

5-1-2014

The Need for Government Oversight Over Do-It-Yourself Biohacking, the Wild West of Synthetic Biology

George Blazeski

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship

Recommended Citation

Blazeski, George, "The Need for Government Oversight Over Do-It-Yourself Biohacking, the Wild West of Synthetic Biology" (2014).
Law School Student Scholarship. 411.
https://scholarship.shu.edu/student_scholarship/411

The Need for Government Oversight Over Do-It-Yourself Biohacking, the Wild West of Synthetic Biology

George Blazeski

In the not too distant past, synthetic biology was limited to well-financed laboratories. Now Do-It-Yourself (DIY) scientists, or “biohackers,” conduct genetic experiments in the comfort of their own homes, garages, and offices. Home laboratories can be set up for the cost of a couple Macbooks. Furthermore, equipment can easily be purchased on ecommerce sites such as Ebay and material used in these experiments are ordered via conventional mail.

In Part I, this paper will explore the current capabilities and history of biohacking, including the communities and cultures which support it. Part II will outline the safety and security concerns raised from biohacking. Part III of this paper will look at the current statutory, regulatory, and executive laws which may apply to biohacking, in addition to actions by the Federal Bureau of Investigations (FBI). Finally, in Part IV this paper will make recommendations on whether another federal agency is needed, what rules may be necessary, or if oversight is needed at all.

I) What is synthetic biology and biohacking?

The term synthetic biology is used and defined in many ways throughout the scientific community.¹ Synthetic biology has been described as engineering biology and is attractive to the private

¹ See, **National Science Advisory Board for Biosecurity**, *Addressing Biosecurity Concerns Related To Synthetic Biology* at ii, available at [http://oba.od.nih.gov/biosecurity/pdf/NSABB%20SynBio%20DRAFT%20Report-FINAL%20\(2\)_6-7-10.pdf](http://oba.od.nih.gov/biosecurity/pdf/NSABB%20SynBio%20DRAFT%20Report-FINAL%20(2)_6-7-10.pdf) (2010) (“a precise definition of synthetic biology will remain elusive and will evolve over time”). [*hereinafter Addressing Biosecurity*]

sector, students, and amateur scientists.² This field of study appeals to biologists, chemists, and engineers who seek to understand nature, create new drugs, or invent new technologies.³

The goal of synthetic biology is to produce novel biological structures with predictable properties and functions.⁴ Scientists attempt to design and construct new biological parts and devices, re-design existing, natural biological systems for specific purposes, and synthesize self-replicating entities from scratch.⁵ Overall, synthetic biologists want to understand the fundamental nature of living organisms or biological materials and develop technology based on the same principles as those found in living systems.⁶

Synthetic biology is sometimes classified as dual-use research. Dual-use refers to research with the potential to generate both scientific knowledge or to be used for nefarious purposes.⁷

One subsection of synthetic biology is biohacking. Biohacking is still a relatively new term in the English language and its definition can vary depending on the source. At the time of this writing, the common definition listed on Wikipedia is “the practice of engaging biology with the hacker ethic.”⁸ Some biohackers refer to themselves as Do-It-Yourself(DIY) scientists.⁹ DIY is an appropriate label since most research in synthetic biology is done in laboratories and biohackers operate in their own private

² *Id.*

³ See, Drew Endy, *Foundations of Engineering Biology*, 438 NATURE 449, 449 (2005) (discussing what synthetic biology is and we people research it).

⁴ See, *Addressing Biosecurity*, *supra* note 1 (“the goal of both is...”).

⁵ *Id.* at 1-2 (bulleted items under “What is synthetic biology”).

⁶ *Id.* at 3 (“With both approaches, the synthetic biologist seeks...”).

⁷ See, E. Megan Davidson, Richard Frothingham & Robert Cook-Deegan, *Practical Experiences in Dual-Use Review*, 316 SCIENCE 1432, 1432 (2007) (discussion in introductory paragraph).

⁸ See, *Biohacking*, WIKIPEDIA.ORG, <http://en.wikipedia.org/wiki/Biohacking> (last visited May 9, 2013) (introductory section).

⁹ See, Brian J. Gorman, *Patent Office As Biosecurity Gatekeeper: Fostering Responsible Science and Building Public Trust in Diy Science*, 10 J. Marshall Rev. Intell. Prop. L. 423, 425 (2011).

spaces.¹⁰ The term biohacker is an analogy to the computer programming enthusiasts from the prior generation.¹¹ As one biohacker puts it, “we try to tinker with DNA, the code of life.”¹²

There is no exact starting point for the beginning of the biohacking movement but the first iGEM competition was a significant step towards establishing the DIY community.¹³ iGEM, the International Genetically Engineered Machine Competition, began in January 2003 at MIT.¹⁴ It started as a one month course and grew into a summer competition with 5 teams in 2004.¹⁵ By 2011, 165 teams joined the competition and in 2012 a High School Division and an Entrepreneurship Division were added.¹⁶ Teams work on projects which “range from a rainbow of pigmented bacteria, to banana and wintergreen smelling bacteria, an arsenic biosensor, Bactoblood, and buoyant bacteria.”¹⁷

While DIY biohackers typically experiment privately, they do have community resources to draw from. There are online communities which are prominent within the field. One of the first organizations to join the biohacking movement is BioBricks. In their own words, Biobricks is a “public-benefit organization founded in 2006 by scientists and engineers who recognized that synthetic biology had the potential to produce big impacts on people and the planet and who wanted to ensure that this emerging

¹⁰ See, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming Biohackers: Learning the Game*, BBC.COM/FUTURE (January 22, 2013), <http://www.bbc.com/future/story/20130122-how-we-became-biohackers-part-1> (last visited May 9, 2013) (discussing the growing number of DIY biologists. [*hereinafter Learning Part 1*]

¹¹ *Id.*

¹² *Id.*

¹³ See, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming Biohackers: Learning the Game*, BBC.COM/FUTURE (January 22, 2013), <http://www.bbc.com/future/story/20130122-how-we-became-biohackers-part-1/4> (last visited at May 9, 2013) (“the seeds of the DIYbio movement...”). [*hereinafter Learning Part 4*]

¹⁴ See, **the iGEM Foundation**, *iGEM Competition History*, IGEN.ORG, <http://igem.org/About> (last visited at May 9, 2013).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

field would serve the public interest.”¹⁸ Biobricks has three main programs to aid the biohacking movement: their Technical Program, SBx.0 Conference Series, and Education Program.¹⁹

Biobricks’s Technical Program features three projects which all strive to make scientific knowledge freely available.²⁰ One project is the development of high-throughput biological design/build facilities (BIOFABs) to produce standard biological parts for the public benefit.²¹ The Stanford BIOFAB will produce BioBrick parts based off of yeast.²² Also in development is the Global BIOFAB Network which will connect all BIOFABs to create community-driven technical standards and standardize biological parts.²³ The last technical project is the SynBio Road Mapping Project.²⁴ This project will lead to the creation of a “Global Roadmap for Synthetic Biology” to document evaluation of progress in key areas, set technical goals for the field over the next 15 years, identify resources that might be best used to ensure that the best technologies would be developed, distributed, and utilized to meet those goals, make recommendations for operational metrics and standards to support efficiency and sharing in the field, and identify ways in which the field can incorporate safety, ethical, legal, and social impacts into its research and community vision.²⁵

The 2nd program is the SBx.0 Conference Series, a conference of the preeminent figures in synthetic biology.²⁶ The first meeting was in 2004 and the most recent, 2011 at Stanford University,

¹⁸ See, **The Biobricks Foundation**, *About*, BIOBRICKS.ORG, <http://biobricks.org/about-foundation/> (last visited at May 9, 2013).

¹⁹ See, **The Biobricks Foundation**, *Programs*, BIOBRICKS.ORG, <http://biobricks.org/programs/> (last visited at May 9, 2013).

²⁰ See, **The Biobricks Foundation**, *Technical Program*, BIOBRICKS.ORG, <http://biobricks.org/programs/technical-program/> (last visited at May 9, 2013) (introductory discussion).

²¹ *Id.*

²² *Id.*, discussing Stanford BIOFAB.

²³ *Id.*, discussing Global BIOFAB network.

²⁴ *Id.*, SynBio Road Mapping Project.

²⁵ *Id.*

²⁶ See, **The Biobricks Foundation**, *SBx.0 Conference Series*, BIOBRICKS.ORG, <http://biobricks.org/programs/sbx-0-conference-series/> (last visited at May 9, 2013) (The Synthetic Biology Conference Series is...).

drew over 700 attendees.²⁷ This series facilitates discussions on how to make biology easier to engineer in order to benefit people across the world.²⁸

Through BioBricks' Education Program the organization wants to reach three communities: professionals, students, and the general public.²⁹ At the 2011 SB conference, BioBricks debuted the BioBrick Public Agreement (BPA), a free-to-use legal tool to allow entities to make their standardized parts free for others to use.³⁰ BioBricks also created the Technical Request for Comment Process to develop standards for synthetic biology research.³¹ Finally, BioBricks manages OpenWetWare, "an online platform for storing, managing, and sharing research data and know-how."³² This wiki provides information on materials, protocols, and other resources utilized by synthetic biologists, all for free.³³

Communities have developed regionally as well. One example is BioCurious, a community centered on the Bay area in California.³⁴ BioCurious describes themselves as "a complete working laboratory and technical library for entrepreneurs to cheaply access equipment, materials, and co-working space a training center for biotechniques, with an emphasis on safety a meeting place for citizen scientists, hobbyists, activists, and students."³⁵ BioCurious does charge a membership fee which features free introductory classes, safety training, and 15% off reagents.³⁶

²⁷ *Id.*

²⁸ *Id.*, (SB 5.0 was the first time in over two years...).

²⁹ See, **The Biobricks Foundation**, *Education Program*, BIOBRICKS.ORG, <http://biobricks.org/programs/education-program/> (last visited at May 9, 2013) (There are three main audiences the BBF Education Program serves...).

³⁰ *Id.*, discussing BioBrick™ Public Agreement (BPA).

³¹ *Id.*, discussing Technical Request for Comment (RFC) Process.

³² *Id.*, discussing OpenWetWare (OWW).

³³ See, **The Biobricks Foundation**, *OPENWETWARE.ORG*, http://openwetware.org/wiki/Main_Page (last visited at May 9, 2013) (OpenWetWare is an effort to promote...).

³⁴ See generally, **Biocurious**, BIOCURIOUS.ORG, <http://biocurious.org/> (last visited at May 9, 2013).

³⁵ See, **Biocurious**, *About*, BIOCURIOUS.ORG, <http://biocurious.org/about/> (last visited at May 9, 2013) (discussing BioCurious is...).

³⁶ See, BIOCURIOUS.ORG, *supra* note 34 (discussing Member discounts and added benefits).

New York City features a community biolab called Genspace.³⁷ Genspace describes itself as “a nonprofit organization dedicated to promoting citizen science and access to biotechnology.”³⁸ The lab opened in December of 2010 as the first-ever community biotechnology laboratory.³⁹ Currently Genspace is mentoring student teams at the high school and college level and occasionally offers internships to work on the lab’s projects.⁴⁰

Boston features its own Boston Open Source Science Lab (BOSSLab).⁴¹ BOSSLab hosts classes and talks and currently is working on a project to synthesize indigo in bacteria.⁴² Baltimore is home to the Baltimore Under Ground Science Space (BUGSS).⁴³ BUGSS is “a Maryland non-profit corporation started in the summer of 2012 to provide a place for people interested in biotechnology to learn, practice and hang-out with others fascinated by the world-changing potential of synthetic biology and biotechnology.”⁴⁴ They host Build-a-BUG workshops and allow members to start their own projects.⁴⁵

The aspiring biohacker has many equipment needs, but everything is now widely available. Ebay is an extraordinary resource; the Healthcare, Lab & Life Science section is full of useful equipment.⁴⁶ Items which used to be exclusive to labs such as centrifuges and PCR machines (also known as

³⁷ See generally, **Genspace**, GENSPACE.ORG, <http://genspace.org/> (last visited at May 9, 2013).

³⁸ See, **Genspace, About**, GENSPACE.ORG, <http://genspace.org/page/About> (last visited at May 9, 2013) (discussing Our Mission).

³⁹ *Id.*

⁴⁰ See, **Genspace, Student Programs**, GENSPACE.ORG, <http://genspace.org/project/Student%20Programs> (last visited at May 9, 2013).

⁴¹ See generally, **Boston's Open Source Science Laboratory**, BOSSLAB.ORG, <http://bosslab.org/> (last visited at May 9, 2013).

⁴² See, **Boston's Open Source Science Laboratory, BlueGene**, BOSSLAB.ORG, <http://bosslab.org/BlueGene> (last visited at May 9, 2013) (“BlueGene is a project to synthesize indigo with bacteria”).

⁴³ See generally, **Baltimore Under Ground Science Space**, BUGSSONLINE.ORG, <http://www.bugssonline.org/> (last visited at May 9, 2013).

⁴⁴ See, **Baltimore Under Ground Science Space, About**, BUGSSONLINE.ORG, <http://www.bugssonline.org/about.html> (last visited at May 9, 2013).

⁴⁵ See, **Baltimore Under Ground Science Space**, BUGSSONLINE.ORG, <http://www.bugssonline.org/projects.html> (last visited at May 9, 2013) (discussing Projects).

⁴⁶ See, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming biohackers: the experiments begin*, BBC.COM/FUTURE, (January 23, 2013) <http://www.bbc.com/future/story/20130123-hacking-genes-in-humble-settings> (last visited at May 9, 2013) (discussion in opening paragraph). [*hereinafter Experiments Begin Part 1*]

thermocyclers) are available for purchase in this section.⁴⁷ More simple items such as pipettes, glassware, lightboxes, and Bunsen burners are for sale as well.⁴⁸ Ebay is not the sole destination for biohacking equipment online, Amazon and other retailers sell these items as well.⁴⁹

Costs for biohacking equipment have become more affordable as well.⁵⁰ An illustrative example is the PCR machine.⁵¹ Twenty years ago one machine would cost a substantial portion of a laboratory budget; in 2012 BBC writers were able to purchase one for a little over \$400.⁵² The same writers, who were starting with no lab experience, were about to put together a complete lab for a under \$5000, including chemicals and biological materials.⁵³

Chemicals and biological materials are easier to obtain than one might imagine. BBC's writers attempted to order ricin from a biotech company in order to test the security and safety aspects of biohacking.⁵⁴ A few days later a courier delivered two tubes full of DNA for making *Ricinus communis* for the cost of \$31.⁵⁵ They had only ordered the beginning and end portions of the necessary genetic code but in theory in would be enough to produce ricin.⁵⁶ In fact, they were able to express the gene and decided to stop before actually producing the dangerous substance.⁵⁷

⁴⁷ See generally, *Healthcare, Lab, and Lab Science*, EBAY.COM, <http://www.ebay.com/sch/Healthcare-Lab-Life-Science-/11815/i.html> (last visited at May 9, 2013).

⁴⁸ See, *Humble Settings Part 1*, supra Note 46 (second paragraph).

⁴⁹ See generally, AMAZON.COM, http://www.amazon.com/s/ref=nb_sb_noss_2?url=search-alias%3Daps&field-keywords=centrifuge (last visited at May 9, 2013).

⁵⁰ See generally, *Humble Settings Part 1*, supra Note 46

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ See, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming biohackers: the experiments begin*, BBC.COM/FUTURE, (January 23, 2013) <http://www.bbc.com/future/story/20130123-hacking-genes-in-humble-settings/3> (last visited at May 9, 2013) (discussing Security Risk). [*hereinafter Experiments Begin Part 3*]

⁵⁵ *Id.*

⁵⁶ See generally, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming biohackers: the experiments begin*, BBC.COM/FUTURE, (January 23, 2013) <http://www.bbc.com/future/story/20130123-hacking-genes-in-humble-settings/4> (last visited at May 9, 2013). [*hereinafter Experiments Begin Part 4*]

⁵⁷ *Id.*

In some instances an individual does not need to purchase any equipment at all. BioCurious provides all the materials an aspiring biohacker would need at \$100 a month.⁵⁸ BUGSS offers many different payment options and its monthly plan is \$85 a month.⁵⁹ Genspace hosts many events for biohackers; its Biohacker Boot Camp spans four evenings and costs \$300 for adults and \$150 for children.⁶⁰

II) Safety and Security Concerns

Terrorist attacks have been a fear of the public for quite some time. Possibly the most devastating attacks occur from bioterrorism. A bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants.⁶¹ Some substances, such as ricin or anthrax, cannot spread from person to person.⁶² These agents have been sent in letters to public officials as recently as 2013.⁶³

Other bioterrorism agents, such as the smallpox virus, can be spread from person-to-person.⁶⁴ To make matters worse, bioterrorism agents could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment.⁶⁵ Movies and books, such as Stephen King's *The Stand*, highlight these fears.⁶⁶ In The

⁵⁸ See, BIOCURIOUS.ORG, *supra* note 34.

⁵⁹ See, **Baltimore Under Ground Science Space**, *Membership fees*, BUGSSONLINE.ORG, <http://www.bugssonline.org/payment.html> (last visited at May 9, 2013).

⁶⁰ See, **Genspace**, *Biohacker Boot Camp*, GENSPACE.ORG, <http://genspace.org/event/20130506/1800/Biohacker%20Boot%20Camp> (last visited at May 9, 2013).

⁶¹ See, **Centers for Disease Control and Prevention**, *Bioterrorism Overview*, BT.CDC.GOV, <http://www.bt.cdc.gov/bioterrorism/overview.asp> (last visited at May 9, 2013) (discussing What is Bioterrorism).

⁶² *Id.*

⁶³ See generally, Ed Payne. Matt Smith & Carol Cratty, *FBI confirms letters to Obama, others contained ricin*, CNN.COM, <http://www.cnn.com/2013/04/18/politics/tainted-letter-intercepted/index.html?iref=allsearch> (last visited at May 9, 2013). [*Hereinafter Letters to Obama*]

⁶⁴ See, *Bioterrorism Overview*, *supra* note 61

⁶⁵ *Id.*

⁶⁶ See generally, Stephen King, *The Stand*, (1978).

Stand, an extremely deadly, contagious virus escaped a government facility, wiping out the world's population.⁶⁷

The FBI has acted on fears of bioterrorism before. In May 2004, Steve Kurtz, an arts professor at the State University of New York, was arrested by the FBI and interrogated as a bioterrorism suspect.⁶⁸ Kurtz's wife had died the previous day and when paramedics arrived they were alarmed by the Petri dishes full of bacterial cultures found throughout his house.⁶⁹ The FBI's anti-bioterrorism unit was notified and they were concerned Kurtz had killed his wife with a toxin he created.⁷⁰ It took 4 years for Kurtz to prove he was growing harmless bacteria for use in a video project.⁷¹

Bioterrorism concerns are not unfounded. Determined actors can produce dangerous substances if they so desire. Production of ricin, a toxic material found on the Center for Disease Control's Select Agents and Toxins list, is within the grasp of a determined group of biohackers.⁷² As it stands now though, it is far easier to harvest ricin naturally from castor beans and manufacture a bioweapon from that material.⁷³

Another major safety concern is the release of scientific information which may aid terrorist acts.⁷⁴ One of the more recent controversies surrounded the release of information on a man-made flu

⁶⁷ *Id.*

⁶⁸ See, Hanno Charisius, Richard Friebe & Sascha Karberg, *Becoming Biohackers: Learning the Game*, BBC.COM/FUTURE, (January 23, 2013) <http://www.bbc.com/future/story/20130122-how-we-became-biohackers-part-1/3> (last visited at May 9, 2013) (discussing Steve Kurtz). [*hereinafter Biohackers Part 3*]

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Compare, **Centers for Disease Control and Prevention**, *Select Agents and Toxins List*, SELECTAGENTS.GOV, <http://www.selectagents.gov/select%20agents%20and%20toxins%20list.html> (last visited at May 9, 2013), with *Letters to Obama*, *supra* note 63

⁷³ See, *Experiments Begin Part 4*, *supra* note 56

⁷⁴ See, Ed Payne, Matt Smith & Carol Cratty, *Becoming biohackers: The long arm of the law*, BBC.COM/FUTURE, (January 24, 2013), <http://www.bbc.com/future/story/20130124-biohacking-fear-and-the-fbi/2> (last visited at May 9, 2013) ("Fouchier and Kawaoka argued...."). [*hereinafter Long Arm Part 2*]

virus.⁷⁵ Two separate teams of scientists had simultaneously mutated the H5N1 bird-flu virus so it could spread through mammals more easily.⁷⁶ Both groups delayed publishing their findings due to public safety concerns but ultimately they released the data months later.⁷⁷ Law enforcement is concerned DIY biohackers could use the data from such scientific publications to nefarious ends, especially since DIY biohackers are not bound by any institutional checks.

III) Current Statutory, Regulatory, and Executive Landscape for Biohacking

Currently the United States has not created legislation in direct response to the DIY biohacking phenomenon. Some bills combat general terrorism while others are in response to bioterrorism threats. Specific legislation for DIY biohacking may be unnecessary if the statutory, regulatory, and executive frameworks alleviate all safety concerns for DIY biohacking. The first pertinent piece of legislation in this area is the Patriot Act.

Heightened public concerns of terrorist attacks came to a head in 2001 with the passage of the Patriot Act. The stated purpose of the Act is “to deter and punish terrorist acts in the United States and around the world, to enhance law enforcement investigatory tools, and for other purposes.”⁷⁸ Congress took further measures to improve the security of the United States after passing the Patriot Act and passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.⁷⁹ However no statute yet addresses the specific issue of DIY biohacking.

A) USA Patriot Act of 2001

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *See*, Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001, PL 107–56, 115 Stat 272 (2001).

⁷⁹ *See*, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, PL 107–188, 116 Stat 594 (2002).

The first mention of bioterrorism in the Patriot Act appears in Section 221 Trade Sanctions.⁸⁰ The Act amended the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) to allow for sanctions against countries which “facilitate the design, development, or production of chemical or biological weapons, missiles, or weapons of mass destruction.”⁸¹ The TSRA governs unilateral agricultural sanctions or unilateral medical sanctions imposed on other countries such as Cuba.⁸² The change to the TSRA is designed to deter terror actors on a national scale and will not target US citizens with homemade laboratories.

The Patriot Act also amended Section 212(a)(3) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(3)) to redefine inadmissible aliens to include those who provide material support to terrorism, such as biological weapons.⁸³ Section 212 of the Immigration and Nationality Act defines the classes of aliens ineligible for visas or admission to the United States.⁸⁴ Again, this is provision which does not directly impact DIY biohackers. This change is targeted towards people outside the United States who support terrorism; material support does not include scientific experiments conducted by citizens of the United States.

Section 801 of the Patriot Act also clarified that terrorist attacks include firing or placing biological weapons near a mass transportation vehicle, ferry, or the facilities which support them.⁸⁵ This clarification was reflected in 18 USCA 1993, however this statute has now been repealed.⁸⁶

The other major change enacted in the Patriot Act in relation to bioterrorism was made to the Biological Weapons Statute.⁸⁷ These changes from the Patriot Act are the ones most relevant to the

⁸⁰ See, section 221 of the USA Patriot Act of 2001, *supra* note 78

⁸¹ *Id.*

⁸² See, **United States Department of the Treasury**, *About TSRA*, TREASURY.GOV, http://www.treasury.gov/resource-center/sanctions/Programs/Pages/tsra_info.aspx (last visited at May 9, 2013) (discussing background).

⁸³ See, section 411 of the USA Patriot Act of 2001, *supra* note 78

⁸⁴ See, 8 U.S.C.A. § 1182 (2010).

⁸⁵ See, section 801 of the USA Patriot Act of 2001, *supra* note 78

⁸⁶ See, 18 U.S.C.A. § 1993 (2006).

biohacking discussion. The Act added an offense for knowingly possessing any biological agent, toxin, or delivery system without justification.⁸⁸ People can only own these items in a quantity or type reasonably justified by a “prophylactic, protective, bona fide research, or other peaceful purpose.”⁸⁹ Violation of this provision results in a fine, imprisonment for no more than 10 years, or both.⁹⁰ However the statute carves out an exception for biological agents or toxins which occur naturally in the environment and have not been cultivated, collected, or otherwise extracted from their natural source.⁹¹

The additional offense added by Congress supplements the existing offense in the Biological Weapons statute. The statute had already instituted criminal penalties for whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon.⁹² It is also a crime to knowingly assist a foreign state or any organization to do so, or attempt, threaten, or conspire to do the same.⁹³ This offense carries the same consequences as the offense written in the Patriot Act.⁹⁴

The Biological Weapons Statute applies to any individual, biohackers included. It also contains exceptions for reasonably justified prophylactic, protective, bona fide research or other peaceful purpose.⁹⁵ However whether DIY research would fall into this exception is unclear; bona fide research may not encompass DIY research. It is also important to note this provision does not encompass any

⁸⁷ See, section 817 of the USA Patriot Act of 2001, *supra* note 78

⁸⁸ See, 18 U.S.C.A. § 175 (2002).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ See, section 817 of the USA Patriot Act of 2001, *supra* note 78

biological agent or toxin that is in its naturally-occurring environment; however biohackers conduct experiments to produce unnatural results so this exception does little to protect DIY biohackers.⁹⁶

The Patriot Act further prohibits restricted persons from shipping or transporting in interstate or foreign commerce, or affecting commerce with, any biological agent or toxin.⁹⁷ The Act defines eight possible criteria to constitute a restricted person.⁹⁸ Restricted persons include people who are indicted, or convicted, for a crime with a prison sentence of more than one year.⁹⁹ Fugitives from justice are also restricted persons.¹⁰⁰ Restricted persons also include unlawful users of any controlled substance as defined in section 102 of the Controlled Substances Act.¹⁰¹ The statute lists drugs which constitute controlled substances, which does not include alcohol or tobacco.¹⁰² Other restricted persons include illegal aliens, aliens from countries which the Secretary of State have deemed to support international terrorism, people dishonorably discharged from the United States armed service, and the mentally ill.¹⁰³

While it is certainly possible some DIY biohackers may fall under this definition of a restricted person, most DIY biohackers are scientists or lay people who have never run afoul of the law and are natural born citizens of the United States. Therefore most DIY biohackers would not constitute restricted persons and this provision of the Patriot Act would not apply to them.

B) Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Bioterrorism Act is the other relevant Congressional authority relevant to DIY biohacking. The stated purpose of the Act is “to improve the ability of the United States to prevent, prepare for, and

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *See*, 21 U.S.C.A. § 802 (2009).

¹⁰³ *See*, section 817 of the USA Patriot Act of 2001, *supra* note 78

respond to bioterrorism and other public health emergencies.”¹⁰⁴ Section 201 of the Act relates to regulation of certain biological agents and toxins.¹⁰⁵ This section sets the following criteria for the Department of Health and Human Services and the Department of Agriculture to determine what is a biological agent or toxin:

- (I) the effect on human health of exposure to the agent or toxin;
- (II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;
- (III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and
- (IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate¹⁰⁶

The Bioterrorism Act sets very similar instructions for the Department of Agriculture.¹⁰⁷

Provisions II, III, and IV are the same but provision I directs the Department of Agriculture to determine what is a biological agent or toxin based on the effects to plant and animal health.¹⁰⁸

The Bioterrorism Act also charged the Secretaries of Agriculture and Health and Human Services to provide new regulations based on four directives.¹⁰⁹ First the agencies were charged with the establishment and enforcement of safety procedures for the transfer of biological agents and toxins.¹¹⁰ Those measures should also include proper laboratory facilities to contain and dispose of biological agents and toxins with properly trained personnel with the appropriate skills to handle biological agents and toxins.¹¹¹ Second, the agencies were instructed to establish and enforce security measures to

¹⁰⁴ See, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, *supra* note 79

¹⁰⁵ See, Section 201 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, *supra* note 79

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

prevent biological agents and toxins from being used in terrorism or any other criminal purpose.¹¹²

Third, the agencies were charged with the establishment of procedures to protect the public in case their proposed safety measures are violated.¹¹³ Lastly, the agencies were instructed to determine the appropriate availability of biological agents and toxins should be for research, education, and other legitimate purposes.¹¹⁴ The regulations crafted by both agencies will be discussed in the next section of this paper.

The Bioterrorism Act further instructs both agencies to create regulations to “provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins ... in order to protect the public health and safety.”¹¹⁵ This provision can directly affect DIY biohackers. If a biohacker does choose to utilize a substance on the restricted list, the Act requires them to register with the Secretary.¹¹⁶

The Bioterrorism Act further requires both agencies to limit access to substances on the restricted list to “only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins.”¹¹⁷ There may be concern from DIY biohackers who want the ability to pursue experiments unfettered. However the registration provisions balance a valid national safety concern, particularly as the restricted substances are evaluated based on their contagiousness and available treatments, amongst other criteria.

C) Failed Congressional Bills

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

Two failed bills are worth noting for the potential effect they could have had on DIY biohacking. The first bill was the Weapons of Mass Destruction Prevention and Preparedness Act of 2010, introduced on April 15, 2010.¹¹⁸ This bill was introduced in the House of Representatives to many subcommittees but ultimately died in committee.¹¹⁹ The stated purpose of the bill was “to prevent the proliferation of weapons of mass destruction, to prepare for attacks using weapons of mass destruction, and for other purposes.”¹²⁰

Section 101 of the WMD Prevention and Preparedness Act of 2010 would have amended Section 351A of the Public Health Service Act to create a designation of Tier I agents.¹²¹ This designation would be determined by the Departments of Health and Human Services and Homeland Security.¹²² The proposed bill set three criteria for determining Tier I agents: '(i) whether the agent or toxin has clear potential to be used effectively in a biological attack that causes significant casualties; (ii) information available from any biological or bioterrorism risk assessments conducted by the Department of Homeland Security or relevant assessments by other agencies; and '(iii) such other criteria and information that the Secretary determines appropriate and relevant.¹²³ The Department of Agriculture would have received almost the exact same instructions, but instead of evaluating significant casualties the Department would determine whether an agent would cause catastrophic consequences.¹²⁴

Section 318 of the WMD Prevention and Preparedness Act of 2010 aimed to enhance the biosecurity measures of the Homeland Security Act.¹²⁵ The Act would have charged Homeland Security to work with other agencies to promulgate security and training standards for persons that possess, use,

¹¹⁸ See, H.R. 5057, 111th Cong. (2nd Sess. 2009).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*, at section 201.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*, at section 318.

or transfer Tier I agents.¹²⁶ Homeland Security would have to create a committee composed of other agencies, research institutions, and other interested parties in order to create those standards.¹²⁷ The Homeland Security Act would have been further amended to allow Homeland Security to inspect laboratories to ensure compliance with the new standards.¹²⁸

Another bill entitled the WMD Prevention and Preparedness Act of 2010 was proposed in June of 2010 which also died in committee.¹²⁹ The purpose of this bill was “to enhance homeland security by improving efforts to prevent, deter, prepare for, detect, attribute, respond to, and recover from an attack with a weapon of mass destruction, and for other purposes.”¹³⁰ Section 203 of this bill, entitled Dual-Use Terrorist Risks from Synthetic Genomics, would have directed Homeland Security to report to the appropriate congressional committees the security implications of dual-use research.¹³¹ The bill laid out three areas of concern: “(1) determining the current capability of synthetic nucleic acid providers to effectively differentiate a legitimate customer from a potential terrorist or other malicious actor; (2) determining the current capability of synthetic nucleic acid providers to effectively screen orders for sequences of homeland security concern; and (3) making recommendations regarding screening software, protocols, and other remaining capability gaps uncovered by the study.”¹³²

D) Regulatory Framework

Both Departments promulgated regulations effective March 18, 2005.¹³³ As each department had different foci, their lists mostly differ but there are overlapping substances.¹³⁴ They also restrict

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *See*, H.R. 5498, 111th Cong. (2nd Sess. 2009).

¹³⁰ *Id.*

¹³¹ *Id.*, at section 203

¹³² *Id.*

¹³³ *See*, 42 C.F.R. § 73 and 7 C.F.R. § 331

¹³⁴ *Id.*

synthetic nucleic acids and all substances are restricted whether in vivo or in vitro.¹³⁵ The Department of HHS does provide an exception, “an attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health or to animal products.”¹³⁶ Of course the only way to obtain this exception is to register with the HHS Department.

The Agriculture Department set standards for restricted experiments.¹³⁷ One type of restricted experiment is the deliberate transfer of, or selection for, a drug or chemical resistance trait to other agents which are not known to acquire the trait naturally, but only if such an experiment would compromise disease control in humans, animals, or agriculture.¹³⁸ The other type of restricted experiment is an experiment which involves the deliberate formation of synthetic or recombinant nucleic acids which can produce toxins lethal to vertebrates.¹³⁹ They forbid any individual or entity from conducting or possessing products resulting from these restricted experiments without the getting the approval of the Department of Agriculture and following the conditions they prescribe.¹⁴⁰ Meanwhile the HHS Department issued almost an exactly similar set of regulations as the Department of Agriculture.¹⁴¹ The only differences between the two sets of regulations are so minor that they operate the same.

E) National Science Advisory Board for Biosecurity

¹³⁵ *Id.*

¹³⁶ *See*, 42 C.F.R. § 73.4

¹³⁷ *See*, 7 C.F.R. § 331.13

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *See*, 42 C.F.R. § 73.13

The White House has created two entities to analyze the issues in synthetic biology. The first was the National Science Advisory Board for Biosecurity (NSABB). This group was founded following a 2003 United States National Research Council report describing experiments of concern which warrant greater scrutiny.¹⁴² The NSABB provided a forum for deliberation on dual-use research and whether oversight or other measures would be necessary.¹⁴³ Their membership includes doctors, scientists, retired military, and academics from both the sciences and the law.¹⁴⁴

In April 2010 the NSABB released a report entitled *Addressing Biosecurity Concerns Related to Synthetic Biology*.¹⁴⁵ The report presents an assessment of any biosecurity concerns presented by the ability to synthesize new genes, biochemical pathways, and biological components with specified or novel properties.¹⁴⁶ The report acknowledges there may be gaps in oversight resulting from practitioners who are not traditional life scientists or who are not affiliated with formal research institutions.¹⁴⁷ The NSABB issued four recommendations for safety in synthetic biology.¹⁴⁸

The first recommendation of the NSABB is synthetic biology should be subject to institutional review and oversight because of the biosecurity risks.¹⁴⁹ The report notes that currently there is no federal policy in place for dual use research.¹⁵⁰ The NSABB recommends local oversight with principal investigators evaluating research for dual use purposes.¹⁵¹ Research identified as a risk would be subject

¹⁴² See, David A. Relman, *The biological century: coming to terms with risk in the life sciences*, 11 NATURE IMMUNOLOGY 275, 276 (2010) (“A report from the US National...”).

¹⁴³ *Id.* (“The subsequent creation of the National...”).

¹⁴⁴ See generally, **National Science Advisory Board for Biosecurity**, *NSABB Member Roster*, OBA.OD.NIH.GOV, http://oba.od.nih.gov/biosecurity/biosecurity_voting_members.html (last visited at May 9, 2013).

¹⁴⁵ See generally, *Addressing Biosecurity*, *supra* note 1

¹⁴⁶ *Id.*, at ii

¹⁴⁷ *Id.*, at iii (“But since current biosafety and biosecurity...”).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*, at 13

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

to additional institutional review.¹⁵² This framework could work very well for research institutions or even organizations such as Genspace where DIY biohackers congregate. However such a framework may not address individual DIY biohackers who never set foot in a laboratory.

The NSABB also recommends oversight of dual use research should extend beyond the boundaries of life sciences and academia.¹⁵³ The NSABB determined a large number of synthetic biology practitioners do not come from life science backgrounds.¹⁵⁴ It is this group of people which constitute DIY biohackers. They also state dual use research occurs outside the life sciences as well; research of high relevance to public health and safety occur in other fields too.¹⁵⁵ They also recommend oversight should be uniform and comprehensive since dual use research is as likely to be conducted in private and voluntary sectors as it is with more conventional research institutions such as academia or government laboratories.¹⁵⁶

The third recommendation of the NSABB is to develop outreach and education strategies to address dual use research issues and to engage those research communities.¹⁵⁷ The NSABB feels extending the oversight over dual use research will need to be preceded by practitioners who have not been involved in recent biosafety discussions.¹⁵⁸ Educational efforts would make people, such as DIY biohackers, aware of the biosecurity risks involved in dual use research.¹⁵⁹ They recommend targeting researchers not subject to federal biosafety requirements, not formally affiliated with traditional institutions, and students.¹⁶⁰ This targeted group would encompass DIY biohackers since they conduct

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*, at 13-14

¹⁶⁰ *Id.*, at 14

their experiments at home, not in a formal laboratory. The NSABB realizes the difficulty of reaching these people, especially biohackers, but stressing its importance.¹⁶¹

The last recommendation in the NSABB's April 2010 report is for the US government to include advances in synthetic biology and pathogenicity (potential of microbes to cause disease) in efforts to monitor new scientific findings.¹⁶² They specifically recommend "tech-watch" or "science-watch" endeavors.¹⁶³ They feel those endeavors will identify emerging dual use technologies and new knowledge to assess dual use activity.¹⁶⁴ The NSABB wants the federal government to convene workshops to assess or re-assess researchers' ability to create novel or unanticipated biosecurity risks and determine whether the current oversight system adequately addresses them.¹⁶⁵

F) Presidential Commission for the Study of Bioethical Issues

In 2010 President Obama created the Presidential Commission for the Study of Bioethical Issues to "review the developing field of synthetic biology and identify appropriate ethical boundaries to maximize public benefits and minimize risks."¹⁶⁶ The Commission held public forums and interviewed prominent scientists and researchers to prepare their findings, which were published in December of 2010.¹⁶⁷ The report is entitled *New Directions: The Ethics of Synthetic Biology and Emerging*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ See, **U.S. Department of Health & Human Services**, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, BIOETHICS.GOV, <http://bioethics.gov/cms/synthetic-biology-report> (last visited at May 9, 2013).

¹⁶⁷ *Id.*

Technologies.¹⁶⁸ The Commission offered 18 recommendations for how to move forward in the synthetic biology field.¹⁶⁹

The Commission's 3rd recommendation urges the Executive branch to prepare the best sharing practices for encouraging innovation in the field of synthetic biology.¹⁷⁰ The Commission makes clear that it does not endorse a moratorium on synthetic biology, but does not favor unfettered freedom either.¹⁷¹ It believes a middle ground of ongoing vigilance to identify and mitigate harms is necessary.¹⁷²

After outlining this approach, in its 4th recommendation the Commission saw "no need at this time to create additional agencies or oversight bodies focused specifically on synthetic biology."¹⁷³ Instead they recommend the Executive branch coordinate a clear, defined approach to synthetic biology research.¹⁷⁴ The report directly addresses the unusual potential risks DIY scientists pose.¹⁷⁵ They maintain "risks must be identified and anticipated, as they are for other emerging technologies, with systems and policies to assess and respond to them while supporting work toward potential benefits."¹⁷⁶

The Commission Report also touched upon the idea of intellectual freedom.¹⁷⁷ Under this principle the Commission asserts "that restrictions on research, whether by self-regulation by scientists or by government intervention, should limit the free pursuit of knowledge only when the perceived risk is too great to proceed without limit."¹⁷⁸ Using this rationale the Commission strikes down the idea of a

¹⁶⁸ See, **Presidential Commission for the Study of Bioethical Issues**, *NEW DIRECTIONS The Ethics of Synthetic Biology and Emerging Technologies*, BIOETHICS.GOV, http://bioethics.gov/cms/sites/default/files/PCSBI-Synthetic-Biology-Report-12.16.10_0.pdf

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*, at 7

¹⁷¹ *Id.*, at 8

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*, At 12

¹⁷⁸ *Id.*

moratorium and insists the scientific community should be allowed to monitor itself.¹⁷⁹ However, the Commission acknowledges government may have to “expand current oversight or engagement activities with non-institutional researchers.”¹⁸⁰ The Commission did not believe there was any serious risk of “completely novel organisms being constructed in non-institutional settings including in the DIY community.”¹⁸¹ However, “scrutiny is required to ensure that DIY scientists have an adequate understanding of necessary constraints to protect public safety and security, but at present the Commission sees no need to impose unique limits on this group.”¹⁸²

G) Law Enforcement Action

The Commission recommended the Department of Homeland Security and the Federal Bureau of Investigation conduct periodic assessments of the DIY biohacking community.¹⁸³ Since then there have been no directives made to law enforcement to oversee DIY biohackers. However the Federal Bureau of Investigation has created a Biological Countermeasures Unit.¹⁸⁴

So far the biohacking community sense the FBI is being open-minded regarding this emerging field.¹⁸⁵ Nathaniel Head, the supervisory special agent of the FBI’s Biological Countermeasures Unit,

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*, At 13

¹⁸² *Id.*

¹⁸³ *Id.*, generally

¹⁸⁴ *See generally*, Ed Payne. Matt Smith & Carol Cratty, *Becoming biohackers: The long arm of the law*, BBC.COM/FUTURE, (January 24, 2013), <http://www.bbc.com/future/story/20130124-biohacking-fear-and-the-fbi/1> (last visited at May 9, 2013). [*hereinafter Long Arm Part 1*]

¹⁸⁵ *Id.* (discussing FBI’s acute awareness)

brought many leaders in the field together at the first DIYbio Outreach Workshop program in June of 2012.¹⁸⁶ He stated the purpose of the conference was to, “learn about biohacking and to be able to separate between the white and the black hats.”¹⁸⁷ The FBI has accepted the neighborhood watch style approach promulgated by the Commission and encourages biohackers to be the first line of defense against nefarious actors.¹⁸⁸

The approach seems to be working. Genspace has worked closely with the FBI since its inception.¹⁸⁹ In fact, the FBI helped smooth out the relationships between Genspace and local fire and police departments.¹⁹⁰ Without direct involvement, DIY biohackers abroad have started developing a biohacker code of ethics to dissuade anyone from running afoul of the law.¹⁹¹ DIY biohackers in the US launched an initiative called Ask a Biosafety Expert which they believe should meet a DIY biohacker’s needs.¹⁹²

IV) Recommendations

This paper agrees with the Presidential Commission that neither a moratorium nor unfettered research is an appropriate course of action. It is imperative that biohackers develop safety and security procedures while retaining the ability to innovate through experiments.¹⁹³ Self-regulation should work in most cases, but gaps in legislation and regulation still need to be filled. One of the statutory concerns going forward is a language clarification in current regulations.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *See, Long Arm Part 2, supra* note 74 (“Collectives such as Genspace...”).

¹⁹⁰ *Id.*

¹⁹¹ *See, Ed Payne. Matt Smith & Carol Cratty, Becoming biohackers: The long arm of the law, BBC.COM/FUTURE, (January 24, 2013), <http://www.bbc.com/future/story/20130124-biohacking-fear-and-the-fbi/3> (last visited at May 9, 2013) (“The German biohackers we got to know...”). [*hereinafter Long Arm Part 3*]*

¹⁹² *Id.*

¹⁹³ *See, Hans Bügl et al., DNA synthesis and biological security, 25 NATURE BIOTECHNOLOGY 627, 628 (2007) (It is imperative that DNA-synthesis..”).*

The Departments of Agriculture and Health and Human Services both carve out exceptions from their select agents list for “prophylactic, protective, bona fide research, or other peaceful purpose.”¹⁹⁴ As far as biohacking is concerned there is still a question about what constitutes “bona fide research.” Neither department sets a definition for the term. The only statutory definition for “bona fide research” exists with regard to marine mammal protection in 16 USC 1362.¹⁹⁵ The statute defines bona fide research as:

- (A) likely would be accepted for publication in a referred scientific journal;
- (B) are likely to contribute to the basic knowledge of marine mammal biology or ecology; or
- (C) are likely to identify, evaluate, or resolve conservation problems.¹⁹⁶

If this definition is used as guidance, most DIY biohackers would not meet the first element and may not necessarily meet the second element either. Thus they would incur criminal penalties under the Patriot Act for working with restricted substances. This certainly does not match the Presidential Commission’s goal of self-regulation for biohackers, but it does alleviate national security concerns which are the basis for the Patriot Act.

The Fourth Circuit offered a definition for “bona fide research” in Chief Judge Wilkinson’s concurring opinion in Urofsky v. Gilmore.¹⁹⁷ In that case “the ultimate judgment on whether a requested waiver is for a bona fide research project resides in the system of university governance.”¹⁹⁸ This definition would preclude all DIY biohackers from qualifying under the “bona fide research” exception of the Patriot Act. Therefore a specific clarification of the “bona fide research” language would clear all uncertainty in the field and provide articulate boundaries for independent research and experimentation.

¹⁹⁴ See, 42 C.F.R. § 73 and 7 C.F.R. § 331, *supra* at note 133

¹⁹⁵ See, 16 U.S.C.A. § 1362 (2003).

¹⁹⁶ *Id.*

¹⁹⁷ See generally, Urofsky v. Gilmore, 216 F.3d 401 (4th Cir. 2000).

¹⁹⁸ *Id.*, at 432.

The primary biosafety concern still left unaddressed is how to restrict the availability of materials sufficient to create hazardous biological agents to nefarious actors. Legislation such as the Patriot Act is effective as a deterrent but does not physically inhibit the availability of potentially dangerous substances. Some believe limiting access to material or equipment is impractical for DNA research.¹⁹⁹ This concern is valid for research institutions but for individual biohackers the risks of unfettered genetic experimentation is too great.

US counterterrorism officials fear ricin can be weaponized in labs similar to those DIY biohackers would use.²⁰⁰ However academics such as Eckhard Wimmer, a virologist at New York State University at Stony Brook, point out it is far easier to weaponize ricin from its natural state rather than produce it synthetically²⁰¹. This is true for ricin in particular but may not hold true for all substances of for antibiotic-resistant bacteria strains.

Despite the opposition for restrictive measures, the potential for a malicious party to create a biological agent or accidentally release contagions is too risky to ignore. This paper does not endorse a moratorium on biohacking but the availability of genetic material for purchase to the DIY biohacker is troubling. Legislation limiting the sale of biological material which is capable of producing synthetic restricted agents or toxins would be a beneficial step for public safety with minimal impact on the ability of DIY biohackers to perform experiments and innovate. For example, such legislation could restrict sales of said biological material to laboratories or individuals which register with the FBI's Biological Countermeasures Unit.

This paper endorses the recommendation of both the NSABB and the Presidential Commission in regards to agency oversight. There is no demonstrable need for another regulatory agency to oversee

¹⁹⁹ See, Bügl, *supra* note 194, at 629 (Table 1).

²⁰⁰ See, *Experiments Begin Part 3*, *supra* note 54 (“As a quarter of a milligramme...”).

²⁰¹ See, *Long Arm Part 2*, *supra* note 74 (“Nature is the better bioterrorist.”).

biohacking. Existing regulations from the Departments of Agriculture and Health and Human Services provide regulations which, although in need of some clarification, are not in conflict with one another. As long as interagency cooperation persists the current state of regulatory oversight is sufficient. The recommendations of the NSABB to keep watch for new technological advances are also prudent and the National Institutes of Health should implement those recommendations as the NSABB suggests in its report.²⁰²

A sensitized community of scientists is more effective than any piece of legislation or regulation.²⁰³ Someone in the same field of study will be more likely to identify risky behavior in their local community than others without the same background or expertise.²⁰⁴ This same idea should translate well to online communities and larger, federal institutions. Education and outreach will go a long way towards national security; a productive working relationship between DIY biohackers and national security communities will also be a boon to national security.²⁰⁵ While the cited adjustments to the current legislative and regulatory landscapes will be beneficial to the DIY biohacking community, ultimately no one can ensure safe, successful growth of the DIY biohacking movement than the biohackers themselves.

²⁰² See, *Addressing Biosecurity*, *supra* note 1 at 13-14

²⁰³ See, Relman, *supra* note 142 at 277

²⁰⁴ *Id.*

²⁰⁵ *Id.*