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#### Interp: **Reduce requires change**

Corrigan 92 – John F. Corrigan, Judge in the Court of Appeals of Ohio, Eighth Appellate District, Cuyahoga County, 1992(“CLEVELAND INDUSTRIAL SQUARE, INC. et al., Appellees and Cross-Appellants, v. CLEVELAND BOARD OF ZONING APPEALS, Appellant and Cross-Appellee,” 83 Ohio App. 3d 301, Court of Appeals of Ohio, 10-22-1992, Available to Subscribing Institutions via Nexis-Lexis)//BM

"P. Any other trade, industry or use that will be injurious, hazardous, noxious or offensive to an extent equal to or greater than any one of the enterprises enumerated in this subsection (c)(2) hereof."

"Incineration" and "reduction" are not defined. Accordingly, these terms are to be construed by considering their common and ordinary meanings. Sammons v. Batavia (1988), 53 Ohio App.3d 87, 89, 557 N.E.2d 1246, 1248.

"Incineration" means to incinerate. Webster's New World Dictionary (1983) 306. "Incinerate" means "to burn to ashes; to burn up." Id. "Reduction" means to reduce. Id. at 501. "Reduce" means "to lessen," or "to change to a different form." Id.

#### Reducing something is distinct from reducing its effects.

White 11 – Helene M. White, United States Circuit Judge of the United States Court of Appeals for the Sixth Circuit. Previously on the Michigan Court of Appeals, 2011(“VIDEO/NEWSSTAND, INC., dba 84 Video/Newsstand; VINE STREET NEWS, INC., dba Adult Mart; NU PHILLY VIDEO/NEWS, INC.; MILE, INC., dba Lion's Den; AMERICAN PRIDE, INC., dba Lion's Den; MIDWEST PRIDE II, INC., dba Lion's Den; ENTERTAINMENT U.S.A. OF CLEVELAND, INC., dba Christie's Cabaret; GOLD RESTAURANT, INC., dba Gold Horse; DONNA AND BATO, LLC, dba Expressions; CALPAL, LLC, dba Dreamgirls; NL CORP INC., dba Diamonds Cabaret; BUCKEYE ASSOCIATION OF CLUB EXECUTIVES, INC., Plaintiffs - Appellants, v. THOMAS SARTINI, in his official capacity as Ashtabula County Prosecutor; ROSS CIRINCIONE, in his official capacity as Law Director of the City of Bedford Heights; DAVID A. LAMBROS, in his official capacity as Law Director of the City of Brookpark; ROBERT TRIOZZI, in his official capacity as Law Director of the City of Cleveland; WILLIAM MASON, in his official capacity as Cuyahoga County Prosecutor; TONY GEIGER, in his official capacity as Law Director for the City of Lima; JEURGEN WALDICK, in his official capacity as Allen County Prosecutor; MIKE MINNIEAR, in his official capacity as Law Director for the City of Milford; ROBIN PIPER, in his official capacity as Butler County Prosecutor; MATTHEW E. CRALL, in his official capacity as Law Director of the City of Bucyrus; STANLEY E. FLEGM, in his official capacity as Crawford County Prosecutor; DAVID KIGER, in his official capacity as Law Director of the City of Jeffersonville; DAVID B. BENDER, in his official capacity as Fayette County Prosecutor; RICHARD C. PFEIFFER, JR., in his official capacity as Columbus City Attorney; RON O'BRIEN, in his official capacity as Franklin County Prosecutor; DONNETTE FISHER, in his official capacity as Law Director for the City of Franklin; RACHEL A. HUTZEL, in his official capacity as Warren County Prosecutor; DANIEL G. PADDEN, in his official capacity as Guernsey County Prosecutor; DAVID A. HACKENBERG, in his official capacity as Law Director of the City of Findlay; MARK C. MILLER, in his official capacity as Hancock County Prosecutor; JOSEPH T. DETERS, in his official capacity as Hamilton County Prosecutor; JOSEPH R. KLAMMER, in his official capacity as Law Director of the City of Eastlake; CHARLES E. COULSON, in his official capacity as Lake County Prosecutor; RICHARD S. BINDLEY, in his official capacity as Law Director of the City of Heath; DOUGLAS SASSEN, in his official capacity as Law Director for the City of Newark; KENNETH W. OSWALT, in his official capacity as Licking County Prosecutor; JOHN T. MADIGAN, in his official capacity as Law Director of the City of Toledo; PAUL S. GOLDBERG, in his official capacity as Law Director for the City of Oregon; JULIA R. BATES, in her official capacity as Lucas County Prosecutor; IRIS TORRES GUGLUCELLO, in her official capacity as Law Director of the City of Youngstown; PAUL J. GAINS, in his official capacity as Mahoning County Prosecutor; KENNETH FISHER, in his official capacity as Law Director of the City of Brunswick; DEAN HOLMAN, in his official capacity as Medina County Prosecutor; PATRICK BONFIELD, in his official capacity as Law Director of the City of Dayton; LORI E. KIRKWOOD, in her official capacity as Law Director for the City of West Carrollton; MATHEW HECK, in his official capacity as Montgomery County Prosecutor; CHARLES HOWLAND, in his official capacity as Morrow County Prosecutor; DAVE REMY, in his official capacity as Law Director for the City of Mansfield; JAMES MAYER, in his official capacity as Richland County Prosecutor; TONI EDDY, in his official capacity as Law Director of the City of Chillicothe; MICHAEL M. ATER, in his official capacity as Ross County Prosecutor; ANDREW L. ZUMBAR, in his official capacity as Law Director of the City of Alliance; JOSEPH MARTUCCIO, in his official capacity as Law Director of the City of Canton; JOHN FERRERO, in his official capacity as Stark County Prosecutor; MAX ROTHAL, in his official capacity as Law Director for the City of Akron; PENELOPE TAYLOR, in her official capacity as Law Director for the City of Tallmadge; SHERRI BEVAN WALSH, in her official capacity as Summit County Prosecutor; JOSEPH T. DULL, in his official capacity as Law Director for the City of Niles; DENNIS WATKINS, in his official capacity as Trumbull County Prosecutor; MIKE JOHNSON, in his official capacity as Law Director for the City of New Philadelphia; AMANDA K. SPIES, in her official capacity as Tuscarawas County Prosecutor; RUSS LEFFLER, in his official capacity as Huron County Prosecutor; DEREK DIVEINE, in his official capacity as Seneca County Prosecutor; TERRY S. SHILLING, in his official capacity as Law Director for the City of Elyria; DENNIS WILL, in his official capacity as Lorain County Prosecutor; MARTIN FRANTZ, in his official capacity as Wayne County Prosecutor; SCOTT HILLIS, in his official capacity as Law Director for the City of Zanesville; D. MICHAEL HADDOX, in his official capacity as Muskingum County Prosecutor; STEPHEN A. SCHUMAKER, in his official capacity as Clark County Prosecutor; NEAL M. JAMISON; PETER M. KOSTOFF, Law Director, Defendants - Appellees, THE STATE OF OHIO, Defendant – Intervenor,” 455 Fed. Appx. 541, United States Court of Appeals for the Sixth Circuit, 9-7-2011, Available to Subscribing Institutions via Lexis Nexis)//BM

The fourth prong of the O'Brien test asks whether the restrictions "pose only an 'incidental [\*\*39] burden on First Amendment freedoms that is no greater than is essential to further the government interest.'" Sensations, 526 F.3d at 298. Justice Kennedy's concurrence in Alameda Books sharpens this inquiry, requiring that a government "must advance some basis to show that its regulation has the purpose and effect of suppressing secondary effects, while leaving the quantity and accessibility of speech substantially intact." 535 U.S. at 449 (Kennedy, J., concurring). In other words, "the necessary rationale for applying intermediate scrutiny is the promise that [regulations] may reduce the costs of secondary effects without substantially reducing speech." Id. at 450. Justice Kennedy's concurrence thus requires a proportionality analysis: a government may not seek to reduce secondary effects by reducing speech on a one-to-one basis. As he put it, "[i]t is true that cutting adult speech in half would probably reduce secondary effects proportionately. But again, a promised proportional reduction does not suffice. Content-based taxes could achieve that, yet these are impermissible." Id. at 451. This court has held that Kennedy's discussion on this point is binding. 729, Inc., 515 F.3d at 491 [\*\*40] ("Although the Alameda Books plurality did not discuss [this] requirement, Justice Kennedy expressly said that consideration of this issue was required for his concurrence in the judgment. Justice Kennedy's opinion binds us on this point.").

Plaintiffs assert that the hours-of-operation restriction fails under this proportionality analysis because it directly reduces a substantial amount of speech. We disagree. Plaintiffs' argument proceeds in two steps: First, they posit that there is insufficient evidence that closing sexually oriented businesses between midnight and 6:00 AM would significantly curtail adverse secondary effects. Second, they argue that they have demonstrated that the hours-of-operation restriction will cause a "massive reduction in speech." Therefore, they argue, § 2907.40 seeks to reduce secondary effects by reducing the amount of speech — measured in hours of operation of the adult businesses — in direct proportion to any secondary effects ameliorated.

[\*555] On the first point, the General Assembly did consider some evidence, including prior court cases, reports and studies from other jurisdictions and anecdotal testimony, that secondary effects of adult businesses are [\*\*41] greater during the late night hours. As discussed above, this evidence provides sufficient basis, even if not overwhelming, to conclude that sexually oriented businesses cause secondary effects late at night that are different in severity or scope from those caused at other times of day. This conclusion is significantly bolstered by this Circuit's prior cases upholding hours-of-operation restrictions. See Richland Bookmart II, 555 F.3d at 519; Sensations, 526 F.3d at 294, 299; Deja Vu of Cincinnati, 411 F.3d at 789-91; Richland Bookmart I, 137 F.3d at 438, 440-41.

On the second point, Plaintiffs offered testimony at the preliminary injunction hearing about the quantity of speech that the hours-of-operation provision would suppress, arguing that it amounts to a "massive reduction." They measured this in terms of economic effect of the law by explaining that prior to passage of § 2907.40, adult bookstores in Ohio did a significant amount of business, measured in millions of dollars per year, during the hours they will now be required to remain closed. Plaintiffs also offered evidence that "juice bars" — establishments that provides nude dancing but do not sell alcoholic beverages — generate [\*\*42] the majority of their revenues between 11:00 P.M. to 4:00 A.M., and so may become unprofitable if subject to the law.

HN25Go to this Headnote in the case. Evidence of a regulation's economic impact is not directly relevant to the First Amendment inquiry. See Deja Vu of Nashville, 274 F.3d at 397 ("[T]he relevant inquiry is not whether the Ordinance will cause any economic impact on the sexually oriented businesses. Although . . . compliance with the Ordinance will cut into the plaintiffs' profits, the plaintiffs have failed to introduce any evidence showing that they will not have a reasonable opportunity to operate their establishments."); DLS, Inc., 107 F.3d at 413 ("[T]he inquiry for First Amendment purposes is not concerned with economic impact. In our view, the First Amendment requires only that [the city] refrain from effectively denying respondents a reasonable opportunity to open and operate an adult theater within the city." (quoting Renton, 475 U.S. at 54)). Plaintiffs assert, however, that the evidence of lost sales during the early morning hours is indicative of the quantity of speech suppressed, and is not offered to prove loss of profits, per se. We assess this claim under Justice Kennedy's proportionality [\*\*43] analysis laid out in Alameda Books. 8 729, Inc., 515 F.3d at 491. HN26Go to this Headnote in the case. Under the 729, Inc. approach, this [\*556] court must ask whether the restriction leaves the "quantity and accessibility of protected speech substantially intact," id. at 492 (quoting Alameda Books, 535 U.S. at 449-50), and must ensure that it "is reasonably likely to cause a substantial reduction in secondary effects while reducing speech very little." Id. at 493 (quoting Alameda Books, 535 U.S. at 451 (Kennedy, J., concurring)).

#### Violation: They don’t meet changing because their aff both allows companies flexibilities to choose + the actual patent process itself doesn't change, it’s not actually more restrictive.

#### Topicality—they justify the aff arbitrarily doing away with words in the resolution which decks negative ground and preparation.

#### Limits and ground - only meaningful and direct reductions are predictable in the literature—else they can defend ANY CHANGE to ipr or the effects of a different change spilling over to increase access and defend that which means i get less case turns and disads and heavily skews my prep burden

#### —competing interps means it’s not just a question of what they do but what they justify and the norm that they have endorsed

#### No 1ar theory

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

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

3] Resolvability double bind—either you automatically accept 2AR responses to 2NR counter-standards which means they always win since I can’t answer those responses, or you have to intervene to determine the credence you give those 2AR responses, which makes it irresolvable and unfair. and Reject infinite abuse claims—1] spikes solve—there are only so many theoretical issues anyway, 2] infinite abuse doesn’t exist since there are a finite number of rounds, 3] if I win I can’t engage in 1AR theory then you could never check infinite abuse since we can’t use your shells to determine what’s abusive, 4] minimizing abuse in other rounds can’t come at the cost of skewing me on theory in this round.

Their stuff

1. Not infinite abuse, 1NC strat based on 1AC so it goes both ways and infinite abuse is unquantifiable and nebulous, 1ar not too short get to leverage 6 mins of ac offense, 2ar gets spin and last word and just read 1ar offense to make 2nr harder

### AMR cp

#### CP Text: The member nations of the World Trade Organization ought to for medicines except for antimicrobials. Antimicrobials ought to be granted indefinite patent extensions so long as they maintain efficacy as described by Salmieri.

#### This is key to overuse and innovation -- generics can't solve.

- Economic theory -- identical to the tragedy of the commons in land use which is solved by property rights

- Enables delinkage of revenue from sales volume -- can use discriminatory pricing or contractual agreements to conserve use and maintain profits

- Generics kill solvency -- no exclusivity rights and the business model for generics is low-cost high-volume which causes overuse

- IP is key -- discovery of effective conservation protocols can only come about through market incentives not by direct government intervention

- The CP makes antibiotics patents more lucrative which increases the incentive to develop new one

Explanation / other planks of the CP:

- Condition for patent renewal is demonstration of resistance below a certain threshold, author suggests 20%

- Auction off existing antibiotics to the highest bidder so that the CP applies to antibiotics currently available as generics

Gregory **Salmieri 18** [Ph.D., Philosophy, 2008, University of Pittsburgh; B.A. 2001, The College of New Jersey. Fellow, The Anthem Foundation for Objectivist Scholarship; Lecturer, Philosophy Department, Rutgers University "Intellectual Property and the Freedom Needed to Solve the Crisis of Resistant Infections." Geo. Mason L. Rev. 26 (2018): 215.]

Consider how the two-fold problem of growing resistance to our current antimicrobial drugs and the dearth of new antimicrobials under development looks once the specifics are omitted. Forget for a moment that the subject is drugs and microbes—or even inventions as opposed to other sorts of property—and just focus on the structure of the predicament.35 There is a resource of immense value that is being used myopically in a way that destroys existing stocks of the resource, and little is being done to find or develop new stocks of it. This is a pattern one expects to see with unowned resources, but not with owned ones. It is the classic “tragedy of the commons.” When a patch of grazing land is owned in common by everyone—which is just to say it is unowned—everyone has an incentive to make what use of it he can, leading to its overuse and destroying its value. By contrast, an owner can use land judiciously in ways that preserve its value or even to invest in improving the land. This is possible because the owner has exclusive control of the land in the present and therefore can control its uses, and because the owner expects to reap the benefit of the land’s future value. If deeds to land expired after twenty years, with the land reverting to the commons, land owners would have no financial incentives to preserve or enhance the land’s value past the twenty-year window. In this scenario, they could not afford to forgo shortterm gains that came at the expense of the land’s later value. Nor could they afford to invest in long-term improvement projects, such as clearing new land for grazing. This is the predicament with antimicrobial drugs. The profligate use of such drugs in the present destroys their value in a future in which they are unowned. This suggests the simple solution of extending the patent terms for antimicrobial drugs. So long as the drug remains under patent, the patent holder has both an interest in preserving its usefulness and the ability to control its use so as to preserve its value. How long should the patent term be extended? The five years of extra market exclusivity offered by the GAIN Act is calculated with a view to incentivizing companies to invest in developing new drugs. The aim of the present proposal is different. It is to enable the creators of drugs to profitably exercise their rights over the drugs in a manner that preserves the drugs’ effectiveness over time—ideally into the indefinite future. This requires extending the term of exclusivity not just a few years or decades, but as far into the future as there is reason to hope that the drugs’ effectiveness can be maintained. There are various ways in which this suggestion could be further developed; perhaps the most promising is simply to allow patents on antimicrobial drugs to be renewed indefinitely, so long as the drugs’ continued effectiveness can be demonstrated. (How exactly continued effectiveness should be demonstrated is a matter of detail, but likely by showing resistance to be below a certain threshold—perhaps 20 percent—in clinical isolates of interest.36) This would allow for a potentially infinite patent term. “Perpetual patents” have occasionally been proposed, 37 but the lack of a fixed term may do violence to the notion of a patent, so it may be better to conceive of this as a proposal for a new type of IP right that combines features of patents and trademarks. Conceptualizing the relevant right in this way highlights its basis. Like a patent, the right would pertain to an invention and would confer market exclusivity; like a trademark, however, it would be renewable in perpetuity on the grounds that the continued value of the property depends on the owner taking continuous action to maintain it. In the case of the right under consideration, the relevant actions would be those of stewarding the drug in such a manner as to prolong its continued effectiveness in the face of resistance. This new sort of property right could, in principle, be applied to drugs that are already off patent or otherwise ineligible for patent protection. The Chatham House Working Group proposes granting “delinkage rewards” to “firms registering a new antibiotic without patent protection (such as new uses for old drugs),”38 and it may be that the sort of IP protection proposed here would be applicable in such cases as well. If so, the right would be justified by the discovery of the new use for the drug and by the fact that intelligent management of this use is required for it to retain its value. A more difficult case is granting such rights to already known antibiotics that have gone off patent and are now available as generics. Removing these drugs from the commons would make it possible for an owner to profit by stewarding them responsibly. The difficulty here is determining who would own them. Professor Kades considers the possibility of granting a new patent to the original patent holder, but suggests “auctioning the patent rights [to such drugs] to the highest bidder.”39 Both are plausible solutions. Another option, in light of the issue of cross-resistance (which will be discussed in Part III) would be to apportion the IP rights to the relevant drugs among the owners of other drugs with similar mechanisms of action. Instituting the sort of property right described here (whether or not it is extended to drugs that are currently unpatentable and/or in the public domain) would create an environment in which pharmaceutical companies and other private entities can compete to develop new policies and business models that maximize the total value derived from antimicrobial drugs over time. An important advantage of this proposal is that it does not require policymakers (or authors of law review articles) to know in advance which specific practices would have this auspicious effect. However, some obvious possibilities suggest themselves. Pharmaceutical companies could sell new antimicrobials at a price high enough to make it prohibitive to use them as anything other than treatments of last resort. In addition to extending the drugs’ useful lives, the high prices would compensate for the lower initial volume of sales, and the drugs could eventually be repriced for wider use as second- and then first-line treatments. This repricing would have to be paced both to the growth of the resistant bacterial population and to the development of new antimicrobial drugs to take their predecessors’ place as treatments of last resort. One can imagine many variations of this strategy with different price points and development cycles. Pharmaceutical companies could also extend the effective lifespan of their antimicrobials through contractual arrangements with healthcare providers, which restrict the latter’s use of the drugs to certain protocols or best practices. Imagine the new business practices whereby pharmaceutical companies might profit from drugs that are never or hardly ever used. Licensing plans like the one proposed by Commissioner Gottlieb might be employed in innovative ways.40 For example, healthcare providers or insurance companies might pay a monthly fee for the right to use these drugs should it ever become necessary to do so. Or the various parties might negotiate a system whereby a pharmaceutical company (or an entity that has licensed drugs from multiple companies) charges a fixed price for treatment in accordance with a proprietary antimicrobial protocol that makes use of several of their drugs, specifying which drugs can used under which conditions. The suggestions in the last paragraph all amount to ways in which revenues from the creation of a new drug might be “delinked” from sales volume. In principle, this delinkage could occur simply through market forces, without any additional policy interventions, but since governments and multinational organizations account for most of the spending in the healthcare sector in much of the world, their adopting policies favoring delinkage would likely stimulate the development of these sorts of business models under an IP regime of the sort suggested. Indeed, such delinkage–promoting policies would likely fare better under the proposed IP regime than under the current IP system because, as The Chatham House Working Group observes, “patent expiry” creates some difficulties for such policies. Obligations for responsible use can be carefully crafted and functional when monopoly rights are in place, but are likely to fail once generic antibiotics are introduced upon the termination of the period of exclusivity. Generic manufacturers ordinarily rely on volume-based rewards, and low prices and large volume of sales without appropriate measures to conserve the antibiotics may be an important driver of indiscriminate use and resistance. A sustainable system will require controls on market entry after termination of the patent, and regulation of the way the generic products are marketed and prescribed.41 It bears emphasizing at this point that the best stewardship policies for antimicrobial drugs remain to be discovered. The Chatham House Working Group report (quoted several times above) represents the cutting edge of research on this issue, and it offers precious few details about the new “delinked” business model it says “needs to be developed.” Successful business models are rarely if ever specified from on high by public policy makers. Securing a long-range IP right to antimicrobial drugs would create the conditions in which the healthcare industry as a whole could invest the resources required to discover the practices, protocols, and business models that maximize the value of these substances. In addition, the ability to capture this value as profit would create an incentive to develop new drugs as needed.

#### Competes -- the plan bans patent extensions while the counterplan allows for potentially infinite patent extensions -- antibiotic patents can continue to be renewed so long as they retain efficacy.

#### c/a abr causes extintcion

### Infrastructure da

#### Infrastructures passes, but ONLY because of Biden’s PC

Harrison 9-10-2021, \*Jaime Harrison, Democratic National Committee Chairman. \*\*Interviewed by Mary C. Curtis, Roll Call columnist and host of the Equal Time podcast. ("Explaining reconciliation and the social issues at stake, with Mary C. Curtis", *Roll Call*, https://www.rollcall.com/2021/09/10/explaining-reconciliation-and-the-social-issues-at-stake-with-mary-c-curtis/)

Curtis: What role is the president plays, and you’re working with him? Harrison: I think the President plays an immense role. You know, he is the leader of our party. And so, you know, when you run into roadblocks in the end of the day, he will be the, you know, the executive, the decider-in-chief to help broker deals when they need to be, need to happen. But he’s laid out the parameters for what he wants, you know, and these are all based off the promises that he made the American people when he ran for president. And so Speaker Pelosi and Leader Schumer and so many leaders in the House and the Senate are working in order to make that happen. And I believe, again, as somebody who’s been a veteran of these issues and these type of deliberations in the past, it will happen and the president will have a bill to sign, and in the end of the day, will make a dramatic and positive impact on the lives of the American people. Curtis: What happens if this bill, after all these markups, etc., compromises, it doesn’t pass? Harrison: It’s going to pass. That’s not an option. We are going to get something to to the president on his desk, so that he can sign and continue to deliver for the American people.

#### Pharma will lobby hard – that’ll – reconciliation proves

David Sirota, 8-23-2021, "Why DC's most powerful corporate lobbying group loves the 'Mod Squad'," Newsweek, https://www.newsweek.com/dcs-most-powerful-corporate-lobbying-group-thanked-these-9-democrats-why-1622111

The reconciliation bill is still being negotiated, and many Democratic lawmakers — including those in key swing districts—are pushing for it to include long-promised legislation to allow Medicare to use its enormous purchasing power to negotiate lower prices for prescription drugs. The pharmaceutical industry has aggressively lobbied against the initiative, which the Congressional Budget Office has estimated would save Medicare $345 billion in medicine costs. The nine House Democrats threatening to derail the reconciliation bill have raked in nearly $1.2 million from donors in the pharmaceutical and health products industries, according to data compiled by OpenSecrets. Joe Manchin Saw Huge Surge in Donations During Debate on For the People Act Manchin to Speak At Fundraiser With Oil Industry Leaders, GOP Donors Joe Manchin Condemns Anti-Fossil Fuel Provisions in Infrastructure Bill Among them are two of the Democratic Party's top recipients of health care industry money: Gottheimer ($228,186) and Schrader ($614,830). Schrader's third biggest career donor is Pfizer's political action committee, and his former chief of staff is now a registered lobbyist for the Pharmaceutical Researchers and Manufacturers Association, the pharmaceutical industry's main lobbying group. Both Gottheimer and Schrader signed a letter earlier this year slamming Democratic leaders' legislation to lower prescription drug prices. Eight out of the nine Democrats threatening to kill the budget bill also declined to sponsor Democrats' standalone legislation to let Medicare negotiate lower drug prices. In the Senate, Sinema's renewed threat to vote down a final reconciliation bill came after she received $519,000 from donors in the pharmaceutical and health products industries.

#### Endgame PC is key

Drum 10 Kevin, Political Blogger, Mother Jones, http://motherjones.com/kevin-drum/2010/03/immigration-coming-back-burner

Not to pick on Ezra or anything, but this attitude betrays a surprisingly common misconception about political issues in general. The fact is that political dogs never bark until an issue becomes an active one. Opposition to Social Security privatization was pretty mild until 2005, when George Bush turned it into an active issue. Opposition to healthcare reform was mild until 2009, when Barack Obama turned it into an active issue. Etc. I only bring this up because we often take a look at polls and think they tell us what the public thinks about something. But for the most part, they don't.1 That is, they don't until the issue in question is squarely on the table and both sides have spent a couple of months filling the airwaves with their best agitprop. Polling data about gays in the military, for example, hasn't changed a lot over the past year or two, but once Congress takes up the issue in earnest and the Focus on the Family newsletters go out, the push polling starts, Rush Limbaugh picks it up, and Fox News creates an incendiary graphic to go with its saturation coverage — well, that's when the polling will tell you something. And it will probably tell you something different from what it tells you now. Immigration was bubbling along as sort of a background issue during the Bush administration too until 2007, when he tried to move an actual bill. Then all hell broke loose. The same thing will happen this time, and without even a John McCain to act as a conservative point man for a moderate solution. The political environment is worse now than it was in 2007, and I'll be very surprised if it's possible to make any serious progress on immigration reform. "Love 'em or hate 'em," says Ezra, illegal immigrants "aren't at the forefront of people's minds." Maybe not. But they will be soon.

#### Crucial investments fight against climate change

Desjardins 21 (Lisa Desjardins is a correspondent for PBS NewsHour, where she covers news from the U.S. Capitol while also traveling across the country to report on how decisions in Washington affect people where they live and work, 8-5-2021, "Breaking down the infrastructure bill's impact on climate change," <https://www.pbs.org/newshour/show/breaking-down-the-infrastructure-bills-impact-on-climate-change)//eli>

The current infrastructure bill includes $150 billion for clean energy and climate change protections. Tens of billions would also be utilized to fight extreme weather like drought, wildfire, flooding and erosion, with a host of smaller programs like low-emission busses, cleaner ports and even more trees. Rebecca Leber, who covers climate change for Vox, joins Lisa Desjardins to discuss. Judy Woodruff: This week, we are turning our focus each night to the trillion-dollar bipartisan infrastructure package and different ways it aims to help the country. The bill makes historic investments in roads, bridges, clean water and broadband. But, as Lisa Desjardins reports, it also includes some unexpected provisions on climate change. Lisa Desjardins: This is an infrastructure bill. It's not a climate bill. But given the little amount of action on the issue so far, what is in this bill would make it the most significant climate legislation to come out of Congress yet. It would include $150 billion for clean energy and to protect from climate change. Tens of billions are to fight drought and respond to wildfire, flooding and erosion. And there's a host of smaller programs, low-emission buses, cleaner ports, streets with less run-off, even more trees. To help us understand what this means, I'm joined by Rebecca Leber, who covers climate change for Vox. Rebecca, tell us, what do you think are the most significant things in this bill for climate change? Rebecca Leber: I think this addresses two important sectors that contribute to climate change. One is our transportation sector. So, the bill makes a lot of investments in electric vehicles and also public transit, which are both critical to bringing down our pollution and the biggest contributor to climate change. It also makes big investments in the electricity sector, so improving things like transmission and electric-buying parts of the country that also make it critical to cleaning up the economy. In addition, this bill addresses the impacts of climate change. So, we have to both bring down emissions at the same time that we prepare for the impacts we know are here and are coming. Lisa Desjardins: We spoke to a young woman from California who is experiencing climate change right now. I want to play what she told us today. Her name is Caroline Choi. Caroline Choi: I live in an island in the Bay Area in California. And within 35 years, part of where I live is going to be flooded and underwater due to sea level rise. Every time I bike on one of our bridges, I can look over the side and see that the water is almost at eye level. Lisa Desjardins: So, that's happening now in real time. Rebecca, you mentioned this, but I'm wondering, overall, what do you get from this bill about whether lawmakers are now thinking more about bracing for climate change vs. actually trying to prevent it? Rebecca Leber: The U.S. has lagged in its investments on climate change when you look at how it compares to other countries. So, this bill is historic, in that the government is finally putting funds in addressing the impacts of climate change. So, we have finally both parties acknowledging, at least in a bill, that people like this young woman are dealing with the actual impacts of sea level rise and increased flooding and wildfires.

#### Warming leads to extinction – it’s a conflict-multiplier and defense doesn’t assume non-linearity

Kareiva 18, Ph.D. in ecology and applied mathematics from Cornell University, director of the Institute of the Environment and Sustainability at UCLA, Pritzker Distinguished Professor in Environment & Sustainability at UCLA, et al. (Peter, “Existential risk due to ecosystem collapse: Nature strikes back,” *Futures*, 102)

In summary, six of the nine proposed planetary boundaries (phosphorous, nitrogen, biodiversity, land use, atmospheric aerosol loading, and chemical pollution) are unlikely to be associated with existential risks. They all correspond to a degraded environment, but in our assessment do not represent existential risks. However, the three remaining boundaries (climate change, global freshwater cycle, and ocean acidification) do pose existential risks. This is because of intrinsic positive feedback loops, substantial lag times between system change and experiencing the consequences of that change, and the fact these different boundaries interact with one another in ways that yield surprises. In addition, climate, freshwater, and ocean acidification are all directly connected to the provision of food and water, and shortages of food and water can create conflict and social unrest. Climate change has a long history of disrupting civilizations and sometimes precipitating the collapse of cultures or mass emigrations (McMichael, 2017). For example, the 12th century drought in the North American Southwest is held responsible for the collapse of the Anasazi pueblo culture. More recently, the infamous potato famine of 1846–1849 and the large migration of Irish to the U.S. can be traced to a combination of factors, one of which was climate. Specifically, 1846 was an unusually warm and moist year in Ireland, providing the climatic conditions favorable to the fungus that caused the potato blight. As is so often the case, poor government had a role as well—as the British government forbade the import of grains from outside Britain (imports that could have helped to redress the ravaged potato yields). Climate change intersects with freshwater resources because it is expected to exacerbate drought and water scarcity, as well as flooding. Climate change can even impair water quality because it is associated with heavy rains that overwhelm sewage treatment facilities, or because it results in higher concentrations of pollutants in groundwater as a result of enhanced evaporation and reduced groundwater recharge. Ample clean water is not a luxury—it is essential for human survival. Consequently, cities, regions and nations that lack clean freshwater are vulnerable to social disruption and disease. Finally, ocean acidification is linked to climate change because it is driven by CO2 emissions just as global warming is. With close to 20% of the world’s protein coming from oceans (FAO, 2016), the potential for severe impacts due to acidification is obvious. Less obvious, but perhaps more insidious, is the interaction between climate change and the loss of oyster and coral reefs due to acidification. Acidification is known to interfere with oyster reef building and coral reefs. Climate change also increases storm frequency and severity. Coral reefs and oyster reefs provide protection from storm surge because they reduce wave energy (Spalding et al., 2014). If these reefs are lost due to acidification at the same time as storms become more severe and sea level rises, coastal communities will be exposed to unprecedented storm surge—and may be ravaged by recurrent storms. A key feature of the risk associated with climate change is that mean annual temperature and mean annual rainfall are not the variables of interest. Rather it is extreme episodic events that place nations and entire regions of the world at risk. These extreme events are by definition “rare” (once every hundred years), and changes in their likelihood are challenging to detect because of their rarity, but are exactly the manifestations of climate change that we must get better at anticipating (Diffenbaugh et al., 2017). Society will have a hard time responding to shorter intervals between rare extreme events because in the lifespan of an individual human, a person might experience as few as two or three extreme events. How likely is it that you would notice a change in the interval between events that are separated by decades, especially given that the interval is not regular but varies stochastically? A concrete example of this dilemma can be found in the past and expected future changes in storm-related flooding of New York City. The highly disruptive flooding of New York City associated with Hurricane Sandy represented a flood height that occurred once every 500 years in the 18th century, and that occurs now once every 25 years, but is expected to occur once every 5 years by 2050 (Garner et al., 2017). This change in frequency of extreme floods has profound implications for the measures New York City should take to protect its infrastructure and its population, yet because of the stochastic nature of such events, this shift in flood frequency is an elevated risk that will go unnoticed by most people. 4. The combination of positive feedback loops and societal inertia is fertile ground for global environmental catastrophes Humans are remarkably ingenious, and have adapted to crises throughout their history. Our doom has been repeatedly predicted, only to be averted by innovation (Ridley, 2011). However, the many stories of human ingenuity successfully addressing existential risks such as global famine or extreme air pollution represent environmental challenges that are largely linear, have immediate consequences, and operate without positive feedbacks. For example, the fact that food is in short supply does not increase the rate at which humans consume food—thereby increasing the shortage. Similarly, massive air pollution episodes such as the London fog of 1952 that killed 12,000 people did not make future air pollution events more likely. In fact it was just the opposite—the London fog sent such a clear message that Britain quickly enacted pollution control measures (Stradling, 2016). Food shortages, air pollution, water pollution, etc. send immediate signals to society of harm, which then trigger a negative feedback of society seeking to reduce the harm. In contrast, today’s great environmental crisis of climate change may cause some harm but there are generally long time delays between rising CO2 concentrations and damage to humans. The consequence of these delays are an absence of urgency; thus although 70% of Americans believe global warming is happening, only 40% think it will harm them (http://climatecommunication.yale.edu/visualizations-data/ycom-us-2016/). Secondly, unlike past environmental challenges, the Earth’s climate system is rife with positive feedback loops. In particular, as CO2 increases and the climate warms, that very warming can cause more CO2 release which further increases global warming, and then more CO2, and so on. Table 2 summarizes the best documented positive feedback loops for the Earth’s climate system. These feedbacks can be neatly categorized into carbon cycle, biogeochemical, biogeophysical, cloud, ice-albedo, and water vapor feedbacks. As important as it is to understand these feedbacks individually, it is even more essential to study the interactive nature of these feedbacks. Modeling studies show that when interactions among feedback loops are included, uncertainty increases dramatically and there is a heightened potential for perturbations to be magnified (e.g., Cox, Betts, Jones, Spall, & Totterdell, 2000; Hajima, Tachiiri, Ito, & Kawamiya, 2014; Knutti & Rugenstein, 2015; Rosenfeld, Sherwood, Wood, & Donner, 2014). This produces a wide range of future scenarios. Positive feedbacks in the carbon cycle involves the enhancement of future carbon contributions to the atmosphere due to some initial increase in atmospheric CO2. This happens because as CO2 accumulates, it reduces the efficiency in which oceans and terrestrial ecosystems sequester carbon, which in return feeds back to exacerbate climate change (Friedlingstein et al., 2001). Warming can also increase the rate at which organic matter decays and carbon is released into the atmosphere, thereby causing more warming (Melillo et al., 2017). Increases in food shortages and lack of water is also of major concern when biogeophysical feedback mechanisms perpetuate drought conditions. The underlying mechanism here is that losses in vegetation increases the surface albedo, which suppresses rainfall, and thus enhances future vegetation loss and more suppression of rainfall—thereby initiating or prolonging a drought (Chamey, Stone, & Quirk, 1975). To top it off, overgrazing depletes the soil, leading to augmented vegetation loss (Anderies, Janssen, & Walker, 2002). Climate change often also increases the risk of forest fires, as a result of higher temperatures and persistent drought conditions. The expectation is that forest fires will become more frequent and severe with climate warming and drought (Scholze, Knorr, Arnell, & Prentice, 2006), a trend for which we have already seen evidence (Allen et al., 2010). Tragically, the increased severity and risk of Southern California wildfires recently predicted by climate scientists (Jin et al., 2015), was realized in December 2017, with the largest fire in the history of California (the “Thomas fire” that burned 282,000 acres, https://www.vox.com/2017/12/27/16822180/thomas-fire-california-largest-wildfire). This catastrophic fire embodies the sorts of positive feedbacks and interacting factors that could catch humanity off-guard and produce a true apocalyptic event. Record-breaking rains produced an extraordinary flush of new vegetation, that then dried out as record heat waves and dry conditions took hold, coupled with stronger than normal winds, and ignition. Of course the record-fire released CO2 into the atmosphere, thereby contributing to future warming. Out of all types of feedbacks, water vapor and the ice-albedo feedbacks are the most clearly understood mechanisms. Losses in reflective snow and ice cover drive up surface temperatures, leading to even more melting of snow and ice cover—this is known as the ice-albedo feedback (Curry, Schramm, & Ebert, 1995). As snow and ice continue to melt at a more rapid pace, millions of people may be displaced by flooding risks as a consequence of sea level rise near coastal communities (Biermann & Boas, 2010; Myers, 2002; Nicholls et al., 2011). The water vapor feedback operates when warmer atmospheric conditions strengthen the saturation vapor pressure, which creates a warming effect given water vapor’s strong greenhouse gas properties (Manabe & Wetherald, 1967). Global warming tends to increase cloud formation because warmer temperatures lead to more evaporation of water into the atmosphere, and warmer temperature also allows the atmosphere to hold more water. The key question is whether this increase in clouds associated with global warming will result in a positive feedback loop (more warming) or a negative feedback loop (less warming). For decades, scientists have sought to answer this question and understand the net role clouds play in future climate projections (Schneider et al., 2017). Clouds are complex because they both have a cooling (reflecting incoming solar radiation) and warming (absorbing incoming solar radiation) effect (Lashof, DeAngelo, Saleska, & Harte, 1997). The type of cloud, altitude, and optical properties combine to determine how these countervailing effects balance out. Although still under debate, it appears that in most circumstances the cloud feedback is likely positive (Boucher et al., 2013). For example, models and observations show that increasing greenhouse gas concentrations reduces the low-level cloud fraction in the Northeast Pacific at decadal time scales. This then has a positive feedback effect and enhances climate warming since less solar radiation is reflected by the atmosphere (Clement, Burgman, & Norris, 2009). The key lesson from the long list of potentially positive feedbacks and their interactions is that runaway climate change, and runaway perturbations have to be taken as a serious possibility. Table 2 is just a snapshot of the type of feedbacks that have been identified (see Supplementary material for a more thorough explanation of positive feedback loops). However, this list is not exhaustive and the possibility of undiscovered positive feedbacks portends even greater existential risks. The many environmental crises humankind has previously averted (famine, ozone depletion, London fog, water pollution, etc.) were averted because of political will based on solid scientific understanding. We cannot count on complete scientific understanding when it comes to positive feedback loops and climate change.

## Case

#### 2. No tricks overview –

#### 1---Yes new 2nr responses to the underview---A] Shiftiness---New 1ar contextualization moots 1nc answers especially because they’re all blippy and the implications aren’t explained B] Clash---Voting us down for missing one blippy spike is antieducational because it moots all of substance for a silly theory argument

#### 2---The underview was super fast and unclear---hold the line and don’t vote on an argument if you can’t trace both the claim and the warrant from your 1ac flow

#### 3---No Timeskew---we both get 13 minutes---Getting faster and more efficient solves small distribution differences

#### 4---Reject sidebias warrants---A] They’re a cool fyi without a reason their interp solves best---Assign their argument 0 risk because its not complete---This is akin to reading a disad without an internal link B] Kills clash and normsetting because its just arbitrary assertions about who should get more leeway instead of the best norm for debate C] No offense---We both debate each side half the time, so skews cancel out and the game is fair D] Skews self-correcting since aff can consolidate and doesn’t have to answer each argument since they get the last speech

#### 5---Reject arguments that always affirm or negate---Incentivizes reusing arguments and intellectual laziness instead of doing research. At best, the research they do do is worthless and doesn’t mirror academic research practices that are the only portable skill.

#### 3. The counter role of the ballot is to determine if implementing the aff is a good idea. To clarify, it’s comparative worlds

#### [1] Topic lit – this ignores very good policy, soft left, and K aff ground which moots prep and pigeonholes negative ground to bad frameworks. Makes your 1NC easy because you prepped for these case positions only. That outweighs – pre-round abuse controls internal link to in round

#### [2] Advocacy skills – policymakers don’t act off truth statements; instead, they act off what they determine they should do. Roleplay forces us to advocate for actions and actively engage each other’s’ advocacies – key to make effective decisions is the most lasting and important skill gained through debating.

#### [3] Truth Testing Collapses—we know a statement is true because it creates a better world

#### [4] Resolvability and destroys topic lit

**Mangus** (Michael, “the value-comparison paradigm: a turn away from truth-testing,”)

irresolvable debates. instead of reaching a sortof strategically-skewed synthesis, these two forces instead create debates that leave judges dumbfounded. the affirmative will drop an overview that “proves” the resolution contradictory while the negative will drop a spike that “proves” the resolution tautological. if the judge is lucky, one of these arguments will somehow respond to or undermine the other and a decision can be rendered with some degree of fairness. oftentimes, however, there is no comparison between the arguments and no obvious interaction between them. even in the first case, this is not the pinnacle of substantive debate. in the latter case, it is a direct invitation for judge intervention. this is not isolated to the lower brackets of tournaments either – many high-powered prelims and elimination rounds feature these strategies.

#### [5] Prefer comparative worlds

* 1. **Truth testing devolves – we still have to compare the worlds of truth and falsity**
  2. **Substantive debate – authors write about the topic from a comparative worlds lens – means our model is more educational because it’s the only one that promotes topic discussion– education is good – it’s the only portable impact from debate, we care about what we learn not if we were fair**
  3. **Ground – our model encourages argument innovation and more possibilities for arguments – lets the neg read CPs, Ks, Das which you wouldn’t get under TT**

#### 2. No reason companies would create new drugs for NTDs specifically -- the aff is missing that internal link.

#### 3. NTDs aren't developed because they aren't profitable -- even with

Shayerah **Ilias 10 summarizes** [Analyst in International Trade and Finance "Intellectual Property Rights and Access to Medicines: International Trade Issues" Congressional Research Services, June 14, 2010 https://www.everycrsreport.com/files/20100614\_R40607\_2b8e2e975a19ba930f7e81899de45322497b6761.pdf]

While patents may provide incentives for innovation, some argue that the economic premise behind patents only holds in situations where markets offer sufficient financial incentives for a return on investment. Many developing countries may be unable to provide a profitable market for treatments against diseases that disproportionately affect their populations. The WHO "Global Strategy and Plan of Action of Public Health, Innovation and Intellectual Property" acknowledges that IPRs serve an important incentive function, but notes, "This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain

(WHA61.21.6)." According to a classification system used by the WHO, there are three main types of diseases that vary in the level of market-based incentives they offer for R&D. • Type I diseases (“chronic diseases”), such as cancer, diabetes, and cardiovascular

disease, are prevalent in developed countries and increasingly in developing

countries. Pharmaceutical companies have a strong financial incentive to invest

in treatments for these diseases.

• Type II diseases are prevalent in developing countries. Pharmaceutical

companies may have incentives to invest in such diseases if there is sufficient

demand by high-income countries for research, as in the case of HIV/AIDS. For

other Type II diseases, such as malaria and tuberculosis, high-income country

demand for treatments is limited and consequently, market-based incentives are

not sufficient for pharmaceutical companies to invest in R&D.

• Type III diseases, such as dengue fever and African sleeping sickness, are those

that have virtually no developed country demand. These diseases (often referred to as “neglected tropical diseases”), largely are concentrated in impoverished areas in developing countries. Pharmaceutical companies have little financial incentive to invest in R&D for these diseases, but may have social motivations.18

#### a) Even if aff boosts innovation that will be in other more profitable areas

#### b) No link -- the problem isn't that NTD drugs are locked behind evergreening patents the problem is that no one is making them in the first place

#### 3. Health diplomacy fails -- no case studies support it, and linking peacebuilding with health undermines trust which turns their impact.

#### 4. No terminal impact -- the tag says escalation but the evidence doesn't go any further than "conflict" or talk about great powers -- at best they access small-scale conflict which doesn't outweigh extinction-level superbugs

#### 3. Innovation strong now

**Ezell and Stevens 20** [Philip Stevens is the executive director of the Geneva Network, which he founded in 2015. He is also a senior fellow at the Institute for Democracy and Economic Affairs, Malaysia. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division. Philip has also worked as director of policy for International Policy Network, a United Kingdom-based think tank, as well as holding research positions with the Adam Smith Institute and Reform—both public policy think tanks in London. He holds degrees from the London School of Economics and the University of Durham, United Kingdom. Stephen J. Ezell is ITIF vice president for Global Innovation Policy and focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" Information Technology & Innovation Foundation, February 3, 2020 https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work]

Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over $1.36 trillion in R&D in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, 943 new active substances have been introduced globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than 500 new medicines since 2000 alone. And these medicines are getting to more individuals: Global medicine use in 2020 will reach 4.5 trillion

doses, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the world’s most intractable diseases, including cancer and Alzheimer’s.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved 41 new medicines (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through enhanced clinical efficacy (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, or better treatment for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39

#### Strong IP protections key to innovation

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As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary to induce companies to invest in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investments.42 Indeed, it’s the ability to recoup fixed costs, not just marginal costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, there would be no new drugs developed, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $3.2 billion.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the confidence to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, in the global public’s long-term interests. Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48

#### Timeframe: any harms stemming from IP restrictions are temporary while the gains from innovation are durable and accumulate over time

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Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### Patents aren't the barrier to access in developing countries -- numerous alt causes

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What about [In] lower- and middle-income countries, where public health coverage is often minimal and most health spending comes out of individuals’ pockets? Here, the real problem is not so much drug pricing, but a lack of coverage. For instance, a survey of 33 low-income countries found that out-of-pocket payments represent more than half of total health expenditures.64 As a result, many people struggle to afford even cheap essential medicines that have been off-patent for decades, let alone far more expensive physician fees and hospital costs. And while delinkage proponents assert the high cost of medicines as key a rationale for their proposals, the reality is the far bigger challenge in developing nations is with access to health care services in general, and access to needed medicines in particular. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.65 A 2014 WHO study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.66 More than 80 countries fail to meet the basic threshold of 23 skilled health professionals per 10,000 people.67 In other instances, individuals lack access to essential medicines, with their cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.68 A 2009 survey of 36 countries found that 15 common generic medicines listed on the WHO Essential Medicines list were frequently unavailable in either the public or private sectors, with regional availability ranging from 29 percent in Africa to 54 percent in the Americas.69 Again, cost remains only part of the problem. Indeed, the vast majority of drugs—at least 90 percent—currently on WHO’s Essential Medicines list are off-patent.70 Yet essential generic medicines are frequently unavailable or unaffordable.71 The problem, in much larger part, stems from countries’ underdeveloped health systems and many people living in rural areas, far from care. In fact, approximately 70 percent of the world’s poor live in rural areas, where it becomes very difficult to cost-effectively deliver health care services and supplies. Improving health coverage and health systems is the answer to better health care in these countries. And of course, boosting productivity and per capita incomes in these nations, in large part through helping all industries—traded and non-traded alike—become more productive is the ultimate solution.72

#### Global vaccine efforts fail – infrastructure, supply chains, inefficiencies

Silverman 3/15 [Rachel Silverman is a policy fellow at the Center for Global Development where she leads policy-oriented research on global health financing and incentive structures. Silverman’s current research focuses on the practical application of results-based financing; global health transitions; efficient global health procurement; innovation models for global health; priority-setting for UHC; alignment and impact in international funding for family planning; and strategies to strengthen evidence and accountability. BA with distinction in international relations and economics from Stanford University.) “Waiving vaccine patents won’t help inoculate poorer nations” Washington Post, PostEverything Perspective, <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/>] RM

According to some activists, the solution to this inequity is relatively simple: By suspending protections on covid-19 vaccine patents, the international community “could help break Big Pharma monopolies and increase supplies so there are enough doses for everyone, everywhere,” [claims](https://peoplesvaccine.org/take-action/)the People’s Vaccine Alliance. Indeed, 58 low- and middle-income countries have mobilized in support of a proposed World Trade Organization [waiver](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) that would temporarily exempt [coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_4)-related intellectual property from normal international rules and protections. And while the effort to waive IP protections has been a global health hot topic for months, it gained a high-profile endorsement in the United States recently from Sen. Bernie Sanders (I-Vt.). In a March 10 video statement, Sanders [called upon President Biden](https://twitter.com/GlobalJusticeUK/status/1369734275818549252?s=20) to support the IP suspension while slamming “huge, multibillion-dollar pharmaceutical companies [that] continue to prioritize profits by protecting their monopolies.”

The logic of the argument seems clear and intuitive — at first. Without patents, which serve narrow commercial interests, companies all over the world could freely produce the vaccine. Sure, Big Pharma would lose money — but this is a pandemic, and human life comes before private profit, especially when vaccines receive substantial public financing to support research and development. As with HIV drugs in years past, widespread generic production would dramatically increase supply and drive down prices to levels affordable even in the developing world.

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have little effect**.** **It could even backfire, with companies using the move as an excuse to disengage from global access efforts**. **There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents.**

The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna [announced in October](https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19) that it would not enforce IP rights on its coronavirus vaccine — and yet it has taken no steps to share information about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the company’s direct control within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine [not yet participating in Covax](https://www.washingtonpost.com/world/coronavirus-vaccine-access-poor-countries-moderna/2021/02/12/0586e532-6712-11eb-bf81-c618c88ed605_story.html?itid=lk_inline_manual_9), a global-aid-funded effort (including a [pledged $4 billion from the United States](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort)) to purchase vaccines for use in low- and middle-income countries.

It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own.

One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, [lowering prices dramatically](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices).

Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. **Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth**. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

#### Drug companies are voluntarily expanding access through donations and tiered pricing.

Donald **McNeil 19** [science reporter for NYT "Drug Companies Are Focusing on the Poor After Decades of Ignoring Them" The New York Times, June 24, 2019 https://www.nytimes.com/2019/06/24/health/drugs-poor-countries-africa.html]

Twenty years ago, thousands of Africans died of AIDS each day as pharmaceutical companies looked on, murmuring sympathy but claiming that they could not afford to cut the prices of their $15,000-a-year H.I.V. drugs. It’s hard to imagine such a nightmare unfolding today. Vast changes have swept the drug industry over the last two decades. Powerful medicines once available only in rich countries are distributed in the most remote regions of the globe, saving millions of lives each year. Nearly 20 million Africans are now on H.I.V. treatment — for less than $100 a year. Top-quality drugs for malaria, tuberculosis, hepatitis C and some cancers are now sold at rock-bottom prices in poor countries. Once demonized as immoral profiteers, many of the world’s biggest 20 pharmaceutical companies now boast about how they help poor countries and fight neglected diseases. They compete on the Access to Medicine Index, which scores their charitable efforts. Several of them even cooperate with the Indian generics companies they once dismissed as “pirates” by sub-licensing patents so the generics makers can produce cheap drugs for Africa, Asia and Latin America.

#### Even with a patent, substitutes exist.

**Ezell and Stevens 20** [Philip Stevens is the executive director of the Geneva Network, which he founded in 2015. He is also a senior fellow at the Institute for Democracy and Economic Affairs, Malaysia. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division. Philip has also worked as director of policy for International Policy Network, a United Kingdom-based think tank, as well as holding research positions with the Adam Smith Institute and Reform—both public policy think tanks in London. He holds degrees from the London School of Economics and the University of Durham, United Kingdom. Stephen J. Ezell is ITIF vice president for Global Innovation Policy and focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" Information Technology & Innovation Foundation, February 3, 2020 https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work]

“The obvious answer is that the benefits from eliminating drug patents would be much smaller than predicted by the prize literature, and there might not be any benefits at all,” argues Benjamin Roin of the MIT Sloan School of Management.63 Professor Roin points out that patents are frequently mischaracterized as giving the right to monopoly profits, effectively forcing consumers to pay the full monopoly price of medicines. In reality, patents grant no such right, merely giving the right to exclude others from copying a specific patented product, and even then only for a limited period of time. Moreover, while patents do provide temporary exclusive rights, there are usually many substitutes and alternatives to a patented product that make market monopoly very rare and always, if they exist, temporary. Markets for products covered by IP are often intensely competitive, because there are usually many substitutes and alternatives. This is particularly true of medicine.

#### Prices declining now.

Thomas B. **Cueni 17** [Director General at the International Federation of Pharmaceutical Manufacturers & Associations, interviewed by John Zarocostas "Perspectives on access to medicines and IP rights" WIPO Magazine, December 2017 https://www.wipo.int/wipo\_magazine/en/2017/06/article\_0002.html]

Thomas Cueni: I understand concerns surrounding the cost of individual drugs and that companies have to justify the value they bring, but I believe the price debate is overblown. On aggregate there is no sign that drug costs are out of control. The latest OECD data, for example, show that between 2009 and 2015, there was a 0.5 percent annual reduction in per capita expenditure for pharmaceuticals. More importantly, expenditures on health should be seen as an investment towards increased welfare, productivity and economic growth. They should not be seen exclusively as a fiscal cost at a given point in time. The research-based biopharmaceutical industry is delivering breakthrough medicines for patients. Over the last 10 years, we have seen dramatic improvements in treatments for HIV, HCV (hepatitis C), oncology and many rare diseases that have transformed the lives of patients. The wider developments driving healthcare spending, and the systemic challenges that limit access to high-quality, safe and effective medicines around the world, need to be considered.

#### TURN: Innovation lowers the price of existing drugs.

Stephen **Moore and** Steve **Forbes 18** [Stephen Moore is the Distinguished Visiting Fellow for Project for Economic Growth at The Heritage Foundation. "Foreign Price Controls Jeopardize Global Health and Raise Drug Costs for Americans" Committee to Unleash Prosperity, JULY 2018 https://web.archive.org/web/20200522024422/https://committeetounleashprosperity.com/wp-content/uploads/2018/07/CTUP\_WhitePaper\_Moore\_Jul2018.pdf]

To equalize the costs of drug development, the Trump administration has proposed a series of reforms to lower drug prices for Americans. Here’s where innovation deserves another look, because pharmaceutical R&D isn’t just the key to unlocking new cures: it’s also one of the main ways of reducing prices for existing drugs, by encouraging competition in the marketplace. Conversely, while some of the White House’s proposed reforms make sense, there is a danger that lowering prices and thus profits with artificial price controls here at home will chase investment outside the U.S. and slow the development of new drugs. In fact, this could paradoxically raise health care costs for several reasons. First, research has shown that the entry of a new drug into the marketplace, often with additional benefits in the form of increased efficacy or tolerability, forces down the prices of other drugs in the same therapeutic class—**even before their patents have expired**. This is because, as physicians begin to sign prescriptions for the new entrant, insurers, pharmacy benefit managers and other intermediaries take advantage of this new competitor product to negotiate better deals for existing drugs. Similarly the introduction of several “me-too” or “follow on” drugs with comparable efficacy diminishes differentiation for each, reducing the price premium drug makers can demand for them.13,14,15 One of the most spectacular examples of the impact of new entrants on drug prices in recent years came in the fast-growing field of Hepatitis C treatments. Following Gilead’s introduction of the breakthrough Hepatitis C cure Sovaldi in 2013, competitors rushed a number of drugs exploiting the same underlying biological mechanism to market, resulting in dramatic price drops across the entire therapeutic class. This competition has resulted in rebates and discounts ranging from about 22 percent in 2014 to about 40-65 percent today.16,17 This analysis doesn’t include the overall cost savings projected from curing 2.9 million Americans with chronic Hepatitis C, including hospital stays and transplant costs, estimated at $100.3 billion in the U.S.18 Hepatitis C drugs are just one of the more dramatic cases of new entrants bringing down prices by offering cheaper alternatives in the same therapeutic class. One study found that seven new “follow-on” drugs developed to treat conditions including nonHodgkin’s lymphoma, ovarian cancer, psoriasis, and Huntington’s disease offered discounts over the incumbent drug ranging from 21 percent to 61 percent.19

#### Waiving IP enforcement results in rampant increase in counterfeit vaccines – turns case.

Mercurio 21 (Bryan Mercurio is a Professor and Vice-Chancellor's Outstanding Fellow of the Faculty of Law at the Chinese University of Hong Kong, February 21, 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820&download=yes>) CS

6. IP enforcement is of vital importance to maintaining safety standards.

The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation **of fraudulent and dangerous goods**. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licences, as this is the most responsible way to bring their technologies to the world and safeguard global health.

In addition, as the COVID-19 pandemic continues there has been a **noticeable increase in the circulation of fake medicines** around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups** have been producing fake drugs and medical products and selling them for **lucrative profits in developing countries**.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to **disastrous consequences**, including **worsened illness and** **death** for the individual and the retardation of herd immunity for the population at large. Effective and proactive **IP** procurement is **essential** and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, **putting millions of human lives at risk** and reducing trust in vaccines.