## OFF

### 1

#### Interpretation: The aff may not defend WTO member nations reducing intellectual property protections for a subset of medicines.

#### Violation – they only defend CRISPR

#### Vote neg:

#### 1] Limits – you can pick anything from COVID vaccines to HIV/AIDS to random biotech to insulin treatments and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible.

FDA 20 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device product categories.

There are over 1,600 FDA-approved animal drug products.

There are about 300 FDA-licensed biologics products.

#### 2] TVA – read the aff as an advantage to a whole rez aff.

#### Don’t allow for RVIs you don’t get a cookie for being fair

### 2

#### Eliminating CRISPR patents causes biohacking.

Zettler 19, Patricia J., Christi J. Guerrini, and Jacob S. Sherkow. "Regulating genetic biohacking." Science 365.6448 (2019): 34-36. (Ohio State University Moritz School of Law)//Elmer

Genetic **biohacking** is also potentially **subject to U.S. laws that are enforced by private** rather than government **actors**. These may fill some of the gaps in public regulators’ ambit (9). **Patent owners**, for example, **can impose ethical restrictions on licensees,** such as the Broad Institute’s licenses for its CRISPR patents to Bayer (formerly Monsanto), **with conditions that** Bayer **avoid research activities that are potentially harmful to public health**, **including** **tobacco research and germline editing** (10). **Such license restrictions can**—and should—**be used to police commercial manufacturers of genome-editing kits and reagents popular in biohacking communities**, just as they have previously been used to prevent activities that pose national security, environmental, or public health risks (11). Even without a license in place, **patent owners can enforce restrictions through threats of patent infringement litigation against any recalcitrant biohackers or manufacturers of biohacking products**. A similar model was proposed as an attempt to restrict the use of “gene drive technology”—inheritable versions of CRISPR designed to drive a specific allele through generations of a population (12). Beyond patents, people injured by genetic biohacking materials could potentially bring tort law claims against biohackers and component suppliers to seek compensation for their injuries. A person injured while using a DIY CRISPR kit, for example, would likely be able to sue the seller of the kit —a potentially strong deterrent to marketers of unsafe biohacking materials.

#### Expanded biohacking means bioterror

Wikswo 14, J., S. Hummel, and V. Quaranta. "The Biohacker: A Threat to National Security." CTC Sentinel 7.1 (2014). (a biological physicist at Vanderbilt University. He was born in Lynchburg, Virginia, United States. Wikswo is noted for his work on biomagnetism and cardiac electrophysiology.)//Elmer

The **ability of non-scientists to create** and deploy **a biological weapon** highlights the emergence of **a new threat, the “biohacker.”** “Biohacking” is not necessarily malicious and could be as innocent as a beer enthusiast altering yeast to create a better brew. Yet the **same technology** **used by** a benign **biohacker** **could** easily **be transformed into** a tool for the disgruntled and disenfranchised12 to modify existing or emerging **biological warfare agents** **and employ them as bioterrorism**. A 2005 Washington Post article by Steve Coll and Susan Glasser presciently stated that “one can find on the web how to inject animals, like rats, with pneumonic plague and how to extract microbes from infected blood…and how to dry them so that they can be used with an aerosol delivery system, and thus how to make a biological weapon. If this information is readily available to all, is it possible to keep a determined terrorist from getting his hands on it?”13 This article argues that the biohacker is a real and existing threat by examining evasive biohacking strategies and limitations of current detection methods. The article finds that more active measures are required to stem the growing, long-term threat of modified BW agents employed by individuals. The **biohacker is** not only **a credible threat**, but also one that can be checked through improved detection and by disrupting BW agent delivery methods. CRIPR access leads to democratization of biotech – makes bioweapons more available.

#### Increased CRISPR access leads to bioterror

Antonio Regalad. February 9, 2016. Top U.S. Intelligence Official Calls Gene Editing a WMD Threat. https://www.technologyreview.com/2016/02/09/71575/top-us-intelligence-official-calls-gene-editing-a-wmd-threat/

Gene editing refers to several novel ways to alter the DNA inside living cells. The most popular method, CRISPR, has been revolutionizing scientific research, leading to novel animals and crops, and is likely to power a new generation of gene treatments for serious diseases (see “Everything You Need to Know About CRISPR’s Monster Year”). It is gene editing’s relative ease of use that worries the U.S. intelligence community, according to the assessment. “Given the broad distribution, low cost, and accelerated pace of development of this dual-use technology, its deliberate or unintentional misuse might lead to far-reaching economic and national security implications,” the report said. The choice by the U.S. spy chief to call out gene editing as a potential weapon of mass destruction, or WMD, surprised some experts. It was the only biotechnology appearing in a tally of six more conventional threats, like North Korea’s suspected nuclear detonation on January 6, Syria’s undeclared chemical weapons, and new Russian cruise missiles that might violate an international treaty. The report is an unclassified version of the “collective insights” of the Central Intelligence Agency, the National Security Agency, and half a dozen other U.S. spy and fact-gathering operations. Although the report doesn’t mention CRISPR by name, Clapper clearly had the newest and the most versatile of the gene-editing systems in mind. The CRISPR technique’s low cost and relative ease of use—the basic ingredients can be bought online for $60—seems to have spooked intelligence agencies. “Research in genome editing conducted by countries with different regulatory or ethical standards than those of Western countries probably increases the risk of the creation of potentially harmful biological agents or products,” the report said. The concern is that biotechnology is a “dual use” technology—meaning normal scientific developments could also be harnessed as weapons. The report noted that new discoveries “move easily in the globalized economy, as do personnel with the scientific expertise to design and use them.” Clapper didn’t lay out any particular bioweapons scenarios, but scientists have previously speculated about whether CRISPR could be used to make “killer mosquitoes,” plagues that wipe out staple crops, or even a virus that snips at people’s DNA. “Biotechnology, more than any other domain, has great potential for human good, but also has the possibility to be misused,” says Daniel Gerstein, a senior policy analyst at RAND and a former under secretary at the Department of Homeland Defense. “We are worried about people developing some sort of pathogen with robust capabilities, but we are also concerned about the chance of misutilization. We could have an accident occur with gene editing that is catastrophic, since the genome is the very essence of life.”

#### State and non-state CBWs are the biggest existential threat – that causes extinction.

Green ‘14 (Brian Patrick Green; Markkula Center for Applied Ethics and School of Engineering, Santa Clara University; 2014; “Little Prevention, Less Cure: Synthetic Biology, Existential Risk, and Ethics,” <https://cns.asu.edu/sites/default/files/greenp_synbiopaper_2014.pdf>; *Applied Ethics and School of Engineering at Santa Clara University*)

The biosecurity, biosafety, bioweapon, and biodefense risks of synthetic biology are enormous and have been discussed in some detail (e.g. Petro et al., 2003, Lemon and Relman et al., 2006). Such risks may include everything up to the destruction of most of life on Earth. These worstcase scenarios should not be discounted, because there are not only individual cults and terrorist groups that would be happy to perform such heinous acts, but also possibly entire states, such as North Korea. Historically, many states have been involved in bioweapon research and production, and as the power of biotechnology is democratized we should also expect non-state actors to become involved, as indeed some already have (e.g. the Rajneeshees in 1984, the 2001 Anthrax attacker, etc.). This raises the question of global catastrophic and existential risks. The philosopher Nick Bostrom has described global catastrophic risks as risks which threaten massive global disaster and existential risks as risks which threaten human extinction (Bostrom, 2002). Synthetic biology presents such risks, especially if permitted as a DIY hobby that anyone, including terrorists, could pick up. Because synbio permits such significant changes to living organisms, we should not expect to be able to prepare for all the various diverse and unpredictable bioweapons that could be produced by a fully democratized DIY synbio milieu. Indeed, we cannot even effectively deal with the natural biological problems that nature throws at us now. The philosopher Hans Jonas has argued that the first and most important rule of ethics, his “imperative of responsibility,” is that humankind must exist in the future (Jonas, 1984). One is not allowed to play a “va banque” game with humanity. Therefore anything that puts humanity at risk ought to be carefully controlled or eliminated, if possible. There are many risky things that we cannot control, but synthetic biology need not be one of them. Recalling the “risk equation” (risk = harm x probability), Michael Davis has argued that for any unacceptable harm with a non-zero probability the risk is too high (Davis, 2012). Human extinction should qualify as an unacceptable harm; therefore, since DIY synbio permits a certain non-zero probability of that harm, it presents an unacceptable risk that ought not be permitted. As we enter the risk terrain of DIY synbio, we – or at least some of us – are deciding that we are willing to risk everything on the possible finite goods synbio might give to us. Reasonable gamblers should not risk everything, including their own lives, on a finite win. Given the dangers presented by synbio and the ethical rule that humans ought to exist in the future (which we ought hardly to need, as self-interest would hopefully suffice), we need a strong governance and policy response to this threat. The current Presidential Commission for the Study of Bioethics Issues response of “prudent vigilance” is insufficient. “Prudent vigilance” would have been an odd solution to the dangers of nuclear power, for example. Synthetic biology permits the creation of destructive capacities worse than nuclear weapons and at much less difficultly. Adaptation to and mitigation of these risks will likely need to be, therefore, even more significant than the changes to the world that occurred due to the advent of nuclear weapons. Perhaps it is only because the power of nuclear weapons was made clear on Hiroshima and Nagasaki that nuclear technology has been controlled as well as it has. In lacking examples of the destructive power of synbio, our collective imaginations seem to fail. How can we respond to this failure of the imagination? We need to present these ideas to the public as best we can.