Necessary Measures: Synthetic Biology & the Biological Weapons Convention

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ABSTRACT

Access to genetic information, gene fragments, and tools for synthetic DNA production is poorly guarded. Anyone seeking to design or manipulate pathogens can obtain the necessary tools to do so from commercial manufacturers in a number of ways. As a result of this regulatory gap, the United States is not taking the "necessary measures" to prevent bioweapon development in violation of the Biological Weapons Convention. This treaty was successfully implemented into federal law, it was not abrogated by its implementing statute, and today it remains the law of the land. Therefore, the United States is not only violating international law; it is also violating federal law. To comply with federal and international law, an executive agency should energetically regulate synthetic biology to prevent it from being weaponized.

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I. INTRODUCTION

The field of synthetic biology involves "redesigning organisms for useful purposes by engineering them to have new abilities."[1] Biological organisms can now be viewed "as a kind of high technology, as nature's own versatile engines of creation."[2] By applying engineering principles to biology, scientists are harnessing nature to solve problems in medicine, manufacturing, and agriculture.[3] Advances in the field show promise for visionary applications—from 'green' biofuels and biomaterials to cheaper pharmaceuticals and cancer-targeting therapies. Re-engineered organisms will change our lives for the better in the coming decades.[4]

New synthetic biology techniques, like building with BioBricks (akin to biological Legos), are tearing down barriers to entry.[5] Synthesizing novel DNA sequences has also become far simpler with the advent of DNA synthesizers, machines that allow researchers to assemble both novel and existing genetic sequences using readily accessible reagents.[6] Because of this, the simplest way to obtain a genetic sequence is to simply order a gene or genome-length stretch of viral or bacterial DNA from a commercial gene synthesis company.[7] Alternatively, a researcher could start with smaller pieces of single-stranded

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[1] *Synthetic Biology*, NAT'L HUM. GENOME RSCH. INST., https://perma.cc/DM8U-6CE7 (archived Oct. 8, 2019).

[2] GEORGE CHURCH & ED REGIS, REGENESIS: HOW SYNTHETIC BIOLOGY WILL REINVENT NATURE AND OURSELVES 4 (2012).

[3] *Synthetic Biology*, *supra* note 1; *see also* Justin Firestone, *The Need for Soft Law to Regulate Synthetic Biology*, 60 JURIMETRICS J. 139, 141–42 (2020).

[4] Ahmad S. Kalil & James J. Collins, *Synthetic Biology: Applications Come of Age*, 11 NATURE REV. GENETICS 367, 367 (2010).

[5] CHURCH & REGIS, *supra* note 2, at 158.

[6] Nicole H. Kalupa, *Black Biology: Genetic Engineering, the Future of Bioterrorism, and the Need for Greater International and Community Regulation of Synthetic Biology*, 34 WIS. INT'L L.J. 952, 964 (2017).

[7] *Id.*

DNA (called oligonucleotides), chemically stitch them together, and replicate their complimentary strand to construct full length DNA sequences.[8]

The democratization of the field has been rapid. The explosion of synthetic biology in the 2000s spawned the iGEM Competition, where students from around the world gather in the United States to compete in creative biological problem solving.[9] Previously, DNA synthesis required research university-level implements and expertise, but 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."[10]

But the issue with making bioengineering techniques easy to use is that it also makes them easy to abuse.[11] Ensuring that synthetic biology research is safe and secure in institutions like universities, industry, or government labs is already an immense challenge.[12] The prospect of "biohackers"—individuals or groups of amateurs working with biological systems that have been intentionally made easy to use—makes matters worse.[13] For all of synthetic biology's potential benefits, George Church explains that it is "potentially more dangerous than chemical or nuclear weaponry, since organisms can self-replicate, spread rapidly throughout the world, and mutate and evolve on their own."[14] This danger applies to well-intentioned and nefarious actors alike.

The same biological materials and facilities used for benevolent purposes in medicine and agriculture can also be used for destruction—a classic "dual use" problem.[15] A nation, corporation, or research lab can disguise its activities

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[8] *Id.*

[9] *See About*, INT'L GENETICALLY ENG'RED MACH., https://perma.cc/BW2P-YWNW (archived Oct. 8, 2021).

[10] Michele S. Garfinkel et al., *Synthetic Genomics | Options for Governance*, 5 BIOSEC. AND BIOTERRORISM: BIODEF. STRATEGY, PRAC., AND SCI., 359, 360 (2007).

[11] CHURCH & REGIS, *supra* note 2, at 230–32.

[12] NAT'L ACADS. OF SCI., ENG'G, & MED., BIODEFENSE IN THE AGE OF SYNTHETIC BIOLOGY 144 (2018) [hereinafter NAS REPORT] ("[I]t would be extremely difficult, if not impossible, to distinguish a facility being used to develop bioweapons based on synthesized pathogenic bacteria from a legitimate academic or commercial facility.").

[13] *See, e.g.*, Firestone, *supra* note 3, at 139, 148 ("[Synthetic biology] allows anyone with $2,000 to manipulate DNA, RNA, and its flow within and without cells. A DIY SB kit is currently available for purchase for under $2,000, which 'provides all the equipment, reagents and materials you need to get started in molecular biology and genetic engineering,' including a centrifuge add-on, shipping not included. There are even cheaper kits for $150, targeted for middle-school science classrooms and home use, which 'let you edit a bacterial gene using instructions made for those without expertise in little more than a weekend.'").

[14] CHURCH & REGIS, *supra* note 2, at 231.

[15] *See* JULIAN KU & JOHN YOO, TAMING GLOBALIZATION: INTERNATIONAL LAW, THE U.S. CONSTITUTION, AND THE NEW WORLD ORDER 64 (2012). The "dual use" problem applies to many species of weapons of mass destruction, including chemical and nuclear weapons.

behind a civilian-use front.[16] While synthetic biology could result in accidental or careless harm, this note will focus solely on the use of synthetic biology for malevolent purposes.[17]

It is easy to see why a biological weapon would be appealing for malicious purposes.[18] Unlike nuclear weapons programs, which require specialized facilities and fissile materials that are difficult and expensive to produce, biological weapons can be produced with readily available dual-use substances and equipment.[19] Thus, biological weapons have been called "the poor man's atom bomb," and given that new synthetic biology techniques have made contorting nature much more accessible, the poor man's atom bomb is now far simpler to create than even a few decades ago.[20]

While bioterrorism may sound like a sci-fi plot, it has been widely researched and occasionally executed.[21] Bioterrorism is "the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants."[22] Biological agents used for terrorism can be very difficult to detect and may spread easily from person to person long before symptoms arise.[23] Because of the complexity and unpredictability of how biological agents spread among human populations, public fear could spread faster than the disease itself.[24] Globalization has allowed disease and terrorism to move through the same quick channels of transportation and communications as international trade and capital.[25]

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[16] *See id.*

[17] There is currently a regulatory gap concerning unintended harm, which is beyond the scope of this piece.

[18] *See, e.g.*, Matthew S. Halpin, *Biological Warfare: The Weaponization of Naturally-Occurring Biological Diseases*, 16 HOUS. J. HEALTH L. & POL'Y 259, 266 (2016) ("Unlike standard military firearms and chemical weapons, significantly less research and development go into the weaponization of naturally-occurring biological diseases. While chemical and physical weapons require significant financial backing for development, production, testing, and other highly-technical aspects of manufacture, naturally-occurring diseases develop through evolution without human interaction.").

[19] 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, 478–79 (1999). Scharf explains that chemical weapons have the same characteristics.

[20] *Id.* at 477; *see also* Rob Reid, *Deterrence – and the Undeterrable*, MEDIUM (Oct. 11, 2018), https://perma.cc/A53W-S6YT.

[21] Andrea Howard, *The Pandemic and America's Response to Future Bioweapons*, WAR ON THE ROCKS (May 1, 2020), https://perma.cc/9MX2-E5GK.

[22] *Bioterrorism*, U.S. DEP'T OF HEALTH & HUM. SERVICES (Feb. 22, 2011), https://perma.cc/4BFY-7RHT.

[23] *Id.*

[24] Halpin, *supra* note 18, at 281-88.

[25] KU & YOO, *supra* note 15, at 63.

And while bioterrorists can try to deploy harmful viruses or bacteria already in existence, such as smallpox, they can also attempt to create "unnatural components."[26] Through this application, a prospective bioterrorist could create a virus or bacterium that does not occur in nature.[27] Such an agent may be entirely novel or a synthetically modified version of an existing anthrax or plague bacterium that is especially virulent or antibiotic resistant.[28]

A prospective bioterrorist could order gene or genome-length viral or bacterial DNA sequences from a commercial gene synthesis company and modify them to increase the pathogenicity of the organism.[29] Pathogens that have been identified as potential biological warfare agents include those that cause "anthrax, botulism, plague, smallpox, tularemia, and the hemorrhagic fevers, among others."[30] A prospective bioterrorist could even attempt to synthesize an extant or novel agent by building it up from oligonucleotides.[31] These biomolecules are commercially available, and it is often difficult to discern harmful applications from such small pieces, making this process much more difficult to monitor.[32] From these two options, motivated individuals, with minimal facilities and resources, could replicate bacteria and viruses for reprehensible purposes.[33]

In the context of chemical weapons, a 1,600 square-foot laboratory can manufacture more than 100 tons of chemical weapons in a single year, and according to the Office of Technology Assessment, the U.S. alone has potentially 10,000 sites that qualify for inspection under the Chemical Weapons Convention.[34] The problem is far worse for synthetic biology.[35] With the advent of powerful new synthetic biology techniques, it is not even worth estimating how many sites could produce dangerous bioagents.

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[26] Kalupa, *supra* note 6, at 963–64.

[27] *Id.* at 964.

[28] *Id.*

[29] *Id.*

[30] *Countering Bioterrorism and Emerging Infectious Diseases*, FDA, https://perma.cc/CU8M-4DTL (archived Oct. 8, 2020).

[31] Kalupa, *supra* note 6, at 964.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *See, e.g.*, Victoria Sutton, *Emerging Biotechnologies and the 1972 Biological Weapons Convention: Can It Keep Up with the Biotechnology Revolution?*, 2 TEX. A&M L. REV. 695, 713 (2015) ("More than once, and before a Congressional hearing, the U.S. Centers for Disease Control and Prevention has declared that it is unknown how many or where all the biological containment laboratories are in the United States and that, because there is no regulation that requires such disclosures, no regulatory agency is tracking this data unless the laboratory is involved in a federally funded contract.").

The publication of virulent pathogen genomes and "do-it-yourself synthetic biology culture" enable misuse, yet "participating journals and authors have only received public reprimands from peers, at most."[36] The open-access mentality that pervades the field of synthetic biology, coupled with a lack of regulatory infrastructure regarding gene fragment distribution, further promotes the potential misuse and delivery of malicious agents.[37]

This note surveys the measures the U.S. is currently taking to prevent bioweapon development from synthetic biology technologies and techniques, analyzes its legal obligations, and concludes that the United States' failure to meaningfully regulate synthetic biology to prevent bioweapon development violates both international and federal law. More broadly, this note hopes to spur discussion about how much energy and resources should be devoted to preventing uncertain, but potentially catastrophic, harms. (This author's view is, in short, "quite a bit").

This note makes two novel contributions to the literature. First, it makes the claim that the U.S. is violating the Biological Weapons Convention of 1972 ("BWC") by failing to meaningfully regulate synthetic biology to prevent bioterrorism. Second, it argues that the BWC was implemented into federal law and became the law of the land. Therefore, by failing to comply with the BWC, the U.S. is also violating federal law.

This note proceeds in five parts. In Part II, I detail the United States' main legal obligations regarding bioweapons under international and federal law. The three most important instruments are the Biological Weapons Convention, the Biological Weapons Act of 1989, and United Nations Security Council Resolution 1540.

In Part III, I argue that the United States is violating international law by failing to comply with its obligations under the BWC. Synthetic biology is encompassed under the Convention, the Convention imposes a mandatory duty to regulate non-state actors, and the U.S. is not taking the "necessary measures" to prevent bioweapon development.

In Part IV, I make the case that the United States is also violating federal law by failing to meet its obligations under the BWC. The treaty was implemented into federal law via the Biological Weapons Act of 1989, thus becoming the law of the land. The "last-in-time" rule, which provides that if a statute and a treaty are in conflict the most recent instrument governs, has no

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[36] Brendan Parent, *Reproduction-Powered Industry: Coordinating Agency Regulations for Synthetic Biology*, 15 N.C. J.L. & TECH. 307, 343–44 (2014).
[37] *Id.*

application here. As the treaty and the statute do not conflict, they rest comfortably alongside one another as federal law.

Finally, in Part V, I explain how the United States can meet its obligations under federal and international law by regulating synthetic biology via a centralized clearinghouse system.

II. U.S. OBLIGATIONS UNDER INTERNATIONAL AND FEDERAL LAW

The three most important instruments regarding how the U.S. must regulate bioweapons are The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction ("BWC");[38] the Biological Weapons Anti-Terrorism Act of 1989 ("Biological Weapons Act"),[39] the statute that implemented the Biological Weapons Convention in the U.S.;[40] and the United Nations Security Council Resolution 1540.[41]

A. The Biological Weapons Convention of 1972

The 1925 Geneva Protocol was the first international agreement to address biological weapons.[42] The parties of the Geneva Protocol extended the prohibition of chemical weapons to the use of "bacteriological methods of warfare."[43] This nascent effort had several deficiencies, which ultimately led to the seminal agreement on biological weapons, the BWC.[44]

The BWC was the first multilateral disarmament treaty banning the development, production, and stockpiling of an entire category of weapons of mass destruction—biological weapons.[45] The United States signed the treaty in 1972, the Senate ratified it in 1974 (giving advice and consent required under Article II of the Constitution),[46] and President Ford signed the instruments of

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[38] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxic Weapons and on Their Destruction, Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163 [hereinafter BWC].
[39] 18 U.S.C. §§ 175-178.
[40] 18 U.S.C. § 175, Purpose and Intent.
[41] S.C. Res. 1540 (Apr. 28, 2004) [hereinafter UNSCR 1540].
[42] 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.
[43] *Id.*
[44] *See* Halpin, *supra* note 18, at 276.
[45] *See id.*; BWC, *supra* note 38.
[46] *See* Biological Weapons Anti-Terrorism Act of 1989 § 2(a).

ratification of the protocol in 1975, whereafter it entered into force with respect to the United States.[47]

Article I of the BWC bans states from developing bioweapons, employing a very capacious definition.[48] It provides that:

> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain . . . 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.[49]

Later on, Article IV notably adds that:

> Each State Party to this Convention shall, in accordance with its constitutional processes, 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.[50]

Subsequently, Article XII provides for the meeting of the parties five years after entry into force, or earlier upon parties' request,

> to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any *new scientific and technological developments* relevant to the Convention.[51]

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[47] *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Status of the Treaty*, UN OFF. FOR DISARMAMENT AFFS., https://perma.cc/U5WA-BGGE (archived Nov. 3, 2021). There are currently 183 State Parties and 109 State Signatories.

[48] *See* BWC, *supra* note 38, at 166.

[49] *Id.* Article I also prohibits weapons, equipment, and delivery systems used for hostile purposes or warfare.

[50] BWC, *supra* note 38, at 167 (emphasis added).

[51] *Id.* at 168. (emphasis added). The BWC also has several major weak points. Most prominently, it does not include a compliance mechanism. Additionally, though it includes a reporting mechanism where a state can complain of another country's violation, it is extremely difficult to determine objectively whether a member is *intentionally* engaging in malicious activity or legitimate research. *See* Kalupa, *supra* note 6, at 968-80.

The obligations created under the BWC are broad, prophylactic, and forward-looking.

B. The Biological Weapons Act Of 1989

Congress gave the BWC domestic effect in 1989 when it passed the Biological Weapons Act.[52] The statute had two principal purposes: (1) "to implement the 1972 Biological Weapons Convention, an international agreement unanimously ratified by the United States Senate in 1974 and signed by more than 100 other nations, including the Soviet Union"; and (2) to "protect the United States against the threat of biological terrorism."[53] To further the latter purpose, the law imposed criminal sanctions for developing bioweapons,[54] allowed the government to seize bioweapons,[55] and provided a cause of action for the U.S. to seek injunctions against violators.[56]

C. Security Council Resolution 1540

In 2004, the United Nations Security Council passed Resolution 1540 to strengthen international efforts to combat the development of biological weapons.[57] As the Security Council acted under Chapter VII of the Charter of the United Nations, this Resolution is binding international law. Resolution 1540 strengthened several points in the BWC by providing: (1) an explicit focus on nonstate actors; (2) applicability to states not parties to the BWC; (3) more specific measures states must take to prevent bioterrorism, including measures regarding security, physical protection, and border and export controls; and (4) very limited verification and enforcement.[58] The Security Council decided,

> that all States, in accordance with their national procedures, shall adopt and enforce appropriate effective laws which *prohibit* any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes, as well as

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[52] 18 U.S.C. § 175, Purpose and Intent.
[53] Biological Weapons Anti-Terrorism Act of 1989 § 2(a).
[54] 18 U.S.C. § 175.
[55] 18 U.S.C. § 176.
[56] 18 U.S.C. § 177.
[57] UNSCR 1540, *supra* note 41.
[58] Eric Merriam, *The International Legal Regime Affecting Bioterrorism Prevention*, 3 NAT'L SEC. L.J. 1, 23-24 (2014).

> attempts to engage in any of the foregoing activities, participate in them as an accomplice, assist or finance them.[59]

In my estimate, the U.S. is currently in compliance with this Resolution with respect to biological weapons because it adopted the Biological Weapons Act.[60] This statute "prohibited" biological weapon-related activities, imposed harsh criminal penalties for violations, and specifically focused on terrorism.[61] However, the story is not the same for the BWC. In addition to mandating that states "prohibit" bioweapons and related activities like Resolution 1540 does, the BWC also mandates that states "take any necessary measures . . . to *prevent*" bioweapon development and use.[62]

III. THE UNITED STATES IS VIOLATING INTERNATIONAL LAW

The United States is in violation of the BWC because of its failure to meaningfully regulate synthetic biology.[63] First, I will demonstrate that the broad definition of biological weapons in the Convention encompasses the nefarious applications of synthetic biology. Next, I will argue that Article IV mandates that states regulate non-state actors. Finally, I will endeavor to show that the U.S. is violating the BWC because it is not taking "necessary measures" to "prevent" synthetic biology from being used to create biological weapons.

According to the Third Restatement of Foreign Relations Law, a treaty is to be interpreted "in good faith in accordance with the ordinary meaning to be given to its terms in their context and in light of its object and purpose."[64] In *Medellin v. Texas*, the Supreme Court provided that "[t]he interpretation of a treaty, like the interpretation of a statute, begins with its text."[65]

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[59] UNSCR 1540, *supra* note 41, ¶ 2 (emphasis added).

[60] *See* 18 U.S.C. §§ 175–178.

[61] *Id.*

[62] BWC, *supra* note 38, at 167.

[63] *See, e.g.*, Parent, *supra* note 36, at 342 ("The United States is a party to the [Biological Weapons] Convention, but has shirked its specified regulatory requirements.").

[64] RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 325(1) (Am. L. Inst. 1987); *see, e.g.*, Sanchez-Llamas v. Oregon, 548 U.S. 331, 346 (2006) (quoting the Restatement).

[65] Medellin v. Texas, 552 U.S. 491, 506 (2008) (citing Air France v. Saks, 470 U.S. 392, 396–97 (1985)). The Court also supplied that the negotiation and drafting history of the treaty as well as "'the postratification understanding'" of signatory nations can be "'aids to its interpretation,'" because a treaty ratified by the United States is "'an agreement among sovereign powers.'" *Id.* at 507 (quoting Zicherman v. Korean Air Lines Co., 516 U.S. 217, 226 (1996)). A more thorough analysis could explore how other nations have interpreted the BWC for persuasive authority.

A. Synthetic Biology is Encompassed

The broad language of the BWC encompasses synthetic biology used for nefarious purposes. Article I defines biological weapons as "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 . . ."[66] DNA is surely a "biological agent[]," and the phrase, "whatever their origin or method of production" ensures that man-made DNA is no exception.[67] Applications of synthetic biology justified by prosocial purposes are clearly not forbidden, while malevolent applications are.[68]

The BWC purposefully used spacious language to encompass all biological entities that could be weaponized.[69] Article VI, which establishes five-year reviews to "take into account any new scientific and technological developments relevant to the Convention," ensures that that the meaning of a biological weapon was not fixed at the time of the Convention.[70] The definition was meant to evolve to encompass future threats. Professor Sutton notes that at the time of the Convention, the parties understood they were in the middle of a biotechnology revolution, and that "there was a clear need to meet every five years to assess any new technologies that were relevant to the treaty."[71] Indeed, the Final Report of the Experts at the BWC Seventh Review Conference in 2014 explicitly determined that synthetic biology was encompassed by the Article I definition.[72] In doing so, the Seventh Review Conference reaffirmed that "Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention."[73]

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[66] BWC, *supra* note 38, at 166.

[67] *See id.*; *see also* Parent, *supra* note 36, at 343 ("The intentional malicious release of synthetic microorganisms is regulated by the [BWC].").

[68] BWC, *supra* note 38, at 166.

[69] *See* Sutton, *supra* note 35, at 705 ("At the First Review Conference, it had been agreed that the scope of the Convention was sufficiently broad to deal with new technological developments.").

[70] *See* BWC, *supra* note 38, at 167.

[71] Sutton, *supra* note 35, at 697.

[72] *See* Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and Their Destruction, *Report of the Meeting of Experts*, at 37, U.N. Doc. BWC/MSP/2014/MX/3 (United States: "The fields relevent to the BWC – microbiology, genomics, *synthetic biology*, just to name a few – are fast moving, and keeping up is no easy task.") (emphasis added).

[73] Seventh Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons

B. Mandatory Duty and Non-State Actors

Article IV extends to states a mandatory duty to regulate non-state actors to prevent bioweapon development. Article IV provides that:

> Each State Party to this Convention shall, in accordance with its constitutional processes, 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.[74]

First, the command "shall" clearly imposes a mandatory duty. Second, the "territory, jurisdiction, or control" language applies this duty to non-state actors. This language was not in the Geneva protocol, which explicitly only applied to states.[75] In addition, Article I already prohibits states from developing bioweapons, so if this phrase is to have any meaning, it must refer to non-state actors.[76]

C. Necessary Measures to Prevent

We now move to the phrase "take any necessary measures to prohibit and prevent."[77] While this is undoubtedly forceful language, it is also quite general. However, a plain reading suggests that it compels energetic state action to prevent the development of bioweapons within its jurisdiction.

Such a reading is bolstered by the BWC's purpose. The BWC's preamble expressly states that its purpose is "to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons" through "effective measures," "[c]onvinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimise this

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and on Their Destruction, *Final Document of the Seventh Review Conference*, at 10, U.N. Doc. BWC/CONF.VII/7 (Jan. 13, 2012).

[74] BWC, *supra* note 38, at 167 (emphasis added).

[75] *See* Merriam, *supra* note 58, at 15 ("[W]hile the BWC . . . does not directly prohibit biological weapons development and retention by non-state actors, the Convention requires states to take any necessary measures to prevent such activity within their jurisdiction. This is a large step forward from the Geneva Protocol, which applied only to state behavior.").

[76] *See* BWC, *supra* note 38, at 166; *see also* Corley v. United States, 556 U.S. 303, 314 (2009) (relying on the "basic interpretive canon that a statute should be construed to give effect to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.").

[77] BWC, *supra* note 38, at 167.

risk."[78] Accordingly, states must take their obligation under the BWC quite seriously.[79] To be clear, I am not suggesting that the BWC mandates state parties to take every conceivable measure to prevent bioweapon development; that would be wasteful and impossible. This provision is more straightforwardly read as requiring states to take reasonable, necessary measures. The crux of my argument is that the United States is in violation of the BWC because it is failing to take necessary measures to prevent synthetic biology from being weaponized.

The United States currently employs two main measures toward compliance with the BWC. First, the Biological Weapons Act criminalizes bioweapon activities, which include the malicious manipulation of synthetic biology.[80] Second, the Centers for Disease Control and Prevention (CDC) and Department of Agriculture (USDA) screen biological product orders for "select agents" that pose severe threats.[81] However, this screening does not extend to synthetic DNA orders. These measures are deeply insufficient to meet the treaty's obligations given the rapid democratization of synthetic biology and the threats it poses.

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[78] *Id.* at 166.

[79] The Second Circuit Court of Appeals gave similarly strong meaning to the BWC in United States v. Le, 902 F.3d 104, 110 (2d Cir. 2018), *cert. denied sub nom*. Cheng Le v. United States, 139 S. Ct. 1274 (2019). The court stated that "[t]he Convention aims to 'exclude completely the possibility' of biological agents and toxins 'being used as weapons' and, toward that end, requires, *inter alia*, that each State signatory, 'in accordance with its constitutional processes,' implement 'any necessary measures' to prohibit the proliferation of such weapons within its territorial jurisdiction."

[80] *See* 18 U.S.C. § 178 (1) ("the term 'biological agent' means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing . . .").

[81] This regulatory patchwork is shared between the HHS/CDC and USDA/APHIS. In enacting the Antiterrorism and Effective Death Penalty Act of 1996, Congress tasked the Secretary for the Department of Health and Human Services to issue regulations governing "the transport of biological agents with the potential to pose a severe threat to public health and safety through their use in bioterrorism." The Secretary delegated the authority to regulate these "select agents" to the CDC. In 2002, Congress enacted the Public Health Security and Bioterrorism Preparedness and Response Act, which gave the U.S. Department of Agriculture, through its Animal and Plant Health Inspection Service ("APHIS"), the authority to regulate the possession, use, and transfer of biological agents that relate to plant and animal health and products, complementing the authority granted to CDC for human pathogens. The "select agent" regulations are codified in 42 C.F.R. § 73 (2021), 9 C.F.R. § 121 (2021), and 7 C.F.R. § 331 (2021).

1. Criminalization is Not Enough

What exactly constitutes "any necessary measures to prohibit and prevent" bioweapons for a specific country at a given time is a more difficult question. Some commentators have interpreted this as merely requiring parties to pass domestic legislation criminalizing the manufacture or possession of biological weapons, which the U.S. did through the Biological Weapons Act.[82] Indeed, Congress may have interpreted the requirement this way, as the Biological Weapons Act is primarily a criminal law, codified in Title 18 (Crimes and Criminal Procedure).[83] However, this interpretation renders the phrase "and prevent" superfluous, because it only mandates "prohibition." One could conceivably argue that the criminal punishments in section 175 provide sufficient deterrence such that the U.S. is taking the necessary measures to both "prohibit" and "prevent" bioterrorism.[84] However, this would bend the meaning of "prevent" to its breaking point. Article IV straightforwardly compels more than prohibition.[85]

2. Screening for "Select Agents" Does Not Fill the Gap

If the criminal statute alone is insufficient, does screening for "select agents" bring the U.S. into compliance with the BWC? The CDC (with authority delegated from the Department of Health and Human Services) and the USDA screen orders of biological products for "select agents"—a specific list of bacteria, viruses, and fungi that have been determined to pose a severe threat to public health. However, neither agency screens synthetic DNA orders for "select agents."[86] In 2010, HHS issued a "watered-down" set of guidelines for screening some synthetic DNA sequence orders.[87] Following these guidelines is

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[82] 18 U.S.C. § 175.

[83] *See* 18 U.S.C. §§ 175–178. Section 175(a) imposes fines, up to life imprisonment, or both, for anyone who "knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same." Section 175(b) imposes fines, sentences for up to ten years, or both, for those who knowingly possess a biological agent that "under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose."

[84] *See* 18 U.S.C. § 175; BWC, *supra* note 38, at 167.

[85] BWC, *supra* note 38, at 167.

[86] *See* 7 C.F.R. § 331 (2021); 9 C.F.R. § 121 (2021); 42 C.F.R. § 73 (2021).

[87] Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA, 75 Fed. Reg. 62,820 (Oct. 13, 2010). The HHS Guidance recommended reporting suspicious orders to the FBI Weapons of Mass Destruction Directorate.

completely voluntary for private industry, and the guidelines are weaker than even industry recommended.[88] This should be deeply disconcerting.

In the absence of meaningful government regulation of synthetic biology, industry has engaged in limited self-regulation. Eleven large gene synthesis companies, representing 80% of the market, voluntarily screen DNA orders of over 200 base pairs and are supposed to alert other members of their industry group when they receive a suspicious order.[89] However, other large companies do not screen their orders at all, and many smaller companies do not either.[90] Economic imperatives further work against DNA screening, as it is quite expensive and places companies at a competitive disadvantage.[91]

Such self-regulation by industry is obviously insufficient to prevent bioterrorism. In addition to many companies not screening, the sufficiency of the screens themselves is questionable. An industry member might not deem an order suspicious enough to alert other companies, or it might fail to notify governmental authorities who could investigate further to determine if an order is part of a nefarious scheme.[92] Moreover, it is unreasonable to hold researchers and investors "solely responsible for preempting the dangers of synthetic biology, when their goals center on the advancement of the field."[93] To counter the economic and advancement incentives private companies face, the government must step in.

Because current government screening for "select agents" does not encompass synthetic DNA and industry self-regulation efforts are

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[88] Firestone, *supra* note 3, at 143 ("In 2010, the Department of Health and Human Services (DHHS) issued what was considered a watered-down set of guidelines for screening DNA sequence orders that suggested faster and cheaper processes compared to what private industry had proposed.").

[89] *Id.* at 168; Diane DiEuliis et al., *Options for DNA Order Screening, Revisited*, 2(4) MOLECULAR BIOLOGY & PHYSIOLOGY 1, 1 (2017) ("Gene synthesis providers affiliated with the International Gene Synthesis Consortium ("IGSC") voluntarily screen double-stranded DNA (dsDNA) synthesis orders over 200 bp to check for matches to regulated pathogens and to screen customers . . . oligonucleotides and tracts of DNA less than 200 bp are not screened."). IGSC precautions exceed the HHS Guidelines.

[90] DiEuliis et al., *supra* note 89, at 1.

[91] *Id.* at 2 ("[T]he HHS Guidance and screening dsDNA orders are increasingly facing serious challenges to their relevance and impact. One challenge is its cost to companies: costs for DNA synthesis continue to decrease, while screening remains relatively constant, making screening costs an increasingly larger percentage of total costs. In particular, some orders are not clearly problematic but require a highly trained person to make a judgment about proceeding; these ambiguous orders make up a majority of sequence screening costs. Companies that screen risk becoming uncompetitive.").

[92] Firestone, *supra* note 3, at 168.

[93] Parent, *supra* note 36, at 336 ("Scientists invest their lives and livelihoods into this work under great pressure from industry and media, so it is foreseeable that they would prioritize the realization of synthetic biology promises over safety considerations.").

incomprehensive, there is a massive gap for aspiring bioterrorists to exploit. First, an individual attempting to design pathogens could attempt to order synthetic DNA from companies that do not screen their orders. They could also order DNA from multiple manufacturers, circumventing suspect combination ordering that might otherwise be detected when ordering from a single gene manufacturer.[94] They could "pad" unnecessary DNA sequences at the beginning and end of the target sequences to further obfuscate malicious intent.[95] More competent individuals could order double-stranded DNA sequences smaller than 200 base pairs and piece them together themselves, or simply make the process one step longer by ordering oligonucleotide (single-stranded DNA) sequences that no companies screen for.[96] Although some laboratory proficiency is required to synthesize pathogens from oligonucleotides, this process is becoming more straightforward, with tools and products readily available.[97] Failing to mitigate potential abuses of synthetic biology is a gargantuan oversight in the United States' biodefense strategy.

As a result, regulating to fill these gaps is a "necessary measure to prevent" bioweapon development that the United States has failed to take. It is telling that the National Academy of Sciences report titled *Biodefense in the Age of Synthetic Biology* states that "overreliance on the Select Agent list is a systemic weakness affecting many aspects of the United States' current biodefense mitigation capability."[98] And that HHS' guidelines for screening synthetic DNA is weaker than even private industry recommendations should be deeply concerning.[99] For the United States to comply with the BWC, it must require *all* gene synthesis companies to screen DNA orders. It must also mitigate malicious individuals' ability to order sequences from multiple manufacturers to avoid red

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[94] *Id.*; *see also* Firestone, *supra* note 3, at 155 ("The cheapest and arguably least challenging method would be to order a known toxic sequence divided into several different chunks from several different synthesis companies. The individual orders are unlikely to trigger red flags during the screening process, and they can be reassembled into the original sequence using the Gibson Assembly method.").

[95] Firestone, *supra* note 3, at 155.

[96] DiEuliis et al., *supra* note 89, at 1.

[97] *Id.* at 2 ("Oligonucleotides are used ubiquitously in modern research laboratories for many different purposes and are synthesized quickly and cheaply at a much larger scale than [double-stranded] DNA. The financial and technical challenges for screening oligonucleotides would be immense and cost-prohibitive.").

[98] NAS REPORT, *supra* note 12, at 102 ("[O]verreliance on the Select Agent list is a systemic weakness affecting many aspects of the United States' current biodefense mitigation capability.").

[99] *See* Firestone, *supra* note 3, at 143. The HHS took public comments on updating its guidelines in 2020, available at https://perma.cc/5L2K-9HPP.

flags. I will delve deeper into how the U.S. can meet its obligations under the BWC in Part V.

3. But It Hasn't Happened Yet...

Skeptics may counter that the United States has not yet suffered catastrophic harm from bioweapons, so current measures must be sufficient. However, it is not clear at all that criminalization and screening for "select agents" have *caused* the paucity of bioweapons incidents. Rather, the historically difficult technological challenges involved in bioweapon development are likely to thank. But the advent of synthetic biology has radically reduced barriers to creating viable bioweapons. It would be foolish to extrapolate the past into the future.

The long history of bioweapons usage admonishes us that attempts to create and deploy them will continue. Biological weapons have been used since ancient times, and their use has continued to recent U.S. history.[100] In 2001, anthrax spores sent in the U.S. Postal System induced 22 cases of anthrax and caused 5 deaths, and in 2004, three U.S. Senate buildings were shut down after ricin was discovered in a mailroom.[101] Although the challenge of disseminating harmful biological agents has so far meant that bioweapons attacks have not induced mass casualties, this dissemination challenge is diminishing rapidly due to new synthetic biology technologies and techniques.[102]

Advances in synthetic biology have vastly reduced barriers for bioterrorists. Past measures are outdated and new ones are now necessary. The knowledge and resources required to engineer *E. coli* cells to produce pathogens are miniscule compared to the knowledge and resources needed to refine uranium into fissile material.[103] An individual with "relatively common cell culture and virus purification skills" and access to basic lab equipment could produce *most* DNA viruses.[104] And that many viruses can be made from scratch has been demonstrated repeatedly, including in the construction of poliovirus, the 1918 influenza virus, and the virus that causes horsepox.[105]

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[100] Howard, *supra* note 21.
[101] *Id.*
[102] *Id.*
[103] Firestone, *supra* note 3, at 146 ("[T]he knowledge, infrastructure, materials, and overall physical footprint needed to refine uranium into fissile material are gargantuan compared to what is needed to engineer *E. coli* cells to produce known pathogens . . .").
[104] *Id.* (emphasis added).
[105] DiEuliis, *supra* note 89, at 1.

As outlined earlier, gene sequences are readily accessible by biohackers and aspiring bioterrorists alike. And the level of potential harm is catastrophic, not trivial.[106] The idea of a man-made plague should appear especially salient during the age of COVID-19. The "poor man's atom bomb" is radically easier to produce now than it was even a decade ago.

As the probability of synthetic biology misuse is yet unknown, we are dealing with vast uncertainty, not quantifiable "risk." Traditional methods of risk assessment are of limited utility, and governance must be informed by precautionary reasoning.[107] If anyone believed that the U.S. was taking the necessary national security measures to prevent a largescale terrorist attack on American soil, or that it was taking the necessary measures to respond to a global pandemic, the September 11th attacks or the impact of the coronavirus pandemic would have disabused them of those views. It is a truism that low-odds risks are difficult to predict, but when these risks can cause massive impacts, a wise society will devote more time and resources to prevent them.

Ultimately, given the new ease of developing bioweapons via synthetic biology technologies and techniques, and the government's almost complete failure to regulate, the U.S. is not taking the "necessary measures . . . to prevent" the development and deployment of bioweapons within its realm of control.[108] This failure to regulate violates the Biological Weapons Convention. The next Part will show that the United States' failure to regulate not only violates international law—it also violates federal law.

IV. THE UNITED STATES IS ALSO VIOLATING FEDERAL LAW

The Biological Weapons Act expressly implemented the BWC into federal law.[109] The statute fulfilled the "prohibition" requirement of the BWC by criminalizing bioweapon development in the United States. However, the U.S. is not taking necessary measures to "prevent" bioweapon development because it has not meaningfully regulated synthetic biology. Thus, we find

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[106] *Gene Intelligence: The Risks and Rewards of Genome Editing Resonate Beyond the Clinic*, 531 NATURE 140, 140 (2016) ("Last month . . . US director of national intelligence James Clapper warned in an annual threat-assessment report to the US Senate" that certain synthetic biology techniques "should be listed as dangers alongside nuclear tests in Noth Korea or clandestine chemical weapons in Syria.").

[107] Alexander Kelle, *Beyond Patchwork Precaution in the Dual-Use Governance of Synthetic Biology*, 19 SCI. ENG'G. ETHICS 1121, 1121 (2013).

[108] *See* BWC, *supra* note 38, at 167. Given the brevity of this effort, I am unable to give the evidence and arguments the treatment they deserve.

[109] 18 U.S.C. § 175, Purpose and Intent ("The purpose of this Act is to . . . implement the Biological Weapons Convention").

ourselves in a peculiar situation where a treaty imposes forceful obligations, but the implementing statute only partially fulfills them. Under current doctrine, treaties and statutes have equivalent stature as federal law, and when they conflict the most recent instrument governs.[110] This "last-in-time" rule dictates whether a treaty is in force as a matter of domestic law.[111] Here, I argue that the BWC and the Biological Weapons Act do not conflict, so the last-in-time rule does not apply. Therefore, the later-enacted statute did not abrogate the prior treaty, and both exist as valid federal law. Because the United States is not complying with all its BWC obligations, it is violating federal law. The next three subsections will switch gears, focusing heavily on the Supreme Court's foreign relations jurisprudence.

A. Not Self-Executing but Implemented

The BWC was not self-executing, but it was implemented into federal law through the Biological Weapons Act. In *Medellin v. Texas*, the Supreme Court expressed that while treaties "may comprise international commitments . . . they are not domestic law unless Congress has either enacted implementing statutes or the treaty itself conveys an intention that it be 'self-executing' and is ratified on these terms."[112] The BWC was not self-executing because Article IV provides that "[e]ach State Party to this Convention shall" meet its obligations under the treaty "*in accordance with its constitutional processes*[.]"[113] Though there is vigorous scholarly debate about whether treaties are typically self-executing, even the most ardent self-execution proponents would likely agree that the BWC was not self-executing, because the political branches were explicitly tasked with implementing it.[114]

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[110] Emily S. Bremer, *The Dynamic Last-in-Time Rule*, 22 IND. INT'L & COMP. L. REV. 27, 28 (2012).
[111] Carlos Manuel Vázquez, *Treaties as Law of the Land: The Supremacy Clause and the Judicial Enforcement of Treaties*, 122 HARV. L. REV. 599, 612 (2008).
[112] Medellin v. Texas, 552 U.S. 491, 505 (2008).
[113] BWC, *supra* note 38, at 167.
[114] Merriam, *supra* note 58, at 15. *See, e.g.*, John Yoo, *Globalism and the Constitution: Treaties, Non-Self-Execution, and the Original Understanding*, 99 COLUM L. REV. 1955 (1999) (contending that the Founders did not intend treaties to be self-executing); Carlos Manuel Vázquez, *The Four Doctrines of Self-Executing Treaties*, 89 AM. J. INT'L L. 695, 697–700 (1995) (arguing that the Supremacy Clause establishes a presumption that treaties are self-executing).

However, the Biological Weapons Act implemented the BWC in the United States,[115] making it binding federal law.[116] Under current Supreme Court foreign relations jurisprudence, the implementing statute is undoubtedly constitutional because "[i]f the treaty is valid there can be no dispute about the validity of the statute under Article 1, Section 8, as a necessary and proper means to execute the powers of the Government."[117]

B. Law of the Land

We now move to the Supremacy Clause, the lynchpin of how treaties interact with statutes in the United States. Article VI of the Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[118]

For our purposes, the Supremacy Clause signifies that treaties and statutes hold equal stature as federal law. In the words of the Supreme Court, "[b]y the constitution, a treaty is placed on the same footing, and made of like obligation, with an act of legislation. Both are declared by that instrument to be the supreme law of the land, and no superior efficacy is given to either over the other."[119] As a result, the BWC and its implementing statute are both the supreme law of the land.

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[115] 18 U.S.C. § 175, Purpose and Intent ("The purpose of this Act is to . . . implement the Biological Weapons Convention").

[116] This analysis assumes that the Biological Weapons Act was validly within Congress's Commerce Power. In *United States v. Le*, the Second Circuit upheld a conviction when a man attempted to acquire the lethal biological toxin ricin in violation of the Biological Weapons Act. 902 F.3d at 110. The court held that Congress's enactment of the Act plainly fell within the scope of its powers under the Commerce Clause, explaining that "§ 175(a) . . . regulates quintessentially economic activity: the development, production, stockpiling, transfer, acquisition, and retention of biological toxins, fungible commodities for which an interstate market exists." *Id.* The court reasoned that it was of "no constitutional import" that the provision regulates an unlawful market, as it is well-settled that Congress has the "power to prohibit commerce in a particular commodity." *Id.* (citing Gonzales v. Raich, 125 S. Ct. 2195, 2219 n.29 (2005)).

[117] Missouri v. Holland, 252 U.S. 416, 432 (1920).

[118] U.S. CONST. art. VI, cl. 2.

[119] Whitney v. Robertson, 124 U.S. 190, 194 (1888).

C. Last-in-Time Rule

We finally come to the "last-in-time" rule: if a statute and treaty are in conflict, the most recent instrument governs.[120] Many scholars dispute this rule, arguing that treaties are superior to statutes,[121] or vice-versa.[122] Nevertheless, the doctrine is entrenched.[123] I argue that this doctrine does not pertain to the BWC and its implementing statute, because they do not conflict. Although the statute's provisions do not entirely fulfill the United States' obligations under the BWC (as they satisfy "prohibition" but not "prevention"), the later-enacted statute does not "conflict" with the prior treaty in the way that the Supreme Court has used the term.[124] Moreover, the Supreme Court typically requires that a later-enacted statute "clearly state" its intent to abrogate a prior treaty.[125] Rather than clearly stating its intent to abrogate the BWC, the Biological Weapons Act states that one of its two express purposes is to implement it.[126] Therefore, the Biological Weapons Act did not abrogate the BWC. They harmoniously coexist as federal law.

The Supreme Court's last-in-time rule was established after Reconstruction in the *Head Money Cases*, which concerned customs duties collected pursuant to a federal statute.[127] The plaintiffs objected to this statute as violating prior treaties.[128] The Supreme Court disagreed but did not decide the case on this ground.[129] Rather, the Court concluded that a later-enacted statute is superior

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[120] Bremer, *supra* note 110, at 27.

[121] *See* Louis Henkin, *The Constitution and United States Sovereignty: A Century of Chinese Exclusion and Its Progeny*, 100 HARV. L. REV. 853, 870-72 (1987).

[122] *See* Vasan Kesavan, *The Three Tiers of Federal Law*, 100 NW. U. L. REV. 1479 (2006).

[123] *See* Carlos Manuel Vázquez, *Laughing at Treaties*, 99 COLUM. L. REV. 2154, 2189 (1999) (assuming validity of last-in-time rule because it is entrenched).

[124] *See, e.g.*, *Chinese Exclusion Case*, 130 U.S. 581, 600 (1889) (finding that a prior treaty and a later-enacted staute conflicted when they engendered opposite results—allowing Chinese laborers to return to the United States, or not).

[125] *See* Trans World Airlines, Inc. v. Franklin Mint Corp., 466 U.S. 243, 252 (1984) ("Legislative silence is not sufficient to abrogate a treaty"); Weinberger v. Rossi, 456 U.S. 25, 32 (1982) ("We think that some affirmative expression of congressional intent to abrogate the United States' international obligations is required . . . "); Washington v. Wash. State Com. Passenger Fishing Vessel Ass'n, 443 U.S. 658, 690 (1979) ("Absent explicit statutory language, we have been extremely reluctant to find congressional abrogation of treaty rights."); Cook v. United States, 288 U.S. 102, 120 (1933) ("A treaty will not be deemed to have been abrogated or modified by a later statute unless such purpose on the part of Congress has been clearly expressed.").

[126] 18 U.S.C. § 175, Purpose and Intent.

[127] *Head Money Cases*, 112 U.S. 580 (1884).

[128] *Id.* at 597.

[129] *Id.*

to a prior treaty if they conflict.[130] *Whitney v. Robertson*, four years later, also concerned customs duties collected pursuant to a federal statute.[131] The plaintiffs sought to import sugar from the Dominican Republic and argued that the treaty with the Dominican Republic provided for the duty-free importation of sugar.[132] However, the Court decided in favor of the United States, resting its decision on dual grounds of treaty interpretation (which denied the plaintiff's interpretation) and the last-in-time rule (which assumed the plaintiff's interpretation and the resulting statute-treaty conflict).[133] Because the statute was passed after the treaty was made, the Court held that the statute trumped the treaty.[134] Importantly, both the *Head Money* and *Whitney* Courts presumed that the relevant statute and treaty did not conflict, and found reasonable interpretations to reconcile the instruments.[135]

Only a year after *Whitney*, in the *Chinese Exclusion Case*, the Court held that a statute preventing a Chinese subject from returning to the United States controlled over earlier treaties with China that would have permitted the subject to return.[136] The language and intent of the statute and treaties directly conflicted, pointing toward opposite results—return or not.[137] Forty years later during prohibition, in *Cook v. United States*, the Supreme Court held that a later-enacted treaty controlled over a prior statute.[138] Again, the treaty directly conflicted with the statute as it changed the distance from the coast that the Coast Guard could seize a British vessel to stop the importation of liquor.[139] Since the adoption of the Constitution, there have been less than a dozen Supreme Court decisions addressing the last-in-time rule, and cases after *Cook* have only found later-enacted statutes to control over prior treaties when they were in direct conflict—engendering opposite results.[140]

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[130] *Id.*

[131] Whitney v. Robertson, 124 U.S. 190 (1888).

[132] *Id.* at 194.

[133] *Id.*

[134] *Id.*; *see also* Kesavan, *supra* note 122, at 1495 n. 81 ("Given the alternative ground for the decision, the Court's analysis of the legal relationship between statutes and treaties is unnecessary.").

[135] *See* 112 U.S. at 597; 124 U.S. at 197.

[136] *Chinese Exclusion Case*, 130 U.S. 581, 600 (1889).

[137] *See id.*

[138] Cook v. United States, 288 U.S. 102, 102 (1933).

[139] *Id.* at 118–19. The treaty changed the distance from four leagues to "the distance which can be traversed in one hour by the vessel suspected of endeavoring to commit the offense." This meant that the Mazel Tov, with speed not exceeding ten miles per hour, was boarded illegally.

[140] In addition to cases discussed, there are a handful of other cases, mostly related to

The BWC and the Biological Weapons Act do not directly conflict; they substantially align. The Biological Weapons Act imposes criminal sanctions,[141] allows the government to seize bioweapons,[142] and creates a right of action for the government to sue for injunctions.[143] These provisions are all perfectly in line with the dictates of BWC Article IV.[144]

While the Biological Weapons Act does not completely fulfill the United States' obligations under the BWC because it does not adequately "prevent" bioweapon development, this does not mean that the statute "conflicts" and abrogates the treaty. As we have seen, the Supreme Court has only found that a statute abrogates a treaty or vice-versa when there is a direct conflict. Unlike the *Chinese Exclusion Case*, where the treaties allowed Chinese subjects to return and the statute forbade it,[145] the BWC and the Biological Weapons Act do not command contradictory results. No Supreme Court decision has found that a later-enacted statute abrogated a prior treaty just because it did not completely fulfill the country's obligations under the treaty.

Moreover, as statutes and treaties are equally valid federal law, the Supreme Court routinely adopts the presumption that a statute and a treaty coexist harmoniously, just as it treats two potentially conflicting statutes, and only finds that a later-enacted statute abrogates a treaty if it "clearly states" this intent.[146] This presumption preserves the President's control over foreign policy and reduces clashes with other countries.[147] Not only did the Biological Weapons Act not "clearly state" its intent to abrogate the BWC, it clearly stated that one of its purposes was to implement it.[148] Just as in *Whitney* and the *Head Money Cases*, where there was a plausible harmonious interpretation of the statute and treaty,[149] so there obviously is here. The treaty simply demands more than the statute fulfills.

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immigration in the late nineteenth century, and one recent *per curiam* decision, all involving later-enacted statutes and prior treaties. Although the last-in-time rule is repeated in this handful of cases, it has formed the basis of decision in an even smaller number of cases. *See, e.g.*, Breard v. Greene, 523 U.S. 371, 376 (1998) (per curiam).

[141] 18 U.S.C. § 175.

[142] 18 U.S.C. § 176.

[143] 18 U.S.C. § 177.

[144] *See* BWC, *supra* note 38, at 167.

[145] *Chinese Exclusion Case*, 130 U.S. 581, 599-600 (1889).

[146] *See supra* note 125 and accompanying text.

[147] Owner-Operator Indep. Drivers Ass'n, Inc. v. U.S. Dep't of Transp., 724 F.3d 230, 236 (D.C. Cir. 2013).

[148] 18 U.S.C. § 175, Purpose and Intent ("The purpose of this Act is to . . . implement the Biological Weapons Convention").

[149] *Head Money Cases*, 112 U.S. 580, 597 (1884); Whitney v. Robertson, 124 U.S. 190, 197 (1888).

In conclusion, the Biological Weapons Act implemented the BWC into federal law. Both the statute and the treaty are valid because they do not directly conflict. A treaty provision whose obligations are not completely met by its implementing statute still places an onus on the political branches, as the provision constitutes the "law of the land."[150] To meet its obligations under the BWC, the U.S. must take the "necessary measure" of regulating synthetic biology to prevent its weaponization. It has not done so. In failing to comply with the BWC, the United States is violating federal law.

V. HOW THE UNITED STATES CAN COMPLY WITH THE BWC

The BWC was clearly addressed to the political branches.[151] To comply with international and domestic law, the United States has two basic options. One, Congress could enact legislation delegating authority to a new executive agency to regulate synthetic biology. If pursued, such regulation should aim to reduce the odds of synthetic biology from being weaponized to the extent it is reasonably feasible. Alternatively, a federal agency like the Centers for Disease Control (CDC) could attempt to regulate under its existing authority.[152] These two options assume that it would be wiser to use an agency's expertise to regulate synthetic biology rather than rely on states to regulate.[153]

No matter the path taken, the dual use capabilities of synthetic biology make it inherently difficult to strike a balance between overregulating and underregulating. The U.S. should be mindful not to dampen the field's positive potential, but it should also take reasonable measures to prevent terrorism and catastrophe. As scientists well-versed in the field have the most knowledge of

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[150] *See* John Yoo, *Treaties and Public Lawmaking: A Textual and Structural Defense of Non-Self-Execution*, 99 COLUM. L. REV. 2218, 2249 (1999).

[151] This raises an interesting issue of treaty interpretation. While the President typically has the primary role in treaty interpretation, should Congress have a greater role when a treaty is "addressed" to Congress? The BWC is arguably addressed to Congress because it provides that each State take "any necessary measures, according to its constitutional processes," signaling that States must implement legislation. The case would be clearer if a treaty clearly stated that states must implement it through legislation.

[152] The language of organic acts establishing federal agencies and declaring their purposes often includes language about regulating in the public interest. A broad delegation to regulate in the public interest concerning a particular subject matter could conceivably be used to regulate synthetic biology to prevent bioweapon development.

[153] For advantages of federal agencies in meeting international commitments, see Amichai Cohen, *Bureaucratic Internalization: Domestic Governmental Agencies and the Legitimization of International Law*, 36 GEO. J. INT'L L. 1079, 1122 (2005) ("Bureaucracy's principal function is to initiate a process of internalization wherever other branches lack the will to do so. This need is particularly acute in many instances of international law, which frequently suffers from a lack of domestic social legitimacy because it is either ignored by the traditional branches or only partially implemented by them.").

synthetic biology's promise and destructive potential, it would be wise to consider their proposals first.[154]

One prominent option, advocated by Dr. George Church, the "father of synthetic biology," is to require screening of all synthetic DNA for dangerous biological agents.[155] Gene synthesis companies would be required to screen all of their DNA orders for suspect sequences and sequences that are substantially similar to those of "select agents."[156] If companies discovered an alarming order, it would automatically be reported to a non-profit DNA "clearinghouse" set up by a federal agency.[157] Staff at the clearinghouse would make an immediate preliminary assessment and then search their system for similar or related DNA orders from other vendors.[158] Church's proposal would also mandate the licensing of instruments and reagents used for synthetic biology.[159] Sales and maintenance of DNA synthesis machines and supplies would be restricted to licensed non-profit, government, and private entities, and all use of reagents and DNA sequences would be automatically tracked.[160] Other scientists have hatched similar plans.[161]

Regulating synthetic biology via a centralized clearinghouse system would meet the United States' obligations under the BWC, pulling the U.S. back into compliance with international and federal law. Mandating DNA screening for *all* gene synthesis companies is critical, as some large companies and many smaller companies do not currently screen.[162] In addition, creating a centralized system would mitigate the "circumvention" problem, making it far more

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[154] Nicole H. Kalupa, *supra* note 6, at 975.

[155] *See* George Church, A Synthetic Biohazard Non-Proliferation Proposal (Aug. 6, 2004) (unpublished manuscript) (available at https://perma.cc/Q8NA-543A).

[156] *Id.* at 1.

[157] *Id.* at 2.

[158] *Id.* Church's proposal would include several other prominent features, like random testing to make sure the system is performing correctly and a function to update the list of alarming DNA sequences.

[159] *Id.* at 1-2.

[160] *Id.*

[161] *See* ALEXANDER KELLE, SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 107–12 (Springer 2010). Over a decade ago, an international coalition of scientists drafted a four-point proposal that focused on risks associated with the DNA synthesis process. They identified the most effective intervention point for preventing the misuse of synthetic biology at the level of DNA synthesis. The plan targets gene synthesis firms, oligonucleotide manufactures, and DNA synthesizers. By screening orders of companies and having a biosecurity officer certify orders, these scientists believed that a lesser burden would be placed on research while accomplishing the necessary national security goals. Declaration of the Second International Meeting on Synthetic Biology (May 29, 2006) (public draft) (available at https://perma.cc/PWA4-LPJP).

[162] DiEuliis, *supra* note 89, at 1.

difficult for bioterrorists to avoid detection by ordering sequences from multiple manufacturers.[163] Licensing of instruments and reagents would further support preventative efforts, as it would allow companies and government agencies to keep close tabs on who is using synthetic biology and allow for more effective oversight.[164] While one might suggest that the cat is already out of the bag given the democratization of these technologies, licensing new instruments and reagents would not be too burdensome, and retrofitting older instruments and reagents may also be feasible. While an in-depth analysis of any of these potential policies is beyond the scope of this piece,[165] it is clear that any viable solution must make DNA screening ubiquitous and create a centralized system to mitigate the circumvention problem.

VI. CONCLUSION

If the political branches do not seek to regulate synthetic biology to prevent bioweapons, the United States will continue to shirk its duties under international and federal law. And in the absence of Presidential or Congressional action, the courts are very unlikely to offer a cure. The BWC was addressed to the political branches and the justiciability doctrines would prevent most foreseeable challenges from being heard.

We have reached an era of human history where the greatest threats are man-made. For the sake of moral and intellectual progress, we must make the best use of our faculties of reason and foresight to anticipate risks and take reasonable measures to prevent them, especially in rapidly advancing technological fields like synthetic biology. Not to do so would be "repugnant to the conscience of mankind."[166]

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[163] Firestone, *supra* note 3, at 155.
[164] *See* Church, *supra* note 155, at 1.
[165] For one bold technical solution, see George Church, *We Should Create a Global DNA Threat-Detection Network to Fight Future Pathogens*, ARS TECHNICA (June 19, 2019), https://perma.cc/BM6J-BCKT. *See also* Rob Reid, *Averting the Apocalypse*, MEDIUM (June 19, 2019), https://perma.cc/A4HT-QHFJ.
[166] *See* BWC, *supra* note 38, at 166.