## 1

#### 1] Interpretation– “medicines” are substances that prevent, diagnose, or treat harms

MRS 20 [(MAINE REVENUE SERVICE SALES, FUEL & SPECIAL TAX DIVISION) “A REFERENCE GUIDE TO THE SALES AND USE TAX LAW” <https://www.maine.gov/revenue/sites/maine.gov.revenue/files/inline-files/Reference%20Guide%202020.pdf> December 2020] SS

[Medicines](https://www.lawinsider.com/dictionary/medicines) means antibiotics, analgesics, antipyretics, stimulants, sedatives, antitoxins, anesthetics, antipruritics, hormones, antihistamines, certain “dermal fillers” (such as BoTox®), injectable contrast agents, vitamins, oxygen, vaccines and other substances that are used in the prevention, diagnosis or treatment of disease or injury and that either (1) require a prescription in order to be purchased or administered to the retail consumer or patient; or (2) are sold in packaging.

#### 2] Violation – CRISPR is a gene-editing tool, NOT a medicine – it’s also used in a variety of non-medical fields.

NewScientist 20 "What is CRISPR" <https://www.newscientist.com/definition/what-is-crispr/> //Elmer

**CRISPR is a technology** **that can be used to edit genes** and, as such, will likely change the world. The essence of CRISPR is simple: it’s a way of finding a specific bit of DNA inside a cell. After that, the next step in CRISPR gene editing is usually to alter that piece of DNA. However, CRISPR has also been adapted to do other things too, such as turning genes on or off without altering their sequence. There were ways to edit the genomes of some plants and animals before the CRISPR method was unveiled in 2012 but it took years and cost hundreds of thousands of dollars. CRISPR has made it cheap and easy. CRISPR is already widely **used for** scientific research, and in the not too distant future many of the **plants** and **animals** in our **farms**, gardens or homes may have been altered with CRISPR. In fact, some people already are eating CRISPRed **food**.

#### It's used in drug discovery but isn’t a drug – makes the Aff effects-Topical.

Enzmann and Wronski 19 Brittany Enzmann and Ania Wronski 1-11-2019 "How CRISPR Is Accelerating Drug Discovery" <https://www.genengnews.com/insights/how-crispr-is-accelerating-drug-discovery/> (scientific communications manager at Synthego)//Elmer

Subsequent cellular repair facilitates knockouts, knockins, or the exchange of nucleotides. Because these types of modifications are made endogenously, scientists can study the subsequent changes to mRNA and protein at native, physiologically relevant levels. Variations of **CRISPR** can be **used for** other modifications, including the activation and inhibition of gene expression. Due to its increased ease and versatility, CRISPR shows promise in overcoming many of the technical challenges of **drug discovery**. Here, we summarize some of the ways in which CRISPR is advancing the stages of preclinical drug development. Drug discovery workflow The drug discovery process often starts with basic scientific **research** and involves many steps before new therapeutics are approved for clinical use. While each pharmaceutical company approaches the discovery and development of new drugs differently, the major steps common to most preclinical processes are **target identification and validation**, high-throughput compound **screening**, **hit validation**, and **lead drug candidate optimization** (Figure 2). All of these steps, and the ways **CRISPR** is **accelerating progress through them**, are discussed below.

#### Here's the burden for the Violation – Medicine must be substances that are used to treat diseases. CRISPR is a technology to find or create those substances BUT isn’t used to treat diseases itself which means it’s not Topical.

#### Answering their Pre-empts:

#### AT Vidyasagar – This says it’s a DNA – a] that’s not a substance and b] it cuts DNA, it’s not a medicine itself – which is our Effects-T offense.

#### AT Sfera – 1] This proves our Extra-T offense – simply being able to be used as a drug doesn’t mean it’s a medicine – this identifies a singular CRISPR tool, CTX001 as a drug, but CRISPR itself isn’t one and 2] Creating medicines is distinct from being a medicine.

#### 3] The Standard is Limits – They explode the topic to include therapies, research areas, treatments, drug discovery techniques, etc. that eviscerate a stable locus of predictability. Limits is a sequencing question to Clash and in-depth Education since we’re only able to prepare if there’s stable core controversies. Independently, massive caselists make debate inaccessible to small school debaters, whose lack of resources make writing individualized disads impossible

#### 4] TVA Solves – reduce IP protections on gene-based medicines.

#### 5] Paradigm Issues –

#### a] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### b] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation.

#### c] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

## 2

### Framework

#### Ethics must begin apriori

#### [1] Uncertainty – our experiences are inaccessible to others which allows people to say they don’t experience the same, however a priori principles are universally applied to all agents.

#### [2] Bindingness – I can keep asking “why should I follow this” which results in relatvism since obligations are predicated on ignorantly accepting rules. Only reason solves since asking “why reason?” requires reason which concedes its authority and equally proves agency as constitutive.

#### [3]Action theory: only evaluating action through reason solves since reason is key to evaluate intent, otherwise we could infinitely divide actions. For example: If I was brewing tea, I could break up that one big action into multiple small actions. Only our intention, to brew tea unifies these actions if we were never able to unify action, we could never classify certain actions as moral or immoral since those actions would be infinitely divisible.

#### That implies universality

#### [1] Apriori truths are true for everyone, i.e. the sum of interior angles in a triangle equaling 180 can’t only be true for me but not you

#### [2] Principle of equality- There is nothing apriori distinct between agents thus our obligations should be equal, which means even if we aren’t bound to the categorical imperative, universality is still a side constraint on other frameworks.

#### Freedom follows

#### [1] Its impossible to will a violation of freedom, since it necessarily entails a violation of your own freedom thus violating your will.

#### [2] We could not hold agents responsible for their actions if we did not assume them to have the freedom to control their actions for themselves.

#### Thus, the standard is consistency with the categorical imperative.

#### Prefer the standard:

#### [1] Resource Disparities- a focus on evidence and statistics privileges debaters with the most preround prep which excludes lone-wolfs who lack huge evidence files. A debate under my framework can easily be won without any prep since huge evidence files aren’t required.

#### [2]Past experiences have no effect on causality or internal link to continuity, i.e. raining yesterday doesn’t mean rain today.

### Offense

#### 1]Reducing IP is a form of free-riding that fails the universality test, but also uses the creators of the medicine as means to an end.

Dyke 18 Dyke, Raymond. “The Categorical Imperative for Innovation and Patenting - IPWatchdog.com: Patents &amp; Patent Law.” IPWatchdog.com | Patents &amp; Patent Law, 1 Oct. 2018, www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/.//dhsNJ

As we shall see, applying Kantian logic entails first acknowledging some basic principles; that the people have a right to express themselves, that that expression (the fruits of their labor) has value and is theirs (unless consent is given otherwise), and that government is obligated to protect people and their property. Thus, an inventor or creator has a right in their own creation, which cannot be taken from them without their consent. So, employing this canon, a proposed Categorical Imperative (CI) is the following Statement: creators should be protected against the unlawful taking of their creation by others. Applying this Statement to everyone, i.e., does the Statement hold water if everyone does this, leads to a yes determination. Whether a child, a book or a prototype, creations of all sorts should be protected, and this CI stands. This result also dovetails with the purpose of government: to protect the people and their possessions by providing laws to that effect, whether for the protection of tangible or intangible things. However, a contrary proposal can be postulated: everyone should be able to use the creations of another without charge. Can this Statement rise to the level of a CI? This proposal, upon analysis would also lead to chaos. Hollywood, for example, unable to protect their films, television shows or any content, would either be out of business or have robust encryption and other trade secret protections, which would seriously undermine content distribution and consumer enjoyment. Likewise, inventors, unable to license or sell their innovations or make any money to cover R&D, would not bother to invent or also resort to strong trade secret. Why even create? This approach thus undermines and greatly hinders the distribution of ideas in a free society, which is contrary to the paradigm of the U.S. patent and copyright systems, which promotes dissemination. By allowing freeriding, innovation and creativity would be thwarted (or at least not encouraged) and trade secret protection would become the mainstay for society with the heightened distrust.

#### 2]IP protections are consistent with libertarian theories of property

Zeidman 16 Zeidman, Bob. “Why Libertarians Should Support a Strong Patent System - Ipwatchdog.com: Patents &amp; Patent Law.” IPWatchdog.com | Patents &amp; Patent Law, 5 Jan. 2016, www.ipwatchdog.com/2016/01/05/why-libertarians-should-support-a-strong-patent-system/id=64438/.//dhsNJ

Ayn Rand strongly supported patents. In her book “Capitalism: The Unknown Ideal,” she states: An idea as such cannot be protected until it has been given a material form. An invention has to be embodied in a physical model before it can be patented; a story has to be written or printed. But what the patent or copyright protects is not the physical object as such, but the idea which it embodies. By forbidding an unauthorized reproduction of the object, the law declares, in effect, that the physical labor of copying is not the source of the object’s value, that that value is created by the originator of the idea and may not be used without his consent; thus the law establishes the property right of a mind to that which it has brought into existence. Many libertarians believe that intellectual property, being intangible, is not real property. A formal libertarian definition of property is difficult to formulate, but we would say that property is that which can be produced or contribute to production. Intellectual property falls clearly within these constraints. Yet some libertarians complain that intellectual is not tangible and is defined by government regulation—the patent laws—such that it would not exist without government definition. Let us look at this argument closer. Land is unquestionably property in the minds of libertarians. Yet the land upon which a house is built was not created by the property owner. It was created by nature or God, depending on your inclination, but no one would claim it to be created by the owner, whereas intellectual property is unquestionably created by the inventor. And how far do property lines extend? Property lines are determined by local governments. One can argue that property lines are negotiated by owners and enforced by governments, but when we moved into our homes, there were no negotiations with surrounding property owners. And how far above ground and below ground do property rights extend? These limitations are definitely not negotiated with other property owners but are determined by laws enforced by governments. Patents also have limitations in terms of scope and time that are determined by government laws. One can see that limitations on patents are similar to those on physical property and in some respects are more closely connected to production. For these reasons, libertarians should recognize patents as they do other forms of property. As a secondary but important example, libertarians are generally concerned about government spying on private conversations. When the government captures a phone conversation, it is not physically taking property. It is simply copying intangible data that exists as a form of transient electrical signals. Copying does not involve removing the original—the phone conversation is not destroyed when it is copied. Yet libertarians recognize that this copying of intangible data is a kind of theft of property. Libertarians should thus be wary of making the argument that intangible patents cannot be property or they may lose their contrary argument that private conversations are personal property to be protected.

#### 3]Patents protect private companies.

Na 19 [Blake Na, "Protecting Intellectual Property Rights in the Pharmaceutical Industry", Chicago-Kent | Journal of Intellectual Property, 4-19-2019, https://studentorgs.kentlaw.iit.edu/ckjip/protecting-intellectual-property-rights-in-the-pharmaceutical-industry/, accessed: 8-24-2021.] //Lex VM

Patent Rights A pharmaceutical company may apply for a patent from the PTO at any time in the development lifetime of a drug.[12] A drug is patentable if it is non-obvious, new, and useful.[13] The drug must be non-obvious when comparing the drug with another previously invented drug, i.e., it does not bring the same type of information as the other drugs. The drug must also not exist, and it must have a purpose. Intellectual property rights, especially patent rights, are the foundation of the pharmaceutical industry. The industry heavily depends on the future profits which innovation (and as a result, exclusivity) enable. Drug patents grant the originator company to market exclusivity for a fixed term of 20 years from the patent’s original filing date. By giving this 20-year patent term in which the government cannot regulate the price, market exclusivity allows pharmaceutical companies to have a monopoly over the market. To maximize their profit, pharmaceutical companies work on extending the exclusivity of a drug. For example, AbbVie extended the manufacturing exclusivity of Humira by delaying generic companies from manufacturing generic entrants until 2023. The market exclusivity can be lengthened anywhere between 180 days to 7 years. Thus, due to efforts to derive profits from patents, pharmaceutical companies’ patents contribute to roughly 70-80 percent of their overall revenues. Patents in the pharmaceutical industry are normally referred to as their product portfolio and are the most effective method for protecting innovation and creating significant returns on investments. Accordingly, as mentioned above, patents help in recouping costs related to research, development, and marketing of a drug. Patents not only help pharmaceutical companies recoup investments, they can also act as a shield against infringement claims. Strong patent protection can safeguard drugs from potential infringers. Without consent from the patentee, other competing companies cannot use, make, or distribute the invention. However, because a drug can be easily imitated by competitors, bringing an infringement suit can also protect a patentee’s rights. Recently, DUSA Pharmaceuticals, Inc.—an arm of the Indian pharmaceutical company Su Pharma and ranked among the top 50 global Pharma Companies—was recently granted injunctive relief from a U.S. court against Biofrontera Inc. in a patent infringement case[14]. The court’s order prohibited Biofrontera from making use of information, including sales data, marketing data, technical information, and unpublished clinical data, of DUSA Pharmaceuticals[15]. Although bringing an infringement suit is a valuable remedial measure for patentees, pharmaceutical companies often face difficulty with the high costs and uncertainty of litigation

#### 4] No aff solvency for turns – the aff reduces protections rather than eliminating them which still allows for freedom violations – Presume neg.

### No 1ar theory

#### 1~ Responses to my counter interp will be new which means 1ar theory necessitates intervention—-outweighs because it makes the decision arbitrary

#### 2~ Deters the 1NC from checking abuse out of fear for 1AR meta-theory, which destroys me since it's also preclusive. Turns their infinite abuse args.

#### 3~ Resolvability double bind—either you automatically accept 2AR responses to 2NR counter-standards which means they always win since I can't answer those responses, or you have to intervene to determine the credence you give those 2AR responses, which makes it irresolvable and unfair. Also turns infinite abuse since intervention allows the judge to be infinitely abusive to either side if they want to be.

### Framework

#### [1]Regress takes out their framework – when asking “why pain is bad,” that raises another question, and so on to infinite

#### [2] Culpability – focus free will is the only way to ascribe culpability to agents, otherwise we would be just acting of non-normative instincts that we can’t control. Just like if someone forced me to steal a cookie, I wouldn’t be held responsible

#### [3] Universality is a side constraint, everyone being equal means our obligations must be equal implying universality, which means my offense applies under ur fw. Ow on probability since synthetic apriori truths are always true

#### AT Moen

#### [1] Is-ought, just cuz ppl do value pleasure doesn’t make it morally binding

#### [2]Masochist objection, masochists find pleasure in pain, which means pleasure/pain calculus is impossible since everyone has their own form of pleasure with no way to weigh between. Also disproves bindingess cuz masochists do deny it. Cross said the warrant -

#### [3] second says pleasure is more important than other consequences

#### AT Bostrom first

#### 1] Debate solves- it allows us to determine which framework is true and what offense matters,

#### 2] we are morally certain – but if we aren’t

#### A] turn – extinction first kills debate about actual philosophical theories which is key if we are morally uncertain

#### B] turn—if were morally uncertain there is a risk that extinction is good under some moral theory, we do not know yet

#### [3] Args assume consequences matter and aggregation

### CRISPR Advantage

#### Top-Level:

#### 1] No solvency – 1AC Sherkow isolates the reason for lack of CRISPR research as lack of funding, but the aff removes all potential for revenue because there aren’t any more patents

#### 2] No impact – the patent disputes will be resolved, at which point all the 1AC innovation begins – make them prove that it’s try or die now

#### The Aff causes Bioterrorism – two internal links –

#### 1] Eliminating CRISPR Patents cause rise of unethical 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 risks Bioterrorism.

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.

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public again and again. It could, with the right mix of genetic traits, even wipe us off the planet

, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

#### The Disease Impact –

#### 1] They can’t solve it – their impact is about future pandemics BUT their CRISPR I/L is about prior-known disease that we can find genetic cures to.

### WTO Advantage

#### Low WTO causes regional trade – yes trade-off

Isfeld 14 Gordon Isfeld 3-17-2014 business.financialpost.com/2014/03/17/with-rise-of-shot-gun-trade-agreements-is-the-wto-even-relevant-anymore/ “With the rise of 'shot-gun' trade agreements, is the WTO even relevant anymore” //Elmer

OTTAWA — It’s getting awfully crowded out there in the free-trading world. The seemingly endless hunt for new global partners is redefining the traditional and hard-fought rules of engagement between nations. So much so, observers say, the old world order — remember the WTO, and GATT before it — has increasingly become a sideshow to the proliferation of bilateral, **trilateral** **and**, often, **multi-lateral** agreements

#### 1] Current Regional Trade isn’t Great Power Competition – it’s regional integration that’s far more open which takes out their Exclusion I/L – that’s 1NC Brkic.