# 1NC

## 1NC - T

### 1NC -- Generic

#### Interpretation: “medicines” is a generic bare plural. The aff may not specify a medicine or subset of medicines.

Nebel 19. [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs. He writes a lot of this stuff lol – duh.] “Genericity on the Standardized Tests Resolution.” Vbriefly. August 12, 2019. <https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/?fbclid=IwAR0hUkKdDzHWrNeqEVI7m59pwsnmqLl490n4uRLQTe7bWmWDO_avWCNzi14> TG

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions.

Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window.

So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why.

“Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons.

First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural.

Second, “colleges and universities” fails the [upward-entailment test](https://plato.stanford.edu/entries/generics/#IsolGeneInte) for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals.

Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universitiesz generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution.

#### It applies to “medicines”–

[1] upward entailment test – “the member nations of the WTO ought to reduce intellectual property protections for medicines” doesn’t entail that member nations of the WTO ought to reduce intellectual property protections for drugs bc cocaine and meth bc they don’t have IPRs.

[2] adverb test -- “member nations of the WTO usually ought to reduce IPPs for medicines” doesn’t substantially change the meaning of the res.

#### Outweighs their evidence – it tells us what to do with indefinite singulars, whereas theirs assumes indefinite singulars can only mean one thing.

#### Standards:

#### [1] precision – the counter-interp justifies them arbitrarily doing away with random words in the resolution which decks negative ground and preparation because the aff is no longer bounded by the resolution. Independent voter for jurisdiction – the judge doesn’t have the jurisdiction to vote aff if there wasn’t a legitimate aff.

#### [2] Limits and ground – they can spec any combinations of medicines including music, vaccines, aspirin, future medicines and many more and allowing any permutation of them explodes my prep burden – I have to prep against thousands of affs individually which massively skews engagement as you have infinite prep time to frontline your one aff whereas I won’t be prepared for yours – it wrecks neg prep since there’s marginal differences in the advantage but it takes out ground like [politics, heg da, econ da, idk other generics] which are some of the few neg generics when affs spec medicines.

#### [3] tva – just read your aff as an advantage under a whole adv, solves all ur offenfse since I can read normal means evidence

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. o/w because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – a] deter future abuse and b] set better norms for debate.

#### Competing interps –

#### [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm

#### [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs –

#### a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument

#### b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices

## 1NC – Deont

### Framework

#### 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>

#### First, Practical Reason exists—

#### [A] An agent’s will acts on a law that it gives to itself. If pleasure were a law, then you would straightaway do the pleasurable act, but since you’re autonomous, you can reason about taking the action. Thus a condition of action is that the will is self-determined. Without practical reason, moral reason and action could not exist

#### Korsgaard

“Self-Constitution in the Ethics of Plato and Kant” by Christine M. Korsgaard

“Now I’m going to argue that that sort of willing is impossible. The first step is this: : **to conceive** of **yourself as the cause of your actions is to identify with** **the principle of choice on which you act.** A rational will is a self-conscious causality, and a self-conscious causality is aware of itself as a cause. To be aware of yourself as a cause is to identify yourself with something in the scenario that gives rise to the action, and this must be the principle of choice. For instance**, suppose you experience a conflict** of desire: you have a desire to do both A and B, and they are incompatible. You have **some principle** that **favors** **A over B,** so you exercise this principle, and **you choose** to do **A. In this** kind of **case**, you do not regard yourself as a mere passive spectator to the battle between A and B. **You regard the choice as yours**, as the product of your own activity, **because you regard the principle** of choice **as expressive**, or representative, **of yourself.** You must do so, for **the** only **alternative** to identifying with the principle of choice **is regarding the principle** of choice **as some third** **thing in you**, another force on a par with the incentives to do A and to do B, which happened to throw in its weight in favor of A, in a battle at which you were, after all, a mere passive spectator. **But then you are not the cause** **of the action.** Self-conscious or rational agency, then, requires identification with the principle of choice on which you act.” (123)

#### [B] Reason’s inescapable – Questioning if one can reason or why to reason requires reason, conceding authority to practical reason—outweighs because any other ethic begs the question of why, meaning it’s arbitrary and nonbinding

#### [C] Performativity – debating in this round forces reason in terms of evaluating arguments and having the authority to decide what to read

#### Second, a rational will must set ends with reciprocal constraints—

#### [A] Anything else justifies that someone could impede your ability to achieve your end in the first place and would restrict self-sufficiency, the root cause of action, which also means reason contains end-based framework.

**Engstrom**, Stephen [“Universal Legislation As the Form of Practical Knowledge. University of Pittsburgh, ND]

I’ll begin with the case of natural justice. **Since this obligation is founded on the practical knowledge of self-sufficiency as an end, and since self-sufficiency, according to its very idea, can never be augmented, but only restricted, by the actions of others, the maxim we have to consider is one prescribing action that restricts others’ self-sufficiency**. This restriction can be more precisely characterized, however, as the **limitation of what Kant calls outer freedom**. For as I’ll now try to explain, outer freedom is just what self-sufficiency requires, as a negative condition, in relation to others. Kant describes outer freedom as an “**independence from the necessitating power of choice of another**” (MS237). In other words, **outer freedom lies in the independence of one’s capacity to pursue one’s ends from hindrance to its exercise stemming from the power of choice of 19another.** That one’s capacity to pursue one’s ends can be subject to such hindrance from another is, of course, clear. Where diverse persons share a practical world, where in other words they are present together in the world in such a way that it’s possible for any one of them both to know what action another of them intends and also to act in ways that prevent or hinder that action (or, as we might also say, where mutual recognition and mutual influence are possible), **the outer freedom of one such person is limited to the extent that another chooses to prevent or to hinder the former’s action and succeeds in the attempt.** Where a person’s actions constitute such hindrances they can accordingly be described—to borrow a phrase from Kant—as “assaults on the freedom... of others” (G430).**19 Now since the material ends a person pursues in acting are all united in the fundamental end of happiness, generically conceived, outer freedom amounts to independence from hindrances by others to one’s pursuit of that basic end. Thus any assault on this freedom, to the extent that it’s successful, is a limitation of a person’s capacity to realize this end. And since this capacity is just what self-sufficiency consists in, this freedom is nothing other than the independence from other persons requisite for self-sufficiency, and it can therefore be regarded,** in a negative sense**, as self-sufficiency itself in relation to others.** Given the preceding considerations, it’s a straightforward matter to see how a maxim of action that assaults the freedom of others with a view to furthering one’s own ends results in a contradiction when we attempt to will it as a universal law in accordance with the foregoing account of the formula of universal law. **Such a maxim would lie in a practical judgment that deems it good on the whole to act to limit others’ outer freedom, and hence their self-sufficiency, their capacity to realize their ends, where doing so** augments, or **extends, one’s own outer freedom and so also one’s own self-sufficiency.** 20Now on the interpretation we’ve been entertaining, applying the formula of universal law involves considering whether it’s possible for every person—every subject capable of practical judgment—to share the practical judgment asserting the goodness of every person’s acting according to the maxim in question. **Thus in the present case the application of the formula involves considering whether it’s possible for every person to deem good every person’s acting to limit others’ freedom, where practicable, with a view to augmenting their own freedom. Since here all persons are on the one hand deeming good both the limitation of others’ freedom and the extension of their own freedom, while on the other hand, insofar as they agree with the similar judgments of others, also deeming good the limitation of their own freedom and the extension of others’ freedom, they are all deeming good both the extension and the limitation of both their own and others’ freedom. These judgments are inconsistent insofar as the extension of a person’s outer freedom is incompatible with the limitation of that same freedom**.

#### [B] If we are under that authority of reason, we act since we reason action is good. Actions can only be good because we have rationally chosen them. Respecting someone as a rational being means respecting their right to make decisions on their actions. That forbids infringing on other’s freedoms because it undermines value to action in the first place because every agent must be able to attribute value to an end. Anything else fails to attribute value to an action – making it impossible to determine moral action.

#### Thus, the standard is respecting a system of inner and outer freedom

#### Prefer:

#### Action Theory: Only reason can explain why we take transitional action to an overall end. For example, setting the end of tea provides me a reason to unify the necessary actions to produce tea, like getting a pot, filling it with water, etc. Any other explanation fails since it can’t give meaning to why we take transitioning action – freezing action. 2 Impacts—

#### That’s a side constraint on the AC—ethics is a guide to action so it must appeal to a structure of action.

#### Bindingness—reason is intrinsic to actions since only it can provide value to transitioning action, which justifies universality

#### Presume freedom since it allows each of us to pursue our individual search for ethics so the NC co-opts every reason your framework is good, but adds an additional side constraint. This also serves as a tiebreaker

### 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!

### 1NC – Hijack – Pain/Pleasure

#### My framework hijacks—happiness requires recognition that one has authority over their happiness, which requires freedom and reason [this is against consequentialism]

**Engstrom**, Stephen [“Universal Legislation As the Form of Practical Knowledge. University of Pittsburgh, ND]

Kant holds that to set something as one’s end is to represent it in practical judgment as one’s effect, or, in other words, to represent oneself as its cause: “an end”, he says, “is the object of a concept, so far as the latter is regarded as the cause of the former (the real ground of its possibility)” (KU 220; cf. MS 384). **Thus the act of practical representation that constitutes the setting of an object as an end essentially includes an understanding of itself as the cause whereby that object is to be brought about. It’s therefore essential to an end that to will something as one’s end is to regard oneself, in one’s representation of that end, as the cause that, through that same representation, is to realize it. Hence every representation of an end—and so every maxim15—contains two components: (i) the representation of the object, and (ii) the representation of the relation of causal dependency in which that object stands to the subject, as the latter’s effect, or (what comes to the same thing) the representation of the subject’s causal sufficiency in respect of the object, that is, the sufficiency of the subject’s action to produce it**. And since what is represented in cognition must correspond to the cognition of it, to these two components in the representation of an end there must correspond two components in the end itself. **In the case of the end of happiness, we can characterize the two components by saying that happiness includes, in addition to the agreeable activities a person represents as its own effect, also the person’s practical sufficiency in respect of that effect.** And since this end is the object of the fundamental act of choice in which a particular person constitutes itself as such, the practical sufficiency it includes can be characterized as practical self- sufficiency. But here I would caution that this expression can mislead if not properly understood. We should not suppose that the idea of self-sufficiency is best exemplified by a Robinson Crusoe or a rugged individualist, or through some exaggerated image of the self-made man. **Self-sufficiency does involve a certain independence**, the ability to stand on one’s own two feet, as we say, and **to manage one’s own affairs**, putting it in proximity to what nowadays is often called “personal autonomy”. But persons who become attached to an inflated ideal of individualism or to some other excessive conception of self-sufficiency do so through the specific objects they opt to include in the content of their end rather than on account of anything belonging to its form. Self- sufficiency can take a collective form to the extent that persons join their wills, entering into communities and other cooperative engagements, and it will have an essentially collective dimension where, as in the human case, persons are naturally sociable and born into families. **Happiness, then, has two components, which are related, I think we can say, as matter and form: the agreeable objects (activities) a person includes as ingredients in specifying what happiness consists in, and self-sufficiency in the production of them. Each of these components is essential. Mere satisfaction of a person’s inclinations through good fortune is not enough, since complete happiness always includes the security that only self-sufficiency can bring.16 And because the material component of happiness depends in part on natural inclinations that reflect a person’s dependent existence, no person can ensure happiness by simply giving up the objects of inclinations to maintain self- sufficiency.17**

## 1nc da

### 1N - off

#### US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages

**Moore** **2020** [(Director of the Penn Global China Program at the University of Pennsylvania. Previously, Moore was a Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S.) “China’s Role In The Global Biotechnology Sector And Implications For U.S. Policy” <https://www.brookings.edu/wp-content/uploads/2020/04/FP_20200427_china_biotechnology_moore.pdf>] EV

EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

#### The aff’s reduction of IPP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech

Rogin 4-8. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] EV

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

#### China will convert biotechnology gains to military advantages, undermining US primacy on a global scale

Kuo 2017 [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] EV

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. **Why is Chinese access to U.S. genomic data a national security concern**? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines, antibiotics**, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

#### Maintenance of the ILO is key to reduce a host of existential threats – establishes great-power peace.

Brands 18. [(Hal Brands is a Henry Kissinger Distinguished Professor at Johns Hopkins University’s School of Advanced International Studies, Scholar at the American Enterprise Institute. “America’s Global Order Is Worth Fighting For, Bloomberg Opinion, Politics & Policy,” August 14, 2018, Bloomberg. <https://www.bloomberg.com/opinion/articles/2018-08-14/america-s-global-order-is-worth-fighting-for>] EV

The first argument is easily disposed of. Yes, the postwar world has been thoroughly imperfect, featuring nuclear arms races, genocides, widespread poverty and other scourges. But the world has always been imperfect, and by any meaningful comparison, the last seven decades have been a veritable golden age. The liberal international economic order has led to an explosion of domestic and global prosperity: According to World Bank data, both U.S. and global per capita income have increased roughly three-fold (in inflation-adjusted terms) since 1960, with U.S. gross domestic product increasing nearly six-fold. The U.S. system of alliances and forward military deployments has contributed critically to the longest period of great-power peace in modern history, and the incidence of war and conquest more broadly have dropped dramatically. The number of democracies in the world has increased from perhaps a dozen during World War II to well over 100 today; respect for basic human rights has also reached impressive levels. As a bevy of scholarship has shown, the policies that the U.S. has pursued and the international order it has built have contributed enormously and directly to these outcomes. If the liberal international order can’t be considered a smashing success, no international order could be. The second critique is also overstated. It is true that Washington, like all great powers throughout history, has been willing to bend the rules to get its way. It is hard to reconcile Cold War-era interventions in Guatemala, Chile and other countries with a professed solicitude for human rights and democracy; the Iraq War of 2003 is only one instance in which the U.S. brushed aside the concerns of international organizations such as the U.N. Security Council. Likewise, when the U.S. government determined that the Bretton Woods system of monetary relations no longer suited its interests in the 1970s, it terminated that scheme and insisted on creating a more favorable one. But again, the proper standard here is not sainthood but reality. And the U.S. has generally enlisted its power in the service of universal values such as democracy and human rights; it has, more often than not, promoted a positive-sum international system in which like-minded nations can be secure and wealthy. This goes back to the very beginning of the liberal order: Washington did not seek to hold its defeated adversaries in subjugation after World War II; it rebuilt Japan and western Germany into thriving, democratic allies that became fierce economic competitors to the U.S. The U.S. has taken this approach not simply because it wanted to do good in the world — powerful as this motivation is — but because of a hard-headed desire to do good for itself. In an interdependent global environment, American officials have long calculated, the U.S. cannot divorce its own well-being from that of the wider world. And in contrast to how other great powers — Imperial Japan, for instance, or the Soviet Union — ruled their spheres of influence, American behavior has been positively enlightened. It is this relatively benign behavior that has convinced so many countries to tolerate American leadership — and it is the emergence of a darker form of U.S. hegemony under the Trump administration that so profoundly worries them today. As for the third critique, the premise is right, but the conclusion can easily go too far. It is always dangerous to become so enraptured by past achievements that one loses sight of the need for adaptation in the future. This is particularly true today, because the strength of the liberal order is being tested from within and without, by issues ranging from unequal burden-sharing among American allies to the ambivalence of the American people themselves. There is little evidence to suggest, however, that either American power or the liberal order it supports have eroded so dramatically that Washington’s postwar project cannot be sustained. Quite the contrary — the U.S. is likely to remain the world’s strongest power for decades to come.

## Case

### Presumption

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

Enrico Bonadio 15 [11-24-2015, "World's poorest countries allowed to keep copying patent-protected drugs," Conversation, <https://theconversation.com/worlds-poorest-countries-allowed-to-keep-copying-patent-protected-drugs-50799>] // WW DL

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 United Nations 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. Higher disease burden 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. We believe good journalism is good for democracy and necessary for it. Keeping antiretrovirals affordable. jonrawlinson/flickr 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. Developing a local pharma industry 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. Least developed countries 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. Patents don’t work for poor countries 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.

### Counterfeit and climate stuff

#### 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

#### 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.

#### 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.