed instructions to do it.[198]

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[194] Arizona Dept. of Health Services, Bureau of Emergency Preparedness and Response (2005). *History of Biowarfare and Bioterrorism*. http://www.azdhs.gov/phs/edc/edrp/es/bthistor2.htm Accessed May 30th 2012.

[195] Terrence M. Tumpey, Christopher F. Basler, Patricia V. Aguilar, Hui Zeng, Alicia Solórzano, David E. Swayne, Nancy J. Cox, Jacqueline M. Katz, Jeffery K. Taubenberger, Peter Palese, and Adolfo García-Sastre (2005). "Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus." *Science*, 310(5745): 77-80. http://www.sciencemag.org/cgi/content/abstract/sci;310/5745/77 Accessed May 30th 2012.

[196] ETC Group (2007). *op. cit*., note 2, p. 24.

[197] Salvia Pagan Westphal (2002). "Ebola Virus Could be Synthesised." *New Scientist* , 17th July. http://www.newscientist.com/article/dn2555-ebola-virus-could-be-synthesised.html Accessed May 30th 12.

[198] ETC Group (2007). *op. cit*., note 2, p. 24.

Sequences of the various Ebola genomes (and many other pathogens) are freely available on the internet.[199] Ebola is similar in length to the polio genome, so to synthesise it is a comparable technical feat. Also, these online sequences could be altered to make the virus more deadly – scientists have done this for mousepox.[200] The more synthetic biology advances, the easier it will be to synthesise such pathogens; they could be released to large population centres.

This scenario is all the more troubling, because biological weapons, like nuclear weapons, have up to now largely been the preserve of a few governments. Their production can be monitored to an extent. But when synthetic biology reaches a certain level of maturity, it will almost certainly be possible for all governments, along with terrorist groups, criminals, and any interested individuals, to make their own bioweapons. All synthetic biology research, including the most beneficial, has the potential to advance the field to a place where "people's bioweapons" will be achievable – the dual-use dilemma.

Already, an amateur bio-hacking culture has developed, analogous to the hacker culture in computing.[201] Amateurs can experiment with creating their own synthetic organisms. Online biohacking forums exist.[202] [203] One biohacking website, the *Open Biohacking Project/Kit*, explains biohacking as follows:

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[199] For example, the complete genome of the Zaire ebola virus, Mayinga strain, is listed in GenBank: http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=10141003 Others are at: http://www.ncbi.nlm.nih.gov/sites/entrez?db=genome&cmd=search&term=ebola. Both accessed May 30th 2012.(This is the website of the National Center for Biotechnology Information in the U.S., and it houses information from the world's major biology databases. A lot of biological information, in addition to DNA sequences, is given – including references to journal articles and books.)

[200] Westphal (2002). *op. cit.*, note 197.

[201] DIY Biology Homepage (2012). http://diybio.org/ Accessed June 1st 2012.

[202] DIY Biology Forum (2012) https://groups.google.com/forum/?fromgroups#!forum/diybio Accessed May 30th 2012.

[203] Biopunk Homepage (2012). http://www.biopunk.org/ Accessed May 30th 2012.

> Join the fight against cancer, against all sorts of disease! Or would you rather see some glowing bacterium, get your own ecoli farm set up to amaze your friends? This open, free synthetic biology kit contains all sorts of information from across the web on how to do it: how to extract and amplify DNA, cloning techniques, making DNA by what's known as oligonucleotides, and all sorts of other tutorials and documents on techniques in genetic engineering, tissue engineering, synbio (synthetic biology), stem cell research,... etc.... [204]

Websites such as the Personal Genome Project[205] are bringing professional scientists and amateurs together. Biohacker collectives are emerging, spaces where amateurs can learn, and advance the science.[206] [207] [208] In 2009, a "BioBrick assembly kit" was created for purchase, to enable hobbyists to build synthetic biology devices; it costs, at the time of writing, US$240.[209] It is likely to become ever easier for people to create genomes of their own design. Most people currently involved in the biohacker culture are technically oriented, as were the early computing pioneers. But as the technology becomes more widespread and more easily usable, it may become as ubiquitous as the internet.

A significant proportion of modern computer technology had its genesis in the homes and garages of young hackers in silicon valley in the 1970s - the term *garage hacking* was used to describe their activities. The first Apple computer was created by Steve Wozniak and Steve Jobs in Jobs' garage.[210] Google was developed in a garage,

[204] The Open Biohacking Project/Kit Homepage (2008). *Biohack*. http://biohack.sourceforge.net/ Accessed May 30th 2012.
[205] Personal Genome Project Homepage (2012). http://www.personalgenomes.org/ Accessed May 30th 2012.
[206] Pui-Wing Tam (2012). "'Biohackers' Get Their Own Space to Create." *Wall Street Journal*, 12th January. http://online.wsj.com/article/SB10001424052970204124204577150801888929704.html Accessed March 29th 2012.
[207] Biocurious Homepage (2012). http://biocurious.org/ Accessed May 30th 2012.
[208] Genspace Homepage (2012). http://genspace.org/ Accessed May 30th 2012.
[209] New England BioLabs (2009). *BioBrick Assembly Kit.* http://www.neb.com/nebecomm/products/productE0546.asp Accessed March 28th 2012.
[210] Amanda Gefter (2011). "Can Hobbyists and Hackers Transform Biotechnology?" *Technology Review*, 11th April. http://www.technologyreview.com/biomedicine/37444/ Accessed May 30th 2012.

as were the first Hewlett Packard devices; Facebook was developed in a Harvard student residence. Bill Gates was also a garage hacker; he has said that if he were starting today, he would hack biological materials: "Creating artificial life with DNA synthesis. That's sort of the equivalent of machine-language programming ...If you want to change the world in some big way, that's where you should start — biological molecules."[211] He said synbio needs: "the same type of crazy fanaticism of youthful genius and naïveté that drove the PC industry — and can have the same impact on the human condition."[212]

The hacker sub-culture in synbio has been given the nickname *garage biohacking*, in honour of its silicon computing predecessors; other nicknames include *biopunk*, *biohacking* and *DIY biology*. *The New York Times* describes a biohacking lab: "Cathal Garvey's home laboratory in Cork, Ireland, is filled with makeshift equipment. His incubator for bacteria is an old Styrofoam shipping box with a heating mat and thermometer that he has modified into a thermostat. He uses a pressure cooker to sterilize instead of an autoclave. Some instruments are fashioned from coffee cans…"[213] *The Wall Street Journal* describes another, maintained by a 23-year old who lives with three roommates and a cat; her synbio lab is in her bedroom closet. Her equipment includes: "a DNA "thermocycler" bought on eBay for $59, and an incubator made by combining a styrofoam box with a heating device meant for an

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[211] Bill Gates. In Stephen Levy (2010). "Geek Power: Stephen Levy Revisits Tech Titans, Hackers, Idealists." *Wired*, May. http://www.wired.com/magazine/2010/04/ff_hackers/all/1 Accessed March 29th 2012.
[212] Ibid.
[213] Ritchie S. King (2012). "When Breakthroughs Begin at Home." *New York Times*, 16th January. http://www.nytimes.com/2012/01/17/science/for-bio-hackers-lab-work-often-begins-at-home.html?_r=2 Accessed March 29th 2012.

iguana cage."[214] These two amateurs have expertise; the first having a graduate degree in biotech,[215] the second being an MIT bioengineering graduate.[216] Biohacking is now at a similar place that computing was in the 1970s. The activities of hackers of that era changed the world; synthetic biology may do the same. Physicist Freeman Dyson wrote of a possible near future:

> Domesticated biotechnology, once it gets into the hands of housewives and children, will give us an explosion of diversity of new living creatures… Designing genomes will be a personal thing, a new art form as creative as painting or sculpture.[217]

It seems unlikely that such creativity will always be used positively; human history suggests that negative uses will also occur. An example, from computer hacking, illustrates how ambitious some negative users can be. The Conficker Worm, released in 2008, infected 1.5 million computers worldwide within a month; within 3 months that had increased to 8 million. It may permit all these computers to be linked, and controlled by Conficker's authors. A huge international collaboration, involving law enforcement, academia and industry, was organized to defeat it, with only partial success; Conficker can defend and update itself. Its ultimate *raison d'etre* isn't known; speculation includes criminal use, such as theft of identity or financial details, or a possible military attack. As well as spreading via the internet, it can spread offline via memory sticks. It remains hidden in millions of computers; its creators

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[214] Jeanne Whalan (2009). "In Attics and Closets, 'Biohackers' Discover Their Inner Frankenstein." *The Wall Street Journal*, 12th May. http://online.wsj.com/article/SB124207326903607931.html Accessed March 29th 2012.

[215] Ritchie S. King (2012). *op. cit*., note 213.

[216] Marcus Wohlsen (2011). *Biopunk: Solving Biotech's Biggest Problems in Kitchens and Garages*. (New York: Penguin).

[217] Freeman Dyson (2007). "Our Biotech Future." *The New York Review of Books*, 19th July. http://www.nybooks.com/articles/archives/2007/jul/19/our-biotech-future/?pagination=false Accessed December 5th 2012.

have not been identified, and remain active in controlling it.[218] Author Mark Bowden has described it as "the first digital world war." [219] [220]

In the earliest days of computer hacking, there were no negative uses. Over time, pranks began to be played, eventually evolving to full scale criminality. The same evolution seems likely to occur in biohacking, as it evolves from being an underground techie movement into society's mainstream.[221]

Threats from malware pose such a significant threat that the European Commission established an EU-wide cyber crime unit in 2012.[222] The US government operates a Computer Crime Section.[223] Cyber crime threatens governments, business and individuals around the world; it has been estimated that it costs international business about €285 billion per year.[224] Though computer hacking and virus creation can be very destructive, they pale in comparison with the potential destructive power of synthetic biology. In the words of, Marcus Wohlsen, author of a book on biohacking:

> This is one important way in which home brew biotech departs from… more traditional hacking. A cook experimenting in the kitchen could end up

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[218] John Markoff (2009). "Defying Experts, Rogue Computer Code Still Works." *The New York Times*, 26th August. http://www.nytimes.com/2009/08/27/technology/27compute.html Accessed March 29th 2012.
[219] Mark Bowden (2011). *Worm: The First Digital World War*. (New York: Atlantic Monthly Press).
[220] See also *The New York Times* "Cyberwar" series: http://topics.nytimes.com/top/features/timestopics/series/cyberwar/index.html Accessed March 29th 2012.
[221] Mark Bowden (2011). *op. cit*., note 218.
[222] European Commission (2012). *Communication from the Commission to the Council and the European Parliament: Tackling Crime in Our Digital Age – Establishing a European Cybercrime Centre*. (Brussels: European Commission). http://ec.europa.eu/home-affairs/doc_centre/crime/docs/Communication%20-%20European%20Cybercrime%20Centre.pdf Accessed March 29th 2012.
[223] United States Department of Justice (2012). *Computer Crime and Intellectual Property Section*. http://www.justice.gov/criminal/cybercrime/ Accessed March 29th 2012.
[224] Reuters (2012). "EU Cyber-Crime Centre Announced." *Irish Times*, 18th March.

> with a fallen soufflé. A computer builder with a soldering iron could end up with burnt fingers and a useless box of metal. A biohacker who is either careless and unlucky or brilliant and evil could someday theoretically unleash a swine flu variant that resists all treatment by known antivirals and has no off switch.[225]

In worst case scenarios, synbio could produce something as deadly, or more deadly, than the atomic bomb, in multiple variants, to be possessed by anyone who wishes. Advances in the science will make it ever easier for individuals to synthesise entire genomes, including those of lethal pathogens.

In 2003, the US National Academy of Sciences convened a panel of biology experts to discuss how advances in bioscience research may affect weapons production. The CIA reported their findings in a short paper, *The Darker Bioweapons Future.*[226] They concluded that a significant bioweapons threat is likely to come into existence, and that "the world's most frightening weapons"[227] could be created. They observed that the pace of biological research is so great, and the increase in knowledge so vast, that "the resulting diversity of new [biowarfare] agents could enable such a broad range of attack scenarios that it would be virtually impossible to anticipate and defend against… As a result, there could be a considerable time-lag in developing effective biodefense measures."[228] A 2008 U.S. bi-partisan Congressional report, *World at Risk*, stated that an attack with a weapon of mass destruction on the U.S. is likely within a few years, and that such a weapon is most likely to be a bioweapon.[229]

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[225] Marcus Wohlsen (2011). *op. cit.*, note 216, p. 6-7.
[226] Central Intelligence Agency Directorate of Intelligence (2003). *The Darker Bioweapons Future.* http://www.fas.org/irp/cia/product/bw1103.pdf. Accessed March 24th 2012.
[227] Ibid.
[228] Ibid.
[229] Bob Graham, Jim Talent, Graham Allison, Robin Cleveland, Steve Rademaker, Tim Roemer, Wendy Sherman, Henry Sokolski and Rich Verma (2008). *World at Risk: The Report of the*

At speeches in Prague in 2009, and Seoul in 2012, President Barack Obama said that he wanted to secure the world's nuclear materials, to prevent nuclear terrorism; and, ultimately, to rid the world of nuclear weapons.[230] [231] Yet, largely unnoticed, in the background, synthetic biology is advancing, which may enable criminals, terrorists, psychopaths and emotionally disturbed people to create weapons of mass destruction. Which raises the question: can it be wise or ethical to allow such a branch of science to advance, knowing that it could lead to such scenarios?

CAN A CONSEQUENTIALIST SUPPORT SYNTHETIC BIOLOGY?

Journalist Fintan O'Toole has extended upon Donald Rumsfeld's known knowns, known unknowns and unknown unknowns, to write of *unknown knowns* – "the stuff we know but choose not to know."[232] His examples include the fact that there was corruption in the financial system during the boom, and abuse in the Catholic Church. Ignoring these unknown knowns eventually led to catastrophe in these areas.

Synthetic biology also has its unknown knowns, as described – the fact that its dangers are so great, and could, in the worst case, destroy much of life on Earth. The potential dangers are clear, yet the research is still going ahead, and without much in

Commission on the Prevention of WMD Proliferation and Terrorism. (New York: Vintage Books). http://www.absa.org/leg/WorldAtRisk.pdf Accessed March 24th 2012.

[230] Mark Landler (2012). "Obama Urges China to Restrain North Korea as he Praises South's Successes." *New York Times*, 26th March. http://www.nytimes.com/2012/03/27/world/asia/president-obama-in-south-korea.html Accessed March 27th 2012.

[231] Barak Obama (2012). *Remarks by President Obama at Hankuk University of Foreign Studies.* Mission of the United States, Geneva website. http://geneva.usmission.gov/2012/03/26/president-obama/ Accessed March 27th 2012.

[232] Fintan O'Toole (2012). "GAA No Amateurs on 'Secret' Payments." *Irish Times*, 28th February 2012. http://www.irishtimes.com/newspaper/opinion/2012/0228/1224312480734.html Accessed February 29th 2012.

the way of regulatory oversight. Reasons for this include the fact that potential positives are great, and could result in benefits for humanity that could be, in best-case scenarios, revolutionary. Also, scientific fame could be achieved by leading practitioners, and there is potential for great wealth. The dangers are known, but the research presses ahead regardless, without significant steps being taken to safeguard against them. The dual use nature of synbio means that the most beneficial advances also have the potential to be used negatively. In between the most extreme potential outcomes, synbio offers a myriad of opportunities and dangers. Ethically, it differs from other fields of science and technology in that the potential for both benefits and harms seems to be much greater.

O'Toole notes that denial and wilful ignorance can be "comforting and congenial", and quotes TS Eliot on such a psychological approach: "human kind/Cannot bear very much reality."[233] Denial and wilful ignorance in the ethical evaluation of synthetic biology could, in worst case scenarios, result in the greatest disasters experienced by humanity. The issues here are not particularly complex – synbio, if it succeeds, and remains on its current path, will almost certainly allow members of the public to become creative using biological materials. This creative power will include the ability to create biological weapons, including weapons of mass destruction. A future Columbine, or something much worse, may be carried out with such weapons. The dangerously, carelessly curious may be able to manufacture them; so may criminals, terrorists and rogue governments. Once this particular pandora's box is opened, there is unlikely to be a means of shutting it.

[233] Ibid.

Although ethical and regulatory reviews are taking place, little is being done currently to ensure that worst case scenarios do not occur. The overall thinking in the field appears to be muddled by the excitement of this great scientific quest.

Encoded into the watermark of the world's first synthetic organism is a quote from Robert Oppenheimer (the father of the atomic bomb), which could be considered a motto for the fledgling field: "See things not as they are but as they might be."[234] It's a motto which could equally be taken account of by ethicists and regulators of the field, who should evaluate the field clearly, without hopes or prejudices, and recognise its potential dangers as well as its potential benefits. It is also worth quoting Oppenheimer's reaction to the first successful detonation of the atomic bomb:

> We knew the world would not be the same. A few people laughed, a few people cried, most people were silent. I remembered the line from the Hindu scripture, the Bhagavad-Gita. Vishnu is trying to persuade the Prince that he should do his duty and to impress him takes on his multi-armed form and says, "Now, I am become Death, the destroyer of worlds." I suppose we all thought that one way or another."[235]

Synbio is not, in itself, aimed towards destruction, as was atomic weapons research; quite the contrary, in general. Be that as it may, it has the potential to introduce far greater destructive power into the world. Its potential benefits are not guaranteed; its destructive uses virtually certain. Even if its benefits could be guaranteed, its application in destructive uses would, almost certainly, far override the benefits.

The legend of *Faust*, which has been retold in various literary works since the 16th century, (by various writers such as Philip Marlowe, Johann Wolfgang von

[234] David Biello and Katherine Harmon (2010), and Aaron Saenz (2010). *op. cit.* note 14.
[235] AtomicArchive.com (2011). *J. Robert Oppenheimer – "Now I am Become Death."* http://www.atomicarchive.com/Movies/Movie8.shtml Accessed May 30th 2012.

Goethe and Thomas Mann) tells the story of a man who sold his soul to the devil in return for knowledge. He obtained the knowledge he desired; but at the price (in most versions of the tale) of eternal destruction in hell. The question must be asked: was it worth it? A similar question can be asked of synthetic biology: are the possible benefits worth the possible risks? Undoubtedly synthetic biology may lead to great scientific advances, including great therapeutic advances. But this could be a Faustian bargain, as its destructive potential is so great.

Balancing the potential benefits against the potential negatives, it is reasonable to conclude that a consequentialist cannot support synthetic biology. That may change if adequate regulations can be developed, that permit the beneficial side of the research to flourish, while minimising hazardous applications. Proper regulation of this field is an ethical imperative, and such regulations will need to go beyond the imposition of sanctions. In the case of computer hacking, viruses, etc., enforcement takes place after a criminal event occurs. Such an approach will be of little use in the case of malevolent synbio creations. Regulation needs to ensure that the chances of worst case scenarios occurring are minimal. Regulation would need to be worldwide in scope, and getting agreement from all governments may be challenging. Also, DIY biology/biohacking by individuals may be impossible to detect. Even in labs, malevolent research is unlikely to be distinguishable from legitimate in all cases; this is difficult, if not impossible, to monitor. It is possible that the banning of certain information from public view may be necessary to achieve public safety.

A moratorium on synbio research until such regulation is achieved may be the safest approach. Such a moratorium was proposed by some scientists in the foundational days of genetic engineering, and was observed by the scientific community. Biosafety issues were then discussed by scientists and other professionals at the Asilomar Conference in California in 1975, which ultimately resulted in the development of regulations that governed the field. Regulations were strict at first, but as security concerns diminished with increasing knowledge, the regulations were relaxed appropriately. Genetics research has flourished since Asilomar; little in the way of safety concerns have been observed so far. [236] A similar approach, taking into account synbio's unique issues, may help to provide solutions for the synthetic biology's dual use dilemma.[237] Perhaps the success of the post-Asilomar approach in genetics has led to a sense of false security among scientists, regulators and ethicists regarding synbio. However, synbio pushes the boundaries of risk vs. reward much further than classical genetics, and this needs to be recognised. In devising appropriate regulations, policymakers must be mindful of the dangers posed by synbio. They must also bear in mind the potential benefits, which could be lost through over-zealous regulation. In the words of John Harris: "How do we assess the loss of life/loss of benefit when beneficial/life saving measures are delayed through caution? Caution is not necessarily beneficial or even cautious"[238] – the essential dilemma of synthetic biology ethics. As mentioned, the potential dangers are so great, at present, that they outweigh any potential benefits. The challenge for regulators is to tip the balance.

[236] Paul Berg and Maxine F. Singer (1995). "The Recombinant DNA Controversy: Twenty Years Later". *Proceedings of the National Academy of Sciences*, 92: 9011-9013. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC40913/pdf/pnas01498-0009.pdf Accessed February 24th 2012.

[237] Paul Berg, David Baltimore, Sydney Brenner, Richard O. Roblin III, and Maxine F. Singer (1975). "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules". *Proceedings of the National Academy of Sciences*, 72(6): 1981-1984. http://authors.library.caltech.edu/11971/1/BERpnas75.pdf Accessed March 24th 2012.

[238] John Harris, private communication.

IS A CONSEQUENTIALIST ANALYSIS ADEQUATE?

It is clear that synthetic biology offers a complex web of potential benefits and dangers, and a consequentialist study is useful in attempting to unravel it. It offers an essential roadmap to policymakers and regulators, in a way which other ethical theories, such as deontology or virtue ethics, seem unlikely to. But is this analysis adequate? Scientific research tends to be applied in ways which are frequently impossible to predict. For example, early pioneers in research into electricity could not have foreseen its applications to uses as diverse as the internet, mass air travel, space travel, MRI scans and mobile phones. Synthetic biology, if it succeeds, may revolutionise human life to a far greater degree. But in what ways will it do this? Can we predict, with any plausibility, how it will be used in 50 years time? In 100? In 500?

To attempt to answer the question, consider an intelligent observer at the following event:

> "But if (and oh! what a big if!) we could conceive in some warm little pond, with all sorts of ammonia and phosphoric salts, light, heat, electricity, etc., present, that a protein compound was chemically formed ready to undergo still more complex changes."
>
> Charles Darwin[239]

The quote is a description, by Charles Darwin, of the origin of life. It should not be taken as scientific truth – scientific origins of life are not yet known.[240] Yet it is a good enough description for our purposes. Imagine that an intelligent observer was at that event, the coming together of certain chemicals, or whatever form the origin of

[239] Charles Darwin (1871). "A Letter to Jospeh Hooker." In Richard Dawkins (2005) *The Ancestors' Tale.: A Pilgrimage to the Dawn of Evolution.* (Boston, MA: Mifflin Harcourt), p. 560.
[240] See, for example: David Deamer (2011). *First Life*. (Berkeley, CA: University of California Press).

life took. Could they have predicted that the earliest protein compounds would, over aeons, evolve into the uncountable myriad of life-forms on earth? Could they have predicted the vast array of bacteria, of swarming insects, of birds, fish, animals? Or humanity, with all its achievements and failings: its technology, art, philosophy, architecture, warfare, poetry, religions, romance, and its propensity to both good and evil? Suppose they came from a place and culture in which none of these things existed? It is obvious that they could not.

If synthetic biology succeeds, we may now be at a point comparable to the earliest days of life on Earth, in terms of evolutionary change. And it will be as difficult for us to predict the outcomes as it would have been for an observer at the beginning of life on Earth.

Of what use is consequentialism in this scenario? What uses will scientists make of synbio, over decades and centuries? Or health care professionals, armies, dictators, the general public? Has synthetic biology rendered consequentialist analysis useless, placing a limit beyond which it cannot go?

Possibly. But objections can be put to this. First, it could be argued that synbio is not equivalent to the first emergence of life. It is already known how life has developed and evolved – so it will be possible to make educated guesses about where synbio may lead. Against this, synbio is already showing a tendency to merge with robotics, computer science and nanotechnology, which may create a world which is currently unimaginable. It is unlikely to be predictable, in any meaningful way, where this may lead.

It could also be argued that synbio, as it is, now, could be analysed with consequentialist thought; then, when the landscape of scientific advance changes, it could be analysed again. This could be done continuously as the landscape keeps changing. Bit by bit, a consequentialist analysis of synbio could be built, reaching an adequate analysis over time. However, at the extremes, synbio may ultimately result in a paradise on earth, or it could lead to a type of hell. By the time such outcomes become clear, it may be impossible to reverse course.

It appears, then, that synthetic biology poses the ultimate challenge to consequentialism, defining a boundary for it. This is an area where meaningful consequentialist analysis becomes impossible, the extreme case that renders it useless. Consequences cannot be predicted, or ethical evaluations made – we are staring into a void. This is not to say that consequentialist analyses must always be able to predict the future. The future is not usually predictable to an accurate degree. Yet consequentialism is perceived to be valid because the future, or a number of posited alternative futures, can be usually predicted up to a point. But this is not so in the case of synthetic biology – it takes humanity to a place of radical departure from what is known or knowable. Perhaps this is as it should be – synthetic biology is such a great step that it may, if it succeeds, change *everything,* including our attitudes to nature and to life, as well as the very nature of life itself; as well as attitudes to God, and the foundations of philosophy and ethics.

While the philosophical literature abounds with critiques of consequentialism, regarding the difficulty of predicting consequences in a meaningful way, the advent of synthetic proves this fact, independently of whether the previous literature existed. It offers something akin to empirical evidence, a scientific proof, of consequentialism's limitations.

NEWTON, EINSTEIN AND CONSEQUENTIALISM: HAS CONSEQUENTIALISM A FUTURE?

If a topic as important as synbio cannot be dealt with meaningfully by consequentialism, then the usefulness, and indeed the validity, of the theory comes into question. If consequentialism fails in this in the important and testing scenario of synthetic biology ethics, then it must be questioned whether it is valid in any scenario.

It is worthwhile to compare consequentialism with a theory in physics that was shown to be wrong – Isaac Newton's theory of gravitation.[241] First presented in the *Principia Mathematica* in 1667, it lasted until the early 20th century. It describes the gravitational force mathematically, stating that every mass attracts every other mass in the universe by a force which is proportional to the product of their masses, and inversely proportional to the square of the distance between them.

Newton's theory was replaced by Albert Einstein's theory of gravity – the theory of general relativity – in the 1920s. Much more mathematically complex, it describes reality in terms of four-dimensional space-time – three dimensions of space,

[241] There are limitations in comparing theoretical approaches across disciplines, but this is not to say that insights cannot be gained.

one of time – in which all matter is embedded. Objects in space-time distort it, its very fabric; this distortion causes gravitational attraction, by causing objects to move along the curve of the distortion.

These are very different descriptions of the universe, & contradict each other. Which is correct? In physics, this can be answered by experimental evidence. Light has no mass, so, according to Newton, a ray of light will not experience gravitational attraction. According to Einstein, it will – if space-time is curved by the existence of some body, this distortion will cause a light-path to change, exerting an apparent “force” upon it. In theory, therefore, the light from stars could be examined, to see if their paths are changed when they go near another astronomical body, such as the sun, which will curve space-time considerably. In 1919, Arthur Eddington, a Cambridge University physicist, tested Newton and Einstein’s theories by examining light paths from stars during a solar eclipse. With minute measurement, he showed that Einstein’s theory was correct.

Newton’s theory of gravitation was proved to be a wrong description of the universe. But it is still taught in schools and universities, as a way of illustrating gravity and its laws. Mathematically, it yields correct answers almost all of the time; it is relatively simple to use. Yet in extreme cases, it will give wrong answers – though they will appear right, the mathematical output of sophisticated physics equations. Scientists know the theory is not a correct description of the universe, but still use it, for the sake of ease.

Because humans tend to evaluate ethical issues in terms of consequences to actions (at least in part), consequentialism may survive, greatly diminished, as Newton’s theory has. But it has been challenged at a fundamental level by synthetic biology; consequentialism cannot function regarding the unknowable. It appears to be flawed at its conceptual roots. Like Newton’s theory, it can give correct, useful answers much of the time. It can also yield answers which may appear logically sound and correctly argued, but are wrong, because the underlying theory itself is wrong. Many examples could be given of such arguments in consequentialist thought.

CONCLUSION

Two major conclusions can be reached from this analysis. First, synthetic biology offers great potential benefits, and great potential dangers. The dangers, of serious destruction, are so great, that they appear to outweigh any potential benefits, no matter how great those benefits may be. Perhaps the dangers could be minimised by appropriate regulation. There will problems in developing such regulations, however, particularly for the case of DIY biology. Unless and until the dangers can be minimised, it seems that synthetic biology research is unethical, and cannot be supported by consequentialist thinkers. There is a strong ethical duty to attempt to develop adequate regulation, to allow positive applications of the field to flourish, but whether such regulation can be achieved is an open question. Until this question is adequately dealt with, a moratorium should be placed on synbio research, following the approach used by the early genetic engineering pioneers.

Second, a consequentialist analysis is invaluable in determining the immediate potential benefits and dangers of synbio, and giving guidance to policymakers as to how to respond in the short term. And yet, paradoxically, it is of no value in determining whether synbio is ethical, ultimately, and whether humanity should take this step. Consequentialism fails in a scenario such as this, where consequences can't be predicted in any meaningful way, beyond the short-term. Synthetic biology has placed a limit on consequentialist thought. In doing so, it appears to have defeated the validity of this class of ethical theories. At best, they may be used as approximate guides, but cannot be seen as a certain path to ethical truth.

CHAPTER 6 A DEONTOLOGICAL ASSESSMENT OF SYNTHETIC BIOLOGY ETHICS

To be published, with some changes, as: Patrick Heavey (2013). “Synthetic Biology: A Deontological Assessment.” *Bioethics*, Special Issue on Synthetic Biology, November.

ABSTRACT

In this paper I discuss the ethics of synthetic biology from a broadly deontological perspective, evaluating its morality in terms of the integrity of nature, the dignity of life and the relationship between God and his creation. Most ethical analyses to date have been largely consequentialist in nature; they reveal a dual use dilemma, showing that synbio has potential for great good and great evil, possibly more so than any step humanity has taken before. A deontological analysis may help to resolve this dilemma, by evaluating whether synbio is right or wrong in itself. I also assess whether deontology alone is a sufficient methodological paradigm for the proper evaluation of synbio ethics.

In Mary Shelley's classic tale, Dr. Victor Frankenstein assembled a human body from parts retrieved from corpses. The novel, first published nearly 200 years ago, raised questions that we would now consider to fall within the realm of bioethics. If Dr. Frankenstein wanted to carry out his experiment today, he would need to bring it to the attention of the IRB (Institutional Review Board) at his university who would doubtlessly reject it. And yet, a number of laboratories around the world are attempting to perform a reconstitution of life eerily similar to Frankenstein's dream – to invent something alive, but on a microscopic scale. There is a name for such a science – synthetic biology.

David Deamer[1]

INTRODUCTION

Synthetic biology may be the most daring step taken in scientific and, indeed, human history, yet it has received relatively little attention from the bioethics community. This is surprising; perhaps its potential radicalness has not yet been grasped. The literature that does exist tends to analyse it from a consequentialist viewpoint, in which the field's "dual use" nature presents a nearly unsolvable conundrum – for the field offers the potential for unimaginable advances in human development, yet also has potentially great destructive power. A deontological analysis may help to resolve the dual use dilemma. Is synthetic biology right or wrong in itself? In the words of Ghandi: "good results will never be achieved by immoral means."[2] Deontology may be useful in determining whether or not humanity should take the path towards creating and engineering life.

[1] D. Deamer. 2011. *First Life*. Berkeley, CA: University of California Press: 241.
[2] M. Gandhi. Quoted in: F. Marsden. 2007. Decline in Morality has led to Animal-human Hybrids. *The Catholic Herald* 16 Sept: 7.

In this paper, I shall examine the ethics of synthetic biology from a mainstream deontological perspective, examining how synbio relates to: the integrity of nature, the dignity of life, and the relationship of God and his creation. Following this, I will compare the outcome of this deontological analysis with those of consequentialism, and evaluate the appropriateness of deontology as a methodological paradigm for evaluating synthetic biology ethics.

A CHALLENGE TO THE INTEGRITY OF NATURE?

Every animal is an end in itself, it issues
Perfect from Nature's womb and its offspring are equally perfect.
All its organs are formed according to laws that are timeless,
Even a form very rare will hold to its type, though in secret.

Johan Wolfgang von Goethe[3]

Many people may be intuitively troubled by the idea of synthetic, or semi-synthetic, life being created. Even before the advent of synbio, Prince Charles commented on certain aspects of biotechnology: "Are we going to allow the industrialisation of Life itself, redesigning the natural world for the sake of convenience and embarking on an Orwellian future? And, if we do, will there eventually be a price to pay?[4] Christopher Preston, an environmental philosopher, has argued that synthetic biology is wrong from a deontological point of view, as it is

[3] J. W. von Goethe. 1806. *Metamorphosis of Animals*. Quoted in: C. Nusslein-Volhard. 2008. *Coming to Life: How Genes Drive Development*. Carlsbad, CA: Kales Press.

[4] Charles, Prince of Wales. 1999. Questions about Genetically Modified Organisms. *Daily Mail* 1 June. See also: BBC News. 1999. Prince Sparks GM Food Row. *BBC News* 1 June. http://news.bbc.co.uk/2/hi/uk_news/357665.stm [Accessed 15 Feb 2013].

unnatural, representing a disconnect from Darwinian evolution."[5] A possible result could be the "end of nature."[6]

Preston observed that in much of environmental ethics there is "a substantial normative commitment to the value of what is biologically natural over what is artefactual… that the *naturalness* of wild nature carries moral weight"[7] A clear line must be drawn between what is natural and what is not. Aristotle made this distinction in *Physics*, observing that artefacts are fashioned by humans, while natural entities are not.[8] Preston acknowledged that there are problems with this distinction, referring to John Stuart Mill's 1874 essay, *Nature*, where he observes that humans are also naturally occurring, and what they do is subject to nature's laws. Yet their actions can also reduce the essence of nature in the raw.

Preston discussed an ethical analysis by Keekok Lee, of "deep… nature replacing" technologies, such as biotechnology and nanotechnology.[9] [10] Lee argued that there is a hierarchy of technologies that damage nature – those that damage it superficially, for example pollution, the negative effects of which can be reversed; and bio and nanotechnology, which manipulate nature at the deepest levels, changing its essence, replacing "nature" with less morally valuable "artefact."[11]

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[5] C. Preston. Synthetic Biology: Drawing a Line in Darwin's Sand. *Environ Value* 2008; 17*:* 23–39.
[6] A concept introduced by Bill McKibbin in the context of the destructive power of climate change. See: B. McKibben. 1989. *The End of Nature*. New York: Random House.
[7] Preston, *op. cit*., note 5, pp. 24-25.
[8] Aristotle. 1941. *Physics*. R.P. Hardie and R.K. Gaye, trans. New York: Random House. (192b8-11). In Preston, *op. cit*., note 5, p. 25.
[9] K. Lee. 2003. *Philosophy and Revolutions in Genetics: Deep Science and Deep Technology*. Basingstoke: Palgrave MacMillan.
[10] K. Lee. 1999. *The Natural and the Artifactual: The Implications of Deep Science and Deep Technology for Environmental Philosophy*. New York: Lexington Books.
[11] Preston, *op. cit*., note 5, p. 28.

Preston correctly rejected that conclusion, on the basis that human activity, such as domestication and cross-breeding of animals and plants, has been modifying nature at the deep level of the genome, significantly changing species and effecting evolution, for millennia, and this is not generally seen as deontologically wrong. He noted that cross-breeding, though guided by human intelligence, is similar to the processes of natural evolution; it is connected to that historical process. So is current mainstream biotech; it changes natural genomes by adding or deleting other naturally occurring DNA. He argued that synbio operates on a different level, however, because designing DNA represents a total break from evolutionary history; here genomes are designed from scratch, using human intelligence, and resulting synthetic organisms have no connection with organisms that have evolved naturally.

There are flaws in this argument. First, synthetic organisms will be created from DNA; even in its modified, designed form, it is a naturally occurring artefact, a product of evolution, albeit one that has been modified by humans. Thus there is no fundamental disconnect from nature's processes, although synbio represents a significant application of human intelligence to those processes. Second, synthetically designed organisms will evolve over time; they will also be affected in their evolution by their interaction with other organisms, both natural and synthetic, and will also affect the evolution of those organisms. Thus they remain connected with the evolutionary process, integrated into the web of life. No matter how advanced synthetic biology may get, it remains embedded in nature. Third, synthetic organisms remain, in spite of the nomenclature, modifications of existing life-forms. Craig Venter's *Synthia*, for example, consists of a synthetically-made genome placed into a living bacterium, thereby changing it to a different species of bacterium; but this new bacterium isn't built from scratch. No matter how radical the DNA design, it still has to be placed in a living organism to make it functional. To build complete synthetic cells, etc., is far beyond the current capabilities of science. This could change in the future, but even if it does, any synthetically designed cells will be based on carbon-based biological materials, products of evolution.[12]

Arguments have also been put forward that certain aspects of biotech cause nature to be commodified, and this violates nature's sanctity.[13] Particularly, the fact that synthetic biology creations can be patented may commodify nature to a higher degree than before.[14] Against this, nature is commodified already. Much of the world's land is privately owned, or owned by governments. Animals and plants are owned; whole industries make profits solely from such ownership. Mainstream ethics would not regard ownership of land, animals and plants as being problematic. Similarly, commoditising synthetic biology creations is not necessarily unethical. It could become so in certain circumstances. For example, some synthetic biologists are attempting to patent fundamental biological processes, such as the minimal microbe genome, potentially taking commodification to a much deeper level.[15] In the words of Leon Kass: "It is one thing to own a mule; it is another to own *mule*."[16] This is a matter for intellectual property law, however, not inherent to or an argument against synthetic biology *per se*.

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[12] P. B. Thompson. Synthetic Biology Needs a Synthetic Bioethics. *Ethics, Policy & Environ* 2012; 15: 1-20.
[13] There are many arguments for this. See for example: Joint Appeal Against Human and Animal Patenting. 1995. Washington, DC: Board of Church and Society of the United Methodist Church.
[14] A. K. Rai and J. Boyle. Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons, *PLoS Biol* 2007; 5: 389-393.
[15] P. Aldhouse. Tycoon Seeks Patent for 'Minimal Genome.' *New Scientist* 2007; 8 June.
[16] L. R. Kass. Patenting Life. *Commentary* 1981; 72: 45-57.

It would appear, therefore, that synthetic biology does not, in itself, cross an ethical boundary regarding nature, as it is simply a significant technological advance on techniques which have used for millennia. But, as we are ethically obliged to preserve the environment for ourselves and future generations, this obligation should also be taken account of in synthetic biology research. With proper care, synthetic biology may yield great benefits without damaging nature's integrity.

A CHALLENGE TO THE DIGNITY OF LIFE?

> *One of the deepest mysteries in biology is how molecules that are no more alive than the tip of a pencil can form a reproducing, metabolizing, evolving organism. If you plop a droplet of any of the molecules that make up living cells (fats, amino acids, water, DNA, other organic molecules) onto a glass slide, it just sits there. No one would mistake it for a living thing. Yet when the right ingredients assemble in the right proportions, the result comes alive, as it did on Earth some 3.8 billion years ago.*
>
> Sharon Begley[17]

Regarding the "creation" of life, human parents and other creatures do it all the time. In doing so, they change the world somewhat. For humans, the person they bring into being has the potential to do great things, or to be a force for evil. In their own breeding, people already select characteristics of their offspring, to an extent, in selecting their mate. Most select potential mates from a particular group, with which they feel affinity. The question must be asked as to whether there a significant ethical difference between creating a life form naturally, but selectively, and creating one synthetically.

[17] S. Begley. 2004. Researchers Seek to Create a Living Cell. *The Wall Street Journal* 2 April.

The question has been dealt with, to an extent, in the above section on synbio and the dignity of nature. But there are other concerns. If the idea of life is changed to something that can be manufactured in a lab, then the value that is currently placed on life might be reduced.[18] Synthetic biology could cause life to be perceived as something that is just produced by industry, akin to other such products. Some of the terminology of synbio can be problematic in this regard. Synthetic biologists discuss microorganisms in terms of "hardware" and "software;" they speak of "living machines," and describe synthetic DNA segments as "BioBricks;" also some synthetic organisms will be designed onto living "chassis" organisms.[19] Such identification of life with artifacts, when the terminology becomes familiar in society at large, could diminish society's respect for life and its dignity.

Advances in science have caused societal attitudes to change in the past. For example, in the 18th century, the Swedish botanist and clergyman Carl Linnaeus, the father of biological classification, developed a classification system for plants. In developing a classification hierarchy, Linnaeus emphasised male characteristics of plants; it seemed natural, as it reflected the organisation of human society. In the words of historian of science Patricia Fara: "The prejudices of Enlightenment Christian moralists are built right into the heart of this scientific plan for plants…"[20] This classification led to the reverse being argued; the hierarchies of human society could be justified on the basis that they reflected those of nature.[21]

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[18] Research in Germany. 2010. *Assembling Life from Building Blocks*. German Ethics Council, Bioethics Forum Meeting, Berlin, 24th February. http://www.research-in-germany.de/news-archive-2010/news-archive-march-2010/42900/2010-03-17-assembling-life-from-building-blocks,print=true,slc=dachportal_2Fen,sourcePageId=64794.html [Accessed 15 Feb 2013].

[19] J. Boldt and O. Muller. Newtons of the Leaves of Grass. *Nat Biotechnol* 2008; 26: 387-389.

[20] P. Fara. 2003. *Sex, Botany and Empire: The Story of Carl Linnaeus and Joseph Banks*. Cambridge: Icon Books: 21.

[21] Ibid: 20-24.

Similarly, Darwin's theory of evolution has given rise to ideologies of Social Darwinism, where science is misapplied to advocate societies based on competition/survival of the fittest, in various ideologies.[22] Could the creation of synthetic life lead to similar misapplication? Even if so, would that challenge the dignity of life *per se*, rather than perceptions of it?

Artist Daisy Ginsberg has created a work called *The Synthetic Kingdom*.[23] It's a simple concept. There are currently three classifications of life in biology – prokaryote (whose cells don't have a nucleus – mostly bacteria), eukaryotes (which do – mostly everything else, including humans) and archea (like prokaryotes, but with a different evolutionary history). Ginsberg created a piece of art that postulates a fourth kingdom of life – *Synthetica*. This artwork is on the cover of the first textbook on synthetic biology,[24] and on walls in some major synio labs.

As well as creating the art, she's involved in classifying life-forms in the *Synthetica* branch. In the other three branches, life forms are listed, and classified according to their characteristics – for example, vertebrates, mammals and individual species,… their Aristotlean *eidos*. Ginsberg did not attempt to classify *Synthetica* herself; she's an artist, not a synthetic biologist. Rather, she liaised with leading synthetic biologists, and let them do it. Here are some of the classifications: Fabricators (adhesives, ceramic-like, coatings, rubbers, fibres, glass-like, self-healing,

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[22] G. Claeys. The "Survival of the Fittest" and the Origins of Social Darwinism. *J Hist Ideas* 2000; 61: 223-240.

[23] A. D. Ginsberg. 2009. *The Synthetic Kingdom*. Available at: http://www.daisyginsberg.com/projects/synthetickingdom.html [Acessed 15 February 2013]; A.D. Ginsberg. 2010. Redesigning the Tree of Life. Available at: http://synthetickingdom.wordpress.com/2010/07/10/redesigning-the-tree-of-life/ [Accessed 15 Feb 2013].

[24] P. S. Freemont, R. I. Kitney, G. Baldwin, T. Bayer, R. Dickinson, T. Ellis, K. Polizzi and G-B Stan. 2012. *Synthetic Biology: A Primer*. London: Imperial College Press.

wood-responsive); Operators (cleaners, computers, counters, pumps, sensors, timers); Printers.[25]

This is a very different, perhaps shocking, concept of “life.” It is utterly functional, and somewhat analogous to classification of people by occupation only, though it goes much deeper. Is there more to life than this? Synthetic biology is primarily an engineering discipline rather than a biological one, and it appears that engineering concepts have taken over in early ideas on classification. Although this classification system is a first step, and may evolve, it reveals the current mindset of some synthetic biologists. Based on previous experience, if this classification solidifies, it may have a knock-on effect on societal attitudes to life. Life could come to be seen as a mere commodity, something unimportant, replaceable, discardable.

In addition, some commentators have suggested that synthetic biology proves reductionist attitudes to life, that life is nothing more than a combination of chemicals.[26] Success in the research may strengthen such attitudes, corroding away concepts of the dignity of living nature, including human dignity.

These issues are a concern, but it is questionable as to whether the concern is inherent to synbio. Any major technological advance can be misapplied and lead to wrong attitudes. The question is, whether synbio in itself challenges life’s dignity. Does the danger of causing negative change in societal attitudes represent an attack on

[25] A. D. Ginsberg. 2009. *Proposal for a Linnean Taxonomy System for the Synthetic Kingdom*. Available at: http://www.daisyginsberg.com/projects/synthetickingdom.html [Accessed 15 Feb 2013].
[26] Church of Scotland, Church and Society Council. 2010. *Synthetic Biology*. Edinburgh: Church of Scotland.
http://www.churchofscotland.org.uk/__data/assets/pdf_file/0004/3793/synthetic_biology_report.pdf [Accessed 21 Feb 2013].

life's dignity *per se*? The answer must surely be no. For example, referring to the previous examples, the misapplication of Linnaeus' classification system was overthrown, yet his scientific classification persists in essence. It could be argued that increasing knowledge and education, including scientific advances, played a part in overthrowing a society that was rigidly stratified according to class and gender. Similarly, social Darwinism is a minority belief; the overall tendency, since the time of Darwin, has been a move away from such societies (notwithstanding current moves in the opposite direction). Synbio may lead to some negative attitudes; it could also be applied in ways that are injurious to life; but that is not to say that synbio *per se* challenges the dignity of life. To say that it could is like saying that politics, literature, science or religion attack life's dignity because they can lead to negative outcomes. Also, the fact that humanity has developed to so advanced a stage that it is on the verge of creating artificial life is a reflection of humanity's dignity, and that of life itself.

"PLAYING GOD" – A CHALLENGE TO THE RELATIONSHIP OF GOD AND HIS CREATION?

Men have become like gods. Isn't it about time that we understood our divinity? Science offers us total mastery over our environment and over our destiny, yet instead of rejoicing we feel deeply afraid. Why should this be? How might these fears be resolved?

Edmund Leach[27]

'In the beginning was the Word,' writes John in the prologue to his Gospel (John 1:1). And all things have come into being through the Word. John is listening to the universe as an expression of God. It is spoken into being by the One from whom

[27] E. Leach. 1968. *A Runaway World?* New York: Oxford University Press: 1.

all things come. It comes directly from the heart of God's being. And in it we can hear the sound of one Heartbeat.

So Iraneus speaks of creation coming out of the very 'substance' of God. It is not as if the elements of the universe are fashioned out of a neutral substance. It is not as if creation is set in motion from afar. The matter of life comes forth directly from the womb of God's being. The glory of the sun rising in the east is the glory of God shining on us now and now and now. The whiteness of the moon, the wildness of the wind, the moisture of the fecund earth is the glow and wildness and moisture of God now. It is the very stuff of God's being of which we and creation are composed.

John Philip Newell[28]

When Craig Venter announced the "creation" of *Synthia*, Pat Mooney of the ETC Group observed: "for the first time, God has competition."[29] Hamilton Smith, Nobel Laureate in Physiology or Medicine and research director at the J. Craig Venter Institute, when asked if the Venter group was playing God, answered: "we don't play."[30] The idea of scientists playing God,[31] and so transgressing a moral boundary, has been raised in the context of synthetic biology, largely by secular commentators. For example, the ETC Group have used the word *syn*[32] when referring to synthetic biology, as well as phrases such as *original syn*[33] and *syn of omission*.[34] David King, director of Human Genetics Alert said: "What is really dangerous is these scientists' ambitions for total and unrestrained control over nature, which many people describe as 'playing God.'"[35] Tom Douglas and Julian Savulescu wrote, on *Synthia's* release:

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[28] J. P. Newell. 2008. *Christ of the Celts: The Healing of Creation*. Glasgow: Wild Goose Publications: 55-56.
[29] ETC Group. 2007. *Patenting Pandora's Bug: Goodbye Dolly …Hello, Synthia!* Available at: http://www.etcgroup.org/upload/publication/631/01/etcnr_syn_final2.pdf [Accessed 15 Feb 2013]
[30] ETC Group. 2007. *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. Ottowa, ON: ETC Group: 15. Available at: http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/602/01/synbioreportweb.pdf [Accessed 15 Feb 2013].
[31] C. Abraham. 2005. Playing God in Running Shoes. *Toronto Globe and Mail*, 16 December.
[32] ETC Group. *op. cit.*, note 30, p. 3
[33] Ibid.
[34] ETC Group. *op. cit.*, note 29.
[35] T. Chivers. 2010. "Craig Venter's Synthetic Life: Is It Really 'Playing God?'" *The Telegraph*, 21 May.

> In synthesising novel organisms from scratch, synthetic biologists are 'playing God', and doing so much more effectively than earlier genetic engineers. They are not just tinkering with life, they are designing and creating it. Synthetic biology of the sort pursued by Venter's team involves the intelligent design of life. For many of us, this is not a problem. But some will hold that it involves usurping the proper role of God, or taking an arrogant and hubristic attitude to life.[36]

Balmer and Martin raised the issue in a report commissioned by the UK's Biotechnology and Biological Scienes Research Council.[37] An editorial in *Nature* said that: "Many a technology has at some time or another been deemed an affront to God, but perhaps none invites the accusation as directly as synthetic biology."[38] Peter Singer wrote, after the release of *Synthia*: "The scientists at the J Craig Venter Institute expected to be told that they were "playing God", and they were not disappointed. Yes, if one believes that life was created by God, then this comes as close to "playing God" as humans have come so far. [39] The issue has arisen repeatedly throughout the secular bioethics literature.[40]

The term "playing God" implies a reproach, of humanity attempting to arise above its natural station, of transcending natural limits, perhaps of megalomania,[41] of challenging God directly by taking on his role. The accusation is not unique to synthetic biology; it has been levelled at various scientific advances, including genetic engineering, anesthesia, organ transplants, artificial contraception and diagnosis of

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[36] T. Douglas and J. Savulescu. 2010. Towards the Creation of Artificial Life? Oxford: Uehiro Centre for Practical Ethics. Available at: http://www.bep.ox.ac.uk/__data/assets/pdf_file/0008/21887/DouglasSavulescu_VenterCommentv1.pdf [Accessed 15 Feb 2013].

[37] A. Balmer and P. Martin. 2008. *Synthetic Biology: Social and Ethical Challenges*. Swindon: BBSRC. Available at: http://www.bbsrc.ac.uk/web/FILES/Reviews/0806_synthetic_biology.pdf [Accessed 15 Feb 2013].

[38] Nature. Meanings of 'Life': Synthetic Biology Provides a Welcome Antidote to Chronic Vitalism. *Nature* 2007; 447: 1031-1032.

[39] P. Singer 2010. Scientists Playing God Will Save Lives. *The Guardian* 13 June.

[40] See: P. Dabrock. Playing God: Synthetic Biology as a Theological and Ethical Challenge. *Systems and Synthetic Biology* 2009; 3: 47-54.

[41] Ibid.

brain death.[42] In 1923, the British geneticist JBS Haldane observed that: "There is no great invention, from fire to flying, which has not been hailed as an insult to some god."[43]

Various commentators have rejected this reproach. An aversion to changing nature would, for example, prohibit the practice of medicine.[44] To that could be added prohibitions on the cross-breeding of plants and animals. Building houses and wearing clothes could also be seen as going against God's natural order; so could education.

Ronald Dworkin has written that it is in humanity's very nature to overstep such apparent boundaries.[45] Willem Drees, a theologian, argues that invoking the 'playing God' rebuke can display an inadequate concept of God; a result of people's own projections of God, who is actually far above their/our comprehension.[46] Craig Venter has denied playing God, noting that synthetic biology "is not about God-like powers, it's about scientific power;"[47] and "so far at least - we are only reconstructing a diminished version of what is out there in nature."[48]

In order to delve more deeply into this issue, it would be useful to look at some mainstream religious responses to synthetic biology. The first formal religious

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[42] Ibid.
[43] J.B.S. Haldane. 1923. *Daedelus, or, Science and the Future*. A Lecture Read to The Heretics, Cambridge, 4th February. Available at: http://vserver1.cscs.lsa.umich.edu/~crshalizi/Daedalus.html [Accessed 15 Feb 2013].
[44] J. Harris. 1985. *The Value of Life: An Introduction to Medical Ethics*. London: Routledge: 38.
[45] R. Dworkin. 2000. *Sovereign Virtue: The Theory and Practice of Equality*. Cambridge, MA: Harvard University Press.
[46] W.B. Drees. Playing God? Yes! Religion in the Light of Technology. *Zygon* 2002; 37:643–654.
[47] R. Von Bredow and J. Grolle. 2010. Spiegel Interview with Craig Venter. *Spiegel Online International* 29 July. Available at: http://www.spiegel.de/international/world/0,1518,709174,00.html [Accessed 15 Feb 2013].
[48] F. Macrae. 2010. Scientist Accused of Playing God after Creating Artificial Life by Making Designer Microbe from Scratch – But Could it Wipe Out Humanity? *Mail Online*, 3rd June. http://www.dailymail.co.uk/sciencetech/article-1279988/Artificial-life-created-Craig-Venter--wipe-humanity.html [Accessed 21 Feb 2012].

teaching on synbio has been issued by the Church of Scotland (Presbyterian), in a report which considers its theological, ethical and social concerns.[49] It addresses the 'playing God' issue, evaluating many of the arguments and concluding that for humanity to play God, they would have to create *ex nihilo*, out of nothing, as he did: "Despite some protestations to the contrary, synthetic biology does not put humanity on a par with God: our creatureliness remains, our undoubted creativity in such areas notwithstanding;"[50] also:

> Everybody, including the Christian world, could welcome this scientific innovation. Eliminating human suffering, protecting the environment, promoting general well-being and advancing scientific knowledge using reason and human ingenuity are goals in harmony with Christian teaching. God has endowed human nature with mental and intellectual capacities. It is our responsibility to use the divine gifts for the benefit of humanity, and of nature as a whole."[51]

They note that synthetic biology could be used unethically, of course, in a spirit of pride or greed, and constant ethical evaluation should take place; but synbio does not, in itself, impinge on God's creative role.

The Catholic Church has yet to issue a formal teaching on synbio. However, its general attitude to innovation in biology and medicine, which will form the foundation of any teachings on synthetic biology, is stated in the *Compendium of the Social Doctrine of the Church,* a formal doctrinal document of the Church's Magisterium, or teaching authority:

> …the human person does not commit an illicit act when, out of respect for the order, beauty and usefulness of individual living beings and their function in the ecosystem, he intervenes by modifying some of their characteristics or properties. Human interventions that damage living beings or

[49] Church of Scotland, Church and Society Council. *op. cit,* note 26.
[50] Ibid: 27.
[51] Ibid: 24

> the natural environment deserve condemnation, while those that improve them are praiseworthy.[52]

Informal statements were made by bishops and theologians when the creation of *Synthia* was announced; these seem likely to indicate what future formal teachings may be. These Church spokesmen mostly welcomed Venter's advance, though emphasized that synbio had the potential to be used for both good and evil, and should be used ethically. Some direct quotes illustrate their position. The head of the Italian Bishops' Conference, Cardinal Angelo Bagnasco, said *Synthia's* manufacture was a "further sign of intelligence, God's gift to understand creation and be able to better govern it... On the other hand, intelligence can never be without responsibility… Any form of intelligence and any scientific acquisition must always be measured against the ethical dimension, which has at its heart the true dignity of every human person." The head of the Pontifical Academy for Life, Monsignor Rino Fisichella, said it was: "a great scientific discovery," but warned: "If we ascertain it is for the good of all, of the environment and man in it, we'll keep the same judgment… If, on the other hand, the use of this discovery should turn against the dignity and respect for human life, then our judgment would change." The issue of playing God was raised by Italian Bishop Domenico Mogavero. He noted that synbio had the potential to be used to play God, without saying that it did so *per se*: "Pretending to be God and parroting his power of creation is an enormous risk that can plunge men into a barbarity... In the

[52] Pontifical Council for Justice and Peace. 2004. *Compendium of the Social Doctrine of the Church*. Vatican City: Libreria Editrice Vaticana: para 473. Available at: http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html [Accessed 21 Feb 2013].

wrong hands, today's development can lead tomorrow to a devastating leap in the dark."[53] [54]

Judaism's general attitude to human creativity is described by Rabbi Jonathan Saks;[55] it provides a foundation for reflection on synbio:

> One of Judaism's most distinctive and challenging ideas is its *ethics of responsibility*, the idea that God invites us to become, in the rabbinic phrase, his 'partners in the work of creation.' The God who created this world in love calls us to create in love. The God who gave us the gift of freedom asks us to honour and enhance the freedom of others.[56]

There is little in the way of published Jewish theological reflection on synthetic biology at present, but the reflection that exists tends to be positive.[57] There is a Jewish myth, of the Golem – an artificial human, created by a righteous medieval rabbi. Some Jewish bioethicists have drawn upon this as a justification for synthetic biology. Paul Wolpe presented to the Presidential Commission for the Study of Bioethical Issues in 2010, on various religious attitudes to synthetic biology, including Jewish. He drew upon the Golem myth, and upon Talmudic stories of rabbis creating life to imply a generally positive Jewish disposition towards synbio.[58] [59] [60]

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[53] A. Rizzo. 2010. *Vatican: Scientists Shouldn't Play God: But Church Officials Say Synthetic Cell Could Have Benefits*. Associated Press 21 May. Available at http://www.msnbc.msn.com/id/37285047/ns/technology_and_science-science [Accessed 15 Feb 2013].

[54] For a full exposition of the Catholic Church's probable teaching on synbio, see: P. Heavey. The Place of God in Synthetic Biology: How Will the Catholic Church Respond? *Bioethics* 2013; 27: 36-47.

[55] Though it must be remembered that there is no single Jewish teaching authority.

[56] Rabbi J. Sacks. 2005. *To Heal A Fractured World: The Ethics of Responsibility*. London: Continuum: 3.

[57] S. Glick. 2012. *Synthetic Biology – A Jewish View*. Presentation, 26th European Conference on the Philosophy of Medicine and Healthcare: Worst Case Bioethics. Nazareth, 23 August.

[58] President's Commission on Bioethics. 2010. *Ethical Issues in Synthetic Biology: Transcript from July 9th 2010, Q&A*. Available at: http://anthropos-lab.net/bio-nano/wp-content/uploads/2011/02/Presidents-Commission-July-9-Extract-Status.pdf [Accesed 15 Feb 2013].

[59] P. R. Wolpe. 2010. Religious Perspectives on Synbio. In *Ethics of Synthetic Biology Part 1: Presentation to the Presidential Commission for the Study of Bioethical Issues*, 9 July. Available at: http://www.c-spanvideo.org/program/294437-1 [Accessed 15 Feb 2013]

One of the leading Jewish Universities in the United States, Brandeis, has a synthetic biology research programme. It is part of the *Brandeis Institute for the Golem*, which aims to combine research in synthetic biology, robotics and artificial life, with appropriate studies in law, ethics and Jewish literary studies on the Golem. They ask, on their home page: "Do we have a right to take on G-d's own work on creation?" The existence of the Institute appears to answer in the affirmative.[61]

The Church of England's Mission and Public Affairs Council has published a collection of papers regarding theological implications of human genomics research. They strongly reject the 'playing God' reproach, stating:

> The term 'playing God' is a weasel term. 'Playing God' is clearly a fundamental form of pride if we understand it mean an abrogation of by human creatures of God's status as creator. But it is wholly appropriate to 'play God' if we understand the term to refer to that measure of creative discretion that God has given human beings in creation. 'God', as Charles Kingsley wrote in *The Water Babies*, 'makes things make themselves.[62]

Paul Wolpe also spoke with representatives of other religious traditions – Islamic, Christian, Buddhist and Hindu. None of them expressed concern about synbio *per se*. They did express concern about potential harms, that it should be used for good, and that it should not be used to 'play God.' But they did not see it as playing God by virtue of its existence.[63]

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[60] J. A. Redfield. 2011. *Cooking the Books; The Golem and the Ethics of Biotechnology*. Center for Biological Futures Working Paper 1. Seattle, WA: Fred Hutchinson Cancer Research Center. Available at: http://authors.fhcrc.org/519/1/CBFWP1_Redfield.pdf [Accessed 15 Feb 2013].
[61] Brandeis Institute for the Golem Homepage (undated). Available at: http://big.brandeis.edu/ [Accessed 15 Feb 2013].
[62] M. Bratton. 2009. Introduction: Autonomy, Solidarity and the Human Genome. In M. Bratton, ed. *God, Ethics and the Human Genome*. London: Church House Publishing: 1-21: 14.
[63] Wolpe. *op. cit*., note 59.

It appears that the views of most mainstream religious thinkers could be summed up in the words of Catholic biochemistry professor William Reville, who asked if man now rivalled God after the development of *Synthia*. Reville wrote:

> I was recently invited to witness a confrontation between God and another scientist who is far more advanced than Craig Venter in his ability to create synthetic life. This scientist challenged God to a contest to determine who is the best at creating life. God agreed and invited the scientist to go first. The scientist bent down and scooped up a fist full of dust saying, "First you take some dust". God jumped in immediately and said - "Hey, get your own dust!"[64]

The creation of *Synthia* does not compare with God's creation *ex nihilo*; neither will anything that synbio can produce.

Further religious opinions will be published on synbio as the science advances and becomes better known. It is clear, though, that some significant religious thinkers do not perceive a problem with it. This is not to say that synbio couldn't be applied with arrogance and hubris in the future, where individuals attempt to place themselves in equality with God; indeed human history suggests it probably will be, and precautions should be taken against this. But for a significant part of mainstream religious thought, synthetic biology does not appear to be, in itself, a usurpation of God's creative role. This is something that many secular commentators could note. Vincent Browne, an atheist journalist, has written that "Some [religious teachings] may be illuminating on the moral or political issues in question, but have no determinative value in themselves."[65] While the arguments must be evaluated on their own merits, a secular philosopher who argues that synbio is playing God may stand alone if the world's major religions do not agree.

[64] W. Reville. 2010. Life in the Lab. *The Irish Catholic* 15 July.
[65] V. Browne. 2012. Bible Not the Rule Book on Gay Marriage. *Irish Times* 16 May.

IS DEONTOLOGY AN APPROPRIATE METHODOLOGICAL PARADIGM FOR EVALUATING SYNTHETIC BIOLOGY ETHICS?

Things which we see are not by themselves what we see… It remains completely unknown to us what the objects may be by themselves and apart from the receptivity of our senses. We know nothing but our manner of perceiving them.

Immanuel Kant[66]

From the above discussion, synthetic biology appears ethical from a deontological point of view. It does not appear to pose problems for humanity's relationship with God, or with nature, nor does it challenge the dignity of life. Indeed, it may enhance these things if used wisely. It appears that as humanity has reached this point of technological progress, it is reasonable to proceed with it.

To determine how useful this conclusion is, it is worth comparing it with consequentialist evaluations. These show that on the positive side, synbio could be a saviour technology. It could lead to great new therapies, greatly alleviating suffering. It could increase agricultural efficiency, in a world where population is rising rapidly, putting a strain on existing resources. Also, our current form of civilisation may be threatened by a diminishing supply of fossil fuels, falling supply combining with rapidly rising demand. Some synthetic biology research aims to find replacement fuels. But there are also potential negatives, to an extreme degree. In worst cases, synthetic organisms could interact with natural ones to cause catastrophic environmental damage, and possible evolutionary change. A greater threat is that of malevolent use. The technology has already advanced to a stage where an underground biohacking subculture exists, analogous to that of the earliest days of computer hacking. Synbio is advancing to a level where any interested members of

[66] I. Kant. 1781. *A Critique of Pure Reason*. F. Max Mueller, trans. 1922. New York: Macmillan: 42.

the public could synthesise biological pathogens and use them as weapons of mass destruction.[67]

This dual use dilemma has led to a divide among consequentialist-oriented ethicists as to whether synbio is ethical. Some see it as a positive (typified by John Harris[68] and Peter Singer[69]); although they are aware of its dangers, their overall view is optimistic. Others focus more on the dangers which, for them, may outweigh any potential benefits. For example, Tom Douglas and Julian Savulescu have stated that synbio may be "the blueprint for humanity's destruction;"[70] Savulescu has waxed poetic on the threat, writing that we should "master the new loom before life's tapestry unravels at our hands."[71] Who is correct?

Notwithstanding the potential benefits, in the face of the potential threats posed by synbio, is the fact that it appears ethical from a deontological point of view adequate? Its optimistic conclusions remind me a poem I learned as a child:

> Here lies the grave of Mike O'Day,
> He died maintaining his right of way.
> His way was clear,
> His will was strong,
> But he's just as dead as if he'd been wrong.[72]

[67] ETC Group. *op.cit.* note 30.
[68] J. Harris. 2010. Promise and Risks from 'Life Not As We Know It.' *Financial Times,* 27 May.
[69] Singer *op. cit,* note 39.
[70] T. Douglas and J. Savulescu. Synthetic Biology and the Ethics of Knowledge. *J. Med. Ethics* 2010; 36: 687-693: 692.
[71] J. Savulescu. 2012. Master the New Loom Before Life's Tapestry Unravels at Our Hands. *Times Higher Education*, 9 April.
[72] Anonymous. *Epitaph.*

Also, is it satisfactory that the answer to whether synthetic biology is ethical or not depends on the ethical method used; and, in within consequentialism, depends on the philosophers' background assumptions?

Such a difference in outcome is nothing new in bioethics. For example, Tristam Engelhardt has written that in the morally pluralistic world we live in, bioethics is "essentially incapable of giving answers to substantive moral questions, such as concerning the permissibility of abortion, human embryonic stem cell research, euthanasia, etc."[73] He claims that moral pluralism is part of the fallen human condition and that bioethics, therefore, at the level of its foundation, is incapable of reaching "Truth." Can a discipline whose practitioners cannot agree on fundamental issues such as human dignity or abortion provide guidance as to whether or how society should proceed with synthetic biology – a technology which has the potential both to lead humanity to a new era of development, or to destroy it?

Limitations on Knowledge in Science

This limitation on the ability of reason to reach definitive truth is not limited to ethics. Science, too, is limited in its ability to get to the complete truth of a situation. Instead of arguing from a theoretical philosophical viewpoint, it may be more useful in this paper to discuss the limitations of knowledge that are inherent to science, the subject of our scrutiny when we evaluate synbio; and how science deals with such limitations. From that, it may be possible to infer a useful path for ethicists.

[73] T. Engelhart. "Confronting Moral Pluralism in Posttraditional Western Societies: Bioethics Critically Reassessed." *J Med Philos* 2011; 36 : 243-260.

In quantum physics, Heisenberg's Uncertainty Principle describes a limit on the ability to simultaneously know both the momentum and position of atomic particles, the building blocks of all matter. The more accurately one is measured, the less the other can be; there is a fundamental limit, inherent to nature, of what can be known.[74] [75] There seem to be some comparable limitations in biology. One is biological complexity. Darwin described nature as a "tangled bank;"[76] as biology descends to the molecular level, the observed complexity gets ever greater. In addition, a biological system is more than the sum of its parts; when disparate parts come together, "emergent" properties (for example, life) arise, which can be neither predicted nor explained.[77] [78]

New mathematical and computational techniques have been developed to deal with complexity.[79] Whether these, or more advanced tools, "crack" complexity over time, solving its unknowns, remains to be seen. There is mathematical evidence that it may be impossible to do so: Gödel's (First) Incompleteness Theorem proves that certain problems are unsolvable in a formal system. For many scientists, this seems to suggest an inherent limitation to knowledge.[80]

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[74] American Institute of Physics and D. Cassidy. 2012. *Quantum Mechanics 1925-1927: The Uncertainty Principle*. Available at: http://www.aip.org/history/heisenberg/p08.htm [Accessed 3 Nov 2012].

[75] G. Brumfiel. 2012. Quantum Uncertainty Not All in the Measurement. *Nature News*, 11th September. Available at: http://www.nature.com/news/quantum-uncertainty-not-all-in-the-measurement-1.11394 [Accessed 1 Nov 2012].

[76] C. Darwin. 1859. *On the Origin of Species by Means of Natural Selection*. London: John Murray: 489.

[77] F. Mazzochi. 2008. Complexity in Biology. Exceeding the Limits of Reductionism and Determinism Using Complexity Theory." *EMBO Reports* 9(1): 10-14.

[78] M. Van Regenmortel. 2004. Reductionism and Complexity in Molecular Biology. *EMBO Reports* 5(11): 1016-1020.

[79] A. Laszlo Barabasi. 2003. *Linked: How Everything is Connected to Everything Else*. New York: Plume.

[80] S. Feferman. 2006. *The Nature and Significance of Gödel's Incompleteness Theorems*. Lecture to Institute for Advanced Study, Princeton: Gödel Centenary Program November 17th. http://math.stanford.edu/~feferman/papers/Godel-IAS.pdf [Accessed 15 Feb 2013].

There are other problems. For example, Denis Noble of Oxford University, a founder of the field of systems biology, criticised "normal" biology for its lack of ability to fully describe life.[81] He gave an example: listening to a certain piece of music on a stereo causes him to cry. Normal, reductionist, scientific investigation, in trying to find the reasons for this, will examine the sound waves, the speakers, the CD, disc reader and more. If all the components – speakers, amps, CD readers, etc. – are replaced, but the same CD is played, the effect will be the same. This would seem to imply that the digital numbers on the disc cause the crying. It would be a valid scientific theory. But it's completely wrong. If the disc is slowed down or sped up, the crying won't occur. The crying was actually caused by the beauty of the music and the context in which he first heard it; something which science can't evaluate. The essence of a symphony cannot be captured by a mathematical description of its sound waves; can the essence of the biological world be captured by such scientific descriptions, valuable as they are? [82] Similarly, Noble argues, modern biology is wrong in its belief that DNA and genes are causes of life. DNA can only operate within a highly complex, pre-existing cell. DNA, in order to "cause" life, also depends on the fact that life exists.

In short, scientific descriptions are sophisticated models of reality, frequently with excellent predictive power, yet do not necessarily correspond completely with reality itself.[83] In the words of Alfred Korzybski: "A map is not the territory it

[81] D. Noble. 2006. *The Music of Life. Biology Beyond Genes*. Oxford: Oxford University Press.
[82] A quote from Einstein may be pertinent here: "Whoever undertakes to set himself up as a judge of Truth and Knowledge is shipwrecked by the laughter of the gods." Judaism Online (undated). *Einstein Quotes on Spirituality*. Available at: http://www.simpletoremember.com/articles/a/einstein/ [Accessed 30 Oct 2012].
[83] Noble, *op. cit.*, note 81.

represents, but if correct, it has a similar structure to the territory, which accounts for its usefulness.[84]

Given these limitations on what can be known, inherently, as well as limitations regarding scientific approaches to knowledge, how do scientific methodologies deal with them? While philosophers have written on the scientific method,[85] practicing scientists tend to reject such a rigid approach. For example, Michael McIntyre, a professor of theoretical physics at Cambridge University, wrote: "It is a dangerous illusion to think that there is a rigidly and explicitly defined `method' guaranteed to produce accurate scientific judgments on demand... If there were such a method, then science would be best turned over to computers. Anyone who has done significant scientific research knows that there is no generally applicable `method' in that sense, especially when we are dealing with the unknown and the unpredictable."[86]

It is useful to illustrate this with an example from the methodology of theoretical computer science, where normal problem solving is done by developing algorithms. These are step by step mathematical-type steps to solving a problem, and are analogous to philosophical reasoning using logic. However, many problems in computer science are too complex to be solved this way. Such problems are referred to as being irreducibly complex, or intractable. They can never be solved, no matter what future technological advances occur; they're too complex in principle, and this

[84] A. Kozybski. 1994. *Science and Sanity: An Introduction to Non-Aristotelian Systems and General Semantics,* 5th edition. New York: Institute of General Semantics: 58.
[85] See, for example: K. Popper. 1935. *Logik der Forschung* (*The Logic of Scientific Discovery).* Vienna: Verlag von Julius Springer; and T. Kuhn. 1962. *The Structure of Scientific Revolutions*. Chicago, IL; University of Chicago Press.
[86] M. E. McIntyre. Lucidity and Science III: Hypercredulity, Quantum Mechanics, and Scientific Truth. *Interdisciplinary Science Reviews* 1996: 23: 29-70: 30.

can be proved mathematically. Many more problems are solvable in principle, but not in practice; they are so complex that it takes too long – in some cases, thousands of years, in others, considerably longer than the age of the universe.[87] But computer scientists don't abandon these problems. They use a different approach, the heuristic approach. Heuristics are a fudge, based on the realisation that the problem can't be solved fully. But a "good enough" solution can be found, by approximation methods. These methods can range from simple trial and error to extremely sophisticated solutions with a good theoretical background, and can yield very useful, albeit incomplete, results. Computer science plays a major role in synthetic biology research (which is interdisciplinary, drawing from several scientific and engineering disciplines). Many synbio problems are computationally intractable. Yet progress is made by heuristic solutions.

Which raises a question: can philosophical ethics be more certain than the science it is attempting to evaluate? Should it be more constrained in its problem-solving paradigms than the science is? To extend Engelhardt's theme of moral plurality being part of fallen human nature: inherent limitations to knowledge may be an integral part of a fallen world. Can bioethics learn from science's flexible problem solving approach? It may have to if it is to meet the ethical challenges posed by synthetic biology. Ethicist Paul B. Thompson has stated that synbio requires us to adopt a new way of thinking in bioethics.[88] The problems in applying just one ethical approach bear this out. Synbio renders these tools ineffectual, though not entirely useless. The fact that deontological argument suggests that synbio is ethical is not

[87] L.J. Stockmeyer and A.K. Chandra. Intrinsically Difficult Problems. *Scientific American* 1979; 240: 140-159.
[88] P. B. Thompson. Synthetic Biology Needs a Synthetic Bioethics. *Ethics, Policy Environ* 2012; 15: 1-20.

very useful in itself, its conclusions being neutered by the potentially great dangers that consequentialist analysis reveals. Yet consequentialism also suggests that synbio may yield great positives. Confusion reigns. Neither approach provides adequate ethical guidance. However, combining the two approaches suggests that synbio *per se* is ethical, and it is good to proceed with it, albeit with stringent safeguards and precautions. Consequentialism's evaluation of potential benefits and dangers provides a useful road map for research directions and governance. The deontological and consequentialist approaches complement each other in this case, and their combination seems essential to obtain an adequate ethical analysis.

CONCLUSION

Synthetic biology poses significant ethical challenges. A deontological analysis shows that it appears to be ethical; it does not seem to challenge the dignity of nature, or of life, or the relationship of God and his creation. However, the potential negatives of synbio are so extreme that it's very questionable as to whether a deontological analysis is sufficient. But consequentialist analysis, by itself, also fails.

The use of different ethical tools, separately from each other, when these tools give contradictory answers, is hardly adequate for an issue of such importance. In the words of Angus Dawson, "pure philosophical argument can conflict with… reality."[89] It appears that no single ethical approach has enough intellectual firepower to perform a complete evaluation of synbio. In evaluating complex scientific advances, bioethics

[89] A. Dawson. 2012. *The Future of Bioethics*. President's Lecture, 11th World Congress of Bioethics, International Association of Bioethics, Rotterdam, June 29th. Available at http://bioethicsrotterdam.com/program-2 [Accessed 15 Feb 2012].

can learn from the pragmatic methodological approach of such sciences. Without abandoning its philosophical foundations, it can build upon them and adapt. Applying a single ethical approach to synbio appears to be equivalent to a failed algorithm, applied to an intractable problem. Mixing approaches in an appropriate way, though, may give a useful, albeit imperfect, heuristic; it may yield something that begins to approach ethical “Truth.”

CHAPTER 7 THE PLACE OF GOD IN SYNTHETIC BIOLOGY: HOW WILL THE CATHOLIC CHURCH RESPOND?

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ABSTRACT

Some religious believers may see synthetic biology as usurping God’s creative role. The Catholic Church has yet to issue a formal teaching on the field (though it has issued some informal statements in response to Craig Venter’s development of a ‘synthetic’ cell). In this paper I examine the likely reaction of the Catholic Magisterium to synthetic biology in its entirety. I begin by examining the Church’s teaching role, from its own viewpoint, to set the necessary background and context for the discussion that follows. I then describe the Church’s attitude to science, and particularly to biotechnology. From this I derive a likely Catholic theology of synthetic biology.

The Church’s teachings on scientific and biotech research show that it is likely to have a generally positive disposition to synthetic biology, if it and its products can be acceptably safe. Proper evaluation of, and protection against, risk will be a significant factor in determining the morality of the research. If the risks can be minimised through regulation or other means, then the Church is likely to be supportive. The Church will also critique the social and legal environment in which the research is done, evaluating issues such as the patenting of scientific discoveries and of life.

… a Jewish fable… the prophet Jeremiah and his son one day succeeded in creating a living man through the correct combination of words and letters. On the forehead of the Golem – the man whom they themselves had formed – were the letters that had helped them to solve the riddle of creation: "Yahweh is the truth." The Golem tore off one of the seven letters that add up to this affirmation in Hebrew, and now the prescription proclaimed: "God is dead." The prophet and his son were horrified and asked the Golem what he was doing. The new man replied as follows: Now that you are able to create a man, God is dead…

Joseph Ratzinger/Pope Benedict XVI[1]

BACKGROUND: THE CHURCH, THE MAGISTERIUM AND SCIENCE

Introduction

A number of prominent scientists gathered at a 2007 Edge Foundation meeting, entitled *Life: What a Concept!* In the introduction to the book containing the meeting's transcript, John Brockman, the founder of the Edge Foundation, wrote excitedly of how current research may allow scientists to transform one species into another, and create new life forms.[2] He also briefly touched upon the place of religion in cutting-edge biotech research: "We are witnessing a point in which the empirical has intersected with the epistemological… don't even try to talk about religion: the gods are gone."[3] A contributor to the online Synbiosafe conference wrote, in a similar vein: "we are defining what is life from zero. This is a HUMAN CREATIONIST

[1] J. Ratzinger/Pope Benedict XVI. 2008. *The God of Jesus Christ: Meditations on the Triune God*. San Francisco, CA: Ignatius Press: 15-16.

[2] For description of synthetic biology, see: ETC Group. 2007. *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. Ottawa, ON: ETC Group. Available at http://www.etcgroup.org/en/node/602 [Accessed 30/11/2010]

[3] J. Brockman, ed. 2008. *Life: What a Concept!* New York: Edge Foundation: 8. Available at http://www.edge.org/documents/life/Life.pdf [Accessed 30/11/2010].

environment. No Gods have any relationship with this crucial moment. No myths. Just human desire."[4]

The gods have a habit of re-appearing, however, and can be quite assertive. Religion remains a potent force in world affairs for a significant portion of the population, probably the vast majority. A debate in the UK, in 2008, showed its power in scientific matters. Parliament was debating the *Human Fertilisation and Embryology Act*, which allowed for experimentation with human-animal hybrid embryos. This received relatively little media coverage until some Catholic Church leaders weighed in, in opposition. Although they were unable to prevent the Act from being passed, their intervention turned it into a big media issue. [5] Catholics are less than 10% of the population of the UK, a now mostly secular country which was largely Protestant for five centuries. Yet Catholic Church leaders were able to set the agenda for debate. Bishops in the Church of England have more power, both as societal leaders and as lawmakers in the House of Lords. Religion is a much greater force in the U.S., where most synthetic biology research takes place. Therefore religious viewpoints *will* enter into debates on synthetic biology.

Up to now, there has been little religious debate on the topic; the reason being that synbio has been relatively little known. That will change as it becomes more successful. Therefore it isn't possible at the moment to list the types of arguments

[4] Synbiosafe e-conference. 2008. Available at http://www.synbiosafe.eu/forum/viewtopic.php?f=3&t=42 [Accessed 17/8/2010].
[5] J. Petre. 2008. Chimera Embryos Have Right to Life, Say Bishops. *Daily Telegraph* 19 April. Available at http://www.telegraph.co.uk/news/uknews/1555639/Chimera-embryos-have-right-to-life,-say-bishops.html [Accessed 30/11/2010]; M. Henderson, R. Gledhill and F. Elliot, 2008. Embryology Bill: Bishop's Frankenstein Attack Smacks of Ignorance, Say Scientists. *The Times* 24 March. Available at http://www.timesonline.co.uk/tol/news/uk/science/article3607660.ece [Accessed 30/11/2010].

made by religious people for or against synthetic biology. But it is possible to infer, with a reasonable degree of accuracy, what those arguments will be, based on their views on other areas of biotech research.

Various religious viewpoints exist on such research, and they can be completely contradictory. At one extreme is the view that nature is sacred. We are stewards of nature, not masters, and may not change it. To do so would be to oppose God's will, and so commit sin.[6] An advance on this viewpoint is that of some Old Calendar Orthodox Christians in the U.S. that I met, who think that all scientific research is sinful in itself, as it represents a wrong orientation, towards the things of the world, not the things of God.

Others have applied the story of the Tower of Babel, as described in Genesis 11:1-9, to science. Here people wished to build a great tower that would reach the heavens. God didn't want this, and confounded their plans by splitting them into different linguistic groups, thus limiting their collective efficiency. They could no longer communicate and build the tower. From this it could be argued that certain types of scientific research – those that impinge on God's creative role – are out of bounds. He has created the world – we can't try to better it.[7]

Other theologians have pointed out that we are created in the image of God – *Imago Dei*. God creates continuously. In order to fulfil our true potential as desired by Him, we should also create. This includes biological creations, which increase

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[6] See, for example, Naveen Chainani. 2006. *Comment on In re Fisher: EST Utility Redux*.. Available at http://patentdocs.typepad.com/patent_docs/2006/10/in_re_fisher_es.html [Accessed 30/11/2010].

[7] N.M. de S. Cameron & A.M. DeBaets. 2008. Germline Modification and the Human Condition Before God. In *Design and Destiny: Jewish and Christian Perspectives on Human Germline Modification.* R. Cole-Turner, ed. Cambridge, MA: MIT Press: 93-118.

knowledge of nature and therefore of the mind of God. They may also help to cure disease, and enhance life in other ways. Although we are dependent on God for every breath we take, and not equal to Him, we are also, in a limited sense, co-creators with Him. We do not have His power to create *ex nihilo*; but we have been given the power and responsibility to create our own civilisation and history, collectively and as individuals. (Lutheran theologian Phillip Hefner has described humans as "created co-creators."[8]) Therefore we have a right and a duty to use our creative powers in biotech research.[9]

The parable of the talents takes this further.[10] In Matthew 25:14-30, Jesus' parable implies that we are obliged to use our talents – not to do so is displeasing to God. From this viewpoint, now that we have the capacity to do biotech research, it is our duty to do it, to advance knowledge and benefit humanity. Pope John Paul II has made this point regarding all aspects of human progress[11] (though what he means by human progress may differ from how others define it.).

It is clear from the above that contradictory religious views on biotech research exist. Conflict exists within and between religious groups. Such groups have hugely differing world views, and cannot agree on many issues, including those in bioethics. As the above selection of arguments shows, evaluating them all, or a significant segment of them, cannot lead to one truth – a certainty that God wants, or

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[8] P. Hefner. 1993. *The Human Factor: Evolution, Culture and Religion*. Minneapolis, MN: Fortress Press: 23-54.

[9] T. Peters. 1997. *Playing God? Genetic Determinism and Human Freedom*. New York, NY: Routledge.

[10] Pope Benedict XVI. 2008. Parable of the Talents Shows Gifts Are Meant to be Multiplied. *L'Osservatore Romano*. 19 November: 1

[11] John Paul II. 1987. *Sollicitudo Rei Socialis.* Vatican City: Libreria Editrice Vaticana: para 30. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_30121987_sollicitudo-rei-socialis_en.html [Accessed 30/11/2010].

does not want, humans to engage in synthetic biology research. It is impossible to do that – all one gets is an incoherent babble of contradictory viewpoints, each of which claims to be expressing God's will. But it doesn't follow that religious viewpoints can be ignored.

Religious beliefs could have a significant influence on the environment in which scientific research is done. For example, the evolution vs. creationist debate in the U.S. causes considerable upset; many teachers and members of the scientific community feel under attack, as do their fundamentalist opponents.[12] The debate has affected policy. In the 1960s, six U.S. states banned the teaching of evolution, and it was not mentioned in most American high school biology textbooks. Only the threat of Soviet dominance in science led to its reinstatement.[13] This debate also exists in Europe, albeit to a lesser degree. In 2004, the Italian government attempted to remove the teaching of evolution from the early secondary school curriculum.[14] A former deputy education minister of Poland, Miroslaw Orzechowski, told a newspaper in 2007 that "the theory of evolution is a lie. It is an error we have legalised as a common truth."[15] Synthetic biologist David Deamer said at a conference that he is frequently contacted by religious fundamentalists who tell him that what he is doing is wrong.[16]

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[12] M.B. Berkman, J.S. Pacheo & E. Plutzer. Evolution and Creationism in America's Classroms: A National Portrait. *PLoS Biol 2008;* 6:e24.
[13] V. Leigh Interview with Steve Jones: The Threat of Creationism. *Science in School* 2008; 9: 9-17
[14] Ibid. 11; DW Staff. 2004. Italy Keeps Darwin in its Classrooms. *Deutsche Welle* 3 May. Available at http://www.dw-world.de/dw/article/0,2144,1188423,00.html [Accessed 30/11/2010].
[15] Leigh *op. cit.* note 13.
[16] D. Deamer. 2008. Systems and Synthetic Biology: Scientific and Social Implications. *9th EMBO/EMBL Joint Conference on Science and Society, Heidelberg*, 7-8 November.

Thus religious attitudes to synthetic biology could have an impact on the research. These attitudes could affect policy, funding, and public opinion. It would be useful, therefore, to examine possible theological attitudes towards synthetic biology.

Why Analyse the Catholic Viewpoint?

Although some papers have been published which discuss the religious significance of synthetic biology in general terms,[17] ultimately formal teachings will be developed by various denominations. I am focussing here on the likely Catholic view, because it is the world's largest religion.[18] In addition, the Catholic Church has a sophisticated approach in terms of developing theologies of bioethics and other areas of morality – their documents are generally produced by teams of skilled people, frequently at the professorial level. They produce far more official teachings on bioethics (and most other issues) than any other religion. They usually take a sophisticated philosophical approach (exceptions exist). Their views are influential, even on those who disagree with and react against them.

Some Background - the Catholic Magisterium

Before I evaluate the Catholic Church's likely response to synthetic biology, I will first explain the Church's role in teaching morality, according to its own self-understanding. The Church regards itself as the Mystical Body of Christ, representing

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[17] For example, H. van den Belt. Playing God in Frankenstein's Footsteps: Synthetic Biology and the Meaning of Life. *Nanoethics* 2009; 3:257-268; and P. Dabrock. Playing God? Synthetic biology as a theological and ethical challenge. *Syst Synth Biol* 2009; 3:47-54.

[18] According to the *Annuario Pontifico* (Pontifical Yearbook) 2010, there were 1.66 billion baptised Catholics in the world in 2008, representing 17.4% of the world's population. Zenit.org. 2010. Number of Catholics Increases Worldwide: 2010 'Annuario' shows Growth in Asia and Africa. Available at http://www.zenit.org/article-28425?l=english [Accessed 30/11/2010].

God on Earth. It does not claim perfection, as it is composed of sinful and error-prone human beings. Nevertheless it has a duty to guide its members – and any interested parties – on a correct moral path, one in which people will be in correct relationship with God, his creation and each other. Canon 747,[19] from the Church's *Code of Canon Law*, states that the Church has a right and an obligation to teach moral truth.

The Church's function requires it to teach, and teaching is carried out by the *Magisterium* – the Church in its teaching role. The word comes from the Latin word *magister* – master – as in master of a trade, a ship, a school, etc. *Magisterium* refers to the authority of one who was master by virtue of their position. The phrase now refers to the authoritative teaching role of the Church hierarchy. Only those formally authorised to teach may do so in the Church's name – normally the Pope and bishops.[20] Others that can teach, albeit with less authority, include various Church bodies – such as the Congregation for the Doctrine of the Faith (CDF), which is the Church's doctrinal teaching and enforcement body; and also theologians (both lay people and clerics).[21] The Magisterium's purpose is to illuminate the world with the truths of divine revelation, including the truth regarding moral action.[22]

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[19] Code of Canon Law. 1983. Vatican City: Libreria Editrice Vaticana: C.747.1 and 747.2 Available at http://www.vatican.va/archive/ENG1104/__P2H.HTM [Accessed 30/11/2010].
[20] F.A. Sullivan. 2003. *Creative Fidelity: Weighing and Interpreting Documents of the Magisterium*. Eugene, OR: Wipf and Stock: 1.
[21] R.P. McBrien. 2008. *The Church: The Evolution of Catholicism*. New York, NY: Harper One: 291-292.
[22] The Church's "ethical method" is based on the theory that a natural law exists, written by God in every human heart, allowing each person (of all religions and none) to tell right from wrong. But not everyone has the ability to perceive natural law to the same degree; hence the Church is required to teach. Reason and experience are the Church's primary tools for evaluating moral issues, for determining the natural law. Scripture is also a source, and it must, in the Catholic viewpoint, be interpreted in the light of reason and experience; the cultural context in which Scripture was written is also taken into account when interpreting it. See *Catechism of the Catholic Church* 416 and 1950-1986; International Theological Commission. 2004. *Communion and Stewardship: Human Persons Created in the Image of God*. Vatican City: Liberia Editrice Vaticana: para 60; and Pontifical Biblical Commission. 1993. *The Interpretation of the Bible in the Church*. Vatican City: Libreria Editrice Vaticana.

How should one respond to magisterial teachings? For a non-Catholic, the Magisterium is simply another voice in the arena of debate. It has to argue its case, and its arguments should be evaluated on their merits. For a Catholic, the Magisterium has religious authority.[23] Existing in tension with the religious authority of the Magisterium is the primacy of conscience.[24] A famous statement of Cardinal Newman describes its role in guiding decision-making: "I shall drink… to Conscience first, and to the Pope afterwards."[25] The role of the Magisterium is to inform conscience. [26] Ultimately conscience binds – to act against it is to sin.[27] But there is a duty for a Catholic (and everyone) to inform their conscience – which, for Catholics, means paying attention to Church teachings. As for the tension between conscience and the duty of response to the Magisterium: where should the line be drawn? Pope Benedict XVI (as Cardinal Ratzinger) asked: can we expect to see the nazis in Heaven – they thought they were right? He thinks that's unlikely (while admitting that we

[23] However, not all of its teachings require the same response. There are hierarchies of truth, with different levels of response required for each. Catholics should be open to magisterial teaching; unquestioning obedience is not expected. The openness requires that Catholics should take Church teachings seriously and try to convince themselves of their truth. According to theologian Fr. Francis Sullivan, formerly dean at the Vatican's Pontifical Gregorian University: "If my effort to achieve assent has been proportionate to the degree of authority that has been exercised, then I have fulfilled my obligation of *obsequium* [respect] toward the magisterium, even though I have not been able to bring myself to agree with some particular point in its teaching." See Sullivan *op.cit* note 20, p. 5.
[24] According to Vatican II's pastoral constitution on the Church in the modern world, *Gaudium et Spes* ('Joys and Hopes'): "In the depths of his conscience, man detects a law which he does not impose upon himself, but which holds him to obedience. Always summoning him to love good and avoid evil, the voice of conscience when necessary speaks to his heart: do this, shun that. For man has in his heart a law written by God; to obey it is the very dignity of man; according to it he will be judged. Conscience is the most secret core and sanctuary of a man. There he is alone with God, Whose voice echoes in his depths. In a wonderful manner conscience reveals that law which is fulfilled by love of God and neighbor. In fidelity to conscience, Christians are joined with the rest of men in the search for truth, and for the genuine solution to the numerous problems which arise in the life of individuals from social relationships. Hence the more right conscience holds sway, the more persons and groups turn aside from blind choice and strive to be guided by the objective norms of morality. Conscience frequently errs from invincible ignorance without losing its dignity. The same cannot be said for a man who cares but little for truth and goodness, or for a conscience which by degrees grows practically sightless as a result of habitual sin." Vatican II. 1965. *Gaudium et Spes*. Vatican City: Libereia Editrice Vaticana: para 16. Available at http://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_cons_19651207_gaudium-et-spes_en.html [Accessed 1/12/2010].
[25] J. Ratzinger/Pope Benedict XVI. 2007. *On Conscience.* San Francisco: Ignatius Press: 23.
[26] Pope John Paul II. 1993. *Veritatis Splendor.* Vatican City: Libreria Editrice Vaticana: para 64. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_06081993_veritatis-splendor_en.html [Accessed 30/11/2010].
[27] Ibid.

cannot know with certainty).[28] An objective morality exists.[29] Where the line should be drawn, though, is much debated by moral theologians.

Non-Overlapping Magisteria?[30] The Magisterium and Science

For many people, the Galileo affair sums up the relationship between the Church and science. But it is not the whole story, nor is it particularly representative. In the Church's billion-plus members, similar attitudes to science are displayed as in the general population – ranging from the indifferent or hostile, to those who work as scientists. Scientific investigation is not a central part of the Church's mission, and it does not claim scientific expertise. Nevertheless, the Magisterium will comment on applications of science when they have moral implications, and it has commented on biotechnology.

It has also commented on science itself. Some quotes from various Popes give a flavour of its attitude. Pope Pius XII described "science, philosophy and revelation" as "instruments of truth, like rays of the same sun."[31] According to Benedict XVI, "the laws of nature… are a great incentive to contemplate the works of the Lord with

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[28] Ratzinger/Pope Benedict XVI. 2007 *op. cit*. note 24, p.17.

[29] For a more complete discussion, see John Paul II, 1993 *op cit*. note 26, particularly chapter II, section II (conscience and truth); Vatican II. *op. cit.* note 24; J. Ratzinger/Pope Benedict XVI. 2007. *op. cit*. note 25; R.M. Gula, 1989. *Reason Informed by Faith: Foundations of Catholic Morality*. Mahwah, NJ: Paulist Press: 123-162.

[30] Palaeontologist and evolutionary biologist Stephen Jay Gould wrote that science and religion occupy two different spheres of enquiry, which do not overlap. S.J. Gould Nonoverlapping Magisteria. *Nat Hist* 1997; 106: 16-22; and S.J. Gould, 1999. *Rocks of Ages: Science and Religion in the Fullness of Life*. New York: Ballantine Book.

[31] Pope Pius XII. 1952. The Proofs for the Existence of God in the Light of Modern Science. *Address to the Pontifical Academy of Sciences*. 22 November. Available at http://www.papalencyclicals.net/Pius12/P12EXIST.HTM [Accessed 30/11/2010].

gratitude."[32] John Paul II wrote: "Science can purify religion from error and superstition; religion can purify science from idolatry and false absolutes. Each can draw the other into a wider world, a world in which both can flourish."[33] And in the same letter, he wrote

> Is the community of world religions, including the Church, ready to enter into a more thorough-going dialogue with the scientific community, a dialogue in which the integrity of both religion and science is supported and the advance of each is fostered? Is the scientific community now prepared to open itself to Christianity, and indeed to all the great world religions, working with us all to build a culture that is more humane and in that way more divine?... We must ask ourselves whether both science and religion will contribute to the integration of human culture or to its fragmentation... A divided community fosters a fragmented vision of the world; a community of interchange encourages its members to expand their partial perspectives and form a new unified vision... Yet the unity that we seek, as we have already stressed, is not identity. The Church does not propose that science should become religion or religion science. On the contrary, unity always presupposes the diversity and the integrity of its elements.[34] [35]

[32] Pope Benedict XVI. 2008. *Angelus, St. Peter's Square, Fourth Sunday of Advent*. 21 December. Available at http://www.vatican.va/holy_father/benedict_xvi/angelus/2008/documents/hf_ben-xvi_ang_20081221_en.html [Accessed 30/11/2010].

[33] Pope John Paul II. 1988. *Letter of His Holiness John Paul II to Reverend George V. Coyne, S.J. Director of the Vatican Observatory*. Vatican City: Libreria Editrice Vaticana. Available at http://www.vatican.va/holy_father/john_paul_ii/letters/1988/documents/hf_jp-ii_let_19880601_padre-coyne_en.html [Accessed 30/11/2010].

[34] Ibid.

[35] For John Paul II, the relationship between religion and science was a part of a broader relationship between faith and reason. In his encyclical on their relationship, *Fides et Ratio* ('Faith and Reason'), he wrote:

"… a cursory glance at ancient history shows clearly how in different parts of the world, with their different cultures, there arise at the same time the fundamental questions which pervade human life: *Who am I? Where have I come from and where am I going? Why is there evil? What is there after this life?* These are the questions which we find in the sacred writings of Israel, as also in the Veda and the Avesta; we find them in the writings of Confucius and Lao-Tze, and in the preaching of Tirthankara and Buddha; they appear in the poetry of Homer and in the tragedies of Euripides and Sophocles, as they do in the philosophical writings of Plato and Aristotle. They are questions which have their common source in the quest for meaning which has always compelled the human heart. In fact, the answer given to these questions decides the direction which people seek to give to their lives." Pope John Paul II. 1998. *Fides et Ratio*. Vatican City : Libreria Editrice Vaticana: para 1. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_15101998_fides-et-ratio_en.html [Accessed 30/11/2010]). In attempting to answer such questions, he observed that "Faith and reason are like two wings on which the human spirit rises to the contemplation of truth." (Ibid.) For John Paul, the relationship between science and religion was summed up by: "truth cannot contradict truth." (Pope John Paul II. 1996. Truth Cannot Contradict Truth. *Address to the Pontifical Academy of Sciences* 22 October. Available at http://www.newadvent.org/library/docs_jp02tc.htm [Accessed 30/11/2010])

The current Pope, the then Joseph Ratzinger, has written that good theology is dependent on scientific thinking:

> [a] theology of prohibitions… would have resulted not in the rescue of the faith but of dooming it to sterility, by separating theology once and for all from modern science and confining it in an ivory tower where it would have gradually withered away… this kind of defense would suffocate the faith from within by cutting off its air supply – i.e., the possibility of faith proving itself in terms suited to modern scientific thinking.[36]

Catholic support for science goes beyond words. Catholic universities generally have science faculties. Their primary and secondary schools teach science. Also, located in the heart of the Vatican City is the Pontifical Academy of Sciences.[37] Initially founded in 1603, it aims to advance science and to discuss ethics, including bioethics. Religious affiliation (or lack of it) is not a factor in election to membership, only scientific prestige, and morality. New academicians are elected by current members of the Academy and appointed by the Pope.[38] Non-Catholic members include Stephen Hawking (atheist) and Francis Collins (Evangelical Christian).[39] The Vatican also operates an astronomical observatory, one of the world's oldest. It has branches at the Pope's summer residence in Castel Gandolfo, near Rome, and in Tucson, Arizona.[40] [41] [42] The father of the big bang theory, Georges Lemaitre, was a Catholic priest.[43]

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36 J. Ratzinger. 1966 *Theological Highlights of Vatican II.* New York, NY: Paulist Press, 1966: 149.

37 Pontifical Academy of Sciences website http://www.vatican.va/roman_curia/pontifical_academies/acdscien/ [Accessed 30/11/2010].

38 Bishop-Chancellor M. Sanchez Sorondo. 2003. *The Pontifical Academy of Sciences: A Historical Profile*. Vatican City: Pontifical Academy of Sciences. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdscien/400_ann/storia_en_qxd.pdf [Accessed 30/11/2010].

39 Pontifical Academy of Sciences. 2010. *List of Academicians*. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdscien/own/documents/rc_pa_acdscien_doc_20020103_academicians_en.html [Accessed 30/11/2010].

40 Vatican Observatory website: http://vaticanobservatory.org/ [Accessed 30/11/2010].

41 G. Johnson. 2009. Vatican's Celestial Eye, Seeking not Angels but Data. *New York Times* 22 June. Available at http://www.nytimes.com/2009/06/23/science/23Vatican.html?_r=1&scp=1&sq=vatican%20observatory%20arizona&st=cse [Accessed 30/11/2010].

For the Church, then, there is no conflict between science and religion. On the contrary, it sees them as investigating different aspects of the same truth. The Church supports science. But it also subjects it to moral evaluation. In the words of the *Catechism of the Catholic Church* (a *precise* of the Church's faith): "methodical research in all branches of knowledge, provided it is carried out in a truly scientific manner and does not override moral laws, can never conflict with the faith;"[44] and "science and technology, by their very nature, require unconditional respect for fundamental moral criteria."[45] It condemns some applications of science, for example nuclear weapons.[46]

Even so, the question could be asked, regarding certain cutting-edge scientific research, including synthetic biology: could religious limitations exist on permissible knowledge? Should humanity only seek so far, and no farther? The Church rejects such a viewpoint. In the words of the Pontifical Academy for Life:

> In principle… there are no ethical limits to the knowledge of the truth, that is, there are no "barriers" beyond which the human person is forbidden to apply his cognitive energy: the Holy Father has wisely defined the human being as "the one who seeks the truth"… but, on the other hand, precise ethical limits are set out for the manner the human being in search of the truth should act, since "what is technically possible is not for that very reason morally admissible."[47]

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[42] G. Consolmagno SJ, ed. 2009. *The Heavens Proclaim: Astronomy and the Vatican*. Vatican City: Vatican Observatory Publications, and Huntington, IN: Our Sunday Visitor.
[43] S. Singh. 2004 *Big Bang*. New York, NY: HarperCollins:.156-61.
[44] *Catechism of the Catholic Church* . Vatican City: Libreria Editrice Vaticana: para 159. Available at http://www.vatican.va/archive/ENG0015/__PX.HTM [Accessed 30/11/2010].
[4545] Ibid: para 2294
[46] D. Roche. 2005. Nuclear Weapons and Morality: An Unequivocal Position. *Address to U.S. Catholic Bishops Panel, Ethics, Policy and the Proliferation of WMD*. Washington, DC. 11 November. Available at http://www.gsinstitute.org/mpi/docs/Roche_CatholicBishopsNuclearWeapons.pdf [Accessed 30/11/2010].
[47] Pontifical Academy for Life. 2003. *Concluding Communiqué on 'the Ethics of Biomedical Research for a Christian Vision,'* 24-26 February. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-acd_life_doc_20030226_ix-gen-assembly-final_en.html [Accessed 30/11/2010].

THE CHURCH, BIOTECHNOLOGY AND SYNTHETIC BIOLOGY

The Church and Biotechnology

The Church has issued several teachings on biotech research. The *Compendium of the Social Doctrine of the Church* is a document of the Magisterium that is concerned primarily with economic and social justice. It also has a section on the environment, which includes a sub-section on biotechnology. That section's introductory paragraph sets out the Church's essential attitude to biotech; it is also likely to be a starting point for any teachings on synthetic biology:

> *The Christian vision of creation makes a positive judgment on the acceptability of human intervention in nature, which also includes other living beings, and at the same time makes a strong appeal for responsibility*. In effect, nature is not a sacred or divine reality that man must leave alone. Rather, it is a gift offered by the Creator to the human community, entrusted to the intelligence and moral responsibility of men and women. For this reason the human person does not commit an illicit act when, out of respect for the order, beauty and usefulness of individual living beings and their function in the ecosystem, he intervenes by modifying some of their characteristics or properties. Human interventions that damage living beings or the natural environment deserve condemnation, while those that improve them are praiseworthy. *The acceptability of the use of biological and biogenetic techniques is only one part of the ethical problem*: as with every human behaviour, it is also necessary to evaluate accurately the real benefits as well as the possible consequences in terms of risks. In the realm of technological-scientific interventions that have forceful and widespread impact on living organisms, with the possibility of significant long-term repercussions, it is unacceptable to act lightly or irresponsibly[48] (their italics).

The *Compendium* develops a desired theology of biotechnology, and sets out the responsibilities of various actors in the field. Regarding commercialisation, it states that commercial exchanges should be just. For disadvantaged countries, such exchanges should go beyond the mere exchange of products, and should promote the

[48] Pontifical Council for Justice and Peace. 2004. *Compendium of the Social Doctrine of the Church.* Vatican City: Libreria Editrice Vaticana: para 473. Available at http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html [Accessed 30/11/2010].

development of the scientific and technological base of such states, with free exchange of information, allowing them to become scientifically autonomous. A spirit of solidarity should prevail.[49] The responsibility for such development does not lie with the wealthier nations alone; the leaders of less developed countries also have a responsibility to invest in technological development in a way that benefits their people and the common good. The characteristics of each country should be taken into account in developing such policies. Those nations also have a responsibility to promote trade policies based on justice.[50]

The *Compendium* observes that biotech scientists and technicians should take account of the need for an adequate food supply and good health care throughout the world. Biological material is part of the patrimony of the human race, belonging to the current generation and to future ones; it is a gift from God. Human intelligence and freedom are also gifts, and they should be used well, with enthusiasm and a good conscience, in research.[51]

Entrepreneurs are permitted to make legitimate profit, but should balance this with the common good. While this is true in all economic life, it is especially important when products are connected with food, healthcare and the ecosystem. These technologies can, and should, be used towards very good ends – curing disease, minimising hunger, and protecting the environment. Such concerns should also be born in mind by those who lead relevant public agencies.[52]

[49] Ibid: para 475.
[50] Ibid: para 476.
[51] Ibid: para 477.
[52] Ibid: para 478.

The *Compendium* states that politicians and those involved in legislation and administration, at national and international levels, should evaluate the benefits and risks involved in biotech. Their decisions should benefit the common good, and they should not be swayed by pressure groups. They should also ensure that public opinion is properly informed.[53] Journalists, editors and others involved in providing information have a duty to ensure that such information is truthful. It should not be superficial; nor should it be an over-enthusiastic promotion of such technologies, nor an alarmist rejection of them. The information provided should allow its consumers to form properly informed opinions on the issues.[54]

Other statements about biotechnology have been made by senior Church figures. Regarding genetic engineering, John Paul II said: "Now there is generally talk of 'genetic engineering' to refer to the extraordinary possibilities that science offers today to intervene in the very sources of life. All genuine progress in this field cannot but be encouraged, on the condition that it always respects the rights and dignity of the human person from conception."[55] With respect to the genetic modification of crops, the dean of the School of Bioethics at the Vatican's Regina Apostolorum University in Rome – the main bioethics programme among the pontifical universities – has stated that the use of GM crops may be a moral duty, and that blocking them may be a serious injustice. [56] (A statement by such a Church figure is not a teaching of the Magisterium, but it may indicate what future Magisterial teachings will be.)

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[53] Ibid: para 479.

[54] Ibid: para 480.

[55] Pope John Paul II. 2003. Genetic Engineering Must be Guided by Respect for Life, Insists Pope: Says Church Supports Research Governed by Ethics*. Message for World Day of the Sick* 11 February. Available at http://www.zenit.org/article-8867?l=english [Accessed 30/11/2010].

[56] Fr. G. Mirando. 2003. Using genetically modified organisms could be a duty, says bioethicist. *Address to the Pontifical Council for Justice and Peace Symposium "Genetically Modified Organisms and the Social Doctrine of the Church"*. Available at Zenit.org. http://www.zenit.org/article-8752?l=english [Accessed 30/11/2010].

Playing God? The Church and Synthetic Biology

When Craig Venter released his Synthia bacterium in May 2010,[57] spokesmen for the Church responded promptly. Monsignor Rino Fisichella, head of the Pontifical Academy for Life, described it as "a great scientific discovery."[58] But as for its ethical importance, he stated: "If we ascertain that it is for the good of all, of the environment and man in it, we'll keep the same judgment... If, on the other hand, the use of this discovery should turn against the dignity of and respect for human life, then our judgment would change."[59] Cardinal Angelo Bagnasco, head of the Italian Bishops' Conference, said the discovery was "further sign of intelligence, God's gift to understand creation and be able to better govern it...On the other hand, intelligence can never be without responsibility... Any form of intelligence and any scientific acquisition... must always be measured against the ethical dimension, which has at its heart the true dignity of every person."[60] Bishop Domenico Mogavero, head of the law department of the Italian Bishops' Conference, sounded a note of caution, noting that: "Pretending to be God and parroting his power of creation is an enormous risk that can plunge men into a barbarity… [Scientists] should never forget that there is only one creator: God. In the wrong hands, today's development can lead tomorrow to a devastating leap in the dark."[61] The official Vatican newspaper, *L'Osservatore Romano*, observed that such research should combine "courage with caution."[62]

[57] D.G. Gibson et al. Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome. *Science* 2010; 329: 52 - 56.
[58] A. Rizzo. 2010. Vatican: Scientists Shouldn't Play God: But Church Officials Say Synthetic Cell Could Have Benefits. *Associated Press* 21 May. Available at http://www.msnbc.msn.com/id/37285047/ns/technology_and_science-science [Accessed 30/11/2010].
[59] Ibid.
[60] Ibid.
[61] Ibid.
[62] Ibid.

Venter's work does not present any ethical or theological problems for the Church in and of itself; but it would do so if used negatively. Venter's elegant work, though, is not synthetic biology in the truest sense – it did not created a novel life-form. It was "merely" a highly sophisticated piece of genetic engineering. So it is pertinent to ask: how will the Church respond as the field advances? Synthetic biology promises to go far beyond Venter's initial work, and may ultimately include, among other things, the successful creation of new life-forms by designing DNA, the building of artificial cells, the re-engineering of cellular metabolisms, and an interface between machines and living things.[63]

Thus it is likely to produce extra ethical and theological issues. Some writers have suggested that synbio is a new paradigm,[64]going beyond the most advanced genetic engineering. Because it may enable the creation of new life out of inanimate materials,[65] it may thus impinge directly on God's creative role in a way that has never been done before. Henk van den Belt has questioned whether it is "playing God and following Frankenstein."[66] It is possible to derive a probable Catholic theology of synthetic biology's main issues from its previous teachings on science and biotechnology.

(i) Can synthetic biology be right in itself?

As mentioned, the Church strongly supports biotech research, when it is carried out morally with proper evaluation of (and protection against) risks. It is likely that all the *Compendium's* theology of biotech will apply to synthetic biology.

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[63] ETC Group *op.cit*. note 2.
[64] T. Potthast. Paradigm Shifts Versus Fashion Shifts?: Systems and Synthetic Biology as New Epistemic Entities in Understanding and Making 'Life.' *EMBO Rep* 2009; 10 S1: 542-545; Dabrock *op. cit*. note 17.
[65] Potthast *op cit*. note 64.
[66] van den Belt *op. cit*. note 17, p. 259.

Regarding the issue of creating organic entities synthetically; the Church was cautiously welcoming of Venter's work. Also, synthesis of organic entities has existed long before synthetic biology, and this has not troubled the Church.[67] Synthetic biology takes this to a new level, to living organisms, but is it different in essence? Logically, perhaps not – it's just another technique that is used to modify life. Venter's creation of an "artificial" cell placed a synthetically-made genome into a living cell, thereby transforming it into a different type of cell; but this relied on a pre-existing cell for its existence, as well as copying pre-existing DNA.[68] *Semi-synthetic biology* may be a better, if less poetic, name for the field. It is a long way from God's creation *ex nihilo*. It is barely comparable, simply changing (albeit in a sophisticated way) what already exists.

Yet many people may be intuitively troubled by the idea of synthetic, or semi-synthetic, life being created. The ETC Group (Canadian environmental activists) have given the heading *Original Syn?* to the introduction to their report on the field.[69] Bioethicist Nigel Cameron has noted that: "There were clearly no branding consultants present at the naming of synthetic biology "synbio," or the homonym would never have been allowed. In religious America, "SinBio" might just catch on as the label "Frankenfood" has in gourmet Europe…"[70]

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[67] For example, Friedrich Wohler successfully synthesised urea in 1828, from inanimate chemicals, and artificial DNA synthesis began as soon as its structure was became known. See E. Wimmer, S. Mueller, T. M. Tumpey & J. K. Taubenberger. "Synthetic Viruses: A New Opportunity to Understand and Prevent Viral Disease." *Nat Biotechnol* 2009; 27: 1163-1172.
[68] D.G. Gibson et al. *op. cit*. note 57.
[69] ETC Group *op.cit*. note 2.
[70] N. M. de S. Cameron and A. Caplan. Our Synthetic Future. *Nat Biotechnol* 2009; 27: 1103-1105: 1104.

Such concerns are likely to exist for every aspect of synbio research, but may be especially pronounced for research into modifying DNA, the blueprint of every life-form. Nelkin and Lindee have observed that “For some, genes have soul-like, mystical properties, expressed in words and images that use the double helix itself as a religious symbol.”[71] When Bill Clinton announced the (near) completion of the human genome project, he said: “Today we are learning the language in which God created life. We are gaining ever more awe for… the wonder of God’s most divine and sacred gift.”[72] Bioethicist Alex Mauron asked whether the genome could be regarded as the secular equivalent of the soul. He concluded that it could not – we are more than our DNA.[73] But the fact that such language is being used illustrates the role DNA plays in the consciousness of many people. Clearly, to engineer DNA may be a transgression for some, the crossing of a barrier that should not be crossed. This taboo may be even greater when it comes to human DNA.

How will the Catholic Church react? Could it extend its approval of modifying nature[74] to an explicit approval of engineering DNA, or creating novel DNA which does not exist in nature? If it approves the engineering of DNA, it is likely to approve other areas of synbio research, such as metabolic engineering and the creation of artificial cells, which appear, on the surface, to be less ethically contentious.

The Church has already issued teachings on the modification of human DNA. Essentially, three things form a human being: nature (DNA), environment and free will (all elements of the person being created, of course, by God). The Catholic

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[71] D. Nelkin & M. S. Lindee. 2004. *The DNA Mystique: The Gene as a Cultural Icon.* Ann Arbor, MI: University of Michigan Press: xix.
[72] Ibid.
[73] A. Mauron. Is the Genome the Secular Equivalent of the Soul? *Science* 2001; 291: 831-832.
[74] Pontifical Council for Justice and Peace *op. cit.* note 48, para 473.

Church (along with most religions) works hard to influence the latter two. It attempts to enhance people's environment, operating institutions such as schools, universities, hospitals and homeless shelters. It also tries to influence the exercise of free will, via its teachings, so that people facing difficult moral choices will have information which will help them make correct decisions. Does it follow from this that humans have a right, or even a duty, to modify DNA in order to improve human life? The answer appears to be yes. The Joint Committee on Bioethical Issues of the Catholic Bishops of England and Wales produced a document in 1996, entitled *Genetic Intervention on Human Subjects.* In their evaluation of this issue, they stated that the "genome is simply one highly influential part of our bodies;"[75] and "the genome may *in principle* be altered, to cure some defect of the body."[76] The bishops could "imagine situations in which to choose this type of treatment would be, not simply a *right* of the person choosing, but morally required"[77] (their italics).

Pope John Paul II has stated: "A strictly therapeutic intervention whose explicit objective is the healing of various maladies such as those stemming from chromosomal defects will, in principle, be considered desirable, provided it is directed to the personal well-being of the individual."[78] Speaking on scientific progress to an audience of doctors, Pope John Paul II noted that: "to you surgeons, specialists in laboratory work, and to you, general practitioners, belongs the task of cooperating

[75] Joint Committee on Bioethical Issues of the Catholic Bishops. 1996. *Genetic Intervention on Human Subjects*. London: Linacre Centre:.33. Quoted in T.A. Shannon, 2008. The Roman Catholic Magisterium and Genetic Research. In *Design and Destiny: Jewish and Christian Perspectives on Human Germline Modification*. R. Cole-Turner, ed. Cambridge, MA: MIT Press: 51-72: 63.
[76] Ibid: 64
[77] Ibid.
[78] Pope John Paul II. 1983. The Dangers of Genetic Manipulation. *Address to the World Medical Association, Vienna* 29 October. Available at http://www.ewtn.com/library/PAPALDOC/JP2GENMP.HTM [Accessed 30/11/2010].

with all the forces of your intelligence in the work of creation begun on the first day of the world"[79] – the co-creator (or "created co-creator") doctrine.

Note that the above statements approve human genetic modification for therapeutic purposes. The methods used, whether those of classical genetics, or more advanced synbio engineering techniques, are unlikely to be an issue, as long as life is respected and the risks are acceptable.

The Compendium warns, though, that human pride and selfishness are always a danger in human activity, even activity that aims to "tend…and transform…" the universe;[80] they are a cause of "asocial… impulses"[81] and may lead to negative consequences unless subdued.[82]

(ii) Synthetic biology and human enhancement

Could the Church approve synthetic biology being for non-therapuetic modification – perhaps as a foundational technology to create an enhanced human being, a "post-human"? Such a scenario appears far away, but it may arise in time, and synthetic biology may be a foundational technology. The Church draws a sharp distinction between therapeutic and non-therapeutic modification, and rejects the latter, strongly. Its main document on bioethics, *Donum Vitae,* ('The Gift of Life'), states:

> "Certain attempts to influence chromosomic or genetic inheritance are not therapeutic but are aimed at producing human beings selected according to sex or other predetermined qualities. These manipulations are contrary to the personal dignity of the human being and his or her integrity and identity,

[79] Ibid.
[80] Pontifical Council for Justice and Peace *op cit.* note 48, para 44.
[81] Ibid: para 150.
[82] Ibid: para 581.

> which are unique and unrepeatable. Therefore in no way can they be justified on the grounds of possible beneficial consequences for future humanity. Every person must be respected for himself: in this consists the dignity and right of every human being from his or her beginning."[83]

This is re-affirmed in its latest document on bioethics, *Dignitas Personae* ('The Dignity of a Person'), which observes that attempts to enhance the gene pool can display a rejection of the value of the human being, a "eugenic mentality," and a desire to replace the role of the Creator. Social stigma could be experienced by those without certain arbitrarily chosen qualities, leading to "an unjust domination of man over man;" a rejection of "the equality of all human beings."[84]

The International Theological Commission has described post human scenarios as "radically immoral."[85] They distinguish between genetic engineering which allows human beings to fulfil their complete identity by the elimination of faulty genes, and that which attempts to change human nature – which was not designed by human hands. The Commission put a limit on the co-creator doctrine, as humans are created in the image of God, and their nature should not be altered.[86] John Paul II stated that genetic modification that significantly alters the species, does not

[83] Congregation for the Doctrine of the Faith, 1987. *Donum Vitae.* Vatican City: Libreria Editrice Vaticana. Para 5.I.6. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html [Accessed 30/11/2010].
[84] Congregation for the Doctrine of the Faith. 2008. *Dignitas Personae*. Vatican City: Libreria Editrice Vaticana: Para 27. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html [Accessed 30/11/2010].
[85] International Theological Commission. 2004. *Communion and Stewardship: Human Persons Created in the Image of God*. Vatican City:Libreria Editrice Vaticana; Para 91. Available at http://www.vatican.va/roman_curia/congregations/cfaith/cti_documents/rc_con_cfaith_doc_20040723_communion-stewardship_en.html [Accessed 30/11/2010].
[86] Ibid.

respect human dignity, causes marginalisation of groups, or deprives persons of autonomy "becomes arbitrary and unjust."[87]

While attempts to change human nature are condemned by the Church, it permits fairly extreme therapeutic interventions. For example, the Pontifical Academy for Life has published a document on xenotransplantation, defining it as the transplanting of animal cells, organs and tissues into humans for curative purposes, where human donors are in short supply. This document approves it, subject to criteria of risk vs. benefit and autonomy; and, if and only if it does not affect the personhood of the person receiving the transplant.[88]

Also, the Magisterium prohibits any form of procreation outside the sex act within marriage;[89] so any type of synthetic creation of human beings would considered a moral wrong. In addition the Church prohibits research that would damage a human being, including an embryo, even if the results of that research could benefit many.[90]

(iii) Synthetic biology and other species

In approving research on human DNA, and significant forms of therapuetic modification such as xenotransplantation, the Church implicitly allows for modification of the DNA and other aspects of all creatures. Could it approve the

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[87] Pope John Paul II, *op. cit*. note 78.
[88] Pontifical Academy for Life, 2002. *Prospects for Xenotransplantation: Scientific Aspects and Ethical Issues*. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html [Accessed 30/11/2010].
[89] Congregation for the Doctrine of the Faith *op. cit*. note 83, para 5.II.A.1, 5.II.B.4, 5.II.B.5
[90] Ibid: para 5.I.1

creation of new animal and plant species? It never had a problem with cross-breeding of plants & animals to create new species; these techniques alter genomes artificially, and have done so for thousands of years, long before the existence of DNA was known. The founder of genetics, Gregor Mendel, crossed different types of peas in his experiments, creating new hybrids; he was a Catholic monk. Research in synthetic biology that alters DNA is simply a more advanced technique to achieve similar ends.

Bishop Elio Sgreccia, who heads the bioethics department of Rome's Sacred Heart University and is vice president of the Pontifical Academy for Life, spoke to Vatican Radio on the issue. He approved the creation of new species, subject to risk assessment and respect for biodiversity – new species should not displace existing ones. He also said that the benefits gained from the production of new life-forms should not be restricted to corporations – they should benefit all.[91]

(iv) The element of risk in synbio

Synthetic biology could be contentious in many ways. Regarding biotech's general risks, the *Compendium* observes that as well as evaluating the moral correctness of research in itself, it is also necessary to take account of potential risks.[92] The Church shares the concern of the general ethics community on risk, and the potential for risk in synthetic biology is significant.[93] The Pontifical Academy for Life has observed:

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[91] Zenit.org. 2003. *Ethical Criteria Outlined for the Creation of Genetically Modified Organisms: Vatican Official Urges Respect for Biodiversity*. Available at http://www.zenit.org/article-7925?l=english [Accessed 30/11/2010].
[92] Pontifical Council for Justice and Peace, *op.cit*. note 48, para 473.
[93] J.B. Tucker & R.A. Zilinskas, 2006. The Promise and Perils of Synthetic Biology. *The New Atlantis* Spring: 25-45. Available at http://www.thenewatlantis.com/publications/the-promise-and-perils-of-synthetic-biology [Accessed 30/11/2010].

> Risk – understood as an unwanted or damaging future event – the actual occurrence of which is not certain but possible – is defined by means of two characteristics: the level of probability and the extent of damage… Naturally, a very probable risk is easily tolerated if the extent of damage associated with it is very small; on the contrary, a risk that causes a high level of damage, however improbable, gives rise to much greater concern and require greater caution. …Together, these two criteria – probability and the extent of damage – define the *acceptability* of the risk, as reflected by the *risk/benefit ratio*. …In the absence of data that allow a reliable assessment of such a risk, greater caution should be used; this does not necessarily mean, however, that a total block should be put on all experimentation… In this situation, therefore, the imperative ethical requirement is to proceed by 'small steps' in the acquisition of new knowledge… with careful and constant monitoring and a readiness at every moment to revise the design of the experiment on the basis of new data emerging.[94]

Thus risk does not necessarily impute immorality to research in the eyes of the Church. But it should be taken seriously and all necessary steps taken to reduce it.[95] There should be appropriate risk assessment and risk management.[96] But where it is very significant, risk could render a research path unethical in the Church's view. The Church has reached this conclusion for human germ line modification (which may cure a patient and their descendents of a genetic disease). It does not regard the research as unethical itself when directed towards therapies – indeed, it approves it in principle. Nevertheless it regards it as being unethical with current scientific knowledge, as the risks are high and potential damage may be irreversible.[97] On the other hand, it has no ethical problems with somatic cell gene therapy (which may cure individual patients only),[98] as the risks are lower, and any potential harm will not pass through the generations.

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[94] Pontifical Academy for Life, *op. cit.* note 88, para.13.
[95] Pontifical Council for Justice and Peace, *op. cit.* note 48, para 473
[96] Pontifical Academy for Life, *op. cit.* note 88, para.13.
[97] Congregation for the Doctrine of the Faith, *op. cit.* note 84, para 26; International Theological Commission, *op. cit.* note 22, para 90; Shannon, *op. cit.* note 75.
[98] Congregation for the Doctrine of the Faith, *op. cit.* note 84, para 26; Shannon, *op. cit.* note 75.

How, then, will the Church judge synbio with regard to its potential risks? Those risks are serious. They include the potential for easy manufacture of biological weapons; and accidental ecological harm. Worst case scenarios could include massive loss of life and extreme environmental damage. The potential risks appear to be far greater than those posed by human germ line modification. It is therefore very likely that the Church will regard the current scenario of largely unregulated synbio research as being unethical. But development of good regulation, which keeps synbio acceptably safe, would change this.

Regarding bioweapons: research into biological weapons using synthetic biology will be condemned by the Church, in the strongest terms. The *Catechism* states:

> Every act of war directed to the indiscriminate destruction of whole cities or vast areas with their inhabitants is a crime against God and man, which merits firm and unequivocal condemnation. A danger of modern warfare is that it provides the opportunity to those who possess modern scientific weapons – especially atomic, biological, or chemical weapons – to commit such crimes.[99]

Thus weapons research is condemned:

> Spending enormous sums to produce ever new types of weapons impedes efforts to aid needy populations; it thwarts the development of peoples. Over-armament multiplies reasons for conflict and increases the danger of escalation.[100]… The production and sale of arms affects the common good of nations and of the international community.[101]

[99] Catechism of the Catholic Church , *op cit*. note 44, para 2314 .
[100] Ibid: para 2315.
[101] Ibid: para 2316.

(v) Intellectual property and synbio

The Church does not approve the patenting of scientific discoveries (as opposed to inventions). It regards them as being part of humanity's patrimony.[102] Pope John Paul II has commented, regarding the widespread commercialisation of biotech, including patenting of biomaterials: "the results of research should be made available to the whole scientific community and cannot be the property of a small group;"[103] and that scientific research should be kept "free from the slavery of political and economic interests."[104] Nature is God's gift to humanity; ownership should not be usurped. As the technology advances, the Church may engage with the issue of whether life can be patentable; from the above statements, it is unlikely to regard it as ethical.

CONCLUSION

Synthetic biology, if it becomes successful, will pose profound ethical and theological challenges. The Catholic Church has yet to issue a document of the Magisterium on the field; it is too early, as synbio does not appear, at this stage, to pose any theological challenges that are significantly distinct from those posed by current biotechnology. As the field progresses, this may change. This paper attempts to show the likely contents of such a Church document, based on previous Magisterial teachings on science and biotechnology, and on statements of influential individuals

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[102] Pontifical Council for Justice and Peace, *op. cit*. note 48, para 475-478; K. D. Warner. Are Life Patents Ethical? Conflict Between Catholic Social Teaching and Agricultural Technology's Patent Regime. *J Agric Enviro Ethics* 2001 14(3):301-19.

[103] Pope John Paul II. 1994. The Human Person – Beginning and End of Scientific Research. *Address to the Pontifical Academy of Sciences*, 28th October.

[104] Pope John Paul II. 2003. *Address to Participants in the Ninth General Assembly of the Pontifical Academy for Life* 24th February. Available at http://www.vatican.va/holy_father/john_paul_ii/speeches/2003/february/documents/hf_jp-ii_spe_20030224_pont-acad-life_en.html [Accessed 30/11/2010].

in the Church. Although those latter statements do not carry Magisterial weight, they do reflect the thinking of upper-level Church personnel, and those who made them may be influential in formulating Magisterial teachings. Thus it is possible to infer, with reasonable confidence, what the Church's teachings on synthetic biology will be.

While some writers have questioned whether synthetic biology may be "playing God," such concerns have been raised since the earliest days of genetic engineering and biotechnology.[105] The *Compendium of the Social Doctrine of the Church* shows that the Catholic Church does not share this concern. The Church is likely to regard the science as a tool that is capable of being used for good or evil. It is likely to critique each sub-field and significant application of synbio – the various sub-fields are quite different and pose different ethical challenges. It seems certain to approve good applications of the research, and condemn evil or unduly risky applications. Issues of patenting pure scientific discoveries, and patenting life, are likely to be ethically problematic for the Church, which will also require that beneficial applications become available to all, not restricted to a few, and that the research be done in an environment of human solidairity, not exploitation. The creativity involved in synbio is likely to be viewed as co-creation with God rather than playing God. The Church will not approve application of the science to the creation of a post-human future, or to the synthetic creation of humans, should these become technically possible.

But the issue of risk is potentially so high that it could make the whole field unethical in the eyes of the Church. John Paul II observed that "in some instances,

[105] Dabrock, *op. cit.* note 17.

technology can cease to be man's ally and become almost his enemy."[106] The Church is likely to be very aware of the dual use issue,[107] and other significant risks that synbio poses, and to require that all possible steps be taken to prevent synthetic biology from being used in negative ways. Science does not take place in a moral vacuum. John Paul II observed:

> We are not yet in a position to assess the biological disturbance that could result from indiscriminate genetic manipulation and from unscrupulous development of new forms of plant and animal life, to say nothing of unacceptable experimentation regarding the origins of human life itself. It is evident to all that in any area as delicate as this, indifference to fundamental ethical norms, or their rejection, would lead mankind to the very threshold of self-destruction.[108]

Risks may be made acceptable, however, by good regulation. The development of such regulations has yet to occur to a significant degree; such development poses significant challenges, but is under discussion by the relevant authorities.[109] If good regulations are developed, the risks may fall within acceptable parameters for the Church. From a deontological viewpoint, the Church is likely to be supportive, generally, if synbio can be made reasonably safe. Indeed, the University of Notre Dame, one of the world's leading Catholic universities, is, at the time of

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[106] John Paul II. 1981. *Laborem Exercens*. Vatican City: Libreria Editrice Vaticana: para 5. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_14091981_laborem-exercens_en.html [Accessed 30/11/2010].

[107] The fact that synbio could have positive applications such as therapies, and negative ones such as biological weapons. See M. Dando. Synthetic Biology: Harbinger of an Uncertain Future? *Bull At Sci* 2010, 16 August. http://www.thebulletin.org/print/web-edition/columnists/malcolm-dando/synthetic-biology-harbinger-of-uncertain-future [Accessed 30/11/2010].

[108] Pope John Paul II. 1996. The Ecological Crisis: A Common Responsibility. In D. Christiansen and W. Grazier, eds, *"And God Saw That It Was Good": Catholic Theology and the Environment*. Washington D.C.: United States Catholic Conference: 215–222. Quoted in Warner *op. cit.* note 101, p. 311.

[109] EGE (European Group on Ethics in Science and New Technologies). 2009. *Ethics of Synthetic Biology*. Brussels: European Commission. Available at http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf [Accessed 30/11/2010]; E. C. Hayden. 2009. Gene-makers form security coalition. *Nature News*, 18 November.

writing, establishing a synthetic biology program,[110] showing the overall positive disposition of the Church to the field.

It has been noted that Catholic ethics tends to mirror mainstream ethics to a large degree[111] (a few well-know exceptions exist, of course). It is also notable that Catholic ethics does not reflect the liberal-conservative divide in society; while it may, in certain instances, agree with one or the other, it is quite different in its approach, and frequently finds itself in opposition to either or both.[112] Probable Catholic support of synthetic biology could be a useful argument against some fundamentalist viewpoints, which are likely to be opposed to synthetic biology in itself, perhaps vehemently so. (Synthetic biology could be a focal point of future culture wars between religion and science.) Finally, it could be useful for synthetic biologists, ethicists, regulators and others to be aware of religious arguments for and against the field, to answer – or be influenced? – by them.

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[110] University of Notre Dame, Department of Biological Sciences. 2010. *News: Notre Dame adds to its expertise in nanobiotechnology*, 28 January. Available at http://biology.nd.edu/news/14506-notre-dame-adds-to-its-expertise-in-nanobiotechnology/ [Accessed 30/11/2010].

[111] Shannon, *op. cit*. note 75, p. 65.

[112] B.M Ashley, J. DeBlois & K.D O'Rourke. 2007. *Health Care Ethics: A Catholic Theological Analysis*. Washington D.C.: Georgetown University Press: 221.

CHAPTER 8 INTEGRATING ETHICAL ANALYSIS "INTO THE DNA" OF SYNTHETIC BIOLOGY

Submitted to *Medicine, Healthcare and Philosophy.*

ABSTRACT

Current ethical analysis tends to evaluate synthetic biology at an overview level. Synthetic biology, however, is an umbrella term that covers a variety of areas of research. These areas contain, in turn, a hierarchy of different research fields. This abstraction hierarchy – the term is borrowed from engineering – permits synthetic biologists to specialise to a very high degree. Though synthetic biology *per se* may create profound ethical challenges, much of the day-to-day research does not. Yet seemingly innocuous research could lead to ethically problematic results. For example, Dolly the sheep resulted from a long series of research steps, none of which presented any ethical problems. The atomic bomb was developed as a result of Einstein's uncontentious theoretical research that proved the equivalence of matter and energy. Therefore it would seem wise for ethicists to evaluate synbio research across its subfields and through its abstraction hierarchies, comparing and inter-relating the various areas of research. In addition, it would be useful if journals that publish synbio papers require an ethical statement from authors, as standard practice, so as to encourage scientists to constantly engage with ethical issues in their work. Also, this would allow an ethical snapshot of the state of the research at any given time to exist, allowing for accurate evaluation by scientists and ethicists, regulators and policymakers.

INTRODUCTION

The standard ethical analysis of synthetic biology tends to consist, at present, of evaluating the field, in overview, in terms of general moral theories and concerns. It discusses issues such as whether synbio equates to playing God, or whether it may offend human dignity or the dignity of creation; or in terms of possible benefits and dangers, ranging from the benefits of biofuels and new therapies, to the dangers of accidental release of synthetic organisms into the environment, to deliberate misuse.[1] [2] Such holistic analyses of the field are essential to gain a broad overview of synbio's ethics. They do not tend to take account of the everyday research, however. Is such a methodology sufficient?

What is more, although synthetic biology conferences have, in the past, tended to have a significant ethics component, ethics and science were presented separately; science by synbio scientists, ethics by ethicists.[3] Generally, scientists do not evaluate the ethics of their own work. But should they?

The creation of life in the laboratory may present us, ultimately, with some of the greatest ethical challenges in history.[4] In this paper I propose a new

[1] See, for example, The European Group on Ethics in Science and New Technologies to the European Commission [EGE Group] (2009). *Ethical Aspects of Synthetic Biology*. (Luxembourg: European Communities).
[2] Thomas Douglas and Julian Savulescu (2012). **"**Synthetic Biology and the Ethics of Knowledge." *Journal of Medical Ethics,* 36:687-693.
[3] Most of the synbio conferences that have taken place, along with links to many of the conference programmes, are listed at http://syntheticbiology.org/Conferences.html Accessed June 12th 2012.
[4] Julian Savulescu (2012). "Master the New Loom Before Life's Tapestry Unravels at Our Hands." *The Times Higher Education,* 9th April. http://www.timeshighereducation.co.uk/story.asp?storyCode=419685&sectioncode=26 Accessed June 8th 2012.

methodological approach to evaluating the ethics of the field. I also propose that the author(s) of every synthetic biology paper be required to publish an ethical evaluation of their work as part of that paper.

HOW ADEQUATE IS THE CURRENT METHODOLOGY?

In conversations I've had with synthetic biologists, most agree that an ethical analysis of synbio is useful or necessary. However, when I asked them if their own research had any ethical implications, all answered, with complete unanimity, that it did not.[5] The unanimity of their responses raised questions for me. Are they right? Or could they be mistaken or in denial? How could it be that in a field which seems to have profound ethical implications, many (or most) people's research appears to have no ethical implications at all? Is it possible that the field, when examined as a whole, has ethical implications, while its sub-parts, generally, do not? If so, what is the ethical relationship of the sub-parts to the whole?

To attempt to answer these questions, I examined much of the research that is taking place, evaluating its ethical aspects. Although synthetic biology aims, on the broad scale, to create life and/or engineer existing life, the everyday research is more prosaic. Some topics, from papers and conference presentations, give its flavour: *design and characterisation of small gene networks with targeted behaviour in E.*

[5] A study of Finnish life scientists in related fields reached a similar conclusion. See Matti Hayry, Jukka Takala, Piia Jallinoja, Salla Lotjonen, Tuija Takala (2006). "Ethicalization in Bioscience – A Pilot Study in Finland." *Cambridge Quarterly of Healthcare Ethics,* 15:282-284.

coli, using computational techniques;[6] *building genetic clocks from engineered oscillators;*[7] *parts, devices, and chassis in support of metabolic engineering;*[8] *biosensors for bioprocessing;*[9] *evolving cell models for synthetic biology;*[10] *engineering* Escherichia Coli *to see light;*[11] *Darwinian evolution as a tool for synthetic biology;*[12] *light driven synthesis of complex molecules,*[13] and so on.

Generally, the research appears to be ethically neutral – building an oscillator, for example, out of biological materials does not seem to differ in essence from building one out of electronic components. In both cases, it is made, ultimately, from inert chemicals. Neither does directing evolution appear significantly different, ethically, from cross-breeding plants or animals. Any devices, biological or electronic, resulting from research like this could later be used in ethical or unethical ways – as could anything. But there is nothing in them *per se* that could be considered ethical or unethical. Should they be ignored, therefore, by ethicists? Or could they be foundational platforms that may be applied negatively in the future, in ways that cannot currently be foreseen?

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[6] Alfonso Jaramillo (2010). "Computational Design and Characterisation of Small Gene Networks with Targeted Behaviour in E.coli." *Presentation, International Conference in Synthetic Biology: Bottom-up, Top-down and Cell-free Approaches, Intellectual Property Issues*. Genopole, Evry, France, 15-16th December. http://www.genopole.fr/Home,4153.html Accessed June 9th 2012.
[7] Jeff Hasty (2010). "Genetic Clocks from Engineered Oscillators." Presentation, Genopole Evry Conference. *op. cit*., note 6.
[8] Kristala Jones Prather (2010). "Parts, Devices and Chassis in Support of Metabolic Engineering." Presentation, Genopole, Evry. *op. cit*., note 6.
[9] Karen Polizzi (2011). "Biosensors for Bioprocessing." *Presentation, Imperial College Systems and Synthetic Biology Annual Autumn Symposium*, London, November 16-17th. http://www3.imperial.ac.uk/syntheticbiology/about/autumnsymposium Accessed November 7th 2012.
[10] Hongqing Cao, Francisco J. Romero-Campero, Stephan Heeb et al. (2010). "Evolving Cell Models for Systems and Synthetic Biology." *Systems and Synthethic Biology*, 4:54-84.
[11] Anselm Levskaya, Aaron A. Chevalier, Jeffrey J. Tabor, et al. (2005). "Synthetic Biology: Engineering *Escherichia coli* to See Light." *Nature*, 438:441-2.
[12] Manuel Porcar (2010). "Beyond Directed Evolution: Darwinian Evolution as a Tool for Synthetic Biology." *Systems and Synthetic Biology*, 4:1-6.
[13] Birger Lindberg Moller (2012). "Light Driven Synthesis of Complex Molecules." *Presentation, Applied Synthetic Biology in Europe Conference*, Barcelona, 6-8th February. http://www.efb-central.org/index.php/syntheticbiology/C52/ Accessed November 2nd 2012.

To answer the question, one may look to scientific history, which shows that research which has been ethically neutral in itself has been used in ways which are far from ethical. For example, Dolly the cloned sheep resulted from a long series of research steps, none of which presented any ethical problems.[14] Perhaps the strongest example is Einstein's discovery of the equivalence of mass and energy, described by the formula $E=mc^2$. It was used in the creation of the atomic bomb. Einstein detested war and did not foresee such a use of his research. He commented afterwards: "If I had only known, I would have been a locksmith."[15] One can only guess at the degree of emotion hidden in this statement. One hopes that some future synthetic biologist may not come to rue their research in a similar way.

SYNTHETIC BIOLOGY'S KNOWLEDGE STRUCTURE OFFERS A 'MAP' FOR EVALUATING SYNTHETIC BIOLOGY ETHICS IN DEPTH

This would suggest that a proper ethical analysis of synthetic biology should dig deeper than the overview approach. The field is in its infancy, as is its ethical evaluation. Given the challenges that it may pose, it would seem that ethical methodologies devised for simpler technologies may not be appropriate for it. To achieve maximum effectiveness, ethical evaluation should examine all the research being produced, looking at each area of research in relationship to the other research activity that is being undertaken, attempting to foresee any ethically problematic issues before they arise. While it is likely that any individual item of research that

[14] Mildred K. Cho, David Magnus, Arthur L. Caplan, Daniel McGee and the Ethics of Genomics Group (1999). "Ethical Considerations in Synthesizing a Minimal Genome." *Science*, 286(5447): 2087-2090. doi: 10.1126/science.286.5447.2087
[15] Glen Elert (2012). "Nuclear Weapons." In: Glen Elert (ed.) *The Physics Hypertextbook*. http://physics.info/weapons Accessed December 30th 2012.

raises immediate ethical flags will be spotted by ethicists, apparently non-contentious research that may have future ethical implications may be missed. Therefore the ethics of all synthetic biology research should be evaluated systematically, both in and of itself, and in relation to other research being carried out in synthetic biology and related fields.

How to do this? Such analysis should take account of the fact that synthetic biology has several distinct sub-fields; these have little in common, other than falling under the umbrella of creating or manipulating life. The main sub-fields are:

- Design of DNA – which can then be placed in a cell, changing the function, or species, of that cell.[16] Related to this is the development of BioBricks, small DNA parts of specific functionality; these can be combined, like parts in an electric circuit, to build specifically designed biological systems.[17]
- Construction of artificial cells (protocells) – consisting of a membrane enclosing a metabolism and an information storage molecule (such as PNA, a redesign of DNA);
- Engineering the metabolisms of cells, causing their changed internal chemistry to produce desired materials, such as drugs;

[16] For example Craig Venter's *Synthia*, the world's first synthetic organism. See Gibson DG, Glass JI, Lartigue C et al. (2010). "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome. *Science*, 329:52-56.
[17] ETC Group (2007). *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. (Ottowa, ON: ETC Group). http://www.etcgroup.org/content/extreme-genetic-engineering-introduction-synthetic-biology Accessed June 7th 2012.

- Discovery of the minimal microbe genome, the smallest collection of genes necessary to maintain life – which could then be used as a chassis on which new life forms could be built;
- Expanding the genetic code – i.e., building DNA-like molecules out of different chemicals.[18] [19]

The ethical issues differ between subfields, to an extent. The area that presents the most ethical challenges is DNA design. Some may question the ethics of tampering with the blueprint of life. Those who are more concerned about the consequences of our actions can draw attention to the growing culture of amateur biohacking, analogous to computer hacking.[20] [21] Potential dangers of this activity include the fact that interested members of the public, criminals and terrorists among them, may be able to create biological weapons, including weapons of mass destruction. Accidents are also possible; they may, in worst case scenarios, affect the course of evolution, if synbio creations are allowed to interact with the ecosystem.[22]

The other subfields do not tamper with life at the blueprint level. Nevertheless, misuse and accidents could occur. For example, cellular metabolisms could be engineered to produce toxins; bioweapons could also be designed using a minimal microbe genome chassis, or they could be built using a new genetic code. Protocells

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[18] Erik Parens, Josephine Johnston and Jacob Moses (2009). *Ethical Issues in Synthetic Biology: An Overview of the Debates.* (Garrison, NY: The Hastings Center). http://www.synbioproject.org/process/assets/files/6334/synbio3.pdf Accessed June 9th 2012.
[19] David A. Drubin, Jeffrey C. Way and Pamela A. Silver (2007). "Designing Biological Systems." *Genes & Development*, 21:242-254. doi: 10.1101/gad.1507207
[20] Markus Wohlson (2011). *Biopunk: DIY Scientists Hack the Software of Life.* (New York: Penguin).
[21] The Biopunk Directory Homepage (2012). http://www.cyberpunked.org/bpkdir/ Accessed June 8th 2012.
[22] ETC Group (2007). *op. cit.*, note 17.

could play a significant role in designing post humans, if the technology gets that far (it's a long way from it now). However, these subfields are more complex, scientifically, requiring the resources of large universities or corporations. The technologies are not in the hands of members of the public, and the potential for disaster is less.

Another facet of synbio research is that *abstraction hierarchies* can be defined for each subfield; these split the research into highly specialised modules.[23] The abstraction concept is imported from engineering and computer science, where the splitting up of complex tasks is a standard tool. For example, abstraction hierarchies ensure that computer programmers are not normally concerned with the details of how their programs are converted to machine code, understandable by the computer, or with their interaction with the computer's electronics.[24] [25]

To illustrate the concept: one proposed abstraction hierarchy, for BioBricks, contains four levels of abstraction: (synthetic) DNA, parts, devices and systems. A part is a DNA segment that codes for a specific biological function. A device is a combination of parts, designed to perform a specific biological task. A system is a

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[23] Barry Canton (undated). *Abstraction Hierarchies.* http://syntheticbiology.org/Abstraction_hierarchy.html Accessed February 2nd 2012.
[24] Austin Che (2007). *Biological Layer Abstraction and Standards Hierarchy v.* 8. http://austinche.name/docs/abstraction.pdf Accessed February 2nd 2012.
[25] Austin Che (undated). *Abstraction Hierarchy Network Layer Model.* http://syntheticbiology.org/Abstraction_hierarchy/Network_layer_model.html Accessed February 2nd 2012.

combination of devices, which can perform tasks of greater complexity.[26] This is equivalent to the building of complex electronic circuits from simpler elements. In the words of synthetic biology pioneer Drew Endy: “parts level researchers might need to know what sorts of parts that device level researchers would like to use, how different types of parts actually work (for example, atomic interactions between amino acids and the major groove of DNA), and how to order a piece of DNA. But, parts-level researchers should not need to know anything about phosphoramidite chemistry, how short oligonucleotides are assembled into longer, continuous DNA fragments, or how a genetic oscillator works...”[27]

At this point, it would be good to present an ethical outline of each level of the research. So far, however, this cannot be done. It is too nearly and not enough information exists, there isn’t a sufficient body of synbio research.

Synthetic biology’s internal subject division and its abstraction level approach offer possible maps to guide ethical evaluation of the field, permitting systematic and thorough ethical evaluation of the research, down to the most granular level. These “maps” should not be interpreted too rigidly by ethicists; abstraction hierarchies do not appear to have been defined yet for every sub-field, and different ones already exist for DNA design.[28] No doubt they will evolve with the science. Yet they offer a

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[26] Geoff Baldwin, Travis Bayer, Robert Dickinson, Tom Ellis, Paul S. Freemont, Richard I. Kitney, Karen Poliizi and Guy-Bart Stan (2012). *Synthetic Biology: A Primer.* (London: Imperial College Press).
[27] Drew Endy (2005). “Foundations of Engineering Biology.” *Nature,* 438:449-453, p. 451.
[28] See Austin Che (2007), *op. cit.*, note 24 and Drew Endy (2005), *op. cit.*, note 27.

conceptual guide for exploring the everyday science to its depths, a way of thinking, in a broad sense, for those who wish to engage with the field.

HOW SHOULD ETHICISTS (AND SYNTHETIC BIOLOGISTS) BEST RESPOND?

It is not the aim of this paper to present detailed ethical analyses that take into account the divisions and levels of synthetic biology. This may take future ethicists and scientists several years. What I can do is to suggest some ways in which the diversity of the field could be tamed.

The Einstein and Dolly examples suggest that synbio research should be evaluated throughout its subfields and abstraction hierarchies, and in overview, as mentioned. In order to do this most effectively, it would be useful to have a significant number of ethicists who are trained in the biological sciences, scientifically literate enough to follow synbio's trends. While it would be absurd to suggest that only those trained in synbio or related fields should critique the field ethically, or are even uniquely qualified to do so, having a cohort of such people in the ethics field could be "leaven in the bread," as it were, and could greatly enhance the discussion. The expertise of non-scientifically trained ethicists may not be such as to allow them to follow the research in detail, at all levels of the abstraction hierarchy, as it occurs; for that, significant technical knowledge would normally be required. For example, consider the following paper title: *Variable production windows for porcine trypsinogen employing synthetic inducible promoter variants in* Pichia pastoris.[29]

[29] C. Ruth, T. Zuellig and A. Mellitzer et al. (2010). "Variable production windows for porcine trypsinogen employing synthetic inducible promoter variants in *Pichia pastoris.*" *Systems and Synthetic Biology,* 4:181-191.

Does this research appear ethical? What are its possible applications? To evaluate such issues properly, the presence in the field of ethicists who have enough scientific knowledge to understand the papers in question would be essential.[30] (The paper describes a method of increasing protein expression by up to 135%, and appears ethically uncontentious; but that may not be obvious to a non-scientist. Perhaps, in combination with other scientific research, it could be used in ethical or unethical ways. To properly evaluate this, some knowledge of the current science seems necessary.)

As well as there being scientifically trained ethicists, in university bioethics departments, think-tanks and the like, it could also be useful for synthetic biology research teams to involve ethicists (particularly scientifically literate ones) in their work, at all levels; not just in occasional collaborations, as tends to be the case at present. The presence of biosafety officers should not be considered as meeting this requirement; the focus is different.

A degree of such integration of ethicists and social scientists into synbio research institutes has already begun. For example, Imperial College London's Centre for Synthetic Biology and Innovation (CSynBI) has a formal link with ethicists and social scientists at the Department of Social Science Health and Medicine at King's College London.[31] The latter hope, in their own words, to: "seek to influence the trajectory of this emerging field of science and technology and contribute to the

[30] Various steps could be made to cross-fertilise the two fields of bioethics and synthetic biology. For example, masters graduates in synthetic biology could be recruited into doctoral programs in bioethics; PhD graduates and practicing synthetic biologists could be encouraged to work in ethics, either part-time or as a career.

[31] Imperial College London, Centre for Synthetic Biology and Innovation Homepage (2012). http://www3.imperial.ac.uk/syntheticbiology Accessed December 29th 2012.

development of an appropriate governance regime."[32] Also, at its opening, Imperial College appointed a sociologist as part of its research team.[33]

Smaller labs, including those of amateurs, should have access to such expertise through appropriate external supports. No group of synthetic biologists should work in isolation. An example of such a support is the *Experiments of Concern Advice Portal* at the University of California, Berkeley.[34] [35] [36] Its founder Stephen Maurer recognised that there can be significant gaps in scientists' or institutional review boards' knowledge regarding biosafety and biosecurity, even though they may have specialised knowledge in biology. The portal was founded to provide "outside sanity checks."[37] The Imperial and Berkeley attempts at integration may provide a useful template for the field.

All professional synthetic biologists should also receive training in ethics; not just at a certain point in their careers, such as at the beginning of their research. The U.S. Presidential Commission for the Study of Bioethical issues recommended that ethics training, of a standard "similar or superior" to that received by healthcare

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32 King's College London Centre for Synthetic Biology and Innovation Homepage (2012). http://www.kcl.ac.uk/sspp/departments/sshm/research/CSynBI/Index.aspx Accessed December 29th 2012.

33 Katherine Sanderson (2009). "Synthetic Biology Gets Ethical: UK Centre Hopes to Blend Science, Policy and Outreach in Burgeoning field." *Nature News*, 12th May. doi:10.1038/news.2009.464

34 'Experiments of Concern Portal Homepage (undated). http://gsppi.berkeley.edu/EoC/uc-berkeley-synthetic-biology-security-program/experiments-of-concern/home Accessed May 5th 2012.

35 Erika Hayden (2009). "Experiments of Concern to be Vetted Online." *Nature*, 457:643.

36 Stephen M. Maurer (2011). "End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It." *Valparaiso University Law Review*, 45(4): 75-132. http://scholar.valpo.edu/cgi/viewcontent.cgi?article=2217&context=vulr&sei-redir=1&referer=http%3A%2F%2Fwww.google.ie%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3Dsynthetic%2520biology%2520worse%2520than%2520atomic%2520bomb%26source%3Dweb%26cd%3D6%26ved%3D0CE4QFjAF%26url%3Dhttp%253A%252F%252Fscholar.valpo.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D2217%2526context%253Dvulr%26ei%3Dsl_XUJn5IsiRhQedk4DoBA%26usg%3DAFQjCNFpPqP9T5dzTNscedXXa2sDe3UFEQ#search=%22synthetic%20biology%20worse%20than%20atomic%20bomb%22 Accessed December 26th 2012.

37 'Experiments of Concern' Portal FAQs (undated). http://gsppi.berkeley.edu/EoC/uc-berkeley-synthetic-biology-security-program/experiments-of-concern/faq Accessed May 15th 2012.

professionals, be provided for scientists and students in disciplines relevant to synthetic biology, including engineering and materials science.[38] This should go deep; in addition to training, ethical analysis could be structured into their work on an ongoing basis, as an essential part of their careers, keeping ethics at the forefront of researchers' minds. My own experience of talking to researchers is that while they are, generally, concerned with ethical issues, such issues appear far less relevant to them than the day-to-day concerns of carrying out cutting edge research in a competitive environment.

In order to encourage ongoing engagement with ethics by synthetic biologists, it would also be useful if it became standard practice for every published paper to contain a brief ethical evaluation of the research. Such descriptions should take account of the research in question and its interactions with other results in the field. The synthetic biology community has tended to engage at a serious level with issues of ethics; a significant portion of the earliest conferences have been devoted to ethics discussions.[39] But a requirement by journals for an ethical statement in every published paper could help to integrate ethical reflection into synthetic biology research's DNA (no pun intended). It could help to create a culture where unethical researchers, and those indifferent to ethics, would not flourish. Where papers do not appear to be ethically contentious, this could be stated, along with an explanation.

A requirement for an ethical statement in synbio would not be so radical. Already, many journals now require authors to describe potential conflicts of interest.

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[38] Presidential Commission for the Study of Bioethical Issues (2012). *New Directions: The Ethics of Synthetic Biology and Emerging Technologies.* (Washington DC: Presidential Commission for the Study of Bioethical Issues), p. 134.

[39] A partial (though fairly comprehensive) list of conferences, with links to many of their programs, can be found at: http://syntheticbiology.org/Conferences.html Accessed June 7th 2012.

Some journals in biology require potential authors to deposit their results in online public databases before being considered for publication.[40] [41] So a requirement for an ethical statement would be a relatively small imposition. These ethical evaluations could be appraised by ethicists and scientists alike, and a detailed snapshot of the ethical issues at every stage of synbio research could be built up. The importance of such constant ethical evaluation of all research should not be underestimated. A proper ethical evaluation of synbio may help to prevent it being applied in vastly destructive ways. Of course, something that is not ethically contentious now could become so in the future, in combination with yet to be published results. An ethical snapshot, being constantly updated, could be thus useful in minimising potential harms and encouraging beneficial applications.

It may be necessary for ethicists to go deeper than reading papers and following conferences. In the case of Einstein's research, for example, once it was published, it was impossible to take the knowledge back. Human nature being what it is, it was probably inevitable that some people would apply it for destructive purposes. It seems unlikely that Einstein would have published his paper if he had foreseen the results.[42] If he had been encouraged by the scientific system of the time to evaluate possible applications of his work, and to discuss the issues with people

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[40] Committee on Responsibilities of Authorship in the Biological Sciences (2003). *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences.* (Washington DC: The National Academies Press). http://www.nap.edu/openbook.php?isbn=0309088593 Accessed February 11th 2012.

[41] Beverly Ventura (2005). "Mandatory Submission of Microarray Data to Public Repositories: How is it Working?" *Physiological Genomics,* 20:153-56.

[42] He once wrote: "He who joyfully marches to music in rank and file has already earned my contempt. He has been given a large brain by mistake, since for him the spinal cord would fully suffice. This disgrace to civilization should be done away with at once. Heroism on command, senseless brutality, deplorable love-of-country stance, how violently I hate all this, how despicable and ignoble war is; I would rather be torn to shreds than be part of so base an action!" It is ironic that the research of such a man was used to create the most destructive weapon in history. In: Otto Nathan and Heinz Norden, eds. (1968). *Einstein on Peace*. (New York, NY: Schoken Books), p.111-12.

outside of his own field, who may have had a broader appreciation of potential applications of the research, the atomic bomb may not have been created.

The field of synbio research is now so small that individual ethicists can review it all, in overview and through its subfields and abstraction hierarchies. This may change as it progresses. For example, the number of papers published in the related and foundational subject of bioinformatics has been increasing exponentially over the last decade.[43] No single person can read them all, and computational text mining techniques have been developed to permit researchers to find relevant material.[44] If similar growth occurs in synthetic biology – and it will, inevitably, if the subject succeeds – ethicists may need to specialise, to an extent, within levels of the subject divisions and/or abstraction hierarchies, without losing the broader view.

There are other areas of synbio research, at varying places in the abstraction hierarchies, that tend not to be published in the literature. These are DIY biology, and research for military applications. DIY biology has a similar culture to that of computer hacking, frequently being carried out in people's homes. It is difficult, perhaps impossible, to monitor much of what is going on in both of these areas, but it can be taken for granted that at least some of it will be used for unethical ends. It is an area that invites significant engagement from ethicists and policymakers, as synthetic biology has the potential to create some of the most powerful weapons humanity has seen.

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[43] Swapan Kumar Patra and Saraj Mishra (2006). "Bibliometric Study of Bioinformatics Literature." *Scientometrics,* 67:477-89.
[44] Kristina Sainani (2008). "Mining Biomedical Literature: Using Computers to Extract Knowledge Nuggets." *Biomedical Computation Review,* July, 16-27.

CONCLUSION

The current approach of evaluating synbio in overview is essential, and will remain so as synbio progresses. But it is not sufficient; some research, while being unproblematic in itself, may have potential to lead to negative outcomes. Regarding worst case scenarios, Douglas and Savulescu have noted that synthetic biology may be “part of the blueprint for humanity’s destruction.”[45] Therefore it would be wise for synthetic biologists, ethicists and policymakers to be familiar with ethical issues in synthetic biology throughout its subfields and abstraction hierarchies, and how different areas of research may interrelate. The advent of synthetic biology is profound. Ethical analysis of the field needs to reflect its importance, and its potential for benefits and harms. For that, such analysis needs to delve deeply into every aspect of the field. The potential for research that is ethically unproblematic in itself to be used in unforeseeable ways, sometimes unethically, seems high in synbio.

Of course, such ethical oversight may not inhibit those whose intention is to apply synthetic biology in an unethical manner. Regulators and policymakers also need to engage very deeply with the subject to attempt to minimise misuse.

[45] Thomas Douglas and Julian Savulescu (2010). *op. cit.* note 2, p. 692.

CHAPTER 9 GLOBAL HEALTH JUSTICE AND GOVERNANCE FOR SYNTHETIC BIOLOGY

Published in *The American Journal of Bioethics*: Patrick Heavey (2012). "Global Health Justice and Governance for Synthetic Biology." *American Journal of Bioethics,* 12(12): 64-65. doi: 10.1080/15265161.2012.739840.

Jennifer Prah Ruger, in her article "Global Health Justice and Governance,"[1] correctly critiques current global healthcare regulation as being fragmented, with regulators concentrating on their own institutions or countries, not focussing on the benefit of humanity throughout the world, and without knowledge of the knock-on effects of their policies. It seems unlikely that such a regime can meet the regulatory challenges of synbio.

Ruger has developed a theory of global health governance that is based on ethics. Synthetic biology (synbio) is a major public health issue, and applying Ruger's approach to it is likely to be a considerable stress test for her theory. Here I briefly summarize the theory's most salient points, to apply it to synbio regulation. The basis of global healthcare regulation is set out in the provincial globalism (PG) model, which is based on nine foundational principles: (1) Virtuous people acknowledge human dignity, and desire universal human flourishing. (2) Health is a foundation for human flourishing. (3) Humans have duties to each other by virtue of their humanity. (4) There is a universal right to good health. (5) The existence of nations and a broad,

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[1] Ruger, J.P. 2012. Global health justice and governance. *American Journal of Bioethics* 12(12): 35-54.

cosmopolitan viewpoint are reconciled. (6) People are “plural subjects,” being autonomous individuals, citizens of nations, and members of a universal human family, and this must be recognized. (7) There should be a multi-level governance system, in which there is individual and collective responsibility, with consistency between national and global governance. The principal regulation should be at national level, with secondary regulation at regional and global levels. (8) The reality of disagreements on central principles can be dealt with by incompletely theorized arguments, which allow people to agree on specific issues without agreement on broader principles or specific details of implementing the issues. (9) There is an aspiration towards global health citizenship, in which all people are entitled to equal health care/well-being.

Having established foundational principles of global healthcare governance, Ruger notes that PG contains within it the concept of shared health governance (SHG). This is based on the premise that those involved in global health care seek health justice on a global scale, as opposed to national or self interest. The features of SHG are, in brief summary: (1) Global health justice, based on ethical values, requires good global health governance. (2) Ethical commitment rather than self or national interest is the motivation for global health justice. (3) There is a duty of co-operation, so that core requirements can be attained. (4) Responsibilities are imposed according to function and need, both at national and international levels (primarily national). (5) A politically independent global institute for health regulation should be created to provide expertise on policy; its membership should include scientists. (6) A global health constitution should be developed, guiding the relevant global, national and regional institutions. (7) The constitution and global institute should reduce inefficiency, wasteful competition and power plays by states. (8) Global health governance does not equate to one world government; voluntarily agreed international policy would be enforced by national governments. (9) All participants, be they in democratic or non-democratic bodies, at national, regional and global levels, are held to standards of mutual collective accountability. (10) Policy should be evidence-based, rather than political. (11) Compliance at the global level should be voluntary, primarily, based on moral consensus. (12) Legitimacy should be achieved by establishing and reaching goals, subject to independent review.

It is imperative that synbio be regulated properly, in ways that allow it to fulfil its potential for good while minimizing its possible negatives. Some synthetic biologists have called for self regulation,[2] [3] and some piecemeal regulation has been developed at the national level in some countries.[4] Such regulation, although a useful beginning, will not be adequate in the medium to long term. While strong regulation at the national level, in the countries where synbio is at its most advanced, is necessary, the mobility of research means that such regulation alone may, paradoxically, lead to looser, more permissive regulations for the field overall, as some research moves to places where regulation is least. Ethically contentious research is most likely to follow this path. Therefore regulation needs to be worldwide in scope.

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[2] *Declaration of the second international meeting on synthetic biology, Berkeley, California* (2006). http://openwetware.org/wiki/Synthetic_Biology/SB2Declaration Accessed December 14th 2012.

[3] Garfinkel, M.S., D. Endy, G. L. Epstein and R. M. Friedman 2007. *Synthetic biology: Options for governance*. (JCVI, CSIS, MIT). http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-genomics-report/synthetic-genomics-report.pdf Accessed December 14th 2012

[4] Bar-Yam, S., Byers-Corbin, J., Casagrande, R., Eichler, F., Lin, A., Oesterricher, M., Regardh, P., Turlington, R.D., Oye, K.A. 2012. *The regulation of synthetic biology: A guide to United States and European Union regulations, rules and guidelines*. Arlington, VA: National Science Foundation (Synthetic Biology Engineering Research Center (SynBERC)). http://synberc.org/sites/default/files/Concise%20Guide%20to%20Synbio%20Regulation%20OYE%20Jan%202012_0.pdf Accessed December 14th 2012.

Regulating it well will be challenging. Paralleling the earliest days of computing research, synbio research is taking place at many levels of society, ranging from universities and corporations to amateur labs in the homes of teenage biohackers. Information exists online that teaches interested parties how to synthesize their own biological "creations;" such information includes the genome sequences of pathogens, such as Ebola virus, smallpox and HIV. Inadequate regulation could lead to destruction of life on a vast scale. Too much regulation could shut down synbio's great potential for good, preventing advances in knowledge, including future therapies.

The different sub-fields within synbio pose very different regulatory problems.[5] The biggest difficulty will be in attempting to regulate biohacking, which will feed off advances in the mainstream science. Current biotechnology laws tend to regulate products rather than the underlying science.[6] Biohacking may become as regular an occurrence as today's computer hacking. This suggests that pure research may have to be regulated, to prevent its results being applied in negative ways, even where it is not negative in itself and may have positive applications. Thus it may become necessary to prevent, or keep from the public domain, certain scientific advances. Because of the potential dangers and benefits of synthetic biology, and its broad array of researchers and sub-fields, getting the regulatory mix right will be a difficult task.

[5] Schmidt M. 2008. "Diffusion of synthetic biology: A challenge to biosafety." *Systems and Synthetic Biology*, 2(1-2): 1-6.

[6] Rodemeyer, M. 2009. *New life, old bottles: Regulating first generation products of synthetic biology.* (Washington DC: Woodrow Wilson International Center for Scholars). http://www.synbioproject.org/process/assets/files/6319/nano_synbio2_electronic_final.pdf Accessed December 14th 2012.

There are other challenges. One is that the major industrial nations are working to build up their synthetic biology industries, in competition (and a degree of co-operation) with each other. Synthetic biology may lead to a societal revolution as great as the computer revolution, and major nations don't want to be left behind. There is similar competition among corporations; for example, energy, medical, and pharmaceutical companies are engaged in synbio research, as is Microsoft. Depending on their success or failure, the corporate landscape could be reshaped. At the level of individual scientists, success in major synbio projects will lead to great prestige and, for some, in this era of increasing privatization of science, great wealth. Thus, under current regulatory mechanisms, while major synbio players will tend to seek a degree of good regulation, there will also be a natural instinct to preserve their own interests in a competitive environment.

Ruger's theory needs little adaptation to apply it to synbio regulation. Synbio's regulatory challenge, where a myriad of opposing needs make it almost impossible to devise an adequate regulatory regime, diminishes when PG/SHG is applied. For example, in the current regime, nations may be faced with the dilemma of permitting potentially hazardous, though beneficial, research rather than risking falling behind others. But with PG/SHG's approach, the problems tend to fade away. The ethical foundation, the multi-level regulation from global to regional, with mutual collective accountability, regulating for the benefit of humanity at large as well as for local interests, should provide an intellectual and ethical framework to solve synbio's regulatory challenges – subject to the proviso that goodwill underlies the negotiations. The timing of the PG/SHG model, coinciding with this extraordinary scientific leap, is propitious.

PART III CONCLUDING SECTION

CHAPTER 10 CONCLUSION

There is grandeur in this view of life, with its several powers, having been originally breathed by the Creator into a few forms or into one; and that, whilst this planet has gone cycling on according to the fixed law of gravity, from so simple a beginning endless forms most beautiful and most wonderful have been, and are being, evolved.

Charles Darwin.[1]

Biology is the highest form of applied chemistry.

Richard E. Dickerson and Irving Geis.[2]

INTRODUCTION

Richard Kitney, director of Imperial College London's Centre for Synthetic Biology and Innovation, has observed that modern technological progress can be divided into three eras. The analogue era began with the invention of Huygens' pendulum clock in 1656; the digital era commenced with the development of information theory by Norbert Wiener and Claude Shannon in the 1940s. We are now in the early stages of the biological era, which began with the completion of the human genome project in 2003.[3] (He spoke of technological revolutions rather than ones in science or approaches to knowledge. Even technological revolutions can change society profoundly, scientific ones more so.)

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[1] Charles Darwin (1860). *On the Origin of Species by Means of Natural Selection*, 2nd edition. (London: John Murray), p. 490.

[2] Richard E. Dickerson and Irving Geis (1976). *Chemistry, Matter and the Universe*. (Menlo Park, CA: W.A. Benjamin). In Scott C. Mohr (2007). *Primer for Synthetic Biology*. http://openwetware.org/images/3/3d/SB_Primer_100707.pdf Accessed December 30th 2012.

[3] Richard Kitney (2011). "Strategic Overview." *Presentation, Imperial College Institute of Systems and Synthetic Biology Autumn Symposium*, London, 16th November. http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/eventssummary/event_26-9-2011-12-51-39 Accessed December 31st 2012.

The analogue era resulted in technological changes as diverse as the steam engine, the car and the airplane. It resulted in vast social change, including the industrial revolution, large scale urbanisation, the emergence of the middle class; and the appearance of new political and economic visions, including capitalism and communism. The digital age has changed the world more subtly, yet very significantly, creating, to an extent, an interconnected global village. The biological era is likely to have as revolutionary an effect on human civilisation as the first two, if not more so.

The scientific revolution, of Copernicus, Galileo, Newton and others led, among other things, to the Enlightenment, a change in attitudes to authority, and a move away from a religious world view by many intellectuals, for the first time in history. It could be argued that such changes are greater than those produced by technological revolutions, as they go deeper than societal change; they changes humanity's concept of itself and of its place in the universe.

Of all the research in the biological era, synthetic biology, humanity's attempt to create life, has the potential to bring the greatest changes. It is also likely to present the greatest ethical challenges. It may cause both scientific and technological revolutions.

IS SYNTHETIC BIOLOGY ETHICAL?

The opportunity to create life has, apparently, arisen. Should this particular path be followed? The input of ethicists may be useful to guide scientists, and society at large, as to whether synbio should go ahead, and what, if any, constraints should be placed on it if allowed. The bioethics community has been slow in realising the importance of synbio, however, and has not engaged with the subject as much as many of the scientists would, almost certainly, have wished.

The central question of my thesis was: *Is synthetic biology ethical?* The answer, based on philosophical and theological analysis, is that *it can be*. Synthetic biology appears ethical from a mainstream deontological perspective (see Chapter 6). From a consequentialist viewpoint, it is dual use, offering great potential benefits and threats. I have argued that a consequentialist cannot support synthetic biology, as its dangers, and their probability of occurrence, are so high (Chapter 5). However, the few consequentialist thinkers that have engaged with it cannot agree on whether it is ethical. The difference may depend on, among other things, their degree of optimism regarding the human condition – will it be used for the great potential evils that it could be? (In my view, to suggest that it wouldn't be, ever, seems naïve.) Add to these differing views the Catholic Church's perspective, which does not see synbio as right or wrong *per se*; rather, as a neutral tool which can be used ethically or unethically (Chapter 7). This position also seems to be held by the mainstream of the world's religions (Chapter 6).

The best approach in terms of offering short-term guidance as to whether/how synbio should be regulated, is consequentialism. It offers the possibility of a detailed analysis of synbio's pros and cons, but it does not offer any guidance at all as to whether synbio is ethical in the medium to long term. Deontology suggests that it is ethical, yet its potential threats are so great that this conclusion seems inadequate by itself.

The pragmatic methodology of the Catholic Church offers, by itself, a more useful approach to evaluating synbio's ethics than either of the two major approaches of secular bioethics alone. Its approach could be summed up, for synbio (and scientific research in general), as: we are stewards of creation, appointed by God. We can do what we wish, as long as it doesn't cause harm. Their approach is based on the natural law, primarily, and offers a flexibility here that the two theories do not. Yet it does not provide the detailed ethical and regulatory roadmap of consequentialism.

Combining the approaches yields the following result. Synthetic biology has great potential dangers, so extreme that in a worst case scenario, it may challenge the continuing existence of humanity, and even of all life. Yet it is not wrong in itself, and also has the potential to greatly improve the human condition, and that of the planet. This suggests it should be allowed to proceed if a regulatory regime can be drawn up which can minimise its dangers to an acceptable degree. Proper regulation is the key to whether synbio can be considered ethical.

REGULATION

I have discussed the difficulties of regulating synbio, and they are great (Chapter 2). I have proposed a possible solution, a global regulatory paradigm with ethics as its core (Chapter 9), which has potential to succeed if pursued in a spirit of goodwill. Success is not certain though. Ruth Macklin praises the theory, but raises the issue that nations may lack the desire to go beyond self interest in their negotiations. This questions whether a global regulatory paradigm is: "'fine in theory but will not work in practice.' That is subject to the usual response: 'If it will not work in practice, it's not good in theory either.'"[4] Be that as it may, the approach offers a potential solution to the difficulties of developing a good regulatory framework for synbio.

Also, a discussion of synbio regulation would not be complete without discussing the elephant in the room – neoliberal ideas on regulation, which are very influential at present. 'Light touch' to 'non-existent' tends to be the range of preferred options, and any attempts to develop good regulations for synbio, where these attitudes predominate, may run into serious opposition.[5] The preference for light touch regulation does not appear to have changed generally, even after evidence of its failure in the financial crisis.[6] *New Yorker* Journalist James Suroweicki has noted that improper regulation has contributed to numerous business disasters.[7] Suroweicki observes that such failures have resulted from the "deregulatory fervor"[8] of the last three decades, where scepticism on regulation's worth is shared by the highest ranks of government and regulators alike.[9] Where significant dangers are apparent and

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[4] Ruth Macklin (2012). "Good in Theory. Can It Work in Practice?" *American Journal of Bioethics,* 12(12): 55-56. doi:10.1080/15265161.2012.739387
[5] Kieran Allen (2007). *The Corporate Takeover of Ireland.* (Dublin: Irish Academic Press).
[6] James Suroweicki (2010). "The Regulation Crisis." *The New Yorker*, 14th June. http://www.newyorker.com/talk/financial/2010/06/14/100614ta_talk_surowiecki Accessed December 25th 2012.
[7] Ibid.
[8] Ibid.
[9] Ibid.

occasional scientific misconduct and fraud are visible,[10] the desire for deregulation seems irrational, and may be part of a greater moral malaise.

Yet there have been positives and negatives in the ongoing attempts to regulate synbio. I mentioned, in Chapter 2, how the International Association Synthetic Biology (IASB) attempted to develop formal self regulation for the DNA synthesis industry. Among other things, they wanted some human monitoring of sequences submitted for commercial synthesis. Within 18 months of the establishment of the standard, 80% of the industry, by capacity, followed it.[11]

At the same time, the US government was attempting to develop standards for the industry. The standards it eventually released were substantially weaker than those developed by and practiced within the industry; automated screening was its choice.[12] Stephen Maurer, a professor of law and public policy who specialises in regulatory issues in synthetic biology, has written that: “This strongly suggests that the U.S. government is more allergic to regulation than industry itself.”[13] As most synbio research takes place in the US, this may influence the development of worldwide

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[10] Gary Marcus (2012). “Cleaning Up Science.” *The New Yorker*, 24th December. http://www.newyorker.com/online/blogs/newsdesk/2012/12/cleaning-up-science.html Accessed December 25th 2012.
[11] Stephen M. Maurer (2011). “End of the Beginning or Beginning of the End? Synthetic Biology’s Stalled Security Agenda and the Prospects for Restarting It.” *Valparaiso University Law Review*, 45(4): 73-132. http://scholar.valpo.edu/cgi/viewcontent.cgi?article=2217&context=vulr&sei-redir=1&referer=http%3A%2F%2Fwww.google.ie%2Furl%3Fsa%3Df%26rct%3Dj%26url%3Dhttp%3A%2F%2Fscholar.valpo.edu%2Fcgi%2Fviewcontent.cgi%253Farticle%253D2217%2526context%253Dvulr%26q%3DEnd%2Bof%2Bthe%2BBeginning%2Bor%2BBeginning%2Bof%2Bthe%2BEnd%253F%2BSynthetic%2BBiology%2527s%2BStalled%2BSecurity%2BAgenda%2Band%2Bthe%2BProspects%2Bfor%2BRestarting%2BIt%26ei%3DKIzbUPW4HoaAhQeoqIDgBQ%26usg%3DAFQjCNEaqmfcpLdCIr3chfC9PnwKoqAL1A#search=%22End%20Beginning%20or%20Beginning%20End%3F%20Synthetic%20Biologys%20Stalled%20Security%20Agenda%20Prospects%20Restarting%22 Accessed December 26th 2012.
[12] Ibid. See also: *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*, 75 Federal Regulations 62, 820 (13th October 2010).
[13] Ibid.

regulation. Maurer notes that this has largely derailed a near decade's worth of attempts to regulate the field.[14]

Yet some members of the synthetic biology community are trying to fill gaps, to an extent, in addition to the IASB and other measures discussed. One third of US universities have integrated some biosecurity concerns into their safety policies.[15] In the Southeastern US, a number of universities joined forces to collaborate on security issues.[16] An "experiments of concern" portal was set up at the University of California, Berkeley, which offered guidance to synthetic biologists.[17] While these steps are laudable, they do not appear comprehensive enough to limit potential misuses. Yet they illustrate an awareness of the dangers, and good intent.

George Church, who is, as mentioned, a founding father of the field, has called for regulation of synthetic biology and surveillance of synthetic biologists.

> Everybody who practices synthetic biology should be licensed, including amateurs. Same as cars, right? You're an amateur car driver, you get a license. Then you don't assume that just because drivers have licenses, they're going to behave themselves. You watch the roads, and do radar monitoring to catch speeders. There should be a similar arrangement for synthetic biology, where the stakes are higher.[18]

Church notes that in spite of all the safety features on cars, and the training and licensing of drivers, that there are still thousands of accidents and road deaths

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[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] Ibid. It operated from 2009 to 2011, and received no queries in that time (see Maurer, *op. cit.*, note 11, p. 1415, footnote 122.
[18] George Church. In Alan Boyle (2012). "How Synthetic Biology Will Change Us." *Cosmic Log on NBCNews.com*, 2nd October. http://cosmiclog.nbcnews.com/_news/2012/10/02/14187258-how-synthetic-biology-will-change-us?lite Accessed December 25th 2012.

every year.[19] Also, he cites a study which showed that 1,448 symptom causing accidents in biological laboratories were reported in scientific journals between 1970 and 2004.[20] Writing that synbio may have more potential destructive power than nuclear or chemical weapons, he observed that it may allow a future Columbine to be carried out with a weapon of mass destruction.[21] I write this just a few days after the Newtown massacre;[22] it is a sobering thought. If one such massacre does occur, it could generate many copycat attacks.

Church's suggestions have not been followed.[23] He has noted that many of his colleagues favour self regulation over external; also that lobbyists can have powerful influence over decision makers, quenching moves towards proper regulation, and leading policy in hazardous directions.[24] He recommended that there be more scientifically oriented people in power, who understand the technical issues, claiming that many of those currently in power, and their advisors, do not.[25]

I would suggest that it is unethical for synbio to progress in the current regulatory environment, as potential dangers are so great. Proper regulation seems to be the key as to whether synbio can be ethical, and if such regulation cannot be developed, for whatever reason, it would be better if a moratorium was to be put in place until it can. Of course, who would impose such a moratorium?

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[19] George Church (2012). *Regenesis; How Synthetic Biology Will Reinvent Nature* and *Ourselves*. (New York: Basic Books), p. 237.
[20] Ibid., p. 231.
[21] Ibid., p. 230.
[22] Adam Gabbat and Matt Williams (2012). "Newtown Gunman Kills 20 Children in Elementary School Shooting." *The Guardian*, 15th December. http://www.guardian.co.uk/world/2012/dec/14/newtown-shooting-gunman-kills-20-children Accessed December 30th 2012.
[23] Alan Boyle (2012). *op. cit*., note 18.
[24] Ibid.
[25] Ibid.

SYNBIO ETHICS; AND THE LIMITATIONS OF BIOETHICS

I had assumed, on beginning the research, that the standard ethical tools would be adequate for the job. But as I evaluated the arguments, in the two main methodologies in isolation, I realised that they weren't; they gave a certain degree of guidance, but nothing approaching a degree of truth that could be relied upon. This is nothing new in bioethics – for example, Alasdair MacIntyre has described the difference between consequentialism and deontology as the difference between permitting and prohibiting the firebombing of Tokyo and Dresden.[26] Universal agreement cannot be reached upon important and emotive issues such as euthanasia, abortion and infanticide; bioethicists are no more united than the general public on such topics. But for a subject of such importance, which may involve humanity's future existence, this is utterly unsatisfactory. What use is bioethics if it cannot offer strong, plausible guidance on such an issue?

For those consequentialists who have a positive disposition towards synbio, it seems to be an ethical imperative to support the field. Those who focus on its potential negatives tend to see it as unethical, regardless of any potential positives, due to its potentially vast destructive power. The problem is compounded by the fact that, in the medium to long term, the consequences of synbio are utterly unpredictable (see Chapter 5).

My deontological analysis suggests that synbio is ethical *per se*. There are many deontological approaches, though, and I focussed on fairly mainstream ones. Similar analyses using different presuppositions, such as fundamentalist Christianity

[26] Alex Voorhoeve (2009). *Conversations on Ethics.* (Oxford: Oxford University Press), p. 115.

or deep ecology, could lead to the opposite conclusion. For example, Richard Land, who has held leadership positions in the Southern Baptists, and is a significant figure in America's religious right,[27] has written: "We see altering life forms, creating new life forms, as a revolt against the sovereignty of God and an attempt to be God."[28] That seems to rule out any moral acceptability of synbio, absolutely; and such views, though not representative of the religious mainstream, are mainstream in parts of the US and elsewhere.

Thus the results of deontological analysis depend on the presuppositions of the person performing the analysis. Also, the results from the deontological approaches that I used are challenged by the likely dangers that a consequentialist analysis yields. If, as seems plausible in the worst case, synbio could be vastly destructive, possibly threatening the existence of all life, it seems to be absurd to say that it's ethical *per se* (see Chapter 6). Thus neither of the main ethical approaches yields a satisfactory answer as to whether synbio is ethical, and whether this research path should be taken. Standard methods of bioethical analysis fail here.

In addition to rivalry between proponents of different methodological approaches in bioethics, and the limitations that result, there can be disagreement among bioethicists as to whether any methodology is appropriate, and if so, to what degree. In the words of John Harris:

> But what are the methodologies FOR? It's not like ways of diagnosing illness, it is ways of thinking productively. How you challenge a wrong methodology may not have a methodology that can be predicted in advance. How do you see an error of logic or of sympathy? What is the methodology

[27] Amy Sullivan (2012). "Richard Land Goes Out at The Bottom." *New Republic*, 7th August.
[28] Ted Peters (2003). *Playing God? Genetic Determinism and Human Free*dom. (New York, NY: Routledge), p. 118.

> for that? …Methodologies in philosophy are for people who cannot think… not all bioethics is theory burdened![29]

This seems reasonable, if a little overstated; methodologies provide a useful foundation for ethical analysis. Yet they should not be followed slavishly. (Not everyone would agree – a paper of mine was rejected by a reviewer, with a hint of anger, because it didn't follow a precise methodology.)

Synbio brings these such issues into a clear focus, and with some urgency. It also proves these limitations in a way that is akin to a scientific result. I did not engage in any theoretical philosophical argument to reach this conclusion; rather I observed it "from the data," as it were. It was absolutely not my intention to critique the conceptual foundations of bioethics, yet the results of my analysis forced this upon me.

As mentioned above, combining the ethical tools gave an answer that was far more complete than could be obtained from either tool alone; namely, that synbio offers great potential promises and dangers (consequentialism), and it seems ethical *per se* (mainstream deontology); which suggests that allowing it to flourish, while regulating it thoroughly to minimise dangers, is the best path to take, *if* appropriate regulation can be developed. It appears necessary for deontology and consequentialism to be combined here because of synbio's potential for extreme good and evil.

[29] John Harris (2012). Private communication.

This suggests that bioethics is ill served by the division of many of its practitioners into camps; it may be easier to find ethical truth by combining different ethical approaches, while maintaining the integrity of each. Such approaches can be used, in a different context, in various scientific disciplines. Physicist Michael McIntyre has described the difficulties of scientific research:

> Trying to make sense of things near the research frontier will always be - fundamentally - like driving a vehicle in swirling fog on an unfamiliar, unmapped, twisty road with many branches and with plenty of oncoming traffic. One has to live with uncertainty, one has to keep one's eyes and ears open, and one has to expect surprises.[30]

Rigid methodologies cannot work, therefore – McIntyre has noted that if they could, science would be done most efficiently by computers.[31] Yet science is successful, because it permits flexibility in its methodologies; for example, computationally intractable problems are solved all the time by heuristic methods (see Chapter 6).

Ethicists can learn from this. The "warmaking model of doing philosophy"[32] could be better replaced with a heuristic approach of regarding different methodologies as being complementary. To quote Alasdair MacIntyre (in a different context):

> Imprisoning philosophy within the professionalizations and specializations of an institutionalized curriculum, after the manner of our

[30] Michael E. McIntyre (1997). "Lucidity and Science II: From Acausality Illusions and Free Will to Final Theories, Mathematics and Music." *Intedisciplinary Science Reviews*, 22(4): 285-303. http://www.atm.damtp.cam.ac.uk/mcintyre/papers/LHCE/lucidity-science-II.pdf Accessed December 30th 2012.

[31] Michael E. McIntyre (1998). "Lucidity and Science III: Hypercredulity, Quantum Mechanics, and Scientific Truth." *Interdisciplinary Science Reviews*, 23(1): 29-70, p.30. http://www.atm.damtp.cam.ac.uk/mcintyre/papers/LHCE/lucidity-science-III-searchable-uncorrected.pdf Accessed November 2nd 2012.

[32] J.B. Sterba (1998). *Justice for Here and Now*. (Cambridge: Cambridge University Press), pp. 2-3. In Søren Holme (2011). "Classification and Normativity: Some Thoughts on Different Ways of Carving Up the Field of Bioethics." *Cambridge Quarterly of Healthcare Ethics*, 20(2): 165-173. http://dx.doi.org/10.1017/S0963180110000812

> contemporary European and North American culture, is arguably a good deal more effective in neutralizing its effects than either religious censorship or political terror.[33]

The "synthetic biology problem" may suggest that bioethics research in general should be, of necessity, interdisciplinary and open in methodological approach, adaptable to the problem under consideration; and while being primary philosophical, may also be informed by knowledge and methodologies of other disciplines. Philosophical approaches could draw from the richness of the field, combining, as appropriate, the concepts of deontology and consequentialism, also rights, duties and virtue, along with religious viewpoints. Those ethicists who constrain themselves to a particular ethical approach may be comparable with the protagonists in John Godfrey Saxe's poem that satirises six blind men trying to describe an elephant; each sees a partial picture of truth, and so they contradict each other. Many different approaches, in combination, may be required in the search for the best ethical solutions for complex issues – while realising that perfect solutions may not always be achievable. In the words of Bernard Williams:

> Philosophy starts from the realization that we don't fully understand our activities and thoughts; its task is to suggest and open up ways in which we might better understand them.[34]

He has suggested that ethical theories may not help in achieving such understanding; indeed they may be a barrier.[35]

[33] Alasdair C. MacIntyre (2006). *Edith Stein: A Philosophical Prologue 1913-1922*. (Lanham, MD: Rowman & Littlefield), p. 4.
[34] Bernard Williams. In Alex Voorhoeve (2009). *op. cit.*, note 26, p. 195.
[35] Ibid. See also: Bernard Williams (2006). *Ethics and the Limits of Philosophy*. (London: Routledge).

Comparing ethics with the science it studies again, mathematician Jacob Schwartz has noted the limitations of maths, limitations which seem to parallel those of ethical theories as discussed here:

> Mathematics is able to deal only with the simplest of situations, more precisely, with a complex situation only to the extent that rare good fortune makes this complex situation hinge upon a few dominant simple factors. Beyond the well traversed path, mathematics loses its bearings in a jumble of un-named special functions and impenetrable combinatorial particularities. Thus, the mathematical technique can only reach far if it starts from a point close to the simple essentials of a problem which has simple essentials. That form of wisdom which is the opposite of single-mindedness, the ability to keep many threads in hand, to draw an argument from many disparate sources, is quite foreign to mathematics.[36]

There is no reason why such wisdom should be foreign to philosophical ethics, unless its practitioners choose it to be so. If those evaluating synbio ethics make such a choice, their evaluations, no matter how brilliant, will only reveal part of the truth. Yet allowing the methodologies to dovetail reveals the truth to a far greater degree.

But could combining different (rival/opposing) methodologies such as deontology and consequentialism, in order to help overcome the limitations of both, lead to incoherence? I would argue that this need not be a concern, first, because doing this is proven to work here. Its effectiveness is established. At a more fundamental level, the seeking of the good in deontological terms is related to the consequences of actions. Also, consequentialism appears to have some unexpressed deontological assumptions. Why, for example, is the greatest happiness theory of utilitarianism a good thing? Why not a principle of indifference, or one of greatest

[36] Jacob T. Schwartz (1960). “The Pernicious Influence of Mathematics on Science.” In Mark Kac, Gian-Calro Rota and Jacob T. Schwartz, eds. (2008). *Discrete Thoughts: Essays on Mathematics, Science and Philosophy*. (Boston: Birkhauser), pp. 21-22.

misery? It appears to have deontological roots.[37] The two approaches are intertwined to a degree.

A heuristic approach here does not imply a mixing of deontology and consequentialism at the whim of the ethicists concerned. Rather, it suggests analysing the arguments, using both approaches in a very complete way, and attempting to reach a best possible conclusion based on their combination. This approach leads to a concrete, plausible answer in the case of synbio.

HOW DEEPLY SHOULD THE ETHICAL ANALYSIS ENGAGE WITH THE SCIENCE?

I have also suggested that the current approach of evaluating synbio in overview is inadequate, regardless of what ethical theory is used (Chapter 8). Although science has greatly improved the human condition, on balance, it has also unleashed occasional horrors. Ethically uncontentious research can be applied further down the line to create things that are highly contentious; this needs to be recognised, and a very deep ethical evaluation of all aspects of synbio undertaken, on an ongoing basis. This is not the norm when evaluating scientific research, but synbio's challenges require a new approach.

[37] James H. Moor has attempted to unite the two. See James H. Moor (1999). "Just Consequentialism and Computing." *Ethics of Information Technology,* 1: 265-9. I will not examine this issue any further – it is worthy of a Ph.D. thesis in itself.

A FURTHER LIMITATION ON BIOETHICAL ANALYSIS: THE TWO CULTURES

C.P. Snow, a Cambridge University physicist and successful novelist, has written of the *two cultures*, those of the arts and sciences. He was proficient at both and, as such, mixed in circles where many people were highly proficient in one or the other, but rarely both. He wrote:

> There have been plenty of days when I have spent the working hours with scientists and then gone off at night with some literary colleagues… It was through living among these groups… through moving regularly from one to the other and back again that I got occupied with the problem of what, long before I put it on paper, I christened the 'two cultures.' For constantly I felt I was moving among two groups – comparable in intelligence, identical in race, not grossly different in social origin, earning about the same incomes, who had almost ceased to communicate at all, who in intellectual, moral and psychological climate had so little in common that instead of going from Burlington House or South Kensington to Chelsea, one might have crossed an ocean.
>
> In fact, one had travelled much further than across an ocean – because after a few thousand Atlantic miles, one found Greenwich Village talking precisely the same language as Chelsea, and both having as much communication with M.I.T. as though the scientists spoke nothing but Tibetan… by and large, this is a problem of the entire West.
>
> I believe the intellectual life of the whole of Western society is increasingly being split into two polar groups… Literary intellectuals at one pole – at the other, scientists… Between the two a gulf of mutual incomprehension – sometimes… hostility and dislike, but most of all lack of understanding.[38]

The views on philosophy held by the Nobel laureate in physics, Richard Feynman, provide a cogent example of this phenomenon:

> There's a tendency to pomposity in all this, to make it all deep and profound. My son is taking a course in philosophy, and last night we were looking at something by Spinoza and there was the most childish reasoning! There were all these attributes, and Substances, and all this meaningless chewing around, and we started to laugh. Now how could we do that? Here's this great Dutch philosopher, and we're laughing at him. It's because there's no excuse for it! In the same period there was Newton, there was Harvey studying the circulation of the blood, there were people with methods of analysis by which progress was being made! You can take every one of Spinoza's

[38] C.P. Snow (1959). *The Two Cultures*. (Cambridge: Cambridge University Press), p. 1

> propositions, and take the contrary propositions, and look at the world and you can't tell which is right.[39]

He has also written that: "philosophy of science is about as useful to scientists as ornithology is to birds."[40] Some words of Stephen Hawking also illustrate this: "…philosophy is dead. Philosophy has not kept up with modern developments in science… Scientists have become bearers of the torch of discovery in our quest for knowledge."[41] Journalist Bryan Appleyard described an interview with him: "in my presence he was contemptuously anti-philosophical."[42]

I have experienced the two cultures in my life. Many of my scientist colleagues were contemptuous of the humanities, proud of their lack of engagement with the liberal arts; such views were fairly standard. My experience of the general disinterest of ethicists in what may be the greatest scientific advance in human history have brought this divide into a very sharp focus. It is a divide that has to be bridged, somehow, so that the science of synthetic biology may be properly guided ethically.[43]

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[39] Richard Feynman (1999) *The Pleasure of Finding Things Out*. (New York: Basic Books), p. 195.
[40] Massimo Pigliucci (2010). "The Future of Philosophy of Science." *Science 2.0*, April 26th. http://www.science20.com/rationally_speaking/future_philosophy_science Accessed December 25th 2012.
[41] Stephen Hawking and Leonard Mlodinov (2010). *The Grand Design*. (New York: Bantam Books), p. 5.
[42] Bryan Appleyard (2012). "The God Wars." *New Statesman*, 28th February. http://www.newstatesman.com/religion/2012/02/neo-atheism-atheists-dawkins Accessed December 25th 2012.
[43] It can be difficult to bridge: "Two Cultures snobbery cuts in both directions. People on the science/engineering side look down on arts/humanities people as mentally weak; people on the arts/humanities side look on the science-engineering people as socially clueless dorks. I once taught a class that was supposed to address its topic in a "bridging" kind of way. I was the science/engineering teacher, and my partner was the arts/humanities teacher. Before every lecture we'd have dinner together and go over what we'd say. For the life of me, I never understand what she was talking about, and I'm pretty sure that she never understood what I was talking about. The resulting schizophrenic experience for the students was pretty jarring." *Erasmussimo*. In Chris C. Mooney (2009). "The 'Two Cultures' 50 Year Anniversary Conference." *Science Blogs*, 10th March. http://scienceblogs.com/intersection/2009/03/10/the-two-cultures-50-year-anniv/ Accessed December 28th 2012.

Some examples from my experience as a reviewer and reviewee seem highly pertinent to this discussion. First, my experience as a reviewee. My paper, *Integrating Ethics "Into the DNA" of Synthetic Biology* was rejected by a journal for reasons that surprised me. There were two reviewers, one appearing to be an ethicist, the other a scientist. The scientist, after reading my discussion on Einstein and Dolly, and how ethically neutral research could be applied in research that is unethical, dismissed it with the comment: "isn't all research ethically neutral?" Is this true? Was the atomic bomb ethically neutral? Was Mengele's "research"? Yes, if that reviewer is correct. I would beg to differ, though.

The ethicist who reviewed it surprised me as much. A major argument in my paper was that at least some ethicists need to engage deeply with the science of synthetic biology, so that ethical surprises may not be sprung upon us. I gave some scientific arguments to bolster my case. The reviewer's response: "There's too much science in this paper." But that was the whole point of the paper, to get ethicists to engage with the science.

An experience as a reviewer also amazed me. The paper in question explained the science of synbio and compared it with other sciences – laudable in itself. But it got much of the science, along with those comparisons, wrong, then based its ethical arguments on some flawed premises.

True cross-disciplinary work, that crosses the arts-science boundary, can be very difficult. (Even cross-disciplinary work within the arts or sciences can be very challenging. It can be done by some. My experience at Manchester is that those trained in pure philosophy can critique scientific ethics to a high degree of excellence. But this is not the case across the board.

I do not intend to offer a solution to the problem of the two cultures.[44] Education may help, up to a point, as may the surrounding culture, but the divide is also likely to have neurophysiological roots. I do, however, believe that synthetic biology is of such great ethical importance that this divide must not be allowed to inhibit its ethical evaluation. There are ways to reduce its effects, which I proposed in Chapter 8; for example, by integrating people who can function well in both ethics and bioscience into major synbio institutes, to guide the research on an ethical path; also, having such people work in advice centres which serve all other synbio researchers, including amateurs. Also, a requirement for scientists to ethically evaluate their work as part of the publication process would, without question, force them to keep ethical issues in their thoughts.

CONCLUSION

A brief personal reflection… When I was a student in physics, undergraduate and graduate, I read widely on the history of the subject. I read of lectures in the Cavendish lab in Cambridge at the time of the emergence of quantum theory and relativity; at the time of this great paradigm shift in physics, lecturers would speak on topics that had been published in the scientific journals of the day, sometimes discussing topics that had just been published that very morning, or within the past

[44] Though the issue has been addressed. See, for example: John Brockman (2005). *The Third Culture: Beyond the Scientific Revolution*. (New York: Simon and Schuster); Also: C.P. Snow (1963). *The Two Cultures: A Second Look*. In C.P. Snow (1963). *The Two Cultures*, 2nd edition. (Cambridge: Cambridge University Press).

few days. Scientists and young students alike lived through the excitement of an intellectual revolution. Physics in my time as a graduate student was far more mundane – the great discoveries had been made, or so it seemed; physics was in a "steady state," rather than a time of "perturbation," to use the lingo. I wished that I could have shared in the intellectual excitement of the twenties.

Then came this research project. As part of my research, I attended most of the synthetic biology conferences that took place, immersing myself in the science in as far as was possible. In doing this, I had the feeling of being privileged to share in the foundations of a possible scientific, intellectual and societal revolution, probably greater than any such revolutions that have gone before.

I'm also aware that synthetic biology may come to nothing; current scientific knowledge may not be advanced enough to carry it through; indeed it may never be. Yet we may be on the edge of an inconceivable transformation.

It is remarkable that relatively little interest is being shown in synbio by society. Surely it should be a headline subject. But then, the previous paradigm shifts probably merited little attention in their time either. Nevertheless, they changed the course of human history.

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That fuckin borin cunt starts readin a fuckin book; bad fuckin manners, then him n this Canadian burd, thir baith sortay students like, start talking aboot aw the fuckin books thuv read. It's getting oan my fuckin tits. See if it was up tae me, ah'd git ivray fuckin book n pit thum on a great big fuckin pile n burn the fuckin loat. Aw books ur fir is fir smart cunts tae show oaf aboot how much shite thuv fuckin read. Ye git aw ye fuckin need tae ken ootay the paper n fae the telly. Posin cunts. Ah'll gie thum fuckin books.

Irvine Walsh *Trainspotting*[1]

or

"*The cloak that I left at Troas with Carpus, when you come, bring with you, and the books, but especially the parchments*." - 2 Timothy 4:13
[Paul] is inspired, and yet he wants books! He has been preaching at least for thirty years, and yet he wants books! He had seen the Lord, and yet he wants books! He had had a wider experience than most men, and yet he wants books! He had been caught up into the third heaven, and had heard things which it was unlawful for a man to utter, yet he wants books! He had written the major part of the New Testament, and yet he wants books!

C.H. Spurgeon[2]

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I have come to believe that the whole world is an enigma, a harmless enigma that is made terrible by our own mad attempt to interpret it as though it had an underlying truth.

Umberto Eco

APPENDIX: PUBLISHED PAPERS

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THE PLACE OF GOD IN SYNTHETIC BIOLOGY: HOW WILL THE CATHOLIC CHURCH RESPOND?

PATRICK HEAVEY

Keywords
synthetic biology,
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ABSTRACT
Some religious believers may see synthetic biology as usurping God's creative role. The Catholic Church has yet to issue a formal teaching on the field (though it has issued some informal statements in response to Craig Venter's development of a 'synthetic' cell). In this paper I examine the likely reaction of the Catholic Magisterium to synthetic biology in its entirety. I begin by examining the Church's teaching role, from its own viewpoint, to set the necessary backround and context for the discussion that follows. I then describe the Church's attitude to science, and particularly to biotechnology. From this I derive a likely Catholic theology of synthetic biology.

The Church's teachings on scientific and biotech research show that it is likely to have a generally positive disposition to synbio, if it and its products can be acceptably safe. Proper evaluation of, and protection against, risk will be a significant factor in determining the morality of the research. If the risks can be minimized through regulation or other means, then the Church is likely to be supportive. The Church will also critique the social and legal environment in which the research is done, evaluating issues such as the patenting of scientific discoveries and of life.

> *. . . a Jewish fable . . . the prophet Jeremiah and his son one day succeeded in creating a living man through the correct combination of words and letters. On the forehead of the Golem – the man whom they themselves had formed – were the letters that had helped them to solve the riddle of creation: 'Yahweh is the truth.' The Golem tore off one of the seven letters that add up to this affirmation in Hebrew, and now the prescription proclaimed: 'God is dead.' The prophet and his son were horrified and asked the Golem what he was doing. The new man replied as follows: Now that you are able to create a man, God is dead . . .*
>
> Joseph Ratzinger/Pope Benedict XVI[1]

BACKGROUND: THE CHURCH, THE MAGISTERIUM AND SCIENCE

Introduction

A number of prominent scientists gathered at a 2007 Edge Foundation meeting, entitled *Life: What a Concept!* In the introduction to the book containing the meeting's transcript, John Brockman, the founder of the Edge Foundation, wrote excitedly of how current research may allow scientists to transform one species into another, and create new life forms.[2] He also briefly touched upon the place of religion in cutting-edge biotech research: 'We

[1] J. Ratzinger/Pope Benedict XVI. 2008. *The God of Jesus Christ: Meditations on the Triune God*. San Francisco, CA: Ignatius Press: 15–16.

[2] For description of synthetic biology, see: ETC Group. 2007. *Extreme Genetic Engineering: An Introduction to Synthetic Biology*. Ottawa, ON: ETC Group. Available at http://www.etcgroup.org/en/node/602 [Accessed 30 Nov 2010].

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are witnessing a point in which the empirical has intersected with the epistemological . . . don't even try to talk about religion: the gods are gone.'[3] A contributor to the online Synbiosafe conference wrote, in a similar vein: 'we are defining what is life from zero. This is a HUMAN CREATIONIST environment. No Gods have any relationship with this crucial moment. No myths. Just human desire.'[4]

The gods have a habit of re-appearing, however, and can be quite assertive. Religion remains a potent force in world affairs for a significant portion of the population, probably the vast majority. A debate in the UK, in 2008, showed its power in scientific matters. Parliament was debating the *Human Fertilization and Embryology Act*, which allowed for experimentation with human-animal hybrid embryos. This received relatively little media coverage until some Catholic Church leaders weighed in, in opposition. Although they were unable to prevent the Act from being passed, their intervention turned it into a big media issue.[5] Catholics are less than 10% of the population of the UK, a now mostly secular country which was largely Protestant for five centuries. Yet Catholic Church leaders were able to set the agenda for debate. Bishops in the Church of England have more power, both as societal leaders and as lawmakers in the House of Lords. Religion is a much greater force in the USA, where most synthetic biology research takes place. Therefore religious viewpoints *will* enter into debates on synthetic biology.

Up to now, there has been little religious debate on the topic because synbio has been relatively little known. That will change as it becomes more successful. Therefore it isn't possible at the moment to list the types of arguments made by religious people for or against synthetic biology. But it is possible to infer, with a reasonable degree of accuracy, what those arguments will be, based on their views on other areas of biotech research.

Various religious viewpoints exist on such research, and they can be completely contradictory. At one extreme is the view that nature is sacred. We are stewards of nature, not masters, and may not change it. To do so would be to oppose God's will, and so commit sin.[6] An advance on this viewpoint is that of some Old Calendar Orthodox Christians in the USA that I met, who think that all scientific research is sinful in itself, as it represents a wrong orientation, towards the things of the world, not the things of God.

Others have applied the story of the Tower of Babel, as described in Genesis 11:1-9, to science. Here people wished to build a great tower that would reach the heavens. God didn't want this, and confounded their plans by splitting them into different linguistic groups, thus limiting their collective efficiency. They could no longer communicate and build the tower. From this it could be argued that certain types of scientific research – those that impinge on God's creative role – are out of bounds. He has created the world – we can't try to better it.[7]

Other theologians have pointed out that we are created in the image of God – *Imago Dei.* God creates continuously. In order to fulfil our true potential as desired by Him, we should also create. This includes biological creations, which increase knowledge of nature and therefore of the mind of God. They may also help to cure disease, and enhance life in other ways. Although we are dependent on God for every breath we take, and not equal to Him, we are also, in a limited sense, co-creators with Him. We do not have His power to create *ex nihilo*; but we have been given the power and responsibility to create our own civilization and history, collectively and as individuals. (Lutheran theologian Phillip Hefner has described humans as 'created co-creators'.)[8] Therefore we have a right and a duty to use our creative powers in biotech research.[9]

The parable of the talents takes this further.[10] In Matthew 25:14-30, Jesus' parable implies that we are obliged to use our talents – not to do so is displeasing to God. From this viewpoint, now that we have the capacity to do biotech research, it is our duty to do it, to advance knowledge and benefit humanity. Pope John Paul II has made this point regarding all aspects of human progress[11]

[3] J. Brockman, ed. 2008. *Life: What a Concept!* New York: Edge Foundation: 8. Available at http://www.edge.org/documents/life/Life.pdf [Accessed 30 Nov 2010].

[4] Synbiosafe e-conference. 2008. Available at http://www.synbiosafe.eu/forum/viewtopic.php?f=3&t=42 [Accessed 17 Aug 2010].

[5] J. Petre. 2008. Chimera Embryos Have Right to Life, Say Bishops. *Daily Telegraph* 19 April. Available at http://www.telegraph.co.uk/news/uknews/1555639/Chimera-embryos-have-right-to-life,-say-bishops.html [Accessed 30/011/2010]; M. Henderson, R. Gledhill and F. Elliot, 2008. Embryology Bill: Bishop's Frankenstein Attack Smacks of Ignorance, Say Scientists. *The Times* 24 March 24. Available at http://www.timesonline.co.uk/tol/news/uk/science/article3607660.ece [Accessed 30 Nov 2010].

[6] See, for example, Naveen Chainani. 2006. *Comment on In re Fisher: EST Utility Redux*. Available at http://patentdocs.typepad.com/patent_docs/2006/10/in_re_fisher_es.html [Accessed 30 Nov 2010].

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[8] P. Hefner. 1993. *The Human Factor: Evolution, Culture and Religion*. Minneapolis, MN: Fortress Press: 23–54.

[9] T. Peters. 1997. *Playing God? Genetic Determinism and Human Freedom*. New York, NY: Routledge.

[10] Pope Benedict XVI. 2008. Parable of the Talents Shows Gifts Are Meant to be Multiplied. *L'Osservatore Romano*. 19 November.

[11] John Paul II. 1987. *Sollicitudo rei socialis.* Vatican City: Libreria Editrice Vaticana: para 30. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_30121987_sollicitudo-rei-socialis_en.html [Accessed 30 Nov 2010].

(though what he means by human progress may differ from how others define it.).

It is clear from the above that contradictory religious views on biotech research exist. Conflict exists within and between religious groups. Such groups have hugely differing world views, and cannot agree on many issues, including those in bioethics. As the above selection of arguments shows, evaluating them all, or a significant segment of them, cannot lead to one truth – a certainty that God wants, or does not want, humans to engage in synthetic biology research. It is impossible to do that – all one gets is an incoherent babble of contradictory viewpoints, each of which claims to be expressing God's will. But it doesn't follow that religious viewpoints can be ignored.

Religious beliefs could have a significant influence on the environment in which scientific research is done. For example, the evolution vs. creationist debate in the USA causes considerable upset; many teachers and members of the scientific community feel under attack, as do their fundamentalist opponents.[12] The debate has affected policy. In the 1960s, six USA states banned the teaching of evolution, and it was not mentioned in most American high school biology textbooks. Only the threat of Soviet dominance in science led to its reinstatement.[13] This debate also exists in Europe, albeit to a lesser degree. In 2004, the Italian government attempted to remove the teaching of evolution from the early secondary school curriculum.[14] A former deputy education minister of Poland, Miroslaw Orzechowski, told a newspaper in 2007 that 'the theory of evolution is a lie. It is an error we have legalized as a common truth.'[15] Synthetic biologist David Deamer said at a conference that he is frequently contacted by religious fundamentalists who tell him that what he is doing is wrong.[16]

Thus religious attitudes to synthetic biology could have an impact on the research. These attitudes could affect policy, funding, and public opinion. It would be useful, therefore, to examine possible theological attitudes towards synthetic biology.

Why analyse the Catholic viewpoint?

Although some papers have been published which discuss the religious significance of synthetic biology in general terms,[17] ultimately formal teachings will be developed by various denominations. I am focussing here on the likely Catholic view, because it is the world's largest religion.[18] In addition, the Catholic Church has a sophisticated approach in terms of developing theologies of bioethics and other areas of morality – their documents are generally produced by teams of skilled people, frequently at the professorial level. They produce far more official teachings on bioethics (and most other issues) than any other religion. They usually take a sophisticated philosophical approach (exceptions exist). Their views are influential, even on those who disagree with and react against them.

Some background – the Catholic Magisterium

Before I evaluate the Catholic Church's likely response to synthetic biology, I will first explain the Church's role in teaching morality, according to its own self-understanding. The Church regards itself as the Mystical Body of Christ, representing God on Earth. It does not claim perfection, as it is composed of sinful and error-prone human beings. Nevertheless it has a duty to guide its members – and any interested parties – on a correct moral path, one in which people will be in correct relationship with God, his creation and each other. Canon 747,[19] from the Church's *Code of Canon Law*, states that the Church has a right and an obligation to teach moral truth.

The Church's function requires it to teach, and teaching is carried out by the *Magisterium* – the Church in its teaching role. The word comes from the Latin word *magister* – master – as in master of a trade, a ship, a school, etc. *Magisterium* refers to the authority of one who was master by virtue of their position. The phrase now refers to the authoritative teaching role of the Church hierarchy. Only those formally authorized to teach may do so in the Church's name – normally the Pope and bishops.[20] Others that can teach, albeit with less authority, include various Church bodies – such as the Congregation for the Doctrine of the Faith (CDF), which is the Church's doctrinal teaching and enforcement body; and also theologians

[12] M.B. Berkman, J.S. Pacheo & E. Plutzer. Evolution and Creationism in America's Classroms: A National Portrait. *PLoS Biol* 2008; 6.
[13] V. Leigh Interview with Steve Jones: The Threat of Creationism. *Science in School* 2008; 9: 9–17.
[14] Ibid. 11; DW Staff. 2004. Italy Keeps Darwin in its Classrooms. *Deutsche Welle* 3 May. Available at http://www.dw-world.de/dw/article/0,2144,1188423,00.html [Accessed 30 Nov 2010].
[15] Leigh, *op. cit*. note 13.
[16] D. Deamer. 2008. Systems and Synthetic Biology: Scientific and Social Implications. *9th EMBO/EMBL Joint Conference on Science and Society, Heidelberg*, 7–8 November.
[17] For example, H. van den Belt. Playing God in Frankenstein's Footsteps: Synthetic Biology and the Meaning of Life. *Nanoethics* 2009; 3: 257–268; and P. Dabrock. Playing God? Synthetic Biology as a Theological and Ethical Challenge. *Syst Synth Biol* 2009; 3: 47–54.
[18] According to the *Annuario Pontifico* (Pontifical Yearbook) 2010, there were 1.66 billion baptised Catholics in the world in 2008, representing 17.4% of the world's population. Zenit.org. 2010. Number of Catholics Increases Worldwide: 2010 'Annuario' shows Growth in Asia and Africa. Available at http://www.zenit.org/article-28425?l=english [Accessed 30 Nov 2010].
[19] Code of Canon Law. 1983. Vatican City: Libreria Editrice Vaticana: C.747.1 and 747.2 Available at http://www.vatican.va/archive/ENG1104/__P2H.HTM [Accessed 30 Nov 2010].
[20] F.A. Sullivan. 2003. *Creative Fidelity: Weighing and Interpreting Documents of the Magisterium*. Eugene, OR: Wipf and Stock.

(both lay people and clerics).[21] The Magisterium's purpose is to illuminate the world with the truths of divine revelation, including the truth regarding moral action.[22]

How should one respond to magisterial teachings? For a non-Catholic, the Magisterium is simply another voice in the arena of debate. It has to argue its case, and its arguments should be evaluated on their merits. For a Catholic, the Magisterium has religious authority.[23] Existing in tension with the religious authority of the Magisterium is the primacy of conscience.[24] A famous statement of Cardinal Newman describes its role in guiding decision-making: 'I shall drink . . . to Conscience first, and to the Pope afterwards.'[25] The role of the Magisterium is to inform conscience.[26] Ultimately conscience binds – to act against it is to sin.[27] But there is a duty for a Catholic (and everyone) to inform their conscience – which, for Catholics, means paying attention to Church teachings. As for the tension between conscience and the duty of response to the Magisterium: where should the line be drawn? Pope Benedict XVI (as Cardinal Ratzinger) asked: can we expect to see the Nazis in Heaven – they thought they were right? He thinks that's unlikely (while admitting that we cannot know with certainty).[28] An objective morality exists.[29] Where the line should be drawn, though, is much debated by moral theologians.

Non-overlapping Magisteria?[30] The Magisterium and science

For many people, the Galileo affair sums up the relationship between the Church and science. But it is not the whole story, nor is it particularly representative. In the Church's billion-plus members, similar attitudes to science are displayed as in the general population – ranging from the indifferent or hostile, to those who work as scientists. Scientific investigation is not a central part of the Church's mission, and it does not claim scientific expertise. Nevertheless, the Magisterium will comment on applications of science when they have moral implications, and it has commented on biotechnology.

It has also commented on science itself. Some quotes from various Popes give a flavour of its attitude. Pope Pius XII described 'science, philosophy and revelation' as 'instruments of truth, like rays of the same sun.'[31] According to Benedict XVI, 'the laws of nature . . . are a great

[21] R.P. McBrien. 2008. *The Church: The Evolution of Catholicism*. New York, NY: Harper One: 291–292.

[22] The Church's 'ethical method' is based on the theory that a natural law exists, written by God in every human heart, allowing each person (of all religions and none) to tell right from wrong. But not everyone has the ability to perceive natural law to the same degree; hence the Church is required to teach. Reason and experience are the Church's primary tools for evaluating moral issues, for determining the natural law. Scripture is also a source, and it must, in the Catholic viewpoint, be interpreted in the light of reason and experience; the cultural context in which Scripture was written is also taken into account when interpreting it. See *Catechism of the Catholic Church* 416 and 1950–1986; International Theological Commission. 2004. *Communion and Stewardship: Human Persons Created in the Image of God*. Vatican City: Liberia Editrice Vaticana: para 60; and Pontifical Biblical Commission. 1993. *The Interpretation of the Bible in the Church*. Vatican City: Libreria Editrice Vaticana.

[23] However, not all of its teachings require the same response. There are hierarchies of truth, with different levels of response required for each. Catholics should be open to magisterial teaching; unquestioning obedience is not expected. The openness requires that Catholics should take Church teachings seriously and try to convince themselves of their truth. According to theologian Fr. Francis Sullivan, formerly dean at the Vatican's Pontifical Gregorian University: 'If my effort to achieve assent has been proportionate to the degree of authority that has been exercised, then I have fulfilled my obligation of *obsequium* [respect] toward the magisterium, even though I have not been able to bring myself to agree with some particular point in its teaching.' See Sullivan, *op. cit.* note 20, p. 5.

[24] According to Vatican II's pastoral constitution on the Church in the modern world, *Gaudium et Spes* ('Joys and Hopes'): 'In the depths of his conscience, man detects a law which he does not impose upon himself, but which holds him to obedience. Always summoning him to love good and avoid evil, the voice of conscience when necessary speaks to his heart: do this, shun that. For man has in his heart a law written by God; to obey it is the very dignity of man; according to it he will be judged. Conscience is the most secret core and sanctuary of a man. There he is alone with God, Whose voice echoes in his depths. In a wonderful manner conscience reveals that law which is fulfilled by love of God and neighbour. In fidelity to conscience, Christians are joined with the rest of men in the search for truth, and for the genuine solution to the numerous problems which arise in the life of individuals from social relationships. Hence the more right conscience holds sway, the more persons and groups turn aside from blind choice and strive to be guided by the objective norms of morality. Conscience frequently errs from invincible ignorance without losing its dignity. The same cannot be said for a man who cares but little for truth and goodness, or for a conscience which by degrees grows practically sightless as a result of habitual sin.' Vatican II. 1965. *Gaudium et Spes*. Vatican City: Libereia Editrice Vaticana: para 16. Available at http://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_cons_19651207_gaudium-et-spes_en.html [Accessed 1 Dec 2010].

[25] J. Ratzinger/Pope Benedict XVI. 2007. *On Conscience.* San Francisco: Ignatius Press: 23.

[26] Pope John Paul II. 1993. *Veritatis Splendor.* Vatican City: Libreria Editrice Vaticana: para 64. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_06081993_veritatis-splendor_en.html [Accessed 30 Nov 2010].

[27] Ibid.

[28] Ratzinger/Pope Benedict XVI, *op. cit*. note 25.

[29] For a more complete discussion, see John Paul II, *op. cit*. note 26, particularly chapter II, section II (conscience and truth); Vatican II, *op. cit.* note 24; J. Ratzinger/Pope Benedict XVI, *op. cit*. note 25; R.M. Gula, 1989. *Reason Informed by Faith: Foundations of Catholic Morality*. Mahwah, NJ: Paulist Press: 123–162.

[30] Palaeontologist and evolutionary biologist Stephen Jay Gould wrote that science and religion occupy two different spheres of enquiry, which do not overlap. S.J. Gould Nonoverlapping Magisteria. *Nat Hist* 1997; 106: 16–22; and S.J. Gould, 1999. *Rocks of Ages: Science and Religion in the Fullness of Life*. New York: Ballantine Book.

[31] Pope Pius XII. 1952. The Proofs for the Existence of God in the Light of Modern Science. *Address to the Pontifical Academy of Sciences*. 22 November. Available at http://www.papalencyclicals.net/Pius12/P12EXIST.HTM [Accessed 30 Nov 2010].

incentive to contemplate the works of the Lord with gratitude.'[32] John Paul II wrote: 'Science can purify religion from error and superstition; religion can purify science from idolatry and false absolutes. Each can draw the other into a wider world, a world in which both can flourish.'[33] And in the same letter, he wrote

> Is the community of world religions, including the Church, ready to enter into a more thorough-going dialogue with the scientific community, a dialogue in which the integrity of both religion and science is supported and the advance of each is fostered? Is the scientific community now prepared to open itself to Christianity, and indeed to all the great world religions, working with us all to build a culture that is more humane and in that way more divine? . . . We must ask ourselves whether both science and religion will contribute to the integration of human culture or to its fragmentation . . . A divided community fosters a fragmented vision of the world; a community of interchange encourages its members to expand their partial perspectives and form a new unified vision . . . Yet the unity that we seek, as we have already stressed, is not identity. The Church does not propose that science should become religion or religion science. On the contrary, unity always presupposes the diversity and the integrity of its elements.[34]

The current Pope, the then Joseph Ratzinger, has written that good theology is dependent on scientific thinking:

> [a] theology of prohibitions . . . would have resulted not in the rescue of the faith but of dooming it to sterility, by separating theology once and for all from modern science and confining it in an ivory tower where it would have gradually withered away . . . this kind of defense would suffocate the faith from within by cutting off its air supply – i.e., the possibility of faith proving itself in terms suited to modern scientific thinking.[35]

Catholic support for science goes beyond words. Catholic universities generally have science faculties. Their primary and secondary schools teach science. Also, located in the heart of the Vatican City is the Pontifical Academy of Sciences.[36] Initially founded in 1603, it aims to advance science and to discuss ethics, including bioethics. Religious affiliation (or lack of it) is not a factor in election to membership, only scientific prestige, and morality. New academicians are elected by current members of the Academy and appointed by the Pope.[37] Non-Catholic members include Stephen Hawking and Francis Collins.[38] The Vatican also operates an astronomical observatory, one of the world's oldest. It has branches at the Pope's summer residence in Castel Gandolfo, near Rome, and in Tucson, Arizona.[39] The father of the big bang theory, Georges Lemaitre, was a Catholic priest.[40]

For the Church, then, there is no conflict between science and religion. On the contrary, it sees them as

[32] Pope Benedict XVI. 2008. *Angelus, St. Peter's Square, Fourth Sunday of Advent*. 21 December. Available at http://www.vatican.va/holy_father/benedict_xvi/angelus/2008/documents/hf_ben-xvi_ang_20081221_en.html [Accessed 30 Nov 2010].

[33] Pope John Paul II. 1988. *Letter of His Holiness John Paul II to Reverend George V. Coyne, S.J. Director of the Vatican Observatory*. Vatican City: Libreria Editrice Vaticana. Available at http://www.vatican.va/holy_father/john_paul_ii/letters/1988/documents/hf_jp-ii_let_19880601_padre-coyne_en.html [Accessed 30 Nov 2010].

[34] Ibid; For John Paul II, the relationship between religion and science was a part of a broader relationship between faith and reason. In his encyclical on their relationship, *Fides et Ratio* ('Faith and Reason'), he wrote: '. . . a cursory glance at ancient history shows clearly how in different parts of the world, with their different cultures, there arise at the same time the fundamental questions which pervade human life: *Who am I? Where have I come from and where am I going? Why is there evil? What is there after this life?* These are the questions which we find in the sacred writings of Israel, as also in the Veda and the Avesta; we find them in the writings of Confucius and Lao-Tze, and in the preaching of Tirthankara and Buddha; they appear in the poetry of Homer and in the tragedies of Euripides and Sophocles, as they do in the philosophical writings of Plato and Aristotle. They are questions which have their common source in the quest for meaning which has always compelled the human heart. In fact, the answer given to these questions decides the direction which people seek to give to their lives.' Pope John Paul II. 1998. *Fides et Ratio*. Vatican City: Libreria Editrice Vaticana: para 1. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_15101998_fides-et-ratio_en.html [Accessed 30/11/2010]). In attempting to answer such questions, he observed that 'Faith and reason are like two wings on which the human spirit rises to the contemplation of truth.' (Ibid.) For John Paul, the relationship between science and religion was summed up by: 'truth cannot contradict truth.' (Pope John Paul II. 1996. Truth Cannot Contradict Truth. *Address to the Pontifical Academy of Sciences* 22 October. Available at http://www.newadvent.org/library/docs_jp02tc.htm [Accessed 30 Nov 2010]).

[35] J. Ratzinger. 1966 *Theological Highlights of Vatican II*. New York, NY: Paulist Press, 1966: 149.

[36] Pontifical Academy of Sciences website http://www.vatican.va/roman_curia/pontifical_academies/acdscien/ [Accessed 30 Nov 2010].

[37] Bishop-Chancellor M. Sanchez Sorondo, 2003. *The Pontifical Academy of Sciences: A Historical Profile*. Vatican City: Pontifical Academy of Sciences. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdscien/400_ann/storia_en_qxd.pdf [Accessed 30 Nov 2010].

[38] Pontifical Academy of Sciences, 2010. *List of Academicians*. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdscien/own/documents/rc_pa_acdscien_doc_20020103_academicians_en.html [Accessed 30 Nov 2010].

[39] Vatican Observatory website: http://vaticanobservatory.org/ [Accessed 30 Nov 2010]; G. Johnson. 2009. Vatican's Celestial Eye, Seeking not Angels but Data. *New York Times* 22 June. Available at http://www.nytimes.com/2009/06/23/science/23Vatican.html?_r=1&scp=1&sq=vatican%20observatory%20arizona&st=cse [Accessed 30 Nov 2010]; G. Consolmagno SJ, ed. 2009. *The Heavens Proclaim: Astronomy and the Vatican*. Vatican City: Vatican Observatory Publications & Huntington, IN: Our Sunday Visitor.

[40] S. Singh. 2004 *Big Bang*. New York, NY: HarperCollins:156–161.

investigating different aspects of the same truth. The Church supports science. But it also subjects it to moral evaluation. In the words of the *Catechism of the Catholic Church* (a *precise* of the Church's faith): 'methodical research in all branches of knowledge, provided it is carried out in a truly scientific manner and does not override moral laws, can never conflict with the faith;'[41] and 'science and technology, by their very nature, require unconditional respect for fundamental moral criteria.'[42] It condemns some applications of science, for example nuclear weapons.[43]

Even so, the question could be asked, regarding certain cutting-edge scientific research, including synthetic biology: could religious limitations exist on permissible knowledge? Should humanity only seek so far, and no farther? The Church rejects such a viewpoint. In the words of the Pontifical Academy for Life:

> In principle . . . there are no ethical limits to the knowledge of the truth, that is, there are no 'barriers' beyond which the human person is forbidden to apply his cognitive energy: the Holy Father has wisely defined the human being as 'the one who seeks the truth' . . . but, on the other hand, precise ethical limits are set out for the manner the human being in search of the truth should act, since 'what is technically possible is not for that very reason morally admissible.'[44]

THE CHURCH, BIOTECHNOLOGY AND SYNTHETIC BIOLOGY

The Church and Biotechnology

The Church has issued several teachings on biotech research. The *Compendium of the Social Doctrine of the Church* is a document of the Magisterium that is concerned primarily with economic and social justice. It also has a section on the environment, which includes a subsection on biotechnology. That section's introductory paragraph sets out the Church's essential attitude to biotech; it is also likely to be a starting point for any teachings on synthetic biology:

> *The Christian vision of creation makes a positive judgment on the acceptability of human intervention in nature, which also includes other living beings, and at the same time makes a strong appeal for responsibility*. In effect, nature is not a sacred or divine reality that man must leave alone. Rather, it is a gift offered by the Creator to the human community, entrusted to the intelligence and moral responsibility of men and women. For this reason the human person does not commit an illicit act when, out of respect for the order, beauty and usefulness of individual living beings and their function in the ecosystem, he intervenes by modifying some of their characteristics or properties. Human interventions that damage living beings or the natural environment deserve condemnation, while those that improve them are praiseworthy. *The acceptability of the use of biological and biogenetic techniques is only one part of the ethical problem*: as with every human behaviour, it is also necessary to evaluate accurately the real benefits as well as the possible consequences in terms of risks. In the realm of technological-scientific interventions that have forceful and widespread impact on living organisms, with the possibility of significant long-term repercussions, it is unacceptable to act lightly or irresponsibly[45] (italics in original).

The *Compendium* develops a desired theology of biotechnology, and sets out the responsibilities of various actors in the field. Regarding commercialization, it states that commercial exchanges should be just. For disadvantaged countries, such exchanges should go beyond the mere exchange of products, and should promote the development of the scientific and technological base of such states, with free exchange of information, allowing them to become scientifically autonomous. A spirit of solidarity should prevail.[46] The responsibility for such development does not lie with the wealthier nations alone; the leaders of less developed countries also have a responsibility to invest in technological development in a way that benefits their people and the common good. The characteristics of each country should be taken into account in developing such policies. Those nations also have a responsibility to promote trade policies based on justice.[47]

The *Compendium* observes that biotech scientists and technicians should take account of the need for an

[41] *Catechism of the Catholic Church*. Vatican City: Libreria Editrice Vaticana: para 159. Available at http://www.vatican.va/archive/ENG0015/__PX.HTM [Accessed 30 Nov 2010].
[42] Ibid: para 2294.
[43] D. Roche. 2005. Nuclear Weapons and Morality: An Unequivocal Position. *Address to U.S. Catholic Bishops Panel, Ethics, Policy and the Proliferation of WMD*. Washington, DC. 11 November. Available at http://www.gsinstitute.org/mpi/docs/Roche_CatholicBishops NuclearWeapons.pdf [Accessed 30 Nov 2010].
[44] Pontifical Academy for Life, 2003. *Concluding Communiqué on 'the Ethics of Biomedical Research for a Christian Vision,'* 24–26 February. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-acd_life_doc_20030226_ix-gen-assembly-final_en.html [Accessed 30 Nov 2010].
[45] Pontifical Council for Justice and Peace. 2004. *Compendium of the Social Doctrine of the Church.* Vatican City: Libreria Editrice Vaticana: para 473. Available at http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html [Accessed 30 Nov 2010].
[46] Ibid.
[47] Ibid.

adequate food supply and good health care throughout the world. Biological material is part of the patrimony of the human race, belonging to the current generation and to future ones; it is a gift from God. Human intelligence and freedom are also gifts, and they should be used well, with enthusiasm and a good conscience, in research.[48]

Entrepreneurs are permitted to make legitimate profit, but should balance this with the common good. While this is true in all economic life, it is especially important when products are connected with food, healthcare and the ecosystem. These technologies can, and should, be used towards very good ends – curing disease, minimizing hunger, and protecting the environment. Such concerns should also be born in mind by those who lead relevant public agencies.[49]

The *Compendium* states that politicians and those involved in legislation and administration, at national and international levels, should evaluate the benefits and risks involved in biotech. Their decisions should benefit the common good, and they should not be swayed by pressure groups. They should also ensure that public opinion is properly informed.[50] Journalists, editors and others involved in providing information have a duty to ensure that such information is truthful. It should not be superficial; nor should it be an over-enthusiastic promotion of such technologies, nor an alarmist rejection of them. The information provided should allow its consumers to form properly informed opinions on the issues.[51]

Other statements about biotechnology have been made by senior Church figures. Regarding genetic engineering, John Paul II said: 'Now there is generally talk of 'genetic engineering' to refer to the extraordinary possibilities that science offers today to intervene in the very sources of life. All genuine progress in this field cannot but be encouraged, on the condition that it always respects the rights and dignity of the human person from conception.'[52] With respect to the genetic modification of crops, the dean of the School of Bioethics at the Vatican's Regina Apostolorum University in Rome – the main bioethics programme among the pontifical universities – has stated that the use of GM crops may be a moral duty, and that blocking them may be a serious injustice.[53] (A statement by such a Church figure is not a teaching of the Magisterium, but it may indicate what future Magisterial teachings will be.)

Playing God? The Church and Synthetic Biology

When Craig Venter released his Synthia bacterium in May 2010,[54] spokesmen for the Church responded promptly. Monsignor Rino Fisichella, head of the Pontifical Academy for Life, described it as 'a great scientific discovery.'[55] But as for its ethical importance, he stated: 'If we ascertain that it is for the good of all, of the environment and man in it, we'll keep the same judgment . . . If, on the other hand, the use of this discovery should turn against the dignity of and respect for human life, then our judgment would change.'[56] Cardinal Angelo Bagnasco, head of the Italian Bishops' Conference, said the discovery was 'further sign of intelligence, God's gift to understand creation and be able to better govern it . . . On the other hand, intelligence can never be without responsibility . . . Any form of intelligence and any scientific acquisition . . . must always be measured against the ethical dimension, which has at its heart the true dignity of every person.'[57] Bishop Domenico Mogavero, head of the law department of the Italian Bishops' Conference, sounded a note of caution, noting that: 'Pretending to be God and parroting his power of creation is an enormous risk that can plunge men into a barbarity . . . [Scientists] should never forget that there is only one creator: God. In the wrong hands, today's development can lead tomorrow to a devastating leap in the dark.'[58] The official Vatican newspaper, *L'Osservatore Romano*, observed that such research should combine 'courage with caution.'[59]

Venter's work does not present any ethical or theological problems for the Church in and of itself; but it would do so if used negatively. Venter's elegant work, though, is not synthetic biology in the truest sense – it did not created a novel life-form. It was 'merely' a highly sophisticated piece of genetic engineering. So it is pertinent to ask: how will the Church respond as the field advances? Synthetic biology promises to go far beyond Venter's initial work, and may ultimately include, among other things, the successful creation of new life-forms by

[48] Ibid.
[49] Ibid.
[50] Ibid.
[51] Ibid.
[52] Pope John Paul II. 2003. Genetic Engineering Must be Guided by Respect for Life, Insists Pope: Says Church Supports Research Governed by Ethics. *Message for World Day of the Sick* 11 February. Available at http://www.zenit.org/article-8867?l=english [Accessed 30 Nov 2010].
[53] Fr. G. Mirando. 2003. Using Genetically Modified Organisms could be a Duty, says Bioethicist. *Address to the Pontifical Council for Justice and Peace Symposium 'Genetically Modified Organisms and the Social Doctrine of the Church'*. Available at Zenit.org. http://www.zenit.org/article-8752?l=english [Accessed 30 Nov 2010].

[54] D.G. Gibson et al. Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome. *Science* 2010; 329: 52– 56.
[55] A. Rizzo. 2010. Vatican: Scientists Shouldn't Play God: But Church Officials Say Synthetic Cell Could Have Benefits. *Associated Press* 21 May. Available at http://www.msnbc.msn.com/id/37285047/ns/technology_and_science-science [Accessed 30 Nov 2010].
[56] Ibid.
[57] Ibid.
[58] Ibid.
[59] Ibid.

designing DNA, the building of artificial cells, the re-engineering of cellular metabolisms, and an interface between machines and living things.[60]

Thus it is likely to produce extra ethical and theological issues. Some writers have suggested that synbio is a new paradigm,[61] going beyond the most advanced genetic engineering. Because it may enable the creation of new life out of inanimate materials,[62] it may thus impinge directly on God's creative role in a way that has never been done before. Henk van den Belt has questioned whether it is 'playing God and following Frankenstein.'[63] It is possible to derive a probable Catholic theology of synthetic biology's main issues from its previous teachings on science and biotechnology.

CAN SYNTHETIC BIOLOGY BE RIGHT IN ITSELF?

As mentioned, the Church strongly supports biotech research, when it is carried out morally with proper evaluation of (and protection against) risks. It is likely that all the *Compendium's* theology of biotech will apply to synthetic biology.

Regarding the issue of creating organic entities synthetically; the Church was cautiously welcoming of Venter's work. Also, synthesis of organic entities has existed long before synthetic biology, and this has not troubled the Church.[64] Synthetic biology takes this to a new level, to living organisms, but is it different in essence? Logically, perhaps not – it's just another technique that is used to modify life. Venter's creation of an 'artificial' cell placed a synthetically-made genome into a living cell, thereby transforming it into a different type of cell; but this relied on a pre-existing cell for its existence, as well as copying pre-existing DNA.[65] *Semi-synthetic biology* may be a better, if less poetic, name for the field. It is a long way from God's creation *ex nihilo*. It is barely comparable, simply changing (albeit in a sophisticated way) what already exists.

Yet many people may be intuitively troubled by the idea of synthetic, or semi-synthetic, life being created. The ETC Group (Canadian environmental activists) have given the heading *Original Syn?* to the introduction to their report on the field.[66] Bioethicist Nigel Cameron has noted that: 'There were clearly no branding consultants present at the naming of synthetic biology 'synbio,' or the homonym would never have been allowed. In religious America, 'SinBio' might just catch on as the label 'Frankenfood' has in gourmet Europe . . .'[67]

Such concerns are likely to exist for every aspect of synbio research, but may be especially pronounced for research into modifying DNA, the blueprint of life. Nelkin and Lindee have observed that 'For some, genes have soul-like, mystical properties, expressed in words and images that use the double helix itself as a religious symbol.'[68] When Bill Clinton announced the (near) completion of the human genome project, he said: 'Today we are learning the language in which God created life. We are gaining ever more awe for . . . the wonder of God's most divine and sacred gift.'[69] Bioethicist Alex Mauron asked whether the genome could be regarded as the secular equivalent of the soul. He concluded that it could not – we are more than our DNA.[70] But the fact that such language is being used illustrates the role DNA plays in the consciousness of many people. Clearly, to engineer DNA may be a transgression for some, the crossing of a barrier that should not be crossed. This taboo may be even greater when it comes to human DNA.

How will the Catholic Church react? Could it extend its approval of modifying nature[71] to an explicit approval of engineering DNA, or creating novel DNA which does not exist in nature? If it approves the engineering of DNA, it is likely to approve other areas of synbio research, such as metabolic engineering and the creation of artificial cells, which appear, on the surface, to be less ethically contentious.

The Church has already issued teachings on the modification of human DNA. Essentially, three things form a human being: nature (DNA), environment and free will (all elements of the person being created, of course, by God). The Catholic Church (along with most religions) works hard to influence the latter two. It attempts to enhance people's environment, operating institutions such as schools, universities, hospitals and homeless shelters. It also tries to influence the exercise of free will, via its teachings, so that people facing difficult moral

[60] ETC Group, *op.cit*. note 2.

[61] T. Potthast. Paradigm Shifts Versus Fashion Shifts?: Systems and Synthetic Biology as New Epistemic Entities in Understanding and Making 'Life.' *EMBO Rep* 2009; 10 S1: 542–545; Dabrock, *op. cit*. note 17.

[62] Potthast, *op. cit*. note 61.

[63] van den Belt, *op. cit*. note 17, p. 259.

[64] For example, Friedrich Wohler successfully synthesized urea in 1828, from inanimate chemicals, and artificial DNA synthesis began as soon as its structure was became known. See E. Wimmer et al. Synthetic Viruses: A New Opportunity to Understand and Prevent Viral Disease. *Nat Biotechnol* 2009; 27: 1163–1172.

[65] D.G. Gibson et al., *op. cit*. note 54.

[66] ETC Group, *op.cit*. note 2.

[67] N.M. de S. Cameron & A. Caplan. Our Synthetic Future. *Nat Biotechnol* 2009; 27: 1103–1105: 1104.

[68] D. Nelkin & M.S. Lindee. 2004. *The DNA Mystique: The Gene as a Cultural Icon*. Ann Arbor, MI: University of Michigan Press: xix.

[69] Ibid.

[70] A. Mauron. Is the Genome the Secular Equivalent of the Soul? *Science* 2001; 291: 831–832.

[71] Pontifical Council for Justice and Peace, *op. cit.* note 45, para 473.

choices will have information which will help them make correct decisions. Does it follow from this that humans have a right, or even a duty, to modify DNA in order to improve human life? The answer appears to be yes. The Joint Committee on Bioethical Issues of the Catholic Bishops of England and Wales produced a document in 1996, entitled *Genetic Intervention on Human Subjects.* In their evaluation of this issue, they stated that the 'genome is simply one highly influential part of our bodies;'[72] and 'the genome may *in principle* be altered, to cure some defect of the body.'[73] The bishops could 'imagine situations in which to choose this type of treatment would be, not simply a *right* of the person choosing, but morally required'[74] (their italics).

Pope John Paul II has stated: 'A strictly therapeutic intervention whose explicit objective is the healing of various maladies such as those stemming from chromosomal defects will, in principle, be considered desirable, provided it is directed to the personal well-being of the individual.'[75] Speaking on scientific progress to an audience of doctors, John Paul noted that: 'to you surgeons, specialists in laboratory work, and to you, general practitioners, belongs the task of cooperating with all the forces of your intelligence in the work of creation begun on the first day of the world'[76] – the co-creator (or 'created co-creator') doctrine.

Note that the above statements approve human genetic modification for therapeutic purposes. The methods used, whether those of classical genetics, or more advanced synbio engineering techniques, are unlikely to be an issue, as long as life is respected and the risks are acceptable.

The *Compendium* warns, though, that human pride and selfishness are always a danger in human activity, even activity that aims to 'tend . . . and transform . . .' the universe;[77] they are a cause of 'asocial . . . impulses'[78] and may lead to negative consequences unless subdued.[79]

[72] Joint Committee on Bioethical Issues of the Catholic Bishops. 1996. *Genetic Intervention on Human Subjects*. London: Linacre Centre:.33. Quoted in T.A. Shannon, 2008. The Roman Catholic Magisterium and Genetic Research. In *Design and Destiny: Jewish and Christian Perspectives on Human Germline Modification*. R. Cole-Turner, ed. Cambridge, MA: MIT Press: 51–72: 63.
[73] Ibid: 64
[74] Ibid.
[75] Pope John Paul II. 1983. The Dangers of Genetic Manipulation. *Address to the World Medical Association, Vienna* 29 October. Available at http://www.ewtn.com/library/PAPALDOC/JP2GENMP.HTM [Accessed 30 Nov 2010].
[76] Ibid.
[77] Pontifical Council for Justice and Peace, *op. cit.* note 45, para 44.
[78] Ibid: para 150.
[79] Ibid: para 581.

SYNTHETIC BIOLOGY AND HUMAN ENHANCEMENT

Could the Church approve synthetic biology being for non-therapuetic modification – perhaps as a foundational technology to create an enhanced human being, a 'post-human'? Such a scenario appears far away, but it may arise in time, and synthetic biology may be a foundational technology. The Church draws a sharp distinction between therapeutic and non-therapeutic modification, and rejects the latter, strongly. Its main document on bioethics, *Donum Vitae*, ('The Gift of Life'), states:

> Certain attempts to influence chromosomic or genetic inheritance are not therapeutic but are aimed at producing human beings selected according to sex or other predetermined qualities. These manipulations are contrary to the personal dignity of the human being and his or her integrity and identity, which are unique and unrepeatable. Therefore in no way can they be justified on the grounds of possible beneficial consequences for future humanity. Every person must be respected for himself: in this consists the dignity and right of every human being from his or her beginning.[80]

This is re-affirmed in its latest document on bioethics, *Dignitas Personae* ('The Dignity of a Person'), which observes that attempts to enhance the gene pool can display a rejection of the value of the human being, a 'eugenic mentality,' and a desire to replace the role of the Creator. Social stigma could be experienced by those without certain arbitrarily chosen qualities, leading to 'an unjust domination of man over man;' a rejection of 'the equality of all human beings.'[81]

The International Theological Commission has described post human scenarios as 'radically immoral'.[82] They distinguish between genetic engineering which allows human beings to fulfil their complete identity by the elimination of faulty genes, and that which attempts to change human nature – which was not designed by human hands. The Commission put a limit on the

[80] Congregation for the Doctrine of the Faith, 1987. *Donum Vitae.* Vatican City: Libreria Editrice Vaticana. Para 5.I.6. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html [Accessed 30 Nov 2010].
[81] Congregation for the Doctrine of the Faith. 2008. *Dignitas Personae*. Vatican City: Libreria Editrice Vaticana: Para 27. Available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html [Accessed 30 Nov 2010].
[82] International Theological Commission. 2004. *Communion and Stewardship: Human Persons Created in the Image of God*. Vatican City: Libreria Editrice Vaticana; Para 91. Available at http://www.vatican.va/roman_curia/congregations/cfaith/cti_documents/rc_con_cfaith_doc_20040723_communion-stewardship_en.html [Accessed 30 Nov 2010].

co-creator doctrine, as humans are created in the image of God, and their nature should not be altered.[83] John Paul stated that genetic modification that significantly alters the species, does not respect human dignity, causes marginalization of groups, or deprives persons of autonomy, 'becomes arbitrary and unjust.'[84]

While attempts to change human nature are condemned by the Church, it permits fairly extreme therapeutic interventions. For example, the Pontifical Academy for Life has published a document on xenotransplantation, defining it as the transplanting of animal cells, organs and tissues into humans for curative purposes, where human donors are in short supply. This document approves it, subject to criteria of risk vs. benefit and autonomy and, if and only if, it does not affect the personhood of the person receiving the transplant.[85]

Also, the Magisterium prohibits any form of procreation outside the sex act within marriage;[86] so any type of synthetic creation of human beings would be considered a moral wrong. In addition the Church prohibits research that would damage a human being, including an embryo, even if the results of that research could benefit many.[87]

SYNTHETIC BIOLOGY AND OTHER SPECIES

In approving research on human DNA, and significant forms of therapuetic modification such as xenotransplantation, the Church implicitly allows for modification of the DNA and other aspects of all creatures. Could it approve the creation of new animal and plant species? It never had a problem with cross-breeding of plants and animals to create new species; these techniques alter genomes artificially, and have done so for thousands of years, long before the existence of DNA was known. The founder of genetics, Gregor Mendel, crossed different types of peas in his experiments, creating new hybrids; he was a Catholic monk. Research in synthetic biology that alters DNA is simply a more advanced technique to achieve similar ends.

Bishop Elio Sgreccia, who heads the bioethics department of Rome's Sacred Heart University and is vice president of the Pontifical Academy for Life, spoke to Vatican Radio on the issue. He approved the creation of new species, subject to risk assessment and respect for biodiversity – new species should not displace existing ones. He also said that the benefits gained from the production of new life-forms should not be restricted to corporations – they should benefit all.[88]

THE ELEMENT OF RISK IN SYNBIO

Synthetic biology could be contentious in many ways. Regarding biotech's general risks, the *Compendium* observes that as well as evaluating the moral correctness of research in itself, it is also necessary to take account of potential risks.[89] The Church shares the concern of the general ethics community on risk, and the potential for risk in synthetic biology is significant.[90] The Pontifical Academy for Life has observed:

> Risk – understood as an unwanted or damaging future event – the actual occurrence of which is not certain but possible – is defined by means of two characteristics: the level of probability and the extent of damage . . . Naturally, a very probable risk is easily tolerated if the extent of damage associated with it is very small; on the contrary, a risk that causes a high level of damage, however improbable, gives rise to much greater concern and require greater caution. . . . Together, these two criteria – probability and the extent of damage – define the *acceptability* of the risk, as reflected by the *risk/benefit ratio*. . . . In the absence of data that allow a reliable assessment of such a risk, greater caution should be used; this does not necessarily mean, however, that a total block should be put on all experimentation . . . In this situation, therefore, the imperative ethical requirement is to proceed by 'small steps' in the acquisition of new knowledge . . . with careful and constant monitoring and a readiness at every moment to revise the design of the experiment on the basis of new data emerging.[91]

Thus risk does not necessarily impute immorality to research in the eyes of the Church. But it should be taken seriously and all necessary steps taken to reduce it.[92] There should be appropriate risk assessment and risk

[83] Ibid.
[84] Pope John Paul II. *op. cit.* note 75.
[85] Pontifical Academy for Life, 2002. *Prospects for Xenotransplantation: Scientific Aspects and Ethical Issues*. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html [Accessed 30 Nov 2010].
[86] Congregation for the Doctrine of the Faith, *op. cit.* note 80, para 5.II.A.1, 5.II.B.4, 5.II.B.5
[87] Ibid: para 5.I.1.
[88] Zenit.org. 2003. *Ethical Criteria Outlined for the Creation of Genetically Modified Organisms: Vatican Official Urges Respect for Biodiversity*. Available at http://www.zenit.org/article-7925?l=english [Accessed 30 Nov 2010].
[89] Pontifical Council for Justice and Peace, *op. cit.* note 45, para 473.
[90] J.B. Tucker & R.A. Zilinskas, 2006. The Promise and Perils of Synthetic Biology. *The New Atlantis* Spring: 25-45. Available at http://www.thenewatlantis.com/publications/the-promise-and-perils-of-synthetic-biology [Accessed 30 Nov 2010].
[91] Pontifical Academy for Life, *op. cit.* note 85, para.13.
[92] Pontifical Council for Justice and Peace, *op. cit.* note 45, para 473.

management.[93] But where it is very significant, risk could render a research path unethical in the Church's view. The Church has reached this conclusion for human germ line modification (which may cure a patient and their descendents of a genetic disease). It does not regard the research as unethical itself when directed towards therapies – indeed, it approves it in principle. Nevertheless it regards it as being unethical with current scientific knowledge, as the risks are high and potential damage may be irreversible.[94] On the other hand, it has no ethical problems with somatic cell gene therapy (which may cure individual patients only),[95] as the risks are lower, and any potential harm will not pass through the generations.

How, then, will the Church judge synbio with regard to its potential risks? Those risks are serious. They include the potential for easy manufacture of biological weapons; and accidental ecological harm. Worst case scenarios could include massive loss of life and extreme environmental damage. The potential risks appear to be far greater than those posed by human germ line modification. It is therefore very likely that the Church will regard the current scenario of largely unregulated synbio research as being unethical. But development of good regulation, which keeps synbio acceptably safe, would change this.

Regarding bioweapons: research into biological weapons using synthetic biology will be condemned by the Church, in the strongest terms. The Catechism states:

> Every act of war directed to the indiscriminate destruction of whole cities or vast areas with their inhabitants is a crime against God and man, which merits firm and unequivocal condemnation. A danger of modern warfare is that it provides the opportunity to those who possess modern scientific weapons – especially atomic, biological, or chemical weapons – to commit such crimes.[96]

Thus weapons research is condemned:

> Spending enormous sums to produce ever new types of weapons impedes efforts to aid needy populations; it thwarts the development of peoples. Over-armament multiplies reasons for conflict and increases the danger of escalation.[97] . . . The production and sale of arms affects the common good of nations and of the international community.[98]

[93] Pontifical Academy for Life, *op. cit.* note 85, para.13.
[94] Congregation for the Doctrine of the Faith, *op. cit.* note 80, para 26; International Theological Commission, *op. cit.* note 22, para 90; Shannon, *op. cit.* note 72.
[95] Congregation for the Doctrine of the Faith. *op. cit.* note 80, para 26; Shannon, *op. cit.* note 72.
[96] Catechism of the Catholic Church , *op cit*. note 44, para 2314 .
[97] Ibid: para 2315.
[98] Ibid: para 2316.

INTELLECTUAL PROPERTY AND SYNBIO

The Church does not approve the patenting of scientific discoveries (as opposed to inventions). It regards them as being part of humanity's patrimony.[99] Pope John Paul has commented, regarding the widespread commercialization of biotech, including patenting of biomaterials: 'the results of research should be made available to the whole scientific community and cannot be the property of a small group;'[100] and that scientific research should be kept 'free from the slavery of political and economic interests.'[101] Nature is God's gift to humanity; ownership should not be usurped. As the technology advances, the Church may engage with the issue of whether life can be patentable; from the above statements, it is unlikely to regard it as ethical.

CONCLUSION

Synthetic biology, if it becomes successful, will pose profound ethical and theological challenges. The Catholic Church has yet to issue a document of the Magisterium on the field; it is too early, as synbio does not appear, at this stage, to pose any theological challenges that are significantly distinct from those posed by current biotechnology. As the field progresses, this may change. This paper attempts to show the likely contents of such a Church document, based on previous Magisterial teachings on science and biotechnology, and on statements of influential individuals in the Church. Although those latter statements do not carry Magisterial weight, they do reflect the thinking of upper-level Church personnel, and those who made them may be influential in formulating Magisterial teachings. Thus it is possible to infer, with reasonable confidence, what the Church's teachings on synthetic biology will be.

While some writers have questioned whether synthetic biology may be 'playing God,' such concerns have been raised since the earliest days of genetic engineering and biotechnology.[102] The *Compendium of the Social Doctrine of the Church* shows that the Catholic Church does not share this concern. The Church is likely to regard the

[99] Pontifical Council for Justice and Peace, *op. cit.* note 45, para 475-478; K.D. Warner. Are Life Patents Ethical? Conflict Between Catholic Social Teaching and Agricultural Technology's Patent Regime. *J Agric Enviro Ethics* 2001; 14(3): 301–319.
[100] Pope John Paul II. 1994. The Human Person – Beginning and End of Scientific Research. *Address to the Pontifical Academy of Sciences, 28 October.*
[101] Pope John Paul II. 2003. *Address to Participants in the Ninth General Assembly of the Pontifical Academy for Life* 24 February. Available at http://www.vatican.va/holy_father/john_paul_ii/speeches/2003/february/documents/hf_jp-ii_spe_20030224_pont-acad-life_en.html [Accessed 30 Nov 2010].
[102] Dabrok, *op. cit.* note 17.

science as a tool that is capable of being used for good or evil. It is likely to critique each sub-field and significant application of synbio – the various sub-fields are quite different and pose different ethical challenges. It seems certain to approve good applications of the research, and condemn evil or unduly risky applications. Issues of patenting pure scientific discoveries, and patenting life, are likely to be ethically problematic for the Church, which will also require that beneficial applications become available to all, not restricted to a few, and that the research be done in an environment of human solidarity, not exploitation. The creativity involved in synbio is likely to be viewed as co-creation with God rather than playing God. The Church will not approve application of the science to the creation of a post-human future, or to the synthetic creation of humans, should these become technically possible.

But the issue of risk is potentially so high that it could make the whole field unethical in the eyes of the Church. John Paul II observed that 'in some instances, technology can cease to be man's ally and become almost his enemy'.[103] The Church is likely to be very aware of the dual use issue,[104] and other significant risks that synbio poses, and to require that all possible steps be taken to prevent synthetic biology from being used in negative ways. Science does not take place in a moral vacuum. John Paul II observed:

> We are not yet in a position to assess the biological disturbance that could result from indiscriminate genetic manipulation and from unscrupulous development of new forms of plant and animal life, to say nothing of unacceptable experimentation regarding the origins of human life itself. It is evident to all that in any area as delicate as this, indifference to fundamental ethical norms, or their rejection, would lead mankind to the very threshold of self-destruction.[105]

Risks may be made acceptable, however, by good regulation. The development of such regulations has yet to occur to a significant degree; such development poses significant challenges, but is under discussion by the relevant authorities.[106] If good regulations are developed, the risks may fall within acceptable parameters for the Church. From a deontological viewpoint, the Church is likely to be supportive, generally, if synbio can be made reasonably safe. Indeed, the University of Notre Dame, one of the world's leading Catholic universities, is, at the time of writing, establishing a synthetic biology program,[107] showing the overall positive disposition of the Church to the field.

It has been noted that Catholic ethics tends to mirror mainstream ethics to a large degree[108] (a few well-know exceptions exist, of course). It is also notable that Catholic ethics does not reflect the liberal-conservative divide in society; while it may, in certain instances, agree with one or the other, it is quite different in its approach, and frequently finds itself in opposition to either or both.[109] Probable Catholic support of synthetic biology could be a useful argument against some fundamentalist viewpoints, which are likely to be opposed to synthetic biology in itself, perhaps vehemently so. (Synthetic biology could be a focal point of future culture wars between religion and science.) Finally, it could be useful for synthetic biologists, ethicists, regulators and others to be aware of religious arguments for and against the field, to answer – or be influenced? – by them.

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[103] Pope John Paul II. 1981. *Laborem exercens*. Vatican City: Libreria Editrice Vaticana: para 5. Available at http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_14091981_laborem-exercens_en.html [Accessed 30 Nov 2010].

[104] The fact that synbio could have positive applications such as therapies, and negative ones such as biological weapons. See M. Dando. Synthetic Biology: Harbinger of an Uncertain Future? *Bull At Sci* 2010, 16 August. http://www.thebulletin.org/print/web-edition/columnists/malcolm-dando/synthetic-biology-harbinger-of-uncertain-future [Accessed 30 Nov 2010].

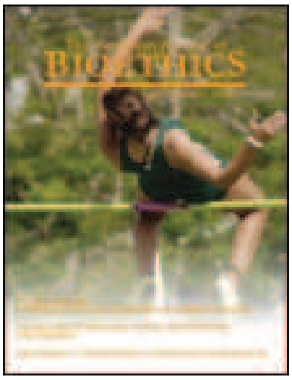
[105] Pope John Paul II. 1996. The Ecological Crisis: A Common Responsibility. In D. Christiansen and W. Grazier, eds, *'And God Saw That It Was Good': Catholic Theology and the Environment*. Washington D.C.: United States Catholic Conference: 215–222. Quoted in Warner, *op. cit.* note 99, p. 311.

[106] EGE (European Group on Ethics in Science and New Technologies). 2009. *Ethics of Synthetic Biology*. Brussels: European Commission. Available at http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf [Accessed 30 Nov 2010]; E.K. Hayden. 2009. Genemakers form security coalition. *Nature News* 18 November; Presidential Commission for the Study of Bioethical Issues. 2010. New Directions: The Ethics of Synthetic Biology and Emerging Technologies. Washington, D.C. Available at http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12-16-10.pdf [Accessed 23 Feb 2011].

[107] University of Notre Dame, Department of Biological Sciences. 2010. *News: Notre Dame adds to its expertise in nanobiotechnology,* 28 January. Available at http://biology.nd.edu/news/14506-notre-dame-adds-to-its-expertise-in-nanobiotechnology/ [Accessed 30 Nov 2010].

[108] Shannon, *op. cit.* note 72.

[109] B.M. Ashley, J. DeBlois & K.D. O'Rourke. 2007. *Health Care Ethics: A Catholic Theological Analysis*. Washington D.C.: Georgetown University Press.



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Global Health Justice and Governance for Synthetic Biology

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Global Health Justice and Governance for Synthetic Biology

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Jennifer Prah Ruger, in her article "Global Health Justice and Governance" (2012), correctly critiques current global health care regulation as being fragmented, with regulators concentrating on their own institutions or countries, not focusing on the benefit of humanity throughout the world, and without knowledge of the knock-on effects of their policies. It seems unlikely that such a regime can meet the regulatory challenges of synthetic biology.

Ruger has developed a theory of global health governance that is based on ethics. Synthetic biology (synbio) is a major public health issue, and applying Ruger's approach to it is likely to be a considerable stress test for her theory. Here I briefly summarize the theory's most salient points, to apply it to synbio regulation. The basis of global health care regulation is set out in the *provincial globalism* (PG) model, which is based on nine foundational principles: (1) Virtuous people acknowledge human dignity, and desire universal human flourishing. (2) Health is a foundation for human flourishing. (3) Humans have duties to each other by virtue of their humanity. (4) There is a universal right to good health. (5) The existence of nations and a broad, cosmopolitan viewpoint can be reconciled. (6) People are "plural subjects," being autonomous individuals, citizens of nations, and members of a universal human family, and this must be recognized. (7) There should be a multilevel governance system, in which there is individual and collective responsibility, with consistency between national and global governance. The principal regulation should be at the national level, with secondary regulation at global and regional levels. (8) The reality of disagreements on central principles can be dealt with by incompletely theorized arguments, which allow people to agree on specific issues without agreement on broader principles or specific details of implementing the issues. (9) There is an aspiration toward global health citizenship, in which all people are entitled to equal health care/well-being.

Having established foundational principles of global healthcare governance, Ruger notes that PG contains within it the concept of shared health governance (SHG). This is based on the premise that those involved in global health care seek health justice on a global scale, as opposed to national interest or self-interest. The features of SHG are, in brief summary: (1) Global health justice, based on ethical values, requires good global health governance. (2) Ethical commitment rather than self-interest or national interest is the motivation for global health justice. (3) There is a duty of cooperation, so that core requirements can be attained. (4) Responsibilities are imposed according to function and need, at both national and international levels (primarily national). (5) A politically independent global institute for health regulation should be created to provide expertise on policy; its membership should include scientists. (6) A global health constitution should be developed, guiding the relevant global, national, and regional institutions. (7) The constitution and global institute should reduce inefficiency, wasteful competition, and power plays by states. (8) Global health governance does not equate to one world government; policy would be enforced by national governments. (9) All participants, be they in democratic or nondemocratic bodies, at national, regional, and global levels, should be held to standards of mutual collective accountability. (10) Policy should be evidence-based, rather than political. (11) Compliance at the global level should be voluntary, primarily, based on moral consensus. (12) Legitimacy should be achieved by establishing and reaching goals, subject to independent review.

It is imperative that synbio be regulated properly, in ways that allow it to fulfill its potential for good while minimizing its possible negatives. Some synthetic biologists have called for self-regulation (Declaration of the Second International Meeting on Synthetic Biology 2006; Garfinkel et al. 2007), and some piecemeal regulation has been developed at the national level in some countries (Bar-Yam et al. 2012). Such regulation, although a useful beginning, will not be adequate in the medium to long term. While strong regulation at the national level, in the countries where synbio is at its most advanced, is necessary, the mobility of research means that such regulation alone may, paradoxically, lead to looser, more permissive regulations for the field overall, as some research moves to places where regulation is least. Ethically contentious research is most likely to follow this path. Therefore, regulation needs to be worldwide in scope.

Regulating it well will be challenging. Paralleling the early days of computing research, synbio research is taking place at many levels of society, ranging from universities and corporations to amateur labs in the homes of teenage biohackers. Information exists online that teaches interested parties how to synthesize their own biological "creations"; such information includes the genome sequences of pathogens, including Ebola virus, smallpox, and HIV. Inadequate regulation could lead to destruction of life on a vast scale. Too much regulation could shut down synbio's great potential for good, preventing advances in knowledge, including future therapies.

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The different subfields within synbio pose very different regulatory problems (Schmidt 2008). The biggest difficulty will be in attempting to regulate biohacking, which will feed off advances in the mainstream science. Current biotechnology laws tend to regulate products rather than the underlying science (Rodemeyer 2009). Biohacking may become as regular an occurrence as today's computer hacking. This suggests that pure research may have to be regulated, to prevent its results being applied in negative ways, even where it is not negative in itself and may have positive applications. Thus it may become necessary to prevent, or keep from the public domain, certain scientific advances. Because of the potential dangers and benefits of synthetic biology, and its broad array of researchers and subfields, getting the regulatory mix right will be a difficult task.

There are other challenges. One is that the major industrial nations are working to build up their synthetic biology industries, in competition (and a degree of cooperation) with each other. Synthetic biology may lead to a societal revolution as great as the computer revolution, and major nations don't want to be left behind. There is similar competition among corporations; for example, energy, medical, and pharmaceutical companies are engaged in synbio research, as is Microsoft. Depending on their success or failure, the corporate landscape could be reshaped. At the level of individual scientists, success in major synbio projects will lead to great prestige and for some, in this era of increasing privatization of science, to great wealth. Thus, under current regulatory mechanisms, while major synbio players will tend to seek a degree of good regulation, there will also be a natural instinct to preserve their own interests in a competitive environment.

Ruger's theory needs little adaptation to apply it to synbio regulation. Synbio's regulatory challenge, where a myriad of opposing needs make it almost impossible to devise an adequate regulatory regime, diminishes when PG/SHG is applied. For example, in the current regime, nations may be faced with the dilemma of permitting potentially hazardous, though beneficial, research, rather than risking falling behind others. But with PG/SHG's approach, such a problem tends to fade away. The ethical foundation, the multilevel regulation from global to regional, with mutual collective accountability, regulating for the benefit of humanity at large as well as for local interests, should provide an ethical and intellectual framework to solve synbio's regulatory challenges—subject to the proviso that goodwill underlies the negotiations. The timing of the PG/SHG model, coinciding with the emergence of this extraordinary scientific leap, is propitious. ■

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