# 1nc

## 1

### 1NC Generic

#### Interpretation: The affirmative debater must defend reducing intellectual property protections for substances that treat diseases. To clarify, they may not defend substances that prevent diseases.

#### Violation: They defend \_\_\_\_\_\_.

#### Medicines treat diseases

Webster (Merriam Webster is America's leading and most-trusted provider of language information, accessed on 6-30-21, Merriam Webster, "Definition of MEDICINE,” https://www.merriam-webster.com/dictionary/medicine)// ww pbj

Definition of medicine 1a: a substance or preparation used in treating disease cough medicine

#### Treatment is different than prevention

Pflanzer 20 (Lydia Ramsey Pflanzer is a healthcare editor for Business Insider. She joined Business Insider in 2015 after graduating from Northwestern University, 4-29-2020, accessed 6/30/21, "Scientists are racing to discover ways to treat and prevent coronavirus. Here's the difference between a treatment and a vaccine.," Business Insider, <https://www.businessinsider.com/whats-the-difference-between-a-vaccine-and-a-treatment-2020-4)//ww> pbj

Vaccines are used to prepare the body's immune system to fight off infections. They work by giving the body a small taste of what the virus is like so that way it can produce antibodies that fight off an intruding virus, ideally keeping people from falling ill. Some vaccines protect better than others, and they're typically administered across broad populations. There are vaccines for some infectious diseases, like the flu, smallpox, measles, and chickenpox. But others, like HIV and hepatitis C, don't have vaccines that protect against them. Vaccines that protect against two other deadly outbreaks, MERS and SARS, have yet to be approved after the outbreaks subsided. There are more than 70 potential coronavirus vaccines in the works, with a number in early human trials. Drugmakers are looking into ways to produce the billions of doses that might be needed to suppress the pandemic. Read more: There are more than 70 potential coronavirus vaccines in the works. Here are the top efforts to watch, including the 16 vaccines set to be tested in people this year. FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) Associated Press Treatments, on the other hand, are meant to do just that: treat COVID-19, helping patients sickened by the virus survive and recover more quickly. Treatments for disease are there to lessen symptoms and ultimately improve the outcomes of a particular disease. Sometimes, medications can be used preventatively. For instance, patients with high cholesterol might be prescribed a medication called a statin to prevent heart attacks. Some potential coronavirus treatments are being studied to see if they can prevent people from contracting the virus in the first place. For COVID-19, researchers are testing everything from antimalarial medications to antivirals, to even common heartburn medications in hospitalized patients with the hopes that more patients will survive severe forms of the illness and potentially recover faster. Some are looking at ways to use patients' own bodies to fight the virus with antibody treatments.

#### Vaccines specifically are different from medicines

Immunize BC 20 (Immunize British Colombia is a collaborative project of the BC Ministry of Health, the BC Centre for Disease Control (an agency of the BC Provincial Health Services Authority), the regional health authorities (First Nations Health Authority, Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health), the BC Pharmacy Association and the Public Health Association of BC. Our mission is to improve the health of British Columbians by continuing to reduce the number of vaccine-preventable diseases, along with the illness, disability and death that they cause, What are vaccines?, Date last reviewed: Thursday, Mar 19, 2020, accessed on 6-30-21, <https://immunizebc.ca/what-are-vaccines)//ww> pbj

Vaccines are products that protect people against many diseases that can be very dangerous and even deadly. Different than most medicines that treat or cure diseases, vaccines prevent you from getting sick with the disease in the first place.

#### Standards:

#### [1] Limits – they explode the topic to include tons of substances that prevent disease rather than treat them like soap, medical supplies, or food and make it so there is *no* unified neg generics. The aff still gets the core of the topic lit: they get medicine, innovation, and global inequality. Explosion of aff ground makes neg prep burden impossible, either killing neg ground or forcing the neg to read generics that barely link, always letting aff win. Force the 1AR to read a definition card with a clear list of what’s included and excluded – otherwise, vote neg since they can’t put a clear limit on the topic. Our interp solves – it establishes a clear bright-line for that gives the neg a chance to predict and prepare for every aff ahead of time. At best, the aff’s extra-T still links to all our offense since they can get extra-T advantages to solve disads and defend whatever they want, magnifying limits.

#### [2] Precision – not defending the text of the resolution justifies the affirmative doing away with random words in the resolution which a] means they’re not within the topic which is a voter for jurisdiction since you can only vote affirmative on the resolution and this debate never should have happened, b] they’re unpredictable and impossible to engage in so we always lose

#### Drop the Debater –

#### [1] sets a precedent that debaters wont be abusive

#### [2] DTA is the same since you drop the aff

#### Voters:

#### [1] Fairness – constitutive to the judge to decide the better debater, only fairness is in your jurisdiction because it skews decision making

#### [2] Education – the only portable education from debate that we care about

#### Competing Interps:

#### [1] reasonability on t is incoherent: you’re either topical or you’re not – it’s impossible to be 77% topical, links to all limits offense

#### [2] functionally the same as reasonability – we debate over a specified briteline which is a counter interp

#### [3] judge intervention – judge has to intervene on what’s reasonable, creates a race to the bottom where debaters exploit judge tolerance for questionable argumentation.

#### No RVIs

#### [1] illogical for you to get offense just for being fair – it’s the 1ac’s burden

#### [2] baiting - rvi’s incentivize debaters to read abusive positions to win off theory

#### [3] discourages checking abuse since debaters will be afraid to lose on theory

## 2

### Fw

#### Permissibility, presumption, and skep negate:

#### [1] Obligations- the resolution indicates the affirmative has to prove an obligation, and permissibility would deny the existence of an obligation

#### [2] Falsity- Statements are more often false than true because proving one part of the statement false disproves the entire statement. Presuming all statements are true creates contradictions which would be ethically bankrupt.

#### [3] Negating is harder – Aff gets last speech to crystallize and shape the debate in a way the favors them with no 3NR

#### [4] Affirmation theory- Affirming requires unconditionally maintaining an obligation

**Affirm: maintain as true.**

**That’s Dictionary.com**- “affirm” <https://www.dictionary.com/browse/affirm>

#### Morality must be derived a priori –

#### Ethical systems must bridge the is/ought gap – experience only tells us what is, not what ought to be, which raises the question why we ought to follow their framework

#### Problem of relativism – inability to know each other’s experience makes it an unreliable basis for ethics. People could just say they don’t experience the same.

#### Next, any moral rule faces the problem of regress – I can keep asking “why should I follow this.” Regress collapses to skep since no one can generate obligations absent grounds for accepting them. Only reason solves since asking “why reason?” asks for a reason for reasons, which concedes its authority.

#### This means constitutivism functions as a meta-ethic – failing to provide a constitutive obligation triggers skep through infinite regress – takes out the theory by itself

#### Thus, moral law must be universal—our judgements can’t only apply to ourselves any more than 2+2=4 can be true only for me. The only constraint is noncontradiction – if we accept a contradiction to be true, we accept all statements to be true since you could switch the first half of a disjunctive statement and render any second half true.

#### Prefer:

#### Action theory– absent a will, we are just blobs of chemicals – only practical reason makes action coherent, otherwise every action can be split into an infinite number of smaller actions.

#### culpability – absent a conception of free will, people can just claim they were acting of desires they can’t control

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

#### Prefer:

1. **Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify a standard without first willing that we can pursue ends free from others.**

#### Ethical frameworks must be theoretically legitimate. Any standard is an interpretation of the word ought. Thus, framework is functionally a topicality debate about how to define the terms of the resolution. Prefer this definition:

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 Kantian debate can easily be won without any prep since only analytical arguments are required. That controls the internal link to other voters because a pre-req to debating is access to the activity.**

#### Real world education—an understanding of Kantianism is key to understanding the law in the real world because most states abide by inviolable side-constraints in their constitutions—Germany proves – inviolable constraints on state authority

#### K2 education – RWA is the only out of round impact

**These arguments precede other phil justifications, but are not reasons to drop the negative—they’re only framing issues.**

#### Existence of extrinsic goodness requires unconditional human worth since to value anything requires a basis from which we value—thus we must treat others as ends in themselves

Korsgaard 83, Christine M (Prof of Phil @ Harvard University). "Two distinctions in goodness." *The Philosophical Review* 92.2 (1983): 169-195.

The argument shows how Kant’s idea of justification works. It can be read as a kind of regress upon the conditions, starting from an important assumption. The assumption is that when a rational being makes a choice or undertakes an action. he or she supposes the object to be good, and its pursuit to be justiﬁed. At least, if there is a categorical imperative there must be objectively good ends, for then there are necessary actions and so necessary ends (G 45-46/427—428 and Doctrine of Virtue 43-44/384—385). In order for there to be any objectively good ends, however, there must be something that is unconditionally good and so can serve as a sufﬁcient condition of their goodness. Kant considers what this might be: it cannot be an object of inclination, for those have only a conditional worth, “for if the inclinations and the needs founded on them did not exist, their object would be without worth” (0 46/428). It cannot be the inclinations themselves because a rational being would rather be free from them. Nor can it be external things, which serve only as means. So, Kant asserts, the unconditionally valuable thing must be “humanity” or “rational nature,” which he deﬁnes as “the power set to an end" (G 56/437 and DV 51/392). Kant explains that regarding your existence as a rational being as an end in itself is a “subjective principle of human action.” By this I understand him to mean that we must regard ourselves as capable of conferring value upon the objects of our choice, the ends that we set, because we must regard our ends as good. But since “every other rational being thinks of his existence by the same rational ground which holds also for myself” (G 47/429). we must regard others as capable of conferring value by reason of their rational choices and so also as ends in themselves. Treating another as an end in itself thus involves making that person’s ends as far as possible your own (G 49/430). The ends that are chosen by any rational being, possessed of the humanity or rational nature that is fully realized in a good will, take on the status of objective goods. They are not intrinsically valuable, but they are objectively

### offense

#### [1] Negates, reducing intellectual property violates rights to property

Riccardo Pozzo 06 [January 2006, "Immanuel Kant on intellectual property," https://www.researchgate.net/publication/250048266\_Immanuel\_Kant\_on\_intellectual\_property] // WW DL

**\*We do not endorse the author’s gendered language**

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator. The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the pub 1 Lecturer (Full Professor) of History of Philosophy at University of Verona. Article received on oct/ 06 and approuved for publication on dec/06. 12 Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 lisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed. Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way. The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other. In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right. In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name” (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 13 that contains them and put it into our library. In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411).

#### Reducing IP rights allows for freeriding which is against the categorical imperative.

**Van Dyke, 18** (Raymond Van Dyke, Raymond Van Dyke is an Attorney and Educator. In his practice he helps a variety of clients in their IP matters., 7-17-2018, accessed on 8-14-2021, IPWatchdog.com | Patents & Patent Law, "The Categorical Imperative for Innovation and Patenting - IPWatchdog.com | Patents & Patent Law", https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/)

But there was another philosopher, contemporaneous with the Founders, that bears notice, Immanuel Kant, who had a different take on moral and political philosophy, including the Categorical Imperative. Kant spent his life trying to distill the issues of morality into a logical framework. Just as the natural scientists of the Enlightenment were forming logical arguments concerning the physical world, e.g., physics, natural science and other disciplines, Kant tried to do the same with human morality: systematize it. In his Categorical Imperative, Kant simplifies a moral argument position for an individual by asking a question: if you thought that your position or Statement would be Universal, i.e., applicable to all people, it would have the stance of a Categorical Imperative and thus you must do it. For example, a Statement that I should try to save a person that is drowning can be considered a Categorical Imperative since this would be a betterment of humanity. However, the proposition or Statement that it should be ok for me to steal another’s car is not a betterment at all. Applying this as a universal law would lead to societal chaos and possible collapse since thievery would reign, and anarchy would result. Since the entire purpose of government is the protection of people (and their possessions), this Statement fails, and you are NOT compelled to act in that manner. This Statement does not rise to the level of a categorical Imperative. Intellectual property has been attacked of late on various grounds, including being less than property, and thus not entitled to the protections of the Constitution, despite the evidence to the contrary. This attitude is most recently, and most troublingly, exemplified by the U.S. Supreme Court in Oil States, where the Court equated patent rights to taxicab medallion rights. Freeriding is also being touted, subverting copyright law. Information must be free is the mantra. 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. Also, allowing the free taking of ideas, content and valuable data, i.e., the fruits of individual intellectual endeavor, would disrupt capitalism in a radical way. The resulting more secretive approach in support of the above free-riding Statement would be akin to a Communist environment where the State owned everything and the citizen owned nothing, i.e., the people “consented” to this. It is, accordingly, manifestly clear that no reasonable and supportable Categorical Imperative can be made for the unwarranted theft of property, whether tangible or intangible, apart from legitimate exigencies. On the positive front, there is a Categorical Imperative that creators should be encouraged to create, which is imminently reasonable and supportable. Likewise, the statement set forth in the Constitution that Congress should pass laws “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” is supportive, as a Categorical Imperative, for the many reasons elucidated two centuries ago by Madison and others, and endorsed by George Washington, Thomas Jefferson, and later by Abraham Lincoln. A Categorical Imperative, universality, however, may be a stretch outside of the United States since other cultures may not treasure the progress of science and the useful arts and freedoms that we Americans do. Nonetheless, it is certainly a supportable proposition in the United States, and even a Categorical Imperative that we must do it!

## 3

#### The counterfeit medicine market is attracting new suppliers, but new technologies are evolving to crack down on counterfeits – it’s prevalence is tentative

Hallie B Forcinio 21 [Hallie Forcinio is BioPharm International's packaging editor, editorhal@sbcglobal.net . PharmTech, 2-2-2021, "Countering Counterfeiters and Diverters," https://www.pharmtech.com/view/countering-counterfeiters-and-diverters]//anop

The never-ending battle against counterfeit pharmaceutical products has become fiercer with the pandemic. With product protection a constant concern, the market for anticounterfeiting technologies is strong, regulatory efforts are ongoing, and authentication and anticounterfeiting technologies are evolving. As a result, the anticounterfeiting packaging market is projected to grow at a 7.8% compound annual growth rate to $189.9 billion in 2026 (1). A major driver for this growth is the expanding use of e-commerce platforms, which make it easy to set up shop to sell fraudulent products and are largely unregulated. A study by Local Circles noted that approximately 20% of all products sold on e-commerce sites are counterfeit (1). Anticounterfeiting laws and regulations, such as the European Union’s Falsified Medicine Directive and the US’s Drug Supply Chain Security Act (DSCSA), safeguard prescription drugs available from pharmacies. “However, pharmaceutical manufacturers should be aware that these measures alone will not guarantee a product’s integrity and authenticity,” says Gene Dul, president of Schreiner MediPharm US. He says, “Only additional counterfeit-proof authenticity features can provide a comprehensive approach against fraud, misuse, and tampering.” Unfortunately, the coronavirus pandemic has increased the opportunities for counterfeiting. “In a survey issued by IDC in June 2020, 70% of companies agreed that their supply chain is ‘very vulnerable’ to suffering more problems if the COVID-19 crisis lasted more than a couple of months longer, and 75% of companies agreed that the COVID-19 pandemic has ‘greatly increased/will greatly increase’ problems with diversion, theft, and counterfeiting of critical products such as test kits, vaccines, and antivirals,” reports Aimee Genzler, vice-president, Corporate & Brand Communications at TraceLink, the study sponsor (2). In fact, in anticipation of a spike in counterfeiting, the US Immigration and Customs Enforcement Homeland Security Investigations (HSI) has launched Operation Stolen Promise 2, to halt the production, distribution, and sale of illicit COVID-19 treatments and vaccines. HSI reported that its agents have seized illicit proceeds and goods, made arrests, and shut down fraudulent websites (3), including the seizure of two domain names in December 2020 (4). The proliferation of counterfeit goods stems in part from the shift to e-commerce, which has been accelerated by stay-at-home orders and advisories and reduced access to physical retail pharmacies. “The emergence of on-line pharmacies poses a significant threat of escalation in counterfeit pharmaceuticals and underscores the urgent need for on-dose countermeasures,” reports Peter Wong, chief operating officer at TruTag Technologies, which recently entered a partnership with Colorcon to provide advanced security coatings for on-dose use. “Counterfeiters are opportunistic,” explains John Pitts, key account manager for Antares Vision, noting, “COVID-19 provided the ‘perfect storm’ for the counterfeiters: panic in consumers; product shortages from the brand name ethical providers; desire and, in many cases, requirement to purchase via e-commerce; and lack of and often conflicting information from the media and authorities.” Joe Farrell, life sciences expert at Loftware, concurs, “It seems clear that whenever there are high-value pharmaceutical products, there will be people trying to profit illegally. The fact that the COVID-19 vaccines need to be shipped in stringent cold storage containers with radio frequency identification (RFID) temperature sensors along with specialized transportation methods will make it more difficult for counterfeiters to enter the supply chain, but not impossible.” With COVID-19 vaccines now rolling out in limited quantities, demand will outstrip supply in the coming months. “This will create a ripe environment for unscrupulous parties to offer fake product,” says Wong, noting, “Distribution of the COVID-19 vaccine is designed to go to many more points of dispensing than for a normal pharmaceutical drug, as governments seek to deliver vaccinations broadly and as quickly as possible while maintaining demanding cold-chain requirements. These logistical requirements will create higher than normal transition points in the overall supply chain, which in turn create increase opportunities for diversion, adulteration, and fake product to reach the patient.” Counterfeiting countermeasures The pharmaceutical industry has been on the leading edge of anticounterfeiting and brand protection efforts for many years. “Anticounterfeit solutions are usually tailor-made according to the needs of the brand owner,” says Paavo Sillanpää, senior business manager, Pharma at UPM Raflatac. A diverse strategy considering threat scenario and product is needed. “Most pharma companies have a multi-layered approach,” notes Farrell. The most common physical solutions are tamper-evident labels and packaging materials, designs that prevent the placement of a counterfeit product into the original packaging, serialization, and overt and covert authentication methods such as holograms, invisible markers, and taggants. “Ideally, multi-level security concepts should be used that are individually tailored to a specific use case, combining analog and digital features, which can be verified by different stakeholders within the supply chain,” says Dul. There is heightened interest in tools and technologies that go beyond the package to protect patients, such as on-dose solutions. In addition, says Wong, “the industry is increasing its public awareness campaigns of the problem of fake and unsafe medicine in an effort to educate consumers about the dangers of unauthentic drug products.” As a result, Pitts predicts an increased focus on consumer engagement. He notes, “Enabling the end consumer and the dispenser to authenticate their products is powerful on so many levels. It makes counterfeiting more difficult, provides vital and real-time data to the consumer, and can offer the manufacturer feedback.” Labeling technologies Labeling plays an important role in the fight against counterfeit products. As the passport for moving products through the global supply chain, it contains any track-and-trace or authentication information. “In the label business, we have seen an increased interest in various tamper-evident (TE) solutions and holograms,” reports Sillanpää. One new product from UPM Raflatac combines heat resistance, advanced adhesion, and conformability. Designed primarily for the European market where cartoned blister packaging is common, the heat-resistant TE label won’t shrink in heat tunnels used to produce multipacks. UPM Raflatac has also introduced sustainable TE labeling. It’s produced from Forest Film, which Sillanpää says is “the world’s first wood-based plastic labeling material.” Benefits include performance equivalent to traditional plastic film label materials and the ability to help pharmaceutical brands achieve sustainability goals. Demand for more sustainable products extends to RFID and near-field communication (NFC) tags. Eco-friendly RFID and NFC tags from Identiv feature paper-based transponder inlays that reduce polyethylene terephthalate content, resulting in a repulpable substrate (5). RFID technology is integral to the Cap-Lock plus RFID cap adapter and label combination from Schreiner MediPharm. The label-integrated RFID inlay provides digital proof of integrity and first-opening evidence for syringes as well as product authentication. Dul explains, “The adapter is placed on top of the syringe’s primary closure and interlinked with it to equalize the diameter differences of the syringe body and closure. The label wraps around the syringe body and cap adapter and—once opened—provides irreversible tamper evidence due to an integrated perforation.” Printing and tagging technologies Magnetic ink is another potential anticounterfeiting tool. Technology from Inspectron relies on a proprietary reader, track-and-trace software, and magnetic ink, long used on checks to facilitate automated sorting. The magnetic ink is used to print a barcode, which is detectable even if it’s not visible to the eye. That means the code, which may be serialized, can be hidden on the inside of a carton or under a label and still be read. The current reader works from a distance of up to 2 mm, but units with longer read ranges are under development. “However, longer read ranges require bigger codes,” notes Nathalie Muller, head of Innovation at Inspectron. Although the first commercial application of the technology inkjets the codes on paper to enable identification of diverted product, Muller says, the permanent magnetic codes could be printed on plastic or glass containers and potentially support tasks like vial tracking. Also under development is a hybrid one- and two-dimensional barcode that would hold more data. On-dose technology enables authentication at the product level. Edible microparticles coupled with the Smart Medicine solution from TruTag Technologies confirms product authenticity and can help boost patient adherence and outcomes. A new Pharma Mobile App allows patients to scan each dose with their smartphone, authenticate it, and record that it was taken. If desired, the record of the dose can be shared with healthcare providers. The system also can link to other product information. In April 2020, FDA accepted molecular tagging technology from Applied DNA Sciences into its Emerging Technology Program (6). The company says that its technology is a multilayered platform that gives both the dose and the packaging an immutable identity for authentication. On Nov. 30, 2020, AlpVision launched its Alpvision COVID-19 Initiative to protect COVID-19-related therapeutics and vaccines against counterfeiting. Under the program, AlpVision provides pharmaceutical companies and their suppliers with the tools to deploy its Cryptoglyph digital security feature on their packaging. Invisible to the human eye, the Cryptoglyph feature can be authenticated via smartphone. Adopting the technology does not change the production process or involve additional consumables. In addition, the smartphone applications connect to AlpVision’s Brand Monitoring System, a centralized server platform that enables real-time monitoring of product authentication activities. AlpVision plans to provide this service for free until the World Health Organization declares the pandemic has ended (7). Software tools Physical technologies are common anticounterfeiting tools, but counterfeit and diversion prevention also relies on software. Farrell reports, “At Loftware, we are being asked for help in getting the correct information onto the label. It’s important to have an enterprise labeling solution that integrates with a company’s sources of data to make sure the correct approved information is automatically applied to the labels. This includes languages, barcodes, regulatory symbology, and regional product information. You also need a labeling solution that can aid with approving, managing, and promoting electronic information for use [data] to help speed the process for a faster time to market for these critical products.” Although not specifically an anticounterfeiting product, Loftware Spectrum software integrates with serialization solutions and ensures labeling is consistent, accurate, and contains the right serialized data and barcodes. “The use of global templates in an enterprise solution also helps our life sciences customers to globally standardize on the look of their supply chain labels to help identify counterfeited products,” he explains. The scalable Track My Way platform from Antares Vision offers single-unit, batch, and custom traceability; provides direct consumer engagement; and can extend from raw materials tracking to end-of-life package disposal/recycling. Geolocation functionality can track the harvesting of the raw materials, packaging locations, the movement of products through the supply chain, and the point-of-sale location. In April 2020, TraceLink released an anticounterfeiting tool called Smart Distribution Tracking. By integrating the Internet of Things with product serialization, Smart Distribution Tracking provides full track-and-trace visibility for the secure delivery of vaccines, test kits, and high-value products. Another software tool, the Summit Authentication Platform from Microtrace Solutions, is a customized system consisting of a self-authenticating, encrypted barcode; a Spectral Taggant; and a handheld detector plus a smartphone mobile app. “Our Spectral Taggant is a chemistry formulated into an ink that, when printed, is a highly secure ‘signature’ or ‘fingerprint,’” explains Brian Brogger, president at Microtrace Solutions. This signature can be authenticated instantly via the handheld spectrometer or smartphone without an Internet connection. For vaccines and therapeutics, the barcode and Spectral Taggant can be applied to security labels. The mobile app is then able to verify that the barcode was genuinely issued and the Spectral Taggant verifies that the barcode has not been copied. The system also can provide real-time reporting and analysis. The latest release of the Systech Brand Protection Suite from Systech International, the software solutions division of Markem-Imaje, delivers a fully integrated solution to combat counterfeiters, identifies product diversion, meets regulatory compliance, and provides analytics. The centerpiece of the suite, the company’s non-additive e-Fingerprint technology, turns any existing barcode into a unique, digital identifier to provide end-to-end visibility and actionable information as a product moves through the supply chain. New functions include the ability to push unique responses and content to users and smartphone authentication of e-Fingerprinted products. Responses can be tailored to the user, location, time, and safety of the product, and include photos or other information. A new analytics platform, Systech Insight, offers a series of Information on Demand dashboards and an analytics data pool (8).

#### **IP protection prevents and quickly stops spread counterfeit medicines – multiple warrants**

FIFARMA 21, [FIFARMA is the Latin American Federation of the Pharmaceutical Industry created in 1962. We represent 16 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles. (Apr 22, 2021), "This is how we fight counterfeit medicines with Intellectual Property," https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/]//anop

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also, IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Pharmaceutical counterfeiting is increasingly used to support terrorism – used for funding and mediums of attacks

née Lybecker 18, Kristina M.L. Acri [Kristina M. L. Acri née Lybecker is an Associate Professor of Economics in the Department of Economics and Business at Colorado College in Colorado Springs, CO. (February 2018), "Pharmaceutical Counterfeiting: Endangering Public Health, Society and the Economy" Fraser Institute, https://www.fraserinstitute.org/sites/default/files/pharmaceutical-counterfeiting-endangering-public-health-society-and-the-economy.pdf]//anop

Pharmaceutical counterfeiting is linked to numerous forms of organized crime: drug trafficking, money laundering, and terrorism (Lybecker, 2016; Pfizer, 2007; Redpath, 2012; Criminal Intelligence Service Canada, 2006; UNODC, 2017). As reported by Redpath (2012: 7), “not only have groups such as the Russian mafia, Colombian drug cartels, Chinese triads and Mexican drug gangs all become heavily involved in producing and trafficking counterfeit drugs over the past decade, but mounting evidence also points to the direct involvement of Hezbollah and al Qaeda.” *Given the profitability of the endeavor, it is not surprising that pharmaceutical counterfeiting is increasingly a source of funding for terrorist groups* (Lybecker, 2016; Pfizer, 2007; Redpath, 2012). Moreover, by their very nature, organized criminal operations are well suited to the intricacies of pharmaceutical counterfeiting. “Criminal organisations have the advantage of huge resources, international networks and skilled labour. They can move with a speed that often confounds the authorities. Counterfeit versions of the antiviral drug Tamiflu were available on fake internet pharmacy sites, like the one posing as the ‘Canadian Pharmacy,’ within weeks of the [World Health Organization] declaration of H1N1 as a pandemic” (Redpath 2012: 8). While anecdotal evidence of the link is quite plentiful, the clandestine nature of the business as well as the secrecy maintained by law enforcement make it virtually impossible to either completely understand or measure the extent of the trade. A 2014 INTERPOL study provides perspective on pharmaceutical crime and organized criminal groups. INTERPOL’s Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate has prepared an analysis of available data, dating from 2008 to 2014, to establish the extent of organized criminal groups (OCGs) activity in the realm of pharmaceutical crime (INTERPOL, 2014).5 According to the report, a recent Europol threat assessment concludes that there are “a wide variety of actors, operating within the pharmaceutical crime arena, encompassing both OCGs and individual criminals, both of which are involved at any point in the supply chain.” The report points to the involvement of both traditionally structured hierarchical crime groups in addition to highly organized, yet generally informal, networks of illicit online pharmacies and finally, small groups of three to ten members. The INTERPOL study, as well as those from other agencies, provides some perspective on the involvement of organized criminal groups in Canada. Numerous investigations in the US, Canada, and Sweden have linked the Hell’s Angels to the production and distribution of counterfeit medicines, in particular ED medications and steroids (INTERPOL, 2014). • Fake oxycontin pills containing fentanyl were responsible for more than 50 deaths in Alberta in 2015. The counterfeit pills are also responsible for three deaths in Saskatchewan (Partnership for Safe Medicines, 2015b). • In November 2013, Canadian authorities began an organized crime investigation named “Project Forseti,” targeting the Hells Angels and the Fallen Saints (Customs Today Report, 2015). In January of 2015, police in Saskatchewan and Alberta, Canada seized guns and drugs, including significant amounts of counterfeit oxycontin. A United Nations Interregional Crime and Justice Research Institute (UNICRI) study suggests that criminal networks use routes and methods to transport counterfeit medicines that are similar to those used to traffic in drugs, firearms, and people (UNICRI, 2012). Evidence suggests that organized criminal gangs involved in the production of synthetic drugs are able to easily access the materials and expertise needed to also produce counterfeit medicines. In both Europe and Southeast Asia, authorities cite evidence of “criminal manufacturers of amphetamine-type substances [that] have been involved in the production and distribution of counterfeit medicines” (INTERPOL, 2014).

#### Terrorism escalates to nuclear war

Ayson 10 (Robert Ayson. Robert Ayson is Professor of Strategic Studies at Victoria University of Wellington, New Zealand, where he works closely with the Centre for Strategic Studies. “After a Terrorist Nuclear Attack: Envisaging Catalytic Effects”. 6-21-2010. Studies in Conflict and Terrorism. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2010.483756?journalCode=uter20>) **//TruLe**

But these two nuclear worlds—a non-state actor nuclear attack and a catastrophic interstate nuclear exchange—are not necessarily separable. It is just possible that some sort of terrorist attack, and especially an act of nuclear terrorism, could precipitate a chain of events leading to a massive exchange of nuclear weapons between two or more of the states that possess them. In this context, today’s and tomorrow’s terrorist groups might assume the place allotted during the early Cold War years to new state possessors of small nuclear arsenals who were seen as raising the risks of a catalytic nuclear war between the superpowers started by third parties. These risks were considered in the late 1950s and early 1960s as concerns grew about nuclear proliferation, the so-called n+1 problem. It may require a considerable amount of imagination to depict an especially plausible situation where an act of nuclear terrorism could lead to such a massive inter-state nuclear war. For example, in the event of a terrorist nuclear attack on the United States, it might well be wondered just how Russia and/or China could plausibly be brought into the picture, not least because they seem unlikely to be fingered as the most obvious state sponsors or encouragers of terrorist groups. They would seem far too responsible to be involved in supporting that sort of terrorist behavior that could just as easily threaten them as well. Some possibilities, however remote, do suggest themselves. For example, how might the United States react if it was thought or discovered that the fissile material used in the act of nuclear terrorism had come from Russian stocks,40 and if for some reason Moscow denied any responsibility for nuclear laxity? The correct attribution of that nuclear material to a particular country might not be a case of science fiction given the observation by Michael May et al. that while the debris resulting from a nuclear explosion would be “spread over a wide area in tiny fragments, its radioactivity makes it detectable, identifiable and collectable, and a wealth of information can be obtained from its analysis: the efficiency of the explosion, the materials used and, most important … some indication of where the nuclear material came from.”41 Alternatively, if the act of nuclear terrorism came as a complete surprise, and American officials refused to believe that a terrorist group was fully responsible (or responsible at all) suspicion would shift immediately to state possessors. Ruling out Western ally countries like the United Kingdom and France, and probably Israel and India as well, authorities in Washington would be left with a very short list consisting of North Korea, perhaps Iran if its program continues, and possibly Pakistan. But at what stage would Russia and China be definitely ruled out in this high stakes game of nuclear Cluedo? In particular, if the act of nuclear terrorism occurred against a backdrop of existing tension in Washington’s relations with Russia and/or China, and at a time when threats had already been traded between these major powers, would officials and political leaders not be tempted to assume the worst? Of course, the chances of this occurring would only seem to increase if the United States was already involved in some sort of limited armed conflict with Russia and/or China, or if they were confronting each other from a distance in a proxy war, as unlikely as these developments may seem at the present time. The reverse might well apply too: should a nuclear terrorist attack occur in Russia or China during a period of heightened tension or even limited conflict with the United States, could Moscow and Beijing resist the pressures that might rise domestically to consider the United States as a possible perpetrator or encourager of the attack? Washington’s early response to a terrorist nuclear attack on its own soil might also raise the possibility of an unwanted (and nuclear aided) confrontation with Russia and/or China. For example, in the noise and confusion during the immediate aftermath of the terrorist nuclear attack, the U.S. president might be expected to place the country’s armed forces, including its nuclear arsenal, on a higher stage of alert. In such a tense environment, when careful planning runs up against the friction of reality, it is just possible that Moscow and/or China might mistakenly read this as a sign of U.S. intentions to use force (and possibly nuclear force) against them. In that situation, the temptations to preempt such actions might grow, although it must be admitted that any preemption would probably still meet with a devastating response. As part of its initial response to the act of nuclear terrorism (as discussed earlier) Washington might decide to order a significant conventional (or nuclear) retaliatory or disarming attack against the leadership of the terrorist group and/or states seen to support that group. Depending on the identity and especially the location of these targets, Russia and/or China might interpret such action as being far too close for their comfort, and potentially as an infringement on their spheres of influence and even on their sovereignty. One far-fetched but perhaps not impossible scenario might stem from a judgment in Washington that some of the main aiders and abetters of the terrorist action resided somewhere such as Chechnya, perhaps in connection with what Allison claims is the “Chechen insurgents’ … long-standing interest in all things nuclear.”42 American pressure on that part of the world would almost certainly raise alarms in Moscow that might require a degree of advanced consultation from Washington that the latter found itself unable or unwilling to provide. There is also the question of how other nuclear-armed states respond to the act of nuclear terrorism on another member of that special club. It could reasonably be expected that following a nuclear terrorist attack on the United States, bothRussia and China would extend immediate sympathy and support to Washington and would work alongside the United States in the Security Council. But there is just a chance, albeit a slim one, where the support of Russia and/or China is less automatic in some cases than in others. For example, what would happen if the United States wished to discuss its right to retaliate against groups based in their territory? If, for some reason, Washington found the responses of Russia and China deeply underwhelming, (neither “for us or against us”) might it also suspect that they secretly were in cahoots with the group, increasing (again perhaps ever so slightly) the chances of a major exchange. If the terrorist group had some connections to groups in Russia and China, or existed in areas of the world over which Russia and China held sway, and if Washington felt that Moscow or Beijing were placing a curiously modest level of pressure on them, what conclusions might it then draw about their culpability.

## Case

#### Permissibility, presumption, and skep negate:

#### [1] Obligations- the resolution indicates the affirmative has to prove an obligation, and permissibility would deny the existence of an obligation

#### [2] Falsity- Statements are more often false than true because proving one part of the statement false disproves the entire statement. Presuming all statements are true creates contradictions which would be ethically bankrupt.

#### [3] Negating is harder – Aff gets last speech to crystallize and shape the debate in a way the favors them with no 3NR

#### [4] Affirmation theory- Affirming requires unconditionally maintaining an obligation

**Affirm: maintain as true.**

**That’s Dictionary.com**- “affirm” <https://www.dictionary.com/browse/affirm>

### Case wooo

#### The aff doesn’t solve – access to medicine is not a one-way street and there are multiple other factors that they just can’t resolve

Motari 21, Marion Motari, [Jean-Baptiste Nikiema](javascript:;), [Ossy M. J. Kasilo](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Ossy_M__J_-Kasilo), [Stanislav Kniazkov](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Stanislav-Kniazkov), [Andre Loua](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Andre-Loua), [Aissatou Sougou](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Aissatou-Sougou), [Prosper Tumusiime](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Prosper-Tumusiime) are Adjunct Faculty, Daystar University School of Law, Nairobi, Kenya, “The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement”, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y>, accessed apark 6/27/21

Although this paper focuses on the role of intellectual property rights on access to medicines, it is recognized that limited access to medicines in countries of the World Health Organization (WHO) African Region[Footnote3](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#Fn3) is a multidimensional problem. It is affected by other factors such as lack of public financing for health care and over-reliance on out of pocket expenditure[[7](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR7)], fragile logistics, storage challenges and high transport and distribution costs [[2](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR2)] and inadequate or inappropriate medicines regulatory frameworks [[8](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR8)]. These factors are further exacerbated by insufficient scientific, technological and local manufacturing capabilities in the Region [[9](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR9)].

### Presumption

#### Vote neg on presumption, the squo solves all of their impacts – it provides less developed countries with access to patent protected drugs

#### and sets precedent for future pandemics

**Bonadio, 15** (Enrico Bonadio, Enrico Bonadio is a reader in Intellectual Property Law at The City Law School and he holds law degrees from the University of Florence (PHD) and the University of Pisa (LLB), and is Associate Editor and Intellectual Property Correspondent of the European Journal of Risk Regulation as well as member of the Editorial Board of NUART Journal, 11/24/2015, accessed on 6/28/2021, The Conversation, "World's poorest countries allowed to keep copying patent-protected drugs", <https://theconversation.com/worlds-poorest-countries-allowed-to-keep-copying-patent-protected-drugs-50799>) WWVL

The **World Trade Organisation** has agreed to **extend** a **waiver** that **allows poor countries to copy patented medicines**. The waiver, which was due to expire in January 2016, has now been **extended to 2033.** The **countries that** will **benefit** from the waiver **are the 48 poorest nations, classified by** the **U**nited **N**ations **as “Least Developed Countries”** or LDCs, and include many African and some Asian countries. About half of the 900m population across these countries live on less than US$1.25 a day. All other countries, including developing countries such as India and China, are still bound by the WTO’s agreement on trade-related intellectual property rights (or TRIPS) with respect to drug patents. The **waiver is critical for the least developed countries**. Compared with richer countries, they have a **much higher disease burden**, especially infectious diseases such as HIV and malaria. In **2011, about 9.7m people in these countries were living with HIV**. **Many** of the **drugs that treat these diseases are still under patent protection**. Drug patents last for 20 years and allow drugs companies time to recoup their investment into research and development and turn a profit. Once the patent protection period ends, other drugs companies can then copy the drug and sell it as a generic medicine. These **generics are much cheaper than branded drugs.** Countries such as Uganda, Cambodia and Rwanda have already taken advantage of the WTO’s temporary waiver and begun to develop their own pharmaceutical industry. This has been helped by investments from drug companies in the developing world. For example, Uganda-based Cipla Quality Chemicals was originally a joint-venture between Cipla, a large Indian generics manufacturer, and the Ugandan government. It is the only company in Africa that makes triple-combination antiretroviral drugs. Developing and strengthening manufacturing capacities in LDCs is important as these countries are often unable to import cheap copies of patent protected drugs from countries like India. India has many large generics firms within its borders and, although it ratified TRIPS in 1995, it only brought its patent laws in line with the treaty in 2005. It too now has to respect international drug patents. So the extension of the **waiver** is important, but it is **only temporary**, which doesn’t please everybody. **L**east **d**eveloped **c**ountrie**s** **and some NGOs** would have **preferred** an **indefinite extension** or at least an extension until a country is no longer classified as a least developed country, rather than the set date of 2033. This position is supported by the European Union, but not by the US. It costs pharmaceuticals companies about US$2.6 billioin to develop a new drug. If these companies were not allowed to protect their investment with patents, it is doubtful that any new drugs would be developed. So patents are an important incentive. But **patent protection doesn’t work for poor countries**. Intellectual property **(IP) rights**, like patents, **aren’t an effective incentive in countries which have not reached an adequate level of economic development because they have no intellectual property to protect**. IP rights might be effective over the long term, but only after a local and relatively strong pharmaceutical industry is developed. The exemption could be dropped once countries that have benefited from it have developed enough, and the industry reaches a self-sustaining size. Although building a home grown pharmaceuticals industry is not a requirement of the WTO waiver, **a strong local industry would give poor countries direct access to much needed cheap medicines.** The WTO’s transitional waiver makes sense. By temporarily allowing LDCs to ignore patents on drugs, it gives them time to develop their own pharmaceuticals industries. And we are already **seeing evidence of this happening**. According to the UN agencies, UNDP and UNAids, the proportion of people with HIV who are not receiving antiretrovirals reduced from 90% in 2006 to 63% in 2013 thanks to the availability of drugs made by LDCs. Despite some criticisms, the WTO’s decision to extend the waiver should be praised. It seems fair and reasonable, and it doesn’t excessively jeopardise companies that make branded (non-generic) drugs. They don’t seem to lose much from missed royalties. Overall, the poorest countries account for less than 2% of the world’s gross domestic product and about 1% of global trade in goods. Not a big business opportunity for big pharma.

#### **Current COVID-19 patent waivers will solve the pandemics advantage**

Pti 21 [6-10-2021, "India, South Africa’s patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary," Hindu, https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece]

The proposal of India and South Africa on providing temporary patent waiver at the World Trade Organisation (WTO) to deal with the COVID-19 pandemic has achieved tremendous mileage and progression as the WTO member countries have agreed to commence text-based negotiations on it, a top government official said on June 10. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council of the World Trade Organization (WTO) on June 9 agreed with consensus to start text-based negotiations on a proposal submitted by India and South Africa seeking patent waivers to deal with the COVID-19 crisis. Commerce Secretary Anup Wadhawan said that the text-based negotiations is the way forward and it means that the members have broadly and in-principle accepted the objective behind the waiver proposal. “India and South Africa’s proposal has achieved tremendous mileage and tremendous progression at a very fast pace,” he told reporters. “There is a deadline that by July-end, the members are expected to come to an agreed text. So it is a very positive development,” he added. How the objective will be given effect and to what extent and for how much duration, all that would happen though text-based negotiations, the Secretary noted. In October 2020, India and South Africa had submitted the first proposal suggesting a waiver for all WTO members on the implementation of certain provisions of the TRIPS Agreement in relation to the prevention, containment or treatment of COVID-19. In May this year, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia. The agreement on TRIPS came into effect in January 1995. It is a multilateral agreement on intellectual property (IP) rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets. According to the revised proposal of 62 co-sponsors, the waiver should be in force for at least three years from the date of the decision on the matter. The co-sponsors have stated that the duration has to be practical for manufacturing to be feasible and viable. The revised text has also proposed waiver for health products and technologies as the prevention, treatment or containment of COVID-19 which involves a range of things and “intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture.”

#### **Vote neg on presumption – the aff can’t solve any of their impacts**

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

#### member nations ALREADY can – vote neg on presumption

**Bacchus**, James. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines.” *Cato.org*, 16 Dec. 20**20**,www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto.

This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”[6](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref6) It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, **in public health emergencies**, it may be impossible to obtain a license. In such cases, “**compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders**.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that **each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”**[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

### Counterfeit and climate stuff

#### Counterfeit drugs lead to drug resistant diseases turns the aff

**Jahnke, 19** (Art Jahnke, Art Jahnke began his career at the Real Paper, a Boston area alternative weekly. He has worked as a writer and editor at Boston Magazine, web editorial director at CXO Media, and executive editor in Marketing & Communications at Boston University, where his work was honored with many awards., 1-14-2019, accessed on 8-17-2021, Boston University, "How Substandard and Counterfeit Drugs Drive Drug-Resistant Infections", https://www.bu.edu/articles/2019/how-bad-drugs-turn-treatable-diseases-deadly/)

Muhammad Zaman learned at an early age that one did not shop for medicine at the convenient neighborhood pharmacy. In Pakistan, where he grew up, the safer thing to do was walk the extra mile to a pharmacy whose drugs were known to be high quality. Four decades later as a Boston University professor of biomedical engineering and materials science and engineering, Zaman was reminded of the dangers of low-quality drugs in his native country when he learned that more than 200 people in the city of Lahore died after being treated with an adulterated version of a hypertension drug. That event, in 2012, altered the course of Zaman’s research. Now, he focuses on the global problem of “substandard drugs,” poorly made medicines containing ingredients that are either ineffective or toxic. His most recent discovery has startling implications for our understanding of drug resistance: a low-quality version of rifampin, a broad spectrum antibiotic typically used as the first line of defense to treat tuberculosis, can greatly contribute to the development of drug-resistant infections. The findings, published in Antimicrobial Agents and Chemotherapy, are particularly pressing because drug-resistant TB is an increasing problem worldwide. Of the 10 million new cases of tuberculosis in 2016, about 600,000 were rifampin resistant, requiring second-line treatments which come with increased toxicity. “There had not been a definitive study showing that lack of [antibiotic] quality leads to resistance,” says Zaman, who is also a Howard Hughes Medical Institute Professor of Biomedical Engineering and International Health. “Now we are sure that it does, and it does with TB, a global problem that has become stubbornly hard to resolve.” “We had always thought of this a scientific issue, but now it is also an ethical issue.”Muhammad Zaman Zaman says substandard drugs, as well as drugs that are deliberate counterfeits, are all too common in developing nations. A recent survey by the World Health Organization found that in low- and middle-income countries, one in ten medicines is substandard or falsified. One contributing factor could be that government enforcement of safe manufacturing practices is feeble or nonexistent. In Pakistan, for example, a country of nearly 200 million people, only a handful of federal inspectors monitor the quality of drug manufacturing. Across sub-Saharan Africa, things are no better. A recent World Health Organization (WHO) study written in part by Paul Newton, an adjunct professor at BU School of Public Health, found that substandard antimalarials killed more than 120,000 children under the age of five in 2013. Another WHO study, conducted in 2008, found that 64 percent of antimalarial drugs tested in Nigeria were substandard. When the same study looked at antimalarials in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania, it found that 28 percent of 267 samples were substandard. Zaman says it’s impossible to know how many deaths globally are caused by substandard drugs because people don’t usually die immediately. They could die, as the Lahore victims did, from a toxic reaction, or they could die from the disease that the drug was supposed to cure. Or, says Zaman, he and other scientists have long speculated that they could die for a third reason: adulterated medicines could encourage the development of drug resistance, rendering the disease incurable with standard treatments. Although that possibility had been considered for years, Zaman and Zohar Weinstein teamed up to finally put the hunch to the test. In the lab, Zaman and Weinstein, a postdoctoral researcher in biomolecular pharmacology who’s nearly finished with her medical degree as well, conducted several tests with rifampin to learn if a degraded form of the TB drug could build drug resistance in bacteria. They first ran a series of in vitro tests pitting rifampin against E. coli, sometimes referred to as the workhorse bacteria of laboratories because its rapid doubling time makes it ideal for such studies. The researchers exposed the bacteria to gradually increasing doses of rifampin, which suppresses RNA transcription in bacteria, leading to cell death. They then ran the same tests with rifampin quinone, the most commonly found form of degraded rifampin. Within a week, they observed that the bacteria became significantly more resistant to the drug. Next, the researchers repeated the experiment, swapping out E. coli for a strain of tuberculosis called M. smegmatis, selected because it has a conveniently short doubling time of two hours, while the more common strain of tuberculosis has a doubling time of about one day. After two weeks, the M. smegmatis also began to show signs of resistance. “We found that over five days, E. coli exposed to [rifampin quinone] became up to 64 times more resistant to rifampin,” says Weinstein. “And over 22 days, M. smegmatis became up to 100 [times] more resistant to rifampin.” “You could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to resistance.”Muhammad Zaman Zaman and Weinstein had expected such responses, but they didn’t expect to find such a powerful resistance. In fact, once the bacteria gained resistance, no amount of standard rifampin would kill them. The researchers also looked for another indicator of rifampin resistance: a genetic mutation in a gene called rpoB. What they discovered was alarming. “We found that the majority of bacteria exposed to [rifampin quinone] also had mutations in this gene, even though they had never been exposed to the standard drug,” says Weinstein. In other words, the degraded drug wasn’t just failing to cure the disease, it was cultivating cross-resistance to the high-quality, standard product. In that sense, says Zaman, bad drugs can become doubly dangerous. “That [observation] was very revealing,” says Zaman. “It changed the equation, because we had always thought of this a scientific issue, but now it is also an ethical issue. We usually think of the spread of resistant TB in two ways. We say you got it because you were exposed to resistant TB, maybe you were living with someone with resistant TB. The second way is you got it because you were supposed to take drugs and you didn’t adhere to the program. But what this study reveals is that you could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to [treatment] resistance.” “While it is well established that subtherapeutic doses of medicines play a role in antimicrobial resistance, this is, as far as I know, the first demonstration of how substandard medicines directly drive the emergence of resistance genes in pathogens,” says Michael Levy, vice president of USP’s Quality Institute, which researches the influence of substandard drugs on health outcomes. USP is a nonprofit organization that sets drug quality standards that are legally recognized in the US and are also used in more than 140 other countries. Zaman’s next steps will be threefold. First, he plans to test the quality of drugs that are available in the community hospitals of several low-income countries, looking specifically for the presence of rifampin quinone, the degraded form of rifampin. Second, he plans to work with researchers at the National Emerging Infectious Diseases Laboratories (NEIDL) on a mouse model to study the resistance mechanism in vivo. Third, he says he hopes to expand his work to investigate adulterated forms of other commonly used, high-impact antibiotics. Meanwhile, patients around the world are still being prescribed substandard antibiotics every day. “The patient may be doing everything he or she is supposed to do and still become resistant [to treatment],” Zaman says. This work was supported by National Institute of General Medical Sciences and USP.

#### Only IPRs can check back against counterfeit production – key to solving crisis.

FIFARMA 4/28. “This Is How We Fight Counterfeit Medicines with Intellectual Property.” FIFARMA, 28 Apr. 2021, fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/.

This is how we fight counterfeit medicines with Intellectual Property There is a threat to health security that is present in every country in the world: counterfeit medicines. These may appear as a promise to cure any disease, but they contain excessive, insufficient or no doses of the active ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated. In the end, the only goal of counterfeit medicines is to make money, regardless of the consequences they may have on people’s health. In fact, according to the World Health Organization (WHO), this business represents more than $30 billion dollars in low- and middle-income countries. Recently, EFPIA did a podcast where it deepens the relationship between the decrease in the distribution of counterfeit medicine and Intellectual Property. You can find it in the following link: [Fighting the fakes – what’s industry’s role?](https://shows.acast.com/19-conversations/episodes/fighting-the-fakes-whats-industrys-role) Why does this relationship occur? Counterfeit medicines are more present where there is less strict regulatory control, where there is a lack of basic medicines, where there are unregulated supply chains, where medicines are priced very differently in the market, where intellectual property is not protected, and where no attention is paid to quality assurance. Therefore, this is a transversal issue to different sectors outside the health industry. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries. Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines. Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP). The role of IP In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also, IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Big pharma is one of the greatest contributers to climate change.

Belkhir 7/28, Lotfi. “Big Pharma Emits More Greenhouse Gases than the Automotive Industry.” The Conversation, 28 Apr. 2021, theconversation.com/big-pharma-emits-more-greenhouse-gases-than-the-automotive-industry-115285.

Rarely does mention of the pharmaceutical industry conjure up images of smoke stacks, pollution and environmental damage. Yet our recent study found [the global pharmaceutical industry is not only a significant contributor to global warming](https://doi.org/10.1016/j.jclepro.2018.11.204), but it is also dirtier than the global automotive production sector. It was a surprise to find how little attention researchers have paid to the industry’s greenhouse gas emissions. Only two other studies had some relevance: one looked at the [environmental impact of the U.S. health-care system](https://www.doi.org/10.1001/jama.2009.1610) and the other at the [pollution (mostly water) discharged by drug manufacturers](https://doi.org/10.1098/rstb.2013.0571). Our study was the first to assess the carbon footprint of the pharma sector. More polluting More than 200 companies represent the global pharmaceutical market, yet only 25 consistently reported their direct and indirect greenhouse gas emissions in the past five years. Of those, only 15 reported their emissions since 2012. One immediate and striking result is that the pharmaceutical sector is far from green. We assessed the sector’s emissions for each one million dollars of revenue in 2015. Larger businesses will always generate more emissions than smaller ones; in order to do a fair comparison, we evaluated emissions intensity. We found it was 48.55 tonnes of CO2e (carbon dioxide equivalent) per million dollars. That’s about 55 per cent greater than the automotive sector at 31.4 tonnes of CO2e/$M for that same year. We restricted our analysis to the direct emissions generated by the companies’ operations and to the indirect emissions generated by the electricity purchased by these companies from their respective utilities companies. The total global emissions of the pharma sector amounts to about 52 megatonnes of CO2e in 2015, more than the 46.4 megatonnes of CO2e generated by the automotive sector in the same year. The value of the pharma market, however, is smaller than the automotive market. By our calculations, the pharma market is 28 per cent smaller yet 13 per cent more polluting than the automotive sector. Extreme variability We also found emissions intensity varied greatly within the pharmaceutical sector. For example, the emissions intensity of Eli Lilly (77.3 tonnes of CO2e/$M) was 5.5 times greater than Roche (14 tonnes CO2e/$M) in 2015, and Procter & Gamble’s CO2 emissions were five times greater than Johnson & Johnson even though the two companies generated the same level of revenues and sell similar lines of products. We found outliers too. The German company Bayer AG reported emissions of 9.7 megatonnes of CO2e and revenues of US$51.4 billion, yielding an emission intensity of 189 tonnes CO2e/$M. This intensity level is more than four times greater than the overall pharmaceutical sector. In trying to explain this incredibly large deviation, we found that Bayer’s revenues derive from pharmaceutical products, medical equipment and agricultural commodities. While Bayer reports its financial revenues separately for each division, it lumps together the emissions from all the divisions. The company also reports and tracks its emission intensity in terms of tonnes of CO2e produced for each tonne of manufactured goods, whether fertilizer or Aspirin, for example. This level of opacity makes it not only impossible to assess the true environmental performance of these kind of companies. It also raises questions about the sincerity of these companies’ strategies and actions in reducing their contribution to climate change. Climate compliance We also estimated how much the pharmaceutical sector would have to reduce its emissions to comply with the [reduction targets in the Paris Agreement](https://unfccc.int/sites/default/files/english_paris_agreement.pdf). We found that by 2025, the overall pharma sector would need to reduce its emissions intensity by about 59 per cent from 2015 levels. While this is clearly a far cry from their current levels, it is interesting to note that some of the 15 largest companies are already operating at that level, namely Amgen Inc., Johnson & Johnson and Roche Holding AG. If those performance levels are achievable by some, why can’t they be achieved by all?

#### More drug production leads to more greenhouse gasses and environmental damage. Also leads to more dumping of medicines.

**Randall, 19** (Ian Randall, 5-29-2019, accessed on 8-17-2021, Daily Mail, "Big Pharma companies create 13% more carbon emissions making medicine than CAR MAKERS", https://www.dailymail.co.uk/sciencetech/article-7081851/Big-Pharma-companies-create-13-carbon-emissions-making-medicine-CAR-MAKERS.html)

Pharmaceutical companies put out 13 per cent more carbon emissions making medicines than car manufacturers - despite having a market that is 28% smaller. Researchers analysed existing public data on the carbon emissions of around 200 pharma companies worldwide. They also did a more focused analysis on emission reports from 15 leading drug manufacturers in the industry, including Bayer AG, Johnson & Johnson and Pfizer. Emissions levels were highly variable, they found, even accounting for the differences between larger and smaller companies. Drug manufacturers emit greenhouse gases directly into the atmosphere from their factories as a result of their production processes, and indirectly through power use. Despite this, financial performance does not mean firms have to pollute, with the three most successful firms also the least polluting. Pharmaceutical companies put out 13 per cent more carbon emissions than car manufacturers despite having a market that is 28 per cent smaller (stock image) Emission reduction measures have traditionally been focused on industrial sectors such as energy production, car manufacturing and mining. However, studies are beginning to highlight that the carbon footprint of the healthcare industry — and particularly the pharmaceutical sector — is also a big problem. In 2007, for example, researchers found that the US Healthcare sector accounted for eight per cent of the nation's total greenhouse emissions. Drug manufacturers directly emit greenhouse gases into the atmosphere from their factories as a result of their production processes. In addition, these companies produce emissions indirectly through the carbon dioxide emitted in the production of the electrical power which they use in their manufacturing systems. Drug companies can also cause other forms of pollution, such as the accidental leak of medicines into the environment. Environmental engineers Lotfi Belkhir and Ahmed Elmeligi of McMaster University in Ontario, Canada, set out to analyse the carbon emissions put out by big pharma. Alongside considering existing data on emissions by the around 200 pharmaceutical firms worldwide, researchers focused in their analysis on the 15 firms that have consistently reported both their direct and indirect greenhouse gas emissions since 2012. Indirect emissions are those that come not as a result each company's operations, but from the emissions resulting from their share of the electricity produced by power companies. As larger businesses will inherently generate more emissions than their smaller counterparts, the researchers assessed each firm's emission intensity per million dollars of revenue. 'One immediate and striking result is that the pharmaceutical sector is far from green,' Professor Belkhir wrote in The Conversation. The researchers found that the global pharmaceutical sector puts out around 48.6 tonnes of carbon dioxide equivalent per million dollars in 2015. Emission reduction measures have traditionally been focused on industrial sectors such as energy production, car manufacturing and mining. However, studies are beginning to highlight that the carbon footprint of the healthcare industry — and particularly the pharmaceutical sector — is also a big problem. In 2007, for example, researchers found that the US Healthcare sector accounted for eight per cent of the nation's total greenhouse emissions. Drug manufacturers directly emit greenhouse gases into the atmosphere from their factories as a result of their production processes. In addition, these companies produce emissions indirectly through the carbon dioxide emitted in the production of the electrical power which they use in their manufacturing systems. Drug companies can also cause other forms of pollution, such as the accidental leak of medicines into the environment. Professor Belkhir reports that this is '55 per cent greater than the automotive sector, at 31.4 tonnes of carbon dioxide equivalent per million dollars for that same year.' 'Rarely does mention of the pharmaceutical industry conjure up images of smoke stacks, pollution and environmental damage,' Professor Belkhir said. 'Yet our recent study found the global pharmaceutical industry is not only a significant contributor to global warming, but it is also dirtier than the global automotive production sector,' he added. The total global emissions from the pharmaceutical sector about to around 52 megatonnes of carbon dioxide equivalent in 2015, compared to the 46.4 megatonnes put out by the car manufacturing industry in the same year. This, the researchers note, is despite drug manufacturing being a smaller market that the automotive industry. 'By our calculations, the pharma market is 28 percent smaller yet 13 percent more polluting than the automotive sector,' Professor Belkhir said. Emission levels vary wildly across the pharmaceutical sector, researchers found. For example, Eli Lilly and Company (pictured, stock image) had an emission intensity in 2015 that was 5.5 times greater than their fellow firm Roche Holding AG Alongside considering existing data on emissions by the around 200 pharmaceutical firms worldwide, researchers focused in their analysis on the intensity of emissions by the 15 firms that have consistently reported both their direct and indirect greenhouse outputs since 2012 Emission levels also vary wildly within the pharmaceutical sector, researchers found. For example, Eli Lilly and Company's emission intensity was 5.5 times greater than Roche Holding AG in 2015, at 77.3 tonnes of carbon dioxide equivalent per million dollars, compared with 14 tonnes. Similarly, experts found that Procter & Gamble's carbon dioxide emissions were around five times greater than those of competitor Johnson & Johnson, despite the two firms selling similar products and generating the same level of revenue. Professor Belkhir and Mr Elmeligi also encountered challenges in accurately assessing the emissions from some companies, such as Bayer AG. They were surprised to find that the German firm had reported emitting 9.7 mega-tonnes of carbon dioxide equivalent in 2015, while receiving a revenue of $51.4 billion (£40.7 billion) during the same period. This would yield an emission intensity of 189 tonnes of carbon dioxide equivalent per million dollars — a level four times larger than the pharmaceutical sector as a whole. Researchers found that the reason for this extreme outlier stemmed from how Bayer lumps together its emission data from across its pharmaceutical, medical equipment and agricultural product divisions, despite declaring revenue individually. 'This level of opacity makes it impossible to assess the true environmental performance of these kind of companies,' said Professor Belkhir. He added: 'It also raises questions about the sincerity of these companies' strategies and actions in reducing their contribution to climate change.' Researchers encountered challenges in accurately assessing the emissions from some companies, such as Bayer AG, who lump together its emission data from across its pharmaceutical, medical equipment and agricultural product divisions Finally, the research duo estimated by how much the pharmaceutical sector would have to cut back on its greenhouse gas emissions in order to meet the targets established by the 2016 Paris Climate agreement. 'We found that by 2025, the overall pharma sector would need to reduce its emissions intensity by about 59 percent from 2015 levels,' Professor Belkhir said.

#### Climate change leads to extinction *by 2050*

Specktor 19 [Brandon Specktor Senior Writer Brandon Specktor writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years. ] “Human Civilization Will Crumble by 2050 If We Don’t Stop Climate Change Now, New Paper Claims.” livescience.com. June 04, 2019 https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html.~Anop

It seems every week there's a scary new report about how man-made climate change is going to cause the collapse of the world's ice sheets, result in the extinction of up to 1 million animal species and — if that wasn't bad enough — make our beer very, very expensive. This week, a new policy paper from an Australian think tank claims that those other reports are slightly off; the risks of climate change are actually much, much worse than anyone can imagine. According to the paper, climate change poses a "near- to mid-term existential threat to human civilization," and there's a good chance society could collapse as soon as 2050 if serious mitigation actions aren't taken in the next decade. Published by the Breakthrough National Centre for Climate Restoration in Melbourne (an independent think tank focused on climate policy) and authored by a climate researcher and a former fossil fuel executive, the paper's central thesis is that climate scientists are too restrained in their predictions of how climate change will affect the planet in the near future. The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the United Nations' Panel on Climate Change (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the sheer complexity of Earth's many interlinked geological processes; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the Amazon rainforest (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with shrinking coastlines and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it." How can this catastrophic vision of the future be prevented? Only with the people of the world accepting climate change for the emergency it is and getting to work — immediately. According to the paper's authors, the human race has about one decade left to mount a global movement to transition the world economy to a zero-carbon-emissions system. (Achieving zero-carbon emissions requires either not emitting carbon or balancing carbon emissions with carbon removal.) The effort required to do so "would be akin in scale to the World War II emergency mobilization," the authors wrote. The new policy paper was endorsed with a foreword by Adm. Chris Barrie, a retired Australian defense chief and senior royal navy commander who has testified before the Australian Senate about the devastating possibilities climate change poses to national security and overall human well-being. "I told the [Senate] Inquiry that, after nuclear war, human-induced global warming is the greatest threat to human life on the planet," Barrie wrote in the new paper. "Human life on Earth may be on the way to extinction, in the most horrible way."

#### Warming is incremental— any climate reform is key to *saving millions*

Wallace-Wells 19, David. [David Wallace-Wells is an American journalist known for his writings on climate change. He wrote the 2017 essay "The Uninhabitable Earth", which he later expanded into the 2019 book The Uninhabitable Earth.“The Cautious Case for Climate Optimism (From a Climate Alarmist).” Intelligencer, February 4, 2019. http://nymag.com/intelligencer/2019/02/book-excerpt-the-uninhabitable-earth-david-wallace-wells.html.]//anop

It’s not too late. In fact, it never will be. Whatever you may have read over the past year — as extreme weather brought a global heat wave and unprecedented wildfires burned through 1.6 million California acres and newspaper headlines declared, “Climate Change Is Here” — global warming is not binary. It is not a matter of “yes” or “no,” not a question of “fucked” or “not.” Instead, it is a problem that gets worse over time the longer we produce greenhouse gas, and can be made better if we choose to stop. Which means that no matter how hot it gets, no matter how fully climate change transforms the planet and the way we live on it, it will always be the case that the next decade could contain more warming, and more suffering, or less warming and less suffering. Just how much is up to us, and always will be. A century and a half after the greenhouse effect was first identified, and a few decades since climate denial and misinformation began muddying our sense of what scientists do know, we are left with a set of predictions that can appear falsifiable — about global temperatures and sea-level rise and even hurricane frequency and wildfire volume. And there are, it is true, feedback loops in the climate system that we do not yet perfectly understand and dynamic processes that remain mysterious. But to the extent that we live today under clouds of uncertainty about the future of climate change, those clouds are, overwhelmingly, not projections of collective ignorance about the natural world but of blindness about the human one, and they can be dispersed by human action. The question of how bad things will get is not, actually, a test of the science; it is a bet on human activity. How much will we do to forestall disaster and how quickly? These are the disconcerting, contradictory lessons of global warming, which counsels both human humility and human grandiosity, each drawn from the same perception of peril. There’s a name for those who hold the fate of the world in their hands, as we do — gods. But for the moment, at least, many of us seem inclined to run from that responsibility rather than embrace it. Or even admit we see it, though it sits in front of us as plainly as a steering wheel. That climate change is all-enveloping means that it targets us all and that we must all share in the responsibility so we do not all share in the suffering — at least not share in so suffocatingly much of it.Since I first began writing about climate a few years ago, I’ve been asked often whether I see any reason for optimism. The thing is, I am optimistic. But optimism is always a matter of perspective, and mine is this: No one wants to believe disaster is coming, but those who look, do. At about two degrees Celsius of warming, just one degree north of where we are today, some of the planet’s ice sheets are expected to begin their collapse, eventually bringing, over centuries, perhaps as much as 50 feet of sea-level rise. In the meantime, major cities in the equatorial band of the planet will become unlivable. There will be, it has been estimated, 32 times as many extreme heat waves in India, and even in the northern latitudes, heat waves will kill thousands each summer. Given only conventional methods of decarbonization (replacing dirty-energy sources like coal and oil with clean ones like wind and solar), this is probably our best-case scenario. It is also what is called — so often nowadays the phrase numbs the lips — “catastrophic warming.” A representative from the Marshall Islands spoke for many of the world’s island nations when he used another word to describe the meaning of two degrees: genocide. You do not need to contemplate worst-case scenarios to be alarmed; this best-case scenario is alarming enough. Two degrees would be terrible, but it’s better than three, at which point Southern Europe would be in permanent drought, African droughts would last five years on average, and the areas burned annually by wildfires in the United States could quadruple, or worse, from last year’s million-plus acres. And three degrees is much better than four, at which point six natural disasters could strike a single community simultaneously; the number of climate refugees, already in the millions, could grow tenfold, or 20-fold, or more; and, globally, damages from warming could reach $600 trillion — about double all the wealth that exists in the world today. We are on track for more warming still — just above four degrees by 2100, the U.N. estimates. So if optimism is always a matter of perspective, the possibility of four degrees shapes mine. It is unlikely, I think, that we reach four degrees this century. But this is what it would take to stay under two: a comprehensively decarbonized economy, a perfectly renewable energy system, a reimagined system of agriculture, perhaps even a planet without meat-eaters. We also need overhauls of the world’s transportation systems and infrastructure. Every year the average American emits enough carbon to melt 10,000 tons of ice in the Antarctic ice sheets — enough to add 10,000 cubic meters of water to the ocean. Every minute, we each add five gallons. If the task of reversing all that seems incomprehensibly big, it is. The scale of the technological transformation required dwarfs every technological revolution ever engineered in human history, including electricity and telecommunications and even the invention of agriculture 10,000 years ago. By definition, it dwarfs them, because it contains all of them — every single sector needs to be rebuilt from the foundation, since every single one breathes on carbon like it’s a ventilator. In October, the U.N.’s Intergovernmental Panel on Climate Change warned that the world has only a dozen years to halve its carbon emissions to safely avoid two degrees of warming and all those “catastrophic” impacts. Is it possible? The short answer is, technically speaking, maybe — though just maybe. But speaking practically, and politically, is another matter