BLACK BIOLOGY: GENETIC ENGINEERING, THE FUTURE OF BIOTERRORISM, AND THE NEED FOR GREATER INTERNATIONAL AND COMMUNITY REGULATION OF SYNTHETIC BIOLOGY

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INTRODUCTION

When the average citizen contemplates terrorism, they likely think of the car bombs and fiery destruction that plague the nightly news.

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They might name ISIS, Boko Haram, or the Boston Bombers as examples of potential terrorist actors. The actions of these groups and individuals shock the conscience and make national security the topic of nearly every political debate. While no less threatening, this form of warfare is familiar, and the American military-industrial complex has worked tirelessly to combat and prevent it. But are we prepared for a threat much more insidious and primarily unseen?

The new terror risk might come from the emission of an aerosolized canister in a crowded train station or airport. Unlike the death and devastation that occur immediately after a modern terror attack, this assault would start with a cough or a sneeze. Botulism, the bubonic plague, or hemorrhagic fever could spread rapidly through America's crowded cities. After an initial outbreak, it would take days for epidemiologists to recognize a pattern of illness, let alone conclusively find that the outbreak had more sinister roots. By the time anyone could determine that the United States was the victim of a bioterrorism attack, the perpetrator could disappear into anonymity.

Bioterrorism events have happened before. After the September 11 attacks, anonymous letters containing anthrax were sent through the US Postal system, killing five people and infecting seventeen others.[1] Fifteen years later, despite enormous sums of federal money and countless man hours, the FBI has been unable to identify a suspect.[2] While the United States reignited its bio-preparedness efforts in the wake of these episodes, the majority of public health experts agree that America is woefully unprepared for any sort of mass-scale bioterrorism event.[3] Furthermore, the anthrax attacks, while relatively small in number, caused enormous damage to the public consciousness and helped shape US domestic and foreign policy for over a decade.[4] Laboratory security procedures can largely combat this type of threat and world governments now keep close tabs on which individuals and organizations have access to these pathogens.[5]

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[1] *Amerithrax or Anthrax Investigation*, FED. BUREAU OF INVESTIGATION, https://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax (lasted visited Mar. 27, 2016).

[2] *See id.*

[3] *See generally* DAVID P. FIDLER & LAWRENCE O. GOSTIN, BIOSECURITY IN THE GLOBAL AGE: BIOLOGICAL WEAPONS, PUBLIC HEALTH, AND THE RULE OF LAW (2008).

[4] *Id.*

[5] *Id.*

Science, however, is always advancing faster than its regulations. "Black" biology is the use of genetic engineering to enhance the virulence of a pathogen or the targeting of a specific genetic code for use in terrorism.[6] This new area of biology could create a designer virus which, while initially mimicking the common cold or flu, could act as a "molecular key" to trigger secondary effects after encountering a certain DNA sequence.[7] This type of modification could prove useful if the secondary effects delivered individualized cancer treatments to afflicted patients, ensuring that their bodies accepted treatment. But more sinisterly, a virus could be designed with secondary effects inducing the neurodegenerative, fatal byproducts of botulinum toxin and the DNA sequence engineered for recognition could be that of the President of the United States.[8]

While this outcome seems like science fiction, it is the imminent future of biotechnology. Even now, the Secret Service sanitizes or destroys objects the President has touched or used in order to prevent terrorists from collecting genetic material.[9] Synthetic biology, or genetic engineering, is the integration of a multitude of scientific disciplines that seek to alter human DNA at a fundamental level.[10] With this technology, scientists are able to "edit" out undesirable sequences for the benefit of human health or create new biological material from DNA building blocks.[11] The field shows remarkable promise for curing, preventing, and treating a multitude of diseases while potentially alleviating the energy crisis.[12] The research of this new biologic frontier will dominate the scientific consciousness for the next century.[13]

As demonstrated above, however, this new technology has a "black" side. Current bioterrorism efforts focus on containment.[14] Cataloguing, regulating, and controlling a calculable amount of a

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[6] Michael J. Ainscough, *Next Generation Bioweapons: The Technology of Genetic Engineering Applied to Biowarfare and Bioterrorism*, 14 THE COUNTERPROLIFERATION PAPERS 253, 253–254 (2002), http://www.au.af.mil/au/awc/awcgate/cpc-pubs/biostorm/ainscough.pdf.

[7] Andrew Hessel et al., *Hacking the President's DNA*, THE ATLANTIC (Nov. 2012), http://www.theatlantic.com/magazine/archive/2012/11/hacking-the-presidents-dna/309147/.

[8] *Id.*

[9] *Id.*

[10] *See* Carolyn M.C. Lam et al., *An Introduction to Synthetic Biology*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 23 (Schmidt et al. eds., 2009).

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *See* FIDLER & GOSTIN, *supra* note 3.

contagious microbe activates safety measures if a specimen goes missing or is removed from a laboratory. But there may be no notice if terrorists create their own pathogen or engineer a genetically-targeted bioweapon. These scenarios move beyond current science and lack regulations and law. Now is the time to police this burgeoning field and set standards to determine what experiments are acceptable. A problem of this magnitude, which has the capacity to cause significant damage, must be confronted immediately by the international community. Past efforts to control bioterrorism have been weak or brushed over in favor of dealing with physical or nuclear disaster. But ignoring bioterrorism does nothing to change the facts: synthetic biology may not only be the future of science, but the future of modern warfare as well, making its regulation crucial for global security.

This Comment will survey the current international regulations surrounding synthetic biology and provide potential legal solutions, examining the opportunities for internal governance within the scientific community. Part I will detail a brief history of bioterrorism and provide an overview of the associated international legal precedent, Part II will examine both the science and issues behind synthetic biology, Part III will explore the current international legal regulation regarding bioterrorism in depth and suggest potential applications to synthetic biology, and Part IV will consider potential options for community policing amongst scientists.

I. A BRIEF HISTORY OF BIOTERRORISM AND ITS ASSOCIATED INTERNATIONAL LEGAL PRECEDENT

Biological warfare has existed since ancient times. The first intentional use of a biological agent by warring armies occurred in 67 B.C in a battle between the Roman armies of Pompey and King Mithridates of Pontus.[15] The Pontus forces tricked the superior Roman army into consuming honeycombs infected with grayanotoxin, which caused impaired consciousness, blurred vision, and other symptoms.[16] In their weakened state, the Roman troops were summarily executed by King Mithridates's soldiers.[17] Quick to learn from their weaknesses, the Romans incorporated biological weapons into their war strategies by

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[15] VICTORIA SUTTON, LAW AND BIOTERRORISM 4 (2003).
[16] *Id.*
[17] *Id.*

polluting the water supply of their enemies with the diseased carcasses of dead animals.[18] Adapting this ancient biological weapon, the Tartars catapulted plague-infected corpses over the walls of Kaffa in 1346, forcing the Genoans to evacuate their besieged city into the awaiting Tartar camp.[19] In 1710, the Germans repeated this strategy to attack their Swedish enemies.[20] But perhaps the most well-known incident of early bioterrorism occurred when the colonial army of Captain John Oldham gifted blankets infected with smallpox to the Narragansett Native American tribe, which contributed to the partial annihilation of the Pequot people.[21]

The United States was the first nation in history to regulate the use of biological warfare. General Order 100, made in 1863 during the Civil War, declared that "the use of poison in any manner, be it to poison wells, or foods, or arms, is wholly excluded from modern warfare."[22] The regulation of bioweapons was first included in the international laws of warfare by the Hague Convention of 1899, which stated that "with Respect to the Laws and Customs of War on Land . . . it is especially prohibited to employ poison or poisoned arms."[23] But these standards were largely ignored in World War I, as the Allies and Central Powers utilized mustard gases and other similar biological weapons to subdue their enemies.[24] It was only after World War I that the international community began to seriously regulate biological weapons, culminating in the Geneva Protocol of 1925 which included chemical prohibitions on "bacteriological" warfare.[25] The United States and Japan, however, did not sign the agreement.[26] Both countries and the Soviet Union began robust biological weapons programs which continued throughout World War II.[27] It was not until 1969 that then-President Richard Nixon converted the US biologic weapons program into a defensive program

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[18] *Id.* at 5.

[19] *Id.* at 4; *see also* ROBERT O'CONNELL, OF ARMS AND MEN: A HISTORY OF WAR, WEAPONS AND AGGRESSION 171 (1989).

[20] *Id.* at 5.

[21] E. WAGNER STEARN & ALLEN E. STEARN, THE EFFECTS OF SMALL POX ON THE DESTINY OF AMERINDIAN 44–45 (1945).

[22] *See* SUTTON, *supra* note 15, at 5.

[23] Hague Convention (IV) Respecting the Laws and Customs of War on Land, with Annex of Regulations, art. 23, Oct. 18, 1907 T.S. No. 539.

[24] *See* SUTTON, *supra* note 15, at 5.

[25] *Id.* at 6.

[26] *Id.*

[27] *Id.*

and called for "the first world treaty to end the research and proliferation of biological weapons."[28] This paved the way for the Biological Weapons Convention of 1972, which completely prohibited the use of biological weapons and was ratified by 140 nation states.

Despite this initial attempt to remove biological weapons from the field of battle, state and non-state groups have continued to develop and utilize biological weapons in the name of defense.[29] Such continued development has led to several incidents of modern biological warfare. For instance, in May 1979, the Soviet city of Svedlovsk experienced a spate of unexplained civilian deaths.[30] The ultimate cause of death was later revealed to be pulmonary anthrax, spores of which had been mistakenly released from a nearby military base.[31] Moreover, non-state terrorist groups have also developed the capabilities to utilize bio-attacks. In 1984, the Rajneeshee cult organization deliberately released Salmonella bacteria into a salad bar at a restaurant in Antelope, Oregon.[32] The attack sickened approximately 750 people[33] and led the United States to establish domestic laws aimed at preventing biological weapons dispersal.[34] The Biological Weapons Act of 1989 made it a federal crime "to develop, manufacture, transfer or possess any biological agent, toxin or delivery system for use as a weapon."[35] Likewise, the Chemical and Biological Weapons Control Act of 1991 created a system of economic and export controls designed to prevent the export of technologies utilized in the development of chemical and biological weapons to designated nationals.[36] Since the 9/11 terrorist attacks on the World Trade Center, however, the proliferation of biological weapons and agents remains a serious problem.

On April 24, 2004, the United Nations (UN) once again dealt with the problem of bioweapons.[37] The UN Security Council unanimously adopted Resolution 1540 under Chapter VII of the United Nations Charter, which reiterates that the proliferation of weapons

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[28] *Id.* at 7.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] Thomas J. Torok et al., *A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars*, 278 J. AM. MED. ASSOC. 389–395 (1997).

[34] SUTTON, *supra* note 15, at 7.

[35] 136 CONG. REC. H2065 (daily ed. May 08, 1990) (statement of Rep. Morrison).

[36] SUTTON, *supra* note 15, at 7.

[37] S.C. Res. 1540, U.N. Doc S/RES/ 1540 (Apr. 28, 2004).

remains a threat to international peace and security.[38] Resolution 1540 "imposes binding obligations on all states to adopt legislation to prevent the proliferation of nuclear, chemical and biological weapons, and their means of delivery, and establish appropriate domestic controls over related materials to prevent their illicit trafficking."[39] The resolution also stipulates increased international cooperation to monitor the research and creation of bioweapons.[40] The Security Council continued to revisit this crucial issue with the adoption of Resolution 1673, which advocated for the intensification of international implementation of Resolution 1540.[41] On April 27, 2008, the Security Council "urged the 1540 Committee to continue strengthening its role in facilitating technical assistance, including by engaging actively in matching offers and requests for assistance."[42] Finally, in 2011, the Security Council adopted Resolution 1977, which lengthened the UN commitment to end the proliferation of biological weapons and other weapons of mass destruction and extended the committee for Resolution 1540 until 2021.[43] To date, however, little progress has been made to further the goals of these resolutions.

Even with these prohibitions against the development of bioweapon technology, science continues to develop faster than any regulation can. Even more problematic, much of the new science with bioweapon potential could also provide numerous benefits. This further complicates the regulatory questions that plague any international attempt to control and prevent the spread of biohazardous weapons and materials.

II. THE SCIENCE OF SYNTHETIC BIOLOGY

Synthetic biology is "a rapidly developing field that aims to engineer new biological systems that do not already exist in nature,"[44] with the goal of creating "artificial cellular or non-cellular biological components with functions that cannot be found in the natural

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38 *Id.*

39 *Id.*

40 *Id.*

41 S.C. Res. 1673 (Apr. 27, 2006).

42 *Id.*

43 S.C. Res. 1977 (Apr. 20, 2011).

44 Karen M. Polizzi, *What is Synthetic Biology?, in* SYNTHETIC BIOLOGY 3 (Karen M. Polizzi & Cleo Kontoravdi eds., 2013).

environment."[45] Synthetic biology also attempts to make "systems made of well-defined parts that resemble living cells and known biological properties via a different architecture,"[46] utilizing the fields of engineering, biological sciences, and computational modeling.[47] Capitalizing on new developments in computer technology and more readily available genetic material, synthetic biologists attempt to create artificial life and reverse-engineer the building blocks of humanity.[48] Though these ideas have been pursued by scientists since the Enlightenment, the field of synthetic biology has only recently grown and expanded into the modern scientific dialogue.[49] While the field is still relatively nascent, many biologists believe that it has the potential to be "an ultimate font of biological knowledge."[50] Even though many practical applications of synthetic biology are years away, it has the potential to change the understanding of life and have far-reaching effects on medicine, chemistry, physics and, more dangerously, warfare.

A. BACKGROUND

In extremely simplistic terms, synthetic biology is genetic engineering. Scientists utilize bioinformatics to reconstruct the proteins and enzymes encoded in the DNA sequence.[51] This process functions by signaling and manipulating the pathways to produce biological functions that are corrected or more desirable than their original functions.[52] Whether genetic editing/engineering is done to the entire genome or a singular gene, it produces staggering and sometimes unpredictable effects.[53] Most of the modeling is done using computational technologies and other bioinformatics techniques to predict the effects certain manipulations will have on human cells.[54] With time, however, the goal

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45 Lam et al., *supra* note 10, at 25.

46 *Id.*

47 *Id.*

48 POLIZZI, *supra* note 44, at 3.

49 Luis Campos, *That was the Synthetic Biology that was*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 5 (Schmidt et al. eds., 2009).

50 *Id.* at 6.

51 Lam et al., *supra* note 10, at 25.

52 *Id.*

53 *Id.*

54 *Id.*

is for synthetic biology to have a meaningful impact on healthcare and industry.[55]

B. ETHICAL ISSUES ASSOCIATED WITH SYNTHETIC BIOLOGY

There are three ethical issues that are generally associated with synthetic biology.[56] The first two are largely philosophical: (1) should humans have the power to design artificial organisms and become the architects of living things; and (2) can the creations of synthetic biology be subject to human ownership or should any beneficial outcomes be free to access for the use of all humanity?[57] These two questions will likely continue to plague scientists, but they are not the subjects of this Comment. Rather the focus is on the third issue, is there a potential for harm resulting from synthetic biology, which has already been demonstrated. The dispersal of human created organisms could have far-reaching and unknowable effects on the global environment; "it is not clear to what extent we should expose nature to such a risk and whether we have the right to interfere with the ecosystem in such as direct manner."[58] Much like the poisoned crops and water supplies of old, synthetic biology has the potential to contaminate the environment on a much larger and more globalized scale. Moreover, and even more threateningly, it has already been demonstrated that *de novo* DNA synthesis can be used to produce pathogenic viruses.[59] In the near future, "it is possible that novel types of infective viruses could be designed and produced" leading to a serious threat against biosafety and biosecurity.[60]

Biologists largely agree that these dangers must be treated with the utmost seriousness. History has shown that state-sponsored biological weapons programs have repeatedly exploited major scientific breakthroughs.[61] Even more terrifying, however, is that traditional biodefense programs only have dealt with a finite number of diseases

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[55] *Id.* at 24.

[56] Anna Deplazes et al., *The Ethics of Synthetic Biology: Outlining the Agenda*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 65, 66 (Schmidt et al. eds., 2009).

[57] *Id.* at 67.

[58] *Id.* at 69.

[59] *Id.*

[60] *Id.*

[61] Alexander Kelle, *Security Issues Related to Synthetic Biology*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 101, 102 (Schmidt et al. eds., 2009).

occurring in nature.[62] In the words of one scientist, "unlike the threats posed by traditional and genetically modified traditional agents, the capability of the threat posed by advanced biological warfare [synthetic biological] agents continues to expand indefinitely in parallel with advances in biotechnology."[63]

Scientists have identified three categories of risk incited by developments in synthetic biology.[64] First, "synthetic microorganisms might escape from a research laboratory or containment facility, proliferate out of control and cause environmental damage or threaten public health."[65] This scenario has already played out in traditional manifestations of state-sponsored bioweapon research development.[66] Second, "a synthetic microorganism developed for some applied purpose might cause harmful side effects after being deliberately released in to the open environment."[67] Third, "outlaw states, terrorist organizations or individuals might exploit synthetic biology for hostile or malicious purposes."[68]

The third threat, which is largely the topic of this paper, has been deliberated amongst scientists for the past decade.[69] The Committee on Research Standards and Practice to Prevent the Destructive Application of Biotechnology (hereinafter "the Fink Committee") was the byproduct of American scientists' concerns that life sciences research could be used for hostile and malicious purposes. These sentiments have fostered a largely internal academic debate about the advisability of experiments in synthetic biology, whether such experiments should be carried out, and, if experiments are executed, whether their results should be made public.[70]

The Fink Committee was commissioned by the American National Research Council, which, although not a government body that can create laws and regulations, advises the US government and has "an

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[62] *See* James B. Petro et al., *Biotechnology: Impact of Biological and Biological Warfare and Biodefense*, 1 BIOSECURITY AND BIOTERRORISM: BIODEFENSE, STRATEGY, PRACTICE, AND SCIENCE 161 (2003).

[63] *Id.* at 162.

[64] *See* Jonathan B. Tucker & Raymond A. Zilinskas, *The Promise and Perils of Synthetic Biology*, 12 NEW ATLANTIS 25, 31 (2006).

[65] *Id.* at 31.

[66] *See* SUTTON, *supra* note 15, at 7.

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] Kelle, *supra* note 61, at 106.

agenda setting function in scientific and academic discourse."[71] The Fink Committee has laid out seven recommendations for the field of synthetic biology: (1) educating the scientific community; (2) reviewing plans for experiments; (3) reviewing at the publication stage; (4) creation of a National Science Advisory Board of Biodefense; (5) adoption of additional elements for protection against misuse; (6) a role for the life sciences in efforts to prevent bioterrorism and bio-warfare; and (7) harmonized international oversight.[72] The committee acknowledged that "DNA synthesis technology could allow for the efficient, rapid synthesis of viral and other pathogen genomes . . . either for the purposes of vaccine or therapeutic research and development, or for malevolent purposes or with unintended consequences."[73] Based on these recommendations, if synthetic biology advances into the scientific mainstream, international regulation will need to play a key role in its development to preserve public health safety.

C. BENEFITS OF SYNTHETIC BIOLOGY RESEARCH

There are currently six main research areas in synthetic biology: (1) DNA circuits; (2) protocells; (3) genome minimization; (4) unnatural components; (5) synthetic microbial consortia; and (6) synthetic metabolic pathways.[74] The field, however, will likely continue to expand into novel subjects in the next decade. While the term "synthetic biology" was first coined by French scientist Stephane Leduc in 1912,[75] the first scientific breakthrough came in 1963 when the first man-made biologically functional DNA molecules were isolated.[76] During 1978, researchers discovered how to alter DNA through cleavage at specific sites by utilizing restriction endonucleases.[77] After the achievement of cleaving DNA, synthetic biology has exploded into a new academic

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[71] *Id.*

[72] *Id.*

[73] *Id.* at 107.

[74] Lam, *supra* note 10, at 26.

[75] *Id.* at 24.

[76] Rose M. Litman & Waclaw Szybalski, *Enzymatic Synthesis of Transforming DNA*, 10 BIOCHEMICAL & BIOPHYSICAL RESEARCH COMMC'NS 473 (1963).

[77] Waclaw Szybalski & Ann Skalka, *Nobel Prizes and Restriction Enzymes*, 4 GENE 181 (1978).

discipline with scientists modifying existing organisms[78] and creating new unnatural building blocks and materials.[79]

Synthetic biology has the potential to offer new solutions to modern day challenges, especially in the areas of health care and energy. Biological switches resulting from DNA circuits can be incorporated into bacterial cells to allow for distribution of bacteria in human bodies for cancer treatment.[80] Additional synthetic circuits can sense the resistance of the tuberculosis virus to the drug ethionamide.[81] Synthetic metabolic pathways can help create bacteria that colonize tumors and deliver anti-cancer, anti-inflammation, and anti-HIV fusion drugs to target sites.[82] The creation of protocells utilizing synthetic building blocks can help scientists understand what environments were necessary for the origin of life.[83] For energy use, synthetic microbial consortia may degrade toxic pollutants resulting from oil spills which cannot be fully metabolized by existing organic organisms.[84] Moreover, synthetic biology projects offer the potential to synthesize hydrocarbon and diesel fuel from sugar and other biomasses[85] and the first usable hydrogen fuel cells could be developed through large scale microbial production of synthetically-modified photosynthetic bacteria.[86]

D. SYNTHETIC BIOLOGY AND BIOTERRORISM

Despite remarkable promise, researchers recognize that synthetic biology could be used for nefarious purposes. Synthetic biology is a dual-use technology, meaning it has the potential for both positive and harmful applications.[87] The most applicable research area to bioterrorism is the creation of unnatural components.[88] Through this application, a

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[78] *See* Ernesto Andrianantoandro et al., *Synthetic Biology: New Engineering Rules for an Emerging Discipline*, MOLECULAR SYSTEMS BIOLOGY, May 17, 2006, at 1.

[79] *See* Steven A. Benner & A. Michael Sismour, *Synthetic Biology*, 6 NATURE REV. GENETICS 533, 533-543 (2005).

[80] *See* Lam, *supra* note 10, at 26.

[81] *Id.* at 29.

[82] *Id.* at 31.

[83] *Id.* at 34.

[84] *Id.* at 37.

[85] *Id.* at 31.

[86] *Id.*

[87] MICHELE S. GARFINKEL ET AL., SYNTHETIC GENOMICS: OPTIONS FOR GOVERNANCE 2 (Oct. 2007).

[88] *Id.*

prospective bioterrorist could create a virus or bacteria that does not occur in nature. This new virus may be entirely novel or a synthetically modified version of an existing anthrax or plague bacterium that is especially virulent or antibiotic resistant.[89] What is more alarming is the recent ease of access to DNA information. Previously, DNA synthesis required research university level implements and expertise, and "now, anyone with a laptop computer can access public DNA sequence databases via the Internet, access free DNA design software, and place an order for synthesized DNA for delivery."[90]

Creating a *de novo* DNA synthesis is rapidly becoming easier through the use of DNA synthesizers.[91] These machines allow researchers to assemble novel and existing genetic sequences using readily accessible reagents.[92] The most simplistic way to construct a genetic sequence is to order a gene or genome-length stretch of viral or bacterial DNA from a commercial gene synthesis company.[93] There are currently forty-five organizations worldwide that have this capacity, with twenty-four companies located in the United States.[94] After obtaining DNA, an individual could utilize it for the purposes of synthetic biology and endeavor to make modifications that would increase the pathogenicity of the organism.[95] These purchases are closely tracked, particularly in the United States, where especially potent viral DNA strands such as anthrax and others are monitored by the US government. Alternatively, a researcher could start with smaller pieces of DNA called oligonucleotides or oligos.[96] Oligos are DNA building blocks of 15-100 base pairs that can be linked together to construct gene and genomic length DNA sequences.[97] As oligos are commercially available, this process is understandably more difficult to monitor. From these two options, motivated individuals can replicate bacteria and viruses for their personal and potentially reprehensible research.

Besides constructing a novel virus genome from scratch, other methods are available to bioterrorists. Currently, replicating genomes

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89 *Id.*
90 *Id.*
91 *Id.* at 2.
92 *Id.*
93 *Id.*
94 *Id.*
95 *Id.* at 15.
96 *Id.* at 2.
97 *Id.*

requires advanced technology and knowledge. While the goal of synthetic biologists is to make the replication process cheaper and easier to access for research purposes, it would still be difficult, though not impossible, for a non-state sponsored organization or terrorist group to utilize this process.[98] For now, the focus of scientists and policy makers is largely on laboratory security.[99] While viruses themselves can also be obtained in nature, isolation requires some skill and luck, and the introduction of foreign strands into a well-studied population such as the United States would immediately signal wary epidemiologists.[100] The more present threat is a bioterrorist obtaining samples of small pox or Spanish influenza from a poorly secured lab.[101] But experts warn that in ten years the situation may be reversed as "constructing a pathogenic virus might actually be easier than going to the trouble of isolating it from nature or stealing it from a secure laboratory."[102]

III. INTERNATIONAL REGULATION AND BIOTERRORISM

While biological threats from synthetic biology are currently only a future danger, it is critical that legal framework be in place to ensure global safety. As previously discussed, bioterrorism and biological warfare have existed for nearly a thousand years. Global regulation and international law, however, remain largely underdeveloped. While multilateral treaties and Security Council resolutions regarding bioterrorism exist, they focus primarily on the prohibition of biological weapons use and creating domestic legislation that has largely failed to materialize in practice. Moreover, there is dangerously little law and precedent for dual-use technologies such as synthetic biology that have the potential to be used for both public benefit and bioterrorism. This section will discuss the existing international law on bioterrorism and its deficiencies while introducing potential areas for improvement.

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98 *Id.* at 21.
99 *Id.* at 13.
100 *Id.*
101 *Id.*
102 *Id.* at 15.

A. OVERVIEW OF BIOLOGICAL WEAPONS PRECEDENT

The first international agreements that put forth regulations regarding the use of biological weapons were the 1899 and 1907 Hague Conventions, banning the use of chemical gases between two warring nation states.[103] Because rouge states and individual terrorists were nearly non-existent at the time, the conventions contain no provisions against the use of bioweapons by singular entities.[104] The 1907 Hague Convention uses more specific language, outright forbidding "poisoned weapons."[105] While these conventions are still under effect in the international legal sphere, they reflect the nascent science of the early twentieth century, when bioterrorism was not viewed as a credible threat because it was not seen as militarily feasible.[106]

The 1925 Geneva Protocol to the Hague Convention was the first international agreement to actually address biological weapons given the use of mustard gas and other noxious weapons during World War I.[107] The parties of Geneva Protocol "agree[d] to extend [the prohibition on the use of chemical weapons] to the use of *bacteriological* methods of warfare and agree to be bound as between themselves according to the terms of this declaration."[108] Though an outright prohibition on the use of biological weapons may seem effective, critics argue that it fails to effectively confront the problem of modern bioterrorism in three ways.[109] First, the Geneva protocol is applied only to the use of biological weapons, and not to their creation, development, or acquisition.[110] Moreover, many nations have entered legally binding reservations on this point and continue to stockpile biological weapons, withholding the right

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[103] Declaration on the Use of Projectiles the Object of Which is the Diffusion of Asphyxiating or Deleterious Gases, Jul. 29, 1899, 32 Stat. 1803.

[104] Eric Merriam, *The International Legal Regime Affecting Bioterrorism Prevention*, 3 NAT'L SECURITY L.J. 1, 6 (2014).

[105] Convention (IV) respecting the Laws and Customs of War on Land and its annex: Regulations concerning the Laws and Customs of War on Land, art. 23, Oct. 18 1907.

[106] BARRY KELLMAN, BIOVIOLENCE: PREVENTING BIOLOGICAL TERROR AND CRIME 56 (Cambridge University Press 2007).

[107] Merriam, *supra* note 104, at 5.

[108] Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571, 94 L.N.T.S. 65 (emphasis added).

[109] Merriam, *supra* note 104, at 12.

[110] *Id.* at 6.

to respond in kind in the event of a biological weapons attack.[111] Second, the Geneva Protocol is an addendum to the original Hague Convention on the international laws of war and, as such, only applies when a war is actually declared and not during internal conflicts or peace time.[112] This provision is especially ill-equipped in the modern era of individual and non-state actors who do not have the capacity to officially declare a war, and are thus exempted from the provision.[113] Third, the Geneva Protocol only applies to "bacteriological" weapons which per se excludes viruses and genes found in synthetic biology experiments.[114] These deficits were the impetus behind a larger and more focused biological weapons treaty.

B. THE BIOLOGICAL WEAPONS CONVENTION OF 1972 AND ITS DEFICIENCIES

The seminal agreement on biological weapons was reached in the Biological Weapons Agreement of 1972. Article 1 of this treaty corrects some of the original problems with the Geneva Protocol and articulates that member states agreed to:

> [N]ever in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[115]

The "never in any circumstances" clause and the prohibition against development and stockpiling clearly address the wartime and development issues in the Geneva Protocol. The clause, however, becomes especially problematic in fields such as synthetic biology where dual-use science exists. While gene editing can be used for nefarious purposes to engineer super-powered viruses and bacteria, it can also be

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[111] Michael P. Scharf, *Clear and Present Danger: Enforcing the International Ban on Biological and Chemical Weapons Through Sanctions, Use of Force, and Criminalization*, 20 MICH. J. INT'L L. 477, 481 (1999).

[112] *See generally* BAREND TER HAAR, THE FUTURE OF BIOLOGICAL WEAPONS 2 (The Washington Papers 1991).

[113] *Id.*

[114] *Id.* at 3.

[115] The Biological Weapons Convention, art. 1, Apr. 10, 1972, 1015 U.N.T.S. 163; 11 ILM 309 (1972).

used to treat disease and advance other fields.[116] An outright ban would "sacrifice science's critical function in improving humanity's health on the altar of narrowly construed notions of national security."[117]

In an attempt to ameliorate the dual-use problem, the Biological Weapons Convention (BWC) leaves open the definition of a "biological weapon," instead focusing on "types" and "quantities" of biological weapons that have "no justification for prophylactic, protective, or other peaceful purposes."[118] The "no justification" clause was designed to "future-proof" the treaty by not outlining specific agents unknown to the treaty authors, but it is worrisomely vague.[119] For example, the vagueness of the clause would not provide an answer to how much botulinum toxin an academic lab is allowed to have in studying disease before it crosses the threshold into "no justification." This lack of specificity permits the production of dangerous biological agents so long as there is a justifiable purpose.[120] Unlike other international agreements, the BWC has never been supplemented with an addenda on agent types or quantities that are prohibited or definitional clarity on what constitutes "prophylactic, protective or peaceful purposes."[121] This allows members to determine for themselves what constitutes a biological weapon and what types of research are prohibited, somewhat defeating the purpose of an international treaty.

Additionally, while the BWC does not exclusively focus on non-state actors, it does include important provisions to counter terrorist actions. Article V of the BWC states: "[i]n accordance with its constitutional processes, [a state may] take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere."[122] Though it does not explicitly mention non-state actors, each state is required to undertake legislation to prevent such activity within its individual jurisdiction.[123] This allows, however, for a great

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[116] SCHMIDT ET AL., *supra* note 45, at 3..
[117] FIDLER, *supra* note 3, at 2-3.
[118] *See* Biological Weapons Convention, *supra* note 115.
[119] TER HAAR, *supra* note 112, at 2
[120] Merriam, *supra* note 104, at 12.
[121] *Id.*
[122] *See* The Biological Weapons Convention art 1, *supra* note 115.
[123] Merriam, *supra* note 104, at 15.

variety of adopted protections chosen by nations, creating barriers to internationally collaborated research and global deficiencies in weapons protection.[124] Because it is not mandatory, only a small number of member states have chosen to adopt comprehensive bioweapons prevention legislation.[125] Moreover, while Article IV of the BWC mandates that states "prevent the development, production, stockpiling, acquisition, or retention" of biological weapons, it does not compel states to limit their use by non-state actors. While preventing these actions may exist in customary international law, such terrorist conduct is not explicitly illegal under international law, creating a seemingly contrary oversight.[126]

While the BWC prohibits the development, production, and stockpiling of biological weapons, its primary deficit is its lack of any sort of verification regime to ensure that member states are not actually creating biological weapons of mass destruction.[127] Exemplifying this weakness, only a single instance of compliance or enforcement language can be found. The language, in Article V, states: "the States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the UN and in accordance with its Charter."[128] While individual states may lodge a complaint with the UN Security Council if they suspect the use or production of biological weapons, filing a complaint requires the complaining state to have knowledge of the act and utilize diplomatic mobilization.[129]

Article V of the BWC provides for "formal consultative meetings" after an allegation of non-compliance, but no individual intelligence gathering is allowed. Instead, information about the biological weapons program is provided by the state accused of malicious intent.[130] While the Security Council could subsequently act if a complaint was substantiated, the practical issues of the time necessary

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[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] *See* The Biological Weapons Convention, *supra* note 115.
[129] *Id.*
[130] Merriam, *supra* note 104, at 18.

for a state to gather evidence and for the Security Council to investigate remains. These issues, combined with the ease of disposing, repurposing, or hiding many of the covered agents and the likely political pressures inherent in the Security Council's permanent member veto system, would make any enforcement action against a violator highly unlikely, especially before the biological weapon's use.[131]

Many of these concerns were recognized by international actors. Numerous attempts were made since 1972 to modify the BWC. For instance, amidst suspicions of Soviet Union non-compliance in 1986, several UN member states undertook voluntary confidence-building measures which "called for the exchange of information about research centers and laboratories with high-containment facilities and data on unusual outbreaks of disease."[132] Currently, confidence building measures include requirements for "state parties to report to all other states parties data on various issues, including laboratories and research centers, national biological defense research and development, outbreaks of infectious diseases that deviate from 'normal patterns,' past activities in offensive or defensive biological research and development, efforts to encourage publication of results of biological research directly related to the BWC, declaration of legislation, regulations or other measures states have taken to implement the BWC, and declaration of vaccine production facilities."[133]

Though an ad hoc group of states attempted to draft a verification protocol amendment to the agreement between 1995-2001, it was later invalidated over the United States' concerns that the proposed protocol was too weak and had too great of an effect on US pharmaceutical companies.[134] After the US anthrax attacks in 2001, the US reopened talks with European countries on revisions to the BWC and offered alternative compliance plans.[135] These proposed plans, however, did not offer a cohesive international solution, but rather encouraged individual member states to improve their internal public health and legal measures to prevent bioterrorism.[136]

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[131] *Id.*
[132] *Id.* at 19.
[133] *Id.* at 20.
[134] Fidler, *supra* note 3, at 13.
[135] *Id.* at 14.
[136] *Id.*

C. UN SECURITY COUNCIL RESOLUTION 1540

In 2004, UN Secretary General Kofi Annan, stated, "we need to pay much closer attention to biological security" and "build an effective global defense against bioterrorism."[137] This call to action inspired the passing of Security Council Regulation 1540 (UNSCR 1540), the current binding international agreement addressing biological weapons.[138] In responding to the post 9/11 world and biological terrorism, UNSCR 1540's critical contributions beyond the BWC are: "1) a focus on non-state actors; 2) the effect of a UN Security Council Resolution, including application to states not parties to BWC; 3) greater specificity regarding measures states must take to help prevent bioterrorism; and 4) a first step in the direction of a quasi-compliance body with some very limited verification and enforcement role."[139] Per the agreement, "states are both prohibited from assisting non-state actors and are compelled to adopt procedures and *effective* laws, which must be enforced, that prohibit non-State actors from using and developing biological weapons."[140] Moreover, as a Security Council resolution, all states must comply with UNSCR 1540; states cannot protect internal biological weapons programs by refusing to sign onto a treaty.[141] The resolution also extends far beyond the vague terms of the Biological Weapons Convention, as UNSCR 1540 "provides specific actions states must take to meet their international obligations, including measures regarding security, physical protection and border and export controls."[142]

The specific actions that states must take are detailed in UNSCR 1540(3). Per the resolution:

> States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall: (a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport; (b) Develop and maintain appropriate effective physical protection measures; (c) Develop and maintain appropriate effective border controls and law enforcement efforts to detect, deter, prevent

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[137] *Id.* at 4.
[138] Merriam, *supra* note 104, at 22.
[139] S.C. Res., *supra* note 37.
[140] Merriam, *supra* note 104, at 24 (emphasis added).
[141] *Id.* at 25.
[142] *Id.* at 30.

> and combat, including through international cooperation when necessary, the illicit trafficking and brokering in such items in accordance with their national legal authorities and legislation and consistent with international law; and (d) Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over such items, including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such export and trans-shipment such as financing, and transporting that would contribute to proliferation, as well as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations.[143]

Though effective at regulating traditional bioterrorism focused on preventing laboratory security breaches and the exchange of already weaponized viruses and bacteria, this provision is not effective at curtailing threats from synthetic biology. It does not require nations to monitor dual-use research within their own borders and is focused largely on containment versus prevention. The BWC cannot provide this governance because it calls for an outright ban, which cannot apply to multiple purpose technology like synthetic biology. Thus, UNSCR 1540 becomes the most pertinent international law. But while UNSCR 1540 could prevent the transport of synthetically-modified bioweapons, it largely relies on states to establish domestic controls. Therefore, more guidance is needed to ensure global safety.

D. POTENTIAL OPTIONS FOR CREATING SYNTHETIC BIOLOGY RESEARCH GOVERNANCE UNDER INTERNATIONAL LAW

Unified international governance is needed to contain the threat created by synthetic biology. Because UNSCR 1540 calls upon member states to establish pertinent domestic legislation, one solution is the Security Council proposing a model act that details the research standards, control guidelines, and containment expectations for synthetic biology experiments. This would likely, however, create a diplomatic relations issue, as model legislation may be perceived as infringing on national sovereignty.

Additionally, the model act would need to pass in the domestic legislatures of 193 UN member states to achieve the global parity

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[143] S.C. Res., *supra* note 37.

necessary for the act to be effective.[144] This would be largely improbable. A better solution might be a new Security Council resolution or addenda to UNSCR 1540 that more directly confronts the issues of synthetic biology and other dual-use technologies. Such a resolution would be automatically binding under international law, creating a concrete legal mechanism.[145] The Security Council, however, does not necessarily have the expert knowledge needed to set research standards for an entire field. Acting in this manner would require the participation of researchers throughout the world to promote compliance and ensure that scientific progress is not unduly stifled.

Another option is to increase criminalization of scientist and terrorist actors who utilize synthetic biology for adverse purposes. Though not formally recognized in any current international treaty, a potential option for increasing biosecurity lies in the International Criminal Court (ICC). The ICC could potentially apply its universal jurisdiction to individual terrorists and terrorist organizations through the international law principle of "*hostis humani generis*"— translated to "an enemy of all human kind."[146] This is especially relevant for concerns about synthetic biology, which due to its bioinformatic aspects, could be performed by anyone with an internet connection and access to basic scientific facilities. Especially with the advent of non-state terrorist organizations, allowing the ICC to prosecute atypical actors could enhance global safety from biological weapons threats.

The Harvard Sussex Program on Chemical and Biological Warfare Armament and Arms Limitation synthesized potential ICC remedies in its proposed Convention on the Prevention and Punishment of the Crime of Developing, Producing, Acquiring, Stockpiling, Retaining, Transferring or Using Biological or Chemical Weapons.[147] Though the use of a biological weapon by an individual terrorist could be subject to ICC criminal sanctions under the 2001 UN Convention on the Suppression of Terrorist Bombings, a separate classification of bioterrorism as *hostis humani generis* would serve as an important indicator that such conduct will be universally prohibited.[148] Proponents

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[144] United Nations, Growth in United Nations Membership 1945-Present, http://www.un.org/en/members/growth.shtml (last visited Mar. 27, 2016).

[145] *See* Marko Divac Oberg, *The Legal Effects of Resolutions of the UN Security Council and General Assembly in the Jurisprudence of the ICJ*, 16 EUR. J. INT'L. L. 879, 879-906 (2006).

[146] *See generally*, Fidler, *supra* note 3, at 14.

[147] *Id.* at 14.

[148] *Id.*

of the proposed Harvard convention seek "express criminalization of the use of biological weapons by states and terrorist organizations."[149] Opponents argue, however, that this classification would largely be useful in name only, because international law does not have a large deterrent effect on individuals.[150] Most terrorist actions are already illegal in the jurisdictions in which such groups operate, and opponents argue that international focus should be on preventing, not prosecuting, biological weapons attacks.[151] Therefore, increasing ICC prosecution, though useful, could only be one small piece of global legal protection against bioterrorism.

A final viable option would be increasing the involvement of the World Health Organization (WHO). An umbrella organization of the UN, the WHO does not shape bioterrorism policy. The WHO does, however, issue guidance for member nations to build bioterrorism preparedness and respond to attacks— one of its six focuses is "preparedness, surveillance, and response."[152] Moreover, part of the mission of WHO is to "shape the research agenda," set international "norms and standards" for research and "articulate ethical . . . policy options."[153] While the WHO has previously only been involved in monitoring disease outbreaks, it could help take an active role in setting the standards for synthetic biology research. Because WHO is an organization that has direct contact with UN member nations through its World Health Assembly, it is a neutral forum for the international community to set guidelines for the security risks inherent to synthetic biology. This space would allow countries to come together with the aid of research scientists to create a comprehensive risk/benefit assessment for the dual-use technology of synthetic biology.

Although the WHO does not create binding legal precedent under international law, its governance constitutes "soft law" as interpreted by the International Court of Justice (ICJ).[154] Article 38(1)(b) of the Statute of the International Court of Justice states that the Court

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[149] *Id.*

[150] *Id.*

[151] *Id*.

[152] Gro H. Brundtland, Former Director-General, Bioterrorism and Military Health Risks (Jan. 25, 2003), *in* WORLD HEALTH ORGANIZATION, *available at* http://www.who.int/dg/brundtland/speeches/2003/DAVOS/en/.

[153] WORLD HEALTH ORG., *What We Do*, http://www.who.int/about/what-we-do/en/ (last visited Mar. 27, 2016).

[154] *Id.*

may consider "international custom . . . as derived from general practice based on perception of a legal requirement."[155] Through this section, the Court has found UN resolutions governing bodies such as the WHO to be credible because the international community expects member states to comply with them.[156] As such, a resolution setting the research standards for synthetic biology could eventually become international law, provided that member states complied with the WHO guidance.

IV. PROPOSALS FOR COMMUNITY POLICING AMONG SCIENTIFIC RESEARCHERS

Any governance proposal for synthetic biologists must include the researchers on the ground. Synthetic biologists are perhaps more aware of biosecurity risks resulting from their research than international legal bodies and policing organizations. Having the strongest grasp on the technology and necessary procedures, scientists may be in a better position to create internal safeguards and police their own community. Because the field is so novel, it is a valid concern that stringent domestic and international regulation may stifle progress and ingenuity, especially considering that synthetic biology has enormous potential to revolutionize several different fields that will benefit humanity. Therefore, legal practitioners seeking to regulate the synthetic biology process should first look to the initiatives proposed by scientists.

A. BIOSAFETY VERSUS BIOSECURITY

For this approach to work, the scientific community must address two crucial issues. First, a distinction must be drawn between biosafety and biosecurity.[157] Many of the current proposed regulations that have dominated recent research proposals and conferences have focused on biosafety.[158] Biosafety addresses the "inherent risks of a biological agent or material to cause unintentional harm to human health and the environment."[159] In contrast, "biosecurity" concerns itself with the intentional muses of a biologic agent or material through loss, theft,

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[155] *Id.*
[156] *Id.*
[157] KELLE, *supra* note 61, at 116.
[158] *Id.*
[159] *Id.*

diversion, release, or inadvertent research results that have security implications.[160] Second, awareness of the risks associated with synthetic biology is decidedly low in the scientific community given that the research itself is both nascent and highly specialized.[161] A recent study conducted by a group of European scientists dedicated to researching the safety and ethical implications of synthetic biology "revealed a number of gaps on the part of synthetic biology practitioners in relation to their awareness of the unfolding biosecurity discourse."[162] In order to have a stake in the developing conversation on regulations of synthetic biology, researchers must educate themselves and their institutions about the biosecurity threats inherent to their field.

B. COMMUNITY POLICING PROPOSALS OF CONTEMPORARY SCIENTISTS

The earliest example of community policing by scientific researchers is George Church's paper "Synthetic Biohazard Non-Proliferation Proposal."[163] Church suggests that a federal agency, such as the Centers for Disease Control, the Federal Bureau of Investigation or the Department of Homeland Security be responsible for setting up a "clearinghouse" to screen commercial DNA and oligonucleotide orders for specific reagents necessary to conduct synthetic biology research.[164] These organizations would issue government licenses for specific instruments and reagents so as to limit their use.[165] This approach has been advocated for in the US Congress.[166]

Through the work of the Fink Committee and the increasing attention on regulation in the scientific community, the US government set up the National Science Advisory Board for Biosecurity (NSABB).[167] This group consults scientists in the field and seeks to "develop criteria

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[160] *Id.*

[161] *Id.*

[162] *Id.*

[163] George Church, *A Synthetic Biohazard Non-Proliferation Proposal*, HARVARD MEDICAL SCHOOL (May 21, 2005), http://arep.med.harvard.edu/SBP/Church_Biohazard04c.htm.

[164] *Id. at 2*

[165] *Id.*

[166] *Id.*

[167] NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents* (2006), *available at* http://osp.od.nih.gov/sites/default/files/resources/Final_NSABB_Report_on_Synthetic_Genomics.pdf.

for identifying dual-use research results" (i.e. research that could be used for both beneficial and malignant purposes) and create guidelines for the oversight of such research, including a risk/benefit analysis of the research and its results.[168] It also seeks to develop strategies to promote international oversight of synthetic biology.[169] A report made by the NSABB that was released to the public in 2006 recommended that the US government utilize the Department of Agriculture and the Department of Health and Human Services to "develop and disseminate harmonized guidance to investigators and genetic providers . . . [and to] develop a process to be used by providers of synthetic DNA for determining the sequences for which to screen."[170] The report also recommended the agencies should further consult with experts in the field to create a Select Agent classification system to determine if it is possible to reconcile the controls needed for such agents and the anticipated scientific advances enabled by synthetic genomics.[171]

Perhaps surprisingly, some of the most restrictive plans to police the field of synthetic biology have been brought forwards by scientists. In 2002, a group of researchers at the University of Maryland developed "a protective oversight system for dangerous biological agents and research."[172] Led by Dr. John Steinbrunner, these scientists advocated for "an oversight process designed to bring independent scrutiny to bear throughout the world without exception on fundamental research activities that might plausibly generate massively destructive or otherwise highly dangerous consequences."[173] The Maryland researchers' system proposed independent scrutiny for all synthetic biology research projects, not just publicly funded work, and promoted a far more global emphasis.[174] Furthermore, the proposed system actually creates a tiered system that necessitates three levels of scrutiny: (1) activities of potential concern that will be subjected to local peer review oversight; (2) activities of modern concern to national oversight; and (3) activities of extreme concern that will receive the largest amount of scrutiny at the international level.[175]

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[168] Kelle, *supra* note 61, at 108.
[169] *Id.*
[170] *Id.* at 109.
[171] *Id.*
[172] KELLE, *supra* note 61, at 109.
[173] *Id.*
[174] *Id.*
[175] *Id.*

Other synthetic biologists chafe at such restrictions to the scientific process and believe that the same national security protections can be achieved "through community self-governance and without outside intervention."[176] Recognizing the potential biosecurity threat from their research, an international coalition of scientists drafted a four-point "Declaration of the Second International Meeting on Synthetic Biology" which focused on risks associated with the DNA synthesis process.[177] The scientists identified the most effective intervention point for preventing the misuse of synthetic biology at the level of DNA synthesis. Accordingly, the plan targets gene synthesis firms, oligonucleotide manufactures, and DNA synthesizers.[178] The authors felt that by screening orders of companies and having a biosecurity officer certify orders, a lesser burden would be placed on research while accomplishing the necessary national security goals.[179]

Other groups have expanded on this proposal. Most notably, the International Consortium for Polynucleotide Synthesis (ICPS) developed a "tiered DNA synthesis Order and Screening Process."[180] First, under the process, individuals who place orders for synthesis supplies would be required to identify themselves and their university organization.[181] The orders would then be compared against a set of select agencies and sequences by validated software tools in order to ensure regulatory compliance.[182] The software would also flag synthesis orders for further review if necessary.[183] Finally, ICPS would interface with global government agencies to continually improve the technologies used to screen orders and identify potentially dangerous sequences while further developing a clear reporting mechanism for flagged dangerous activity.[184]

Alexander Kelle, a leading scholar in the field, however, has offered the most comprehensive strategy. Kelle's proposal focuses on developing a "broader-based approach that includes all stakeholders in the development of synthetic biology as a discipline and its potential future application that is flexible enough to accommodate a range of

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[176] *Id.* at 111.
[177] *Id.* at 107.
[178] *Id.*
[179] *Id.*
[180] *Id.* at 112.
[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *Id.*

scenarios of how the field might develop."[185] Titled the "5P-strategy," Kelle's model focuses on five different policy intervention points, most notably: the principle investigator, the project, the premises, the provider of genetic material, and its purchaser.[186] Kelle argues that while screening the purchasing process for potential biosecurity threats is a way to regulate the field, it fails to address the "full spectrum of potentially available measures to minimize biosecurity concerns."[187]

Additionally, Kelle points to the BWC for specific instances where international legal regulation must improve. While the BWC in principle covers the study of synthetic biology, it does little to prevent biosecurity threats at a practical level. For one, the BWC is so general that it does not provide specific guidance to regulators.[188] While it is likely that the drafters of the convention anticipated that each individual sovereign nation would enact legislation on the national level to address this deficiency, most state parties have either enacted insufficient laws or none at all.[189] Additionally, there are no verification protocols in the BWC and thus no mechanisms in place to inspect state facilities to ensure that the treaty is not being violated.[190]

Partially alleviating this gap in regulation, international trade regulations have been implemented by a consortium of countries called "the Australia group."[191] An informal union of nation states, the Australia group utilizes the harmonization of export controls to "ensure that exports do not contribute to the development of chemical or biological weapons.[192] As such, the group is currently responsible for screening most synthetic DNA orders.[193] These include:

> genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms on [the biological weapons convention] list, genetic elements that contain nucleic acid sequences coding for any of the toxins on the list or their subunits, genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms on

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185 *Id.* at 114.
186 *Id.*
187 *Id.*
188 *Id.* at 115.
189 *Id.*
190 *Id.*
191 *Id.*
192 *Id.*
193 AUSTRALIA GROUP, *List of Human and Animal Pathogens and Toxins for Export Control* (Aug. 2016), http://www.australiagroup.net/en/human_animal_pathogens.html.

> the list, and genetically modified organisms that contain nucleic acid sequences for any of the toxins in the list or their subunits.[194]

Again, the Australia Group recommendations are not wholly sufficient because they do not provide any mechanism for the regulation of domestic transfers. Rather, they merely apply to genetic materials that pass through international customs. Even in countries with well-regulated scientific communities such as the United States and the EU, such transfers are more relaxed, with the rule of law focused on biosafety in the transfer or biologics and not targeted toward biosecurity threats.[195] The harmonization of domestic and international regulations must be undertaken at the global level to ensure the greatest level of effectiveness in policing synthetic biology. It is clear, however, that scientists can make significant contributions towards creating legal regulation that confronts bioterrorism concerns while also ensuring the greatest freedom of research.

V. CONCLUSION

Synthetic biology may be the future of bioterrorism. To be prepared, the international community must move beyond outdated conventions and UN regulations and take this threat seriously. A comprehensive coalition must be mobilized to undertake these efforts and write the laws and regulations that will help contain the science without stifling its enormous potential. Existing regulation must be bolstered and new addenda or model legislation specific to synthetic biology should be drafted. Additionally, regulators must work with the scientists on the front lines to develop research procedures that foster biosecurity while promoting the advancement of science for public use. Now is the time to create international legal standards that will preserve global safety.

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[194] *Id.*

[195] KELLE, *supra* note 61, at 115.